Swedish Radiation Safety Authority Regulatory Code

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Swedish Radiation Safety Authority

SSMFS 2008:1

The Swedish Radiation Safety Authority's Regulations and General Advice concerning Safety in Nuclear Facilities

Consolidated version with amendments made up to and including SSMFS 2010:3

Please note that translated versions of the Authority's regulations lack legal force and are for information purposes only.

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The Swedish Radiation Safety Authority's Regulations concerning Safety in Nuclear Facilities;[1]

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On the basis of Sections 20a and 21 of the Ordinance on Nuclear Activities (1984:14), the Swedish Radiation Safety Authority has issued the following regulations.

Chapter 1. Application and definitions

Section 1 These regulations apply to measures required to maintain safety in connection with the construction, possession and operation of nuclear facilities with the aim of, as far as reasonably achievable, taking into account the best available technology, preventing radiological accidents and preventing the unlawful handling of nuclear material and nuclear waste. The regulations comprise provisions on technical, organisational and administrative measures.

These regulations apply to the following types of nuclear facilities for which permission to conduct nuclear activities has been granted on the basis of Section 5 of the Nuclear Activities Act (1984:3):

- a nuclear power reactor,
- a research or materials testing reactor,
- a facility for the handling, treatment or storage of nuclear material,
- a facility for the handling, treatment or storage of nuclear waste,
- a facility for the disposal of nuclear material or nuclear waste which has not been finally closed.

Basic provisions on the safety of nuclear activities are stipulated in Section 4 of the Nuclear Activities Act (1984:3).

[1] These regulations and general advice were previously published in the Swedish Nuclear Power Inspectorate Regulatory Code (SKIFS 2004:1), with the exceptions of Chapter 2, Section 10, Chapter 4, Sections 1 and 2, Chapter 5, Section 1, Appendix 2, "Design rules", "Radiation protection", "Operation of the facility" and "References", in addition to general advice for Chapter 1, Section 1, Chapter 2, Section 10, Chapter 4, Sections 1-3 and Appendix 2.

Regulations on the safety of a repository for nuclear material or nuclear waste after its final closure are stipulated in the Swedish Radiation Safety Authority's regulations (SSMFS 2008:21) concerning safety in connection with the disposal of nuclear material and nuclear waste.

Section 2 In these regulations, 'nuclear facility', 'nuclear material' and 'nuclear waste' refer to the same terms as those defined in Section 2 of the Nuclear Activities Act (1984:3). The following terms and definitions are also used in these regulations:

decommissioning:	Measures adopted by licensees after the final shutdown of a facility in order to dismantle the facility in a safe manner, as well as handle the nuclear material and nuclear waste located at the facility site.
barrier:	Physical confinement of radioactive substances.
defence in depth:	Application of several, overlapping levels of technical equipment, operational measures and administrative procedures to protect the facility's barriers and to maintain their effectiveness as well as to protect the surroundings if the barriers should not function as intended.
physical protection:	Technical, administrative and organisational measuresfor the purpose of protecting a facility against unauthorised access, sabotage and other such impact which can result in a radiological accident and for the purpose of preventing unauthorised dealing with nuclear material and nuclear waste.
normal operation:	Operation within the conditions and limitations stipulated in the Operational Limits and Conditions for a facility.
radiological accident:	A deficiency arising in a barrier or some other condition leading to the dispersion of radioactive substances, or which leads to radiation doses exceeding permissible limits during normal operation.
safety function:	Technical systems with which a facility is specifically equipped to protect the facility's barriers with the aim of preventing a radiological accident.
safe state:	An operating state that minimises the risk of a radiological accident. For a nuclear power reactor, the following normally applies: assured sub-criticality and a temperature below 100 degrees Celsius in the reactor pressure vessel.

Chapter 2. Basic safety provisions

Barriers and defence in depth

Section 1 Radiological accidents shall be prevented through a facility-specific and fundamental design which shall incorporate multiple barriers as well as a facility-specific system for defence in depth.

Defence in depth shall be achieved by:

- ensuring that the design, construction, operation, monitoring and maintenance of a facility are such that abnormal operation and accidents are prevented,
- ensuring that multiple devices are available and prepared measures are in place to protect the integrity of the barriers and, if the integrity should be breached, to mitigate the ensuing consequences, and
- ensuring that any release of radioactive substances to the environment, which may nevertheless occur as a result of abnormal operation and accidents, is prevented, or, if this is not possible, controlled and mitigated through devices and prepared measures.

Handling of deficiencies in barriers and in defence in depth

Section 2 The facility shall be brought to a safe state without delay if it is found that the facility is functioning in an unexpected manner, or if it is difficult to determine the severity of an observed deficiency.

Section 3 If a deficiency is observed or if there is reason to suspect that there is a deficiency in a barrier or in the defence in depth system, measures shall be taken to the extent and within the time frame necessary depending on the severity of the deficiency. For this purpose, the deficiencies shall be evaluated, classified and investigated without delay. The deficiencies shall be classified in accordance with Appendix 1 while taking into account the degree of severity.

Section 4 When a **category 1** deficiency in accordance with Appendix 1 has been observed, or if there is reason to suspect such deficiency, the facility shall be brought to a safe state without delay.

Before the facility may be allowed to return from a safe state to operations without special limitations, a safety review in accordance with Chapter 4, Section 3 shall be conducted of the investigations carried out and the measures taken as a result of the deficiency, and such investigations and measures shall be reviewed and approved by the Swedish Radiation Safety Authority.

Section 5 When a **category 2** deficiency in accordance with Appendix 1 has been observed, or when there is reason to suspect such deficiency, the facility may remain in operation during the period of time when corrective

action is being taken. In connection with this, the necessary limitations or controls to maintain safety shall be observed.

If corrective action in accordance with the first paragraph can be taken within the allowed repair time in accordance with the Operational Limits and Conditions, the facility may resume operations without special limitations after the measures have been taken and readiness for operation has been checked. A safety review in accordance with Chapter 4, Section 3 shall subsequently confirm that the safety margins of the facility have been restored through the measures taken.

In cases where conditions for corrective action are not specified in the Operational Limits and Conditions, the facility may not resume operations without special limitations until corrective action has been taken and a safety review in accordance with Chapter 4, Section 3 has confirmed that the safety margins are restored.

If it should be found during the investigation of the deficiency that the deficiency is of a more severe nature than covered by the category 2 classification or that there is significant uncertainty concerning the safety margins, the deficiency shall be re-classified as category 1 and the measures that are then necessary shall be taken without delay.

Section 6 In the event of a **category 3** deficiency in accordance with Appendix 1, the facility may remain in operation with the limitations necessary for maintaining safety, taking into account the deficiency, during the period of time when corrective action is being taken. Before measures are taken as a result of the deficiency, a safety review of the point in time and means of implementing the measures shall be performed in accordance with Chapter 4, Section 3.

Organisation, management and control of the nuclear activity

Section 7 Provisions concerning the organisation and financial, administrative and human resources for the nuclear activity are contained in Section 13, first paragraph, item 2 of the Nuclear Activities Act (1984:3).

Section 8 The nuclear activity shall be managed, controlled, evaluated and developed with the support of a management system that is designed so that the safety requirements are met. The management system, including the routines and instructions that are necessary for the control of the nuclear activity, shall be kept up to date and be documented.

The application of the management system and its effectiveness and efficiency shall be systematically and periodically investigated by an audit function which shall have an independent position in relation to the activities to be audited. The facility shall have an established audit programme.

Section 9 The licensee shall ensure that:

1. there are documented safety objectives and directives in place describing how safety is to be maintained and improved in the nuclear activity and that persons who work with this activity are well acquainted with these objectives and directives,
2. responsibilities, authority and co-operation are defined and documented for the personnel performing duties which are important for safety in the nuclear activity,
3. the nuclear activity is planned so that adequate time and adequate resources are allocated for the safety measures and safety review that need to be performed,
4. decisions on safety issues are preceded by adequate investigation and consultation so that the issues are comprehensively examined,
5. the personnel have the competence and suitability otherwise needed for tasks which are of importance for safety in the nuclear activity and ensure that this is documented,
6. the personnel working in the nuclear activity are provided with the necessary conditions to carry out work in a safe manner,
7. experience of importance for safety from the facility's own nuclear activity and from similar activities is continuously utilised and communicated to the personnel concerned, and that
8. safety in the nuclear activity is routinely monitored and followed up, and deviations are identified and managed so that safety is maintained and continually improved in accordance with the objectives and directives that apply.

Additional provisions concerning the competence of personnel are stipulated in the Swedish Radiation Safety Authority's regulations (SSMFS 2008:32) concerning the competence of operations personnel at reactor facilities.

Safety programme

Section 10 After it has been taken into operation, the safety of a facility shall be continuously analysed and assessed in a systematic manner. Such analysis and assessment shall also encompass applicable rules for design, construction and operation as well as design assumptions having arisen following commissioning of the facility. An established safety programme shall be in place for the safety improvement measures, i.e. technical as well as organisational measures arising as a result of this continuous analysis and assessment. The safety programme shall be evaluated and updated on an annual basis.

Physical protection

Section 11 A facility shall have physical protection.

The design of such protection shall be based on an analysis of the threat scenarios for the facility and shall be documented in a plan where the design, organisation, management and staffing of this protection shall

be described. The analysis of the threat scenarios and plan shall be kept up to date and the effectiveness of the plan shall be investigated through exercises conducted on a regular basis.

Before the facility may be taken into operation, a safety review shall be conducted of the plan for physical protection in accordance with Chapter 4, Section 3 and the plan shall be reviewed and approved by the Swedish Radiation Safety Authority. Safety reviews in accordance with Chapter 4, Section 3 shall be conducted of modifications to the plan affecting the physical protection. Before the modifications may be implemented, the Swedish Radiation Safety Authority shall be notified of the modifications.

Emergency preparedness

Section 12 In the event of abnormal operation and accident conditions which may require protective measures within and outside a facility, there shall be preparedness for:

- the classification of events in accordance with the applicable alarm criteria,
- alerting the facility's emergency preparedness personnel,
- assessing the risk and extent of possible releases of radioactive substances and time-related aspects,
- returning the facility to a safe and stable state, and
- providing information to the competent authorities about the technical situation at the facility.

It shall be possible to immediately initiate necessary measures at the facility site in order to fulfil the tasks stipulated in the first paragraph.

Additional provisions concerning emergency preparedness are stipulated in the Civil Protection Act (2003:778) and the Civil Protection Ordinance (2003:789).

Section 13 The measures in accordance with Section 12 shall be documented in an emergency response plan which, before the facility may be taken into operation, shall be subjected to a safety review in accordance with Chapter 4, Section 3 as well as reviewed and approved by the Swedish Radiation Safety Authority. The plan shall be kept up to date and its effectiveness shall be investigated through exercises conducted on a regular basis.

A safety review in accordance with Chapter 4, Section 3 shall be conducted on modifications to the emergency response plan affecting the measures as stipulated in Section 12. Before the modifications may be implemented, the Swedish Radiation Safety Authority shall be notified of the modifications.

The licensee shall appoint special personnel as well as ensure that adequate management centres, technical systems, aids and protective equipment are available to the extent necessary in order to perform the tasks stipulated in Section 12.

Chapter 3. Facility design

Section 1 The design of a facility shall:
- be able to withstand component and system failures,
- be reliable and have operational stability, and
- be able to withstand events and conditions which can affect the safety functions of the barriers or those of the defence in depth system.

