

# Sweden's report under Article 9.1 of Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, as amended by the Council Directive 2014/87/Euratom of 8 July 2014

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## A. Introduction

### A.1 Purpose of the report

Under Article 9.1 Member States are required to submit a report to the Commission demonstrating how they are addressing their obligations under the Nuclear Safety Directive and illustrating their national approaches. This report describes how Sweden complies with the obligations under the Directive.

The report has been prepared by the Swedish Radiation Safety Authority (SSM) and the Ministry of the Environment, and is based on, among other things, Sweden's national framework, SSM's management system and Sweden's eight national report under the Convention on Nuclear Safety<sup>1</sup>.

## A.2 Nuclear installations in Sweden

At present, in June 2020, there are in total seven nuclear power reactors in operation, distributed between the three nuclear power plants Forsmark, Oskarshamn and Ringhals, as specified in Table 1. There are four nuclear power reactors in decommissioning. A further nuclear power reactor, Ringhals 1, is scheduled to be shut down permanently in the end of 2020.

Other nuclear installations covered by the scope of the Directive are the shutdown research reactors in Studsvik, the nuclear fuel fabrication plant in Västervik and the interim storage facility for spent nuclear fuel (Clab) in Oskarshamn, specified in table 2. In addition, there are also a number of waste facilities directly related to the main nuclear installation.

Table 1. Main data for nuclear power installations in Sweden, including waste facilities.

Name	Type	Capacity (MW <sub>th</sub> )	Status	Associated waste facilities
Ågesta	PHWR	105	In decommissioning	
Barsebäck 1	BWR	1800	In decommissioning	
Barsebäck 2	BWR	1800	In decommissioning	
Forsmark 1	BWR	2928	Operating	Interim storage for replaced components
Forsmark 2	BWR	3253	Operating	
Forsmark 3	BWR	3300	Operating	
Oskarshamn 1	BWR	1375	In decommissioning	Interim storage for replaced components
Oskarshamn 2	BWR	1800	In decommissioning	
Oskarshamn 3	BWR	3900	Operating	
Ringhals 1	PWR	2540	Operating	
Ringhals 2	PWR	2660	In decommissioning	
Ringhals 3	PWR	3144	Operating	
Ringhals 4	PWR	2783	Operating	

<sup>1</sup> Sweden's eight national report under the Convention on Nuclear Safety. Sweden's implementation of the obligations of the Convention. Ds 2019:16. Government Office of Sweden. Ministry of the Environment, June 2019. (8<sup>th</sup> Swedish CNS Report)

Table 2. Main data for other nuclear installations in Sweden, including waste facilities

Name	Type of facility	Status	Associated waste facilities
Clab	Interim storage for spent nuclear fuel	Operating	
Westinghouse	Nuclear fuel fabrication plant	Operating	
R2	Research reactor	In decommissioning	
R2-0	Research reactor	In decommissioning	

## B. Reporting article by article

### Article 4 – Legislative, regulatory and organisational framework

#### Article 4

1. Member States shall establish and maintain a national legislative, regulatory and organisational framework ("national framework") for the nuclear safety of nuclear installations.

#### *Hierarchy of Swedish legislation and the regulatory framework*

The basis for the legal order is the constitution, which in Sweden consist of the four fundamental laws. These are the Instrument of Government (Regeringsformen), the Freedom of the Press Act (Tryckfrihetsförordningen), the Fundamental Law on Freedom of Expression (Yttrandefrihetsgrundlagen) and the Act of Succession (Successionsordningen). The instrument of Government is in this context the most important and regulates the basic order of political life and the distribution of powers between the parliament, government, courts and authorities. The parliament (riksdagen) is according to the Instrument of government the national legislature and the supreme decision-making body of Sweden. In the Swedish system the parliament decides on acts which may include authorisations for, the government to adoption ordinances. An ordinance may, if the act allows, include authorisations to a competent authority to adopt more detailed technical regulations. All of these are legally binding instruments and deviation from these may be subject to sanctions by a court or the competent authority.

The competent authority may also publish general advice accompanying the technical regulations which are not legally binding. They should however be seen as a strong recommendation on how to implement requirements and cannot be ignored by the licensee without risking actions being taken by the regulatory body. The general advice belonging to a regulation can be seen as a strong recommendation. Measures should be taken according to the general advice or, alternatively, methods that are deemed as justified, and equivalent from a safety point of view, should be implemented. Guidance is provided for comprehension of the implications of the regulations, with explanations and examples of application. Guidance is not binding. See also Figure 1 below.

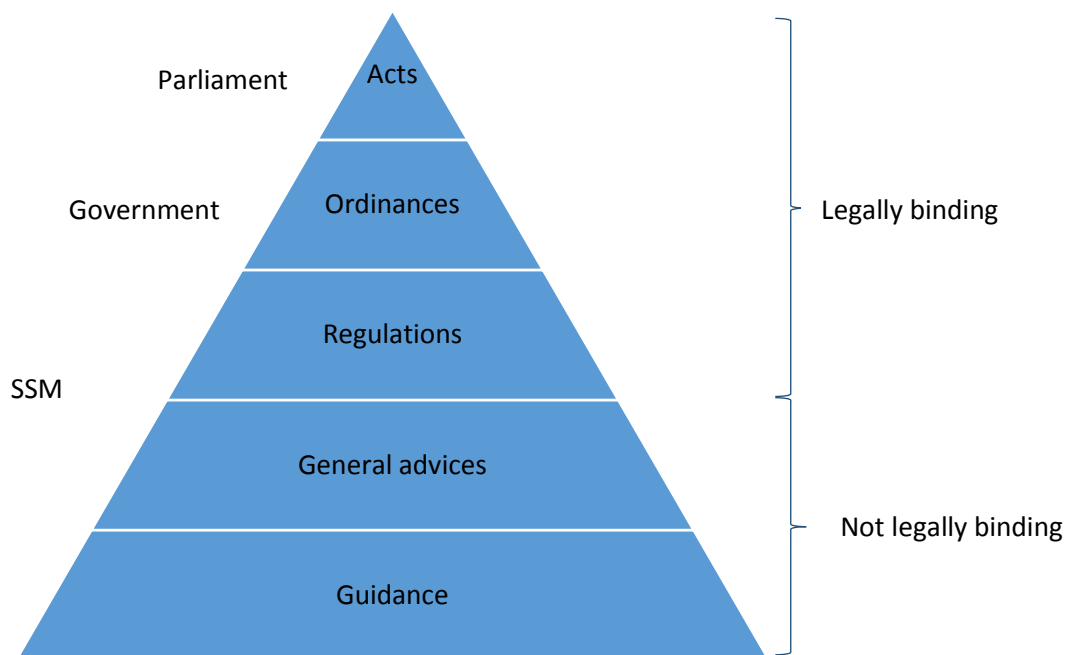


Figure 1. Hierarchy of Swedish legislation and the regulatory framework in the nuclear area

#### *Basic nuclear safety and radiation protection legislation*

The following five enactments constitute the basic nuclear safety and radiation protection legislation in Sweden:

- The Act on Nuclear Activities (1984:3),
- The Radiation Protection Act (2018:396),
- The Environmental Code (1998:808),
- The Act on the Financing of Management of Residual Products from Nuclear Activities (2006:647), and
- The Nuclear Liability Act (1968:45).

All acts and the code are supplemented by a number of ordinances and other secondary legislation which contain more detailed provisions for particular aspects of the regime.

Operation of a nuclear facility may only be conducted in accordance with a licence issued under the Act on Nuclear Activities, as well as with a licence issued under the Environmental Code. The Act on Nuclear Activities mainly concerns issues of nuclear safety and nuclear security, while the Environmental Code regulates general aspects of the environment and the possible impacts of “environmentally hazardous activities”. Nuclear activities are defined as belonging here.

The objective of the Radiation Protection Act is to protect human health and the environment from harmful effects of radiation. The Act applies to radiation protection in general and, in this context, provides provisions regarding workers’ protection, radioactive waste management, and the protection of the general public and the environment.

The objective of the Environmental Code (1998:808) is to promote sustainable development and thereby ensure a healthy environment for current and future generations. The Code includes general provisions on environmental protection. The Code is applicable to nuclear activities and activities involving radiation and must be applied in parallel with the Act on Nuclear Activities and the Radiation Protection Act. The Code is supplemented by a number of ordinances. These are laid down by the Swedish Government.

The Act on the Financing of Management of Residual Products from Nuclear Activities contains provisions concerning the future costs of spent fuel disposal, decommissioning of reactors, and research in the field of nuclear waste. Financial means for these purposes must be available when needed.

The Nuclear Liability Act implements Sweden's obligations as a party to the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, and the 1963 Brussels Convention Supplementary to the Paris Convention.

Other relevant acts are the Act on Control of Export of Dual-Use Products and Technical Assistance (2000:1064) and the Act on Inspections According to International Agreements on Non-proliferation of Nuclear Weapons (2000:140). Emergency preparedness and response matters are regulated by the Civil Protection Act (2003:778) and Ordinance (2003:789).

See section 7.1.2-7.1.4 of the 8<sup>th</sup> Swedish CNS Report for further information on these acts and related ordinances.

#### *National nuclear safety, nuclear security and radiation protection regulations*

With reference to its legal mandate, SSM issues legally binding safety-, security- and radiation protection regulations for nuclear facilities in its Code of Statutes, SSMFS.

SSM's regulations also implement binding European legislation and international obligations. In preparing SSM's regulations, IAEA safety and security standards, international recommendations, industrial standards and codes, and the rule-making of other Swedish authorities are considered. The SSM regulations are issued according to an established management procedure<sup>2,3</sup> which stipulates technical and legal reviews of the draft. In accordance with governmental rules, a review of the final draft by authorities, licensees, various stakeholders, and industrial and environmental organizations is performed.

In addition to these regulations in the SSMFS, the authority is mandated to decide on license conditions as well as injunctions in the individual case.

#### *Regulatory and organizational framework*

SSM is a central administrative authority reporting to the Ministry of Environment. According to section 22 of the Ordinance on Nuclear Activities (1984:14), SSM shall supervise that the Act on Nuclear Activities (1984:3) and conditions and regulations that have been adopted under the Act are complied with and monitor and control final disposal of nuclear waste. The Ordinance also specifies that SSM is authorised to impose licence conditions and to issue general regulations concerning measures to maintain and improve the safety and security of nuclear activities. See also the information below on how Sweden complies with Article 5.3 (a).

It follows from section 24 of the Ordinance that SSM shall assess and prepare applications for licenses for nuclear facilities, obtain necessary opinions and, together with these and its own opinion, submit the application to the Government for decision.

Corresponding regulatory tasks and mandate to decide on regulations and directives regarding radiation protection follow from the Ordinance on Radiation Protection (2018:506).

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<sup>2</sup> STYR2011-51, Regulatory work process. (*Föreskriftsarbete – processen*). SSM internal control document.

<sup>3</sup> STYR2013-51, Regulatory work – design (*Föreskriftsarbete – utformning*) . SSM internal control document.

## *Ratification of relevant international conventions and legal instruments related to the scope of the Directive*

### *Convention on Nuclear Safety*

Sweden signed the Convention on Nuclear Safety on 20 September 1994, the first day it was open for signing, during the ongoing General Conference at the IAEA. The Convention was ratified on 11 September 1995<sup>4</sup> and entered into force on 24 October, 1996.

### *Joint Convention*

Sweden signed the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 29 September 1997, the first day it was open for signing, during the ongoing General Conference at IAEA. The Convention was ratified about two years later, on 29 July, 1999<sup>5</sup> and it entered into force on 18 June 2001.

#### Article 4

The national framework shall provide in particular for:

1. (a) the allocation of responsibilities and coordination between relevant state bodies;

### *SSM's missions and tasks*

SSM's missions and tasks are defined in the Ordinance (SFS 2008:452) with instructions for the Swedish Radiation Safety Authority and in annual appropriation directions. In the latter, the Government issues directives for authorities including the use of appropriations.

The Ordinance declares that SSM is the administrative authority for protection of human health and the environment against harmful effects of ionising and non-ionising radiation, for issues on nuclear safety including physical protection in nuclear technology activities as well as in other activities involving radiation, and for issues regarding non-proliferation. SSM shall actively and preventively work for high levels of nuclear safety and radiation protection in the society and through its activities act to:

- Prevent radiological emergencies and ensure safe operations and safe waste management at the nuclear facilities,
- Minimize risks and optimise the effects of radiation in medical applications,
- Minimize radiation risks in the use of products and services, or which arise as a by-product in the use of products and services,
- Minimize the risks with exposure to naturally occurring radiation, and
- Contribute to an enhanced level of nuclear safety and radiation protection, internationally.

See section 8.1-8.3 of the 8th Swedish CNS Report for further information on SSM's Mandate, missions and tasks.

### *Responsibilities and coordination in the Swedish emergency management system*

The Swedish emergency management system is based on three principles:

- The principle of responsibility – meaning that the entity that is responsible for an activity under normal conditions also should have this responsibility in the case of an emergency.
- The principle of parity – meaning that to the extent possible, operations should be organised in the same way during emergencies as under normal conditions.

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<sup>4</sup> Sweden's international agreements, SÖ 1995: 71

<sup>5</sup> Sweden's international agreements, SÖ 1999:60

- The principle of proximity – meaning that emergencies should be dealt with where they occur and at the most local level possible in society (the affected municipality or county).

Furthermore, the Swedish emergency management system distinguishes between authorities having jurisdiction in a specific region (municipality, county or country) and authorities having mandates in specific areas of expertise, for instance SSM in the fields of radiation protection and nuclear safety. The system is based on collaboration between authorities in order to enable agreement on how to direct handling and coordination of available resources. MSB (Swedish Civil Contingencies Agency) has the task of supporting coordination between the public sector and various stakeholders. MSB has developed recommendations for the shared foundations of collaboration and management, which will contribute to an improved capability to cope with emergency situations in Sweden. The aim is to provide guidance to authorities on joint methods and approaches for enabling shared direction and coordination. The recommendations developed by MSB have resulted in a review of SSM's emergency response organisation to enable SSM's role in the emergency response system to efficiently provide advice and recommendations to other authorities.

See section 16.2 of the 8<sup>th</sup> Swedish CNS Report for further information on responsibilities and coordination in the Swedish emergency management system.

See also the information below on how Sweden complies with Article 5 (1).

#### Article 4

The national framework shall provide in particular for:

1. (b) national nuclear safety requirements, covering all stages of the lifecycle of nuclear installations;

#### *The Swedish nuclear safety, nuclear security and radiation protection regulations*

As stated above, the Swedish national regulatory framework for nuclear installations consist of basic nuclear safety and radiation protection legislation with related ordinances, and regulations published in SSMFS SSM's Code of Statutes, SSMFS.

The current regulations in SSMFS for nuclear installations covered by the directive consists of 12 parts with provisions on safety, security and radiation protection. In these regulations, the basic requirements in the acts and ordinances have been specified in various respects. The regulations apply to varying degrees in construction and operation, including operation during decommissioning.

The relevant regulations in this context, their scope and main content are presented in Table A.1 in Appendix A. Most of these regulations generally apply to nuclear installations, so a graded approach is needed in the application with regard to the nature and risk profile of the different nuclear installations. The regulations are also relatively generally formulated.

In addition to these regulations in the SSMFS license conditions as well as injunctions in the individual case have been decided. License conditions and regulatory decisions of importance to comply with the provisions of the Directive are presented in Table A.2 in Appendix A.

See section 7.2.1 of the 8<sup>th</sup> Swedish CNS Report for further information on the Swedish nuclear safety, nuclear security and radiation protection regulations.

#### Article 4

The national framework shall provide in particular for:

1. (c) a system of licensing and prohibition of operation of nuclear installations without a licence;

#### *System of licensing*

Licensing of nuclear activities is governed by several acts having different purposes. This also involves a number of authorities. A general permissibility consideration has to be made as to whether or not to grant licence for an activity. Furthermore, a nuclear activity must be approved in accordance with aspects of nuclear safety and radiation protection to ensure the protection of human health and the environment. Lastly, licensing conditions are issued under the various acts by the authorities responsible.

New nuclear installations and major modifications of existing installations that are subject to authorisation must be considered under both the Act on Nuclear Activities and the Environmental Code. As stipulated by the procedure for applications, a licence application must be submitted to the Swedish Radiation Safety Authority, which processes the matter under the Act on Nuclear Activities, and to the Land and the Environment Court, which processes the case under the Environmental Code. Applications are to be accompanied by an environmental impact assessment under chapter 6 of the Environmental Code. Figure 2 below is a schematic illustration of the licensing process for construction of a new nuclear facility. The figure depicts how related review and licensing tasks are assigned.

It should be noted that the preparation and review of an application, as well as the issuing of a licence and conditions, take place in open court hearings at the Land and Environment Court. At these hearings, all interested parties may attend and comment, including the relevant authorities. The applicant must verbally describe all relevant aspects of its case. Questions may be submitted during the proceedings.

In a case where SSM approves the application and proposes that the Government grant the licence under the Act on Nuclear Activities, SSM shall in these matters also propose that the Government take a decision on licence conditions enabling a continued step-wise review process until such date that the planned installation may begin regular operation.

As regards nuclear facilities, depending on the type of matter, one or more of the following licence conditions are to be proposed:

- The installation may not commence construction prior to approval by SSM.
- The installation may not commence test operation (commissioning) prior to approval by SSM.
- The installation may not commence regular operation prior to approval by SSM.

Based on these licence conditions, a step-wise review process then follows, where SSM decides at each stage if the licensee is allowed to proceed to the next step.

It should also be noted that for all nuclear installations in operation in Sweden, the operating licence are granted with an indefinite term. This means that the operation of a nuclear installation is allowed as long as the licensee meets the requirements set by the applicable laws, government ordinances, regulation of the nuclear regulatory authority, and conditions imposed by the initial licence.

See section 7.3 of the 8<sup>th</sup> Swedish CNS Report for further information on the Swedish system of licensing of nuclear installations.



