



Rapport

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Sweden's first national report on implementation of Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations



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Foreword

This report has been prepared by Sweden to meet the requirement of Article 9.1 of Council Directive 2009/71/Euratom of 25 June 2009, establishing a Community framework for the nuclear safety of nuclear installations. Article 9.1 requires that Member States shall submit a report to the Commission on the implementation of this Directive for the first time by 22 July 2014, and every 3 years thereafter, taking advantage of the review and reporting under the Convention on Nuclear Safety.

The basic nuclear legislation of Sweden applies to all nuclear activities. The Swedish Radiation Safety Authority's basic nuclear safety regulations SSMFS 2008:1 were developed for nuclear power reactors but are applicable, subject to graded approach, on all licensed nuclear facilities. However, the main focus in this report is the nuclear power reactors even though a number of requirements mentioned in the report are applicable to other nuclear facilities covered by the scope of the Directive.



List of abbreviations

BWR	Boiling Water Reactor
BAT	Best Available Technique
CCF	Common Cause Failure
Clab	Central Interim Storage Facility for Spent Nuclear Fuel
CNRA	Committee on Nuclear Regulatory Activities
DBA	Design Basis Accident
ENSREG	European Nuclear Safety Regulators Group
FSAR	Final Safety Analysis Report
I&C	Instrumentation and Control
INPO	Institute of Nuclear Power Operations
IRRS	IAEA Integrated Regulatory Review Service
KSU	KärnkraftSäkerhet och Utbildning AB (the Swedish Nuclear Training and Safety Center)
KTH	Kungliga Tekniska Högskolan (Royal Institute of Technology)
LTO	Long-term Operation
MTO	Interaction between Man-Technology and Organisation
NDT	Non Destructive Testing
NPP	Nuclear Power Plant (including all nuclear power units at one site)
OKG	OKG AB (licence holder of Oskarshamn NPP)
OLC	Operational Limits and Conditions
OSART	Operational Safety Review Team (a service of IAEA)
PSA	Probabilistic Safety Analysis Report (or Assessment)
PSAR	Preliminary Safety Analysis Report
PSR	Periodic Safety Review
PWR	Pressurized Water Reactor
R&D	Research and Development
SAR	Safety Analysis Report
SFR	Final repository for short-lived radioactive waste
SKB	Svensk Kärnbränslehantering AB (the Swedish Nuclear Fuel and Waste Management Company)
SKC	Swedish Centre of Nuclear Technology
SKI	Statens Kärnkraftinspektion
SSI	Statens Strålskyddsinstitut
SSM	Strålsäkerhetsmyndigheten (Swedish Radiation Safety Authority)
SSMFS	Strålsäkerhetsmyndighetens författningssamling (the SSM Code of Statues)
STF	Säkerhetstekniska driftförutsättningar (Technical Specifications, Operational Limits)
SVAFO	Swedish company engaged in management of radioactive waste
SWEDAC	Swedish Board for Accreditation and Conformity Assessment
TMI	Three Mile Island (a US NPP)
WANO	World Association of Nuclear Operators
WENRA	Western European Nuclear Regulator's Association



A. INTRODUCTION

1. Nuclear installations in Sweden

At present, in May 2014, there are in total ten nuclear power reactors in operation, distributed between the three nuclear power plants Forsmark, Oskarshamn and Ringhals, as specified in Table 1.

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

Name	Type	Capacity MW	Status	Associated waste facilities
Ågesta	PHWR	105	In decommissioning	None
Barsebäck 1	BWR	1800	In decommissioning	None
Barsbäck 2	BWR	1800	In decommissioning	
Forsmark 1	BWR	2928	Operating	• Interim storage for internal parts
Forsmark 2	BWR	3253	Operating	
Forsmark 3	BWR	3300	Operating	
Oskarshamn 1	BWR	1375	Operating	• Interim storage for internal parts
Oskarshamn 2	BWR	1800	Operating	
Oskarshamn 3	BWR	3900	Operating	
Ringhals 1	BWR	2540	Operating	
Ringhals 2	PWR	2660	Operating	
Ringhals 3	PWR	3160	Operating	
Ringhals 4	PWR	2783	Operating	

Table 1. Main data for nuclear power 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	

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

2. The Swedish policy

2.1. Historical background

Nuclear engineering was launched in 1947, when AB Atomenergi was established to realise a development programme resolved by Parliament. As a result, the first research reactor went critical in 1954. This was followed by the first prototype nuclear power plant (PHWR), Ågesta, located in a rock cavern in a suburb of Stockholm. The Ågesta reactor was mainly used for district heating and operated between 1964 and 1974, when it was permanently shut down. The first commercial nuclear power plant, Oskarshamn 1, was commissioned in 1972 and was followed by another eleven units sited at Barsebäck, Oskarshamn, Ringhals and Forsmark up until 1985. The twelve commercial reactors constructed in Sweden comprise nine BWRs (ASEA- ATOM design) and three PWRs (Westinghouse design). As a result of political decisions, the twin BWR units Barsebäck 1 and 2 were shut down permanently in 1999 and 2005, respectively.

The two research reactors (R2 and R2-0) on the Studsvik site were closed in June 2005 and are currently undergoing decommissioning.

2.2. Regulatory framework and nuclear safety legislation

Through the years, a mature and well-developed regulatory framework has emerged covering all aspects of nuclear activities, not only safety requirements but also the environmental impact aspects, a financial system to ensure necessary means concerning the future costs of nuclear waste and a nuclear liability regime. The regulatory authority, the Swedish Safety Radiation Authority (SSM), has a strong mandate and extensive legal and enforcement powers. The authority is also authorized to issue legally binding requirements regarding all aspects of nuclear activities and radiation protection.

The general principles for nuclear safety are laid down in the Act on Nuclear Activities (1984:3). The Act focuses partly on safety in nuclear activities, partly on Sweden's obligations in the field of non-proliferation. The Act also contains central provisions regarding the management and final disposal of nuclear waste and spent nuclear fuel. The key element of the legislation concerning nuclear safety is the principle of the licensee's full responsibility for safety. A licensee must not only maintain but also improve safety where this is justified.

Since the introduction of the Environmental Code (1988:808) issues relating to radiation – ionizing as well as non-ionizing – are covered by the provisions in the Code. Operation of



nuclear facilities is considered an environmentally hazardous activity which requires a licence. Since nuclear facilities also requires a licence under the Act on Nuclear Activities (1984:3), operation of a nuclear facilities are subject to two different licensing procedures. All major nuclear facilities in Sweden are licensed according to both legislations.

2.3. Political development of the nuclear power issue

In December 2008, the Government decided to appoint a special investigator to review legislation in the areas of nuclear technology and radiation protection. The Inquiry's remit was extended in April 2009 to include drafting of new legislation making controlled generational shifts possible in the Swedish fleet of nuclear power facilities, and extended again in August 2009 to include analysing matters of liability in the event of radiological accidents.

Due to the suggestions from the Inquiry, certain legislative changes entered into force on 1 January, 2011. Amendments were made to the Act on Nuclear Activities (1984:3) and the Environmental Code (1988:808) to make it possible to gradually replace existing nuclear power reactors with new ones. One precondition for obtaining permission to construct new reactors is that the new reactor must replace one of the older reactors that have been permanently shut down. The new nuclear power reactors may only be constructed at one of the sites where the present reactors are in operation. This legislation is to enable controlled generational shifts in Swedish nuclear power. Also, the Nuclear Power Phase-Out Act (1997:1320) was abolished and the prohibitions in the Act on Nuclear Activities (1984:3) on the construction of new nuclear power reactors removed.

Furthermore, Parliament has passed the new Act on Liability and Compensation in the event of Radiological Accidents (2010:950) that will replace the existing Nuclear Liability Act (1968:45) and has given the Government the powers to decide when the Act will enter into force. The new act imposes unlimited liability for radiological damage on the operator of a facility and regulates the extent to which the operator of a facility must provide financial guarantees for compensation to those affected by a radiological accident.

2.4. Current development from license holder point of view

An application for a licence to construct, own and operate a nuclear facility consisting of one or two nuclear power reactors with adjacent facilities was presented to SSM in July 2012. The applicant, Vattenfall AB, intends to replace old units by the planned new capacity from operation by 2025 - 2035.

3. The Swedish nuclear programme

3.1. Ownership issues

The ownership of the nuclear power plants is to a large extent characterised by cross ownership. The actors are mainly Vattenfall AB, E.ON Kärnkraft Sverige AB and Fortum Generation AB. These companies own different shares in the three companies which have licenses to possess and operate the nuclear power reactors in Sweden – Forsmark Kraftgrupp AB, OKG Aktiebolag and Ringhals AB.

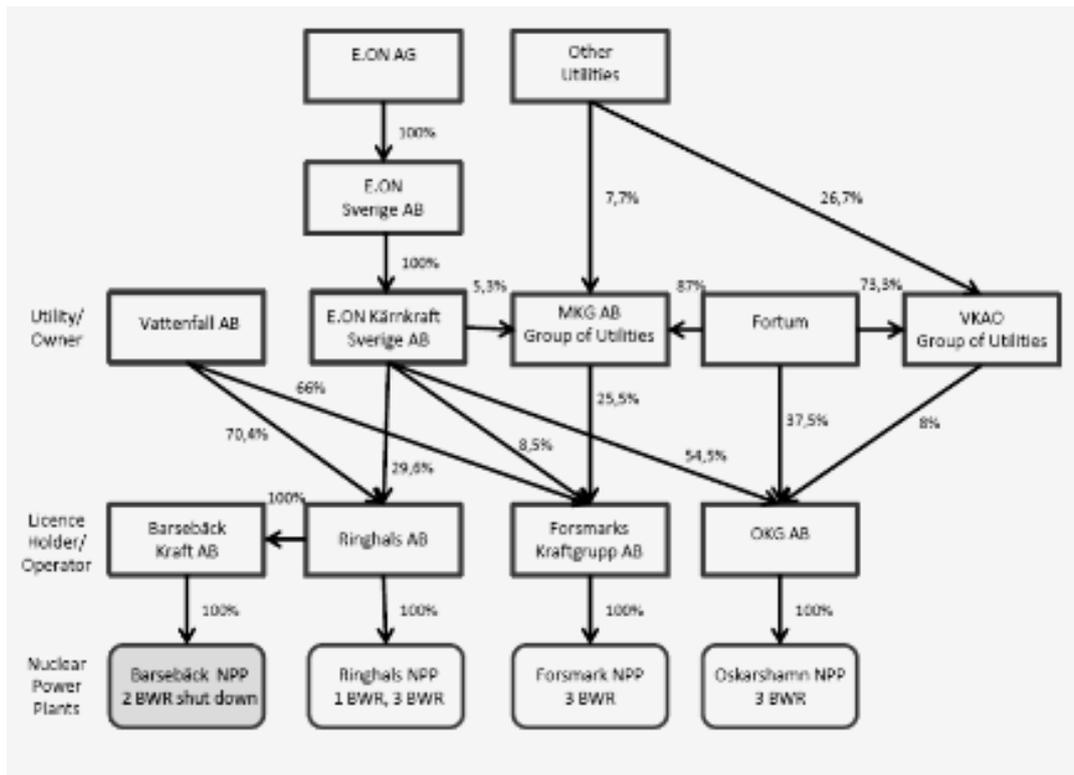


Figure 1 Utility and ownership structure.

During 2008 and 2009 the conditions for the present cross ownership was analysed by a group of government officials. However, in 2010, after discussions with all involved parties, it was concluded that no regulations should be introduced. The Swedish State owns 100% of the stocks of Vattenfall AB.

3.2. Own support organizations and companies

The nuclear power plant operators jointly own the following support organizations:

- KSU AB (Nuclear Safety and Training): provides operational training, including simulator training, on a contractual basis for all the nuclear power plants.
- SQC (Swedish Qualification Centre): a company for independent qualification of NDT systems to be used by NDT-companies in Swedish nuclear power plants.
- Norderf: an extended cooperation between the Swedish and Finnish operators and Westinghouse Electric Sweden AB (former ABB Atom) to carry out experience feedback analysis of events in Swedish and Finnish reactors as well as of international operational experiences. In contrast to the predecessor ERFATOM the cooperation covers not only the BWRs but also the PWRs.

The owners of the nuclear power plants jointly own the following companies:

- SKB (Swedish Nuclear Fuel and Waste Management Company): a company for dealing with spent nuclear fuel and radioactive waste. SKB owns and operates the central interim storage facility for spent nuclear fuel (Clab) in Oskarshamn and the final repository for short-lived radioactive waste (SFR) in Forsmark.
- AB SVAFO: a special company formed by the utilities in 1992 to deal with legacy waste from past practices in the Swedish nuclear research program. AB SVAFO is in charge of decommissioning facilities used in the early research and development period of the 1950s and 1960s, manages waste from these facilities



and also responsible for the decommissioning of the Studsvik research reactor facility.

3.3. Other commercial services in the nuclear power field

The supply of services in the nuclear field has been concentrated to a few companies in the recent years. The main Swedish vendor ASEA-ATOM, later ABB Atom, is now included in the Westinghouse Corporation owned by Toshiba under the name Westinghouse Electric Sweden AB. Other active vendors on the Swedish market are Areva, Westinghouse USA, General Electric, Siemens, and Alstom Power.

According to Swedish law, a licence holder needs a permit from the Government or SSM for contracting out a major part of the nuclear activity. For minor portions it is sufficient under certain conditions to notify SSM that a contract has been awarded. SSM requires the licensees to make the necessary check of quality and competence of a contractor and to take full responsibility for the work done by the contractor. There is, however, no formal licensing of contractors for normal commercial services, except for NDT-companies where an accreditation by SWEDAC is required, or for companies handling asbestos.

The nuclear power plant licensees have noticed over the last few years that fewer companies are bidding on qualified technical projects and services. This reflects the concentration of vendors and service companies on the market and also the increasing demand as a result of the extensive upgrading of the Swedish reactors and the nuclear construction project in Finland.

Studsvik Nuclear AB is a contractor for materials testing and nuclear fuel investigations. The materials testing reactors are closed but the company cooperates with the Halden reactor in Norway and the hot-cell laboratory is maintained. Studsvik Nuclear AB also provides decommissioning and waste treatment services.

3.4. Nuclear waste

The quantity of spent fuel to be disposed of from the Swedish nuclear power programme, amounts to about 12,000 tonnes of uranium (counted as uranium). The programme, including the Studsvik facilities and the Westinghouse Electric Sweden AB fuel fabrication plant in Västerås, will also generate approximately 60,000 m³ of short-lived low and intermediate level waste, 10,000 m³ of long-lived low and intermediate level waste and 160,000 m³ of decommissioning waste (based on 50-year operation of Forsmark and Ringhals and 60-year operation of Oskarshamn). The typical total annual generation of low and intermediate level radioactive wastes at the nuclear facilities is 1,000 – 1,500 m³.

In addition to waste management practices at the NPPs, the following practices exist: The waste treatment facilities at Studsvik, the repository for short-lived radioactive waste (SFR), shallow land burials at the nuclear power plants and Studsvik, the interim storage facility for spent nuclear fuel (Clab), the transportation system and the use of clearance.

Four major waste facilities are foreseen to be designed, sited, constructed and licensed: A plant for the encapsulation of spent nuclear fuel, a disposal facility for spent fuel, a disposal facility for long-lived low, and intermediate level waste and the extension of SFR for the waste from decommissioning. Additional land burials may also be constructed.



Further information regarding the system for nuclear waste will be given in the coming national report on implementation of Council Directive 2011/70/Euratom of the 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

3.5. Nuclear education, research and development

Higher education in nuclear technology is mainly concentrated at the Royal Institute of Technology in Stockholm (KTH), Chalmers University of Technology in Gothenburg (Chalmers) and Uppsala University. The three Swedish nuclear power plants and Westinghouse Electric Sweden jointly support these three universities through the Swedish Centre of Nuclear Technology (SKC), an organization for sponsoring and coordination that has been in existence since 1992. The Centre supports undergraduate education, graduate schools as well as research.

The last three years have represented an all-time high in funding of generation IV research to the universities since 1980. This is the result of two separate one-off projects. First, a special grant on Generation-IV research was issued in 2009 by the Swedish Research Council, and a year later, an even larger project on joint research and education with France was established. The latter was part of building a deeper collaboration with France, in which France co-finances the ESS (European Spallation Source) materials research laboratory under construction in Lund, and Sweden has increased its scientific cooperation with France in many areas, nuclear power being one of them. Within this programme, 15 Swedish PhD students spend a significant part of their study period at French laboratories. This includes involvement in development of a sodium-cooled fast reactor and its fuel cycle.

Thus, at the PhD and Masters level, the output from universities is presently satisfactory. At the lower level, the situation more challenging. The number of Bachelor's degrees is far below the needs of society. This is not a problem unique to the nuclear industry; it affects all industries. For each student graduating, two employees retire. The nuclear power plant operators have jointly financed a new Bachelor degree programme on nuclear power at Uppsala University that has partly remedied the situation. There is an ambition in the industry to raise the educational level of its employees, motivating another such programme. Discussions are in progress with Chalmers on launching a similar programme.

3.6. Main safety issues in Sweden

The nuclear safety has been undergoing a strong development in recent years. Focus has been on the extensive modernization programmes of the nuclear power reactors according to SSMFS 2008:17, aimed at improving safety and prepare for long-term operation.

The severe accident at Fukushima Daiichi NPP and the following EU stress tests resulted in a national action plan covering all nuclear power plants. The purpose is to implement lessons learned from the accident by managing all plant weaknesses identified by the EU stress tests. The measures listed in the Swedish national action plan are scheduled in three different categories, 2013, 2014 and 2015, corresponding to the year when the measures shall be completed. This categorization is based on an assessment of the urgency of the measures' implementation as well as the complexities of these measures.



3.7. Preparation and structure

The present report has been produced within SSM.

