

Western European Nuclear Regulators' Association

**Pilot Study on Harmonisation of Reactor Safety
in WENRA Countries**

Abstract

WENRA Working Group on Reactor Harmonisation

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Table of contents

1. Background	3
2. What is harmonisation?	3
3. Methodology	4
3.1 Selection of significant safety issues	4
3.2 Identification of national requirements	5
3.3 Description of national requirements	6
3.4 Establishment of reference levels	7
3.5 Comparison with IAEA safety standards	8
3.6 Assessment of differences between national practices and reference levels	10
3.7 Conclusion about differences between national practices and reference levels	11
3.8 Summary of results	13
4. Conclusions about the methodology	13
Annex	15
Reference levels developed and used in the Pilot Study	

1. Background

In November 1999, WENRA decided to set up a Working Group in charge of investigating how to proceed towards a harmonised view on reactor safety in EU countries with nuclear programmes.

The Working Group should address principal differences and similarities in the substance of safety requirements in the areas of deterministic and probabilistic requirements as well as in the area of safety management and safety culture. The Group should not go too deeply into legal and technical details.

In March 2000, an outline of a Pilot Study was presented and approved by WENRA. The objective of the Pilot Study was to develop and test a methodology for systematic comparison of national requirements on selected safety issues. The results should make conclusions possible about specific needs for harmonisation of national requirements connected with these issues, in order to reach a comparable safety level. The detailed means necessary for each country to reach the harmonised level was not to be suggested, but the conclusions should be sufficiently clear about what needs to be further addressed on the national level.

A first report, with a preliminary study of six safety issues, was issued in February 2001. WENRA endorsed the proposed methodology and asked the Working Group to continue its work along the suggested lines in order to make the study of the six safety issues more complete¹. The Group was also asked to compare the reference levels used in the study with the most recent IAEA safety standards, and on that basis amend the reference levels if justified. In addition the Group was asked to propose how the study could be continued with further safety issues to be decided later.

2. What is harmonisation?

In order to design the methodology, an operational definition of harmonisation was necessary. For this purpose, the Working Group defined harmonisation as: ***no substantial differences between countries from the safety point of view in generic formally issued national safety requirements, and in the resulting implementation on the Nuclear Power Plants.***

This definition has several implications for harmonisation work aiming at equal safety levels in the different countries:

- both the legal and the implementation (technical) aspects need to be considered,
- requirements need to be formally issued on a legal basis,
- requirements need to be public and transparent,
- requirements need to be generic (apply equally on the licensees),
- harmonised requirements need to be interpreted and implemented in an equal way,
- harmonised requirements need to be enforced in an equal way.

¹ Switzerland did not participate in the Pilot Study. The Netherlands did not participate in the second phase of the study.

3. Methodology

The Working Group set some conditions for the design of the methodology. The national requirements to be included in the study needed to be selected and described in a consistent way. Differences in the principal design of the legal systems and in regulatory practices should be disregarded as much as possible, in order to focus on the substantial differences and similarities of comparable requirements. It should be possible to identify and describe whether national requirements are applied in a consistent way or if, for instance, older reactors are exempted from certain requirements. As mentioned, not only the legal aspects of harmonisation but also the implementation should be considered, i.e. it should be possible to identify those cases where existing requirements are not implemented and cases where an implementation exist but not formally required. It should be possible to get a convenient overview of differences and similarities between the countries without losing too much information. The conclusions about differences should be based on a safety justification and should be detailed enough to provide input to a further more detailed analysis on the national level. The methodology should be transparent, i.e. it should be possible to understand on what basis the conclusions were drawn.

Following the conditions, the methodology was designed in eight working steps as follows:

1. Select significant safety issues to be included in the project.
2. Identify, for each country and safety issue the relevant legal documents.
3. Describe in a standardised way (description matrix) the substance of each country's national requirements and status of implementation.
4. On the basis of the national requirements, establish reference levels on each issue, reflecting the best national practices (the study uses the terminology "highest quartile" of existing requirements).
5. Compare with the most recent IAEA safety standards, amend the reference levels if justified, make a comment on the relations between the finally agreed reference levels and the IAEA safety standards.
6. Assess (in a panel with all countries represented) and document in a systematic way (comparison matrix) to what extent the reference levels exist and are implemented in each country.
7. Conclude from the panel assessments whether there are any substantial differences or not between the reference levels and the respective national practices, conclude about which differences can be justified from the safety point of view and which differences should be further addressed for harmonisation, provide justifications and explanations.
8. Summarise the results of the analysis.

In the following these steps are commented briefly.