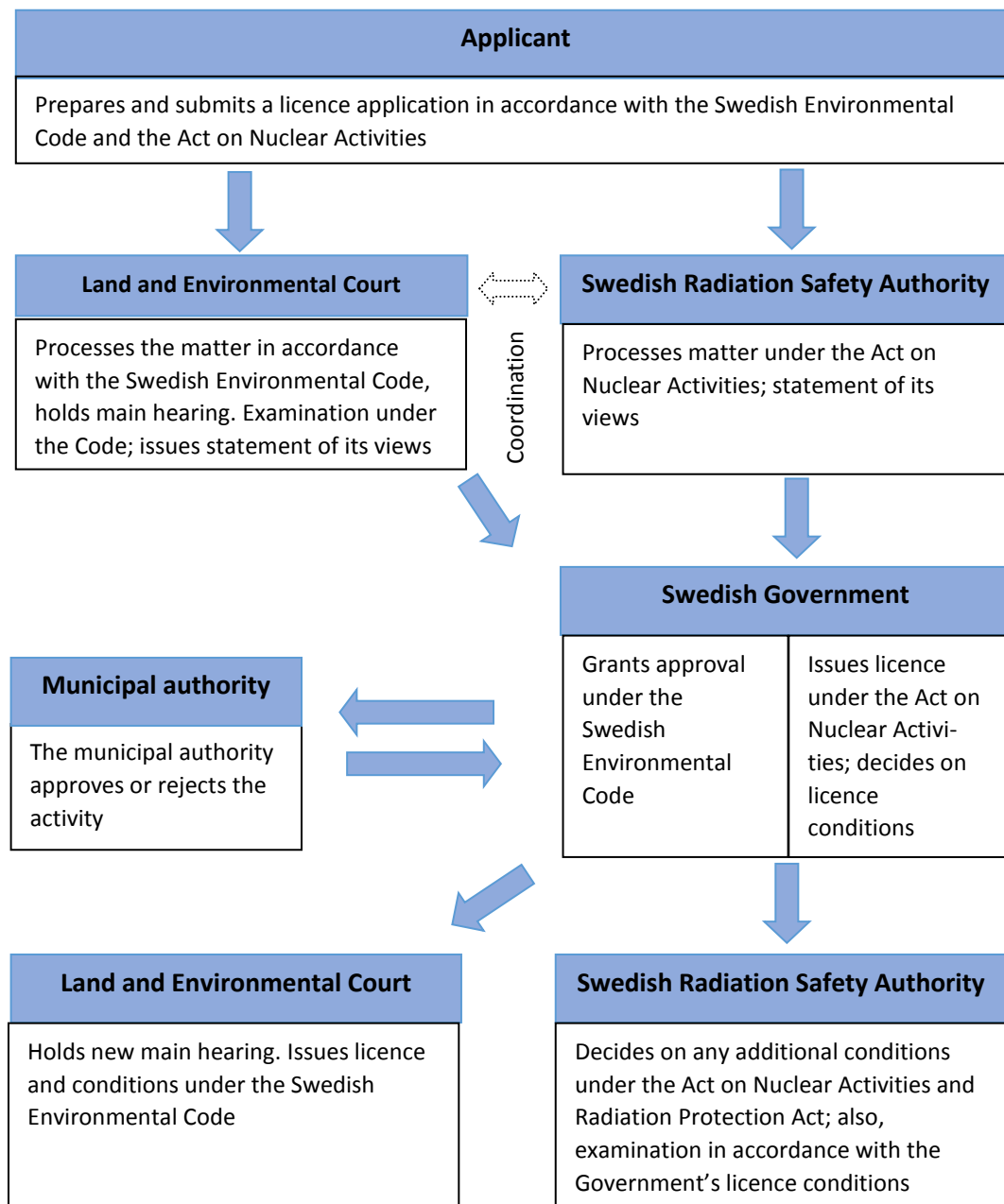


Figure 2. Schematic illustration of the licensing process for a new nuclear facility.

#### *Revocation of a license*

If a licensee fails to comply with conditions attached to the licence or with safety obligations arising in any other manner under the Act on Nuclear Activities (1984:3), the Government or SSM has the authority to revoke the licence altogether. The decision lies with the authority that has issued the particular licence.

#### *Preventing operation without a valid licence*

It is a criminal offense to conduct nuclear activities without a licence (Sections 25 and 25 a in the Act on Nuclear Activities). The operator of nuclear activities without a licence shall be sentenced to a fine or imprisonment not exceeding two years. If the offense is intentionally and is regarded as a serious criminal offense the operator is sentenced to imprisonment of between six months and a maximum of four years.

It is also an offense to engage in environmental activities without a licence, which is regulated in the Environmental Code (chapter 29, section 4). Anyone who deliberately or by negligence conducts an activity without a licence shall be sentenced to fines or imprisonment for two years.

Within SSM's supervisory role lies an obligation to ensure that violations of regulations and conditions are met with relevant measures. If there is a clear suspicion that someone intentionally or negligently breaches against provisions of the Act on Nuclear Activities (1984:3) or conditions or regulations issued under the Act, SSM is obligated to report the incident to a prosecutor. It can involve, for example that a nuclear reactor operated at a higher thermal output than it has authorization for. Frequently, the licence is associated with licence conditions. If such conditions are not complied with, this corresponds to operations conducted without a licence.

#### Article 4

The national framework shall provide in particular for:

1. (d) a system of regulatory control of nuclear safety performed by the competent regulatory authority;

#### *Regulatory supervision and supervisory programme*

Regulatory inspections and safety assessments are carried out by SSM, according to a supervisory Programme, as authorized by the Ordinance on Nuclear Activities and Radiation Protection Ordinance. This supervisory programme is structured into two basic parts, baseline supervision and demand-based supervision. Figure 3 below is a schematic illustration of the programme.

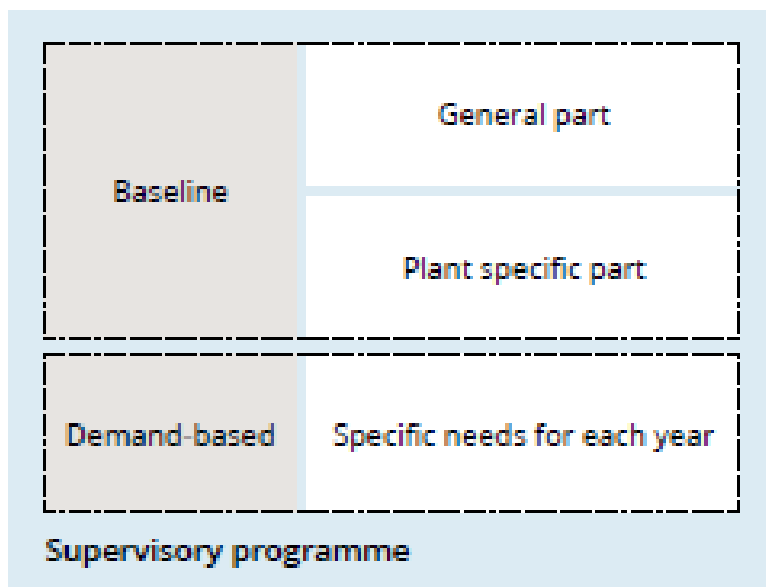


Figure 3. Structure of the supervisory programme

The baseline supervision part is divided into six fundamental aspects of the installations and activities:

- Management and control
- Safety analysis
- Design

- Plant status
- Operation
- Environmental impact

As an important complement to the baseline supervision, the demand-based supervision is defined yearly. It can therefore differ from year to year, depending on:

- Results from integrated safety assessments
- Results from inspections carried out or events that have occurred
- Identified areas where supervision is deemed necessary from, e.g., events or concerns
- Major ongoing changes, technical or organisational
- Other identified needs

#### *The supervisory process*

The supervisory process is divided into the following seven sub-processes:

- Compliance inspections
- Surveillance inspections
- Reviews and safety assessments
- Managing of reported events at the nuclear installations
- Managing other reports from the licensees
- Integrated safety assessments
- Assessment of the licensee's periodic safety review, PSR

More detailed information on the applied supervisory programs and supervisory process as well as performed supervisions recent years at the Swedish nuclear power reactors can be found in section 8.8. in the 8<sup>th</sup> Swedish CNS Report.

#### Article 4

The national framework shall provide in particular for:

1. (e) effective and proportionate enforcement actions, including, where appropriate, corrective action or suspension of operation and modification or revocation of a licence.

#### *Legal basis for enforcement actions*

SSM has extensive legal powers to enforce its decisions.

Section 17 of the Act on Nuclear Activities (1984:3) stipulates that a licensee have to provide SSM with all information, documentation and access to installations that are needed for the regulatory supervision. If necessary the police authority shall, according to section 17, provide the assistance needed for the supervision.

According to Section 18 of the Act, SSM is authorized to decide on measures that are needed and issue orders and prohibitions in individual cases in order to enforce the Act, regulations or licensing conditions issued with support of the Act. If a licensee fails to take necessary action, SSM is authorized to carry out the action on the licensee's expense.

SSM can also decide on fines in cases of non-compliance with licence conditions or regulations according to Section 22. According to Section 8 of the Act, SSM due to safety considerations is authorized to decide on licence conditions when the licence being granted or during the validity of the licence.

In accordance with Section 8 of the Act a licence can be revoked by the authority which granted the licence. The Swedish nuclear installations have been granted their licences from the Government, which means only the Government is authorized to revoke them.

Finally, according to Section 25 of the Act, it is a criminal offence to violate the Act as well as conditions or regulations issued with support of the Act. SSM hands over suspected cases of criminal violations to a public prosecutor. This has been done in a few cases where it was evident, in the opinion of SSM, that the licensee had violated a legally binding requirement.

#### *Practice used to remedy a non-compliance situation*

Thus, based on the legal grounds, SSM has access to a variety of measures that can be used to remedy a non-compliance situation. Here, an overarching principle is to avoid taking a measure that is more restrictive than necessary in the specific case. Also, the SSM management system provides guidance<sup>6</sup> on how different measures should be taken for compliance with this principle. Whoever becomes the subject of a regulatory decision always has the option to appeal the decision.

Normally SSM uses a scale of administrative sanctions in cases where the licensees deviate from the regulations. The different steps are:

- Issuing a remark on issues to be corrected by the licensee.
- Ordering an action plan to be developed and actions to be taken within a certain time period.
- Ordering specified actions to be taken within a certain time period and the results submitted for review and approval. This can be applied in combination with a fine.
- Ordering suspension of operations until deficiencies are corrected and the measures taken are reviewed and approved by the SSM.
- Revoking a licence.

In combination with the above sanctions, the regulatory body can take the following actions:

- Refer suspected cases of criminal violations to a public prosecutor.
- Impose additional licensing conditions.

#### Article 4

2. Member States shall ensure that the national framework is maintained and improved when appropriate, taking into account operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research, when available and relevant.

#### *General basis for improvement of the national regulatory framework*

The improvement of the national framework is based on different aspects.

Firstly, incidents at the facilities significant to safety are reported according to the relevant reporting requirements in SSMFS 2008:1. Hereby SSM is informed not only about the incident itself but also safety significance and circumstances which may have caused the incident. From the reporting, SSM may draw conclusions which are important when evaluating the need for updating of the framework.

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<sup>6</sup> STYR2011-87, Assessments of compliance at supervision (*Bedömningar av kravuppfyllelse vid tillsyn*). SSM internal control document.

Secondly, from the general supervisory function point of view, the authority may observe tendencies in different safety issues which in the long term can be necessary to meet with new or revised requirements or recommendations. This is a constant ongoing process at SSM.

Thirdly, the outcome of the periodic safety reviews (PSR) can contribute to the knowledge that clarification of current provisions may be necessary. In general, the regulatory reviews of the PSR reports have supported the safety improvement programmes adopted by the licensees. Also WANO peer reviews can serve the same purpose in response to operating experience.

Fourthly, international peer reviews, such as IRRS and IPPAS, also give valuable input to improvement of the national framework.

A relatively recent (2015) addition to the Swedish regulatory framework is the decision on new license conditions regarding the introduction of independent core cooling (ICC). These license conditions have been added following the evaluation of the experience of the accident at the Japanese nuclear power plant Fukushima Dai-Ichi and the subsequent European stress tests. The license conditions require that all Swedish nuclear power reactors operating after 2020 must have an additional and fully independent system for cooling of the reactor core in place before 2021. The introduction of an independent core-cooling function strengthens the reactor's ability to prevent core damage for extreme events previously not included in the design basis. Further information is provided in Appendix A, Table A2.

The same internal processes are used in the revision of regulations as in the preparation of new regulations. See also the information above about Sweden's compliance with Article 4.1.

#### *Major revision of the Code of Statutes, SSMFS*

SSM is currently revising its Code of Statutes relating to nuclear safety, nuclear security and radiation protection. Experience has demonstrated the need to clarify and broaden the regulations in order to create more predictability for the licensees and to improve the regulatory support. Other reasons for this revision are the IRPAS mission reports to Sweden in 2011/2016 and the IRRS mission reports to Sweden in 2012/2016. The 2012 IRRS mission report concluded that Swedish regulations for nuclear facilities have, historically, emerged as the need for regulation arose.

Moreover, the Swedish Government has, through appropriation directions, ordered SSM in 2012 and 2013 to review the regulations concerning nuclear power reactors, to ensure that appropriate requirements are in place for potential new nuclear power plants, taking into account the experiences of events and accidents that have occurred and new international safety standards. In 2015, the government assignment was amended and expanded to include a general review of regulations on the safety of nuclear power reactors.

The first parts of the new Code of Statutes were finalised, issued and entered into force in June 2018. The remaining parts are planned to gradually be completed and come into force between 2022 and 2023.

Further information on the major revision of the SSMFS can be found in section 7.2.2 of the 8<sup>th</sup> Swedish CNS Report.

#### *Article 5 - Competent regulatory authority*

##### Article 5

1. Member States shall establish and maintain a competent regulatory authority in the field of nuclear safety of nuclear installations.

### *Legal foundations of the regulatory authority of SSM*

According to Section 16 of the Act on Nuclear Activities (1984:3) the supervision of compliance of the Act and the conditions or regulations issued under the Act is exercised by the authority appointed by the Government.

As stated above (Article 4 (1)), it is clarified in Section 22 of the Ordinance on Nuclear Activities (1984:3) that SSM is the appointed authority. As also stated above SSM's missions and tasks are defined in the Ordinance (SFS 2008:452) with instructions for the Swedish Radiation Safety Authority and in annual appropriation directions.

### *Other authorities with responsibilities related to nuclear safety and radiation protection*

SSM is the main regulatory body regarding nuclear safety and radiation protection in Sweden. Nevertheless, there are other authorities responsible for different aspects related to nuclear safety.

#### *The Land and Environmental Courts*

The Land and Environmental Courts are responsible for matters in relation to the Environmental Code (1988:808), for example applications for power up-grades. The court examines the application including the content of the environmental impact statement and how it has been developed by the applicant. The court must examine the overall issues such as siting and the planned facility's impact on the environment. However, there is no barrier for the court to also consider matters relating to nuclear safety and radiation protection.

#### *The County Administrative Board (Länsstyrelse)*

The County Administrative Board has a coordinating role in the environmental impact assessments in the licensing process of a nuclear installations. The County Administrative Board also have a dedicated role within the emergency preparedness and response system regarding nuclear accidents. The nuclear installations covered by the scope of the Directive in Sweden are located in four different counties.

#### *The Swedish Civil Contingencies Agency (MSB)*

MSB is responsible for issues concerning civil protection, public safety, emergency management and civil defence as long as no other authority has responsibility. Responsibility refers to measures taken before, during and after an emergency or crisis.

#### *Swedish National Grid (Svenska kraftnät)*

The Swedish National Grid is a state-owned public utility. One of its important tasks is to transmit electricity from the major power stations to regional electricity networks, via the national electrical grid. This means that Swedish National Grid controls the power supply from the external grid towards the NPPs in Sweden. Swedish National Grid also has the task as regulatory body for the security regarding the Swedish energy supply, in this respect. The Swedish National Grid has a status as an authority.

#### *Swedish National Debt Office*

The Swedish National Debt Office is the central government financial manager. Since 2018, the regulatory responsibility for securing the financing of decommissioning of nuclear reactors, nuclear waste management and disposal has changed from the Swedish Radiation Safety Authority to the National Debt Office. The Debt Office review cost estimates submitted by nuclear licensees and calculate the nuclear waste fees and financial guarantees for each utility in accordance with the provisions of the Act and Ordinance on Financing of Management of Residual Products from Nuclear Activities. The fees are calculated on the assumption that each reactor will generate electricity for 50 years, though always with a minimum remaining operating time of six years. Based on the Debt Office's proposal, the Government decides on the nuclear waste fees and financial guarantees for a period of three years. The nuclear waste funds' assets are managed by a Government authority, the Nuclear Waste Fund.

See also the information above on how Sweden complies with Article 4.1 (a).

Article 5

2. Member States shall ensure the effective independence from undue influence of the competent regulatory authority in its regulatory decision-making. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:

- (a) is functionally separate from any other body or organisation concerned with the promotion or utilisation of nuclear energy, and does not seek or take instructions from any such body or organisation when carrying out its regulatory tasks;

*The national framework that ensure the effective separation*

Pursuant to chapter 1 section 16 of the Instrument of Government, the Government governs the realm and is responsible to the Parliament. In chapter 7 there are provisions on the work of the government. The Government offices prepares bills and assists the ministers of the government in their duties. The Government offices consists of ministries for different societal areas and the tasks are distributed accordingly by the government. Pursuant to chapter 7 section 3 of the Instrument of Government, decisions regarding specific tasks shall be taken by the cabinet of ministers collectively at a dedicated meeting. At the cabinet meeting, the responsible minister is the rapporteur of the task that belongs to her or his ministry (chapter 7, section 5).

Pursuant to section 2 of the ordinance (1996:1515) with instruction to the Government offices, the Ministry of the Environment, the Ministry of Enterprise and Innovation and the Ministry of Infrastructure are parts of the Government offices. In section 6 it is stated that the head of a ministry is the minister appointed by the Prime minister in accordance with chapter 7, section 1 of the Instrument of Government.

