



Strålsäkerhets  
myndigheten

Swedish Radiation Safety Authority

Report

# Kingdom of Sweden IRRS ARM Summary Report 2022

The IAEA Integrated Regulatory Review Service  
Mission to Sweden in November 2022

## 2022:11

**Author:** Swedish Radiation Safety Authority

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# Strålsäkerhetsmyndigheten

Swedish Radiation Safety Authority

## Foreword

In January 2018, the Swedish Radiation Safety Authority, SSM, submitted a request to the IAEA on behalf of the Swedish Government for international peer reviews to be conducted of the Swedish national frameworks for nuclear safety regulation (IRRS) and the safe management of spent fuel and radioactive waste (ARTEMIS). In dialogue with the IAEA, and in support of the Ministry of the Environment, it has been agreed that the IRRS review will be conducted 13-25 November 2022 back-to-back with the ARTEMIS review 16-27 April 2023.

The EU Nuclear Safety Directive stipulates that EU Member States shall at least every ten years organise periodic self-assessments of their national frameworks and competent supervisory authorities and invite an international peer review of relevant parts of their national frameworks and competent supervisory authorities, with a view to continuously improve nuclear safety. The first IRRS peer review in Sweden, after the Nuclear Safety Directive came into force, was conducted in 2012 with a follow-up mission in 2016.

A preparatory meeting was held with IRRS mission representatives on 26-27 April 2022. Organisational elements of the IRRS mission were discussed and some of the detailed expectations of the IAEA and the leaders of the international peer review team were clarified.

This report summarises the results of Sweden's self-assessment in preparation of the IRRS-mission, according to the prescribed IAEA template. There are some minor variations from the standard format, however, mainly due to the way in which the Swedish regulatory system works in practice.

NINA CROMNIER  
Director General



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# Introduction

The first full-scope IAEA IRRS mission to Sweden was performed February 2012 and the resulting recommendations were addressed, on behalf of the Swedish Government, by the Swedish Radiation Safety Authority (SSM) in an action plan. A follow-up mission took place in April 2016. On behalf of The Swedish Government, SSM officially requested IAEA to carry out the next IRRS mission along with a back-to-back ARTEMIS mission in Sweden during 2022 and 2023, respectively.

An IRRS mission peer-reviews the governmental, legal and regulatory infrastructure for nuclear, radiation, radioactive waste and transport safety including the interface with security. It provides a member state with an independent review of its regulatory functions and infrastructure, and the outcome and recommendations from the mission can be used to strengthen and enhance effectiveness.

An ARTEMIS mission peer-reviews the national programmes for radioactive waste and spent fuel management, decommissioning and remediation. There are some overlaps between these two missions, but the decision was made not to reduce the content of the IRRS Self-Assessment.

## **IRRS self-assessment and Advance Reference Material**

On behalf of The Swedish Government, SSM officially requested IAEA to carry out the second full-scope IRRS mission along with a back-to-back ARTEMIS mission in Sweden during 2022 and 2023, respectively. SSM is coordinating Sweden's self-assessment for both IRRS and ARTEMIS.

During 2020 SSM initiated a project with the task of planning and leading the preparations for both the IRRS- and ARTEMIS-missions. Several subprojects was formed to deal with specific tasks. One such subproject was responsible for the IRRS self-assessment.

SSM's objectives with the Self-Assessment was to strengthen the national framework and provide support for continuous improvement of radiation safety, to protect people and environment from harmful effects of radiation. The Self-Assessment should be of such quality that it allowed the conduction of the IRRS-mission to be performed in an efficient way, in order to allow for a result that is true and fair. Furthermore, it should promote learning and knowledge transfer within SSM. SSM's approach to shortcomings and improvement opportunities as well as the relation to IAEA and the international experts (review team) shall take place in a spirit of openness, learning and the promotion of radiation safety.

The Self-Assessment project attended a technical meeting with IAEA on e-SARIS in November 2020. The project also facilitated so that the whole of SSM was able to attend the webinar IAEA held in December 2020 on "Introduction to the IAEA Safety Standards". An official project kick-off was held in conjunction with an IAEA led webinar in January 2021 on "IRRS and National Self-Assessment". During the spring of 2021, approximately 100 participants in 21 response teams answered the Self-Assessment questions and gave evidence how the expectations are met. During the fall of 2021, approximately 60 participants in 21 teams analysed the Self-Assessment answers and

suggested actions for improvements. SSM's senior management developed the Initial Action Plan (IAP) included in this report. The Self-Assessment was performed in accordance with the SARIS guidelines (IAEA SVS 27) and is documented in SSM2021-1032-16.