3.1. Selection of significant safety issues

Since the scope of requirements on reactor safety is very large and requirements exist on several levels of detail, every harmonisation project needs for practical reasons to make an inventory and a selection of issues to deal with. This selection can be done according to different principles. One principle is to make a safety map by defining a structure of issues, with the ambition to cover the whole field of reactor safety. Another consistent approach is to identify the safety issues following from the Convention on Nuclear Safety. A further selection principle is to define and select harmonisation issues taking into account known differences between the countries as outlined in several reports from IAEA, the EC advisory groups and the committees and working groups within OECD/NEA. Another principle is to focus on common regulatory challenges for the near future and to identify the safety issues and requirements associated with these challenges.

It is also possible to group and select safety issues on the basis of safety factors to be included in a Periodic Safety Review².

There are also a number of pragmatic approaches that can be used in the selection of issues. One is to look through the IAEA Safety Requirements³ or published requirements from different countries⁴ to check which issues are addressed in those documents. Obviously issues included in these documents are considered to be important to safety, although the basis for this is not always clear.

The Working Group followed a pragmatic approach in its selection of issues. It was clear that only a few issues could be analysed within the frame of the Pilot Study. The selection was done primarily to find issues, which would provide a good test of the methodology. For this purpose the following selection criteria were used:

- the issues should represent different safety areas as identified in the IAEA Safety Requirements,
- some issues should at face value be more difficult and some more easy to analyse,
- there should be differences between the national requirements related to the issues.

The following issues were finally selected:

Safety area	Issues
Safety Management	- Safety Policy - Operating Organisation
Design	- Verification and Improvement of the Design
Operation	- Beyond Design Basis Accident Management
Safety verification	- Probabilistic Safety Analysis - Periodic Safety Review

3.2 Identification of national requirements

The Working Group used the following definition of a national requirement: a legally binding generic safety requirement currently in force, or a formally issued general recommendation. These requirements are of two types, both legally based but with different legal powers.

² See IAEA Draft Safety Guide DS 307

³ For instance NS-R-1 Design and NS-R-2 Operation

⁴ For instance the Swedish SKIFS or the Finnish YVL-Guides.

A legally binding requirement, such as a law, ordinance or regulation, is mandatory and enforced, if necessary with use of legal sanctions. These requirements are issued by the parliament, the government, or the regulatory body on behalf of the government. All WENRA countries have an established procedure for issuing such requirements, including, to a varied degree, public hearings or other mechanisms for soliciting the opinion of the stakeholders. In some cases a cost/benefit analysis must also be made. In most countries, the legally binding requirements are expressed as “shall” statements.

A formally issued general recommendation is a rule or guideline that the regulatory body is authorised to issue with reference to a legally binding document or other formal authorisation. These recommendations are not legally binding and enforced like regulations, however they can not be ignored by the licensee without risking some sanction by the regulatory body. General recommendations are most often, in a similar manner as legally binding requirements, issued according to a formal procedure including soliciting the opinion of the stakeholders. The licensee has a choice to implement the specific recommendation or an alternative, justified to be equal from the safety point of view. In most countries these recommendations are expressed as “should” statements.

Both the legally binding requirements and formally issued general recommendations are published in official documents, which depending on national practice can be requested by the public and media. In many cases they are published in official publications and posted on the internet web site of the government and/or the regulatory body. From the harmonisation point of view, it is important that the requirements are open to the public and transparently enforced in order to ensure equal conditions for the licensees in the different countries. Requirements defined and enforced by specific licensing documents only, such as SARs and Operational Manuals have limitations here, since these are non-public documents.

The study deals only with generic requirements. This means that specific regulatory decisions, which are legally binding and documented, but not addressing all licensees in the same manner are excluded.

The legally binding generic requirements and formally issued general recommendations were identified from the document hierarchy of each country. This was in itself not an easy exercise, since the picture is more or less complicated. It is however clear that regardless of legal system and regulatory practice, the two types of requirements exist in all WENRA countries.

3.3 *Description of national requirements*

The identified national requirements related to each issue were described in a condensed way in the matrix format below, i.e. only the substance of the requirements was described and not the full text of the original document. The level of detail regarding the substance was however the same as in the original document. References to the original documents were given.

It was indicated in the matrix if there were any legal exemptions from the mentioned requirements or possibilities for exemptions, for instance if older reactors are excepted or if a certain reactor design is excepted. It was also indicated if compensatory measures were allowed, i.e. if a certain requirement could be considered fulfilled by complying with another requirement. Finally the implementation status as known by the regulatory body was indicated. In cases where

measures related to the issue were judged as implemented but not formally required, a comment was made about this.