The report is structured in accordance with the ENSREG Guidelines for reporting under Article 9.1 of Council Directive 2009/71 Euratom.

B. SUMMARY

The Swedish legal framework is well-developed covering all aspects of nuclear activities, such as nuclear safety, radiation protection, financial system to ensure necessary means for future costs of nuclear waste and nuclear liability. The responsibility for all these issues rests with the licence holder.

The legislation also gives a strong mandate to the regulatory authority, SSM, and extensive supervisory and enforcement powers. The authority is authorized to issue legally binding requirements regarding all aspects of nuclear activities and radiation protection. SSM is currently revising its regulations since as well experience as the IRRS mission to Sweden has highlighted the need for a consistent and more comprehensive set of regulations and general advices.

SSM has received additional staff resources for strengthening its regulatory supervision and developing safety regulations for new nuclear power plants as Vattenfall AB has submitted an application for permission to replace old reactors with new ones. SSM has started a broad competence survey in order to get clear view of the Authority's overall competence. The survey will be used to analyze what skills are needed in the short and long term to meet current and future tasks, such as the review of application for new nuclear reactors. Also the licensees work continuously with analyses of competence requirements and training needs.

Based on SSM's regulations on design and construction of nuclear power reactors (SSMFS 2008:17) the licensees are implementing safety improvement programmes in order to meet the challenges of modernization and safety upgrading of the Swedish reactors for the their remaining operational lifetime. The accident at Fukushima Daiichi NPP 2011 and the following stress tests conducted have added several new safety issues which will be addressed in the safety programmes.

C. REPORTING ARTICLE BY ARTICLE

4. Article 4 – Legislative, regulatory and organizational framework

Article 4

1. Member States shall establish and maintain a national legislative, regulatory and organisational framework (hereinafter referred to as the 'national framework') for nuclear safety of nuclear installations that allocates responsibilities and provides for coordination between relevant state bodies. The national framework shall establish responsibilities for:

- (a) the adoption of national nuclear safety requirements. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States;*
- (b) the provision of a system of licensing and prohibition of operation of nuclear installations without a licence;*
- (c) the provision of a system of nuclear safety supervision;*
- (d) enforcement actions, including suspension of operation and modification or*

revocation of a licence.

4.1. Legislative framework

4.1.1. Basic nuclear safety and radiation protection legislation

The following five acts¹ constitute the basic nuclear safety and radiation protection legislation of Sweden:

- The Act on Nuclear Activities (1984:3),
- The Radiation Protection Act (1988:220),
- 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).

With the exception of the Nuclear Liability Act, all acts 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 can only be conducted in accordance with a licence issued under the Act on Nuclear Activities (1984:3) as well as with a licence issued under the Environmental Code (1988:808). The Act on Nuclear Activities (1984:3) is mainly concerned with issues of safety and security, while the Environmental Code regulates general aspects of the environment and the possible impacts of “environmentally hazardous activities”, to which nuclear activities are defined to belong.

The objective of the Radiation Protection Act (1988:220) is to protect people, animals and the environment from the harmful effects of radiation. The Act applies to radiation protection in general and, in this context, it provides provisions regarding worker’s protection, radioactive waste management, and the protection of the general public and the environment.

The Act on the Financing of Management of Residual Products from Nuclear Activities (2006:647) contains provisions concerning the future costs of spent fuel disposal, decommissioning of reactors and research in the field of nuclear waste. Means for that purpose have to be available when needed.

The Nuclear Liability Act (1968:45) 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 matters are regulated by the Civil Protection Act (2003:778) and Ordinance (2003:789).

4.1.1.1. The Act on Nuclear Activities

The Act on Nuclear Activities (1984:3) contains basic provisions on safety in connection with nuclear activities and applies both to the operation of nuclear plants and to the handling of all nuclear material and nuclear waste. It also contains regulations on the obligation to obtain a licence and on the obligations entailed by the licence requirements. Great importance has been attached to provisions about management of nuclear waste and research concerning nuclear waste.

¹ All Swedish Acts and Ordinances are published in the Swedish Statute Book, hereinafter referred to as ”SFS”.



As stated above, the Act on Nuclear Activities (1984:3) applies to all nuclear activities. Nuclear activities are defined as:

- The construction, possession and operation of a nuclear installation
- Acquisition, possession, transfer, handling, processing, transport or other dealings with nuclear substances and nuclear waste
- Import of nuclear substances and nuclear waste
- Export of nuclear waste

Nuclear activities can only be conducted in accordance with a licence issued under the Act. The licence holder is fully responsible for the safety of every aspect of the operation. All safety measures needed in order to prevent a radiological accident shall be taken. As well as having a general responsibility to maintain safety, the licence holder is responsible for ensuring the safe handling and final storage of nuclear waste arising from the activity and the safe shut-down and decommissioning of plants in which nuclear activities are no longer conducted.

The Act also contains a wide set of means for efficient supervision by the regulatory authority. Among these are administrative and criminal sanctions for non-compliance.

Furthermore, the Act provides for public insight into the safety- and radiation protection work of the licensee through local safety council established in the municipalities hosting major nuclear facilities. The licensee has to give the council any information, documents and access to the installations it requires in order to be informed and in turn to inform the public.

Decisions made by SSM with reference to the Act can be appealed to the Government. If the decision calls for urgent measures, they have to be taken while the appeal is handled by the Government.

4.1.1.2. Licences for Operation of Nuclear Installations

With a few exceptions, licences for nuclear installations are decided upon and issued by the Government. SSM is given the mandate to decide and attach safety conditions to any licence issued under the Act on Nuclear Activities (1984:3). An application for a licence to construct, possess or operate a nuclear installation shall – along with the particular documents concerning construction and nuclear safety – contain an Environmental Impact Assessment (EIA).

Procedures regarding the EIA are laid down in the Environmental Code (1988:808). These provisions are also applicable in the licensing procedures according to the Act on Nuclear Activities (1984:3). The purpose of the EIA is to assess the effects of the planned operation on human health and the environment and on the management of natural resources. Prior to the drafting of an EIA, the operator must obtain and compile available data and consult other parties, authorities and organizations involved, including the general public.

If an 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.

4.1.1.3. Rules on the use of Contractors in Nuclear Operations

All contractors whom the licence holders plan to use in nuclear operations need approval – upon application – by SSM. On 1 July 2006, more strict requirements on the use of contractors for nuclear activities entered into force. According to the new wording of the Act on Nuclear Activities (1984:3), Section 5, at most two contractors are allowed to be involved in a specific task. This means that it is no longer possible to run a system where one general entrepreneur has several sub-contractors. Based on the amendment of the Ordinance (1984:14) on Nuclear Activities, the regulatory authority issued regulations on some specific exemptions from the requirement of approval of contractors. A simplified notification procedure can be used for most types of nuclear activities, provided that the



prescribed management and control measures, as well as satisfying assessment of contractors, has been conducted. Such exemption from approval is only allowed in cases with a single (one) contractor.

4.1.1.4. The Protection of the Environment against Harmful Radiation Effects

In 1998 the Act on Nuclear Activities (1984:3) was amended to incorporate references to the Environmental Code (1998:808). The amendments, which entered into force on 1 January, 1999, state that the general rules of consideration and the environmental quality standards of the Code shall apply when considering matters under the Act on Nuclear Activities (1984:3). In the preparatory work to the Code the operation of a nuclear installation and handling of radioactive waste are specified as examples of hazardous activities.

The general rules of consideration state that operations must be conducted and measures taken so that harm to human health and to the environment is avoided, and that the following fundamental principles are properly followed:

- The burden of proof principle,
- The knowledge requirement,
- The precautionary principle,
- The best possible (available) technology principle (BAT),
- The appropriate location principle,
- The resource management and eco-cycle principles,
- The product choice principle, and
- The principle of reasonableness.

The environmental quality standards specify the maximum levels of pollution or disturbance to land, water, air or the environment in general, and that humans may be exposed to without any significant risk. Permits, approvals or exemptions may not be issued for a new operation that would contravene an environmental quality standard unless precautionary measures to alleviate the negative effects are taken.

The rules of the Environmental Code (1988:808) are on an overall level and do not generally specify limits for various operations or detail how to balance between different interests. Many operations that fall within the scope of the Code are also subject to other acts, which apply in parallel with the Code – e.g. for nuclear activities the Act on Nuclear Activities (1984:3) and the Radiation Protection Act (1988:220).

All operations and measures, which may be detrimental to human health or to the environment are covered by the Code and must therefore pursue its objectives. Licenses issued under the Code are tried by special courts of law, the Land and Environmental Courts.

4.1.2. Decided and planned changes in Swedish legislation

As stated above, the Swedish Government decided to appoint a special investigator to review the legislation in the area of nuclear technology and radiation protection in December 2008. In October 2009 a first, partial inquiry report, covering the issues of generational shifts in the Swedish nuclear power fleet and nuclear liability including proposed changes in the Act on Nuclear Activities (1984:3), Environmental Code and other legislation was presented. The report was circulated for comment to the parties concerned, including several Swedish Authorities, the nuclear industry, professional and industrial organizations and interest groups.

On 23 March 2010, two different bills were sent to the Swedish Parliament: 2009/10:172 on the preconditions for generational change of nuclear reactors, and 2009/10:173 on the issue of increased liability for owners of nuclear power reactors. Parliament passed these bills in mid-June 2010. The main content of the legislative changes adopted by the Parliament is as follows:



- Authorisation to build and operate a new nuclear power reactor can be granted if it replaces an existing reactor, is built on a site with existing nuclear reactors in operation, and the replaced reactor unit is permanently shut down when the new reactor is operational.
- The Nuclear Phase-Out Act (1997:1320) has been annulled.
- Certain tasks concerning inspection and enforcement under the Environmental Code relating to nuclear activities and activities using radiation are to be taken over by SSM.
- Requirements on periodic safety reviews of the nuclear safety and radiation protection at a nuclear facility are now mandatory by law.
- Sweden will accede to the 2004 amendments of the Paris Convention and the Supplementary Convention on liability. It has been decided that the Nuclear Liability Act (SFS 1968:45) will be replaced by a new act concerning liability. When this act enters into force, the owner of a nuclear facility will have unlimited liability and the owner of a nuclear reactor will be required to provide financial guarantees amounting to up to 1,200 million euros. The owners of non-reactor facilities will be required to provide financial guarantees of a minimum of 700 million euros.
- The legislative amendments to allow for replacement of existing reactors entered into force on 1 January, 2011. The Parliament has given the Government the powers to decide when the new liability legislation will enter into force.

In March 2011, the Inquiry presented its final report which included several proposals for legislative changes. In this work, the Inquiry studied the possibilities of bringing together the provisions of the Act on Nuclear Activities (1984:3) and the Radiation Protection Act (1988:220) in a single act and will also consider the possibilities for better coordination with the provisions of the Environmental Code. The aim is to simplify the structure and formulation of the provisions and make them more effective. Today's parallel application of the Environmental Code (1988:808), the Act on Nuclear Activities (1984:3) and the Radiation Protection Act (1988:220) results in a 'dual' licensing process with significant overlapping of the regulatory processes and the issuance of two permits with similar legal requirements.

The plans for the consolidation of the legislation into a single act are progressing and the Government has completed an extensive consultation.

4.1.3. National safety and radiation protection regulations

With reference to its legal mandate, the Swedish Radiation Safety Authority (SSM), issues legally binding safety and radiation protection regulations for nuclear facilities in its Code of Statutes SSMFS

In addition, general advice on the interpretation of most of the safety regulations is issued. The general advice is not legally binding per se, but cannot be ignored by the licensee without risking sanctions by the regulatory body. Measures should be taken according to the general advice or, alternatively, methods justified to be equal from the safety point of view should be implemented.

SSM's regulations also implement binding EU legislation and international obligations. In preparing SSM's regulations, IAEA safety standards, international recommendations, industrial standards and norms, and the rule-making of other Swedish authorities are considered. The SSM regulations are issued according to an established management procedure 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.



4.1.3.1. Regulations concerning safety in nuclear facilities (SSMFS 2008:1)

These regulations were developed for nuclear power reactors but are applicable, in a graded way, on all licensed nuclear facilities. The regulations aim at specifying measures needed for preventing and mitigating radiological accidents, preventing illegal handling of nuclear material and nuclear waste and for conducting an efficient supervision:

- Application of multiple barriers and defence-in-depth
- Handling of detected deficiencies in barriers and the defence-in-depth
- Organisation, management and control of safety significant activities
- Actions and resources for maintaining and development of safety
- Physical protection and emergency preparedness
- 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

General advice on the interpretation of most of the requirements is given.

In 2012, changes were made to SSMFS 2008:1. These include some new requirements and amendments, mainly in the areas of nuclear waste and decommissioning, justified by a desire to bring together provisions currently found in several of SSM's regulations. Some of the changes were also made in order to obtain better agreement with the reference levels developed within the framework of WENRA cooperation.

For a complete list of all regulations applicable to nuclear installations, see Appendix.

4.1.3.2. Major revision of the Authority's regulations

SSM has now begun a major review of its regulations. There are three main reasons for performing major revision of the Authority's regulations and making supplements to them. These reasons are as follows:

In the appropriation directions for the financial years 2012, 2013 and 2014, SSM has been commissioned by the Swedish Government to develop regulations for new nuclear power plants.

SSM's own application experience has demonstrated the need to clarify and supplement the regulations in order to create more predictability for the licensees and improve the regulatory support for SSM in its supervisory activities. These clarifications and additions are necessary in a situation where continuing safety modernization of the existing nuclear power plants will take place and where the plants now gradually enter into 'long-term operation' (LTO). The regulations also need to be revised to encompass experiences from the Fukushima Daiichi NPP accident and subsequent stress tests of Swedish nuclear power plants.

The report on the IRRS review of SSM's activities performed by the IAEA during the period 6-17 February 2012 concluded that the Swedish regulations for nuclear facilities have historically emerged as the need for regulation arose. The report also notes that the IAEA's safety standards were used as the basis for the nuclear safety rules or referenced therein, but not in a systematic way. The IRRS review team highlighted examples of this by pointing to areas that they considered to be inadequately regulated relative to those required by the IAEA Safety Standards. Therefore, the report recommended that SSM review the existing regulatory framework and make it clearer, more consistent and comprehensive. This is now one important part of the SSM action plan to deal with recommendations and suggestions from the IRRS review.



Moreover, the need for revision of the regulations is also part of the conclusions contained in the SSM report to the Swedish Government presented in October 2012 concerning an analysis of long-term safety in the Swedish nuclear power industry.

Other events that will lead to further changes to the regulations include the ongoing review of Swedish Acts concerning nuclear safety and radiation protection and the new, revised European Basic Safety Standards Directive which will supersede the Council Directive 96/29/Euratom of 13 May 1996.

The work to revise SSM's regulations will be an ongoing process for many years to come.

4.2. Regulatory and organizational framework

4.2.1. The regulatory body and its mandate

4.2.1.1. General

The Swedish Radiation Safety Authority (SSM) was established on July 1, 2008. SSM took over the responsibility and tasks from the Swedish Nuclear Power Inspectorate and the Swedish Radiation Protection Institute when these were merged into the new authority. SSM works towards protecting people and the environment from harmful effects of radiation, now and in the future. The main motive for the merger was to strengthen and reinforce the supervision of both nuclear and non-nuclear activities, relating to nuclear safety and radiation protection, but also a general ambition by the Government to make civil service more efficient by reducing the number of administrative authorities.

The mission and tasks of SSM are defined in an ordinance with instructions for the authority and in the annual government appropriation directions, containing detailed objectives and reporting obligations.

SSM is a central administrative authority reporting to the Ministry of Environment. According to the constitution, the administrative authorities are quite independent within the legislation and statutes given by the Government. An individual minister cannot interfere in a specific case handled by an administrative authority. The Cabinet as a whole is responsible for all governmental decisions. Although in practice a large number of routine matters are decided upon by individual ministers, and only formally confirmed by the Government, the principle of collective responsibility is reflected in all forms of governmental work.

The Director General of the Swedish Radiation Safety Authority is appointed by the Government, normally for a period of six years. SSM has no board; the Director General is exclusively responsible and reports the authority activities directly to the Government. The authority has an advisory council with a maximum of ten members which are appointed by the Government. Those are usually members of the parliament, agency officials or independent experts. The functions of the council are to advise the Director General and to ensure public transparency (insight) in the authority's activities but it has no decision-making powers.

The requirements on SSM for openness and provision of information services to the public, politicians and media are very high. Official documents are 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 September 11, 2001, more safety systems documentation related to nuclear power plants became classified information and SSM has established more stringent security practices.

As all Swedish authorities, SSM issues an annual activity report to the Government summarizing major results, effects, revenues and costs. The Government carries out follow-up work and evaluates the agency's operations based on this report. In addition, SSM submits an annual report to the Government on the status and management of nuclear safety and radiation protection at the Swedish nuclear plants. The report summarizes major findings and conclusions on operational experience, regulatory inspections and reviews: technical safety status, radiation protection work, environmental impact, waste management, emergency preparedness as well as organizational matters, safety culture, physical protection and safeguards.

SSM publishes reports to inform interested parties and stakeholders. The SSM website is used for information on current events and authority decisions. All the publications of the SKI and SSI are still available and in the SSM report series; R&D-reports and central regulatory assessments are published. All reports issued by SSM can be ordered. Most of them are available for download from the SSM website.

SSM maintains a function on duty "around the clock" to respond to incidents and other urgent matters. In case of severe events, the emergency staff will be mobilised. SSM also has one employee available for press contacts and IT support during outside office hours.

4.2.1.2. Missions and tasks of SSM

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. After the merger of SKI and SSI into SSM, more direct formulations about nuclear safety or radiation protection are less frequent and the Ordinance is mostly formulated in terms covering all of the authority's fields of expertise, when not directly addressing issues connected to duties of international agreements or conventions.