A preparatory meeting was held with IRRS mission representatives on 26-27 April 2022. Organisational elements of the IRRS mission were discussed and some of the detailed expectations of the IAEA and the leaders of the international peer review team were clarified. Since there are no operational research reactors in Sweden it has been agreed with the IRRS mission representatives that research reactors are out of scope for this IRRS mission.

This report is based on IAEA Template and Guidance for the IRRS ARM Summary Report, Version 5 of May 2020. The main goal of this report is to provide a concise collection and presentation of the conclusions drawn and actions foreseen from Sweden's self-assessment in preparation for the full-scope IRRS mission scheduled for November 2022.

Some notable events have had an impact on the self-assessment. SSM carried out a major reorganization on 1 June 2021 with a new organisational structure. The new structure is based on the authority's mission. The senior management have developed a roadmap for the strategic objectives to be implemented until 2025. The Initial Action Plan is linked to the roadmap, see Initial Action Plan. Due to the reorganisation, many steering documents were updated and some are still being revised.

Since 2012, SSM has been working on a new modern regulatory package based on IAEA standards. When the self-assessment was carried out, certain central regulations were on final referral. These regulations have since been published. It is the referral editions that are referenced in the self-assessment report and present report.

Furthermore, the Covid-19 pandemic affected the authority's work. Among other things, the self-assessment group work has been exclusively carried out digitally, see further Module 13.

In total, more than one-third of SSM staff has contributed in the preparations for the IRRS 2022 mission to Sweden.

## **SSM's vision and mission statement**

SSM embraces the fundamental values held by Swedish public administration based on the platform of democracy and human rights, while continually striving to follow the rule of law, maintain efficiency and effectiveness, and have a citizen's perspective. The fundamental values of the Authority comprise its vision, mission statement and key values. These fundamental values also shape the Authority's safety culture.

SSM's vision is *A society safe from the harmful effects of radiation.*

SSM's mission statement is *SSM works proactively and preventively to protect people and the environment from harmful effects of radiation, now and in the future. We have a systematic and structured approach to continual improvements to our processes in order to develop our operations, render them more efficient and achieve our objectives.*

SSM's three Key values are *Credibility, Integrity and Openness*.

- *Credibility* means pursuing our work on the basis of facts. Credibility is achieved when employees are competent, objective and impartial. 'Competence' means employees having the requisite professional skills, education, training and experience.
- *Integrity* means maintaining the Authority's independence and not allowing us to be unduly influenced when it comes to our own decisions, standpoints, advice and recommendations. Integrity involves taking charge, both while exercising authority and on an employee level.
- *Openness* means that the work of the Authority is transparent to the outside world and that we clearly and proactively provide information about our work, standpoints, advice, recommendations and decisions. Openness also involves our willingness to be attentive to and consider external views.

The key values are an active component of all the Authority's activities. They are for instance used to underpin the decision making of the Authority.

### **The term Radiation Safety (Strålsäkerhet)**

The term *Radiation Safety* (*strålsäkerhet* in Swedish) is a generic term for radiation protection and safety (SSMFS 2018:1). Radiation protection is regulated in the Radiation Protection Act (2018:396). The concept of *säkerhet* (safety) according to the Act (1984:3) on Nuclear Activities includes both nuclear safety and security.

# Background

## General Information

The Kingdom of Sweden is a parliamentary democracy, which means that all public power proceeds from the people. At the national level, the people are represented by the Riksdag (Swedish parliament) which has legislative power. The Government implements the Riksdag's decisions and draws up proposals for new laws or law amendments.

Basic provisions defining how Sweden shall be governed are enshrined in the Constitution. In these fundamental laws the relationship between decision-making and executive power is set out and also the freedoms and rights enjoyed by citizens. The principle of public access to official documents is set out in order to guarantee an open society with access to information about the work of the Riksdag, the Government and public agencies. This openness entitles the Swedish people to study official documents.