Furthermore, the design shall make it possible to maintain, inspect and test the systems, components and devices necessary for safety. In addition, the design shall, as far as possible and reasonable, take into account the implementation of safe future decommissioning of the facility.

The design of nuclear fuel shall be adapted to the specific reactor facility where the nuclear fuel is used, to devices for handling and storage at the reactor facility and to the existing or planned systems for transport, interim storage, processing and disposal of spent nuclear fuel.

Additional provisions on the design of nuclear reactors are stipulated in the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors.

Section 2 Design principles and design solutions shall be tested under conditions corresponding to those that can occur during their intended application in a facility. If this is not possible or reasonable, the design principles and design solutions shall be subjected to testing or evaluation in a way demonstrating that they have the necessary durability, reliability and operational stability, taking into account their function and importance for the safety of the facility.

Section 3 The design shall be adapted to the personnel's ability to, in a safe manner, monitor and manage the facility and the abnormal operation and accident conditions which can occur.

More detailed provisions concerning control room design and emergency control posts for nuclear reactors are stipulated in the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors.

Section 4 Structures, systems, components and devices shall be designed, manufactured, installed, inspected and tested in accordance with requirements adapted to their function and importance for the facility's safety.

Chapter 4. Assessment and reporting of the safety of facilities

Safety analysis

Section 1 The capacity of a facility's barriers and defence in depth system to prevent radiological accidents and mitigate the consequences in the event of an accident shall be analysed using deterministic methods before

the facility is constructed, or modified and taken into operation. The analyses shall subsequently be kept up to date.

The safety analyses shall be based on a systematic inventory of events, event sequences and conditions which can lead to a radiological accident. Such events, sequences and conditions that have been identified are to be broken down into event classes. For each event class, quantitative analyses are to demonstrate that limits applying to barriers are maintained and that a radiological impact on the environment is acceptable in relation to the limits stated under the Radiation Protection Act (1988:220).

More detailed provisions on division into event classes and analysis assumptions for nuclear power reactors are stipulated in the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors.

Models, methods and data used for safety analyses and for determining design and operating limits are to have been validated and forthcoming uncertainties are to have been taken into account.

In addition to deterministic analyses in accordance with the first paragraph, the facility shall be analysed using probabilistic methods in order to obtain as comprehensive a view as possible of safety.

Safety analysis report[2]

Section 2 A safety analysis report shall provide an overall view of how the safety of the facility is arranged in order to protect human health and the environment against radiological accidents. The report shall reflect the facility as it is built, analysed and verified, as well as show how the requirements on its design, function, organisation and activities are met.[3] The safety analysis report shall contain no less than the information specified in Appendix 2 in addition to the Operational Limits and Conditions stipulated in Chapter 5, Section 1, first paragraph. Modifications to the facility shall be evaluated on the basis of the conditions specified in the safety analysis report.

A preliminary safety analysis report shall be drawn up before a facility may be constructed and, for an existing facility, before major refurbishing or rebuilding work or major modifications are carried out. The safety analysis report shall be updated before trial operation of the facility may commence so that the report reflects the construction of the facility. The safety analysis report shall be supplemented, taking the experiences of such trial operation into account, before the facility is subsequently taken into regular operation.

The preliminary safety analysis report as well as the updated and supplemented safety analysis report in accordance with the second paragraph

[2] Corresponds to a Safety Analysis Report (SAR) in accordance with the IAEA's terminology.

[3] Valid requirements are stipulated in applicable regulations and licensing conditions as well as rules, such as industrial standards, that the licensee also applies to the facility.

shall at all stages have been reviewed for safety in accordance with Section 3 and reviewed and approved by the Swedish Radiation Safety Authority. The safety analysis report shall be kept up to date thereafter.

More detailed provisions concerning safety analysis reporting for disposal of nuclear material and nuclear waste are stipulated in the Swedish Radiation Safety Authority's regulations (SSMFS 2008:21) concerning safety in connection with the disposal of nuclear material and nuclear waste.

Safety review

Section 3 A safety review in accordance with the provisions of these regulations shall be performed in order to verify that applicable safety aspects have been taken into account and that applicable safety requirements with respect to the design, performance, organisation and activities of the facility are met. The review shall be performed in a comprehensive and systematic manner and shall be documented.

The safety review shall be performed in two stages. The first stage, the primary review, shall be performed within the parts of the facility's organisation that are responsible for the specific issue. The second stage, the independent safety review, shall be performed within a safety review function appointed for this purpose, which shall have an independent position relative to the parts of the organisation responsible for the specific issue.

Periodic safety review of the facility

Section 4 Provisions concerning periodic safety reviews of a facility and its radiation protection are contained in Section 10a of the Nuclear Activities Act (1984:3). The Swedish Radiation Safety Authority shall determine the specific point in time for submission of periodic safety reviews for each facility.

Modifications

Section 5 Technical and organisational modifications to a facility, which can affect the conditions specified in the safety analysis report, as well as principal modifications in the safety analysis report, shall be subject to a safety review in accordance with Section 3.

Before modifications in accordance with the first paragraph may be implemented, the Swedish Radiation Safety Authority shall be notified of the modifications.

Chapter 5. Operation of the facility

Operational Limits and Conditions[4]

Section 1 The licensee shall prepare Operational Limits and Conditions for the management of facility operation. The Operational Limits and Conditions shall contain the information stated in Appendix 3. The Operational Limits and Conditions shall, together with the procedures stipulated in Section 2, provide personnel with the necessary guidance for ensuring that facility operations are conducted in accordance with the conditions stated in the facility's safety analysis report.

Before the facility may be taken into trial or routine operation, the Operational Limits and Conditions shall be reported and approved in accordance with Chapter 4, Section 2.

The Operational Limits and Conditions shall be kept up to date. A safety review in accordance with Chapter 4, Section 3 shall be performed relating to any modifications or any planned temporary deviations from the Operational Limits and Conditions. The Swedish Radiation Safety Authority shall be notified of such modifications or of planned temporary deviations before they may be applied.

Procedures and guidelines

Section 2 Procedures established by the licensee shall have been drawn up for measures to be taken at a facility during normal operation, abnormal operation and design basis accidents. Furthermore, in the case of a nuclear power reactor, symptom-based emergency operating procedures shall have been drawn up in order to re-establish or in order to compensate for lost safety functions with the aim of avoiding core damage. The procedures mentioned shall be adequate, documented and kept up to date. The personnel concerned shall be well acquainted with the procedures.

In addition to procedures in accordance with the first paragraph, documented guidelines shall have been drawn up at the facility for measures which may be necessary to implement in order to control and mitigate the consequences of beyond design basis accidents.

Procedures concerning the control of readiness for operation as well as procedures and guidelines intended for application in connection with abnormal operation and accidents in accordance with the first and second paragraphs shall, before they may be applied, have been subject to a safety review in accordance with Chapter 4, Section 3.

Maintenance, continuous surveillance, inspection and testing

Section 3 Structures, systems, components and devices of importance for safety at a facility shall be inspected, tested and maintained on a continuous basis in such a way that they meet the safety requirements. Programmes for maintenance, continuous surveillance, inspections and testing as well as for the management of ageing degradation and damage

[4] Usually referred to as 'STF'.

shall be in place. The programmes shall be documented and shall be reviewed and updated in the light of experience gained as well as developments in science and technology.

Detailed provisions on in-service inspection of mechanical components are stipulated in the Swedish Radiation Safety Authority's regulations (SSMFS 2008:13) concerning mechanical components in certain nuclear facilities.

Functional testing shall be conducted to verify the facility's readiness to operate before the facility, structures, systems, components and devices in accordance with the first paragraph are taken into operation following maintenance work or other intervention.

Investigation of events and conditions

Section 4 The kind of investigation as required by Chapter 2, Section 3, or performed for other safety-related reasons, shall be conducted systematically. As far as possible and reasonable, the investigation shall determine the sequence and causes of an event or the causes of another demonstrated safety deficiency as well as establish the measures needed to restore the facility's safety margins and to prevent the recurrence of safety deficiencies.

The results of investigations in accordance with the first paragraph shall be communicated to the personnel concerned at the facility and shall be used to improve facility safety. Furthermore, the results shall be reported to the Swedish Radiation Safety Authority in accordance with the provisions of Chapter 7, Sections 1-3.

Chapter 6. Nuclear material and nuclear waste

Section 1 An inventory shall be made of nuclear waste within the site area of a facility. An identity-marked waste package or other unit that allows for unique identification shall correspond to each registered waste item. The list shall be kept up to date.

Section 2 Measures shall be undertaken to prevent criticality in connection with handling, treatment and storage of nuclear material at the facility. Such measures shall be specified in a safety analysis report in accordance with Chapter 4, Section 2.

Section 3 Nuclear material and nuclear waste that is handled, processed, stored or disposed of at the facility shall be confined in a safe manner.

The necessary preparatory measures shall also be taken at the facility for safe confinement of nuclear material and nuclear waste in connection with transport to and storage or disposal in another facility. Measures required in accordance with the first and second paragraphs shall be specified in the safety analysis report in accordance with Chapter 4, Section 2.

Section 4 If nuclear waste arises which, in terms of quantity and type, deviates from that specified in the safety analysis report, the necessary measures for safe confinement of the non-conforming waste shall be documented in a plan. Before the measures may be initiated, a safety review of the plan shall be performed in accordance with Chapter 4, Section 3 and the Swedish Radiation Safety Authority shall be notified of the plan.

Chapter 7. Reporting of events and conditions to the Swedish Radiation Safety Authority

Section 1 Events which have occurred and conditions which are detected and which have an essential impact on the safety of a facility shall, without delay, be reported to the Swedish Radiation Safety Authority in the manner described in Appendix 4.

Section 2 Events which have occurred and conditions which are detected and which are of a less severe nature than mentioned in Section 1 but of importance for the safety of the facility shall be reported as soon as possible to the Swedish Radiation Safety Authority in accordance with Appendix 4.

Section 3 Routine reports concerning the operational state and concerning activities which are of importance for the safety of the facility shall be submitted in accordance with Appendix 4.

Chapter 8. Documentation and document retention

Section 1 Technical documentation concerning the facility and safety analysis reports which have been prepared in accordance with Chapter 4, Section 2 shall be retained for as long as the nuclear activity is carried out at a facility.

Section 2 Documentation of the operational activity and of other activities which are of importance for the safety of a facility shall be retained for the necessary length of time in order to be able to investigate and analyse the causes of events that have occurred in the facility and to facilitate periodic safety reviews of the facility in accordance with Chapter 4, Section 4 for as long as the nuclear activity is conducted at the facility.

Chapter 9. Decommissioning of a facility

Section 1 Before a facility may be constructed, a preliminary plan shall be drawn up for the future decommissioning of the facility. The plan shall contain the information specified in Appendix 5. The preliminary plan shall be supplemented and kept up to date for the duration of the facility's operation and shall be reported to the Swedish Radiation Safety Authority every ten years.

Section 2 Before dismantling of the facility may be initiated, the decommissioning plan in accordance with Section 1 shall be supplemented and incorporated into the facility's safety analysis report as stipulated in Chapter 4, Section 2. A safety review in accordance with Chapter 4, Section 3 shall be performed of the revised safety analysis report and the report shall be reviewed and approved by the Swedish Radiation Safety Authority.

The Environmental Impact Assessment which is submitted to the Environmental Court in accordance with the Ordinance on Environmental Impact Assessments (1998:905) shall be attached to the revised safety analysis report stipulated in the first paragraph.