The separation of responsibilities of government ministries is set out in the annex to the Ordinance on the Functioning of the Government Offices (1996:1515). Pursuant to section 8 of the annex to the Ordinance, the Ministry of the Environment is responsible for issues concerning the Environmental Code, radiation protection and nuclear activities as well as for legislation in these areas. National authorities under the Ministry of the Environment include the Swedish Radiation Safety Authority (SSM), local nuclear safety boards, the Nuclear Waste Fund, and the Swedish National Council for Nuclear Waste.

Pursuant to section 12 of the annex, the Ministry for Infrastructure is responsible for general issues concerning energy, including energy supply, as well as for legislation in these areas. National authorities under the Ministry for Infrastructure include Swedish National Grid which is the authority responsible for ensuring that Sweden's transmission system for electricity is safe, environmentally sound and cost-effective, the National Electrical Safety Board, the Swedish Energy Agency, and the Swedish Energy Markets Inspectorate.

Pursuant to section 9 of the annex the Ministry of Enterprise and Innovation is responsible for general trade and industry policies.

Pursuant to chapter 12, section 2 of the Instrument of Government, no authority, including Parliament or local or regional administrations, may decide (may not interfere) how a competent authority should act in a specific case which involves exercise of public authority or the application of law. This article stipulates that competent authorities are independent in their application of laws

and regulations and that the government, a minister or a ministry is not allowed to interfere in specific cases.

Article 5

2. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:
  - (b) takes regulatory decisions founded on robust and transparent nuclear safety-related requirements;

*The national framework that ensure that regulatory decisions founded on robust and transparent nuclear safety-related requirements*

Pursuant to chapter 7, section 2 of the 1974 Instrument of Government, relevant information should be gathered and stakeholder consultation carried out to the extent necessary in the specific circumstances before any government decision is taken. This principle is valid for all public decision-making. The general obligations of national authorities when carrying out their tasks are stipulated in the Administrative Procedure Act (2017:900). Pursuant to section 5, agencies should act with impartiality and proportionality. Pursuant to section 23, agencies should ensure that any clarifications needed are made before a decision is taken. Pursuant to section 32, all decisions should be reasoned unless it is obvious that there is no need. Pursuant to section 34, all decisions should contain information on how they can be appealed.

Chapter 2 of the Freedom of the Press Act, one of the four fundamental laws of the Swedish Constitution, contains provisions on public access to official records. This means that all (public) documents submitted to, sent out from or drawn up by the authorities are public. Anyone can ask the authority to gain access to these documents. However, some information in the documents could be confidential and hence will not be disclosed. In such cases, the authorities must state on what ground this information is confidential. The authority's decision not to disclose certain documents based on confidentiality can be appealed in the General Administrative Court and the Supreme Administrative Court.

SSM's supervision policy (STYR2011-97)<sup>7</sup>, stipulates that all supervisory activities shall be carried out so that they provide the conditions for well-founded assessments, conclusions and decisions. SSM's assessments in licensing and supervisory matters are made against requirements in acts, ordinances and regulations, and which are published. As stated above (Article 4 .1) the SSM regulations are issued according to an established management procedure which stipulates technical and legal reviews of the draft. In accordance with the general obligations of national authorities when carrying out their tasks (see reply in the first paragraph above), a review of the final draft by authorities, license holders, industrial and environmental organisations and other stakeholders is performed before the regulations are adopted.

The principles for how assessments are to be made by SSM's staff are regulated in the internal control document on assessments of compliance at supervision (STYR2011-87). See also the information above on how Sweden complies with Article 4.1 (e).

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<sup>7</sup> STYR2011-97, Supervision policy (*Tillsynspolicy*). SSM internal control document.



Article 5

2. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:
  - c) is given dedicated and appropriate budget allocations to allow for the delivery of its regulatory tasks as defined in the national framework and is responsible for the implementation of the allocated budget

*Regulation and process for financing the competent regulatory authority*

Article 5 (2) (c) of the revised Nuclear Safety Directive, partially corresponds to Article 8 paragraph 1 of the Nuclear Safety Convention, which states "Each Contracting Party shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7, and provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities".

Pursuant to chapter 9, section 1 of the Instrument of Government, the Parliament decides on taxes and fees to the state and on the state budget. Pursuant to section 2, the Government submits a budget bill to the Parliament.

The activities of the competent authority (SSM) is mainly financed by grants from the state budget but also to a certain extent through direct fees. The grants from the state budget is financed by fees from the licensees.

The Nuclear Activities Act (1984:3), authorizes the government or the authority that the government may issue regulations on fees for activities carried out by an authority (section 30). Based on the authorization, the Government has adopted Ordinance (2008: 463) on certain fees to the Radiation Safety Authority. The fees from the licensees are transferred by the authority to the state treasury.

In the process for the elaboration of the Governments bill to the Parliament on the state budget and specifically the part regarding grants to the competent authority, the competent authority has according to the Ordinance (2000:605) on annual accounts and budgetary requests, to present a report to the Government. This report has to include both how the appropriations from the previous year have been used and what budgetary needs exist for the three in the following years. The information provided is used to calculate the annual budget appropriations, which are specified in appropriation directions from the Government to the authorities for each financial year. The adequate funding of the competent authority is therefore not achieved through an explicit provision but through a framework that establishes a process that will ensure adequate funding of the competent authority. Within the framework of the approved budget and the fees are the basis for this budget SSM decides how appropriated funds are used for different licensing and regulatory activities. If events occur during the budget year or other circumstances arise that require increased supervision activities, SSM may request additional funds or use grant credits which allows the costs to spread out on several years.

More detailed information about SSM financial resources in various fields can be found in section 8.5.9 of the 8<sup>th</sup> Swedish CNS Report.

Article 5

2. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:

- (d) employs an appropriate number of staff with qualifications, experience and expertise necessary to fulfil its obligations. It may use external scientific and technical resources and expertise in support of its regulatory functions;

*Ensuring that SSM has appropriate number of staff with qualifications, experience and expertise necessary to fulfil its obligations*

Pursuant to Section 6 of the Ordinance with Instructions for the Swedish Radiation Safety Authority (2008:452), the authority has a general obligation to promote competence and expertise in its field.

Pursuant to Section 15 of the same Ordinance the Swedish Radiation Safety Authority shall, within the scope of national radiation protection preparedness, coordinate the emergency measures necessary to prevent, identify and detect nuclear or radiological events that may lead to damage to human health or the environment. In this context the authority shall, pursuant to Section 15 paragraph 4, respond to expert competence and knowledge and decision-making documentation in the field of radiation protection including dispersion calculations and radiological assessments.

Section 3.2 of the SSM's rules of procedure (STYR2012-27)<sup>8</sup> states that the authority's departments and sections are responsible for monitoring and developing their respective areas of responsibility. The responsibility includes maintaining and continuously developing the authority's knowledge and competence in the area. Further internal governance applies through the authority's competence supply process (STYR2014-41)<sup>9</sup> and the control document on competence profile and development programme for staff working with supervision (STYR2011-171)<sup>10</sup>.

Competence mapping of all employees at the SSM is an ongoing effort focusing on the core competencies. The mapping is documented and managed in an electronic skills module.

SSM has (end of 2019) a staff with 307 employees, 54% are men and 46% women. The staff number has been higher but a reduction was made when it was realized that new nuclear power plants would not be built in near future.

Compared with many other authorities, the staff of SSM has a rather high educational level. About 90% have a higher level of education. This is a result of the many specialist areas covered by the authority, and to some extent the fact that there is no designated Technical Support Organization (TSO) in Sweden to support the regulatory body with specialist knowledge.

Many staff members are typically involved in several tasks, such as inspections, regulatory reviews and supervision tasks, revision of regulations, handling of technical support and research contracts, and participation in public information activities, each activity requiring his or her expertise.

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<sup>8</sup> STYR2012-27, Rules of procedure. (*Arbetsordning*). SSM internal control document.

<sup>9</sup> STYR2014-41, Competence Supply Process. (*Kompetensförsörjningsprocessen*). SSM internal control document.

<sup>10</sup> STYR2011-171, Competence profile and development program for staff working with supervision. (*Kompetensprofil och utvecklingsprogram för befattningshavare som utövar tillsyn*). SSM internal control document.

## Article 5

2. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:
  - (e) establishes procedures for the prevention and resolution of any conflicts of interest;

### *Measures for the prevention and resolution of any conflicts of interest*

General obligations relating to conflict of interest applicable to the staff of Swedish national authorities are stipulated in Sections 16–18 of the Administrative Procedure Act (2017:900).

SSM's decision-making and preparation scheme (STYR2011-28)<sup>11</sup> contains internal rules on conflict of interest. This document requires that a conflict of interest assessment should always be made by each person who participates in the handling of a case.

Further internal control in these respects applies through the document on other tasks outside the employment at SSM and conflict of interest (STYR2011-2)<sup>12</sup>.

In addition, there are internal regulations in SSM's control document on supervision policy (STYR2011-97)<sup>13</sup> and on Integrity and credibility aspects when recruiting (STYR2011-129)<sup>14</sup> on a mandatory waiting period, i.e. a new employee may not be responsible for the supervision or participate in the preparation of decisions involving his/her previous employer during the first two years of his/her employment. Furthermore, there are internal rules stating that

- the responsibility as coordinating inspector against the respective supervisory object / facility shall not exceed four years. This means that the task as coordinating inspector rotates in order to maintain independence.
- inspections should normally be carried out by at least two people, but in exceptional cases may be carried out by a person provided that personal safety is not compromised.

Internal rules on conflicts of interest in the case of organizations that provide SSM with advice or services follow from the control document<sup>15</sup> on managing disputes and conflicts of interest in connection with the use of external support. It follows from this document, among other things, that organisations or experts who are to be commissioned by SSM must in advance report on any circumstances that may be assumed to have significance for the organisations or person's objectivity and impartiality in the assignment for the authority. Individuals and experts are also required, after commencing their assignment, to report such relationships on an ongoing basis to the Authority. This

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<sup>11</sup>STYR2011-28, Decision-making and preparation scheme (*Besluts- och beredningsordning*). SSM internal control document.

<sup>12</sup>STYR2011-2, Other tasks outside the employment at SSM and conflict of interest. (*Bisyssla och jäv*). SSM internal control document.

<sup>13</sup>STYR2011-97, Supervision policy. (*Tillsynspolicy*). SSM internal control document.

<sup>14</sup>STYR2011-129, Integrity and credibility aspects when recruiting. (*Integritets- och trovärdighetsaspekter vid rekrytering till SSM*). SSM internal control document.

<sup>15</sup> STYR2011-138, Managing disputes and conflicts of interest in connection with the use of external support (*Hantering av jäv och intressekonflikter i samband med att externt stöd anlitas*). SSM internal control document.

obligation to report and report also applies to the circumstances of the person's employer and of related parties.

Article 5

2. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:
  - (f) provides nuclear safety-related information without clearance from any other body or organisation, provided that this does not jeopardise other overriding interests, such as security, recognised in relevant legislation or international instruments.

*SSM's obligation to inform*

SSM's obligation to inform follows from the Ordinance with Instructions for the Swedish Radiation Safety Authority (2008:452). Section 7 states that SSM, through information and transparency, shall contribute to providing the public with insight into all activities covered by the authority's responsibility. This work should aim to

1. promote health and prevent ill-health due to harmful effects of ionizing radiation,
2. prevent acute radiation injuries and reduce the risk of late damage due to radiation, and
3. advise and inform about radiation, its properties and uses as well as radiation protection.

Section 15 (1) of the same ordinance states that SSM shall advise on radiation protection and remediation after release of radioactive substances, if a nuclear or radiological emergency occurs within or outside the country.

Section 15 (6) states that, in an event that has or could have led to consequences that are not of negligible significance for safety or radiation protection, SSM shall immediately inform regulatory authorities in neighbouring countries.

Section 15 (7) states that, in the case of releases of radioactive substances leading to off-site emergency or protection measures for the public, SSM shall submit a proposal to the Government on the appropriate form and scope of an international review of the event in accordance with Article 8e 4 of Council Directive 2009/71 /Euratom.

See also the information below on how Sweden complies with Article 8 (1).

Article 5

3. Member States shall ensure that the competent regulatory authority is given the legal powers necessary to fulfil its obligations in connection with the national framework described in Article 4(1). For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks, to:
  - (a) propose, define or participate in the definition of national nuclear safety requirements;

#### *SSM's mandate to decide on regulations*

According to section 4 of the Nuclear Activities Act (1984:3), the safety of nuclear activities shall be maintained by implementing the measures necessary in order to:

1. prevent errors in equipment, malfunction of equipment, wrongful acts, sabotage or other events leading to a radiological emergency and to restrict and delay the release of radioactive material if an emergency does occur,
2. at an early stage of a radiological emergency, prevent release of radioactive substances which would require protective measures to be taken outside the nuclear facility but will not be possible due to a lack of time;
3. prevent such large radioactive releases that would require protective measures that could not be limited in area or time, and
4. prevent unauthorized possession of nuclear material or nuclear waste.

Section 10 (2) of the Act states that the licensee is responsible for the safety of a nuclear activity and shall take the measures specified in section 4 with regard to the conditions under which the operation is conducted. According to section 10 (b)1, the Government or the authority appointed by the Government may issue regulations on measures to be taken and information to be provided to meet the requirements of section 10 (2).

According to section 20 a of the Ordinance of Nuclear Activities (1984:14), SSM is authorized to issue regulations regarding measures required to comply with the requirement in section 10 (2) of the Nuclear Activities Act. According the same ordinance SSM is also authorized to issue regulations regarding, inter alia, measures regarding nuclear waste, decommissioning, and testing, examination and inspection of equipment important to safety.

#### Article 5

- 3 For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks, to:
  - b) require that the licence holder complies and demonstrates compliance with national nuclear safety requirements;

#### *SSM's mandate to require that the licence holder complies with safety requirements*

It follows from section 16 of the Nuclear Activities Act (1984:3) that supervision of compliance with this law and of conditions or regulations issued under the law as well as supervision and control of final repository are exercised by the authority that the Government decides. Section 16 a states that anyone who is authorized to conduct a nuclear operation shall provide the supervisory authority with the opportunity to inspect and review how the safety requirements are followed in relation to tasks performed by suppliers or their sub-suppliers or by contractors, subcontractors or other organisations.

As stated above (Article 4 (1)) follows from section 17 of the Act that the licensee at the request of the supervisory authority,

1. provide the authority with the information and provide the necessary documents for the supervision; and

2. grant the authority access to a facility or site where he carries out operations, for investigations and sampling, to the extent necessary for the supervision.

Section 18 states that the supervisory authority may decide on the necessary measures and orders and prohibitions needed in individual cases in order to comply with this law or regulations or conditions that have been notified under the law.

As also stated above (Article 4 (1)), it is clarified in Section 22 of the Ordinance on Nuclear Activities (1984:3) that SSM is the appointed authority.

Corresponding regulatory tasks and mandate regarding radiation protection follow from the Ordinance on Radiation Protection (2018:506).

#### Article 5

- 3 For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks, to:
- (c) verify such compliance through regulatory assessments and inspections;

#### *SSM's tasks to verify compliance with safety requirements*

It is stated in Section 22 of the Ordinance on Nuclear Activities (1984:3) that SSM shall supervise that the Nuclear Activities Act (1984: 3) and conditions and regulations that have been decided under the Act are complied with.

How the supervision is conducted is shown above in the description of how Sweden complies with Article 4 (1) (d).

#### Article 5

- 3 For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks, to:
- (d) propose or carry out effective and proportionate enforcement actions;

#### *SSM's mandate and effective and practice for proportionate enforcement actions*

The legal basis for enforcement actions and the practice used to remedy a non-compliance situation is set out above in the description of how Sweden complies with Article 4 (1) (e).

#### Article 6 – Licence holders

#### Article 6

Member States shall ensure that the national framework requires that:

- (a) the prime responsibility for the nuclear safety of a nuclear installation rests with the licence holder. That responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might affect the nuclear safety of a nuclear installation;

### *The licensee's prime responsibility for nuclear safety*

Pursuant to Section 5 of the Nuclear Activities Act it is prohibited to carry out nuclear activities without a licence. Pursuant to Section 10 of the Act, the licence holder is responsible for the safety of the nuclear activity being carried out and thus also obliged to take a number of measures listed in the section (e.g. continuously and systematically evaluate and improve the safety of the operation and take measures in event of a radiological emergency). Pursuant to Section 13 of the Act, the licensee is obliged to bear the costs of the measures and to have an organization with sufficient financial, personnel and administrative resources to fulfil its obligations under the Act. The licence holder is also responsible for ensuring that any contractors or sub-contractors have the relevant capabilities and skills necessary for the licence holder to fulfil its obligations. These provisions were amended in 2017.

In the Government bill where the amendments were proposed (see prop. 2016/17:157 p. 36) it is stated that the purpose of amending Section 10 is to clarify that the licence holder is responsible for the safety of the activity, and that this is in line with article 6 (a) of the Directive which states that responsibility cannot be delegated. A proposal from an inquiry<sup>16</sup> is under consideration in the Government offices where a clarification of the responsibility is proposed. According to this proposal, it should be explicitly stated that the responsibility cannot be delegated.

However, according to Chapter 3. Section 2 of SSMFS 2018: 1, responsibilities, powers and working relationships for tasks that are of significance to the radiation safety (i.e. nuclear safety, nuclear security and radiation protection) shall be defined and documented and known within the organization. Section 2 also requires that it must be clear from the management system that the licensee has the ultimate responsibility for radiation safety. According to Chapter 3. Section 5 of SSMFS 2018: 1, a licensee's management system shall include, inter alia, information on how the requirements for nuclear safety, nuclear security and radiation protection are met when procuring or purchasing services and products. Based on Section 10, 13 and 16a of the Act, including the clarifications in the bill, and these provisions in SSMFS 2008: 1, SSM supervises that the licensees assume their full responsibility when hiring contractors and when procuring products and services

#### Article 6

Member States shall ensure that the national framework requires that:

- (b) when applying for a licence, the applicant is required to submit a demonstration of nuclear safety. Its scope and level of detail shall be commensurate with the potential magnitude and nature of the hazard relevant for the nuclear installation and its site;

### *Demonstration of nuclear safety when applying for a licence*

As stated above (Article 4 (1) (c)), it follows from the licensing procedure applied in Sweden that a licence application must be submitted to the SSM, which processes the matter under the Act on

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<sup>16</sup> New law on nuclear activities - with clarified responsibilities (see. page 37). (*Ny kärntekniklag – med förtydligat ansvar*). SOU 2019:16. (The inquiry proposes changes to the provisions of the current Nuclear Activities Act in relation to the responsibility for the safety of the nuclear activities and the responsibility for the management and disposal of spent nuclear fuel and nuclear waste, including the decommissioning of closed nuclear facilities, and for the financing of costs for the latter.)