Description matrix

Substance of national requirements

Safety issue:

Country:

Ref req theme	Legally binding requirement	General recommendation	Comments ¹
1			
2			
3			
N			

1/I = implemented in all NPPs to an acceptable extent I- = not sufficiently implemented in all NPPs
 I+ = implemented above requirements in all NPPs I? = implementation status not known
 E = permanent exemptions allowed (NE= not allowed) C = compensatory measures allowed (NC= not allowed)

The matrix was further structured to make it possible to identify which national requirements are related to the themes of the reference levels (see section 3.4). This would make it easier to understand the basis for the comparison assessments. However, in some cases the national requirements on the safety issue under examination were different from the reference levels to such an extent that it was not possible to directly relate them. In those cases the matrix has no references to the themes of the reference levels. One matrix was developed per issue (6) and country (8).

3.4 Establishment of reference levels

In order to compare in a systematic manner, and conclude on the substantial differences and similarities between national requirements, it was necessary to define a reference against which to make the comparisons. Without references it seemed impossible to draw systematic conclusions based on technical criteria. The references were elaborated as reference levels related to each selected safety issue. These levels were chosen from the national requirements already existing in the WENRA countries. Somewhere in these countries the reference levels should be in force and probably also implemented on the nuclear power plants. This also implies that the reference levels most probably had been scrutinised and reviewed by the stakeholders according to a formal procedure, and found to be realistic and useful for safety. Hence, the reference levels have a real background and are not abstractions.

The Working Group reviewed the legally binding requirements and recommendations existing in the different countries, related to each issue, and selected from these the most safety significant (key) requirements in the opinion of the Group. It was important that the result of this exercise was not a compromise between already existing national requirements, but an informed decision on a reasonable level for the near future based on current regulatory experience. The expected

outcome was, in the terminology of the study, in the "highest quartile" of existing national requirements. This means that the reference levels do not necessarily reflect the most advanced requirement currently existing in at least one of the countries, but is selected among the most advanced existing requirements, where such a grading is possible. In the end this is an expert judgement where the Working Group applied its rather long experience as regulators to select reference levels, which were considered to be significant, realistic, cost-efficient and which have proved to be useful for safety.

The substance of the reference levels should reflect as much as possible the national requirements used as a model. This means that the reference levels should correspond as much as possible in strictness, prescriptiveness and level of detail to the national requirements used as model. In many cases this means that the reference levels are non-prescriptive and do not regulate in detail. In other cases the reference requirements are more detailed.

The Working Group tried to find a practical and neutral model for the structure and wording of the reference levels. For each safety issue, the reference levels were grouped under themes in order to provide a logical structure and an easier overview. The reference levels themselves are formulated in "shall" sentences. The number of reference levels under each theme depends on the complexity of the theme and varies between one and nine.

The themes are shown in the table below. The complete set of reference levels is presented in the enclosed annex.

Safety area	Issue	Reference level themes
Safety Management	- Safety Policy	<ol style="list-style-type: none"> 1. Issuing and communication of a safety policy 2. Strategy for implementing the safety policy and monitoring safety performance 3. Evaluation of the safety policy
	- Operating Organisation	<ol style="list-style-type: none"> 1. Organisational structure 2. Management of safety and quality 3. Sufficiency and competency of staff
Design	- Verification and Improvement of the Design	<ol style="list-style-type: none"> 1. Selection of design basis events and hazards 2. Demonstration of reasonable conservatism and safety margins of the design basis 3. Definition and application of technical acceptance criteria 4. Extension of the design 5. Instrumentation and hardware provisions for the management of severe accident conditions 6. Improvement of the design
Operation	- Beyond Design Basis Accident Management	<ol style="list-style-type: none"> 1. Procedures and guidelines for dealing with beyond design basis accidents 2. Training and exercises for accidents beyond design
Safety verification	- Probabilistic Safety Analysis	<ol style="list-style-type: none"> 1. Scope and content of PSA 2. Quality of PSA 3. Use of PSA
	- Periodic Safety Review	<ol style="list-style-type: none"> 1. Objective of the periodic safety review 2. Scope of the periodic safety review 3. Methodology of the periodic safety review

Areas, issues and reference level themes selected for the Pilot Study

3.5 Comparison with IAEA safety standards

For this comparison, the following procedure was used:

2. The relevant IAEA documents were identified from the categories Safety Requirements and Safety Guides of the IAEA Safety Standards Series. These two categories correspond in the IAEA system to the definition of national requirements used in the Pilot Study.