## The Government Offices

The Government Offices consists of the Prime Minister's Office, eleven ministries and the Administration Department. Each ministry's management has one or more ministers, one of whom is the head of the ministry. The remit of each ministry includes responsibility for a number of government agencies. The agencies must apply the laws and carry out the activities decided by the Riksdag and Government.

Government agencies are the Government's most important instruments in carrying out its policies. Agency heads are often accountable to the Government for the agency's operations, which is why the Government's power of appointment and managerial policy is important. The Government's power of appointment covers decisions on the employment of agency heads, deputy directors-general and county directors. Decisions on other appointments are the responsibility of the agency in question.

The Government monitors agencies' activities to ensure that the public sector utilises resources in an optimal manner and where they are most needed. The agencies submit an annual report to the Government containing information about, inter alia, expenses, revenue and results. On the basis of the reports, the Government can follow up and evaluate agencies' operations. The annual reports together with budget data submitted by agencies are also the basis for work on next year's national budget and appropriation directives.

The Government has quite substantial scope for steering the operations of government agencies. However, it has no powers to intervene in an agency's decisions in specific matters relating to the application of the law or the due exercise of its authority. Collective Government decision-making and the ban on instructing agencies on individual matters are expressions of the prohibition of 'ministerial rule', as it is often called. The Riksdag is responsible for monitoring to ensure that ministerial rule does not occur. Should the Government consider that an agency has not applied a law correctly its only remedy is to seek to amend the relevant legislation.

In addition to the general system of rules on financial management and the agencies' powers and obligations, the Government decides on the preconditions for the individual agency's operations. This is effected on the one hand in the annual appropriations directives and, on the other, by ordinances. The practical work of producing appropriation directives and ordinances is done in the Government Offices. The appropriations directives set out, among other things, 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 concerning how the agencies are to carry out their work.

## The Ministry of the Environment

The Ministry of the Environment is responsible for the Government's environmental and climate policy. The Ministry works on issues concerning the climate, biological diversity, chemicals, eco-cycles, nature and forest conservation, marine and water environments, radiation safety and international environmental cooperation. The Ministry of the Environment has around 160 employees, mainly divided between eight divisions and secretariats, see Figure 1. In addition, around 40 employees in committees of inquiry within the Ministry's areas of responsibility. The Chemicals Division works with issues concerning a non-toxic environment, chemicals in products, the environment and health, and circular economy issues. This covers chemicals control, waste management and waste prevention, the environmental dimension of biotechnology and genetic engineering, environmental research, protection of the ozone layer and the remediation of contaminated sites. The Division is also responsible for nuclear safety, radiation protection and radioactive waste management.



Figure 1 - Organisation of the Ministry of the Environment

## County Administrative Boards

Sweden is divided into 21 counties. In each county there is a County Administrative Board which is responsible for state administration in the county, insofar as no other authority is responsible for specific administrative tasks. The mission of the Boards is broad and cross-sectoral, which means that they work both from a government-wide perspective and across sectors. The Boards must work to ensure that national objectives are implemented in the county, while taking account of regional conditions and circumstances. Each county administrative board is headed by a county governor appointed by the government. The Boards and municipalities have the authority to regulate the on-site emergency preparedness and response arrangements of operating organisations.

## Primary legislation on radiation safety

The policy and strategy for radiation safety in Sweden is expressed in primary legislation, consisting of the following legal acts

- Act (1984:3) on Nuclear Activities,
- Radiation Protection Act (2018:396),
- Environmental Code (1998:808),
- Act (2006:647) on Financial Measures for the Management of Residual Products from Nuclear Activities,
- Act on Liability and Compensation for Radiological Accidents (2010:950) and
- The Civil Protection Act (2003:778).

The legal and regulatory framework clearly allocates responsibilities for nuclear safety and radiation protection. The framework ensures the effective regulatory control of facilities and activities and complies with international obligations.