The Ordinance declares that SSM is the administrative authority for protection of people 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 accidents 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.

SSM shall ensure that regulations and work routines are cost-effective and uncomplicated for citizens and enterprises to apply/understand. SSM shall handle financial issues connected with the management of radioactive wastes from nuclear activities. The Authority shall inform the Nuclear Waste Fund about the size of payments and disbursements from the fund, planned or forecasted, by each reactor operator or other relevant licensee, and of SSM's own activities regarding financing issues, so that the Nuclear Waste Fund can fulfil its tasks. SSM is in charge of the Swedish metrology institute for ionising radiation. SSM shall operate a national dose register and, as appropriate, issue national individual dose passports. SSM shall furthermore:

- Carry out Swedish obligations according to conventions, EU-ordinances/directives, and other binding agreements (e.g. contact point, report drafting, and to be the national competent authority);
- Supervise that nuclear material and equipment is used as declared and in agreement with international commitments;



- Carry out international cooperation work with national and multinational organisations;
- Follow and contribute to the progress of international standards and recommendations;
- Coordinate activities needed to prevent, identify and detect nuclear or radiological events. SSM shall organise and lead the national organisation for expert advice to authorities involved in, or leading, rescue operations;
- Contribute to the national competence development within the authority's field of activities;
- Provide data for radiation protection assessments and maintain the competence to predict and manage evolving issues; and
- Ensure public insight into all the authority's activities.

The work within reactor and nuclear materials safety and related radiation protection is mainly performed within the Department of Nuclear Power Plant Safety but some units of the Department of Radioactive Materials and the Department of Radiation Protection are also involved. Achievements in these tasks are annually assessed and reported back to Government.

SSM has, related to safety of nuclear facilities, permanent advisory committees on reactor safety, radioactive waste and spent nuclear fuel, and research and development. SSM also has advisory committees in other fields such as UV, electromagnetic fields, and the use of ionising radiation in oncology.

4.3. Local Safety Councils

Five of the nuclear facilities have a Local Safety Council; Barsebäck, Ringhals, Oskarshamn, Studsvik and Forsmark.

The Local Safety Councils 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 Council will gather information on the 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
- 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
- Be responsible for informing the public, authorities and institutions at the local level.

The Local Safety Councils 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 councils 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 section 19-21 in the Act on Nuclear Activities (1984:3) the licensees are obliged to provide the local safety councils access to safety and radiation protection work at the facility.

The licensees shall, upon request of the councils, provide information on available facts and let the councils having access to available documents, all to the extent necessary for the committee to fulfill the requirements of section 20 of Act on Nuclear Activities (1984:3).



4.3.1. Supervision of the safety and radiation protection and transparency

Public supervision, i.e. control that the nuclear facilities comply with applicable regulations concerning nuclear safety and radiation protection, is performed by SSM. The public transparency that includes gathering information about the license holder's safety related work, compilation and analysis of information and the dissemination of information to the public, is performed by both SSM and the Local Safety Councils. Both will inform the public about safety and radiation protection work at the facility as well as the emergency preparedness of a nuclear accident. In practice, the division of roles has been that SSM informs the public about safety and radiation protection issues in general and on the results from the oversight of all nuclear facilities while the Safety Council provides information about local safety and radiation protection work and the planning for emergency preparedness in the event of a nuclear accident at the local site.

4.4. Ratification of relevant international conventions

4.4.1. 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 and entered into force on 24 October, 1996.

4.4.2. 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 and it entered into force on 18 June 2001.

Article 4

1. The national framework shall establish responsibilities for:

(a) the adoption of national nuclear safety requirements. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States;

4.5. SSM issues national nuclear safety requirements

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

- Prevent defects in or the malfunction of equipment, improper handling, sabotage or other circumstance that could result in a radiological accident, and
- Prevent unlawful handling of nuclear material and nuclear waste.
- The Government or the public authority appointed by the Government may issue more detailed regulations concerning the measures referred to in the first paragraph.

According to section 20 a of the Ordinance of Nuclear Activities (1984:14), SSM is authorized to issue regulations regarding maintaining safety of nuclear activities according to section 4 of the Nuclear Activities Act.

Section 9 of the Nuclear Activities Act (1984:3) stipulates that as regards devices for nuclear operations that are of importance from a safety perspective, the Government or the authority appointed by the Government may issue regulations concerning testing, verification or inspection.

In section 21 of the Ordinance, SSM is authorized to issue regulations regarding verification, testing and inspection necessary to fulfil the safety requirements stipulated in section 9 of the Act.



4.5.1. The process of establishing national nuclear safety requirements

SSM has developed a specific process for development of new or revised regulations as well as for development of general advice to the regulations. After a decision at management level, a project group is established involving both technical and legal expertise to develop a draft proposal for new/revised regulations. A standing advisory council on regulations provides for advice to the project group as well as for quality assurance of the work performed.

Remittance is essential in the legislative process. The Instrument of Government stipulates that the government must obtain the appropriate information and an opinion before a case is decided. This also applies to authorities that are subordinate to the government. It is a mandatory part of the authority's regulatory and advisory process to provide feedback through an external referral.

When a proposal for new or modified regulations is prepared and has been submitted to the advisory council of SSM, an internal referral to the proposal is made. When this is done, the proposal and an impact assessment is submitted to external consultation of interested parties, interest groups and NGOs. The proposal is also posted on the authority's website so that any other citizen can make comments. The submitted comments are considered by the authority and additional contacts may occur to eliminate any uncertainties. It may also be that there are meetings with industry representatives and others as a part of the regulatory and advisory process.

When the referral period has expired and the comments are dealt with, the case is finally presented, first for the council and then the Director General who decides on the regulations and general advice.

Article 4

***1. The national framework shall establish responsibilities for:
(b) the provision of a system of licensing and prohibition of operation of nuclear installations without a licence;***

4.6. The licensing system

4.6.1. Licensing procedure according to the Act on Nuclear Activities (1984:3)

A licence application for nuclear activities to the Government is handed in to the Swedish Radiation Safety Authority, SSM. SSM assesses whether the following provisions have been satisfactorily complied with (or executed):

- The safety regulations according to the Act on Nuclear Activities (1984:3),
- The general rules of consideration in Chapter 2 of the Environmental Code (1988:808) and the measures proposed by the applicant to avoid any environmental hazards,
- Relevant environmental quality standards in Chapter 5 of the Environmental Code, and
- The Environmental Impact Assessment (EIA), contents and report of the consultations held with concerned parties.

SSM will, as part of the procedures for such a licence application, collect opinions and statements from concerned parties, local authorities etc. Concerned parties are given the



opportunity to express their views at local hearings. Before handing over the application to the Government for its decision, SSM attaches its expert opinion and any special conditions that it deems necessary to be part of a future licence, such as precautionary measures to minimize the involved hazards.

A key element in the regulatory framework is the clearly defined step-wise licensing process. A Government license is needed for the construction, possession, operation and decommissioning of a nuclear facility. The license thus covers the whole lifecycle of the facility. A license application is reviewed by the regulatory body and the environmental court before the Government's decision. Following a Government approval the regulatory body authorizes the start of constructions, the start of trial operations, the start of routine operations, and the decommissioning of the facility. A Government decision is then again needed for de-licensing and exemption from responsibilities. The regulatory body reviews the application to ensure that all obligations and licensing conditions have been fulfilled.

The safety analysis report (SAR) is central in the review process and shall be kept to date through all the steps. SSM also approves of the routine operations at least every ten years through the Periodic Safety Review, PSR. This is to determine whether the necessary conditions exist to operate the facility in a safe manner until the next review.

4.6.2..Licensing Procedure according to the Environmental Code

A permit under the Environmental Code is also required. An application including EIA, similar to those submitted to SSM, shall be handed in to a Land and Environmental Court for consideration under the Environmental Code. During its deliberation, the court will assess whether the provisions in the Code have been complied with satisfactorily and thus that all kinds of emissions and disturbances are considered, i.e. also those caused by radioactive substances and ionising radiation.

If the application concerns a new nuclear facility, the Land and Environmental Court shall, together with its opinion, always hand over the matter to the Government for its consideration of permissibility.

4.6.3.The Government's Consideration of Permissibility

Since normally the Environmental Court refers the question of permissibility to the Government, the Government has a fundamental role in both licensing procedures. In the case according to the Act on Nuclear Activities (1984:3), the Government itself takes the final decision, often referring the questions on different conditions regarding nuclear safety and radiation protection to SSM. The Government takes the expert opinions of SSM and the Land and Environmental Court under consideration before making its decision. The case according to the Environmental Code is returned to the Land and Environmental Court for final trial, after the Government has decided on the issue of permissibility.

4.6.4.Considerations made by Other Parties Concerned

During the procedure of completing the Environmental Impact Assessment, the applicant must consult with those that may be or are concerned, e.g. local organizations and the public. 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.



In accordance with Article 37 of the Euratom Treaty each Member State is obliged to inform the European Commission about its plans for the disposal of radioactive waste. The information shall be such that it becomes possible for the Commission to determine whether the implementation of the plan may result in the radioactive contamination of water, soil or airspace of another Member State.

The Commission shall, after hearing the so-called Article 37 group, give comments on the plans within six months. The purpose of Article 37 is to prevent another State from being affected by any radioactive contamination.

The Convention on Environmental Impact Assessment in a Transboundary Context (the Espoo Convention) is an environmental protection convention for Europe, Canada and the US on cooperation to prevent transboundary environmental effects. The Convention contains requirements on information of neighbors and the public about planned activities that may cause environmental effects.

4.6.5.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.

4.6.6.Preventing operation without a valid licence

It is a criminal offense to conduct nuclear activities without permission (Sections 25 and 25 a in the Act on Nuclear Activities). The operator of nuclear activities without a permit 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 permit, which is regulated in the Environmental Code (Chapter 29 Section 4). Anyone who deliberately or by negligence conducts an activity without a permit 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

*1 The national framework shall establish responsibilities for:
(c) the provision of a system of nuclear safety supervision;*

4.7. The system for safety supervision

Regulatory inspections and safety assessments are carried out by SSM as authorized by the Ordinance on Nuclear Activities (1984:3) as instructed by the Government.

SSM's responsibility is to impose requirements, ensure that requirements are complied with, be proactive regarding the operator's radiation safety and take supervisory measures where deficiencies are found. Supervision aims to verify that safety and radiation protection are maintained and developed.

This is done by checking that laws, ordinances, regulations, licensing conditions and other requirements are followed by the operator.

The supervision is exercised by compliance inspections, surveillance inspections and reviews as well as rapid investigations. In extraordinary circumstances SSM can decide upon special supervision. Furthermore, integrated safety assessments are made to capture tendencies regarding safety which can be difficult to see in a short term perspective or individual supervisory initiative. Finally, also PSRs give valuable input to the supervisory work. For nuclear power plants, 17 areas are defined for which corresponding requirements are found in regulations, licensing conditions and to some extent in regulatory decisions (for further information, see Section 5.10.3). SSM conducts announced as well as unannounced inspections.

4.7.1. Compliance inspections

Compliance inspection means that in a planned and systematic way to analyse and assess whether the licensee in charge of the activity complies with applicable legislation, regulations and conditions relating to the operation and the licence. The inspections are carried out by teams composed of the site inspector(s) and one or more experts on the subject matter of the inspection and may vary in terms of scope and extent. An exit meeting is held where preliminary results are communicated to the licensee. The inspection report documents the purpose and objects of the inspection, observations, compliance and deviations from requirements, an assessment of the significance of any deviations, and a proposal on any further regulatory actions.

4.7.2. Surveillance inspections

Surveillance inspection is a procedure in which supervision is exercised in order to give impetus to nuclear safety work. A surveillance inspection takes place through continuous monitoring of a licensee's activity and by providing and gathering information. Special inspections are made in connection with events, to follow up organizational change and other current issues such as findings from earlier inspections. In many cases these inspections have also focused on non-technical issues, such as safety management and safety culture.

The preparation and documentation of surveillance inspections are simplified in comparison with compliance inspections, but results are systematically documented and reported at SSM management meetings. Each surveillance inspection typically takes 1-2



days on site for 1-2 inspectors. Often a specialist on the subject matter for the visit accompanies the inspector.

4.7.3. Rapid investigation

Rapid investigation is a procedure to be used when an event has occurred or a circumstance has been discovered requiring additional detailed information before SSM can decide on supervisory measures. Based on the outcome of the investigation, SSM can also decide whether the measures suggested by the licensee are sufficient. If the information received by the authority is sufficient for performing a compliance inspection, that type of action will be considered.

4.7.4. Special supervision

SSM also has an instrument called "special supervision". The use is decided by the Director General and is applied when the authority is dissatisfied with the safety performance of a licensee. It can also be applied for other special safety reasons, e.g. during test operations after a large plant modification. The special supervision regime means that more inspections are done and particular progress reporting is required. Special supervision has been applied in a several cases; for example the ongoing case in Oskarshamn where SSM more closely wants to follow the safety developments.

4.7.5. Integrated safety assessments

SSM's integrated safety assessments are annual nuclear safety and radiation protection assessments of each major facility under SSM supervision, and are performed by a specific group of persons at the Department of nuclear power plant safety. Based on all compliance inspections, surveillance inspections, reviews, authority decisions and other relevant information, evaluations and a general appraisal are made of the nuclear safety, radiation protection and non-proliferation control status of the facility in relation to relevant requirements. The basic material should also cover earlier information and conclusions in order to identify trends that could otherwise be difficult to detect in a short-term perspective.

Of importance when drafting the report is the traceability from the basis of data, via the analysis, to the final conclusions and the appraisal. It should be clearly described how SSM evaluated the relevant issues and it should be comprehensible to interested parties lacking expert knowledge in the assessed areas. In order to perform the integrated safety assessments more effectively and to improve the quality of the assessment, SSM has developed a database with the aim of covering all identified deficiencies and issues from performed supervisory activities. The database was taken into operation in 2012.

In accordance with the Authority's established procedures, the draft report is distributed for comments in the organisation. The report is ultimately approved by SSM's Director General and presented at top level management meetings with all licensees.

4.7.6. Periodic Safety Review

The periodic safety reviews which are conducted at least once every ten years, is an important part of the safety supervision (for further information, see Sections 5.9 and 6.2)

4.7.7. Responsible bodies

SSM is the only Swedish authority which has been imposed a supervisory responsibility for safety issues at nuclear installations and activities.

There are other authorities that are responsible of different aspects of nuclear safety (see section 5.2) but none of them have a supervisory function.



SSM does not presently have access to designated technical support organizations in the same way as many of the nuclear safety authorities in other countries. On the other hand, SSM has research funds at its disposal which are allocated to universities and technical institutes for various research projects. SSM has also financial resources to, through public procurement, purchase technical support necessary for the Authority to fulfill its tasks.

Article 4

*1. The national framework shall establish responsibilities for:
d) enforcement actions, including suspension of operation and modification or revocation of a licence.*

4.8. 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 has to provide SSM with all information, documentation and access to facilities that are needed for the regulatory 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.

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

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



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.

4.9. Effectiveness of the national framework for nuclear safety

Before the introduction of new legislation or major amendments of current legislation, a Committee or inquiry is appointed by the Government. The purpose is to investigate the issues in a comprehensive manner. To optimize the process and to ensure that no negative effects of the proposal will arise, the Committee or inquiry is staffed with people with the necessary expertise.

When SSM finds it necessary to introduce new regulations or revise current regulations, the Authority has to follow a specific procedure established in SSM's management system. Before a project is started an analysis report is required which among other things will summarize experiences of the supervisory activities or other background that causes the need for regulations. In addition, before an authority decides on regulations or general advice, the authority - in the extent necessary in each case – must investigate the cost implications and other consequences. Hereby SSM considers all consequences for not only the licensees but also the society in general before deciding upon new or revised regulations.

4.10. Improvement of the national framework

The improvement of the national framework can be 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.

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 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 serve the same purpose. In response to operating experience, Sweden has implemented comprehensive safety assessments at all its nuclear power plants over the past three years, including the performance of OSART missions.

Fourthly, international peer reviews give valuable input to improvement of the national framework. The IRRS mission in Sweden in 2012 is a clear example. One of the recommendations regarded SSM's regulations. The report on the IRRS review recommended that SSM review the existing regulatory framework and make it clearer,



more consistent and comprehensive. SSM has now begun a major review of its regulations.

In 2010 the Swedish Government assigned to SSM to present an analysis of long-term safety in the Swedish nuclear power industry. This assignment included an analysis of the Swedish regulatory model in the field of reactor safety. The result of the assignment regarding regulatory aspects could be of interest in this context:

SSM currently has a satisfactory model for regulation and regulatory supervision in the field of reactor safety. This model stands up relatively well in relation to international standards and practice in the field, but it needs to be developed in various respects. The result of this analysis shows that further development and modification need to encompass not only the regulatory framework, in the form of regulations and general advice, but also regulatory supervision. As up until now regulatory supervision is to have its foundation on the controlling element in the supervision, but with an orientation and execution that are more adapted to the varying nature of the matters of supervisory work. The objective for the further development and this change is each situation having a correct orientation of regulatory supervision that is pursued in a way that is fit for purpose and effective.

SSM will consequently, at the same time as the revision of the regulatory framework takes place, be refining strategies and approaches for conducting regulatory supervision in the field of reactor safety. In order to achieve a regulatory supervision that is more effective and even more appropriate for purpose, approaches and strategies need to be developed for various areas of regulatory supervision and be adapted to the nature of the areas and matters of regulatory supervision as well as their importance for safety. The starting point for this work will be the findings of the present studies within international co-operation concerning regulatory approaches and strategies. This means that SSM will be defining the areas of supervision for which different supervisory strategies are to be developed. For each area, it will be defined which combinations of approaches are to be applied and serve as the basis for the strategy per area. This strategy is also to be designed so as to facilitate application of the graded approach. In certain areas, consideration will also be given to recommendations from the IRRS review mission, as well as recommendations from collaboration as part of CNRA, WENRA and ENSREG.