For the purpose of the Pilot Study, the Working Group used the most current version of the relevant IAEA standards, even if some documents still were under revision and not yet formally issued. Two of the documents were issued during the study.

The following documents were found relevant for the purpose of the Pilot Study:

Safety Requirements

Safety of Nuclear Power Plants: Design. NS-R-1, IAEA Vienna, 2000.

Safety of Nuclear Power Plants: Operation. NS-R-2, IAEA Vienna, 2000.

Safety Guides

The Operating Organisation for Nuclear Power Plants. NS-G-2.4. IAEA Vienna, 2001.

Safety Assessment and Verification for Nuclear Power Plants. NS-G-1.2. IAEA Vienna, 2001.

Periodic Safety Review of Nuclear Power Plants. DS 307, Draft 8. IAEA Vienna, 2001-12-07⁵.

3. The IAEA documents above were screened in order to find the corresponding IAEA requirements related to each reference level. These IAEA requirements were documented on the reference levels paper under the headline "Related IAEA safety standards".

As a first step the IAEA Safety Requirements were screened (shall statements). As a second step the corresponding Safety Guide was screened in order to check for any additional relevant requirements (should statements).

4. An analysis was made about the correspondence between each reference level and the related IAEA standard. An amendment was made of the reference level in the following cases:

The IAEA standard addressed additional aspects which were considered useful for safety reasonable and practicable by the Working Group,

The IAEA standard had a more clear and functional wording.

5. After amendments, an overall conclusion was made and a comment about the correspondence between the final set of reference levels on each issue and the related IAEA safety standards, regarding scope and strictness.

The IAEA standards provide an internationally agreed framework for the safety of nuclear installations. In many cases they are rather extensive descriptive documents, each dealing with or making cross-references to several safety issues. It is not easy to directly compare these

⁵ Endorsed by CSS for publication in June 2002.

documents with the more explicit national requirements in force in WENRA countries, on which the reference levels were modelled. However the substance can be compared.

Only a few amendments were made to the original reference levels, as a result of the comparison with the IAEA standards, mostly regarding the issues Verification and improvement of the Design and Periodic Safety Review. In those cases the IAEA standards had a more functional wording on some points.

As a general conclusion, there is a rather good correspondence in substance between the reference levels and the most recent IAEA standards⁶. In no cases were the IAEA requirements found to be stricter than the original reference levels. On the issues Operating Organisation, Verification and improvement of the Design, Beyond Design Basis Accident Management and PSA, several reference levels are stricter than the IAEA standards. For instance regarding measures to cope with accidents beyond the design basis, the reference levels include specified measures, some of which only mentioned in the IAEA Safety Guides as examples of Member State practice.

3.6 Assessment of differences between national practices and reference levels

A consistent approach is needed for making these assessments with sufficient reliability. From the first test of the methodology it was concluded that several provisions were needed in order to reduce subjectivity and increase transparency of these assessments. Several modifications of the methodology were implemented during the study to provide for this:

- The descriptions of national requirements were restructured so it is easier to identify how they compare with the reference levels,

- A panel was created for the comparison assessments consisting of representatives from all participating countries,

- A documented procedure was developed for the assessments,

- Documented criteria were used in the assessments,

- The documentation format (comparison matrix) was simplified.

The comparison assessment was documented in a matrix consisting of three sheets. The matrix shows the situation in each country in terms of which reference levels exist in national requirements and are implemented. Sheet 1 was designed for documentation of the assessment results and the general conclusions. Sheet 2 was intended for explaining differences, which could be justified and sheet 3 was used to explain differences, which could not be justified and hence should be addressed for harmonisation. One comparison matrix (3 sheets) was developed for each safety issue under examination.

Each reference level was allocated to one of two categories in the comparison matrix addressing the legal aspect and one of two categories addressing the implementation:

Rather strict criteria were applied in these assessments. To qualify as a national requirement, the requirement had strictly to satisfy “formally issued, generic and legally based” as explained in section 3.2. **Required** means that the reference level was judged to be equal in substance to a national requirement. Minor differences in wording and contextual differences might exist, such

⁶ The Working Group identified several cases where the wording of the IAEA documents could be directly related to input given from WENRA countries during the production of the documents.

that the reference level can be included in other national requirements, rather than being self-standing, but must in such cases be possible to identify. No difference in substance means that the reference level and the national requirement will lead to equal implementation measures at the NPP level, i.e. are judged in the end to result in equal safety margins of the barriers and defence in depth system.

Comparison matrix- Issue:

Sheet 1(3)

Assessment	Belgium	Finland	France	Germany	Italy	Spain	Sweden	UK
Required								
Not Required								
Implemented								
Not Implemented								
Conclusion X, Y								

Implemented means that the reference level was judged to having been implemented in **all** NPPs of the country.