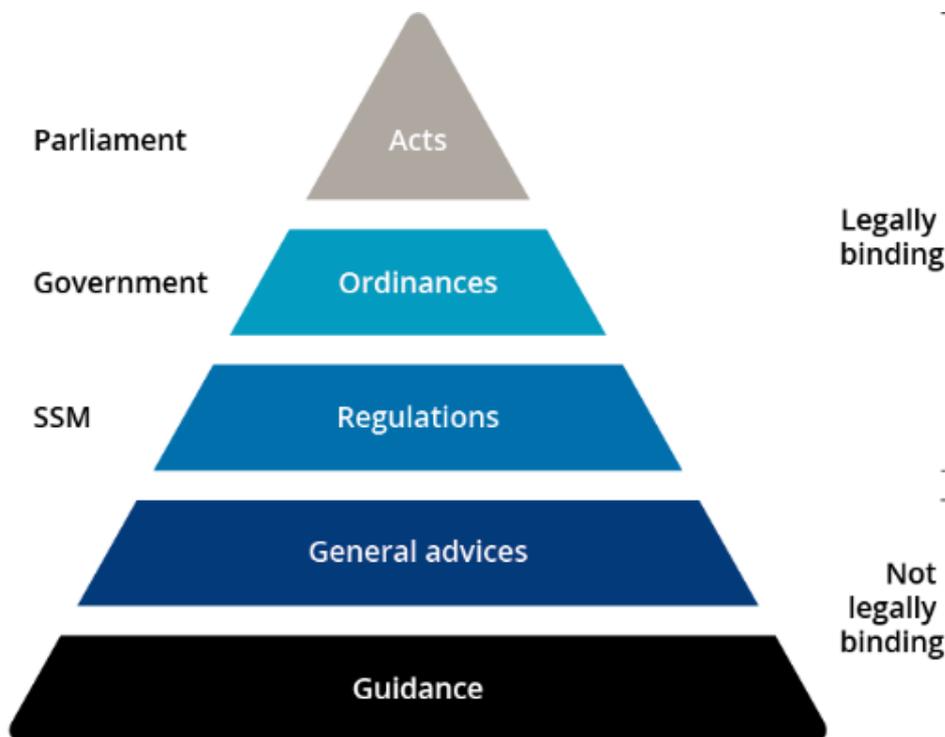


Figure 2 - Hierarchy of Swedish legislation and the regulatory framework

The legal and regulatory framework clearly allocates responsibilities for nuclear safety and radiation protection. The framework ensures the effective regulatory control of facilities and activities and complies with international obligations. The hierarchy of Swedish legislation is shown in Figure 2.

## Nuclear facilities

Sweden has six nuclear power reactors in operation, as specified in Table 1 below. Seven nuclear power reactors have been permanently shut-down, namely Ågesta, Barsebäck unit 1, Barsebäck unit 2, Oskarshamn unit 1, Oskarshamn unit 2, Ringhals unit 1 and Ringhals unit 2.

Table 1 - Nuclear Power Reactors in Sweden

Power reactor	Licensed thermal power level (MW)	Electrical gross output (MW)	Type	Operator	Construction start	Commercial operation
Ågesta	105	12	PHWR	AB Atomenergi Vattenfall	1957	1964-1974
Barsebäck 1	1800	615	BWR	Barsebäck Kraft AB	1970	1975-1999
Barsebäck 2	1800	615	BWR		1972	1977-2005
Forsmark 1	2928	984	BWR	Forsmarks Kraftgrupp AB	1971	1980
Forsmark 2	3253	1120	BWR		1975	1981
Forsmark 3	3300	1167	BWR		1978	1985
Oskarshamn 1	1375	492	BWR	OKG Aktiebolag	1966	1972-2017
Oskarshamn 2	1800	661	BWR		1969	1975-2015
Oskarshamn 3	3900	1450	BWR		1980	1985
Ringhals 1	2540	910	BWR	Ringhals AB	1968	1976-2020
Ringhals 2	2660	966	PWR		1969	1975-2020
Ringhals 3	3144	1117	PWR		1972	1981
Ringhals 4	3300	1171	PWR		1973	1983

All Swedish nuclear facilities are situated in the southern half of Sweden, see Figure 3.

The national waste programme includes the waste treatment facilities at Studsvik, the repository for short-lived LILW and operational radioactive waste at the Forsmark site (SFR), shallow land burials at the nuclear power plant sites (besides Barsebäck) and at Studsvik, the interim storage facility for spent nuclear fuel at Oskarshamn (Clab), the transportation system, and the use of clearance.