Nuclear Activities, and to the Land and the Environment Court, which processes the case under the Environmental Code. Applications are to be accompanied by an environmental impact assessment under chapter 6 of the Environmental Code.

The aim of the SSM's licensing assessment is to consider whether a nuclear installation is likely to be located, designed and operated in a way so that requirements imposed on nuclear safety, nuclear security and radiation protection and the general rules of consideration can be fulfilled. The scope and orientation of this work are defined by the nature of the matter, for example whether it involves modifications of an existing installation that are subject to authorisation, construction of a new installation, or involves new and untested design solutions or proven solutions are to be applied. A graded approach is applied where both the application documentation and SSM's examinations depend on the type of installation and the risks of harmful effects of radiation that may arise.

SSM's licensing reviews are governed by an internal control document<sup>17</sup> and includes information on what documentation a licence applicant needs to attach to their application. It follows from section 5.4.1 of the control document that the application needs to include, among other things

- a first preliminary safety analysis report (Licensing Preliminary Safety Analysis Report, LPSAR) containing information about the planned facility's location, design, construction and activity,
- safety analyses of its capability to prevent radiological emergencies and mitigate the impact of an emergency situation if one should nevertheless take place, as well as analyses of its capability to prevent unauthorised access and sabotage,
- an environmental impact assessment (EIA) enabling an overall assessment of the planned activity's expected environmental impact,
- an account of how the general rules of consideration in the Environmental Code are fulfilled,
- information about the planned activity's releases and radiation protection of workers, in addition to radiation impact from releases to the environment during normal and abnormal operating conditions as well as assumed accident sequences,
- information about the design of the planned security/physical protection and planned emergency preparedness for dealing with radiological emergencies,
- information about planned management of nuclear waste and other radioactive waste generated by the activity in addition to plans for future decommissioning of the installation, and
- information about the applicant's organisation, financial and human resources in addition to competence for the purpose of maintaining nuclear safety, nuclear security and radiation protection.

#### Article 6

Member States shall ensure that the national framework requires that:

- (c) licence holders are to regularly assess, verify, and continuously improve, as far as reasonably practicable, the nuclear safety of their nuclear installations in a systematic and verifiable manner. That shall include verification that measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including the verification of the application of defence-in-depth provisions;

<sup>17</sup> STYR2011-131, Licensing work and examination of licence conditions as regards nuclear facilities and other complex installations where radiation is used. (*Beredning av tillstånd och prövning av tillståndsvillkor gällande kärntekniska anläggningar och andra komplexa anläggningar där strålning används*). SSM internal control document.



*Requirement to regularly assess, verify, and continuously improve the nuclear safety*

According to the provisions of section 10 (1) in the Nuclear Activities Act, anyone who has a license for nuclear activities are responsible for the safety of the installation and its operation and shall continuously and systematically evaluate, verify and, as far as possible and reasonably, improve the safety with regard to

- a) the circumstances under which the activities are carried out,
- b) how equipment and installations are affected by operation and age,
- c) experiences from operations and similar activities, and
- d) developments in science and technology.

According to chapter 2, section 10 of SSMFS 2008: 1 the continuous and systematic evaluation and verification in accordance with section 10 (1) in the Nuclear Activities Act shall also include applicable rules for design, construction and operation as well as the design conditions that have been added after the commissioning of the plant. A defined safety program shall be in place for the safety enhancement measures, both technical and organizational, that are the result of this continuous and systematic evaluation and verification. The safety program shall be evaluated and updated annually.

General advice to chapter 2, section 10 of SSMFS 2008: 1 points out that in the continuous and systematic evaluation and verification of the plant's safety, particular consideration should be given to technical and organizational experiences from its own operations, experiences from similar plants, results from safety analyses, results from research and development projects that may have an impact on the assessment of the safety and development of the rules used in the construction and operation of the plant. Organizational experience refers, for example, to results from analyses of the interaction between man-technology organization, evaluations of the organization and staff working conditions, and self-evaluations of safety climate and safety culture.

The general advice to chapter 2, section 10 of SSMFS 2008: 1 also points out that the safety program should specify overall priorities and schedules for the measures included in the program. It is also pointed out that opportunities for improving safety should be taken into account in any measure that results in changes in the plant or in its operations.

In addition to the requirements for continuous and systematic evaluation and verification in accordance with section 10 (1) of the Nuclear Activities Act, the Swedish national framework include long-standing requirements for periodic safety reviews (PSR). Requirements for PSR were introduced in Sweden in the early 1980s as a result of the Three Mile Island accident. The requirements for PSR were introduced into the Nuclear Activities Act through amendments in 2010. The PSR requirements were further amended in 2017 and the current requirements according to section 10a stipulates that the licensee shall, at least every ten years, make a new systematic overall assessment of safety and radiation protection. In the overall assessment, the licensee shall assess how safety and radiation protection can be maintained and improved until the next systematic overall assessment or until the plant the plant has been permanently shut down. Particular consideration shall be given to the circumstances set out in section 10 (1) a-d.

In the Government bill where the amendments 2010 were proposed (see prop. 2009/10:172 p. 41) it is stated that the aim is to ensure that older nuclear power reactors as far as possible and reasonably achieve a comparable level of safety as new nuclear power reactors. In the Government bill where the amendments 2017 were proposed (see prop. 2016/17: 157 p. 27) it is stated that measures shall be taken so far as is reasonable and possible. It does not allow for any arbitrary assessment of what is an

acceptable level of safety. Any action that is possible should be implemented if it is not unreasonable in relation to the safety improvement expected by the measure. The license holder shall not only maintain safety but also improve it and demonstrate that the measures taken are sufficient.

This type of assessment and consideration of what are possible and reasonable safety improvements in individual cases includes assessing the need to take action and if safety improvements are proportionate to the extent of the measures that are possible to implement. Also, time and cost aspects may need to be considered. In such considerations, it is important to assess the impact for the nuclear installation's overall safety.

It is consequently case-by-case assessments and considerations that determine the outcome. Major safety improvements that requiring comprehensive measures may take time to implement. This was for example the case in the mid-1980s when the systems for filtered pressure relief of nuclear power reactor containments were introduced and is also the case now that the independent core cooling system (ICC) is being introduced during 2020. On the other hand, events have occurred that have shown the presence of designs with previously unknown deficiencies that requires immediate actions and safety improvements. This was for example the case after the 'strainer event' in Barsebäck unit 2 in 1992 and the electric power system event at Forsmark unit 1 in 2006.

#### Article 6

Member States shall ensure that the national framework requires that:

- (d) licence holders establish and implement management systems which give due priority to nuclear safety;

#### *Requirements for licensees' management system*

According to chapter 3, section 4 of SSMFS 2018: 1, the activity shall be managed, controlled, evaluated and developed with the support of a management system. The management system shall be designed so that the requirements for radiation safety (i.e. nuclear safety, nuclear security and radiation protection) are met in coordination with the other requirements of the activity. The management system shall be documented, up-to-date and appropriate for the activity.

According to chapter 3, section 5 of SSMFS 2018: 1, the management system shall include a description of how it is designed and contain information on

1. radiation safety targets and guidelines,
2. how the radiation safety requirements are implemented and met,
3. the structure, responsibilities and decision-making structure of the organization,
4. how the activities and possible processes of the activity are to be implemented, evaluated and developed,
5. contact areas with external organizations that are important for radiation safety,
6. how radiation safety requirements are met when procuring or purchasing services and products, and
7. other circumstances relevant to radiation safety

According to chapter 3, section 6 of SSMFS 2018: 1, the management system shall support and promote a culture that means that issues that are of importance to the radiation safety receive the attention and priority that their importance requires.

Chapter 3 sections 7-9 of SSMFS 2018: 1 contains provisions on the licensee's internal audit of the management system's application and effectiveness, as well as audit programs and management of deviations.

Detailed information on how licensees of nuclear power plants comply with the requirements of the management system is available in Section 13.2 of the 8<sup>th</sup> Swedish CNS Report.

SSM's continuous monitoring of the licensee's application and how licensees comply with the requirements for management systems are included in the authority's supervisory programme, the baseline supervision part. See above about how Sweden complies with Article 4 (1) (d).

#### Article 6

Member States shall ensure that the national framework requires that:

(e) licence holders provide for appropriate on-site emergency procedures and arrangements, including severe accident management guidelines or equivalent arrangements, for responding effectively to accidents in order to prevent or mitigate their consequences. Those shall in particular:

- (i) be consistent with other operational procedures and periodically exercised to verify their practicability;
- (ii) address accidents and severe accidents that could occur in all operational modes and those that simultaneously involve or affect several units;
- (iii) provide arrangements to receive external assistance;
- (iv) be periodically reviewed and regularly updated, taking account of experience from exercises and lessons learned from accidents;

#### *Requirements on on-site emergency preparedness and arrangements*

Chapter 2, Section 5 of SSMFS 2018: 1 contains general provisions that the activity shall have a preparedness and crisis management that is adapted to the emergency preparedness category in which the activity is placed in accordance with Section 4 in the same regulation. Preparedness and crisis management shall be described in an emergency response plan that specifies what preparations have been made and the crisis management that is available to manage and mitigate the consequences of a radiological emergency. The emergency response plan shall be tested through regular exercises. Experience from these shall be utilized to improve preparedness and crisis management. The emergency response plan must be kept up to date, (iv).

(i). Provisions on accident management instructions are contained in chapter 5, Section 2 of SSMFS 2008:1. According to the provision in Section 2 these instructions shall include the actions that must be taken at a plant during normal operation, in the event of incidents, abnormal operations and design basis accidents. It should be noted here that with normal operation is meant operation within the defined conditions and constraints according to the plants Technical Specification, which thus encompasses both power operation, power increase and power decrease with a reactor and outages for refuelling, etc.

According to the provision in chapter 5, section 2 of SSMFS 2008:1, the instructions shall also include actions that need to be taken to control and limit the consequences of accidents that are not considered in the design of the plant.

The provision in Section 2 also require that the instructions and guidelines shall be appropriate, consistent with other operations and documented and kept up to date with regard to plant modifications and changes in operating mode.

(ii). In addition, instructions according to the provision in section 2 shall be provided for handling events and conditions that may affect several plants simultaneously at a site.

(iv). The instructions according to the provision in section 2 shall be updated periodically in the light of experiences from exercises and lessons learned from past incidents and accidents at similar facilities. The personnel concerned shall be familiar with the instructions and guidelines.

Provisions on the planning of the emergency preparedness are contained in chapter 2 of SSMFS 2014:2. Chapter 2, section 4 states that the licence holder shall identify and document the conditions that may arise during different events and which form the basis for the planning and design of the emergency preparedness activities.

(iii). According to chapter 2, section 6a of SSMFS 2014:2 the licensee shall take the preventive measures needed to receive equipment and other support from external organizations in a radiological emergency situation to the extent reasonably foreseeable.

In recent years, regulatory control of on-site emergency preparedness and response has focused on implementation of the new requirements contained in regulation SSMFS 2014:2. A number of emergency response exercises of varying scope are conducted annually in Sweden. These exercises vary in complexity from limited scope to full-scale exercises. Periodical tests of the alerting systems between the power plants and the authorities are performed each year. Every other year, a full-scale exercise is held at one of the three nuclear power sites to check the planning and capability of the on-site and off-site organisations. More detailed information on on-site and off-site emergency at the Swedish nuclear power reactors can be found in Section 16 of the 8<sup>th</sup> Swedish CNS Report.

#### Article 6

Member States shall ensure that the national framework requires that:

- (f) licence holders provide for and maintain financial and human resources with appropriate qualifications and competences, necessary to fulfil their obligations with respect to the nuclear safety of a nuclear installation. Licence holders shall also ensure that contractors and subcontractors under their responsibility and whose activities might affect the nuclear safety of a nuclear installation have the necessary human resources with appropriate qualifications and competences to fulfil their obligations.

#### *Requirements on licence holders financial and human resources*

Basic provisions with requirements for human and financial resources of the licensee are set out in Section 13 of the Nuclear Activities Act. It follows from paragraph 2 of this provision that the licence holder shall have an organization for the operation of a nuclear facility with the financial, administrative and human resources sufficient to, inter alia, fulfil

- a) the measures needed to prevent radiological emergencies, as well as to continuously and regularly undertake safety assessment and periodic safety reviews (PSR) with implementation of safety improvement measures identified in such assessments;

- b) measures resulting from license conditions and other injunctions or regulations that have been issued under the Act;
- c) protection measures in the event of incidents or accidents in the nuclear facility.

According to section 13, paragraph 3 of the Nuclear Activities Act, shall the licensee when contractors are undertaking actions on behalf of the licensee, and in respect of such contractors' subcontractors, ensure that they have the human resources with the appropriate qualifications and skills required for the licensee to be able to fulfil their obligations.

Pursuant to section 16a of the Nuclear Activities Act, the licensee shall provide SSM with the opportunity to inspect and review how the safety requirements are followed in relation to tasks performed by suppliers or their sub-suppliers or by contractors, subcontractors or other contractors.

According to chapter 2, section 9, paragraph 2 of SSMFS 2008:1, the licensee shall ensure that the nuclear operations are planned so that sufficient time and resources are allocated for the safety measures and the safety reviews that need to be carried out.

According to chapter 3, section 10 of SSMFS 2018: 1, it shall be ensured that those who work in the activity have the skills and suitability otherwise necessary for tasks that are of significance for the radiation safety (i.e. nuclear safety, nuclear security and radiation protection). The skills needed within the activity and the skills that are available shall be systematically identified and documented. If it is necessary to achieve and maintain the necessary skills, training should be carried out or other measures taken.

According to chapter 3, section 11 of SSMFS 2018: 1, a licensee's organization shall have the necessary skills to order, manage and evaluate the result of work that is of significance to the radiation safety and which is performed by contractors or other hired personnel. A careful balance shall be made between using own staff and contractors or other hired staff for tasks that are of importance for radiation safety.

#### *Supervision of the licensee's financial resources*

SSM does not carry out any explicit reviews and assessments of the financial resources and needs of the licensees. The assessments are done indirectly through SSM's supervision of how the licence holders fulfil their obligations. This supervision includes inspections and reviews of the operating and support organizations of the licence holders, their applied competence insurance systems and actual personnel resources in different areas, results of continuous safety assessments and PSRs, and whether identified safety improvement measures are implemented within a reasonable time. If SSM observes shortcomings when carrying out this supervision the authority has the possibility, according to section 18 of the Nuclear Activities Act, to issue an injunction requiring the licence holder to take the necessary measures to rectify the situation within a certain time.

#### *Supervision of the licensee's human resources*

One area of focus in SSM's supervisory programme (see the information above how Sweden complies with Article 4 (1) (d)) is the licensees' competence provision and staffing considering the challenges of licensees in maintain the necessary human resources and skills, and develop these further as the situation at the plants change. Furthermore, due to the shutdown of nuclear power reactors and decommissioning planning at Oskarshamn and Ringhals, SSM conducts cross-organisational supervision of this situation to ensure that current regulations regarding human resources and competence remain satisfied. This means that the licensees are subjected to continuous supervision.

Section 8.8 of the 8<sup>th</sup> Swedish CNS Report contains further detailed information on the applied supervisory program and section 12 contains further detailed information on the nuclear power reactors licensees' work with resource and expertise assurance and SSM's supervision in this area.

#### *Supervision of the licensee's contractors and sub-contractors*

The provisions in accordance with Section 13, paragraph 3, and Section 16a of the Nuclear Activities Act were added through the 2017 amendments to the Act. This increased the possibilities for SSM to follow up on how the licensees procure products and services and control and manage their contractors and suppliers. Since then, only limited supervision has been carried out, mainly through examinations of how the licensees in their management systems control and ensure that their suppliers and contractors have the human resources with the appropriate qualifications and other resources that are necessary with regard to nuclear safety.

However, it should in this context also be noted that the Swedish regulations<sup>18</sup> have since long time required that design, manufacture and installation of pressure-bearing and other mechanical components shall be examined through independent (accredited) bodies in third party position to assess compliance with SSM's regulations.

#### *Article 7 – Expertise and skills in nuclear safety*

##### **Article 7**

Member States shall ensure that the national framework requires all parties to make arrangements for the education and training for their staff having responsibilities related to the nuclear safety of nuclear installations so as to obtain, maintain and to further develop expertise and skills in nuclear safety and on-site emergency preparedness.

#### *Legal requirements concerning education, training and retraining the staff of licence holders*

As stated above (Article 6 (f)), the Swedish national framework imposes general requirements on licence holders for obtaining, maintaining and further developing expertise and skills in nuclear safety and on-site emergency preparedness through Section 13, paragraph 2 of the Nuclear Activities Act and the provision according to sections 10 and 11 of SSMFS 2018: 1. Section 12 and Section 13 of SSMFS 2018: 1 set specific requirements for personnel to be included in a Radiation Protection Expert's function.

In addition, there are specific provisions regarding competence and training of personnel that are included in the licensees' emergency preparedness organization in chapter 10, section 2 of SSMFS 2014: 2. According to these provisions, the licensee shall have specified competence requirements as well as short and long-term training and exercise plans for personnel in the crisis organization. Staff participation in training and exercises shall be documented and preserved for each person. There shall be documented routines to follow up the personnel's competence in each position in the emergency preparedness organization. Experiences from completed exercises shall be documented and form the basis for developing the emergency preparedness organization.

The Swedish national framework also includes specific regulations, SSMFS 2008: 32, on the competence of operation personnel at reactor facilities. These regulations and general advice include requirements on competence analysis, competence assessment, authorization by the licensee,

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<sup>18</sup> Currently, there are provisions for these requirements in SSMFS 2008: 13.

recruitment and training for a position, and retraining of operation personnel belonging to the categories for operations management, control room personnel and station technicians. The regulations require the use of full scale simulators for operational training.