Section 3 When a decision has been made on final shutdown of a facility within a certain period of time, an integrated analysis and assessment of how safety is to be maintained during the time remaining until the facility's closure shall be conducted without delay. The analyses, assessments and measures emanating from these shall be documented and reported to the Swedish Radiation Safety Authority.

Chapter 10. Exemptions

Section 1 If there are particular grounds, the Swedish Radiation Safety Authority may grant exemptions from these regulations if this can be done without circumventing the aim of the regulations.

These regulations shall enter into force on 1 February 2009.

SWEDISH RADIATION SAFETY AUTHORITY

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Appendix 1

Classification of deficiencies in barriers and the defence in depth system

Category 1

Serious deficiencies observed in one or more barriers or in the defence in depth system, as well as a well-founded suspicion that safety is severely threatened, shall be classified as Category 1.

The following events or conditions shall be assigned to Category 1:

1.1 exceeding the highest permissible limit ('HTG'), in accordance with the definition provided in the Operational Limits and Conditions,

1.2 a deterioration in the integrity of any of the barriers for the containment of radioactive materials, such as
- damage to nuclear fuel resulting in an extensive release of fission products to the reactor coolant,
- damage to the primary system pressure boundary which results in the activation of the facility's safety functions,
- damage to the reactor containment which means that the containment does not fulfil the postulated leaktightness and structural integrity requirements in the safety analysis report,

1.3 an unplanned reactivity increase in a reactor, or unintentional criticality in a reactor, or criticality in areas where nuclear material is handled, stored or kept,

1.4 deficiency in an activity, management or control which is of such an extent that it severely threatens safety,

1.5 a deficiency or deviation of such a severe nature or extent that it calls into question the safety analysis report of the facility, and

1.6 an event or deficiency in the physical protection which is of such a nature or extent that it is a severe threat to safety.

Category 2

Observed deficiencies in one barrier or in the defence in depth system which are less severe than that which is referred to in Category 1, as well as a well-founded suspicion that safety is threatened, shall be classified as Category 2.

The following events or conditions shall be assigned to Category 2:

2.1 deviation from the Operational Limits and Conditions which is within the assumptions and conditions stated in the safety analysis report,

2.2 a deviation from specified system or component performance,

2.3 a condition which results in operational limitations or in limitations on the duration of operation, though not including

planned measures specified in the Operational Limits and Conditions,

2.4 a condition which has prevented or could have prevented the intended functioning of equipment which is of importance for safety,

2.5 the limit for the activation of the safety function is observed to result in a lower margin to the safety limit than specified in the safety analysis report,

2.6 nuclear fuel damage entailing damage to the cladding or other defect of the fuel pin which results in releases of radioactivity, or mechanical damage, geometric deformation or some other condition which may make a fuel bundle unsuitable for continued operation, though not including fuel which is being investigated in a special research or materials testing reactor,

2.7 a condition in the facility which results in nuclear material being present in equipment which is not approved for this,

2.8 a condition in the facility which means that a substance with moderating properties is present to a greater extent than that postulated during normal operation in a structure or equipment where moderation control is necessary,

2.9 a deficiency having a material impact on safety in a single analysis that is part of the safety analysis report or a method used for such analysis,

2.10 another technical or organisational condition which threatens safety, and

2.11 an event or deficiency in physical protection which threatens safety.

Category 3

A temporary deficiency in the defence in depth system which arises when an event or condition is corrected and which, without measures, could lead to a more severe condition, and which is documented in the Operational Limits and Conditions in accordance with Chapter 5, Section 1, shall be classified as Category 3.

An event or condition assigned to Category 3 may not prevent the function of the facility but indicates the need for measures or testing since there is a risk that a component or system might not fulfil requirements concerning readiness for operation in accordance with the Operational Limits and Conditions. However, the duration of the measures may not exceed the analysed permissible repair time specified in the Operational Limits and Conditions.

For Category 3 to apply, the event or condition must be of such a nature that immediate measures are not warranted.

Appendix 2

Information in safety analysis reports

The safety analysis report for a facility shall contain no less than the following information. Furthermore, the report shall, in a suitable manner, while taking into account the need for confidentiality, contain information on the design assumptions and design of the physical protection.

Site

An account of how the site and its surroundings, from the standpoint of safety, can affect the facility, for example with respect to hydrological conditions, geology and seismic conditions as well as ongoing activities within the area.

Design rules

An account of the requirements including design principles, design assumptions and design rules that governed the design and construction of the facility. An account of how the facility fulfils the rules and assumptions mentioned, as well as of how structures, systems, components and devices in the facility have been assigned to classes specifying their importance for safety.

Such account shall also encompass rules which can be derived from the safety analysis report for the respective repository of nuclear material and nuclear waste following its closure.

Facility and functional description

A description of the facility and its systems, function and performance during normal operation, including the handling of nuclear material and nuclear waste. Detailed descriptions of the facility's barriers, safety functions and associated safety systems. Descriptions of the systems and equipment which, besides the safety systems, have been found to be of essential importance for the defence in depth system. An account of the principles for control room design and other monitoring/manoeuvring devices where the interface between the personnel and facility is of importance for safety.

An account of the criteria for including equipment in the Operational Limits and Conditions as well as the principles for determining the functional testing and testing intervals necessary to ensure that the facility is being operated within the established limits (readiness for operation).

Radioactive substances

An account of the basis for determining the quantities and types of radioactive substances that can be released in the event of radiological accidents, known as 'source terms'.

Radiation protection

An account of the information about radiation protection determined under the Radiation Protection Act (1988:220).

Operation of the facility

An account of the organisation and principles for the management and control of:

- operations, including control room work,
- maintenance, continuous surveillance and testing as well as the handling of ageing degradation and damage,
- nuclear material and nuclear waste,
- the safety work at the facility, and
- preparedness for abnormal operation and emergencies.

A description of the packages of procedures applied during normal operation, abnormal operation and accidents.

An account of the principles for the facility's system for experience feedback.

An account of the principles for the facility's systems for staffing, training and competence evaluation of personnel with tasks of importance for safety in the nuclear activity.

Analysis of operational conditions

An account of the safety analyses conducted in accordance with Chapter 4, Section 1 and of studies that have been carried out relating to the construction of the facility and its environmental impact during normal operation, abnormal operation and accidents.

An account of analyses performed concerning mitigating measures in connection with severe accidents.

References

The investigations, analyses and sub-reports for the safety analysis report of importance for demonstrating how applicable requirements have been met.

Drawings

General drawings of the facility and of its systems, as well as flow charts.

Appendix 3

Information contained in the Operational Limits and Conditions

In order to ensure that the conditions reported or assumed in the safety analysis report are maintained at the facility, the Operational Limits and Conditions in accordance with Chapter 5, Section 1 shall contain a specification of:

- the highest permissible limits ('HTG')[5] which are of importance for the fuel cladding and primary system integrity in a reactor facility
- the other safety limits that are necessary to ensure that the fuel cladding, primary system and reactor containment design limits are not exceeded in a reactor facility
- other conditions and limitations that are necessary to maintain and control the facility's readiness for operation to ensure that its performance does not exceed or fall below the specified levels during the necessary period of time in systems and components of importance for safety during a particular operational state
- safety functions as well as other equipment of essential importance for the defence in depth system with:
  - information on the systems and components included
  - the requirements on readiness for operation[6] for the operational states in question, as well as
- the measures to be taken when readiness for operation does not apply, for example limitations in the form of a permitted repair time or a permitted power level
- the principles for the management and control of facility operations
- the rules for the handling of failures, abnormal operation as well as maintenance, testing and modification work
- the necessary staffing to ensure safe operation during different operational states
- the events and conditions at the facility which result in the measures stipulated in Chapter 2, Sections 2-6, investigations as stipulated in Chapter 5, Section 4 as well as reporting to the Swedish Radiation Safety Authority in accordance with Chapter 7, Sections 1-3

[5] In the case of pressurized water reactors, the term 'safety limits' is used instead of 'limits'.
[6] For non-safety classified equipment, 'requirement' refers to availability for operation.

Reporting

Reporting in accordance with Chapter 7, Section 1

1. The following shall be reported without delay:

- an event or condition which causes an alarm for increased preparedness or an accident fulfilling the alarm criteria established by the Swedish Radiation Safety Authority
- an event or condition which belongs to Category 1 in accordance with Appendix 1
- a scram in a reactor facility where expected consequential functions of importance for safety have failed

The Swedish Radiation Safety Authority shall in these cases be informed within one hour after the event has occurred or the condition is detected.

The following information shall be reported to the Swedish Radiation Safety Authority when such an event or condition has occurred:

- what has occurred,
- when it occurred,
- which immediate consequences it has resulted in,
- which actions have been taken,
- which actions are planned, and
- an assessment of the progression of the situation.

Follow-up reports shall be submitted in the event of any essential change in the safety state or when a new assessment is made of the progression of the situation.

2. The following shall be reported within 16 hours:

- an event or condition which, in accordance with the applicable technical criteria, is classified as Level 2 or higher on the International Nuclear and Radiological Event Scale (INES).

3. The following shall be reported within 7 days:

- a comprehensive report on any event or condition which has resulted in an alarm in accordance with item 1 above or which has been assigned to Category 1 in accordance with Appendix 1. Such report shall contain:
    - a description of the event and event sequence
    - a preliminary analysis of causes and consequences as well as an assessment of the significance of the event or condition in terms of safety
    - measures that have been taken or are planned to restore the safety margins and to prevent a recurrence

A record or corresponding statements of undertaken safety reviews shall be attached to the report.

Reporting in accordance with Chapter 7, Section 2

4. The following shall be reported within 30 days:

- a comprehensive report on any event or condition which has been assigned to Category 2 in accordance with Appendix 1
- an event or condition that is assigned to Level 1 on the International Nuclear and Radiological Event Scale (INES)
- a scram report for a reactor facility

If there are particular grounds meaning that a final report in accordance with the first paragraph cannot be submitted within 30 days, a preliminary report shall be submitted to the Swedish Radiation Safety Authority. This report shall also contain a justification of the particular grounds and a fixed time schedule specifying when a final report can be ready. A safety review of such justification and time schedule shall be carried out in accordance with Chapter 4, Section 3.

In addition to the above-mentioned reporting of events and conditions, the Swedish Radiation Safety Authority's regulations (SSMFS 2008:13) concerning mechanical components contain requirements on special reporting of damage that has occurred.

Reporting in accordance with Chapter 7, Section 3

5. A nuclear power reactor shall submit the following report every day (daily report):

- operational state during the day,
- thermal power level in per cent,
- event or condition of Category 1, 2 or 3 that has occurred,
- abnormal operation, for example the activation of the reactor protection system, and
- other circumstance which may be of importance for safety.

6. Other facilities shall submit the following report every week (weekly report):

- abnormal operation,
- event or condition of Category 1, 2 or 3 that has occurred, and
- other circumstance which may be of importance for safety.

7. The following report shall be submitted every year (annual report):

– an integrated report of activities at the facility during the calendar year with experience gained and conclusions reached with regard to safety. An account of events or conditions that have been assigned to Categories 1, 2 or 3 or that have resulted in a reactor scram shall also be included in the report. Conditions which have been assigned to Category 3 shall also be described with respect to the purpose of the measures and the time utilised to implement the measures (prevention time).

The annual report shall be submitted to the Swedish Radiation Safety Authority no later than 1 March the following year.