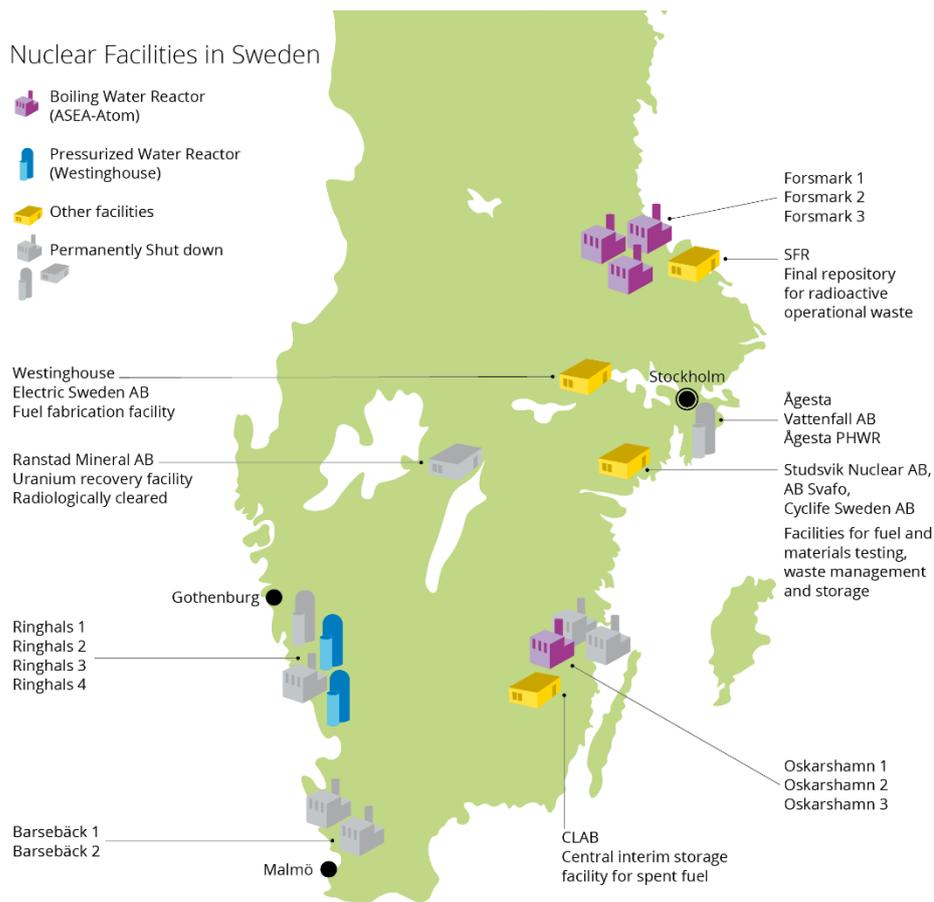


Figure 3 - Nuclear Facilities in Sweden

Chalmers University of Technology in Gothenburg is licensed according to the act on nuclear activities.

There are currently no operational research reactors in Sweden.

Mining and related processing of minerals on Swedish territory for the purpose of uranium production was prohibited in 2018 (Chapter 9 Section 6 in the Environmental Code). The permit for uranium mining at the Ranstad plant expired at the end of 2009/2010 and the plant was recently decommissioned.

## Regulatory Bodies

### The Swedish Radiation Safety Authority

The Swedish Radiation Safety Authority (SSM) works to promote protection of people and the environment from harmful effects of radiation, now and in the future. The Authority reports to the Ministry of the Environment and has mandates from the Swedish Government within the areas of nuclear safety, radiation protection and nuclear non-proliferation. The mission and tasks are defined in an ordinance with instructions for the Authority and in the annual government appropriation directions, which contains detailed objectives and reporting obligations.

The Authority has a budget of approximately 520 million Swedish kronor per year. There are just over 300 employees with expertise in fields such as engineering, natural and behavioural sciences, law, economics and communications. The Riksdag and Government of Sweden decide on the assignments and budget of the Authority, but like other public authorities in Sweden, the Authority makes decisions independently on individual matters. The work is largely financed through fees and tax funds. SSM is headed by a Director General, who is appointed by the Government.