KSU (Nuclear Training and Safety Centre) are used by the licence holders to carry out most of the operator training and annual re-training. KSU also offers open courses in various areas for others who work in the nuclear sector. This applies, among other things, courses on nuclear technology, human performance, safety training and knowledge about the management of nuclear waste and the decommissioning of nuclear power plants. KSU is part of the Vattenfall Group and is owned by the Swedish nuclear power licence holders Forsmarks Kraftgrupp AB, OKG AB, and Ringhals AB.

Section 12 of the 8<sup>th</sup> Swedish CNS Report contains further detailed information on the nuclear power reactors licensees' work with resource and expertise assurance and SSM's supervision in this area.

#### [Requirements for the education, training and retraining of the staff of the regulatory authority](#)

Pursuant to Section 6 of the Ordinance with Instructions for the Swedish Radiation Safety Authority (2008:452), the authority has a general obligation to promote competence and expertise in its field.

The Swedish national framework does not contain any other specific legal provisions for the education, training and retraining of the staff of the SSM. This is currently governed by SSM's management system in the manner that is shown in the above information on how Sweden comply with the provisions in Article 5 (2) (d).

#### [Article 8: Transparency](#)

##### Article 8

1. Member States shall ensure that necessary information in relation to the nuclear safety of nuclear installations and its regulation is made available to workers and the general public, with specific consideration to local authorities, population and stakeholders in the vicinity of a nuclear installation. That obligation includes ensuring that the competent regulatory authority and the licence holders, within their fields of responsibility, provide in the framework of their communication policy:

(a) information on normal operating conditions of nuclear installations to workers and the general public;

#### [The licensee's and SSM's obligations and practices to provide information - normal operating conditions](#)

##### [Legal requirements for information on normal operating conditions](#)

Section 19 of the Nuclear Activities Act requires that licensees for nuclear facilities shall

1. provide the local safety board with information and insight into the safety and radiation protection work at the facility, and
2. ensure that workers and the public have access to information about the safety of the installation under normal operating conditions.

More information on local safety boards can be found below.



As stated in the information above about how Sweden complies with Article 5 (2) (f), SSM is obliged according to Section 7 of Ordinance (2008:452) with Instructions for authority through information and transparency, contribute to providing the public with insight into all activities covered by the authority's responsibility.

#### Applied communication policies for normal operating conditions

The licensee's communication policy or practice varies. Some have documented communication policies; others do not have such documents. Common to all licence holders is that they inform their local safety boards, where the public is often invited. Meetings of the boards are held 3-4 times a year, and provide information on the operating state, events that have occurred, plans and measures taken or are underway at the plants.

Most licence holders provide information to their employees through work meetings, intranets and internal information meetings, and to the public through the websites of the licence holders and, in some cases, through information meetings and public media

SSM's control document on Communication Policy<sup>19</sup> states that the authority's communication shall be characterized by the value words:

#### Credibility

- Our messages are based on acts and regulations, facts and on our assessments and decisions.
- We are clear on what grounds our recommendations and decisions rest.

#### Integrity

- We communicate based on our mission - to put radiation safety first - and let us not be affected by other interests.
- We are clear about what is our mission and actions, and what is the task and actions of others.

#### Openness

- We communicate actively and understandably about our activities and our issues.
- We make our recommendations, reports and decisions easily accessible.
- We are quick with our information.
- We are open even with things that are negative for us.
- We listen to and seek new communication paths with our stakeholders.

According to SSM's communication strategy<sup>20</sup>, the prioritized target groups are the public, licensees, employees and media.

#### Local Safety Boards

Five of the nuclear facilities have a Local Safety Council; Barsebäck, Ringhals, Oskarshamn, Studsvik and Forsmark. The Local Safety Boards are so-called Board authorities whose members are appointed by the Government. The Board consists of 13 members. A majority of them are appointed on the recommendations of the municipality in which the nuclear facility is located. A Local Safety Board will gather information on the nuclear safety and radiation protection work carried out or planned at the nuclear facility. The Board shall, in particular:

- Follow the nuclear safety and radiation protection work at the nuclear facility;
- Gather information on nuclear safety and radiation protection work carried out or planned at the facility;

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<sup>19</sup> STYR2011-68, Communication Policy (*Kommunikationspolicy*). SSM internal control document.

<sup>20</sup> STYR2011-96, Communication strategy (*Kommunikationsstrategi*) SSM internal control document.



- Gather information on the planning of emergency preparedness against nuclear accidents at the facility;
- Compile materials for information on safety and radiation protection work and emergency preparedness planning, and
- Be responsible for informing the public, authorities and institutions at the local level.

The Local Safety Boards tasks are set out in the Ordinance with instruction for the local safety committees at nuclear facilities (2007:1054). In order to facilitate for the local safety boards to gather information and compile material for public information the license holders are required to provide the councils with as complete information as possible. According to Sections 19-21 in the Nuclear Activities Act the licensees are obliged to provide the local safety board access to nuclear safety and radiation protection work at the facility. The licensees shall, upon request of the board, provide information on available facts and let the board having access to available documents, all to the extent necessary for the committee to fulfil the requirements of section 20 of Nuclear Activities Act.

#### Article 8

1. Member States shall ensure that necessary information in relation to the nuclear safety of nuclear installations and its regulation is made available to workers and the general public, with specific consideration to local authorities, population and stakeholders in the vicinity of a nuclear installation. That obligation includes ensuring that the competent regulatory authority and the licence holders, within their fields of responsibility, provide in the framework of their communication policy:

(b) prompt information in case of incidents and accidents to workers and the general public and to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation.

#### *The licensee's and SSM's obligations and practices to provide information - in case of incidents and accidents*

##### *Legal requirements for information in case of incidents and accidents*

According to chapter 1, section 7 of the Civil Protection Act (2003:778), municipalities and state authorities responsible for rescue services shall ensure that the public is informed of the ability to make rescue efforts. In addition, they shall provide information on how warnings and information to the public occur in the event of serious accidents. Chapter 2, Section 5 of the Act requires the operator of a facility to inform the county administrative board, in the event of release of toxic or harmful substances from a plant, and to also inform the police and the municipality if the release requires special measures to protect the public. Notification should also be given if there is imminent danger of such releases. If an accident occurs that can cause serious damage to human health or the environment or if there is an imminent danger of such an accident, the operator shall, in accordance with chapter 2, section 4 of the Civil Protection Ordinance (2003:789), immediately inform the municipality where the facility is located and the Swedish Civil Contingencies Agency.

According to chapter 4. section 18 of the Civil Protection Ordinance, a county administrative board shall ensure that the population that is likely to be affected in the event of a radiological emergency is given information about the health protection measures to be taken and the rules that apply in such a situation. The county administrative board shall further ensure that the population actually affected in the event of a radiological emergency is immediately informed of the facts of the accident, the rules that apply to the population and the health protection measures to be taken.

If the effects of an accident may require special measures to protect the population or the environment in a country other than Sweden, chapter 6, section 10 of the Civil Protection Act requires that the rescue agency that makes the rescue operation immediately shall notify the relevant authority in the other country.

Chapter 7, section 1 of SSMFS 2008:1 stipulates that licensee's shall report to SSM occurrences and conditions of significant importance to the safety of a facility. Appendix 1 of SSMFS 2008:1 contains more detailed provisions concerning which deficiencies in a barrier or in the defence in depth that are to be reported and how they are to be classified. Furthermore, Appendix 4 of SSMFS 2008:1 provides more detailed provisions on what is to be reported and when the reporting is to take place.

According to chapter 4, section 1 of SSMFS 2014: 2, the licensee shall prepare criteria for alarms and for information. These criteria must be approved by the SSM before the plant can be commissioned. Furthermore, must the licensee, according to section 2, trigger alarms at the appropriate level when a criterion for alarms has been met and notify the SSM within one hour. According to section 5, alarm signals shall be given inside buildings as well as outdoors over plant areas where immediate protective measures may become relevant. Notification in connection with an alarm signal must be given at each collection sites. According to chapter 10, section 1 of SSMFS 2014: 2, the licensee shall also ensure that all personnel at the plant are informed of what alarm signals mean, where the collection sites are located and about the procedures for how the plant is to be evacuated.

In addition to the general information obligations according to section 7 of Ordinance (2008: 452) with instructions for authority, shall SSM according to Section 15 paragraph 1 of the same ordinance advise on radiation protection and remediation after release of radioactive substances, if a nuclear or radiological emergency occurs within or outside the country. Section 15 paragraph 6 states that, in an event that has or could have led to consequences that are not of negligible significance for safety or radiation protection, shall SSM immediately inform regulatory authorities in neighbouring countries. Section 15 paragraph 7 states that, in the case of releases of radioactive substances leading to off-site emergency or protection measures for the public, shall SSM submit a proposal to the Government on the appropriate form and scope of an international review of the event in accordance with Article 8e (4) of the Directive 2009/71 /Euratom.

#### [Licensee's and SSM's information to workers and the general public in case of incidents and accidents](#)

In the event of incidents and accidents, the licensee's information functions are to varying degrees responsible for the companies' internal and external communication. The information functions' tasks include coordinating and compiling information about the ongoing incident and accident. The information functions have the duty to establish contact with communication managers at concerned national authorities and other stakeholders at an early stage, and provide them with frequent updates of the situation. Important parties are the County Administrative Board, SSM, the municipality concerned and the owner. In initial stages, information exchange takes place via fax, e-mail and telephone.

In events where licensee's accident preparedness or crisis management organisations are activated, prompt and accurate information to employees and the public is of the highest priority. It is the responsibility of the information functions to coordinate and organize the communication, as well as to inform to their own staff, to collaborating authorities and stakeholders. The information functions have also the task to establish external monitoring and produce press information for the media and the public.

SSM's emergency response organization includes a communication function. The tasks for this function are governed by SSM's plan for radiological emergencies<sup>21</sup>. The duties include, with support of the organisation's nuclear analysis function and radiological analysis function, to inform the public about

- the situation at the affected facility or activity,
- radioactive substances present at the affected facility or activity, and
- radiation protection issues related to the incident or accident and radiation risks that may be present.

The information SSM's communication function provides to the public shall be coordinated with the authority, normally the County Administrative Board which is responsible for the coordination of the information that is linked to the state rescue service at the incident or accident.

#### Information in emergency situations (national crisis communication arrangements)

As stated above the county administrative board shall, according to chapter 4. Section 18 of the Civil Protection Ordinance, ensure that the population affected in the event of a radiological emergency is immediately informed of the facts of the accident, the rules that apply to the population and the health protection measures to be taken.

According to Sweden's National preparedness plan for the management of a nuclear accident<sup>22</sup>, the County Administrative Board is responsible for the coordination of the information that is linked to the state rescue service. The County Administrative Board coordinates the actors directly affected by the accident, and MSB assists in disseminating its results at national level. SSM is responsible for communicating the effects of radiation on human health and the environment. The municipalities are responsible for providing information to those who are in the municipality about the incident. Each sector authority is responsible for informing about the consequences in their area of responsibility as a result of the incident. For issues relating to geographical area responsibility, each municipality and county administrative board is responsible. In order to achieve coordinated communication to the public, organized cooperation between responsible actors is needed. This is done by the County Administrative Board calling for regional information coordination conferences and MSBs for national ones.

#### Arrangements for information to regulatory authorities in MS in the vicinity of Swedish nuclear installations

Taking into account the bilateral and multilateral agreements between the Nordic states, to improve information flow between the Nordic authorities<sup>23</sup> and to harmonise the Nordic policy with the IAEA guidelines, in particular the Operations Manual for Incident and Emergency Communication (IEComm), the IAEA Safety Requirements for Preparedness and Response for a Nuclear or Radiological Emergency (GSR Part 7) and the IAEA Safety Guide on Arrangements for Preparedness for a Nuclear or Radiological Emergency (GS-G-2.1), recommended principles for communicating during incidents and emergencies have been agreed.

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<sup>21</sup> STYR2011-54, Swedish Radiation Safety Authority's plan for radiological emergencies (*Strålsäkerhetsmyndighetens krisplan för radiologiska nödsituationer*). SSM internal control document.

<sup>22</sup> National preparedness plan for the management of a Nuclear Accident.  
<https://www.stralsakerhetsmyndigheten.se/globalassets/beredskap/nationell-beredskapsplan-for-hanteringen-av-en-karnteknisk-olycka.pdf>

<sup>23</sup> The term "Nordic authorities" covers all authorities within the NEP group. This should not be confused with the term NCA as defined in the IAEA IEComm.

This agreement<sup>24</sup> specifies what information should be provided in different situations, when and how this should be done. The agreement includes the Danish Emergency Management Agency (DEMA) and the National Institute of Radiation Protection (SIS), the Finnish Radiation and Nuclear Safety Authority (STUK), the Icelandic Radiation Safety Authority (GR), the Norwegian Radiation and Nuclear Safety Authority (DSA) and the Swedish Radiation Safety Authority (SSM).

In the case of an accident at nuclear power plants in Ringhals or Forsmark, the County Administrative Boards in Halland and Uppsala inform the relevant authorities in Denmark and Finland, respectively.

SSM also notifies IAEA and EU in accordance with the IAEA Convention on Early Notification in the Case of a Nuclear Accident (INFCIRC/335) and EU Council Decision (87/600/Euratom) on early notification.

#### Article 8

2. Information shall be made available to the public in accordance with relevant legislation and international instruments, provided that this does not jeopardise other overriding interests, such as security, which are recognised in relevant legislation or international instruments.

#### *Information available to the public*

In line with the Aarhus Convention, Sweden's legal framework contains provisions regulating access to information, public participation in decision making, and access to justice.

To guarantee transparency, the principles of public access to official documents are enshrined in one of the fundamental laws, chapters 2 and 3 of the Freedom of the Press Act. The principle of public access entitles the general public to access official documents submitted to or drawn up by the authorities. Anyone may avail him/herself of this possibility whenever they wish. Documents that are received or sent out by the Government Offices and other government agencies, e.g. letters, decisions and inquiries, usually constitute official documents. As a general rule, all incoming documents should be registered by the receiving authority. Notes and draft decisions are not normally classified as official documents. If a member of the public wants to know what documents are held by a government agency or wants to get hold of them, this person should contact the agency in question.

Swedish official documents are thus public unless a decision is made to classify them according to the Public Access to Information and Secrecy Act (SFS 2009:400). The reasons for secrecy could be those of national security, international relations, commercial relations, or the individual right to privacy. No-one needs to justify a wish to see a public document or to reveal her/his identity to have access to a document. After 11 September, 2001, more safety systems documentation related to nuclear power plants became classified information and SSM has established more stringent security practices.

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<sup>24</sup> The Nordic Manual (NORMAN): Co-operation between the Nordic Authorities in Response to and Preparedness for Nuclear and Radiological Emergencies and Incidents. 20 June 2006. Revised November 2019.

If an authority has rejected a request to obtain a document, the applicant is generally entitled to appeal against the decision. Appeals are usually presented to an administrative court of appeal. A decision of such a court may be appealed against to the Supreme Administrative Court.

#### Article 8

3. Member States shall, without prejudice to Article 5(2), ensure that the competent regulatory authority engages, as appropriate, in cooperation activities on the nuclear safety of nuclear installations with competent regulatory authorities of other Member States in the vicinity of a nuclear installation, inter alia, via the exchange and/or sharing of information.

#### *SSM's cooperation with other competent regulatory authorities*

The international nuclear safety cooperation is substantial; SSM is involved in about 140 international groups. The majority of groups are related to nuclear safety and radiation protection issues. The cooperation takes place within the frameworks of IAEA, OECD/NEA and EU, but also in connection with the international conventions ratified by Sweden and in non- governmental organizations such as the Western European Nuclear Regulator's Association (WENRA), Heads of European Radiation Control Authorities (HERCA), and the International Nuclear Regulator's Association (INRA).

In addition to multilateral collaboration, SSM has bilateral agreements with nine countries to exchange information and to cooperate on agreed issues (e.g. nuclear safety, emergency preparedness, occupational exposure, environmental radiological protection and radioactive waste management). These are Australia, Canada, Germany, Japan, Lithuania, Ukraine, Russia, South Africa and USA. Additionally, Sweden has special agreements with the Nordic Countries (Denmark, Finland, Iceland and Norway) regarding emergency preparedness and information exchange on the technical design of nuclear facilities.

In 1976, an agreement<sup>25</sup> was concluded between the Nordic countries with the intention of 'communicating' safety concerns to each other pertaining to nuclear energy facilities located in close proximity to these countries' shared borders. Under this agreement, the 'respective authority of the constructing country' shall provide 'messages containing relevant material' to the 'neighbouring countries' authorities', for instance concerning licences for the operation of nuclear power plants or changes to the licence conditions. According to Section 2 of the agreement, 'messages containing associated and relevant material are to be provided on a timely basis so that any comments and remarks from the neighbouring country can be taken into consideration prior to decision-making when the constructing country processes the application'. This means also that SSM sends license applications together with environmental impact assessments (EIA) and suitable reports summarising the application documents to the authorities in Denmark (the Danish Emergency Management Agency, DEMA), Finland (STUK, the Radiation and Nuclear Safety Authority), and Norway (the Norwegian Radiation Protection Authority, NRPA).

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<sup>25</sup> Exchange of notes between Sweden, Denmark, Finland and Norway concerning guidelines for maintaining contact in safety concerns on the part of nuclear energy facilities along national borders between Sweden, Denmark, Finland and Norway.

Notifications according to the agreement have been made, among other things, in connection with applications for increasing the thermal power in nuclear reactors, planned decommissioning and ongoing licensing preparation of new final repositories.

#### Article 8

4. Member States shall ensure that the general public is given the appropriate opportunities to participate effectively in the decision-making process relating to the licensing of nuclear installations, in accordance with relevant legislation and international instruments.

#### *Opportunities for the general public to participate licensing processes*

As stated above (Article 4 (1) (c)) nuclear operations require a licence under two separate regulations; namely, the Environmental Code and the Nuclear Activities Act (1984: 3). The laws apply in parallel. Thus, two separate licences are required to conduct nuclear activities. The licence under the Environmental Code is normally approved by the Land and Environmental Court. The licence under the Nuclear Activities Act is approved by the Government or, in some cases, SSM.