5. 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.

5.1. Legal foundations of the regulatory authority

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.

In Section 22 of the Ordinance on Nuclear Activities (1984:3) it is stated that SSM is the appointed authority.

According to the Ordinance (2008:452) with instruction for the authority, SSM is the central administrative authority for issues of protection of people and the environment



from harmful effects of ionizing and non-ionizing radiation, for issues in nuclear safety including security of nuclear technology activities as well as in other activities with radiation, and for issues regarding nuclear non-proliferation. SSM shall actively and preventively work for high levels of nuclear safety and radiation protection in the society.

SSM shall be a driving force for good radiation safety in the society in general and focus on the following

- Preventing nuclear accidents and ensure safe operation and disposal of nuclear activities,
- Minimize risks and optimize the effects of radiation for medical purposes,
- Minimize the risks of radiation used in the products and services or which arise as a byproduct of the use of products and services;
- Minimize the risks associated with exposure to naturally occurring radiation, and
- Improve radiation safety internationally

5.2. Other authorities with responsibilities concerning nuclear safety

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

5.2.1. 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.

5.2.2. The County Administrative Board

The County Administrative Board has a coordinating role in the environmental impact assessments in the licensing process of a nuclear facility. The three County Administrative Boards where the NPPs in Sweden are located also have a dedicated role within the emergency preparedness system regarding nuclear accidents.

5.2.3. The Swedish Civil Contingencies Agency (MSB)

The authority was established on January 1, 2009. The task of the MSB is to enhance and support societal capacities for preparedness for and prevention of emergencies and crisis. When one does occur, the MSB support stakeholders involved by taking the right measures to control the situation.

5.2.4. Swedish National Grid (Svenska kraftnät)

Svenska Kraftnät 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 Svenska Kraftnät controls the power supply from the external grid towards the NPPs in Sweden. Svenska Kraftnät also has the task as regulatory body for the security regarding the Swedish energy supply, in this respect Svenska Kraftnät has a status as an authority.

Article 5

2. Member States shall ensure that the competent regulatory authority is functionally separate from any other body or organisation concerned with the promotion, or utilisation of nuclear energy, including electricity production, in order to ensure effective independence from undue influence in its regulatory decision making.



5.3. Functional separation

The Parliament is the supreme political decision-making body in the country. The Government has the overall responsibility for the implementation of the legislation enacted by the Parliament. The Government decides on the preconditions for the different authorities' operations. This is effected on the one hand in the annual appropriations directives and, on the other hand, by ordinances containing instructions to authorities. The appropriations directives set out the goals an agency is to reach in its operations, how much money the authority has at its disposal and how the money is to be distributed between its different activities. The ordinances contain various general administrative provisions, duties and tasks concerning how the agencies are to carry out their work.

SSM is, as mentioned above, the administrative authority for issues regarding nuclear safety and radiation protection.

5.3.1. Separation of bodies regarding supervision and utilization of nuclear energy

The Government, through its ownership of the state company Vattenfall AB, is partner to some of the nuclear power plants. The Government has identified that there is a potential conflict of simultaneously being co-owners of nuclear plants and simultaneously be part of the regulatory chain, including a role in the licensing process.

To minimize the risks for any shortcomings in rule of law or to extraneous into account in different cases, the Government has organized safety issues and issues regarding ownership, promotion or utilization of nuclear energy in various ministries (the Ministry of the Environment and the Ministry of Enterprise, Energy and Communications respectively).

Chapter 12 Section 2 in the Instrument of Government (Swedish Constitution) shows that no authority, nor the Parliament or a local decision-making body, may determine how an administrative authority in a particular case is to decide in a case involving public authority against an individual or against a municipality or of the application of law. This means, among other things, that individual representatives from any authority, including various ministers or government as a whole, cannot interfere in a specific case handled by the SSM.

As assurance against undue influence of other kind there are provisions in the Administrative Procedure Act (SFS 1986:225), which means that people, who on various grounds are suspected of being biased, may not participate in the decision.

In addition to the above, it should be mentioned that the Criminal Code provides for punishment of officials who disregard the requirements of their service. This means that anyone who breaches the high standards of impartiality and objectivity that governs the Swedish authorities, runs the risk of being prosecuted.

5.3.2. Effective independence of the regulatory decision making

The regulatory body's independence is of fundamental importance in the Swedish constitution. The Government has quite substantial scope for steering the operations of government agencies but the authorities are independent when exercising public authority and the decisions made in individual cases according to existing law



5.3.3. Reporting arrangements of the regulatory authority

As stated above, it is obviously of fundamental importance that the regulator is independent and that the legal framework has barriers against undue influence on decisions by various special interests.

The Director General of SSM is appointed by the Government for a period of six years. SSM has no formal board; the Director General is exclusively responsible and reports the authority's activities directly to the Government. SSM has an advisory council with maximum ten members, all of them appointed by the Government. Those are usually members of the Parliament, agency officials or non-governmental organisations or acting as independent experts. The functions of the council are to advise the Director General and to ensure public transparency in the authority's activities.

As mentioned above, the provisions in Administrative Procedure Act (SFS 1986:225) regarding conflicts of interest are always applicable. The aim is to prevent people who might have a vested interest in the issues to be decided to take part in the decision-making process.

These principles serve as guidance when SSM report to the parliament or government in various issues such as annual reports and special government assignments.

Article 5

3. Member States shall ensure that the competent regulatory authority is given the legal powers and human and financial resources necessary to fulfil its obligations in connection with the national framework described in Article 4(1) with due priority to safety. This includes the powers and resources to:

- (a) require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;*
- (b) require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6;*
- (c) verify this compliance through regulatory assessments and inspections; and*
- (d) carry out regulatory enforcement actions, including suspending the operation of nuclear installation in accordance with conditions defined by the national framework referred to in Article 4(1).*

5.4. Description of the legal powers and financial resources

SSM has a legal mandate which enables the authority to issue legally binding safety and radiation protection regulations for nuclear facilities in its Code of Statutes SSMFS. Beyond this, SSM also has the legal powers to impose licensing conditions if necessary due to safety reasons. SSM also has extensive legal powers to enforce its decisions and is authorized to decide in measures that are needed and issue orders and prohibitions in individual cases in order to enforce the Act on Nuclear Activities (1984:3), regulations or licensing conditions issued with support of the Act.

The regulatory activities of SSM are financed by the State budget. The costs are largely recovered from the licensees in the form of fees covering the cost of regulatory activities and related research. The fees are distributed to revenue heading and funding made through yearly budget appropriations. The amounts of the fees and the yearly budget appropriations to SSM regarding regulatory activities are decided by the Government. The budgets for 2012, 2013 and 2014 are shown in Table 3.



Budget item	2012	2013	2014 (budget)	Source of funding
Nuclear safety, emergency preparedness and radiation protection (including	256.6	280.2	284.7	Mainly fees
Supervision of nuclear facilities (proportion of above)	113.3	123.7	136.0	Fees
Licensing of new nuclear facilities	13.0	45.3	38.0	Fees
Scientific research and development work	73.9	80.3	76.0	Mainly fees
Final disposal of radioactive waste	63.6	70.7	70.7	Fees
Historical wastes etc.	1.3	2.0	2.0	Tax funded
Scientific research and development work	22.3	6.6	6.0	Tax funded
International co-operation and development	49.6	45.1	29.5	Tax funded
Total (million SEK)	480.3	530.2	506.9	

5.5. Identification of the relevant legislation

According to Section 4 and 9 of the Act on Nuclear Activities (1984:3) the regulatory authority is authorized to issue regulations concerning safety matters and issues regarding verification, testing and inspection.

According to Section 20 a and 21 of the Ordinance on Nuclear Activities (1984:14) SSM is the appointed authority to issue regulations concerning the above mentioned matters.

According to Section 8 of the Act on Nuclear Activities (1984:3) the regulatory authority may issue necessary licensing conditions due to safety considerations.

Section 20 of the Ordinance establishes that SSM is the authority which will consider matters relating to conditions.

According to Section 17 of the Nuclear Activities Act (1984:3) a licensee has to provide SSM with all information, documentation and access to facilities that are needed for the regulatory 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.

According to Section 22 of the Act, SSM can also decide on fines in cases of non-compliance with licence conditions or regulations.

Section 30 of the Act on Nuclear Activities (1984:3) states that the Government or an authority appointed by the Government is authorized to issue regulations concerning fees for the authority's function according to the Act.

The Ordinance on certain fees to the Radiation Safety Authority (2008:463) provides for audit fees, fees for continuous supervision and research fees for various categories of nuclear facilities in order to ensure the authority the necessary financial resources.



5.6. Arrangements regarding availability of human resources

SSM has (end of 2013) staff totalling 312 persons, which is an increase by 65 persons since 2009. The average age is 46 years. Of the staff, 29% are younger than 40 years, 32% are between 40 and 49 years of age, and 39% are 50 years of age and older. Around 15% of SSM employees will retire (65 years) within five years, but one can opt to work until the age of 67.

In 2013, 58 persons were recruited (24 women and 34 men) and their average age was 40. The staff turnover rate, excluding retirements, was 4% in 2013, which is normal. SSM is working on a long-term plan for its competence needs and this work will continue in 2014.

In 2010, the Government assigned SSM to investigate and report on the competence situation in the disciplines of importance to the Authority, taking into account both internal and national needs. In the report, dated February 2011, it was concluded that SSM had a lack of redundancy in some competence areas within nuclear safety, for example I/C, PWR operation, maintenance, instrumentation and PSA, and that SSM was dependent on a few key persons within these areas. The competence situation has now (May 2014) improved since SSM has recruited several persons within these areas of competence.

The Department of Nuclear Power Plant Safety has (end of 2013) a staff of 96 persons who work with supervision of nuclear safety and radiation protection at the ten nuclear power reactors in operation. Of the 96 staff members, 19% have a postgraduate degree and 68% have a Bachelor's or Master's degree. SSM has designated one inspector for each plant as a 'site coordinator' who serves as the main point of contact between the respective facility and the Authority.

The 70 persons belonging to the Department of Radioactive Materials use about 10-12 person-years on issues of waste management, spent fuels and nuclear non-proliferation towards the operation of nuclear power plants. This department mainly work with inspections of non-power producing nuclear installations (e.g. fuel factory at Vasterås, waste treatment and material investigation facilities at Studsvik), decommissioning, financial issues, nuclear security, radioactive wastes and releases from non-nuclear facilities, and with planned or existing off-site spent fuel and waste management facilities, including final repositories.

The 70 persons at the Department of Radiation Protection devote some (roughly 20 person-years) of their work resources to the national emergency preparedness activities, laboratory measurements, calibrations and use of radiation sources, x-ray equipment, etc. related to the operation of the Swedish nuclear facilities.

The supportive sections of SSM account for 64 persons in total. They include the Development Department (the units of research and development, legal services and communication) and the Organisational Services Department (including the units of human resources, finance and IT).

The educational background of SSM staff at the end of 2013 is shown in Table 4.

Education	Percentage
Post graduate degree	20
Bachelor's/Master's	66
Upper secondary school	13
Other	1
Total	100

Table 4 Educational background of SSM staff

Compared with many other authorities, the staff of SSM has a rather high educational level. This is a result of the many specialist areas covered by the authority, and to some extent the fact that there is no Technical Support Organisations in Sweden to support the regulatory body with specialist knowledge.

Comparing internationally, the number of regulatory staff in Sweden is small for the size of the nuclear programme. Many staff members are typically involved in several tasks, such as inspections, regulatory reviews and approval tasks, revision of regulations, handling research contracts, and participation in public information activities, each activity requiring his or her expertise. When comparing the sizes of staff between different countries, it is however important not only to count the staff members per reactor, but also to consider the types of legal obligations put on the licensees and the different oversight practices.

5.6.1. Sufficient human resources

One of the recommendations from the IRRS review stipulated that the Government should increase the financial resources allocated to SSM in order to fulfil its regulatory responsibilities and shortfalls in the areas of supervision inspections, back fitting safety assessment and dealing with licencing requests. This should be based on a resource assessment of SSM.

In 2012 SSM presented, as part of a governmental assignment, an analysis of long-term safety in the Swedish nuclear power industry. One of the conclusions was that changes to the regulatory framework and regulatory supervision mean major challenges for SSM and will require more resources. This applies both to work on changes to the regulatory framework and to the Authority's regulatory supervision, as well as to efforts to examine periodic safety reviews of facilities prior to decision-making on the nuclear power reactors' long-term operation (LTO).

After the Fukushima Daiichi NPP accident SSM's budget appropriation increased by SEK 25 million per year. In addition, the disbursement from the Nuclear Waste Fund increased by up to SEK 70 million per year for handling of the application of final repository for spent nuclear fuel, relevant research within this area, decommissioning of Barsebäck NPP and financial supervision. SSM has also received SEK 100 million for preparations



concerning the review of new nuclear power reactors. In summary, SSM has received essential increased resources but is still a rather small organization compared to other countries with a medium-sized nuclear programme and similar major challenges.

5.7. Arrangements regarding meeting financial needs

SSM has a balance sheet total of just over SEK 500 million per year. Its operations are largely financed through central government appropriations, charges paid by the nuclear power industry and funding earmarked for reviewing a licence application for construction of a spent nuclear fuel repository. In the areas of administrative and research work, around 80 per cent is funded by charges paid by the industry and around 20 per cent by tax revenues. Charges paid by the industry are regulated in the form of a fees ordinance whose charge levels are set annually by the Swedish Government.

In its annual budget proposal to the Government, the Authority suggests a level of appropriations. The Government has in all material respects granted approval to the enhanced resources requested by the Authority. In the assessment of the Authority, it has adequate resources for the purposes of recruiting and retaining personnel.

Table illustrating SSM's sources of funding in 2013

Funding	Amount (SEK thousands)	Of which charges paid by the industry
Appropriations for administration	280 000	242 000
Appropriations for research	80 000	67 000
Miscellaneous grants	42 000	-
Spent nuclear fuel	52 000	-
Other kinds of funding	47 000	-
Total	501 000	309 000

Table 5SSM's source of funding in 2013



Distribution of administrative and research expense in 2013

Funding	Amount (SEK thousands)
Operations budgets	84 186
Financial resources for research, research administration, support to national competence-building and for engaging TSOs	80 300
Office and equipment	24 180
Communications and transport	11 195
Training	3 039

Table 6 Distribution of administrative and research expense in 2013

5.7.1. Adequacy of salaries to attract and retain staff with necessary qualifications

SSM has generally no major problems in recruiting and retaining staff in the nuclear safety field. Although salary levels may be higher for certain categories of personnel within competing segments of industry and private sector, SSM can offer other professional advantages that weigh up these salary differentials.

Article 5

3. This includes the powers and resources to:

(a) require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;

5.8. Compliance with nuclear safety requirement

5.8.1. Legal provisions

As mentioned above, SSMs legal powers as a regulatory body is extraordinary far-reaching and range from reminding a licensee of his obligations to decide on prohibition of the activity. According to Section 17 of the Act on Nuclear Activities (1984:3) a licensee has to provide SSM with all information, documentation and access to facilities that are needed for the regulatory supervision. If it is necessary SSM is entitled to ask the police for assistance in these matters. Section 18 of the Act states that SSM authorized to decide in measures that are needed and issue orders and prohibitions in individual cases in order to enforce the Act on Nuclear Activities (1984:3), regulations or licensing conditions issued with support of the Act. The meaning of the provisions of the Act is that SSM in its supervision has the right to decide on any action that the authority considers necessary for safety.

5.8.2.Examples of implementations

In 2012 SSM issued an injunction concerning OKG to report an action plan which showed how OKG intended to deal with the deficiencies which had affected the defence-in-depth. The following areas had to be addressed in the action plan:

- Management, regarding communication and acceptance in the organization.
- How aims and strategies functioned as a basis for prioritizing.
- The systematic approach concerning need's analysis and need's description
- Implementation of the new organization
- Working process, regarding management, acceptance and compliance.

Furthermore, the injunction also included a requirement to report an investigation and action plan how OKG would ensure that the safety review meet the requirements in SSMFS 2008:1 regarding the following aspects:

- Versatility
- Structure
- Independence
- Traceability
- Safety review of the safety analysis report in all stages (SSM2012-37-19).

Article 5

3. This includes the powers and resources to:

(b) require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6;

5.9. Demonstration of how licensees meet safety nuclear requirements

Regulations concerning safety in nuclear facilities (SSMFS 2008:1) aim at specifying measures needed for preventing and mitigating radiological accidents, preventing illegal handling of nuclear material and nuclear waste and for conducting an efficient supervision:

- Application of multiple barriers and defence-in-depth
- Handling of detected deficiencies in barriers and the defence-in-depth
- Organisation, management and control of safety significant activities
- Actions and resources for maintaining and development of safety
- Physical protection and emergency preparedness
- 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

Requirements on safety assessment, safety review and reporting are collected in a separate chapter (Chapter 4) of the general safety regulations SSMFS 2008:1. The legally binding requirements are summarized in the following points:

- A comprehensive deterministic safety analysis shall be performed before a facility is constructed and before it is taken into operation. The analysis shall subsequently be kept up-to-date. The analyses shall be based on a systematic inventory of events, event sequences and conditions which can lead to a radiological accident. In addition to the deterministic analysis, the facility shall be



analysed using probabilistic methods in order to provide a more complete picture of safety. The regulations' general advice helps to determine the acceptability of using probabilistic arguments when assessing the design and operation of a reactor facility.