Other authorities that have a supervisory mandate relating to nuclear power plants are the Swedish Civil Contingencies Agency, the Swedish Work Environment Authority, the Nuclear Waste Fund, and the National Electrical Safety Board. Those agencies that have a role in the IRRS mission are listed below.

### **The Swedish Civil Contingencies Agency**

The Swedish Civil Contingencies Agency (MSB) is responsible for issues concerning civil protection, public safety, emergency management and civil defence as long as no other authority has responsibility. The Swedish Civil Contingencies Agency reports to the Ministry of Justice. Responsibility refers to measures taken before, during and after an emergency or crisis. The work is led by a Director General appointed by the Government. There are approximately 1,000 employees working in Karlstad, Kristinehamn, Stockholm, Sandö, Revinge and Rosersberg.

### **The Swedish National Debt Office**

The Swedish National Debt Office is the central government financial manager. The Debt Office reports to the Ministry of Finance. The Debt Office is responsible for ensuring that the nuclear power industry can finance the management and disposal of nuclear waste and spent nuclear fuel, the decommissioning and demolition of the plants, and the research necessary to enable this. The Debt Office was given a mandate effective 1 January 2022 to assess the financial security for radiological accidents. This means that the Debt Office is to assess whether the nuclear power companies' have sufficient insurance and other security for costs that may arise from an incident at a nuclear power facility or during the transport of radioactive material.

### **The Swedish Ethical Review Authority**

The Swedish Ethical Review Authority is a public agency under the Ministry of Education. The Authority examines applications for ethics review of research involving humans and human biological material. The Authority has 18 departments. Each department consists of ten representatives with a scientific background and five from the public. The chairperson of a department must be or have been a judge.

# Module 1: Responsibilities and Functions of the Government

## 1.1 National Policy and Strategy for Safety

### *Related to GSR Part 1 (Rev. 1): Requirement 1*

Sweden meets the expectations of GSR Part 1 Requirement 1 through a policy and strategy for radiation safety that is expressed in primary legislation, consisting of the following legal acts

- Act (1984:3) on Nuclear Activities,
- Radiation Protection Act (2018:396),
- Environmental Code (1998:808),
- Act (2006:647) on Financial Measures for the Management of Residual Products from Nuclear Activities,
- Act (2010:950) on Liability and Compensation for Radiological Accidents and
- The Civil Protection Act (2003:778).

This is in turn set in the context of a national system of Environmental Objectives, which consists of an overall Generational Goal and a set of 16 environmental quality objectives. Together, these seek to guide environmental action at every level of society, with the aim of handing over to the next generation a society in which major environmental problems have been solved, without increasing environmental and health problems outside Sweden's borders. Primary legislation addresses basic expectations and provisions relating to radiation safety, consistent with the underlying environmental quality objective of achieving a "Safe Radiation Environment". All Euratom Directives and binding international agreements relating to radiation safety have been implemented in Swedish legislation.

The fundamental policy principles expressed in primary legislation can be summarised as:

- The operator of a nuclear facility has strict, unlimited liability for radiological damage. The operator is also obliged to ensure that security is provided for damage at a level that varies depending on the facility.
- The licensees are required to pay fees that shall cover costs for the management and disposal of spent fuel and radioactive waste from nuclear activities.
- Facilities and activities that give rise to radiation risks are justified only if they can be shown to yield an overall benefit.
- People and the environment, present and future, must be protected against radiation risks.
- Protection against the harmful effects of ionising radiation must be optimised to provide the highest level of safety that can reasonably be achieved.
- Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
- All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.
- The prime responsibility for safety rests with the person or organisation responsible for facilities and activities that give rise to radiation risks.

- An effective legal and governmental framework for safety, including an independent regulatory body, shall be established and sustained.
- Effective leadership and management for safety must be established and sustained in organisations concerned with, and in facilities and activities that give rise to, radiation risks.
- Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.
- Protective actions to reduce existing or unregulated radiation risks must be justified and optimised.

Application of a graded approach to the implementation of these policy objectives is achieved primarily through underlying regulations and regulatory practice that seek to ensure that activities entailing greater risks are examined more thoroughly and inspected more frequently in accordance with more extensive rules than activities that involve lesser risks. The regulatory body with primary responsibility for oversight of radiation safety, SSM, therefore allocates resources in terms of licensing and inspection according to the safety significance of a facility or activity. The graded approach is applied at the level of the overall radiation risk presented by a facility or activity, as well as in relation to individual components, systems or sub-activities.