An important modification of the methodology during the Pilot Study was the establishment of a panel for making the assessments. The panel consisted of the entire Working Group with one representative for each participating country. In the panel session, each member explained and if necessary evidenced his prepared national position on the safety issues, which then was opened for questioning by the other members. The final classification on sheet 1 was decided collectively. In cases of disagreement, the country representative was given time to adjust his position including consulting his home office.

This procedure improved the reliability and consistency of the assessments to a great extent. In many cases complex judgement had to be exercised and the procedure supported that kind of problem solving in a good way. Voting was not necessary.

3.7 Conclusion about differences between national practices and reference levels

A summary conclusion of the overall position of each country on the safety issue under examination was confirmed by the panel and documented in the bottom row of the comparison matrix sheet 1. This conclusion was drawn in two dimensions:

- (X) Difference between national requirements and reference levels,
- (Y) Difference between national implementation and implementation of reference levels.

Under each dimension the following was indicated:

- A. In principle already harmonised,
- B. Differences exist but can be justified from the safety point of view,
- C. Differences exist which should be addressed for harmonisation.

To qualify as an **A**, all reference levels had to be graded as **required** or **implemented**, i.e. there were no substantial differences between the reference levels and the national requirements and no differences in the implementation. For a **B**, there were substantial differences, i.e. at least one reference level was **not required** or **not implemented**, but this difference was possible to justify from the safety point of view. Conclusion **C** indicated that there were one or more differences, which could not be justified.

Approved justifications were:

- Regulations are under development or revision and will include the missing reference level(s),
- The reference level is covered by a different national requirement to such an extent that the added safety value of the reference level is minor,
- Implementation of a reference level is lacking in an older plant for which a shut down decision has been taken,
- Implementation of a reference level is in progress and it is only a matter of time before completion,
- Implementation of a reference level is not reasonably practicable on a specific reactor design and has been exempted on the basis of a technical justification that has been accepted by the regulatory body.

The last justification applies only in a few specific cases where technical back-fitting would be unreasonable from the safety point of view.

Since substantial differences can be graded as B or C, there were cases where both applied (BC). In those cases, substantial differences were identified, some of those possible to justify and some not.

On sheet 2 of the matrix, the differences between national requirements and reference levels possible to justify (B-differences) were described and the justifications provided.

Comparison matrix- Issue:

Sheet 2(3)

Justification of differences

Country	Difference	Justification
Belgium		
Finland		
France		
Germany		
Italy		
Spain		
Sweden		
UK		

On sheet 3, the differences not possible to justify (C-differences) were described.

Differences which should be addressed for harmonisation

Country	Difference
Belgium	
Finland	
France	
Germany	
Italy	
Spain	
Sweden	
UK	

3.8 Summary of results

The main result of the study is that none of the WENRA countries that were involved in the Pilot Study totally complies with the reference levels as stated in the Annex. In many cases the differences between national requirements and reference levels have been justified according to the pre-established criteria. However, several differences which should be further addressed by the respective country for harmonisation (C-differences) have been identified. Hence, for those cases measures should be taken to bring the national situation up to the reference level.

In the opinion of the Working Group, it is also important when reviewing the results to look at the B-differences, i.e. the differences between national requirements and reference levels, which were possible to justify. Although these differences need not to be addressed for harmonisation, they should be reviewed anyhow. For instance it could be useful to check if the national requirements could be improved or clarified on these points. In cases where differences with regard to a certain reactor design have been justified, since harmonisation measures are not judged to be reasonably practicable, an extended analysis of possible compensatory measures is recommended in the framework of the next Periodic Safety Review.

4. Conclusions about the methodology

Most of the objectives, set for the Pilot Study, were met. It can be concluded that the methodology was adequate for its purpose. National requirements on selected safety issues have been systematically compared and the major gaps and differences have been identified. Convenient overviews have been provided of differences and similarities between the countries. Furthermore, the conclusions are based on a safety justification and are detailed enough to provide input to a further more detailed analysis on the national level. It was not possible, however, to provide fully verified conclusions about the implementation of the reference levels in the different countries. This has to do with the following constraints on the study.

In line with the Terms of Reference, the comparison of formal requirements did not address the more detailed use of criteria and methods to verify compliance. The same requirement could be enforced differently in different regulatory systems, and hence lead to different implementation. The Pilot Study also assessed the implementation, but it was not possible to do this in sufficient detail to identify such differences. The implementation was assessed on the basis of current knowledge of the respective regulatory body, but it was not possible to provide the panels with

evidence of the implementation. For these reasons, conclusions about implemented safety provisions in the different countries should be drawn with precaution.