#### *Licensing according to the Environmental Code*

Licence obligation A, means that a licences application for a nuclear activity is examined by the Land and Environmental Court, which applies when examining nuclear activities in accordance with the Environmental Code. Pursuant to the Environmental Assessment Regulation (2013: 251), appendix 7, chapter 11, sections 8 and 9, licence obligation A applies for reprocessing of irradiated nuclear fuel, production or enrichment of nuclear fuel, or treatment, storage or final storage of irradiated nuclear fuel and for the treatment or storage of unirradiated nuclear fuel. Pursuant to chapter 21, section 7, licence obligation A applies to nuclear power reactor or other nuclear reactors. Pursuant to Chapter 22. Section 1, licence obligation A applies for operations whereby a nuclear reactor or other nuclear reactor is installed or decommissioned from the time the reactor is shut down until after the shutdown operation, service operation and decommissioning, all nuclear fuel and other radioactive contaminated material have been removed from the site. Pursuant to chapter 29, section 58, licence obligation A applies to treat high-level radioactive waste, final disposal of radioactive waste or to store radioactive waste. Pursuant to chapter 29, section 59, licence obligation A applies to process, store, finalize or otherwise handle spent nuclear fuel, nuclear waste or other radioactive waste in accordance with the Nuclear Activities Act or the Radiation Protection Act (2018: 396), if the handling is not subject to a licence according to section 58.

Chapter 6 of the Environmental Code, Appendix 8, contains provisions on environmental assessments, including detailed provisions on environmental impact assessments and consultations. Certain activities subject to licences or measures must always be assumed to have a significant environmental impact in accordance with chapter 6. Section 20, first paragraph 2 and section 23, second paragraph 2, of the Environmental Code. It applies to activities or measures that are stated in section 6 of the Environmental Assessment Regulation (2017: 966), Appendix 9. A specific environmental assessment must therefore always be made for these activities or measures. For all licences that are not subject to a mandatory requirement for a specific environmental assessment, an investigation and assessment in the individual case of whether a project can be assumed to have a significant environmental impact shall be made in accordance with chapter 6, section 23 of the Environmental Code.

### [Licensing according to the Nuclear Activities Act](#)

Pursuant to section 5c of the Nuclear Activities Act (1984: 3), a specific environmental assessment must be made, in connection with the licencing of the construction, possession or operation of a nuclear plant, information must be provided, and coordination shall be carried out in accordance with Chapter 6. Sections 28–46 of the Environmental Code if operations can be assumed to have a significant environmental impact. The provisions of Chapter 6. The Environmental Code thus becomes applicable even in the examination that is carried out in accordance with the Nuclear Activities Act.

### [Details of the contents of Chapter 6 in the Environmental Code](#)

The provisions of chapter 6. sections 28–46 of the Environmental Code will be applicable to nuclear activities, regardless of whether the licencing is carried out in accordance with the Environmental Code or the Nuclear Activities Act. This means that environmental review, including environmental impact assessments and reports for consultation with the general public, will need to be made when examining these cases.

Chapter 6, section 28 of the Environmental Code lists what the specific environmental assessment entails. It means inter alia that anyone intending to conduct activities or take action should consult on how to define an environmental impact assessment. It also means that (in addition to competent authorities) the public and authorities that may be assumed to be affected by the activity may submit comments on the environmental impact assessment and that the specific environmental assessment is completed by the authority which licences the activity or measure.

Chapter 6, sections 29–32 contains provisions on how the so-called the consultations referred to in chapter 6, section 28 shall be made. The consultation shall allow sufficient time for meaningful consultations before the operator prepares the environmental impact assessment and the final licence application, see chapter 6, section 31 of the Environmental Code. According to chapter 6, section 29, the consultation shall inter alia deal with the location, scope and design of the activity or measure, the environmental impacts the activity or measure may be causing in itself or as a result of external events, and about the content and design of the environmental impact assessment (EIA).

According to chapter 6, section 30 the consultation, shall inter alia, be done with those who may be presumed to be particularly affected by the activity or measure and the general public which may be assumed to be affected by the activity or measure. During the consultation, the County Administrative Board shall, in accordance with chapter 6, section 32 ensure that the content of the environmental impact assessment receives the extent and degree of detail required for the licencing process. Chapter 6, section 35 specifies what the environmental impact assessment in the specific environmental assessment should contain. The environmental impact statement must here inter alia include information on the location, design, scope, scope and other characteristics of the activity or measure that may have an impact on the environmental assessment. The environmental impact statement must also include an account of the consultations that have taken place and what has emerged in the consultations. (The information in the Environmental Impact Statement must, according to chapter 6, section 37 of the Environmental Code, have the extent and degree of detail that is reasonable with regard to the prevailing knowledge and assessment methods needed for a comprehensive assessment to be made of the significant environmental impacts that the activity or measure can assume).

Pursuant to chapter 6, section 39 the competent authority examining the licence application must announce whether the environmental impact statement exists, make it available to the public and give the public a reasonable time (at least 30 days) to comment. Chapter 6, section 40 specifies



important information that must be included in the announcement, including: to whom and within what time comments can be made. Pursuant to chapter 6, section 41, the announcement shall be made on a suitable website and in a local newspaper or at a specially prescribed place. Pursuant to chapter 6, section 44 the licence decision shall be announced as soon as possible. The announcement shall include how the public can access the content of the decision.

As also stated above with information on how Sweden complies with Article 4 (1) (c) the applied licensing process includes that the preparation and review of an application, as well as the issuing of a license and conditions, take place in open court hearings at the Land and Environment Court. At these hearings, all interested parties may attend and comment, including the relevant authorities. The applicant must verbally describe all relevant aspects of his case. Questions may be submitted during the proceedings.

The applicant must also consult with those that may be or are concerned, e.g. local organizations and the public during the procedure of completing the Environmental Impact Assessment (EIA). Such stakeholders are thereby given the opportunity to express their opinions and have them considered in the process. Notification of the application as well as the EIA shall be published, in order to give everyone concerned an opportunity to comment before the matter is decided.

Chapter 6, section 6 of the Swedish Environmental Code stipulates that if an activity is likely to have a significant environmental impact in another country, the Swedish Environmental Protection Agency must inform the competent authority in that country about the planned activity and give the country concerned and the citizens who are affected the opportunity to take part in a consultation procedure concerning the application and the environmental impact assessment. Such information shall also be supplied where another country which is likely to be exposed to a significant environmental impact so requests.

The responsibility of the Swedish Environmental Protection Agency under chapter 6, section 6 is described in section 9 of the Environmental Impact Assessment Ordinance (1998:905). The Swedish Environmental Protection Agency shall assess whether a new nuclear power plant or power uprate of an existing nuclear power plant, or construction or modification of another nuclear facility that requires authorisation, may be assumed to imply a significant environmental impact in another country, and in this case must provide information to the competent authority of this country. Moreover, the Swedish Environmental Protection Agency shall allow the country that could be affected and its citizens' opportunities to participate in a consultation procedure concerning the application and the EIA.

#### Article 8a: Nuclear safety objective for nuclear installations

##### Article 8a

1. Member States shall ensure that the national nuclear safety framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:

- (a) early radioactive releases that would require off-site emergency measures but with insufficient time to implement them;
- (b) large radioactive releases that would require protective measures that could not be limited in area or time



### *Nuclear safety objective*

Basic provisions for the transposition of Article 8a (1) into the Swedish national safety framework are contained in Sections 3a and 4 of the Nuclear Activities Act. More detailed requirements are contained in SSM's regulations SSMFS 2008:1, SSMFS 2017:1, SSMFS 2014:2 and SSMFS 2018:1, and in license conditions according to Appendix 1.

It follows from chapter 1, section 1 in SSMFS 2008:1 that the regulations apply to measures that are necessary to maintain the safety in design, construction, commissioning and operation, including operation during the decommissioning, of nuclear facilities in order to prevent radiological emergency situations as far as reasonably possible, taking into account best available technology (BAT). The regulations include provisions on technical, organizational and administrative measures.

Chapter 2, section 1 of SSMFS 2008:1 requires that radiological emergency situations shall be prevented and such releases as referred to in Section 4 paragraph 2 and 3 of the Nuclear Activities Act shall be prevented by a design, which shall include several barriers, and a defence in depth adapted to each plant according to chapter 2, section 2 of SSMFS 2018:1. The provision contains general requirements for the application of defence in depth.

Further clarification is then made in SSMFS 2018:17 through more detailed provisions on fundamental safety functions and certain aspects in the implementation of defence in depth. Chapter 1, section 1 states that the regulations supplement, for application to nuclear power plants, what is said about design, construction and safety assessment in SSMFS 2008:1. Correspondingly, the requirements in SSMFS 2008:1 are supplemented and specified on prepared measures to mitigating the consequences if an accident occurs, through the regulations on emergency preparedness at nuclear facilities, SSMFS 2014:2.

It is thus these regulations that together implement the Directive's provisions on nuclear safety objective in Article 8a (1) in the Swedish national nuclear safety framework.

However, it should also be noted in this context that license conditions (see Appendix 1, Table A.2), issued by the Swedish Government, for all Swedish nuclear power plants are in place since the mid to late 1980s. These license conditions require the reactors to withstand a core melt accident without any casualties or ground contamination of significance to the population. The license conditions state that these requirements can be considered to have been met if a release is limited to a maximum of 0.1 % of the reactor core content of caesium-134 and caesium-137 in a reactor core of 1800 MW thermal power, provided that other nuclides of significance are limited to the same extent as caesium (later interpreted to corresponds to 100 TBq). This resulted in an extensive back fitting for all Swedish nuclear power reactors including the introduction of

- filtered containment venting through an inert Multi Venturi Scrubber System (MVSS) with a decontamination factor of at least 500,
- unfiltered pressure relief in BWRs in the case of large LOCA and degraded pressure suppression function to protect the containment from early over pressurization,
- independent containment spray,
- all mitigating systems designed to withstand an earthquake, and
- a comprehensive set of SAM procedures and guidelines.

It was assumed during back-fitting design that the environmental protection requirements can be met if containment integrity is maintained during accident sequences (core melt scenarios) and that

the releases and leakage from the containment can be controlled and limited. This is now considered to correspond to the term "avoiding" in Section 4 (4 §) of the Nuclear Activities Act and in Article 8a (1) (a) (b) of the Directive.

These license conditions, along with other SSM regulations and decisions, thus mean that the following acceptance criteria apply to different event categories, and which in the Swedish national safety framework contributes to fulfilling the safety objective according to article 8a (1).

Terms according to Article 3 in the Directive	Event classes according to SSMFS 2008:17	Acceptance criteria ("Referensvärden") (mSv) for existing nuclear power reactors (with respect to the general public)	Regulations or decisions (according to Appendix 1) that specify the requirements on acceptance criteria
Normal operation	H1	0,1*	Chapter 5 section 4 in SSMFS 2018:1
Incident	H2	1	SSM decision SSM2008-1945-6,7,8
Abnormal operation	H3	10	SSM decision SSM2008-1945-6,7,8
Design basis accident	H4	100	SSM decision SSM2008-1945-6,7,8
Severe conditions	H5	**	Government license condition no. 2717/85

\*) Per year and for all nuclear facilities at the site

\*\*) No dose criterion is specified. Instead, here is a maximum permissible emission of Cesium-134 and 137, which corresponds to 100 TBq.

Acceptance criteria for any new nuclear power reactors and other new nuclear installations are under preparation.

#### Article 8a

2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1:

(a) applies to nuclear installations for which a construction licence is granted for the first time after 14 August 2014;

#### *No new construction licence after 14 August 2014*

No construction licence for new nuclear power plants or other new nuclear installations has been granted for the first time after 14 August 2014.

#### Article 8a

2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1:

(b) is used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations, including in the framework of the periodic safety reviews as defined in Article 8c(b).

### *Reasonably practicable safety improvements*

As stated above (Article 6 (c)), Section 10 (1) of the Nuclear Activities Act states that anyone who has a license for nuclear activities is responsible for the safety of the installation and its operation and shall continuously and systematically evaluate, verify and, as far as possible and reasonably, improve safety.

In addition to the requirements for continuous and systematic evaluation and verification in accordance with section 10 (1) of the Nuclear Activities Act, the Swedish national framework include long-standing requirements for periodic safety reviews (PSR). According to Section 10a of the Act stipulates that the licensee shall, at least every ten years, make a new systematic overall assessment of safety and radiation protection. In the overall assessment, the licensee shall assess how safety and radiation protection can be maintained and improved until the next systematic overall assessment or until the plant the plant has been permanently shut down.

In the Government bill where the amendments 2010 were proposed (see prop. 2009/10:172 p. 41) it is stated that the aim is to ensure that older nuclear power reactors as far as possible and reasonably achieve a comparable level of safety as new nuclear power reactors. In the Government bill where PSR amendments 2017 were proposed (see prop. 2016/17: 157 p. 27) it is stated that measures shall be taken so far as is reasonable and possible. It does not allow for any arbitrary assessment of what is an acceptable level of safety. Any action that is possible should be implemented if it is not unreasonable in relation to the safety improvement expected by the measure. The license holder shall not only maintain safety but also improve it and demonstrate that the measures taken are sufficient.

As also stated above (Article 6 (c)) this type of assessment and consideration of what are possible and reasonable safety improvements in individual cases includes assessing the need to take action and if safety improvements are proportionate to the extent of the measures that are possible to implement. Also, time and cost aspects may need to be considered. In such considerations, it is important to assess the impact for the nuclear installation's overall safety. It is consequently case-by-case assessments and considerations that determine the outcome. Major safety improvements that requiring comprehensive measures may take time to implement. This was for example the case in the mid-1980s when the systems for filtered pressure relief of nuclear power reactor containments were introduced and that is also the case now that the independent core cooling system (ICC) is being introduced during 2020.

The WENRA Guidance on "Timely Implementation of Reasonably Practicable Safety Improvements to Existing Nuclear Power Plants" along with other internal documents guide SSMs assessments and consideration on issues regarding timely introduction of possible and reasonable safety improvements.

Additional information on the work with safety improvements in Swedish nuclear power plants can be found in Appendix 1 to the 8<sup>th</sup> Swedish CNS Report.

### *Article 8b: Implementation of the nuclear safety objective for nuclear installations*

#### **Article 8b**

1. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that where defence-in-depth applies, it shall be applied to ensure that:

(a) the impact of extreme external natural and unintended man-made hazards is minimised;

- (b) abnormal operation and failures are prevented;
- (c) abnormal operation is controlled and failures are detected;
- (d) accidents within the design basis are controlled;
- (e) severe conditions are controlled, including prevention of accidents progression and mitigation of the consequences of severe accidents;
- (f) organisational structures according to Article 8d (1) are in place.

#### *Implementation of the nuclear safety objective*

As can be seen from the information above about how Sweden complies with Article 8a (1), it is through the provisions of Sections 3a and 4 of the Nuclear Activities Act and the more detailed provisions in accordance with SSM's regulations SSMFS 2008: 1, SSMFS 2017: 1, SSMFS 2014: 2 and SSMFS 2018: 1, and license conditions according to Appendix 1 which in Sweden mainly implements the nuclear safety objective for nuclear installations.

General requirements for the application of defence in depth at all nuclear installations according to SSMFS 2018:1 are supplemented with further requirements and recommendations in SSMFS 2008: 1. The recommendations, in the form of general advice, are based on and refer to IAEA-INSAG-10.

The regulations of SSMFS 2008:17 contain specific requirements for nuclear power reactors on design principles and the implementation of the defence-in-depth concept. According to Section 3 shall a nuclear power reactor be designed so that the safety functions reactivity control, protection of the primary system integrity, emergency core cooling, residual heat removal and the containment function can be maintained, to the extent needed depending on the operational state, in all events to and including the event class improbable events (severe accidents). Section 4 states that the following design principles shall be taken into account in the design of the reactor's defence-in-depth to the extent reasonably practicable

- Simplicity and durability in the design of the safety systems;
- Redundancy, including diversification as well as physical and functional separation in the design of the safety functions;
- Automatic control or passive function in necessary activation and operational changeovers of the safety functions;
- Failure in safety classified equipment leads to an acceptable safety level;
- Failure in operations classified equipment may not affect the performance of equipment with safety function;
- When sharing of safety systems between reactors, a failure in one of the reactors shall not affect the possibility to perform shutdown and residual heat removal in the other reactors.

Section 4 also states that manual measures in connection with necessary activation and operational changeover of the safety functions may only be applied if the personnel is given sufficient time – time for consideration – in order to conduct the measures in a safe manner.

According to Section 14 of SSMFS 2008:17 shall a nuclear reactor be designed to withstand natural phenomena and other events that arise outside or inside the facility and which can lead to an accident. In the case of such natural phenomena and events, dimensioning values shall be established. Natural phenomena and events with such rapid sequences that there is no time to implement protective measures when they occur, shall also be assigned to an event class. For each type of natural phenomenon that can lead to an accident, an established action plan shall exist for the situations where the dimensioning values run the risk of being exceeded.

According to SSM decisions SSM2008/1945-6,7,8 all Swedish nuclear power reactors operating after 2020 must have an additional and fully independent system for cooling, ICC. This system shall strengthen the reactor's ability to prevent core damage in situations with extreme events previously not included in the design basis.

According to the Government license condition no. 2717/85 shall measures be in place for prevention of accidents progression and mitigation of the consequences of severe accidents without any casualties or ground contamination of significance to the population.

See further in the information below about how Sweden meets the requirements of Article 8d (1).

Further information on implementation of defence in depth in existing Swedish nuclear power plants can be found in section 18 of the 8<sup>th</sup> Swedish CNS Report. Further information on mitigation systems implemented after the TMI accident can be found in Sweden's national report to the Convention on nuclear safety 2012 extra ordinary meeting (Ds 2012:18). See also the Swedish National Report on European stress test (December 2011, Doc. No. 11-1471), including section 1.8, and subsequent reports (National Action Plan 2012 and updated National Action Plans December 2014 and December 2017) with information on actions taken as a result of observed shortcomings. These reports are published on the ENSREG website.