Appendix 5

Information contained in the decommissioning plan

The complete decommissioning plan for a facility shall contain the following information. The preliminary decommissioning plans which are reported in accordance with Chapter 9, Section 1 shall contain the information described below which it is reasonable to expect should be available at the time of reporting. In cases where the corresponding information is provided in the facility's safety analysis report or in other safety documentation, it is sufficient to refer to this information. Radiation protection provisions are stipulated in the Swedish Radiation Protection Authority's regulations (SSMFS 2008:19) on planning before and during decommissioning of nuclear facilities.

Documentation of the facility

- Current facility description with drawings.
- Operating data, operating experience and events that may be of importance for safety during decommissioning.
- A description of the radioactive material that remains in the facility after final shutdown.

Prerequisites for planning

- An account of available or planned systems for disposal of the nuclear waste arising in connection with decommissioning.
- An account of the ultimate objective of decommissioning.
- An account of intended deadlines for the start and end of decommissioning.
- These deadlines are to be justified while, among other things, taking into account the availability of personnel with operating experience from the facility and from decommissioning.

Decommissioning activity

- A description of the planned activity from final shutdown until the point in time when decommissioning is completed. The division into different stages and the choice of methods for decontamination and dismantling shall be justified.
- An account of the planned organisation, the management and control of the decommissioning activity in addition to an estimate of the need for personnel and competence at different stages.
- An assessment of the planned activity's safety consequences, taking into account the risk of radiological accidents.
- An account of the planned handling of radioactive material as well as measures that must be taken for the safe confinement of nuclear waste arising as described in Chapter 6, Section 3.

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The Swedish Radiation Safety Authority's general advice on the application of the regulations (SSMFS 2008:1) concerning safety in nuclear facilities

SSMFS 2008:1

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The Swedish Radiation Safety Authority hereby issues the following general advice.

Chapter 1, Section 1

A nuclear power reactor is the complete facility needed for production of nuclear energy, including secondary and auxiliary systems as well as devices within the facility necessary for the handling of nuclear material and nuclear waste.

It should be noted that, according to the Nuclear Activities Act (1984:3), spent nuclear fuel is considered to be nuclear material until it is deposited in a repository. According to the definition contained in the Act, it is then considered to be nuclear waste.

The regulations also apply to measures implemented before closure of a repository and which may affect safety following closure.[1]

A facility for the storage of nuclear waste which has a separate licence and which is operated by the same licensee as a nuclear power plant may, in connection with the application of these regulations, be considered to be part of the nuclear power plant.

The decommissioning of a nuclear facility is also included in the concept of nuclear activity as this is defined in the Nuclear Activities Act (1984:3).

[1] Requirements on safety after final closure are stipulated in the Swedish Radiation Safety Authority's regulations (SSMFS 2008:21) concerning safety in connection with the disposal of nuclear material and nuclear waste.

Chapter 1, Section 2

The decommissioning process includes measures for shutdown operations, service operations and dismantling, as well as for handling of the nuclear material and nuclear waste located at the facility site at final shutdown, and the nuclear waste which arises in connection with dismantling. The shutdown operations stage comprises necessary measures as long as nuclear material remains in the facility. The service operations stage comprises necessary measures after the nuclear material has been removed from the facility and until dismantling has started.

It should be noted that the concept of normal operation covers all of the operating states included in the Operational Limits and Conditions.

Definitions of 'management system' and 'audit' are provided in the Swedish Standard, SS-EN ISO 9000:2000: Management Systems for Quality – Principles and Terminology.

Chapter 2, Section 1

The overall purpose of the defence in depth system is to compensate for possible technical failures and errors in the handling of the facility, to maintain the effectiveness of the barriers by averting damage and malfunctions in the facility as well as to protect the public and the environment from harmful effects if the barriers should not perform as intended.

The defence in depth system should be applied on five levels in accordance with the table below.[2] If one level of defence should fail, the next level will take over. A failure in a component or in a manoeuver on one level, or combinations of failures which occur simultaneously on different levels, must not jeopardise the function on the next level. Thus, independence between the different levels in the defence in depth system is essential to achieve this. An additional strength in one barrier or defence in depth level should therefore not be credited in order to accept deficiencies in another barrier or defence in depth level.

[2] See also "Defence in Depth in Nuclear Safety", IAEA-INSAG-10. A report by the International Nuclear Safety Advisory Group. International Atomic Energy Agency, Vienna, 1996 and "Basic Safety Principles for Nuclear Power Plants", IAEA-INSAG 12. A report by the International Nuclear Safety Advisory Group, International Atomic Energy Agency, Vienna, 1999.

Level	Purpose	Main measures
1	Prevention of abnormal operation and failures	Robust design and high standards on design, operation and maintenance
2	Control of abnormal operation and detection of failures	Control and protection systems as well as surveillance and in-service inspection
3	Control of accidents within the design basis	Technical safety functions as well as emergency operating procedures
4	Control of severe plant conditions, including prevention of accident progression and mitigation of the consequences of severe accidents	Prepared engineered measures and effective accident management at the facility
5	Mitigation of consequences of significant releases of radioactive substances	Effective co-operation with the competent authorities for protection of the public and the environment

Important general conditions for achieving and maintaining an effective defence in depth system include implementing a suitable organisation and an effective system for the management, control and follow-up of activities at the facility.

This for example means that:
- safety is prioritised
- sufficient financial resources and personnel with adequate competence are available
- safety is monitored and followed up, failures and deficiencies are identified and corrected, as well as the organisation learning from its own mistakes and from those of others so that deficiencies in safety do not recur
- conservative assumptions and good safety margins are applied in the design and operation of the facility
- quality assurance is applied in the nuclear activity
- opportunities for safety improvement are utilised
- the organisation as a whole is characterised by a good safety culture
-

Provisions regarding the organisation, management and control of the nuclear activity are stipulated in Sections 7-10.

The defence in depth system is based on the assumption that there are a number of specially adapted physical barriers placed between the radioactive material and the personnel of a facility and its environment. The design of the barriers may vary depending on the characteristics of the contained material and on possible deviations from normal operation which may result from the breach of other barriers.

For nuclear power reactors which are in operation, the barriers usually comprise the fuel geometry, the cladding, the primary system pressure boundary and the reactor containment. Barriers can also comprise spent nuclear fuel containers and other qualified packaging, stocks and storage

facilities used to confine nuclear material and nuclear waste. As regards barriers in connection with disposal of nuclear material and nuclear waste, see the Swedish Radiation Safety Authority's regulations (SSMFS 2008:21) concerning safety in connection with the disposal of nuclear material and nuclear waste.

The defence in depth system comprises different quantities and types of technical systems, operational measures and administrative procedures to protect the barriers and to maintain their effectiveness during normal operation and during postulated events, incidents and accidents. If these provisions should fail, measures which have been established in advance must be in place to limit and mitigate the consequences of a more severe accident.

In order to ensure that the overall level of safety is satisfactory, it should be analysed which barriers and components on different levels of the defence in depth system must function during different operational states in a facility. When a facility is in full operation, all barriers and parts of the defence in depth system should be in function. When the facility is shut down for maintenance or a barrier must be disabled for other reasons, this should be compensated for by other measures of a technical, operational or administrative nature. Chapter 5, Section 1 stipulates how this is to be controlled.

Chapter 2, Section 3

The requirements regarding investigating and taking measures when there is a deficiency in a barrier or in the defence in depth system also apply in the event of suspicion that safety is threatened from the basis of safety analyses performed as well as ensuing from events that have occurred and from conditions detected at other similar facilities. The degree of severity of the failure type or deficiency as such, the possible safety impact that it might have, as well as the safety impact in the particular case in question should be determined by the investigation made.

The requirement regarding taking a measure without delay means that it must be taken as soon as the necessary basis for the measure is available.

Chapter 2, Section 4, Appendix 1

Item 1.2: Damage as a result of dryout is an example of damage that can lead to an extensive release of fission products and nuclear material to the reactor coolant.

Item 1.3: When deciding which unplanned reactivity increase in the reactor should be assigned to Category 1, reactivity increases which are greater than half of the average value of the delayed neutrons in the core may provide guidance. A lower unplanned reactivity increase, or if the event is

included in the safety analysis report of the facility, may be assigned to Category 2.

Item 1.5: The deficiency or deviation referred to may have been identified through an event, investigation, analysis or other experience which has emerged at the facility itself or at another similar facility. Fuel bending, which can prevent control rods being inserted into the core, is an example of a deficiency that is of such a serious nature that the safety analysis report of the facility can be called into question.

Chapter 2, Section 5, Appendix 1

Item 2.6: When nuclear fuel damage occurs which can lead to difficulties in detecting new damage or the release of uranium to the primary system which makes testing and maintenance difficult, or if the quantity of alpha activity in the operational waste from the facility exceeds the acceptable limit for nuclear waste disposal, the reactor should be shut down as soon as this is possible and suitable and the damaged fuel should be removed from the core.

Chapter 2, Section 7

The organisation should be set up and staffed so that it supports safe and reliable operation of the facility while allowing for effective measures to be taken in an emergency situation. The suitability of the organisation in these respects should be evaluated regularly.

Chapter 2, Section 8

The management system should encompass the entire nuclear activity at the facility. Therefore, the scope should not be overly narrow. The IAEA's standards for management systems can provide guidance in terms of the design of the management system needed with respect to safety.[3]

The management system should especially focus on the crosscutting organisational processes in the nuclear activity. The crosscutting processes place special demands on co-ordination, transparent allocation of responsibilities and authority, etc. One example is the management and control of plant modifications which normally concern several units in the facility's organisation.

The management system should clearly specify how contractors and suppliers of services and equipment for the nuclear activity are assessed and how these assessments are kept up to date.

[3] Latest edition: IAEA Safety Standards/Safety Requirements No. GS-R-3: The Management System for Facilities and Activities. International Atomic Energy Agency, Vienna, 2006.

The audit function should be given a sufficiently strong and independent position in the organisation and should have the authority to report directly to the highest manager of the facility. The auditors should be appointed so that the audit activity has continuity and is performed by individuals with a good knowledge of the activity being audited.

When determining suitable audit intervals, the importance of the different activities for safety and the special auditing needs that may arise should be taken into account. All of the audit areas should normally be evaluated at least once every four years.

The audit activity as such and the facility management function should also periodically undergo an audit.

Chapter 2, Section 9

Item 1: The directives for safety should, in a tangible manner, specify how the safety objectives will be achieved. The objectives and directives should clearly specify that safety is always prioritised in the nuclear activity.

The safety objectives may be both quantitative and qualitative. Objectives should be formulated so that they can be followed up.

The suitability and application of the objectives and directives should be evaluated on a regular basis.

All personnel working in the nuclear activity should be familiar with the safety objectives and directives, including hired personnel and, to a suitable extent, suppliers of the nuclear activity.

Item 2: The personnel should be well acquainted with responsibilities, authority and conditions for co-operation, and suitable processes should be established for communication in the organisation. In cases where a category of personnel is conducting similar tasks of importance for safety in the nuclear activity, it is sufficient to define the responsibilities and authority for the personnel category.

Item 3: The requirement imposed on planning encompasses both the regular activity at the plant and procurements conducted of an activity of importance for safety.

Item 4: In order to ensure adequate investigation and consultation, in addition to the provisions of Chapter 4, Section 3, a safety committee should be established with the aim of functioning as an advisory group for principal safety issues. The committee members should have a high level of integrity and broadly-based expertise in nuclear safety issues and

should report to the manager who has the ultimate responsibility for safety at the facility.

Item 5: The requirements concerning personnel also apply to contractors and other temporarily hired personnel for the nuclear activity, where applicable.