The introduction of the panel assessments greatly improved the quality and consistency of the comparison assessments. Uncertainties in the assessments are mainly connected with lack of time to make a detailed analysis in some cases. The reliability of the assessments seems to be sufficient for the objectives of the Pilot Study.

The introduction of the IAEA safety standards in the study proved to be helpful and provided confidence in the scope and strictness of the reference levels.

This Pilot Study has contributed to understand how to approach harmonisation and has provided a basis for further progress on this important safety and policy issue. The study has further provided a systematic opportunity to learning from best national and international practices in order to promote safety and has already contributed to improvements.

Annex

Reference levels developed and used in the Pilot Study

Safety area: Safety Management

Issue: Safety policy

1. Issuing and communication of a safety policy

Reference levels:

- 1.1 A written safety policy shall be issued by the licensee.
- 1.2 The safety policy shall be clear about giving safety first priority in all plant activities.
- 1.3 The safety policy shall include a commitment to continuously develop safety.
- 1.4 The safety policy shall be communicated to all staff⁷, with tasks important to safety, in such a way that the policy is understood and applied.
- 1.5 The safety policy shall be communicated to subcontractors, in such a way that the policy is understood and applied in their on-site activities.

2. Strategy for implementing the safety policy and monitoring safety performance

Reference levels:

- 2.1 The safety policy shall require a strategy for implementing the safety policy and monitoring safety performance.
- 2.2 The safety policy shall require safety objectives and targets, clearly formulated in such a way that they can be easily monitored and followed up by the plant management.

3. Evaluation of the safety policy

Reference level:

- 3.1 The adequacy and the implementation status of the safety policy shall be evaluated by the licensee on a regular basis, more frequent than the periodic safety reviews.

⁷ This is understood as the licensee's own staff

Safety area: Safety Management
Issue: Operating Organisation

1. Organisational structure

Reference levels:

- 1.1 The organisational structure for safe and reliable operation of the plant, and for ensuring an appropriate response in emergencies, shall be justified and documented.
- 1.2 The adequacy of the organisational structure, for its purposes according to 1.1, shall be assessed on a regular basis, more frequent than the periodic safety reviews.
- 1.3 Responsibilities, authorities and lines of communication shall be clearly defined and documented for all staff with duties important to safety.
- 1.4 Changes to the organisational structure which might be significant for safety shall be justified in advance, carefully planned and evaluated after implementation.

2. Management of safety and quality

Reference levels:

- 2.1 The licensee shall ensure that the plant is operated in a safe manner and in accordance with all applicable legal and regulatory requirements.
- 2.2 The licensee shall ensure that decisions on safety matters are preceded by appropriate investigation and consultation.
- 2.3 The licensee shall ensure that the staff is provided with the necessary resources and conditions to carry out work in a safe manner.
- 2.4 The licensee shall ensure that safety performance is continuously monitored through an appropriate review system in order to ensure that safety is maintained and improved as needed.
- 2.5 The licensee shall ensure that relevant operating experience, international development of safety standards and new knowledge gained through R&D-projects are systematically analysed and continuously used to improve plant activities.
- 2.6 The licensee shall ensure that plant activities (processes) are controlled through a documented quality management system covering all activities, including relevant activities of vendors and contractors, which may affect the safe operation of the plant.
- 2.7 The quality management system shall be regularly audited by independent auditors, and kept up-to-date.
- 2.8 Significant safety issues shall be subjected to appropriate safety review, by a suitably qualified independent review function, before being submitted to the regulatory body.

3. Sufficiency and competency of staff

Reference levels:

- 3.1 The required number of staff for safe operation, and their competence, shall be analysed in a systematic and documented way.
- 3.2 The sufficiency of staff for safe operation, their competence and suitability for safety work shall be verified on a regular basis and documented.
- 3.3 A long term staffing plan shall exist for activities which are important to safety.
- 3.4 Changes to the level of staffing which might be significant for safety shall be justified in advance, carefully planned and evaluated after implementation.
- 3.5 The licensee shall always have, in house, sufficient and competent staff and resources to understand the licensing basis of the plant (e.g. Safety Analysis Report or Safety Case and other documents based thereon), as well as to understand the actual design and operation of the plant in all plant states.
- 3.6 The licensee shall maintain, in house, sufficient and competent staff and resources to specify, set standards manage and evaluate safety work carried out by contractors.