#### Article 8b

2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. Those measures include in particular:

(a) management systems which give due priority to nuclear safety and promote, at all levels of staff and management, the ability to question the effective delivery of relevant safety principles and practices, and to report in a timely manner on safety issues, in accordance with Article 6(d);

#### *Measures to promote and enhance an effective nuclear safety culture*

##### *Requirements for licensees and application*

SSM's regulations SSMFS 2018: 1 provides that the management system should support and promote a culture so that issues relevant to radiation safety (i.e. nuclear safety, nuclear security and radiation protection) receive the attention and priority that their importance requires. The provision refers to both Safety Culture and Security Culture. With this provision, SSM emphasize thus the simultaneous and balanced considerations that need to be addressed for nuclear safety, nuclear security and radiation protection.

Regulations and policies that provided due priority to safety can be understood as normal safety policies and safety strategies but also safety management provisions and tools to manage a nuclear power plant in such a way that safety is prioritised and a good safety culture is created and maintained. A good safety culture that gives safety issues the attention warranted by their significance, is also a prerequisite for a robust implementation of a management system.

Maintaining a strong safety and security culture in the operation of nuclear installations is considered vital by both SSM and the Swedish licensees, and is emphasised in the policies of the different plants and in their strategic plans. Management at all levels, including the managing directors, is involved in

activities to enhance the safety and security culture and to stress the responsibility of all personnel to work actively in maintaining and developing the safety and security culture standard.

SSM follows the licensees work with safety and security culture issues mainly through its supervision. The role of SSM in this context is to ensure that the licensees have proactive safety management. SSM expects the licensees to create and maintain a strong safety culture. It is essential that the licensees react in a timely manner to indications of deficiencies in their safety culture. If such deficiencies are not corrected, the ability of the operating organisation to handle difficult situations and maintain safety will deteriorate.

As stated above chapter 3, section 4 of SSMFS 2018: 1, require that the licensee's activity shall be managed, controlled, evaluated and developed with the support of a management system. The management system shall be designed so that the requirements for radiation safety (i.e. nuclear safety, nuclear security and radiation protection) are met in coordination with the other requirements of the activity.

More detailed information on the Swedish licensees work with safety culture and SSMs supervision of this work can be found in 8<sup>th</sup> Swedish CNS Report, including section 8.4.

#### Requirements for SSM and application

The Government Ordinance (2007: 515), Appendix 10, applies to administrative authorities under the Government. According to Section 3, the management of the authority is responsible to the Government for its activities and shall ensure that it is conducted efficiently and in accordance with applicable law and the obligations arising from Sweden's membership of the European Union, that it is reported in a reliable and fair manner and that the authority maintains efficiently with the state funds. According to § 4, the authority's management shall, inter alia, ensure that the authority has internal control and control that functions in a satisfactory manner.

SSM has an integrated and process-based management system which is certified in the areas of environment, quality management and occupational health and safety in accordance with SS-EN ISO 14001:2015, SS-EN ISO 9001:2015 and SIS-OHSAS 18001:2007. The management system encompasses all activities of SSM. The system is supplemented with a section on Information Security following SS-ISO/IEC 27001:2017, although the authority is not certified in that area. Internal and external audits are performed yearly, which are one of the bases for continuous improvements to the system.

The control document on Operation Management<sup>26</sup>, which are part of the management system, state, among other things, that all employees are responsible for, on the basis of the authority's values, constantly working to strengthen the safety culture. Furthermore, it is stated that SSM's safety culture is characterized by:

- that safety is clearly included in the authority's leadership;
- that all employees in the authority have an individual responsibility for behaviour that affects safety;
- a culture that promotes safety, facilitates collaboration and open communication;
- that the authority has a holistic view of safety;
- continuous improvement, learning and self-assessment at all levels of the organization.

The forms for education and training of SSM's staff and the management of these activities follows from the information above on how Sweden comply with Article 5 (2) (d).

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<sup>26</sup> STYR2011-71, Operation Management (*Verksamhetsstyrning*). SSM internal control document.

SSM has also conducted several internal seminars, some with invited speakers, on different themes related to the safety culture of the regulator, such as leadership, the roles of the regulatory body, the content of the OECD-NEA booklet “The Safety Culture of an Effective Nuclear Regulatory Body”, and information safety and information classification.

Furthermore, SSM procured an external evaluation of the safety culture, conducted by Lund University. The evaluation involved interviews, focus groups and a questionnaire, and resulted in a valuable baseline evaluation of the status of the safety culture. SSM is still working on some of the findings from the evaluation in its continuous effort to support and promote the safety culture of the regulatory body.

Article 8b

2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. Those measures include in particular:

(b) arrangements by the licence holder to register, evaluate and document internal and external safety significant operating experience;

*Evaluation and documentation of internal and external safety significant operating experience*

The objective of the operating experience analysis and feedback programme in Sweden is to learn from experience, from the licensees one’s own plant and from other plants, and to prevent recurrences of events, particularly events that might affect plant safety. The operating experience process consists of a wide variety of activities within plants organisations as well as externally.

SSM imposes strict requirements, in SSMFS 2008:1 and SSMFS 2018:1, for both incident event reporting and systematic investigations and analyses of events. According to section 16 of SSMFS 2018: 1, experiences that are of significance to the radiation safety in the licensee’s own operations and from other similar activities shall be utilized continuously to develop the radiation safety. There shall be documented experience feedback procedures that specify how such experiences should be collected, evaluated and utilized. According to section 17 of SSMFS 2018: 1, shall those who are working in the activity be encouraged to report events and conditions that imply or could pose a threat to the radiation safety. According to Section 18 of SSMFS 2018: 1, incidents and observed conditions that are of significance to the radiation safety shall be investigated in a systematic way. The investigation shall identify any deficiencies in the activity and include

1. sequence of events,
2. causes,
3. any radiation doses,
4. actual and potential consequences, and
5. measures taken.

The investigation shall take into account both the interaction between man-technology organization and safety culture. Based on the investigation result shall, according to section 19 of SSMFS 2018: 1 measures be taken to prevent identified shortcomings from recurring. For implementation of these measures there shall be a documented plan. The plan shall include the expected effect of the



measures, the date and responsibility for implementation, and how and when they should be followed up.

Chapter 2, section 3 SSMFS 2008: 1 require that licensees shall categorize events that have occurred and conditions based on the importance for safety. Appendix 1 contains detailed provisions on this categorization. Chapter 7 of SSMFS 2008: 1 and its appendix 4 sets requirements for licensees when and how reporting to SSM shall take place and what information should be included in this reporting.

Further information on evaluation and documentation of internal and external safety significant operating experience can be found in sections 19.5 and 19.6 in the 8<sup>th</sup> Swedish CNS Report.

Article 8b

2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. Those measures include in particular:

(c) the obligation of the licence holder to report events with a potential impact on nuclear safety to the competent regulatory authority;

*Obligation of the licence holder to report events*

As stated above chapter 2 Section 3 SSMFS 2008: 1 require that licensees shall categorize events that have occurred and conditions based on the importance for safety. Appendix 1 contains detailed provisions on this categorization. This categorization also relates to the IAEA's INES scale.

Chapter 7 of SSMFS 2008: 1 and its appendix 4 sets requirements for licensees when and how reporting to SSM shall take place and what information should be included in this reporting. Depending on the categorization, and thus the severity of the event, reporting to SSM should take place within 1 hour, 16 hours or 7 days with final reports within 30 days.

Article 8b

2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. Those measures include in particular:

(d) arrangements for education and training, in accordance with Article 7.

*Arrangements for education and training*

Arrangements for education and training related to the nuclear safety of nuclear installations follows from the information above about how Sweden complies with Article 7.



## Article 8c: Initial assessment and periodic safety reviews

### Article 8c

Member States shall ensure that the national framework requires that:

(a) any grant of a licence to construct a nuclear installation or operate a nuclear installation, is based upon an appropriate site and installation-specific assessment, comprising a nuclear safety demonstration with respect to the national nuclear safety requirements based on the objective set in Article 8a;

### *Site and installation-specific assessment as a basis for a licence decision*

#### General information on the plans for new nuclear installations in Sweden and how these are to be assessed

There are currently no plans to construct new nuclear power plants in Sweden. However, several other new nuclear installations are planned, of which one will be covered by this Directive according to Article 3 (1). This applies to a facility ("Clink") for encapsulation of spent nuclear fuel for final disposal.

At the same time, as stated above (Article 4 (2)), a major revision of SSM's Code of Statutes relating to nuclear safety, nuclear security and radiation protection is currently underway. This means that new regulations are planned to come into force during the period 2022 -2023, both regarding nuclear power reactors and other nuclear installations. The new regulations will apply to existing nuclear installations as well as new ones, and there will be some differences with stricter requirements for new installations. This applies, for example, to the dose to the general public and the environment. In addition, an inquiry (SOU 2019:16) has proposed a new Act on Nuclear Activities, which would include clarification of the Swedish licensing and approval processes for new nuclear installations. A new Act on Nuclear Activities may come into force sometime in 2021 or 2022.

This means that it will only be the Clink facility that will in part be assessed against the current Swedish national framework supplemented with certain specific license conditions. The following is a description of how the directive is complied with in this context.

As stated above (Article 4 (1) (c)), licensing of new nuclear installations and major modifications of existing installations subject to authorization shall be made in accordance with both the Act on Nuclear Activities and the Environmental Code. As also stated above the aim of the authority's licensing work is to consider whether an activity is likely to be located, designed and operated in a way so that requirements imposed on safety, security and radiation protection and the general rules of consideration can be fulfilled. This means that the applicant's documentation must contain sufficient information so that the conditions for complying with all the relevant provisions of the Acts, Ordinances and SSM's regulations and decisions according to Appendix 1 can be assessed.

### Siting

When considering matters subject to the Act on Nuclear Activities, chapter 6 of the Environmental Code concerning environmental impact assessments (EIA) is to be applied. This kind of description must enable an overall assessment of the direct and indirect impact that may be implied by the activity (Section 3). The licensing authority (the Government) must, by means of a separate decision or in connection with determination of the matter, adopt a standpoint as to whether the description

submitted fulfils the requirements imposed by chapter 6 (Section 9) as well as whether the formal requirements on completed consultation meetings have been fulfilled.

Section 7 describes the content of EIA. While taking the nature and scope of the activity into account, an EIA must contain the information needed in order to make an overall assessment of direct and indirect impact that may be implied by the activity. However, an EIA must always contain the following information:

- a description of the activity or measure with information about location, design and scope,
- a description of the measures being planned to avoid, reduce or remedy harmful effects and how to avoid the activity's contribution to infringing an environmental quality standard under chapter 5,
- the information necessary for demonstrating and assessing the primary impact on human health, the environment and management of land and water in addition to other resources that the activity may be assumed to imply,
- an account of alternative locations, if feasible, in addition to alternative designs together with a) the justification for selection of a particular alternative, and b) a description of the impact of the activity not being realised.

The impact of an activity refers to the nature, strength and extent of the disruptions it may imply. An account is also to be provided for all other consequences of significance to health and the environment that the activity may be assumed to imply. 'Other consequences' also refer to what will be generated by the activity or measure beyond the immediate impact on the environment.

When it comes to the requirement imposed on accounting for alternative sites, the wording of legislation directly states that such sites need only be accounted for if it is feasible. The licensing authority determines if the applicant may omit accounting for alternative sites.

When considering matters subject to the Act on Nuclear Activities, chapter 2 of the Environmental Code concerning general rules of consideration is also to be applied. These rules include the location principle which involves selecting a location for fulfilment of the aim of the activity with a minimum of intrusion and detriment for human health and the environment.

As far as siting is concerned, in addition to the EIA, a Licensing Preliminary Safety Analysis Report (LPSAR) is expected which contain information, as required in chapter 4. Section 2 of SSMFS 2008: 1 with associated general advice, on all external factors and conditions that may affect the nuclear installation. This should include both the site where the plant is planned to be constructed and surrounding areas that may in some way affect safety. For example, if there may be land, sea or air transport of hazardous or explosive substances and industries where such substances are produced or handled. Furthermore, it is expected that a systematic inventory of all external factors and conditions that may affect the safety to be included in the report together with summaries of and references to underlying investigations and analyses that show how safety can be affected and how this will be taken into account in the planned design and construction.

#### Design and Construction

As stated above (Article 6 (b)), a licence applicant needs to attach to their application documentation and information which include

- a first preliminary safety analysis report (Licensing Preliminary Safety Analysis Report, LPSAR) containing information about the planned facility's location, design, construction and activity,

- safety analyses of its capability to prevent radiological emergencies and mitigate the impact of an emergency situation if one should nevertheless take place, as well as analyses of its capability to prevent unauthorised access and sabotage,
- information about the planned activity's releases and radiation protection of workers, in addition to radiation impact from releases to the environment during normal and abnormal operating conditions as well as assumed accident sequences,
- information about the design of the planned security/physical protection and planned emergency preparedness for dealing with radiological emergencies, and
- information about planned management of nuclear waste and other radioactive waste generated by the activity in addition to plans for future decommissioning of the installation.

This and other information and documentation must, in order for SSM to submit a positive opinion to the Government, demonstrate that the applicable provisions in the regulations and conditions in accordance with Appendix 1 will be fulfilled.

When applying licence conditions, as stated above (Article 6 (b)), a continued review during constructing new installations and modifications of existing installations subject to authorisation will consist of the following main steps:

1. Review and decision-making in connection with approval of a more advanced preliminary safety analysis report (PSAR), compared to the first report (LPSAR) attached to the licence application, as basis for detailed design and construction of a new facility or a modification of an existing facility subject to authorisation. This review aims to assess whether the regulations concerning nuclear safety, nuclear security and radiation protection will be fulfilled.
2. Review of organisational, human and administrative resources for procuring structures and components and carrying out construction work to the extent and having the standard implied by the PSAR approved by the SSM. This step also includes reviewing measures taken for nuclear security during the construction phase and reviewing preliminary plans for future decommissioning of the facility. These reviews serve as the basis of the SSM's decision-making in terms of whether to grant approval to begin construction of a new facility. This is followed by supervision of facility work as part of the input for issues to be decided in the subsequent steps.
3. Review and decision-making in terms of whether to grant approval of an updated SAR reflecting the facility as it was constructed or modified and demonstrating how the requirements imposed have been fulfilled. This step also includes reviewing the Operational Limits and Conditions (OLCs) and procedures to guide the working staff as well as reviewing test operation programmes and reviewing training programmes for working staff. This includes a new review of plans for nuclear security and emergency preparedness in the event of abnormal operation and accidents. These reviews serve as the basis of the SSM's decision-making in terms of whether to grant approval to begin the commissioning. This is followed by supervision of commissioning activities as part of the input for issues to be decided in the subsequent steps.
4. Review and decision-making in terms of whether to grant approval of a (final) SAR that has been supplemented with results from commissioning activities, and the first refuelling and maintenance outage in the event this is applicable. Other components include reviews of the OLCs and procedures supplemented by experience gained from test operation. These reviews serve as the basis of the SSM's decision-making in terms of whether to grant approval for regular operation.

#### Article 8c

Member States shall ensure that the national framework requires that:

(b) the licence holder under the regulatory control of the competent regulatory authority, re-assesses systematically and regularly, at least every 10 years, the safety of the nuclear installation as laid down in Article 6(c). That safety reassessment aims at ensuring compliance with the current design basis and identifies further safety improvements by taking into account ageing issues, operational experience, most recent research results and developments in international standards, using as a reference the objective set in Article 8a.

#### *Regularly systematic re-assessment of the safety*

As stated above (Article 6 (c)), Section 10 (1) of the Nuclear Activities Act requires that the safety of a nuclear installation and its operation shall be continuously and systematically evaluated, verified and that the safety as far as possible and reasonably shall be improved with regard to

- a) the circumstances under which the activities are carried out,
- b) how equipment and installations are affected by operation and age,
- c) experiences from operations and similar activities; and
- d) developments in science and technology.

In addition to the requirements for continuous and systematic evaluation and verification in accordance with section 10 (1) of the Nuclear Activities Act, the Swedish national framework include requirements for periodic safety reviews (PSR). Section 10a of the Act stipulates that the licensee shall, at least every ten years, make a new systematic overall re-assessment of safety and radiation protection. In the overall assessment, the licensee shall assess how safety and radiation protection can be maintained and improved until the next systematic overall assessment or until the plant has been permanently shut down. Particular consideration shall be given to the circumstances set out in Section 10 (1) a-d.

According to general advice to chapter 4, section 4 of SSMFS 2008: 1, the licensee should notify the Authority in good time that work with PSR is started so that a necessary dialogue can be conducted on the planning of the work. It is also clear from the general advice that the re-assessment should be supported by adequate analyses of the plant and its operations. The analyses should be carried out in a systematic way method and with a recognized methodology.

In the general advice, it is pointed out that the PSR in accordance with Section 10a of the Nuclear Activities Act should be done in a number of areas that together cover the parts of the plant and its activities that are important for safety and radiation protection. Further advice is given on 17 areas that should be applied. These 17 areas cover the 14 areas (Safety Factors) specified in WENRA SRL Issue P.2.2 and in IAEA SSG 25.

In the general advice, it is also pointed out that analyses should be made of how systems, structures and components as well as operations in each area meet both regulatory requirements and internal requirements at the time of analysis and whether the solutions applied have continued capacity to prevent such possible deficiencies in barriers and the defence-in-depth that may lead to a radiological emergency. Furthermore, a systematic analysis should be made in each area of how systems, structures and components and operations comply with the relevant new safety standard and practice. Action needs arising from these analyses should be listed and their safety significance

assessed using deterministic and, where appropriate, probabilistic methods, or where this is not possible or reasonable through expert judgment with specified criteria.

Where the systems, structures and components or operations does not meet the relevant new safety standard, measures should be taken if reasonable in view of the safety benefit and appropriate given the installation's existing design conditions. For measures that are not of an acute nature, but which may be necessary in order for the installation to be operated with high level of safety until the next PSR, an action plan should be drawn up. The action plan should set priorities, type of measures and time for implementation. The plan should be included in the installation's safety program in accordance with chapter 2, section 10 of SSMFS 2008:1.