In order to ensure the availability of personnel with adequate competence, competence and staffing plans should be prepared for several years in advance. In order to analyse the need for personnel and the competence required in the nuclear activity, a systematic method should be used which, based on analyses of the tasks, identifies the staffing and competence requirements as well as the need for training. The systematic method shall also include a regular evaluation of the effectiveness and efficiency of completed training.

A systematic competence follow-up should be conducted each year in order to check that personnel performing tasks of importance for safety in the nuclear activity have the competence required for the tasks, and to analyse the need for supplementary training and further education. The follow-up should be conducted by using explicit criteria for acceptable performance.

In order to develop and maintain adequate competence within the organisation of the facility, the advantages and disadvantages of using in-house personnel should be weighed against using contractors and other temporarily hired personnel. The necessary competence to be able to request, lead and evaluate the performance of work which is of importance for safety in the nuclear activity and which is carried out by contractors or other hired personnel should always be maintained within the facility's organisation.

For an evaluation of general personnel suitability, an analysis must be carried out of the medical demands of various tasks of importance for safety in the nuclear activity, e.g. with regard to keenness of vision, ability to distinguish colours and hearing ability, as well as medical conditions that may affect work capability. A documented policy should also be drawn up to manage other factors which can negatively affect the performance of personnel in terms of safety, for example, alcohol and other drugs. This kind of policy should include preventive measures and other measures to be taken if the personnel should be found to be under the influence of a drug, or in the event of abuse. The division of responsibilities for such measures should be defined and supervisors and other personnel concerned should be given training in these areas.

Adequate security clearance of the personnel must also be performed as part of an evaluation of general suitability.

Item 6: Many factors at a workplace affect human performance, for example the organisation of the activity, the layout of the workplace, equipment and aids, the physical environment, how work is supervised, instructions and procedures, communication with others, the workload and working hours. The correction of any deficiencies in working conditions which could have a detrimental impact on safety is an important part of preventive safety work. For this purpose, and in order to further improve the conditions for safe work, analyses and evaluations of the man-technology-organisation interaction should be conducted and recurrent evaluations performed.

Item 7: Efficient procedures should be in place for continuous experience feedback within the nuclear activity. In the light of experience gained, it should be continuously investigated whether the facility and its activities comply with the applicable conditions and regulations.

Item 8: The management system should clearly control how deviations identified in audits and other follow-ups are corrected. The deviations may concern deviations from safety objectives and directives in accordance with Item 1 as well as deviations from procedures and instructions applied in the nuclear activity. Safety indicators can be a suitable aid when monitoring and conducting follow-ups of the nuclear activity.

Chapter 2, Section 10

The continuous analysis and evaluation of facility safety should particularly take into account technical and organisational experience from one's own activity, from similar facilities, results from safety analyses and results from research and development projects which may be of importance when evaluating safety and for the improvement of rules used when constructing and operating the facility. Organisational experience for example refers to results from analyses of man-technology-organisation interaction, evaluations of the organisation and the personnel's working conditions as well as self-assessments of the safety climate and safety culture.

Applicable rules for construction, design and operation as well as construction assumptions arising after the facility has been taken into operation and which are assessed as being of significance for the safety of the facility should be documented within the framework of the safety programme and be included in the safety analysis report as soon as the ensuing measures have been taken.

The safety programme should specify overall priorities and timetables for the measures in the programme.

The possibility of improving safety should be taken into account in every measure resulting in modifications to the facility or its activities.

Chapter 2, Section 11

In order to elucidate the focus and scope of physical protection, it should be noted that the expression "measures which aim at protecting a facility" normally encompasses measures necessary for obstructing, delaying and limiting the consequences of unauthorised intrusion, sabotage and similar actions.

An analysis of the threat scenarios for the facility should include a number of typical cases/scenarios included in the design basis threat scenario[4] for the physical protection. For each of these typical cases/scenarios, overall assumptions for the threat as well as acceptable consequences and essential countermeasures should be described. Changes in the threat scenarios should be analysed to verify that the plan for physical protection is still adequate.

Physical protection should be planned as a comprehensive activity, i.e. ensuring that technical systems and administrative and organisational measures have been established in combination with adequate personnel resources. The awareness of the entire staff concerning the need for physical protection and its procedures is a fundamental factor for the effectiveness of such protection.

'Regular exercises' means that exercises should be conducted to the extent necessary to maintain effective protection. Each facility should have a training and exercise plan that is reviewed on an annual basis. Each exercise should be evaluated systematically in order to verify the adequacy of the physical protection and to identify the need for training of the personnel concerned.

Chapter 2, Section 12

In order to ensure that alarming and other initial measures in an accident situation can be implemented without delay, there should be adequate coordination between the emergency operating procedures of a facility and the alarm criteria established by the Swedish Radiation Safety Authority. Furthermore, efficient in-house procedures should be in place for decision-making concerning the mobilisation of emergency preparedness personnel and sufficient checklists and procedures should be available as support for decision-makers.

The technical systems used for alerting the emergency preparedness personnel should be tested on a regular basis to check that they will perform as intended.

[4] The design basis threat scenario is currently reported in document SSM 2008/2966 (confidential).

Individuals should be appointed by name and should have received training and have participated in exercises for the emergency preparedness tasks. Furthermore, for each task, a number of back-up personnel should have been appointed to ensure that personnel is always available and so that the necessary endurance is ensured in connection with accident sequences of long duration.

Aids and procedures should be in place to the extent needed for the evaluation of source terms in order to determine the quantity of radioactive material that risks being released, both in terms of the amount that should be contained as well as the amount that could be released to the environment.

A technical support function should be set up to assist the operations personnel on duty in analysing the event sequence and in proposing the measures which also might be necessary to implement in the long term. Furthermore, the support function may be in charge of preparing work which must be done in connection with emergency repairs and other measures necessary in the facility.

Chapter 2, Section 13

Planning should cover all types of accidents for which the facility is designed as well as measures to mitigate the consequences of possible accident sequences which can occur in addition to this. Furthermore, combinations of events should be taken into account, such as fire or sabotage in combination with a radiological accident.

'Adequate management centres' means that the centres are equipped with the necessary communication equipment and other necessary tools, access routes, radiation protection and protective ventilation.

Technical systems for instance include communication equipment and equipment allowing for an evaluation of the state of the facility even during severe conditions and during an extended event sequence. This for example means that the evaluation can also be conducted during severe radiological conditions.

'Regular exercises' means that exercises should be carried out to the extent necessary for emergency preparedness personnel to be able to safely and effectively perform the duties stipulated in Section 12. Each facility should have a training and exercise plan that is updated on an annual basis. Each exercise should be evaluated systematically to ensure the adequacy of the preparedness as well as to identify the emergency preparedness personnel's need for training.

Chapter 3, Section 1

The design requirements specified in the regulation are of a fundamental nature and should, to an appropriate extent, be taken into account during all design work, both before a facility is taken into operation as well as in connection with later plant modifications.

Ability to withstand events or conditions which could affect the function of the barriers or the defence in depth system refers to events or conditions which, in safety analyses, in accordance with Chapter 4, Section 1, have been found to significantly affect the safety functions. Examples of such events or conditions include pipe breaks, transients, fire, flooding, earthquakes, clogging of cooling water intakes, acts of sabotage and disturbances in, or loss of, offsite power.

Chapter 3, Section 2

The provisions in this section refer, among other things, to environmental qualification in the form of documented tests to ensure that components function as postulated in the safety analysis report. In order to meet this requirement, it is important that such qualification should be performed taking into account normal operating conditions as well as conditions arising in connection with abnormal operation and design basis accidents. This requirement also concerns components intended for a facility for the disposal of nuclear waste and which are necessary for maintaining safety following closure of the facility.

Chapter 3, Section 3

The design should be adapted to the functions and tasks to be carried out as well as to the capabilities and limitations of human beings. Experience from the facility in question should be utilised at an early stage in the design process. To ensure a knowledgeable evaluation of design solutions where the capability of personnel is an important prerequisite, experts on the man-technology-organisation interaction should be engaged to take part in the design, analysis and evaluation of the solutions.

The design of the facility should allow sufficient time for consideration of operator actions affecting the safety functions. Information and annunciator systems in control rooms should ensure that personnel have access to the information they need during different operational states without becoming overwhelmed by information during abnormal operation, accidents and refuelling and maintenance outages. The man-machine interfaces should be designed in accordance with good ergonomic practice so that the interfaces are compatible with human conditions and satisfy the need for interaction and communication during work. The solutions developed should be evaluated in the context where they will be used.

Chapter 3, Section 4

In order to ensure that structures, systems, components and devices are as well adapted as possible in relation to their importance for safety, a classification system should be applied for controlling requirements with respect to design and quality control.

Chapter 4, Section 1

Safety analyses should include a set of events or scenarios which, as far as possible, covers the event sequences and conditions that can affect the function of the barriers and the defence in depth system and thereby ultimately have a radiological impact on the environment. The frequency of different events or scenarios is a basis for division into different event classes.

Design basis events should be identified for the function of the barriers and defence in depth system on the basis of these event classes. This refers to events that determine requirements for facility design, namely with respect to the properties of barriers and the protection of the barriers, in order to ensure an acceptable level of safety. Probable as well as less probable design basis events should be specified. Identified events that are not subject to further analysis should be specified in the safety analysis.

Anticipated operational occurrences and component failures in a facility, as well as the possible action of operations personnel and incorrect action, should be analysed in order to investigate the potential of the facility to withstand the postulated events. In the analyses of how the facility should cope with design basis events, a random failure[5] should also be assumed to occur in the safety functions in connection with the initiating event or thereafter. The impact of uncertainties that are significant to the results should also be analysed.

One of the purposes of analysing postulated events should be to identify the necessary action by personnel and to judge the degree to which the procedures, instrumentation as well as other factors determining such action are adequate.

A safety analysis should generally be of a high level of quality with respect to documentation, references, review procedures, etc. The objective of the analysis should be clearly specified as well as the uncertainties and limitations of the analysis. Furthermore, the analysis should be characterised by good traceability and well-justified assumptions and data relevant for the facility. The results reported should include an explicit conclusion

[5] Often called a 'single failure' in connection with safety analysis.

regarding the safety of the facility within the conditions and limitations of the analysis.

The safety analysis for the decommissioning of a facility should particularly take into account factors such as rapid changes in facility status, the removal of both active and passive safety functions, the handling of large quantities of nuclear waste, as well as unusual and changing working conditions.

Specifically for probabilistic methods

Probabilistic methods for example include the calculation or estimation of probabilities of the given consequences of various chains of events ('probabilistic safety analysis', or 'PSA'). Depending on the type of facility and the complexity and risk picture of an operation, the need for a certain level of detail and the scope of the probabilistic analyses required also vary. For simpler facilities with a small risk of environmental impact, a simple line of reasoning as to the probability of various events may be sufficient.

The deterministically analysed requirements serve as the basis of the facility's operating permit. The requirements imposed on facility design should be verified and developed using probabilistic methods in order to achieve a more certain basis for the design.

For a reactor facility, probabilistic safety analyses ('PSA') should encompass:

- level 1: an analysis of the probability of core damage occurring, as well as
- level 2: an analysis of the probability of releases of radioactive material to the environment.

Furthermore, the analyses should cover the following operational states: power operation, also including startup and planned shutdown of the reactor, in addition to scheduled outages, which also include refuelling.

Probabilistic safety analyses should be as realistic as possible with respect to models and data. These analyses should also consider the impact of uncertainties significant for the results.