Safety area: Design

Issue: Verification and Improvement of the Design

1. Selection of design basis events and hazards

Reference levels:

- 1.1 The current design basis shall be clearly and systematically defined and documented.
- 1.2 The design basis shall include a set of postulated initiating events, with consideration of failures and hazards (internal and external, natural and man-induced), selected with deterministic or probabilistic methods or a combination of both, to demonstrate that the necessary safety functions are accomplished and the safety objectives met.

2. Demonstration of reasonable conservatism and safety margins of the design basis

Reference levels:

- 2.1 The initial and boundary conditions shall be specified in a conservative way.
- 2.2 The single failure criterion shall be applied in all design basis analyses of postulated initiating events.
- 2.3 Non-safety systems, including off-site power, shall be assumed to operate only if they aggravate the effect of the initiating event.
- 2.4 The safety systems shall be assumed to operate at their minimum performance level.
- 2.5 Any failure, occurring as a consequence of a postulated initiating event, shall be included in the design basis analysis.
- 2.6 The impact of uncertainties, which are of importance for the results, shall be addressed in the design basis analyses.

3. Definition and application of technical acceptance criteria

Reference levels:

- 3.1 Radiological and other technical acceptance criteria shall be assigned to each plant condition (typically normal operation, anticipated operational occurrences, design basis accidents, additional failure assumptions, and severe accidents), according to its probability of occurrence.
- 3.2 Criteria for protection of the fuel cladding shall be specified, including fuel temperature, DNB, cladding temperature, fuel rod integrity and maximum allowable fuel damage during any design basis accident.
- 3.3 Criteria for the protection of the (primary) coolant pressure boundary shall be specified, including maximum pressure, maximum temperature, thermal- and pressure transients and stresses.
- 3.4 For PWR only: Criteria in 3.2 shall be specified as well for protection of the secondary coolant system.
- 3.5 Criteria shall be specified for protection of the containment, including temperatures, pressure and leak rates.

4. Extension of the design

Reference levels:

- 4.1 Consideration shall be given to the performance of the plant in specified accidents beyond the design basis, including a selection of severe accidents, to determine those sequences for which reasonable practicable preventive or mitigation measures can be identified (accident vulnerability study). For this study a combination of engineering judgement and probabilistic methods can be used and evaluations be made on a best estimate basis.
- 4.2 Consideration shall be given, in the same manner as in 4.1, to combination of postulated initiating events with internal and external hazards.

- 4.3 The specified accidents beyond the design basis shall include station blackout, ATWS, multiple SG tube rupture, loss of main heat sink, and loss of required safety systems in the long term after a postulated initiating event.

5. Instrumentation and hardware provisions for the management of severe accident conditions

Reference levels:

- 5.1 Adequate instrumentation shall exist which can survive severe accident environmental conditions in order to manage such accidents according to guidelines/procedures for severe accidents.
- 5.2 Necessary information from instruments shall be relayed to the control room and presented in such a way to enable a timely assessment of the plant status and critical safety functions in accident conditions.
- 5.3 Means shall exist for containment isolation in a severe accident, including bypass prevention⁸.
- 5.4 The containment leaktightness shall be ensured for a reasonable time after a severe accident.
- 5.5 Means shall be provided to manage pressure and temperature in the containment during a severe accident
- 5.6 Means shall be provided to control combustible gases in a severe accident.
- 5.7 Means shall be provided for containment overpressure protection in a severe accident.
- 5.8 Means shall be provided for prevention of high pressure core melt scenarios.
- 5.9 Means shall be provided to prevent containment melt through.

6. Improvement of the design

Reference level:

- 6.1 The current design shall on a regular basis, and when needed as a result of operating experience and significant new safety information, be reviewed, using both a deterministic and a probabilistic approach, against current requirements and practices to identify deviations. The safety significance of identified deviations shall be determined with respect to possible design improvements or backfitting or other measures justified from a safety point of view.

⁸ It is understood that the means mentioned in 5.3-5.9 shall be able to perform its functions in relevant severe accident conditions, although not formally qualified.

Safety area: Operation

Issue: Beyond Design Basis Accident Management

1. Procedures and guidelines for dealing with beyond design basis accidents

Reference levels:

- 1.1 Symptom based Emergency Operating Procedures (EOPs) shall exist to re-establish or compensate for lost safety functions. They shall include measures or actions to prevent core damage, such as feed and bleed, alternative water and power supplies.
- 1.2 Transition from the use of EOPs to Severe Accident Management and corresponding organisational arrangements shall be stated in procedures⁹.
- 1.3 Guidelines/procedures shall address containment protection including hydrogen management, temperature, and pressure control inside the containment..
- 1.4 Guidelines/procedures shall address containment isolation and protection of personnel and the public including management of exposures and releases.
- 1.5 Guidelines/procedures shall address core debris cooling and prevention of re-criticality.
- 1.6 Guidelines/procedures shall address prevention of high pressure core melt scenarios.