- A preliminary safety analysis report shall be prepared before a facility may be constructed. The safety analysis report (SAR) shall be renewed before trial operation and completed before the facility may be taken into routine operation. The SAR shall contain information as specified in the regulations. All stages of the SAR shall be reviewed by the licensee as required, and reviewed and approved by SSM. Thereafter the safety analysis report shall be kept up-to-date.
- The SAR shall reflect the plant as built, analysed and verified and show how the valid safety requirements are met. All plant structures, systems and components of importance for the defence-in-depth shall be described in the SAR, not only the safety systems. New safety standards and practices, which have been assessed by the licensee and found applicable, shall be documented and incorporated into the SAR as soon as the corresponding modifications or other plant measures have been taken.
- After being taken into operation, the safety of a facility shall be analysed continuously and assessed in a systematic manner. Any need for safety improvement measures, engineering as well as organizational, resulting from such analyses and assessments shall be documented in a safety programme. This programme shall be updated on an annual basis.
- At least once every ten years, an integrated holistic analysis and assessment shall be conducted of the safety of the facility (PSR). The analyses, assessments and measures resulting from these shall be documented and submitted to SSM. This requirement has been stipulated in the Act on Nuclear Activities (1984:3) since 2011. The purpose of a PSR should be to check how the facility complies with the current safety requirements and assess whether it can be operated safely until the next PSR, taking into account developments in science and technology. In the general advice on the periodic safety review, 17 safety areas (see Section 5.10.3) are pointed out where the plant must be assessed with regard to current regulations, licensing conditions and applicable safety standards, as well as against applicable new safety standards and practices. Deviations from current requirements must be corrected without delay. Deviations from newer requirements, standards and practices should be assessed with deterministic or probabilistic methods or engineering judgement, with reasonable practicable measures defined and included in the safety programme of the plant. The review methodology used must be specified in the report.

5.9.1.Examples of implementation

As a result of more stringent regulations in SSMFS 2008:1 the work to supplement the SARs with additional information has continued. Some additions that recently have been made or are in progress are:

- Information on how the requirements on design and construction in SSMFS 2008:17 are being met.
- Extending of the systems descriptions beyond the safety systems to include other SSCs of importance for the defence-in-depth.

The licensees have nearly completed this work. When the work is complete all nuclear units will have up to date SAR's complying with the Swedish regulations.

Still the SARs will need to be updated continuously over the next years with the plants



modifications following from the ongoing modernization and uprating programmes. SSM requires that for major plant modification projects, such as the modernization and uprating projects, a PSAR is submitted which is then renewed before trial operations and completed before routine operation. This strategy ensures the relevant updating of the SAR documents.

The safety requirements in the SAR are assessed continuously for their applicability, and the licensees have specific procedures in place to evaluate new or revised codes and standards. These procedures include:

- Periodical check-up on the release of new codes and standards
- Assessment of the applicability of international standards and requirements
- Decision on specific application to the plant
- Revision of the requirements in the SAR

As an example, the licensees have norm committees which hold periodical meetings. If it is concluded that the SARs should be updated, the matter is handed over to the department of technology and reactor safety.

In 2013 SSM issued an injunction regarding an update of the safety analysis report for Clab in the following aspects:

- Safety functions of the facility and the requirements provided specifically for these
- Inventory of events, event sequences and division into event classes
- Principles for division in safety classes and quality classes plus the implementation of these
- The use of probabilistic methods in safety analysis, and
- The immediacy of the safety analysis report.

SKB was required to hand in an action plan with specified measures to implement the modifications in the safety analysis report plus eventual other measures which may follow due to these modifications (SSM2013-2538).

Article 5

3. This includes the powers and resources to:

(c) verify this compliance through regulatory assessments and inspections; and

5.10. Basic requirements regarding assessment, verification and continuous improvement

SSMFS 2008:1, Chapter 4, Section 5 stipulates that technical or organizational modifications to a facility which can affect the conditions specified in the safety analysis report, as well as essential modifications to the report shall be subjected to a so-called twofold safety review. Before the modifications may be implemented, SSM shall be notified of the modifications.

Chapter 4, Section 3 specifies the requirements for the safety reviews. The objective is to make sure that all relevant aspects of a safety issue have been taken into account and that all relevant requirements concerning the design, function, organisation and activities of a facility are met. The review shall be carried out systematically and be documented.



The safety review shall be performed in two steps. The first step, the primary review, shall be carried out within those parts of the licensee's organisation which are responsible for the specific issues. The primary safety review should be as complete as possible and not take credit for the outcome of an independent review. The second step, the independent review, shall be carried out by a safety review function, established for this purpose and with an independent position in relation to the organisation responsible for the specific issues. The independent review should not duplicate the primary review but apply another perspective and focus on:

- Whether the matter has been handled in a correct manner by the line organisation,
- Whether conclusions and proposals have been justified in a professionally correct way,
- Whether all relevant safety aspects, including physical protection, have been considered and the relevant safety requirements been met, and
- Whether the proposed measures will result in a maintained or increased level of safety.

SSMFS 2008:1 also includes requirements on use of the twofold safety review in other cases than those to be notified to SSM. One example is the review of emergency operating procedures and beyond design basis accident management guidelines.

SSMFS 2008:1 also stipulates (Chapter 2, Section 9, item 4) that decisions on safety issues shall be preceded by sufficient preparation and gathering of advice so that all aspects of the issues are considered. In addition to the twofold safety review, a safety committee should be established to provide advice to the Chief Executive Officer on principal safety issues.

SSMFS 2008:1 Chapter 2 Section 9, contains legally binding requirements regarding continuous improvement of safety:

- The licensee shall have documented safety objectives and directives in place describing how safety is to be maintained and improved in the nuclear activity and that persons who work with this activity are well acquainted with these objectives and directives.
- Experience of importance for safety from the facility's own nuclear activity and from similar activities shall be continuously utilised and communicated to the personnel concerned
- Safety in the nuclear activity shall be routinely monitored and followed up, and deviations are identified and managed so that safety is maintained and continually improved in accordance with the objectives and directives that apply.

5.10.1. Prevention of accidents and mitigation of consequences

For the prevention of accidents, SSM regulations (SSMFS 2008:1) are in place which prescribe that nuclear safety shall be ensured using the defense in depth approach and that the design shall include several barriers. The regulation is judged to be modern and comparable to the IAEA-standards.

For the mitigation of accidents, a filtered venting system together with monitoring system and severe accident management instructions have been installed on all existing units by a governmental decision issued 1986.

5.10.2. Priority to Nuclear Safety

Section 10 of the Act on Nuclear Activities (1984:3) states clearly that the responsibility for nuclear safety rests with the licensee. The licensee shall ensure, among other things,

that all measures are taken which are needed for maintaining safety. In the pre-work to the Act it is stated that the licensee shall not only take measures to maintain safety but also measures to improve safety where this is justified.

The SSM general safety regulations SSMFS 2008:1, Chapter 2, Section 8 require that nuclear activities with regard to design and construction, operation and decommissioning, shall be managed, controlled, assessed and developed through a management system so designed that requirements on safety will be met. The management system, including the necessary routines and procedures, shall be kept up to date and be documented.

SSMFS 2008:1 Chapter 2, Sections 7 to 9, as legally binding requirements on safety management aimed at giving safety the right priority:

- The operating organisation shall have the necessary economical and personnel resources and be designed to maintain safety.
- A management system shall be implemented and kept up to date so that requirements on safety are met in all relevant activities.
- There shall be documented safety objectives and safety strategies so that safety is always prioritised.
- Responsibilities, authorities and cooperation shall be defined for staff with tasks of importance for safety.
- Activities shall be planned in such a way that necessary time is allocated for safety measures and safety reviews.
- Safety decisions shall be preceded by sufficient safety investigation and review, for instance an independent safety committee should be used to review issues of principal importance for safety.
- Staff shall be given the working conditions needed to work in a safe manner.
- Relevant operational experience shall be assessed continuously and reported to the relevant staff.
- Safety shall be assessed and followed up on a routine basis, deviations identified and corrective measures taken so that safety is maintained and developed according to the established safety objectives and strategies.

SSMFS 2008:1, Chapter 2, Section 10 requires that the licensee has a living safety programme: After being taken into operation, the safety of a facility shall be analysed continuously and assessed in a systematic manner. Necessary technical and organisational measures that need to be taken as a result of this analysis and assessment shall be included in an established safety programme. This programme shall be evaluated and updated annually and identify priorities and time schedules for measures to be taken.

The continued analysis and assessment should include technical and organisational experience from the plant's own activities as well as from other similar plants, results of relevant R&D- projects and development of safety standards. Organisational experience means for instance, results of MTO analyses, evaluation of organisational changes, evaluation of work conditions and self-assessments of the working climate and safety culture.

5.10.3. Verification of compliance

For verification of compliance through regulatory assessments and inspections SSM presently has defined in total, 17 areas for which the corresponding requirements are found in regulations, licensing conditions and to some extent in regulatory decisions. The ambition is to successively cover these areas in a basic inspection programme and to document the inspection findings. Moreover, the same 17 areas are applied in the annual assessments of the licensees (SSM's integrated safety assessments, see Section 4.7.5) as

well as in the periodic 10-year safety reviews. In this way, SSM is able to systematically supervise the safety situation and monitor developments. When new assessments are begun, previously performed and documented assessments of the areas can be consulted and any emerging picture consolidated. The idea is to apply the regulatory information and knowledge in a more efficient way. In order to further guide inspections and safety assessments, there is also a sub-structure in each of the 17 areas. The areas applied are:

1. Design and construction of facilities, including modifications
2. Organisation, management and control of the nuclear activity
3. Competence and staffing of the nuclear activity
4. Operations, including handling of deficiencies in barriers and the defence-in-depth
5. Core and fuel issues and criticality issues
6. Emergency preparedness
7. Maintenance, including materials- and control issues with special consideration of degradation due to ageing
8. Primary and independent safety review, including the quality of notifications to SSM
9. Investigation of events, experience feedback and external reporting
10. Physical protection
11. Safety analyses and safety analysis report
12. Safety programme
13. Archiving, handling of plant documentation
14. Management of nuclear material and radioactive waste
15. Nuclear non-proliferation, exports control and transport safety
16. On-site radiation protection
17. Radiation protection of general public and the environment

As a result of assessments within these areas, safety conclusions can be drawn in terms of the integrity of the physical barriers and the functioning of the five levels of the defence-in-depth.

Verification that the licensee programmes, activities and results of surveillance and in-service inspection of mechanical components are done according to SSM regulations, are performed by an accredited inspection body (“third-party control”). If the requirements are fulfilled, a “conformity assessment certificate” is issued by the inspection organization.

5.10.4. Examples of implementation

The following is an example of continuous improvement of the nuclear power plants: Ever since the Swedish nuclear power plants were commissioned between 1972 and 1985, safety improvements at the facilities have been made when problems have arisen and events have occurred. After the position taken by the Riksdag (Swedish parliament) in 1997 owing to the Government Bill ‘A Sustainable Energy Supply’, which for instance led to removal of the year when the last nuclear power reactor in Sweden was to be shut down, the need for more extensive safety upgrades was accentuated as far as concerns operation over an extended period of time into the future. For this reason, the former Swedish Nuclear Power Inspectorate (SKI) drew up regulations concerning the design and construction of nuclear power reactors, implying that this kind of modernisation work at the nuclear power plants was launched. The regulations (the former SKIFS 2004:2, now SSMFS 2008:17) entered into force on 1 January, 2005 with certain transitional provisions.

The purpose of these regulations was to give the licensees time to plan and safely perform modernisation work. Using these regulations and decided transitional action plans as a point of departure, the licensees have since then worked on analyses and measures for fulfilment of the requirements.

These extensive modernisation work is now in its final stage. SSM has followed the introduction of the measures through reviews and inspections. SSM assesses that the measures taken and planned to fulfil the requirements imposed by SSMFS 2008:17 strengthen the protective system of the nuclear power reactors' barriers, mainly through increased redundancy and separation, which is the primary purpose of the regulations. Also, when fully implemented, the measures imply a strengthening of the defence in depth system of all facilities. Another safety-related consequence of these measures, other than the purely physical modifications of the facilities, is the improved level of knowledge about the facilities' characteristics that the analyses vis-à-vis the legal requirements of SSMFS 2008:17 have resulted in among the licensees, as well as the fact that the technical documentation concerning the plants has been improved. These conditions are crucial prerequisites for ensuring safe nuclear power plants.

Article 5

3. This includes the powers and resources to:

(d) carry out regulatory enforcement actions, including suspending the operation of nuclear installation in accordance with conditions defined by the national framework referred to in Article 4(1).

5.11. Ensuring the enforcement process

SSM has extensive legal powers to enforce its decisions. According to Section 17 of the Act on Nuclear Activities (1984:3), a licensee has to provide SSM with all information, documentation and access to facilities that are needed for the regulatory 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. According to Section 22, SSM can also decide on fines in cases of non-compliance with licence conditions or regulations.

According to Section 22 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. Normally however, SSM uses a scale of administrative sanctions in cases where the licensees deviate from the regulations of SSMFS. The different steps are:

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

5.12. Examples of implementation

In December 2012 SSM decided that Oskarshamn NPP without delay must stop the operation at the nuclear power reactor O2. The licensee could not verify that significant safety features met SSM's requirements for operational readiness and reliability.



The safety functions which did not meet the requirements in a satisfactory manner were the diesel generators and switches for diesel secured rails. OKG could not take reactor O2 in operation again until the following actions were completed and reported to the Authority:

- One diesel generator was not served as planned in 2011, a service that had to be implemented; at the second diesel generator, an endurance test for at least 48 hours had to be performed.
- Enhanced maintenance of the switches on diesel secured rails (SSM2012-1864)

Two weeks later SSM issued a decision regarding OKG where the licence holder was required to investigate and report the causes of the identified deficiencies. The report would cover the following areas:

- Strategies and planning
- Need's analysis and need's descriptions
- Management
- Organisation
- Working processes

In addition, SSM issued special licensing conditions for the operation of OKG. The same date, SSM also placed OKG under special supervision (SSM2012-5780).

6. Article 6 – Licence holders

Article 6

1. Member States shall ensure that the prime responsibility for nuclear safety of a nuclear installation rests with the licence holder. This responsibility cannot be delegated.

6.1. Prime responsibility for nuclear safety

The Act on Nuclear Activities (1984:3) is clear about the prime responsibility for safety: Section 10: The holder of a licence for nuclear activities shall ensure that all measures are taken which are needed for

- Maintaining safety, taking into account the nature of the activities and conditions under which they are conducted,
- The safe management and disposal of nuclear waste arising in the activities or therein arising nuclear material which is not reused, and
- The safe decommissioning and dismantling of facilities in which no longer nuclear activities are carried out.

Section 10, was amended in 2006 as follows:

The holder of a licence for nuclear activities shall, in connection with near-accidents, threats or other similar circumstance, without delay to the regulatory body report such information which is of consequence for the assessment of safety.

In the pre-work to the Act on Nuclear Activities (1984:3) it is stated that the licensee shall not only take measures to maintain safety but also measures to improve safety where this is justified.

According to Section 14, the obligations under Section 10 shall remain until they have been fulfilled, regardless of whether:



- A licence has been revoked,
- A licence expires,
- The right to operate a nuclear power reactor has ceased under the repealed Act on Nuclear Power Phase-Out (1997:1320), or
- A nuclear power reactor has been permanently shut down.

Despite the first paragraph, an exemption from the obligations imposed under Section 10 may be granted by the Government or the public authority appointed by the Government.

It should be noted that the Act does not explicitly stipulates that the responsibility cannot be delegated.

The SSM regulations (SSMFS 2008:1) on safety in nuclear facilities specify the responsibility of the licensee through a number of fundamental requirements on safety management, design and construction, safety analysis and review, operations, nuclear materials-/waste management and documentation/archiving. In addition it is clearly pointed out in these regulations (Chapter 2, Section 9, item 8) that safety shall be monitored and followed up by the licensee on a routine basis, deviations identified and corrected so that safety is maintained and further developed according to valid objectives and strategies. The meaning of this provision is that a continuous preventive safety work is legally required, including safety reassessments, analysis of events in the own and other facilities, analysis of relevant new safety standards and practices and research results. Any reasonable measure useful for safety shall be taken as a result of this proactive and continuous safety work and be documented in a safety programme that shall be updated annually (Chapter 2, Section 10).

The SSM regulations spell out three basic control principles, making the roles clear between licensee and regulator:

- Approval by SSM (in specified matters) after primary and independent safety review by the licensee.
- Notification of SSM (in specified matters) after primary and independent safety review by the licensee.
- Self-inspection by the licensees according to their own management systems.

The basic safety documentation (SAR including OLCs, plans for emergency response and physical protection) must be formally approved by SSM. Plant and organizational modifications and changes in the safety documentation are to be notified and SSM can, if needed, impose additional conditions and requirements. All other issues are handled under the licensees' self- inspection. SSM examines how this liability is managed.

6.1.1. Rules on the Use of contractors in Nuclear Operation

All contractors whom the licence holders plan to use in nuclear operations need approval – upon application – by SSM. On 1 July, 2006, more strict requirements on the use of contractors for nuclear activities entered into force. According to the new wording of the Act on Nuclear Activities (1984:3), Section 5, at most two contractors are allowed to be involved in a specific task. This means that it is no longer possible to run a system where one general entrepreneur has several sub-contractors. Based on the amendment of the Ordinance (1984:14) on Nuclear Activities, the regulatory authority issued regulations on some specific exemptions from the requirement of approval of contractors. A simplified notification procedure can be used for most types of nuclear activities, provided that the prescribed management and control measures, as well as satisfying assessment of contractors, has been conducted. Such exemption from approval is only allowed in cases with a single (one) contractor.



6.1.2. Issues concerning that the prime responsibility rests with the license holder

Section 5 of the Act on Nuclear Activities (1984:3) stipulates that nuclear activities can only be conducted in accordance with a licence issued under the Act. A licence is required for construction, possession and operation of a nuclear facility. A licence to operate a facility applies only to the licensee and is not transferable to another person. If a transfer takes place, the new operator has to apply for a licence to possess and operate the facility. The reason for this is that a licensee is subject to strict requirements and therefore it is not possible to obtain a license without undergoing a rigorous evaluation to assess the ability to meet all obligations regarding nuclear safety and radiation protection.