Probabilistic analysis should be routinely used in a reactor facility to evaluate the safety significance of events and plant modifications.

When applying probabilistic analysis for the evaluation of a facility's design and operation, the following should be taken into account:

- One aim should be to achieve a level of safety excluding dominant weaknesses.

– The consequence of changes in design requirements based on probabilistic analysis should be evaluated using a sensitivity analysis to demonstrate that the design will remain sufficiently robust. The fact that simplicity and transparency are essential properties for achieving a high level of safety should be taken into account.
– When changing one requirement, other requirements imposed on systems belonging to the same safety function or barrier should be taken into account. For example, in connection with a change to the frequency of component testing, other components and systems contributing to the same safety function should be evaluated.

Chapter 4, Section 2, first paragraph

The safety analysis report is the key technical documentation concerning the facility that is a comprehensive report showing all the licensing conditions, regulations and other requirements applying to a nuclear facility and its operations, as well as how these requirements have been interpreted and how they are fulfilled. For this reason, the comprehensive account of the requirements should also contain references to other parts of the safety analysis report containing information about how these requirements are fulfilled.

The scope and level of detail of the safety analysis report should reflect the complexity and risk picture of the facility.

An account of how applicable technical requirements are fulfilled should be verifiable through a specific investigation or analysis. An account of how the administrative requirements are fulfilled should be verifiable by means of information about the control and management systems applied at the facility. Compare the regulations in accordance with Appendix 2. Therefore, good traceability should consistently characterise the safety analysis report's information on current requirements, including descriptions of how such requirements are complied with and investigations and analyses confirming that the requirements are actually being complied with.

In its entirety, the safety analysis report should contain the information needed in order to draw up Operational Limits and Conditions ('STF') in accordance with Chapter 5, Section 1 and procedures and guidelines in accordance with Chapter 5, Section 2.

Against the background stated above, the safety analysis report should be clearly and logically structured. The presumptions and methodology should be well described with clear references to all underlying data. Furthermore, the report should contain an overall conclusion concerning the safety and radiological environmental impact of the facility.

Chapter 4, Section 2, second paragraph

A preliminary safety analysis report in connection with major rebuilding work or major modification of a facility should be based on the facility's present safety analysis report and be provided with:

- information about the design of the facility following the rebuilding work or facility's modification
- information about the planned mode of operation including operating limits
- descriptions of the safety analyses and other verifying analyses conducted concerning new, planned or modified components or functions of the facility, in addition to components of the facility that have not been changed but which are affected by the changes
- references to safety analyses and other verifying analyses

Chapter 4, Section 2, third paragraph

When technical modifications to a nuclear facility or modifications of its activities are made, consequential changes to the safety analysis report need to be implemented as quickly and feasibly as possible, taking the nature of the change into account. For this reason, in order to keep the safety analysis report up to date, consequential changes to the safety analysis report should be prepared in parallel with modifications to the facility or its activities, and be notified in accordance with Chapter 4, Section 5 simultaneously with these changes.

The safety analysis report and its underlying data should be documented so as to enable the report to be kept effectively updated and available. Also note the provisions of Chapter 9, Section 2.

Appendix 2, item entitled 'Site'

An account of the external factors and circumstances that can affect a nuclear facility should encompass both the location where the facility has been constructed and surrounding areas where activities take place, which in some respect may have an impact on safety. Examples include land, sea and air transports of hazardous and explosive substances and industries where such substances are produced or handled.

A systematic inventory of all the external factors and circumstances which may have an impact on safety at the nuclear facility should be a part of such account, together with summaries of, and references to, underlying investigations and analyses showing how safety can be impacted and how this has been taken into account in the design, construction or in some other way. Examples of natural phenomena and other events that should be taken into account and reported for a nuclear power reactor are contained in the general advice for Section 14 of the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors. Examples of external factors

that may have an impact on a repository following its closure are stated in the general advice for Section 9 and the Appendix to the Swedish Radiation Safety Authority's regulations (SSMFS 2008:21) concerning safety in connection with the disposal of nuclear material and nuclear waste.

Appendix 2, item entitled 'Design rules'

An account of the safety principles should, for example, include the application of the principles of barriers and defence in depth in accordance with Chapter 2, Section 1 and, for nuclear power reactors, the design principles contained in Section 4 of the regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors.

An account of the design assumptions should encompass the specific requirements and assumptions that need to be taken into account in connection with the design and construction of structures, systems, components, devices and equipment so that these can function as intended while maintaining their integrity during and after initiating events and scenarios.

An account of the design rules should encompass the various rules applied in connection with the design and construction of structures, systems, components, devices and equipment at the facility. This may include international and national rules, standards and guidance.[6] In cases where a design rule has not been applied fully in some respect, the reasons for the deviation should be described together with the safety-related justifications behind acceptance of such deviation.

An account of the safety principles, design assumptions and design rules that governed the design and construction of the facility should, with a sufficient level of detail, be provided in the respective and relevant part of the safety analysis report.

Design assumptions should be described on a system level (see also the advice for the item concerning facility and functional description) with reference to the reports that describe in more detail the design assumptions for the facility's various active and passive devices, equipment and structures. An account of the design assumptions for electrical equipment should, in addition to the events, event sequences and conditions which may arise at the facility, also encompass disruptions and other circumstances that may affect offsite power.

In cases where the design and construction have been subjected to testing in accordance with Chapter 3, Section 2, the safety analysis report should

[6] Examples include applied Safety Requirements and Safety Guides issued by the International Atomic Energy Agency (IAEA), General Design Criteria (GDC), Regulatory Guides (RG) and Standard Review Plans (SRP) issued by the U.S. Regulatory Commission (NRC), Nuclear Safety Criteria issued by the American Nuclear Society (ANS), and Boiler and Pressure Vessel Codes issued by the American Society of Mechanical Engineers (ASME).

include summaries of and references to the evaluations confirming that the design has the durability, reliability and operational stability needed, while taking into account the function and importance of the device or equipment in terms of facility safety.

For a nuclear power reactor, an account of how structures, systems, components and devices in the reactor have been assigned to classes should contain information about safety classification in accordance with Section 21 of the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors, in addition to how such classification relates to:

- quality classes in accordance with Chapter 4, Section 1 of the Swedish Radiation Safety Authority's regulations (SSMFS 2008:13) concerning mechanical components in certain nuclear facilities
- electrical functional classification
- seismic classification
- environmental classification

Appendix 2, item entitled 'Facility and functional description'

'Systems' and 'equipment', which apart from the safety systems, are of essential importance for the facility's defence in depth, refer to such facility, structures, systems, components and devices that have been found to be of significance for the protection of the environment in accordance with operational experience and probabilistic safety analyses.

The safety analysis report should contain a detailed description of the facility's construction, with included systems and their function and tasks relating to operation and safety. For each system containing barriers or which is of essential importance for defence in depth, the following should be described:

- a description of the system's function and tasks during normal operation[7] and during various events and conditions which may arise, including specification of the events for which the system is credited in the facility's safety analyses,
- information about the system's impact and dependence on other systems at the facility,
- a description of the system's layout, including information about its components, devices and equipment,
- a description of design assumptions, design rules and classifications applied, in addition to information about and references to analyses confirming that the assumptions and regulations are complied with,
- information about design and operating limits,

[7] According to the definition contained in Chapter 1, Section 2.

- information about the system's power supply, instrumentation and regulation during normal operation and during various events and conditions,
- a description of the system's setup for operation and the relevant requirements imposed on readiness for operation, and
- information about the kind of verification of the facility's readiness to operate and other functional testing that needs to be conducted in various situations, in addition to the manner in which and the intervals this needs to be conducted for the purpose of fulfilling the requirements of Chapter 5, Section 3.

In the event that functional testing does not reflect the conditions expected to prevail at the time the safety function is needed, the safety analysis report should refer to the analyses that should be conducted in accordance with the general advice for Chapter 5, Section 3 and which demonstrate that sufficient verification of the safety function has been made despite the limitations of the functional testing.

For a nuclear power reactor, the safety analysis report of the nuclear power reactor's control rooms and emergency control posts in addition to, where applicable, other local monitoring and manoeuvring devices, should include:

- information about ergonomic and other principles that have been applied for various types of analogue, digital and computer-based control, regulation and monitoring equipment as well as annunciators, presentation of information and the interaction between man and machine,
- information about other aspects in terms of the interaction between man and machine, as well as aspects of the working environment that served as a basis for the design and layout of the reactor's central and local control rooms, and
- summaries of and references to the underlying analyses and investigations confirming that the layout of the reactor's central and local control rooms complies with the requirements imposed by Sections 18-20 of the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors.

An account of the facility's functional description should include an account of the kinds of nuclear materials and nuclear waste that are handled or generated at the facility, including a description of treatment and storage of these materials in accordance with the requirements imposed by Chapter 6, Sections 2 and 3.

Appendix 2, item entitled 'Radioactive substances'

For a nuclear power reactor, the account should encompass a list of the radioactive substances that may be released from the primary system or nuclear fuel storage system and further through the reactor containment or buildings to the environment in connection with radiological accidents, known as 'internal and external source terms'.

Appendix 2, item entitled 'Facility operations'

An account of facility operations should include an overall description of the organisation in addition to the principles applied for the purpose of managing, controlling and evaluating the work in accordance with the requirements imposed by Chapter 2, Section 8. The principles applied in order to utilise experiences and to develop the activity should also be described. This should include a description of the principles for how safety and the safety culture are maintained and improved. Furthermore, the principles for allocation of responsibility, authority and co-operation in accordance with Chapter 2, Section 9, item 2 concerning safety should be described overall.

An account of the operational activity including control room work should also include a description of the principles for:

- monitoring of operation
- implementation of operational changeovers
- safety evaluation and the management of operational disruptions that have occurred, in addition to deficiencies in accordance with Chapter 2, Sections 2-6

An account of maintenance work, continuous surveillance and testing, in addition to the management of ageing degradation and damage, should also include a description of the principles for:

- preventive and corrective maintenance in accordance with Chapter 5, Section 3
- planned maintenance, inspection and testing during operation in accordance with Chapter 5, Section 3 and Sections 15-16 of the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors and control in accordance with Chapter 3 of the Swedish Radiation Safety Authority's regulations (SSMFS 2008:13) concerning mechanical components in certain nuclear facilities
- performance of periodic testing and functional testing in accordance with Chapter 5, Section 3
- the overall management of ageing degradation at the facility in accordance with Chapter 5, Section 3

An account of the safety work at the facility should also include a description of the principles for:

- how the safety goals are to be maintained and developed in accordance with Chapter 2, Section 9, item 1
- how work is to be planned so that a sufficient period of time and sufficient resources can be allocated for the necessary implementation of the safety measures and performance of the safety review in accordance with Chapter 2, Section 9, item 3 and Chapter 4, Section 3
- how decisions on safety issues are to be preceded by adequate investigation and consultation so that the issues are comprehensively examined in accordance with Chapter 2, Section 9, item 4

An account of the emergency preparedness should also include a description of the principles for:

- responsibility, authority and co-operation that are to be applied for the facility's emergency response organisation in accordance with Chapter 2, Section 12
- establishment of competence requirements and competence follow-ups for the personnel belonging to the facility's emergency response organisation in accordance with Chapter 2, Section 12

An account of the packages of procedures applied at the facility for normal operation, abnormal operation and accidents in accordance with Chapter 5, Section 2 should include overall descriptions of the content and structure of the packages of procedures, as well as how the procedures are to be applied and kept up to date and the relevant requirements applying to changes to the procedures.