SSM's tasks in connection with PSR are governed by an internal control document<sup>27</sup>, and include, in addition to necessary dialogue during the licensee's PSR planning, to review the results of re-assessments made. SSM then makes assessments of how the requirements for PSR have been met, how applicable regulations are fulfilled and whether experiences and new knowledge according Section 10 (1) a-d of the Nuclear Activities Act have been sufficiently taken into account. Furthermore, it is included in SSM's tasks to assess and, if necessary, decide on the licensee's action plan. SSM has also decided to address issues related long term operation (LTO) within the framework of PSR's, which is in line with the IAEA's view in the SSG 25 standard.

Recently performed and ongoing PSR's have concerned the nuclear power plants Oskarshamn 3 (2017 – 2018), Forsmark 1 and 2 (2018 – 2019), and Ringhals 3 and 4 (2019 – 2020). Other recently performed and ongoing PSRs concern the safety and radiation protection at the interim storage for spent nuclear fuel (Clab) (2018-) and the WSE nuclear fuel fabrication plant in Västeraås (2017-2019).

Further information on the PSR process applied in Sweden can be found in sections 14.2 and 14.3 of the 8<sup>th</sup> Swedish CNS Report. These sections also contain information on findings (strengths and weaknesses) and safety improvements that have followed the reviews.

#### Article 8d: On-site emergency preparedness and response

##### Article 8 d

1. Without prejudice to the provisions of the Directive 2013/59/Euratom, Member States shall ensure that the national framework requires that an organisational structure for on-site emergency preparedness and response is established with a clear allocation of responsibilities and coordination between the licence holder, and competent authorities and organisations, taking into account all phases of an emergency.

#### National framework for on-site emergency preparedness and response

##### Overview of the national framework

Requirements for emergency activities and plans for the nuclear facilities are included in several legally binding documents:

- SSM's regulations (SSMFS 2014:2) concerning emergency preparedness at nuclear facilities (on-site emergency preparedness and response),

<sup>27</sup> STRYR2011-123, Review of overall assessments (*Granskning av helhetsbedömning*). SSM internal control document.

- SSM’s regulations (SSMFS 2018:1, chapter 2) concerning basic rules for licensed activities involving ionising radiation,
- Civil Protection Act (2003:778) regarding protection against accidents with serious potential consequences for human health and the environment (on-site and off-site emergency preparedness and response),
- Civil Protection Ordinance (2003:789) regarding protection against accidents with serious potential consequences for human health and the environment (on-site and off-site emergency preparedness and response),
- Ordinance with instructions for the Swedish Radiation Safety Authority (2008:452) (off-site emergency preparedness and response),
- Ordinance on Emergency Preparedness and Surveillance Responsible Authorities’ Measures at Heightened Alert (2015:1052) (off-site emergency preparedness and response),
- Ordinance on Total Defence and Heightened Alert (2015:1053) (off-site emergency preparedness and response), and
- Health Care Act (2017:30) (off-site emergency preparedness and response).

#### Requirements for on-site activities

As far as concerns on-site emergency preparedness and response, the Civil Protection Act (2003:778) and Ordinance (2003:789) stipulate general requirements applying to facilities that conduct dangerous activities. The Act requires preventive measures and emergency preparedness to be arranged by the owner or operator of a facility that conducts dangerous activities.

The Act on Nuclear Activities (1984:3) contains general provisions on emergency response in the event of an accident at a nuclear facility. According to Section 13, paragraph 2 of the Act the licensee shall have an organisation with sufficient financial, administrative and human resources to carry out protective measures in connection with an accident at the facility.

SSM’s regulation SSMFS 2014:2 uses the concept of emergency preparedness categories (1, 2, 3 and 4) based on the IAEA’s emergency preparedness categories. SSMFS 2014:2 requires the licensee to take prompt actions in the event of an emergency in order to:

- Classify the event according to predefined alarm criteria,
- Alert the facility’s emergency response organisation,
- Assess the risk and magnitude of possible radioactive releases and time-related aspects,
- Return the facility to a safe and stable state, and
- Notify SSM.

As stated above (Article 6 (e)), the actions planned to be taken in the event of an emergency shall be documented in an emergency response plan, along with instructions for the on-site emergency response organisation, including the chain of command, relevant facilities, resources and coordination of emergency response activities (both on-site and off-site). The plan is subject to a safety review by the licensee and must be approved by SSM. The plan is to be kept up to date and validated through regular exercises.

Chapter 2, section 7 of SSMFS 2014:2 requires nuclear power plant licensees to have in place an emergency response organisation capable of dealing with simultaneous emergencies at all reactor units at their site over a minimum period of one week. Chapter 3 of SSMFS 2014:2 states that the licensees of facilities categorised as belonging to emergency preparedness category 1 must be capable of setting up a logistics centre in a location distanced from the site. This logistics centre should have capabilities for serving as the forward control point for transports of personnel and

equipment to and from the facility during an emergency, including facilities and equipment for dosimetry and decontamination.

SSMFS 2014:2 also addresses alarm criteria and alerting, emergency facilities, evacuation plans, training and exercises, and other aspects of emergency preparedness (e.g. iodine prophylaxis, personal protective equipment, monitoring, ventilation filters and meteorological data).

The overarching objective of the Civil Protection Act (2003:778) is civil protection for all of Sweden with consideration given to local conditions – for life, health, property and the environment, against all types of incidents, accidents, emergencies, crises and disasters. The act defines the responsibilities for individuals, local authorities and central government in cases of serious accidents, including radiological and nuclear accidents. The act contains provisions on how community rescue services shall be organised and operated, and also stipulates that a rescue commander with a specified competence, and far-reaching authority, is to be engaged in all rescue operations.

The ordinance with instructions for SSM (2008:452) contains provisions imposed on SSM that apply in the case of a nuclear or radiological emergency. SSM's role in the Swedish emergency management system is mainly to give advice and recommendations on radiation protection to the public and authorities in charge, maintain a national expert response organisation for monitoring, and provide information on the technical state of nuclear installations in the case of a nuclear emergency. The provisions imposed on SSM relating to nuclear and radiological emergencies are described under Article 5 2 (d) and (f).

Article 8 d

2. Member States shall ensure that there is consistency and continuity between the on-site emergency preparedness and response arrangements required by the national framework and other emergency preparedness and response arrangements required under Directive 2013/59/Euratom.

*Consistency and continuity with arrangements required under Directive 2013/59/Euratom*

The main transposition in Sweden of Directive 2013/59/Euratom has been implemented in the form of additions to the amended Radiation Protection Act (2018:396) and its appurtenant ordinance (2018:506), together with SSM's regulations (SSMFS 2018:1) on basic rules for all licensed activities involving ionising radiation, which all entered into force on 1 June 2018. In addition, five other acts as well as several ordinances and authority regulations have been amended to fully transpose provisions of the Directive 2013/59/Euratom in Sweden. These amendments also entered into force on 1 June 2018.

An emergency management system according to Directive 2013/59/Euratom, Article 97, is established in Sweden. There is a clear division of responsibility between the licensees and the government, through its authorities. The licensees have the full responsibility for the safety of the plant and for the safety of their personnel. The government, through its authorities, has the full responsibility for protecting the public in case of nuclear emergencies. The emergency management system is commensurate with the results of a hazard assessment (SSM Report 2017:27e). Provisions are in place to be able to respond effectively to emergency exposure situations as required by the Swedish national framework. The overall objective for the emergency response plans are to avoid tissue reactions leading to severe deterministic effects in any individual from the affected population



and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels.

#### Article 8e: Peer reviews

##### Article 8 e

1. Member States shall, at least once every 10 years, arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and competent regulatory authorities with the aim of continuously improving nuclear safety. Outcomes of such peer reviews shall be reported to the Member States and the Commission, when available.

#### *IRRS-mission and follow-up-mission*

Between 6 and 17 February 2012, an IRRS mission of Sweden's and SSM's activities in nuclear safety and radiation protection was conducted. The mission was essentially a so-called full scope review, i.e. the review covered mainly the entire radiation safety area. However, issues of nuclear security and non-ionizing radiation were not included. The mission results are presented in the report IAEA-NS-IRRS-2012/01<sup>28</sup>.

Based on the results of the self-evaluation that preceded the mission and the IRRS results, Sweden has produced an action plan that shows how and when measures shall be taken to address identified improvement needs. The plan<sup>29</sup> has been reported to the IAEA.

Between 25 April and 3 May 2016, an IRRS follow-up was conducted with focus on how Sweden and SSM handled the recommendations and suggestions from the 2012 mission. The follow-up mission results are presented in the report IAEA-NS-2016/05<sup>30</sup>.

On behalf of the Swedish Government, SSM has requested<sup>31</sup> a new IRRS mission in 2022.

##### Article 8 e

2. Member States shall ensure that, on a coordinated basis:

- (a) a national assessment is performed, based on a specific topic related to nuclear safety of the relevant nuclear installations on their territory;
- (b) all other Member States, and the Commission as observer, are invited to peer review the national assessment referred to in point (a);
- (c) appropriate follow-up measures are taken of relevant findings resulting from the peer review process;
- (d) relevant reports are published on the above mentioned process and its main outcome when results are available.

<sup>28</sup> Integrated Regulatory Review Service to Sweden, 6 to 17 February 2012. International Atomic Energy Agency, 2012. IAEA-NS-IRRS-2012/01.

<sup>29</sup> Action plan IRRS 2012 Sweden. SSM2012-854. Strålsäkerhetsmyndigheten, 28 April 2012.

<sup>30</sup> Integrated Regulatory Review Service, follow-up mission, to Sweden 25 April – 3 May 2016. International Atomic Energy Agency, 2010. IAEA-NS-2016/05.

<sup>31</sup> Request for an IRRS and Artemis mission. SSM2018-348-2. Strålsäkerhetsmyndigheten 2018-01-17.



*Participation in the first topical Peer Review*

Sweden participated in the first topical peer review (TPR) on aging management of nuclear power plants and research reactors. SSM also contributed in WENRA's work to develop the technical specification for TPR. The national report of Sweden is available on ENSREG's website:  
<http://www.ensreg.eu/country-specific-reports/EU-Member-States/Sweden>

## Appendix 1

Table A.1 SSM Regulations relating to nuclear installations as referred to in Article 3 (1) of the Directive

<b>Regulatory designation</b>	<b>Title</b>	<b>Scope and main content</b>
<b>SSMFS 2008:1</b>	Regulations concerning safety in nuclear facilities	These regulations with general advice include requirements on measures needed to preventing and mitigating radiological emergency situations by application of multiple barriers and defence-in-depth; effective handling of detected deficiencies in barriers and the defence-in-depth; effective organisation, management and control of safety significant activities and actions and resources for maintaining and development of safety. The regulations also contain provisions on basic design principles; assessment, review and reporting of safety, operations of the facility; on-site management of nuclear materials and waste; reporting to SSM of deficiencies, incidents and accidents; documentation and archiving of safety documentation; final closure and decommissioning.
<b>SSMFS 2008:3</b>	Regulations on control of nuclear material	These regulations with general advice include requirements on measures needed to prevent the spread of nuclear weapons and illegal possession of nuclear material, disposed spent nuclear fuel, nuclear equipment and associated software and techniques.
<b>SSMFS 2008:12</b>	Regulations on security of nuclear facilities	These non-classified regulations with general advice contain requirements on the organisation of the security (physical protection), clearance of staff, tasks for the security staff, central alarm station, perimeter protection, protection of buildings, protection of compartments vital for safety, access control for persons and vehicles, protection of control rooms, communication equipment, search for illegal items, handling of information about the physical protection and IT security.
<b>SSMFS 2008:13</b>	Regulations concerning mechanical components in certain nuclear facilities	These regulations contain requirements for the use of pressure-bearing and other mechanical components, requirements on limits and conditions, analysis in the event of degradation, requirements on in-service inspection, requirements in connection with repair, exchange and modification of structures and components, requirements on conformity assessment and annual reporting to SSM.
<b>SSMFS 2008:17</b>	Regulations on design and construction of nuclear power reactors	The regulations with general advice contain specific requirements for nuclear power reactors on design principles and the implementation of the defence-in-depth concept, withstanding of failures and other internal and external events, withstanding of environmental conditions, requirements on the main and the emergency control room, safety classification, event classification,

		requirements on the design and operation of the reactor core.
<b>SSMFS 2008:23</b>	Regulations on protection of human health and the environment from discharges of radioactive substances from certain nuclear facilities	These regulations are applicable to releases of radioactive substances from nuclear facilities that are directly related to the normal operation at each facility. The limitation of releases of radioactive substances from nuclear facilities shall be based on the optimisation of radiation protection and shall be achieved by using the best available technique. The effective dose to an individual in the critical group from one year of releases of radioactive substances to air and water from all facilities located in the same geographically delimited area shall not exceed 0.1 millisievert (mSv).
<b>SSMFS 2008:24</b>	Regulations on radiation protection managers at nuclear facilities	These regulations require any licence holder shall appoint a radiation protection manager at the facility, with formal and good knowledge in radiation protection competences, in order to promote active radiation protection work and check on the implementation of the radiation protection legislation. SSM formally approves the appointment of the radiation protection manager and his/her substitute.
<b>SSMFS 2008:26</b>	Regulations on radiation protection of workers at nuclear facilities	These regulations apply to the radiation protection of workers at nuclear facilities. They contain provisions on the optimisation of radiation protection; procedures for information and education; local radiation protection instructions and their content; procedures for controlled areas; monitoring of work places; individual dose monitoring and exposure assessments; the calibration of, and instructions for, instruments and equipment; procedures connected to work with fuel elements; and documentation, reporting and archiving of radiation dose data.
<b>SSMFS 2008:32</b>	Regulations on the competence of operations personnel at reactor facilities	These regulations and general advice include requirements on competence analysis, competence assessment, authorization by the licensee, recruitment and training for a position, and retraining of operations personnel belonging to the categories operations management, control room personnel and station technicians. The regulations require the use of full scale simulators for operational training.
<b>SSMFS 2008:38</b>	Regulations on archiving at nuclear facilities	These regulations apply to the archiving of documents that are drawn up or received in connection with the operations of a nuclear facility, record-keeping and the archives. They specify which documents and records that must be filed and how long they must be kept.
<b>SSMFS 2014:2</b>	Regulations on emergency preparedness at nuclear facilities	The regulations apply to the planning of emergency preparedness and radiation protection measures in the case of an emergency or a threat of an emergency in nuclear facilities of threat category I, II or III and address alarm criteria and alerting, emergency facilities, evacuation

		plans, training and exercises and other issues related to emergency preparedness (e.g. iodine prophylaxis, personal protective equipment, monitoring, ventilation filters, meteorological data).
<b>SSMFS 2018:1</b>	Regulations on basic provisions for licensable activities with ionizing radiation	These regulations apply to all activities with ionizing radiation that require a license. The regulations contain basic provisions on the identification, evaluation and management of events and conditions of importance for radiation safety; basic rules on the application of defense in depth; physical protection; preparedness and management of radiological emergencies; organization, management and control of operations including competence requirements; worker protection; protection of the public and the environment; radiation sources intended for exposure.

These regulations are available (in Swedish) on SSM's website:

<https://www.stralsakerhetsmyndigheten.se/regler/foreskrifter/>

Table A.2 Licence conditions and regulatory decisions of importance to comply with the provisions of the Directive

<b>Document identification</b>	<b>Title</b>	<b>Scope and main content</b>
<b>Government license condition no. 2717/85</b>	Conditions for continued license pursuant to section 5 of the Act (1984: 3) on nuclear activities to operate the nuclear power reactors Oskarshamn I, II and III. Government decision 2717/85, 1986-02-27 (Corresponding license conditions have also been decided for the nuclear power reactors at Forsmark and Ringhals.)	These license conditions require the nuclear power reactors to withstand a core melt accident without any casualties or ground contamination of significance to the population. The license conditions state that these requirements can be considered to have been met if a release is limited to a maximum of 0.1 % of the reactor core content of caesium-134 and caesium-137 in a reactor core of 1800 MW thermal power, provided that other nuclides of significance are limited to the same extent as caesium (later interpreted to corresponds to 100 TBq).
<b>SSM decision SSM2008/1945-6,7,8</b>	Injunction regarding renewed analysis of the radiological environmental impacts for nuclear power plants at Forsmark, Oskarshamn and Ringhals. SSM2008/1945-6,7,8. 2009-04-02.	The decisions required renewed deterministic safety analyses of such events and conditions that may have radiological environmental consequences. Both the release of fission products from fuel as well as external source terms and the environmental consequences would be analysed for two types of cases, realistic and conservative. The realistic cases were to be analysed using the best available methods and using the current state of knowledge. The conservative cases were to be analysed according to the US Nuclear Regulatory Commission, Regulatory Guide 1.183 (USNRC RG

		1.183). For the realistic analyses, calculation assumptions were provided and the reference values (acceptance criteria) for radiation doses and activity quantities that could be demonstrated to be met
<b>SSM license condition SSM2012-3021-12-17</b>	Decisions on conditions for operation of nuclear power reactors after 2020 - Introduction of independent core cooling. (The license conditions have been decided for Forsmark 1-3, Oskarshamn 3, Ringhals 3 and 4, SSM2012-3021-12-17, 2014-12-15).	These license conditions require that all Swedish nuclear power reactors operating after 2020 must have an additional and fully independent system for cooling of the reactor core in place before 2021. The introduction of an independent core-cooling function strengthens the reactor's ability to prevent core damage for extreme events previously not included in the design basis. The independent core cooling function protects the plant against the events leading to the extended loss of normal auxiliary core cooling function. The license conditions specify basic design preconditions for the independent core cooling, including events and conditions that shall form the basis for the design, safety classification, diversification and separation.
<b>SSM license condition SSM2016-5866-26</b>	License conditions for decommissioning of nuclear power reactors. 2018-11-15 (These license conditions are an update 2018 of previous conditions. Similar conditions have also been decided for other nuclear facilities under decommissioning).	These license conditions contain requirements for preparatory measures for dismantling and demolition; safety assessment for the stage of dismantling and demolition; safety-technical operating conditions for the stage of dismantling and demolition; decommissioning strategy and decommissioning plan; disposal of nuclear waste and other radioactive material; release of radioactive substances into the environment; documentation and storage.