According to Section 5 second paragraph stipulates a requirement for approval before a licensee engages a contractor to carry out a measure that is covered by the licence under the Act. According to the same Section, an approval is mandatory in order for a contractor who has been engaged by the licensee to subcontract someone else (a third person) to carry out the assignment. Further subcontracting by that person is not permitted.

According to the third paragraph, all approved contractors and subcontractors are to be regarded as licensees when it comes to upholding safety in operation of the activity to which the assignment pertains. They are also obligated to adopt the safety measures according to the provisions in SSM's regulations. Also in terms of criminal responsibility the contractor is equated with the licensee.

Approved contractors are also equated with licensees with respect to the provisions regarding regulatory supervision. This means that SSM are allowed the same insight into the contractor's activities as into the licensee's and given the same opportunities to issue injunctions and prohibitions.

The Swedish nuclear power reactors are in a process of modernization, safety upgrading and power uprating. All these projects and not the least further major construction projects such as the final repository for spent nuclear fuel and new nuclear power reactors illustrate the need for the licensees to engage contractors to carry out measures covered by the licence under the Act.

As mentioned above, the licensee has the prime responsibility for safety. However, the use of contractors raises certain questions regarding this issue. When a contractor is approved by SSM, the contractor is equated with the licensee and thereby obligated to uphold safety measures required in SSM's regulations. The contractor is also equated with the licensee regarding regulatory supervision, which means that SSM's far-reaching mandate to perform supervision and enforce its decision is applicable. By applying the above construction it could be questioned whether the licensee is not allowed – at least partially - to delegate its prime responsibility for safety to the contractor. A comparison with other countries with nuclear installations shows that the countries respective legislation is clear about the licensee's responsibility for safety both for their own work and the work performed by the contractor.

Further circumstances in support of emphasizing the principle of the licensee's prime responsibility is the Swedish practice which shows that rather an approval by SSM, it's the licensee's own measures regarding supplier assessment, management and follow-up which constitutes the guarantee that tasks relevant for safety are carried out safely even when the contractor carries out the functions.

In the light of the above, there are reasons to consider amendments of Section 5 of the Act on Nuclear Activities (1984:3) in order to clarify the licensee's prime responsibility for safety and obligations to control, manage and monitor their suppliers and contractors. Hereby it can be assured that the Act does not open up the possibility of delegating the licensee's safety responsibility.

Article 6

2. Member States shall ensure that the national framework in place requires licence holders, under the supervision of the competent regulatory authority, to regularly assess and verify, and continuously improve, as far as reasonably achievable, the nuclear safety of their nuclear installations in a systematic and verifiable manner.

6.2. Regulatory requirements for performing safety assessment, verification and continuous improvement

Requirements on safety assessment, safety review and reporting are collected in a separate chapter (Chapter 4) of the general safety regulations SSMFS 2008:1. The legally binding requirements are summarized in the following points:

- A comprehensive deterministic safety analysis shall be performed before a facility is constructed and before it is taken into operation. The analysis shall subsequently be kept up-to-date. The analyses shall be based on a systematic inventory of events, event sequences and conditions which can lead to a radiological accident. In addition to the deterministic analysis, the facility shall be analysed using probabilistic methods in order to provide a more complete picture of safety. The regulations' general advice helps to determine the acceptability of using probabilistic arguments when assessing the design and operation of a reactor facility.
- A preliminary safety analysis report shall be prepared before a facility may be constructed. The safety analysis report (SAR) shall be renewed before trial operation and completed before the facility may be taken into routine operation. The SAR shall contain information as specified in the regulations. All stages of the SAR shall be reviewed by the licensee as required, and reviewed and approved by SSM. Thereafter the safety analysis report shall be kept up-to-date.
- The SAR shall reflect the plant as built, analysed and verified and show how the valid safety requirements are met. All plant structures, systems and components of importance for the defence-in-depth shall be described in the SAR, not only the safety systems. New safety standards and practices, which have been assessed by the licensee and found applicable, shall be documented and incorporated into the SAR as soon as the corresponding modifications or other plant measures have been taken.
- After being taken into operation, the safety of a facility shall be analysed continuously and assessed in a systematic manner. Any need for safety improvement measures, engineering as well as organizational, resulting from such analyses and assessments shall be documented in a safety programme. This programme shall be updated on an annual basis.
- At least once every ten years, an integrated holistic analysis and assessment shall be conducted of the safety of the facility (PSR). The analyses, assessments and measures resulting from these shall be documented and submitted to SSM. This requirement has been stipulated in the Act on Nuclear Activities (1984:3) since 2011. The purpose of a PSR should be to check how the facility complies with the current safety requirements and assess whether it can be operated safely until the



next PSR, taking into account developments in science and technology. In the general advice on the periodic safety review, 17 safety areas (see also section B 8.3) are pointed out where the plant must be assessed with regard to current regulations, licensing conditions and applicable safety standards, as well as against applicable new safety standards and practices. Deviations from current requirements must be corrected without delay. Deviations from newer requirements, standards and practices should be assessed with deterministic or probabilistic methods or engineering judgement, with reasonable practicable measures defined and included in the safety programme of the plant. The review methodology used must be specified in the report.

These requirements apply to all nuclear facilities and thus not only the nuclear power reactors. A graded approach is necessary in this context.

6.2.1. Verification of the physical condition and operation

Sweden has since the beginning of its nuclear programme had specific requirements on surveillance, testing and in-service inspection to ensure that the operation and the material condition of the reactors comply with design requirements and operational limits and conditions.

SSMFS 2008:1, Chapter 5 on operations includes requirements on continuous surveillance, maintenance and testing of structures, systems and components to ensure that they meet the safety requirements. Programmes are required for maintenance, surveillance, inspection and testing as well as for ageing management. The programmes shall be documented and kept up to date. The ageing management programme should include identification, surveillance, handling and documentation of all ageing mechanisms, which could affect structures, systems and components of importance for safety.

Functional testing to verify operability has to be performed periodically as well as before structures, systems, and components are taken in operation after maintenance or other interventions. Programmes for testing active components should reflect consequences for malfunction and the probability of this occurring. The functional testing has to be carried out with the frequency and scope that provide confidence that the equipment will function as credited in the safety analyses. Integral tests of the entire safety function should be performed. If it is not possible to fully verify the safety function by testing, it should be justified that the function can be verified sufficiently despite limitations of the testing.

Specific regulations (SSMFS 2008:13) cover mechanical components. They contain requirements for the use of mechanical equipment, limits and conditions, damage control, accreditation of control organizations and laboratories, requirements on in-service inspection and control, requirements concerning repair, replacement and modification of structures and components, as well as requirements on compliance control and annual reporting to SSM.

6.2.2. Verification of safety decisions

SSMFS 2008:1, Chapter 4, Section 5 stipulates that technical or organizational modifications to a facility which can affect the conditions specified in the safety analysis report, as well as essential modifications to the report shall be subjected to a so-called twofold safety review. Before the modifications may be implemented, SSM shall be notified of the modifications.



Chapter 4, Section 3 specifies the requirements for the safety reviews. The objective is to make sure that all relevant aspects of a safety issue have been taken into account and that all relevant requirements concerning the design, function, organisation and activities of a facility are met. The review shall be carried out systematically and be documented.

The safety review shall be performed in two steps. The first step, the primary review, shall be carried out within those parts of the licensee's organisation which are responsible for the specific issues. The primary safety review should be as complete as possible and not take credit for the outcome of an independent review. The second step, the independent review, shall be carried out by a safety review function, established for this purpose and with an independent position in relation to the organisation responsible for the specific issues. The independent review should not duplicate the primary review but apply another perspective and focus on:

- Whether the matter has been handled in a correct manner by the line organisation,
- Whether conclusions and proposals have been justified in a professionally correct way,
- Whether all relevant safety aspects, including physical protection, have been considered and the relevant safety requirements been met, and
- Whether the proposed measures will result in a maintained or increased level of safety.

SSMFS 2008:1 also includes requirements on use of the twofold safety review in other cases than those to be notified to SSM. One example is the review of emergency operating procedures and beyond design basis accident management guidelines.

SSMFS 2008:1 also stipulates (Chapter 2, Section 9, item 4) that decisions on safety issues shall be preceded by sufficient preparation and gathering of advice so that all aspects of the issues are considered. In addition to the twofold safety review, a safety committee should be established to provide advice to the Chief Executive Officer on principal safety issues.

6.2.3. Continuous improvement

SSMFS 2008:1 Chapter 2 Section 9, contains legally binding requirements regarding continuous improvement of safety:

- The licensee shall have documented safety objectives and directives in place describing how safety is to be maintained and improved in the nuclear activity and that persons who work with this activity are well acquainted with these objectives and directives.
- Experience of importance for safety from the facility's own nuclear activity and from similar activities shall be continuously utilised and communicated to the personnel concerned
- Safety in the nuclear activity shall be routinely monitored and followed up, and deviations are identified and managed so that safety is maintained and continually improved in accordance with the objectives and directives that apply.

SSMFS 2008:1, Chapter 2, Section 10 requires that the licensee has a living safety programme: After being taken into operation, the safety of a facility shall be analysed continuously and assessed in a systematic manner. Necessary technical and organisational measures that need to be taken as a result of this analysis and assessment shall be included



in an established safety programme. This programme shall be evaluated and updated annually and identify priorities and time schedules for measures to be taken.

SSM's regulations on design and construction of nuclear power reactors (SSMFS 2008:17) were issued to meet the challenges of modernization and safety upgrading of the Swedish reactors for their remaining operational life. Based on the provisions in these regulations, safety improvement programmes are being implemented by the licensees. This started long before the Fukushima Daiichi NPP accident of 2011 but the accident and the stress tests conducted have added several new safety issues which will be addressed in these safety programmes.

The regulations are based on Swedish and international operating experience, recent safety analyses, results from research and development projects and the development of IAEA safety standards and industrial standards that were applied in the construction of the facilities. However, the new regulations do not cover all aspects of a design standard but those issues which are considered important to regulate for the Swedish reactors.

The regulations 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.

Transitional rules to the regulations stipulate that measures to comply with certain paragraphs shall be implemented at the latest at time points decided by SSM. The reason for this is that the licensees must be given time to investigate in depth, specify, procure, install, test, and safety review the back fitting measures needed to comply with the regulations. SSM has reviewed and decided on these plans.

SSM has as a result of the above-mentioned stress tests imposed requirements on more in-depth analyses in certain areas, and has demanded actions to be taken in accordance to the Swedish National Action Plan, which was issued by the authority in December 2012. It has been prepared in order to cover all the issues identified in the review process on national and European levels. The measures listed in the Swedish national action plan are scheduled in three different categories, 2013, 2014 and 2015, corresponding to the year when the measures shall be completed. The topics the licensees must respond to are the following:

- Natural hazards
- Design issues
- Severe accidents and recovery
- National organizations
- Emergency preparedness and response and post-accident management (off-site)
- International cooperation

6.3. Examples of how the licensees address the following:

6.3.1. Systematic safety assessments

6.3.1.1. Deterministic safety assessments

The safety analyses of the Swedish plants in the FSARs from the beginning were essentially structured according to the US rules. The events to be analysed were divided into different classes depending on the expected frequency and significance (severity) of



the event. The highest class contains the DBA, typically a large loss of coolant accident: double ended guillotine break of the largest pipe. The evaluation models were essentially based on 10 CFR 50.46 Appendix K. Design criteria to be fulfilled comprise limited fuel cladding damage and no zirconium-water reaction (maximum cladding temperature 2200 deg. F). Although the DBA did not include core melt, it was postulated that a large part of the fission products would be released to the containment. It was then shown that the containment would contain the radioactive material, so that the radiation dose to the critical group in the environment was acceptably low.

The introduction of the severe accident mitigation requirements in 1986 meant that a new class of accidents, including severe fuel damage (core melt), had to be introduced, and the FSAR analyses needed to be extended to show that the criteria for this case were satisfied.

As a result of the new regulations SSMFS 2008:17, the need for an update and extension of certain analyses was identified and these tasks were included in the reactor specific implementation plans. The review and update work necessary consists mainly of a few external events and some beyond design basis events.

6.3.1.2. Probabilistic safety assessments

Deterministic safety criteria and analysis will continue to serve as the licensing basis for design and construction. Various risk-informed applications are being developed and used as a complementary tool in the safety work at the plants.

The PSA programme was started in the late 1970s with limited assessments of Oskarshamn 1, Forsmark 3 and somewhat later of Ringhals 1. When the PSR programme was initiated in the early 1980s, a basic PSA study (level 1, internal events) had to be included in the first cycle. In the second PSR cycle a more comprehensive PSA was required.

Extensive development of the methods and tools for PSA has been performed over the years. As a result, up-to-date software and considerable expertise is at hand both within the Swedish utilities, the authority and at the consultants/vendors. One item of particular importance is the reliability data base accumulated from operational experience. This data base is available in the so-called reliability handbook (the T-book), which provides specific reliability data of high quality for a large number of components since 1977. Extensive development of CCF data was also performed in the last decade within an OECD project. These dependency data are now in the process of being transferred into the domestic PSA models.

According to the safety regulations SSMFS 2008:1, all Swedish reactors have to be analysed with probabilistic methods to supplement the basic deterministic safety studies. All power reactors have to perform complete level-1 and level-2 PSA studies including all operating modes and all relevant internal and external hazards for the sites. Today, all power reactors have performed level 1 and level 2 studies. The level-1 studies have been updated continuously with regard to plant modifications. Work has been performed to fill gaps in the level-1 studies and to finalize studies for low power operation, area events and external hazards.

The basic PSA studies are expected to be updated every year taking into account the past year's plant modifications which have an impact on the PSA-result. In principle most licensees are moving towards practicing a so-called "Living PSA".



PSA results are also used routinely by the licensees to support decisions concerning significant modification of the designs, modification of operations, documentation and assessment of events.

The numerical PSA figures are not regarded as a definitive and exact value of the actual risk level. There are no requirements related to numerical PSA results, although the licensees have such safety objectives. The studies should be sufficiently detailed, comprehensive and realistic to identify weaknesses in the designs and to be used to assess plant modifications, modifications of technical specifications and procedures as well as assessment of the risk significance of events.

A large number of safety improvements based on PSA have been implemented over the past years. Generally, they cover measures to protect against CCF, improvement of fire protection, improvement of operator support and improvements in maintenance and testing. Other important safety improvements projects are installations of new surveillance and control (I&C) techniques, due to the aged original analogue technique.

Historically, the PSA results were an important input for the modernization of Oskarshamn 1, which took place some years ago, as well as for Ringhals 1 and Ringhals 2. PSA results have during the current review period been of great importance for the further modernization of Oskarshamn 1 and 3 and the ongoing modernization project for Oskarshamn 2. The PSA tool has also been used in planning measures to be taken to comply with the new construction regulation SSMFS 2008:17. For newer reactor generations, for which deterministic requirements are more feasible to comply with, PSAs have been used less frequently for justification of the planned measures.

6.3.2. Continuous improvement

6.3.2.1. Safety management

The licensees work continuously with safety improvement. All of them have safety programmes in place as required by SSM regulations SSMFS 2008:1. The programmes are part of the management system documentation. They contain priorities and time schedules for technical, organizational and administrative measures to be implemented as a result of safety analyses, audits, safety culture surveys and other evaluations done at the plant.

6.3.2.2. WANO performance indicators

All licensees utilize the entire WANO programme of Performance Indicators (PI) including the WANO Indicator Index. This is a weighted index consisting of ten specific indicators. The calculation of the Indicator Index was developed by INPO and is used for evaluation and setting goals for NPPs.

6.3.2.3. Safety culture programmes

Maintaining a strong safety culture in the operation of nuclear plants is considered vital by the Swedish utilities and is emphasized 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 culture and to stress the responsibility of all personnel to work actively in maintaining and developing the safety culture standard.

6.3.2.4. Probabilistic safety assessments

A large number of safety improvements based on PSA have been implemented over the past years. Generally, they cover measures to protect against CCF, improvement of fire protection, improvement of operator support and improvements in maintenance and



testing. Other important safety improvements projects are installations of new surveillance and control (I&C) techniques, due to the aged original analogue technique.

6.3.2.5. Severe accident management

The introduction of the severe accident mitigation requirements in 1986 meant that a new class of accidents, including severe fuel damage (core melt), had to be introduced. Core melt and melt-through of the reactor pressure vessel are design basis accidents for the consequence mitigating systems at the NPPs where the system for filtered containment venting is the main component. The containment filtered venting systems, including relevant instrumentation, are designed for passive operation over at least 24 hours.

In the light of the Fukushima Daiichi NPP accident this can be considered an important improvement.

6.3.2.6. Improvements based on SSMFS 2008:17

SSM assesses that the measures taken and planned to fulfil the requirements imposed by SSMFS 2008:17 strengthen the protective system of the nuclear power reactors' barriers, mainly through increased redundancy and separation, which is the primary purpose of the regulations. Also, when fully implemented, the measures imply a strengthening of the defence in depth system of all facilities. Another safety-related consequence of these measures, other than the purely physical modifications of the facilities, is the improved level of knowledge about the facilities' characteristics that the analyses vis-à-vis the legal requirements of SSMFS 2008:17 have resulted in among the licensees, as well as the fact that the technical documentation concerning the plants has been improved. These conditions are crucial prerequisites for ensuring safe nuclear power plants.

6.3.2.7. International cooperation

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.

The utilities in Sweden have traditionally been quite active in international cooperation to enhance nuclear safety by sharing experience, contributing to work with international regulation and guidelines and participating in safety assessments and peer reviews. This is today primarily accomplished through memberships in WANO, in owner's group associations of the major European and US vendors, and by participation in the Foratom initiative European Nuclear Installations Safety Standards, the European Utilities Requirements project, IAEA activities, and various task forces representing most of the disciplines in nuclear facilities.