An account of the principles for the facility's system for operational experience feedback should include information about the system's design and how it is intended to ensure that experience of importance for safety in the activity itself and from other similar activities is continuously utilised and communicated to the personnel concerned in accordance with Chapter 2, Section 9, item 7.

An account of the principles for the facility's system for staffing in addition to training and skills assessment of personnel should include information about the system's design and how this is intended to ensure that adequate human resources are available and that the personnel have the competence needed for tasks of importance for safety in accordance with Chapter 2, Section 7 and Section 9, item 5. The principles for the preparation and use of training programmes should also be included in such account.

Appendix 2, item entitled 'Analysis of operational conditions'

Both the account of the deterministic analyses and the account of the analyses using probabilistic methods should encompass events, event

sequences and conditions that may arise under various operating conditions as well as concerning nuclear power reactors, the startup and planned shutdown of a reactor as well as a planned shutdown for refuelling or maintenance.

An account of the facility's deterministic safety analyses should contain:
- descriptions of methods applied under Chapter 4, Section 1 in order to systematically identify the events, event sequences and conditions that can lead to a radiological accident
- information about which of these events, event sequences and conditions have become subject to further analysis and how they have been assigned to event classes in accordance with Sections 2 and 22 of the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors, or corresponding classes for facilities other than nuclear power reactors, in addition to the grounds applied for such classification
- information about which identified events, event sequences and conditions that have not become subject to further analysis and the motives for this
- information about the specific analysis assumptions, reference values for radiological impact on the environment and other acceptance criteria applied for different events, event sequences and conditions
- descriptions of the methods and models that have been applied for different types of analyses in addition to summaries of and references to underlying reports stating the potential and limitations of the methods and models as well as how they have been validated
- information about key assumptions made in the analyses
- summaries of the findings of analyses and conclusions made concerning the capacity of the facility's barriers and defence in depth system for the prevention of a radiological accident and mitigation of the consequences in the event of an accident
- references to the complete deterministic safety analyses

Concerning nuclear power reactors, an account of probabilistic safety analyses should contain:
- a description of the analyses' scope, focus and delimitations
- information about methods applied when modelling events, event sequences and conditions, including action of operators and other aspects of the interaction between man and machine
- information about the bases for and assumptions made concerning the frequencies of initiating events, failure frequencies on the part of devices and equipment, probabilities for failures having a shared origin, and human error
- summaries of the findings of analyses and conclusions made concerning the capacity of the nuclear power reactor's barriers and defence in

depth system for the prevention of a radiological accident and mitigation of the consequences in the event of an accident
– references to the complete probabilistic safety analyses

An account of the analyses of design and operating limits for the reactor core which, in accordance with Section 27 of the Swedish Radiation Safety Authority's regulations (SSMFS 2008:17) concerning the design and construction of nuclear power reactors, are to be included in the safety analysis report, may be drawn up by using the 'cycle-specific safety analysis report' as a reference in the safety analysis report for the nuclear power reactor.

Appendix 2, item entitled 'References'

Examples of investigations, analyses and other underlying reports which should serve as references in the safety analysis report include:

– lists showing how the nuclear power reactor's structures, systems, components and devices have been divided into classes in terms of safety and quality, electrical functional classification in addition to classification in terms of seismic tolerance and environmental tolerance
– lists showing how other nuclear facility structures, systems, components and devices have been assigned to classes specifying their importance for safety
– reports on design assumptions for the facility's structures and systems, in addition to active and passive components and devices
– analytical and investigative reports verifying that the design assumptions and design rules applied are being complied with, including analyses showing that the facility's structural integrity fulfils the applicable rules under different conditions and regarding nuclear power reactors in connection with different event classes
– other investigative and analytical reports having controlled the design and operating limits, e.g. reports containing findings from testing and evaluations in accordance with Chapter 3, Section 2
– reports including deterministic and probabilistic safety analyses in accordance with Chapter 4, Section 1
– reports including validation of methods and models for analyses in accordance with Chapter 4, Section 1
– investigative and analytical reports showing how the requirements imposed by Chapter 5, Section 3 are fulfilled in the event functional testing does not reflect conditions expected to occur when the safety function is needed
– analytical and investigative reports verifying the safe disposal of nuclear material and nuclear waste generated at the facility

Chapter 4, Section 3

The safety review should comprise a review of technical factors as well as are view of the man-technology-organisation interaction. Thus, personnel with adequate technical competence within the areas in question as well as personnel with competence in behavioural sciences should participate in the review work. Personnel working with the independent safety review should have such knowledge and experience that they can independently assess the matters that are submitted for review.

The primary safety review should be as comprehensive as possible and should not take the performance of a separate, independent review into account. The following issues should normally be addressed in a primary safety review:

- that the motives for implementing a measure are acceptable from the standpoint of safety,
- that presumptions and delimitations as well as input data for analyses, investigations and modifications are correct and reasonable, as well as that standards and other rules cited are suitable for the case in question,
- that the methods and analysis and calculation models applied are verified and qualified or well tested, that they are applicable in the case in question and that they have been applied within the parameters of their possibilities and limitations,
- that the analysis, investigation or calculation results are correct, that the measures are suitable from the standpoint of safety and that they can be conducted in the intended manner and with a sufficient level of quality, as well as that proposals for measures in response to events that have occurred or conditions that have been detected are such that they are capable of preventing a recurrence, and
- that the measures, as a minimum, lead to maintaining, yet preferably improving, the level of safety.

The independent safety review should, in the light of how an issue has been handled within the responsible parts of the organisation, include checking whether the issue has been handled correctly from the standpoint of safety. The aim is not to repeat the primary safety review, although it may be necessary to repeat some part of it. Furthermore, a broader perspective should be applied than that in the primary review. The independent safety review should therefore consider:

- whether the issue in question has been correctly dealt with,
- whether the conclusions drawn and proposals reported have been factually supported in a correct manner,
- whether applicable safety aspects, including physical protection, have been taken into account and whether applicable safety requirements have been met, and

– whether measures adopted are leading to a maintained or improved level of safety.

The independent safety review thereby comprises both the quality of the case's handling and a factual assessment of the case.

The independent function for safety review should be given a sufficiently strong and independent position in the organisation with the authority to report directly to the highest manager of the facility. Furthermore, its personnel should not participate in work on analyses or investigations of issues as long as such work is carried out within parts of the organisation in charge of this area of expertise.

Both the primary and independent safety reviews should be documented in such a way enabling their respective review by another body.

Chapter 4, Section 4

The periodic review of the facility's safety and radiation protection should provide a basis which can be utilised in connection with a regulatory review of the safety of the facility, namely in order to check, at an established point in time, whether the facility can continue its operation with the levels of safety, radiation protection and physical protection assumed in the licence for the nuclear activity and which shall be described in the safety analysis report in accordance with Section 2. The traveaux preparatoires of the Nuclear Activities Act (1984:3) state that, in terms of the provisions contained in the Environmental Act, it is first and foremost the general rules of consideration contained in Chapter 2 that should be of significance for the periodic safety review.[8]

The licensee should, in good time, inform the Swedish Radiation Safety Authority that the work on the review has started so that a necessary dialogue can be conducted regarding planning of the work.

The periodic safety review should be supported by sufficient analyses of the facility and its activities. These analyses should be conducted in a systematic manner while employing pre-defined methods.

References to the requirements and standards that apply to the design of the facility should be reported, as should the more recent safety standards and practices which are a result of developments in science and technology and are judged to be applicable to the type of facility in question. It should be possible to justify the selection made with respect to the more recent standards.

[8] Government Bill 2009/10:172, page 55.

The periodic safety review should cover, to an applicable extent, safety, radiation protection and physical protection within the following areas:

1. Design and construction of the facility (including modifications)
2. Management, control and organisation of the nuclear activity
3. Competence and staffing of the nuclear activity
4. The operational activity, including the handling of deficiencies in barriers and defence in depth
5. Core and fuel issues as well as criticality issues
6. Emergency preparedness
7. Maintenance, materials and in-service inspection issues, particularly taking into account degradation due to ageing
8. Primary and independent safety reviews
9. Investigation of events, experience feedback and external reporting
10. Physical protection
11. Safety analyses and safety analysis reporting
12. Safety programme
13. Management and retention of facility documentation
14. Handling of nuclear material and nuclear waste
15. Non-proliferation control, export control and transport safety
16. Radiation protection of workers
17. Control of releases and environmental monitoring

Analyses should be conducted as to whether devices and activities in each area comply with regulatory requirements as well as internal requirements at the time of analysis, and whether the solutions applied have a continued capacity to prevent possible deficiencies in barriers and defence in depth that could lead to a radiological accident. Furthermore, a systematic analysis should be conducted in each area as to whether devices and activities meet new safety standards and practices relevant for the facility. The need for measures that follow from these analyses should be listed and the importance for safety should be assessed using deterministic, and where appropriate, probabilistic methods, or, where this is not possible or reasonable, through expert assessment using specified criteria.

Where the facility does not fulfil relevant, new safety standards, measures should be implemented if this is considered to be reasonable and suitable with respect to the benefit to safety, taking into account the existing design assumptions of the facility. An action plan should be prepared for such measures and other measures that are not of an acute nature, but which are deemed necessary so that the facility can continue to be operated with a high level of safety up to the time of the next safety review. The action plan should state priorities, types of measures and time of implementation. After it is decided, the plan should be incorporated into the facility's safety programme.

The periodic safety review should be documented systematically and clearly in an integrated report. The report should contain an overview of the analyses and evaluations conducted in the different areas as well as an overall evaluation. References to underlying documents should be explicitly stated.

Chapter 4, Section 5

All consequences of a modification should be analysed so that improved safety in one respect does not lead to degraded safety in another respect in such a way that overall safety is degraded.

In this context, technical modifications refer to modifications in the design or construction of barriers as well as such systems, components and devices that are necessary in order for defence in depth to function in the way intended in the safety analysis report. Modifications of software in control equipment which affect a safety function are also considered to be technical modifications.

Organisational modifications refer to changes that are of importance for the management and control of the nuclear activity. Examples include changes in the principles for decisions on, or the financing of, safety measures, mergers, division of production units, outsourcing of activities that are of importance for safety, reduction of the personnel working with operation and maintenance, centralisation or decentralisation of technical support and maintenance functions, as well as changes in the functions for safety review and auditing.

Essential modifications in the safety analysis report for example refer to modifications of design or functional requirements, modifications in the principles for maintenance and the principles for the control of readiness for operation, modifications in the classification into event or safety classes and modifications resulting from safety analyses.

The Swedish Radiation Safety Authority should be notified of any modifications well in advance if this is possible and reasonable, taking into account the nature of the matter. A notification of a modification should contain an explicit description of what has been changed in relation to previous designs, the justification for the modification, assessed impact on safety, as well as statements from the independent safety review in accordance with Chapter 4, Section 3.

In connection with major modifications, it is suitable to submit an early initial notification that encompasses the implementation plan and the preconditions for the modification, including the standards that will be applied.

Chapter 5, Section 1

The Operational Limits and Conditions should be formulated in a clear and unambiguous manner. The personnel concerned should be well acquainted with the Operational Limits and Conditions and their background so that their intended purpose is clear if problems of interpretation should arise. The Operational Limits and Conditions should be modified if this is justified by modifications in the facility or new knowledge. The Swedish Radiation Safety Authority should be notified of modifications well in advance if this is possible and reasonable, while taking into account the nature of the matter.