2. Training and exercises for accidents beyond design

Reference levels:

- 2.1 The control room staff and on-site technical support shall be regularly trained and exercised, using simulators and diagnostic tools for at least the EOPs, and as far as practicable for the guidelines for management of severe accidents.
- 2.2 The transition from EOPs to guidelines for management of severe accidents shall be exercised.
- 2.3 Planning and regular exercises shall exist for emergency repairs and other interventions needed to restore necessary safety functions.

⁹ It is understood that EOPs are normally used by the control room staff and mostly address prevention within and beyond the design basis, while guidelines for management of severe accidents are normally used by the emergency management team and mostly address mitigation of severe accidents.

Safety area: Safety verification
Issue: Probabilistic Safety Analysis (PSA)

1. Scope and content of PSA

Reference levels:

- 1.1 PSA shall be developed for levels 1 and 2.
- 1.2 PSA shall include all modes of operation, all relevant initiating events and hazards, including internal fire, internal flooding, severe weather conditions and seismic events.
- 1.3 PSA shall include all relevant dependencies (functional dependencies, area dependencies and other common cause failures).
- 1.4 PSA shall contain uncertainty and/or sensitivity analyses.
- 1.5 PSA shall be based on a realistic modelling of plant response, taking into account human performance to the extent assumed in operating and accident procedures.
- 1.6 Human errors shall be analysed, taking into account the factors which can influence the performance of the operators in all plant states.

2. Quality of PSA

Reference levels:

- 2.1 PSA shall be performed, documented and maintained according to the quality management system of the licensee.
- 2.2 PSA shall be performed according to the state-of-the-art methodology.

3. Use of PSA

Reference levels:

- 3.1 PSA shall be used for safety management purposes. Its role in the decision making process shall be defined.
- 3.2 PSA shall be used to identify the need for modifications to the plant and its procedures, in order to reduce the risk from the plant.
- 3.3 PSA shall be used to assess the overall risk from the plant, to demonstrate that a balanced design has been achieved, and to provide confidence that there are no "cliff edge effects".
- 3.4 PSA shall be used to assess the adequacy of plant modifications, changes to technical specifications and procedures and to assess the significance of operational occurrences.
- 3.5 Insights from PSA shall be used as input to development and validation of the safety significant training programmes of the licensee, including simulator training of control room operators.

Safety area: Safety verification
Issue: Periodic Safety Review

1. Objective of the periodic safety review

Reference levels:

- 1.1 The licensee shall have the prime responsibility for performing the review.
- 1.2 The review shall confirm the compliance of the plant with its licensing requirements and any deviations shall be resolved.
- 1.3 The review shall identify and evaluate the safety significance of deviations from applicable current safety standards and best practices.
- 1.4 All reasonably practicable improvement measures shall be taken by the licensee as a result of the review.
- 1.5 An overall assessment of the safety of the plant shall be provided, and adequate confidence in plant safety for continued operation demonstrated, as a result of the full scope review, taking into account all identified strengths and decided corrective actions, as well as any shortcomings that cannot be reasonably and practicably resolved.

2. Scope of the periodic safety review

Reference levels:

- 2.1 The review shall be made periodically, at least every ten years.
- 2.2 The scope of the review shall be clearly defined and justified.
- 2.3 The scope shall be as comprehensive as reasonably practical with regard to significant safety aspects of an operating plant.
- 2.4 As a minimum the following areas shall be covered by the review:
 - plant design as built and actual condition of systems, structures and components,
 - current safety analyses and their use,
 - operating experience during the review period and the effectiveness of the system used for experience feed-back,
 - organisational arrangements,
 - safety performance and the effectiveness of safety and quality management,
 - staffing and qualification of staff,
 - emergency preparedness, and
 - radiological impact on the environment.

3. Methodology of the periodic safety review

Reference levels:

- 3.1 The review shall use an up to date systematic and documented methodology, taking into account deterministic as well as probabilistic assessments.
- 3.2 Each area shall be reviewed and the findings compared to the licensing requirements as well as to current safety standards and practices. Conclusions shall be drawn with regard to reasonable and practical improvement measures taking into account interactions and overlaps between the different safety issues.
- 3.3 If studies made for other purposes are utilised in the periodic safety review, their contribution to the review shall be explained. These studies shall be available and appropriate references given.