6.3.3. Verification of safety

A number of different verification programmes are used in order to ensure that the physical state and the operation of the nuclear installation continue to be in accordance with its design, safety requirements, and its operational limits and conditions. These programs can be gathered in the groups: surveillance, in-service inspection, preventive maintenance and safety reviews. The programs have been described in earlier national reports. The following are the most important points.

6.3.3.1. Surveillance

The operational limits and conditions (OLC) are described in the operational limits and conditions document. The OLC document also clarifies what types and with what frequency functional tests are to be carried out in order to verify that components and systems are ready for operation. These tests are carried out in accordance with documented procedures and all test results are reviewed and documented.

Special attention has been paid to the verification of the operability of safety systems when going from shut-down to a power operating mode, and is ensured today by the use of a large number of parameters, computerised tools and new procedures. However, more can still be done to further improve the verification of safety system operability. The operability is further commented on in Chapter 19.

6.3.3.2. In-service inspection

In order to document the industry's interpretation of the regulations SSMFS 2008:13, the Swedish nuclear plants have revised their earlier common document serving as an industry standard. This document is divided into general, technical, quality control, and in-service inspection requirements; and has served as support for the development of plant specific documents in these areas.

Organizations required for the qualification of NDT systems and techniques as well as for carrying out and evaluating such inspections have been established in accordance with regulatory requirements.

The regulations require that all safety related components be assigned to specific inspection groups related to their safety significance. The assignment to inspection groups is documented together with relevant information concerning the inspection in question. The assignment is reviewed and approved by the plant organisation. The overall objectives of the total inspection programme and the fulfilment of the requirements of the regulations are also reviewed by a specifically accredited inspection body. The information concerning inspection group assignments and inspection areas is maintained by the plant organisation in a database, and forms the basis for the creation of the inspection programmes to be performed at given inspection times.

The inspection group assignment is reviewed annually, and modified if deemed necessary, depending on plant modifications, damage found in Swedish or foreign power plants, or new relevant research information. The volume of inspections is high, between 1,000 - 5,000 inspections and tests per site are performed every year.

Extensive replacement of piping, found to be sensitive to specific damage mechanisms, has been carried out in power plants. Many of these replacements were carried out to mitigate future damage as knowledge was gained on damage mechanisms. In other cases replacements were carried out when damage occurred.

6.3.3.3. Preventive maintenance

Maintenance is optimised with regard to the relation between corrective and preventive maintenance. The preventive maintenance implemented at the Swedish nuclear power plants includes predictive (condition-based), periodic and planned maintenance, and serves the purpose of maintaining equipment within its design and operating conditions and extending its life, thereby eliminating, or at least minimizing, the risk for failures that can limit safe and reliable plant operation, or result in forced outages. A well-balanced preventive maintenance programme is based on engineering analysis in which safety as well as economic aspects are considered. The programme is well defined and periodically revised as additional operational experience is gained.

Predictive maintenance results are used to trend and monitor equipment performance so that planned maintenance can be performed prior to equipment failure. Examples include the following:

- Vibration monitoring and diagnostics
- Acoustic analysis
- Lubrication oil and grease analysis
- Non-destructive examination
- Bearing temperature analysis
- Insulation analysis
- Valve diagnostics/Active power measurement

Periodic maintenance consists of activities performed on a routine basis, and may include any combination of external/internal inspection, alignment or calibration, overhaul, and component or equipment replacement. Typically, any deficiencies found by predictive or periodic maintenance are addressed by corrective or planned maintenance.

Planned maintenance includes activities performed prior to equipment failure and is typically carried out during outages, or on spare or redundant equipment that is available during plant operation. The safety regulations SSMFS 2008:1 allow preventive maintenance to be performed during operation, if specific conditions are met. This is specified in the OLCs and lies within the conditions analysed and described in the Safety Analysis Report (SAR).

Optimization is also carried out in order to find the right balance between maintenance and equipment modification.

Modification activities are also carried out as part of the Plant Life Management (PLM) programme, that deals with the life expectancy of components, to fulfil the total plant life expectancy. Various PLM-programmes exist at all the nuclear power plants. They are part of the long-term plans and strategies included in the safety programmes.

6.3.4. Periodic safety assessments

Periodic safety reviews started in Sweden in the early 1980s as a result of the Three Mile Island accident. The requirements regarding the reviews have developed over the years and are now quite similar to those recommended in the IAEA safety standards. The first and second cycle of PSRs is completed for all reactors and also the third cycle for seven of the reactors.

The licensees are required to submit a PSR of each reactor unit at least every 10 years. The review shall verify that the plant complies with the current safety requirements as well as having the prerequisites for safe operation until the next periodic safety review, taking into account advances in science and technology. The analyses, assessments and



proposed measures as a result of the review shall be submitted to SSM. The requirement applies to all nuclear facilities but SSM has been authorized to decide exemptions when the risks associated with the facility are small.

Starting in 2005 the PSR included 15 defined safety areas as well as an integrated assessment. The areas are the same as those used in the SSM inspection programme (see Section 5.10.3.).

The PSRs are submitted to SSM, who performs a comprehensive review and assessment of the report and its references. The results of the regulatory assessment are reported to the Government.

The licensee must take the initiative to begin a PSR and must inform SSM when the planning starts. A meeting is held with SSM to discuss the proposed scope, contents and methodology of the review. Typically a project is formed to conduct the review, involving 15-20 staff of the operating organisation. One goal is to include a few young engineers in every project in order to transfer knowledge. The total work effort is calculated to be of the order of 8-10 man years.

Aging management is an important issue in the forthcoming PSRs. When performing the fourth PSR of a reactor, the licensee must specifically address the safety issue of long-term operation and demonstrate (through sufficient analyses) that the plant is able to operate safely beyond 40 years of operation.

Article 6

3. The assessments referred to in paragraph 2 shall include verification that measures are in place for prevention of accidents and mitigation of consequences of accidents, including verification of the physical barriers and licence holder's administrative procedures of protection that would have to fail before workers and the general public would be significantly affected by ionizing radiations.

6.4. General requirements regarding prevention of accidents and mitigation of consequences

The general safety regulations SSMFS 2008:1 apply to measures required to maintain safety in connection with the construction, possession and operation of nuclear facilities with the aim of, as far as reasonably achievable, taking into account the best available technology, preventing radiological accidents and preventing the unlawful handling of nuclear material and nuclear waste.

According to Chapter 2 Section 1 radiological accidents shall be prevented through a facility-specific and fundamental design which shall incorporate multiple barriers as well as a facility-specific system for defence-in-depth. Defence-in-depth shall be achieved by preventing accidents and mitigate the consequences if an accident does occur.

Chapter 2 Section 3 stipulates that an observed deficiency or if there is reason to suspect that there is a deficiency in a barrier or in the defence-in-depth system, measures shall be taken to the extent and within the time frame necessary depending on the severity of the deficiency. For this purpose, the deficiencies shall be evaluated, classified and investigated without delay.

Chapter 4 Section 1 requires an analysis of a facility's barriers and defence-in-depth system to prevent radiological accidents and mitigate the consequences in the



event of an accident.

6.4.1. Prevention of accidents during design state

More specific requirements on design and construction are given in Chapter 3 of SSMFS 2008:1. These can be summarized in the following points.

The design shall

- Be able to withstand component and system failures,
- Be reliable and have operational stability,
- Be able to withstand such events and conditions which can affect the safety function of the barriers or defence-in-depth, as well as
- Make it possible to maintain, inspect and test structures, systems and components and as far as reasonable facilitate a safe future decommissioning.

It is further required that design principles and design solutions shall be tested under realistic conditions, or if this is not possible or reasonable, have undergone the necessary testing or evaluation with regard to safety. Design solutions shall be adapted to the ability of the personnel to manage the facility in a safe manner as well as to manage abnormal events, incidents and accidents. Functionally based safety classification is also required. In the general advice on these legally binding requirements, guidance is given on their interpretation and application.

More specific design requirements are posed in separate regulations on the design and construction of nuclear power reactors, SSMFS 2008:17. The regulations cover general design principles for the –defence-in-depth. The following principles shall be applied to the extent that is 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 change of the safety functions
- Failure in safety classified equipment leading to an acceptable level for safety
- Failure in operations classified equipment may not affect the performance of equipment with a safety function
- When safety systems are shared 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

6.4.2. Preventions of accidents during the operation

6.4.2.1. Operation manuals and guidelines

According to SSMFS 2008:1 Chapter 5 section 1, the licensee are obliged to establish procedures which have been drawn up for measures to be taken at a facility during normal operation, abnormal operation and design basis accidents. Furthermore, for nuclear power reactors, symptom-based emergency operating procedures must have been drawn up in order to re-establish or in order to compensate for lost safety functions with the aim of avoiding core damage.

It is also necessary for the licensees to establish documented guidelines for measures which may be necessary to implement in order to control and mitigate the consequences of beyond design basis accidents.

6.4.2.2. Operational limits and conditions

The operational limits and conditions of the reactor units are included in an operational document named STF in Sweden (Säkerhetstekniska driftförutsättningar = Technical

Specifications). This document is considered one of the cornerstones in the governing and regulation of the operations of the Swedish plants. According to SSMFS 2008:1 Chapter 5 Section 1 the licensee shall prepare Operational Limits and Conditions for the management of facility operation. As required by SSM, all control room operators and operations managers as well as engineers on duty at the plants are given extensive training, and annual retraining, on the intent and content of this document. Every STF is unit-specific and is in its basic version approved by SSM.

The original STF for each unit is derived from the safety analyses in FSAR, where the behaviour of the unit, when different transients and abnormal events occurred, was described. However, several revisions have been made in all STFs since the first versions were issued. Corrections and updating takes place, when new and better knowledge is available, either from research and tests or operational experience. Suggestions for changes in STF are subjected to a twofold safety review and are notified to SSM. Today the STF are integrated into the plant management systems in order to ensure adequate use and updating of the document.

6.4.3. Mitigation of consequences of accidents

SSM's regulations SSMFS 2008:1 require the licensee, in the event of emergencies, to take prompt actions in order to:

- Classify the event according to the alarm criteria,
- Alert the facility's emergency preparedness organisation,
- Assess the risk for and size of possible releases and time related aspects,
- Return the facility to a safe and stable state, and
- Inform the responsible authorities.

The actions shall be documented in an emergency preparedness plan which is subject to safety review by the licensee and must be approved by SSM. The plan shall be kept up to date and validated through regular exercises. SSM shall be notified of changes in the plan. The licensee has to assign staff, provide suitable facilities, technical systems, tools and protective equipment needed to solve the emergency preparedness tasks.

The emergency planning should include all design basis accidents, as well as beyond design basis events, including severe events, and combinations of events, such as fire or sabotage in connection with a radiological accident.

The SSM regulations SSMFS 2008:15 on emergency planning and preparedness at nuclear installations have a radiation protection perspective. They are mainly based on the IAEA Safety Standards GS-R-2: Preparedness and Response for a Nuclear or Radiological Emergency and include requirements on:

- Emergency planning
- Alarm criteria and alarming
- Emergency rooms/premises/facilities
- Assembly places
- Iodine prophylaxis
- Personal protective equipment
- Evacuation plan
- Training and exercises
- Contacts with SSM
- Radiation monitoring
- Emergency ventilation
- Collection of meteorological data.



Depending on which threat category a facility belongs to (threat categories I, II or III depending on the radiological hazard potential at the facility), the requirements regarding radiation monitoring, emergency ventilation, and collection of meteorological data differ.

6.5. Examples of how the licensees address the following:

6.5.1. Measures to prevent incidents becoming accidents

The Swedish reactors are of varying age and design generation. The later generations were all subject to stronger requirements on physical separation of the safety systems, and the development went from two-train to four-train redundancy of the safety systems. The latest reactors (Forsmark 3 and Oskarshamn 3) both have complete physical separation of the safety systems.

The separation of systems, physically and functionally, is an important area in which a number of back-fitting measures have been implemented over many years as reported previously. In many cases, the need for improved separation was identified through PSA analyses. Swedish reactors have been retrofitted to comply with the regulatory requirement of functional diversification. The functions of: (1) reactivity control, (2) overpressure protection, (3) core cooling, (4) residual heat removal, and (5) the containment shall have a diversified backup. Some measures remain to be installed between 2013 and 2015 on the PWRs.

6.5.2. Emergency management procedures

Regulations for Emergency preparedness is covered by SSM's regulations regarding emergency preparedness SSMFS 2008:15.

SSMFS 2008:15 is subject to major revision. The amendments are planned to be decided in June 2014 and enter into force at the end of the year. Following the severe accident at the Fukushima Daiichi nuclear power plant in 2011 and the EU stress tests completed in 2012, the proposed revised regulations should make clearer and more stringent demands regarding radiation protection of personnel and the communications infrastructure at a nuclear power plant. Furthermore the revised regulation makes specific demands regarding more stringent requirements for the licensee to be able to deal with the consequences and the evolution of those events that are used as the basis for emergency planning, for example with respect to initial response time, staffing, endurance, equipment and facilities.

Furthermore, the nuclear power plants shall be able to handle an accident at all units simultaneously. There shall also be operational support centers outside of the power plant grounds to act as a collection point for incoming and outgoing personnel and equipment to the site. The response organization at each site, not only the NPPs shall be able to deal with an emergency over a period of at least one week. To comply, the licensees will have to expand staffing of emergency personnel.

Although the revised regulations are not yet decided, the licensees have already started the implementation of them. These future revised regulations provide more specific requirements which make it necessary for the licensees to highlight emergency preparedness issues in their organizational structures. To comply with the regulations, the licensees will have to expand staffing of emergency personnel.

6.5.3. Severe accident guidelines

The general design criteria for the prevention of accidents are given in SSMFS 2008:1, where Chapter 3 covers the design, Chapter 4 the safety analyses, and Chapter 5 the



operation of the plant. The design is based on defense-in-depth with several barriers. The analyses shall be performed with both deterministic and probabilistic methods. For the operation, the licensee shall provide technical specification. According to the regulations the emergency operating procedures shall be symptom-based. There severe accident management handbooks and this will be strengthened in new regulations to be severe accident management guidelines as specified by IAEA.

6.5.4. Measures for the mitigation of consequences

A number of emergency preparedness exercises of varying scope are conducted annually in Sweden. These vary in complexity from simple tests of alarm systems to full-scale exercises. Periodical tests of the alert systems between the power plants and the authorities involved are performed several times each year.

The County Administrative Boards in the counties with nuclear power plants conduct, at intervals of a few years, a full-scale exercise to check the plans and the capabilities of the on-site and off-site organizations. The full-scale exercises are designed to enable evaluation of command at the regional level, national inter-agency cooperation and public information. The full-scale exercises are often also used for testing international communications.

In addition, a number of more limited on-site functional exercises are conducted at all the Swedish plants every year. Specific plans exist for these exercises. Exercised functions are for instance accident management, communication within the emergency preparedness organization, environmental monitoring and sampling, assessment of core damage and source terms and assessment of total environmental consequences of a scenario. The rescue forces are exercised regularly, as well as first aid and emergency maintenance. One or several off-site organizations normally participate in these exercises. SSM frequently participates in such exercises both as an observer, in its supervisory role, or to exercise the Authority's own emergency staff.

6.5.5. Regulatory verification of implemented measures

SSM conducts supervision in the usual manner in the field of emergency preparedness. For example, SSM evaluates the licensees' planning, organizational structure, division of responsibility, relevant documentation, management system and human resources factors such as the sufficiency of resources in order to comply with the requirements. As mentioned above, SSM also takes part as observers at different exercises. Observations made at those exercises form the basis for future inspections.

Regulatory review of design solutions is mostly carried out in connection with notifications to SSM before implementation of plant modifications or changes in the safety documentation. The notifications have to be substantiated and justified in such a way that SSM can assess that they comply with the regulations. SSM occasionally makes its own analyses to verify the calculations submitted by the licensees. The independent safety review required of the licensee also has to be submitted in the notification. SSM checks that this independent review has sufficient quality. If SSM is not satisfied with a notification, the licensee has to supplement it, or SSM can pose further requirements or conditions on the proposed solution before it may be implemented. If more investigation time is needed, SSM can stop the implementation until the case has been investigated further. Notifications dealing with new or complex technology are most often reviewed further by SSM, if necessary assisted by external experts. Larger plant modifications have to be notified as a PSAR in order to systematically clarify all the interactions with the existing safety case. Before test operations, the PSAR shall be supplemented to get a pre-operation SAR (POSAR), which justifies the finalized detailed design of the plant



and presents a demonstration of its safety. The final report (SSAR) incorporates any necessary revisions to the POSAR following the commissioning and licensing process for the first entry into routine operation of the as-built nuclear power plant.

Article 6

4. Member States shall ensure that the national framework in place requires licence holders to establish and implement management systems which give due priority to nuclear safety and are regularly verified by the competent regulatory authority.

6.6. Legal framework for licensees to establish and implement management systems

The SSM general safety regulations SSMFS 2008:1, Chapter 2, Section 8 require that nuclear activities with regard to design and construction, operation and decommissioning, shall be managed, controlled, assessed and developed through a management system so designed that requirements on safety will be met. The management system, including the necessary routines and procedures, shall be kept up to date and be documented. This view on quality and safety being integrated with other business concerns into a total integrated management system is in line with the IAEA Safety Requirements on Management Systems, GS-R-3.

It is further required in SSMFS 2008:1 that the application of the management system, its efficiency and effectiveness, shall be audited systematically and periodically by a function having an independent position in relation to the activities being audited. An established audit programme shall exist at the facility.

In the general advice to the regulations it is made clear that the management system should cover all nuclear activities at the plant. Furthermore, it should be clear from the management system how contractors and vendors are to be audited, and how to keep results from these audits up to date.