That which is stated about the safety analysis report in the first paragraph of the section also applies to planned temporary deviations.

Chapter 5, Section 2

The procedures should be technically correct and easy to use under the conditions for which they are intended. Thus, if possible and to the extent applicable, a simulator should be used to verify the technical content and the adequacy of the procedures. The users of the procedures should also personally participate in preparing and revising the procedures. The procedures should also be used on a regular basis in operator training.

Maintenance of the facility should also be controlled by adequate procedures to the extent needed for safety.

Guidelines for management of accidents that have not been taken into account in the facility design should be developed to the extent that is possible and reasonable with respect to the need for the protection of the environment. The guidelines should be well co-ordinated with the facility's emergency operating procedures.

Chapter 5, Section 3

It should be noted that equipment of importance for the physical protection of the facility, such as annunciator systems, surveillance equipment and communication equipment, are also classified as structures, components, systems and other devices of importance for safety.

In order to achieve suitable programmes for the periodic functional testing of active components, the consequences of a failure as well as the probability of its occurrence should be considered. Quantitative measures of failure probabilities as well as qualitative indicators should be based on systematic analyses of the failures and deviations which can arise with respect to different components.

The functional testing should reflect the conditions expected to occur when the safety function is needed. If this is not possible or reasonable, an

analysis should show that adequate verification of the safety function has been made despite the limitations in the functional testing. The functional testing should be of a frequency and scope generating confidence that the equipment, when needed, complies with the functional requirements credited in the safety analyses. Functional testing should also encompass necessary auxiliary systems such as the auxiliary power supply and cooling systems.

Functional testing should be carried out so that the safety function can be fulfilled if it should be called upon during testing. Deviations from this can be applied during a limited period if a safety analysis demonstrates that the risk contribution that thereby arises is very small.

Preventive maintenance with adequate safety and quality requires extensive analyses of component reliability, which should be performed on the basis of maintenance statistics as well as on good monitoring of the component's status during operation and in-service inspection. It is appropriate here to also use experience from the same types of components at other similar facilities.

The programme for the management of ageing degradation and damage should comprise the identification, monitoring, handling and documentation of all the ageing mechanisms that can affect structures, systems and components as well as other devices that are of importance for safety.

A clear distinction should be made between maintenance work and plant modifications. The latter involves changing the specifications of the facility, which requires a type of handling procedure other than a direct replacement or repair of existing equipment.

Additional guidance on maintenance and the management of ageing degradation can be found in the IAEA's safety standard on maintenance, surveillance and in-service inspection in nuclear power plants.[9]

Chapter 5, Section 4

Events that have occurred and conditions arising of importance for safety should be investigated systematically so that the event sequence is completely clear, including the circumstances that could have prevented or stopped the event progression, so that the consequences are determined, the underlying causes are investigated and well-founded measures are specified in order to prevent similar events, conditions or deficiencies from occurring again.

[9] Latest edition of IAEA Safety Guide NS-G-2.6: Maintenance, Surveillance and In-Service Inspection in Nuclear Power Plants. International Atomic Energy Agency, Vienna, 2002.

In this context, 'systematic' means that the investigation must be carried out in a logical manner with a documented methodology, clearly documented results and must encompass conclusions for safety based on the results obtained. The investigation methodology should be characterised by all relevant aspects and circumstances having been taken into account, including technical factors as well as those relating to the man-technology-organisation interaction.

Chapter 6, Section 1

An inventory is a list or register that is divided into waste units corresponding to packages, components, containers or other units that correspond to the handling of the waste. For each waste unit, the list should contain information about:

1. the identity of the unit,
2. the origin of the waste or from which facility, structure, system or component the waste originates,
3. the treatment of the waste and its physical and chemical form,
4. waste quantity,
5. nuclide-specific content of radioactive substances with reference date,
6. external radiation level with distance and reference date,
7. storage position, and
8. date for completed treatment.

Clear identity marking should, in the first instance, be conducted through a unique marking of the waste package or, in the second instance, through a unique marking of the site, space or container where a certain waste item is stored.

Chapter 6, Section 2

The requirement on preventing criticality encompasses all dealings with nuclear material apart from its intended use in a reactor. In order to limit the risk of criticality in the storage of nuclear material and in systems for the handling of nuclear material, physical principles should be applied. A suitable means of reducing the risk of criticality is to use geometrically safe configurations.

Chapter 6, Section 3

Safe confinement refers to measures for ensuring the barrier function, namely, with respect to the volume contained, radioactive inventory and other properties, and the safe design of containers, packaging or other confinement, as well as, to an adequate degree, devices and prepared measures to protect confinement integrity.

The handling of nuclear material and nuclear waste conducted at the facility should be adapted to the requirements, with respect to safe confinement, which are set in connection with the further handling, the subsequent transports as well as in connection with the disposal of the nuclear waste.

The requirement that the specified measures must be described in the safety analysis report for example means that only waste packages notified to the Swedish Radiation Safety Authority may be brought to a repository for disposal. A precondition for this is that the waste meets the requirements stipulated in the safety analysis report for the repository. For waste which is routinely handled and treated, notification may be made pertaining to the particular type of waste package. For such type descriptions, a template is available that has been drawn up by the Swedish Radiation Safety Authority. The type descriptions comprise part of the safety analysis report for the facility where the waste is produced and treated as well as for the repository.

Chapter 6, Section 4

The plan concerns such cases where nuclear waste is temporarily generated in connection with special projects and which falls outside the scope of the normal procedures in terms of type and quantity. Examples here include waste generated when large components are replaced and in connection with decontamination of reactor systems. Additional examples of nonconforming waste include old waste, with deficient characterisation or documentation, which is placed in temporary storage and which must be reconditioned, or that the originally stated chemical/physical properties have been re-evaluated prior to disposal. Changes to the originally declared radionuclide inventory in the waste can also be assigned to the category of nonconforming nuclear waste.

If nonconforming waste is found to occur more regularly at a facility, the measures for safe confinement of the waste should be incorporated into the safety analysis report in accordance with Chapter 4, Section 2.

Chapter 7, Sections 1-3, Appendix 4

Reporting in accordance with Section 1

To enable its notification within one hour, the Swedish Radiation Safety Authority maintains 24-hour emergency preparedness by means of an officer on duty.

Events and conditions which are within the scope of the International Nuclear and Radiological Event Scale (INES) are described in the International Atomic Energy Agency's (IAEA) and the Nuclear Energy Agen-

cy's (NEA)[10] publication, "INES: The International Nuclear and Radiological Event Scale – User's Manual". The manual describes how the events are to be classified and what a report should contain.

Reporting of events within 16 hours that have been assigned to INES Level 2 or higher is required to enable the Swedish Radiation Safety Authority to confirm the classification and to, in its turn, report to the IAEA within 24 hours after the event occurred in compliance with the agreement concluded between Sweden and the IAEA.

Reporting in accordance with Section 2

These reports should primarily contain an informative description of the event sequence and of the operational consequences, assessments of the importance for safety and of the root causes as well as a description of measures implemented and planned in order to re-establish the safety margins and to prevent a recurrence. A report should also contain information on the experience gained on the basis of the event as well as the conclusions of the safety review of the investigation carried out at the facility.

A summary report can be submitted when any of the following occurs or is detected during a planned nuclear reactor shutdown:

- single earth fault
- instrument instability and unstable setting detected during calibration
- containment isolation valve leakage exceeding the stipulated total leakage[11]

The summary report should describe the individual events and should contain an integrated analysis and evaluation of the respective failure type the events represent.

Nuclear fuel damage that requires dismantling of the fuel in order to investigate root causes may constitute a special reason for not submitting a final report within 30 days. However, in such cases, the final reporting should be conducted as soon as the results from the investigations are available.

Reporting in accordance with Section 3

In addition to an account of experience gained and conclusions drawn from the standpoint of safety, the annual report of a reactor facility should contain a summary of the following information:

[10] Nuclear Energy Agency within OECD
[11] Specified in the Operational Limits and Conditions for the facility

a. operating experience and events and conditions which have been assigned to Categories 1, 2 or 3 in accordance with Appendix 1
b. production data
c. core and fuel conditions and criticality safety issues
d. hydrochemical conditions
e. planned and unplanned outages as well as a report on completed refuelling and maintenance outages
f. repairs in equipment of importance for safety
g. modifications to the facility design as well as changes to the organisation, management and control of the nuclear activity
h. expert tasks performed and service work conducted within the nuclear activity that have been contracted out
i. changes in competence requirements and training programmes caused by modifications to the facility and to its activity as well as a summary of training activities planned and conducted for personnel with tasks of importance for safety in the nuclear activity
j. investigations and analyses performed, the results of which are expected to affect the conditions specified in the safety analysis report
k. production, storage, transport from as well as disposal within the facility in terms of nuclear waste and information on material that has been given clearance
l. experience from the physical protection of the facility

With respect to other facilities, the report should contain the above information to the extent applicable.

Annual reporting required by other regulations or licence conditions issued by the Swedish Radiation Safety Authority may either take place separately or be encompassed by the above-mentioned annual report.

Chapter 8, Section 1

In this context, technical documentation concerning the facility comprises up-to-date drawings of the facility, its building structures, systems, components and devices as well as documents showing how these have been manufactured, installed and inspected. Where relevant, information on modifications that have been made to the facility should also be included in the documentation.

The technical documentation concerning the facility should also include up-to-date process and flow charts, investigations and analyses upon which safety analysis reports are based as well as the inventories mentioned in Chapter 6, Section 1.

Here, 'document retention' refers to storage of documents in accordance with the regulations and general recommendations[12] of the National Ar-

[12] Currently RA-FS 1997:3

chives concerning the planning, design and operation of archive premises. In addition to these requirements on retention, requirements have been imposed concerning the retention of nuclear documentation[13] in accordance with the Radiation Protection Act.

Chapter 8, Section 2

In the evaluation of the extent and period of time during which registered process and parameter data from the operational activity should be retained, operating conditions, events and abnormal operation which can give rise to damage to or the failure of the facility, structures, systems and components a long time after the event or abnormal event or incident has occurred should also be taken into account. Examples of such events include thermal and chemical transients.

Other safety-related activities for instance include maintenance and modification activities as well as investigations of events, safety reviews, quality audits, training activities and competence follow-ups.

In order to fulfil the requirements, the documentation of the maintenance activity which is retained should also contain information on surveillance testing and other recurrent tests, calibrations and inspections.

Chapter 9, Section 1

If several facilities are located at one site, the decommissioning plan for each facility should be based on a general decommissioning plan or decommissioning strategy for the entire site. The strategy may be reported as a separate basis for the decommissioning plan or included as a special part of the planning prerequisites to be reported in accordance with Appendix 5.

Chapter 9, Section 2

The safety requirements intended for waste management in connection with dismantling should correspond to the requirements imposed on the confinement of radioactive material that applied to similar activities, such as maintenance work and waste management, during the period of time when the facility was in operation.

Chapter 9, Section 3

'Final shutdown within a certain period of time' means a duration comprising a minimum of six months and a maximum of five years from the time of the decision made to the final shutdown date.

The integrated analysis and overall evaluation should primarily encompass how operational safety is maintained, for example with respect to the

[13] Currently SSMFS 2008:38

risk of personnel resignations and the impact on the motivation of the personnel. Furthermore, an evaluation should be made of the need to reinforce supervision of activities that are of importance for safety, as well as continued measures for in-service inspection, testing and maintenance of the facility.

These general recommendations apply as of 1 February 2009.

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