The internal audit function should have a sufficiently strong and independent position in the organization and should report to the highest management of the facility. The audits should have continuity and auditors should have good knowledge about activities being audited.

SSM has started a revising process regarding SSMFS Chapter 2 Section 8 in order to clarify the requirements on a management system in terms of content.

6.6.1. Main features of the management systems implemented by the licensees

The licence holders have integrated management systems where requirements addressed to the operation are provided for in a systematic manner. Safety issues have a special status in the management systems.

The main features of the licence holder's management systems can be summarized in the following areas:

- The structure of the management system
- How requirements regarding radiation safety are converted and met,
- Aims and guidelines for radiation safety
- Structure, responsibility and decision-making of the organization,
- How organization modifications are handled



- Procedures for competence assurance,
- The operative radiation protection work,
- Activities and eventual processes identify process owners plus how activities and processes are evaluated and developed.
- Interaction with external organizations of importance for radiation safety
- How the requirements on radiation safety are satisfied when tendering products and services,
- How guiding documents shall be initiated, reviewed, approved and revised.

6.7. Regular verification of the existence and adequacy of the management system

In a systematic and continuous manner SSM follows-up how the management system is structured and how the licensees work with its suitability. Important factors are that the management systems are up-dated and how the licensees deal with requirements management.

Furthermore, SSM also carries out random sampling within different areas. The purpose is to review how a specific area, for example system for feedback of experience, is controlled and applied by the management systems.

Article 6

5. Member States shall ensure that the national framework in place requires licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to nuclear safety of a nuclear installation, laid down in paragraphs 1 to 4.

6.8. Legal requirements regarding adequate financial and human resources

According to Section 13 of the Act on Nuclear Activities (1983:4), a licensee is obliged to have an organisation for the activity with sufficient financial, administrative and human resources to uphold safety and to take protective measures in the event of disruptions in the operations or accidents in the facility.

The legal requirement clarifies the licensee's obligation to have an organization formed and staffed in such a manner that it ensures a safe and reliable operation of all activities related to nuclear safety and meets the need for effective measures in an emergency situation. This applies even to the contractors hired by the licensee.

Great importance is given to the licensee's ability to be responsible for the obligations arising from the nuclear activities. The licensee must demonstrate that he either directly, eg by a sufficient share capital or commitment of the highest parent company in the company group the licensee may belong to, have the financial capacity required to meet the far reaching obligations in a long term.

In addition to this basic requirement above, licensees must pay a fee on every produced kWh to a state controlled fund, the Nuclear Waste Fund, according to the Act (2006:647) on Financing of Management of Residual Products from Nuclear Activities. This is to ensure the financing of decommissioning, handling and disposal of spent fuel and nuclear waste, including the research needed for these activities. The amount is



calculated based on an operating time of 40 years. In the event of a longer operating time, fees for the handling the additional spent fuel will have to be paid, but all the fixed costs are included in the cost estimate for 40 operating years. In order to account for earlier shut down, the licence holders must also provide financial securities to the Nuclear Waste Fund.

6.9. Regulatory confirmation process

If SSM in its supervisory function finds indications for concern regarding lack of financial resources the authority has extensive legal powers to take actions. However, there is no established process for evaluating licensee's financial resources.

Regarding the adequacy of the licensees' human resources SSM evaluates their process for competence assurance every third year.

Besides the evaluation, SSM also carries out random samplings in different areas by asking staff whether they experience that they have sufficient education and competence for the task performed. Hereby, SSM is given verification from two separate processes.

7. Article 7 – Expertise and skills in nuclear safety

Article 7

Member States shall ensure that the national framework in place requires arrangements for education and training to be made by all parties for their staff having responsibilities relating to the nuclear safety of nuclear installation in order to maintain and to further develop expertise and skills in nuclear safety.

7.1. Legal requirements concerning education, training and retraining

SSM general safety regulations (SSMFS 2008:1) are clear about the staffing, competence and training of personnel at the nuclear facilities. The licensee has to ensure that the staff has the competence and suitability needed for all tasks of importance for safety and this has to be documented. Long-term planning is required in order to ensure enough staff with sufficient competence and suitability for the safety related tasks are available. A systematic approach should be used for the definition of competence requirements, planning and evaluation of all safety related training. Annual competence assessments shall be performed. These general requirements apply also to the extent applicable on the use of contractors. It is also a requirement that there is a careful balance between the use of in-house personnel and contractors for safety related tasks. The competence necessary for ordering, managing and evaluation of the results of contracted work should always exist within the organization of a nuclear installation.

For operational staff at the nuclear power plants and research reactors there are more specific regulations, SSMFS 2008:32. 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 field operators. If an individual satisfies all requirements regarding competence and suitability, the licensee may issue an authorization valid for three years. Every year, an intermediate follow up shall be done in order to check that the essential competence is maintained. The regulations require the use of full scale simulators for operational training.



7.2. System established by the licence holders

7.2.1. Analysis of competence requirements and training needs

All licensees have an established process for competence assurance. The process usually consists of the following parts:

- Identification of tasks relevant for safety,
- Identification of existing staff competence
- Identification of relevant and necessary staff competence
- Performing a gap analysis.

In view of the performed gap analysis, the licensees develop relevant educational programmes or training in order to achieve the right skills among the staff, both in short and long term perspective.

7.2.2. Initial training and retraining

All licensees have a systematic approach in place for the training of operators. Training programmes are developed based on task analysis and definitions of required competence. A systematic method is also used to define the annual re-training that is required. The training programmes include theoretical courses, on-site training with experienced colleagues and full scope replica simulator training, as well as training performed in a workplace environment.

For control room personnel an internal promotion schedule is applied in which the operators begin as field operators. The qualification time to become a reactor operator is about 5 years, and to become a shift supervisor not less than 7 years.

The mandatory training programmes typically include basic courses in nuclear technology and safety, plant knowledge including systems, processes and dynamics, operational limits and conditions (Tech-Spec), radiation protection, plant organisation and work routines. Operational personnel is given extended courses on systems, processes and dynamics, transients and accident scenarios, operational procedures, emergency operating procedures and Tech-Spec.

The control room operators receive about 10 days annual re-training, partly on a simulator, divided into two periods, one focused on normal operation start up and shut down procedures and one on transients and accidents. All simulator sessions are evaluated systematically.

Competence assessments are performed every year by operations management against specified criteria to check the required competence for the specific position and to define further training needs. Every three years a more extended check is made also with regard to fitness for duty. This extended check is required in order to issue the authorization which is valid for three years. The systematic approach is being extended to maintenance staff and other groups with tasks of importance for safety.

The line managers of the operating organizations are responsible for the training of their staff and for providing the necessary resources. KSU (the Swedish Nuclear Training and Safety Centre) has been contracted by the licensees to carry out most of the operator training and annual re-training. The training and competence follow up systems are audited by the licensees on a regular basis to ensure that they fulfil specifications and requirements. Procedures for plant- and safety documentation modifications ensure that such modifications are introduced into the training programmes. The annual training



inventories ensure that domestic and relevant international operational experience is fed into the training programmes.

KSU has significant resources for training and production of training material. In 2012 the company had 285 employees of whom 136 were located at local centres. About 4,900 training-days were provided during 2012 (3,964 in 2009). KSU also has an extensive instructor training programme for its own staff with several qualification levels.

7.2.3. Capabilities of plant simulators

Since 2000 most operator training has been moved from the KSU central facility in Studsvik to the local centres situated near the power plants. Full scale simulators for most operating reactors are now located at these local centres. The old Barsebäck simulator is used for special projects and the general training will also remain in Studsvik.

Since 2008 KSU also utilizes the decommissioned Barsebäck 1 and 2 power plants for training of maintenance personal in realistic environments. Training is also provided to operational personnel in areas in which a real environment enhances the training but the use of an operating plant would be impossible.

7.2.4. Training of maintenance and technical support staff

When the licensees replace existing equipment or components at facilities, the supplier normally provides for training. Otherwise, the licensees arrange specialized training within each function respectively. Since 2008 KSU also utilizes the decommissioned Barsebäck 1 and 2 power plants for training of maintenance personal in realistic environments.

7.2.5. Improvement of training programmes

The licensees have a learning organization at their disposal and all sorts of feedback of experience is taken into account when improving the training programmes.

7.3. Education, training and retraining of the staff of the regulatory authority

7.3.1. National level

The legislation is clear about the need for the licensees to secure and maintain adequate competences. SSM is the appointed authority to supervise the licensees compliance to the requirements.

The academic institutions are a source of specialists to the nuclear sector. The Government is responsible for funding of basic university training. SSM has completed projects to survey the availability of graduate/post graduate courses and research capability across the academic sector. For example experimental research within safety and radiation protection is performed at Chalmers University, Royal Institute of Technology, Uppsala University, Stockholm University and Lund University.

However, there is no comprehensive national strategy for education and training. In this context it may be noted that the Directive requires the national framework to cover education and training to be made by *all parties*, which likely includes the regulatory authority as well.

Between 6 and 17 February 2012, an IRRS review was performed of activities in Sweden and at SSM in the fields of nuclear safety and radiation protection. The IRRS team submitted a number of recommendations on improvements. One of the recommendations



was directed at the Swedish Government and urged the Government to take measures to maintain competence for nuclear safety and radiation protection on a national level such that it is ensured that all parties have access to competent staff to ensure continued safety.

7.3.2.Regulatory level

Since a couple of years SSM experiences a high workload depending on the safety modernizations of the Swedish reactors, upgrading of the physical protection of the plants, as well as applications to uprate the power levels of several reactors. This makes it important to implement a good long-term planning and to develop the necessary assessment and administrative tools to deal with the tasks without overloading the staff. Such planning is being carried out. Special procedures were developed for review of the power uprate applications and the authority presently re-examines its processes for reviews and assessments.

The authority costs for managing applications for new licences and for safety reviews (including periodic safety reviews) are now covered by fees to the licensees, in accordance with the Swedish Radiation Safety Authority Ordinance (SFS 2008:463). This new system made it possible to employ some additional staff for work with such licence applications and safety reviews.

The Department of Nuclear Power Plant Safety has increased its staff significantly so that the number of employees at the end of 2013 will total around 100 analysts and inspectors. The increased human resources are both intended for conducting supervision of present nuclear installations and to be able to process the application submitted by Vattenfall on 31 July, 2012 for permission to replace one or two reactors with new ones. Furthermore, the increased level of resources will also enable SSM to partake in more extensive international regulatory cooperation in the light of the Fukushima Daiichi NPP accident.

7.3.3.Internal staff training

Competence development has been conducted in all departments and units in 2013 and about 1 669 days have been used for training this is an average of 5.5 days per employee.

A basic training programme is given to all new employees in the following areas: authority role, occupational health, safety and SSM's core operations. The aim is to foster a deeper understanding of the Authority's activities and to give new employees an important network.

SSM also launched a development programme in skilled supervision in spring 2012. The programme concerns all employees involved in supervisory work at SSM. The aim is for them to have the same basic skills and perform supervision consistently regardless of the supervised entities. Since 2012 a total of 470 days have been used in this programme.

There are plans to further develop employees' supervisory skills at the Authority. During the last two years SSM has exchanged experiences internationally with sister agencies that have come further than SSM in this respect. These experiences have been very interesting and have given SSM knowledge and ideas to further development of the programme.

Training courses given to the employees covers the internal processes of the management system, the legal framework for regulatory activities, IT and security routines, project management, inspection methodology, nuclear technology, nuclear power plant and systems courses, as well as media training. Individual needs of training courses and competence development in general are usually met by training courses on the market.



During 2013, SSM conducted around 70 agency training sessions in the areas of supervision, preparedness, monitoring, skills exercises and the work environment. For technical training, SSM also uses the licensee training programmes for operations staff, including simulator training. Newly employed SSM staff were also given the opportunity to observe on-site work in a control room for several weeks.

In 2013 SSM continued with a general analysis of the Authority in the area of expertise. The purpose of the skills survey is to provide SSM's leadership and managers with a clear picture of the Authority's current skills and, based on this, perform a gap analysis. With this analysis SSM can determine the skills needed in the short and long term in order to deal with current and future tasks.

Regarding arrangements for the improvement of training programmes, SSM has noted that some improvements have been done but the programmes have not been fully evaluated yet.

8. Article 8 – Information to the public

Article 8

Member States shall ensure that information in relation to the regulation of nuclear safety is made available to the workers and the general public. This obligation includes ensuring that the competent regulatory authority informs the public in the fields of its competence. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

8.1. Legal requirements for making information available

SSM's missions and tasks are defined in the Ordinance (SFS 2008:452) with instructions for the Swedish Radiation Safety Authority. According to Section 7 SSM is responsible to contribute toward public insight into all activities performed by the authority. The aim is to promote health and prevent ill-health, prevent acute radiation injuries and reduce the risk of delayed injuries due to radiation, and to provide advice and information about radiation, its properties and areas of application and about radiation protection.

According to Sections 19-21 of the Nuclear Activities Act, a licensee of a nuclear facility is obliged to provide the Local Safety Council with the insight and information necessary for it to be able to inform the public about safety and radiation protection work at the facility.

According to the right-of-access principle every citizen has the right to take part of the authorities' public documents to the extent they are not subject to secrecy.

8.2. SSM's communication strategy

SSM's main communication channel is their website. On the website the Authority publish their core messages, recommendations, reports, decisions and news articles. The authority also communicates through traditional and social media. The authority arranges press conferences and sometimes arranges seminars and conferences. Also the Authority



uses films to communicate. For example they have produced two films about sun safety, one about laser regulations and one about the Authority.

The authority communicates its core messages, recommendations, information about their supervision and about crisis communication. The main language is Swedish, but information that would be of use for citizens or authorities in other countries translates into English. SSM also have basic information on the minority languages.

SSM publish information on decisions or other information that would be of interest for the public as soon as possible after the information is provided. SSM publish about 80 news articles every year.

SSM has a crisis communication strategy. The strategy states that:

- The mass media is the main and prioritised channel for communicating to the general public. This is why SSM always need to have spokespersons available who can answer questions posed by the media.
- SSM must also, to the best of the Authority's ability, respond to questions from the general public in the channels used by the public, for example our website, the relevant social media as well as by telephone.
- All communication is to use the Authority's mission statement and key values as a platform. In a crisis, SSM will need to particularly take into account the requirements on responding to the situation at hand. This includes continually providing information throughout a crisis to avoid an information vacuum that raises the risk of speculation and spreading incorrect information.

8.3. Information subject to secrecy

Swedish official documents are 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.

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.



Appendix

Regulations on control of nuclear material (SSMFS 2008:3)

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.

General advice on the interpretation of Section 5 in the Act on Nuclear Activities (1984:3) on the use of contractors (SSMFS 2008:6)

SSM has issued general advice on the interpretation of Section 5 in the Act on Nuclear Activities (1984:3) regarding the use of contractors. If a contractor is approved by SSM and a permit is issued although the overall responsibility for safety rests with the licensee, the contractor has legal duties and obligations for the nuclear activities defined by the contract and permit.

Regulations on exemption from the requirement on approval of contractors (SSMFS 2008:7)

The Act on Nuclear Activities (1984:3) provides rules regarding the allowed use of contractors. In general, a licensee cannot contract out an activity included in the nuclear licence without a permit by the Government or SSM. However, if the licensee controls and follows up on the contractor's work, for certain activities the permit procedure can be replaced by a notification to the regulatory body. SSM is authorized by the Government to specify the prerequisites for such exemptions.

Regulations on physical protection of nuclear facilities (SSMFS 2008:12)

These non-classified regulations with general advice contain requirements on the organisation of the 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.

Regulations concerning mechanical components in certain nuclear facilities (SSMFS 2008:13)

These regulations contain requirements for the use of mechanical equipment, requirements on limits and conditions, damage control, and accreditation of control organizations and laboratories, requirements on in-service inspection and control, requirements in connection with repair, exchange and modification of structures and components, requirements on compliance control and annual reporting to SSM.

Regulations on emergency preparedness at certain nuclear facilities (SSMFS 2008:15)

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).



Regulations on design and construction of nuclear power reactors (SSMFS 2008:17)

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.

Regulations on protection of human health and the environment from discharges of radioactive substances from certain nuclear facilities (SSMFS 2008:23)

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).

Regulations on radiation protection managers at nuclear facilities (SSMFS 2008:24)

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.

Regulations on radiation protection of workers at nuclear facilities (SSMFS 2008:26)

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.

Regulations on the competence of operations personnel at reactor facilities (SSMFS 2008:32)

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 field operators. The regulations require the use of full scale simulators for operational training.

Regulations on archiving at nuclear facilities (SSMFS 2008:38)

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.

Regulations concerning clearance of materials, rooms, buildings and land in practices involving ionising radiation (SSMFS 2011:2)

The regulations stipulate requirements on procedures for clearance of material, rooms, buildings and land. The regulations also stipulate nuclide specific clearance levels for different objects subject to clearance. Clearance levels are given for clearance of materials for reuse or for disposal as conventional waste, as well as for clearance of rooms or buildings after cessation of practices or decommissioning of facilities. The clearance levels are based on recommendations from the European Commission (reports RP 113 and RP 122 part 1).

Regulations on basic requirements for the protection of workers and the public in connection with work with ionising radiation (SSMFS 2008:51)

The regulations are general and apply to the exposure of workers and the public in both planned and emergency exposure situations. They contain fundamental requirements on the licensee/operator for justification of the activities, optimisation of the radiation protection and limitation of individual doses (dose limits). They address the categorisation of workers and work places; stipulate Swedish dose limits for workers (including apprentices) and the public, and address the required information and protection of pregnant or breast-feeding women.

Regulations concerning outside workers who work with ionising radiation (SSMFS 2008:52)

These regulations apply to outside workers of category A, working within controlled areas in Sweden and when Swedish workers of category A perform similar tasks in other countries. The regulations put obligations on both the licensee (e.g. operator of a nuclear facility) and the outside workers undertaking.