## 1.2 Establishment of a Framework for Safety

### *Related to GSR Part 1 (Rev. 1): Requirement 2 and GSR Part 3: Requirement 2*

The Riksdag (Swedish parliament) is the supreme political decision-making body in the country. The Riksdag has determined the overall responsibility for the national Environmental Quality Objectives and decides on primary legislation and the state budget. The Government is responsible for the implementation of legislation enacted by the Riksdag. The Government also determines the overall framework within which different governmental agencies are expected to operate. This is achieved on the one hand via the annual appropriation directives (*regleringsbrev*) and, on the other, by Ordinances containing instructions to authorities relating to the discharge of statutory responsibilities. The Ordinances specify various general administrative provisions, duties and tasks concerning how government agencies are to carry out their work. The appropriation directives set out, among other things, certain key objectives an agency is to reach in its operations, as well as how much money the agency has at its disposal and how the money is to be distributed between different activities.

The Act on Nuclear Activities and the Radiation Protection Act are the primary legislative instruments that establish safety principles for the protection of people and the environment with regard to nuclear safety and radiation protection in Sweden. This primary legislation also establishes obligations and requirements relating to licensing and registration as well as general obligations on licensees, including legal responsibility for safety, requirements for periodic safety review and responsibilities for nuclear security and nuclear materials safeguards. The regulatory body has extensive legal powers to enforce the regulations and its decisions. An overarching principle is to avoid taking a measure that is more restrictive than necessary. Examples of measures are adjustment of the supervision (connected to intensified supervision), correction at the licensee's expense and refer suspected cases of criminal violations to a public prosecutor. Underlying Ordinances establish provisions relating to processes and responsibilities for licensing, authorisation, review, evaluation, inspection, enforcement and appeals. The Ordinances

also specify the regulatory authority assigned by the Government with a mandate to issue legally binding regulations relating to radiation safety as well as with responsibility for assessing compliance with the legal and regulatory provisions.

As the responsible regulatory authority for radiation safety under the Act on Nuclear Activities and Radiation Protection Act, SSM has established a regulatory framework that addresses in more detail the safety obligations of licensees with respect to design, assessment and operation of different types of facility and activity, including reporting requirements, emergency preparedness and nuclear security. SSM is also authorised to issue permits for transports of nuclear materials and wastes, to impose licence conditions relating to a specific facility or activity, and to act as the primary interface for Sweden's interactions with the international system for accountancy and control of nuclear material.

Other key items of primary legislation that have a bearing on specific aspects of nuclear safety and radiation protection are the Environmental Code, the Civil Protection Act, the Act on Financial Measures for the Management of Residual Products from Nuclear Activities, and the Act on Liability and Compensation for Radiological Accidents. The Environmental Code, which applies in parallel to radiation safety legislation with regard to the permitting of environmentally hazardous activities, incorporates, inter alia, requirements relating to Environmental Impact Assessment and associated public consultation. The licensing process under the Environmental Code involves open court hearings at the Land and Environment Court in association with preparation and review of an application, as well as with regard to the issuing of a licence and conditions. Ordinances underlying each of these acts specify, inter alia, the role and responsibilities of other government agencies within specific fields such as licensing under the Environmental Code, the co-ordination of Environmental Impact Assessment, contingency planning for emergencies and supervision of payments into and out of the Nuclear Waste Fund.

The Swedish Government has an established general process (Swedish Government Official Reports – *Statens offentliga utredningar*) whereby specially appointed committees or investigators are convened to undertake an analysis of issues in anticipation of a proposed legislation (or amendments to legislation) before the Riksdag or the issuance of Ordinances. Such reviews may be initiated based on policy proposals by the Government itself, recommendations from parliamentary committees or based on proposals from governmental agencies, organisations or individual citizens. In the field of radiation safety, SSM has a designated responsibility to participate in, and monitor developments associated with, related work carried out within the EU and internationally. This covers advancements in scientific knowledge and technology as well as in relation to standard setting. Based on its statutory regulatory activities, SSM also monitors the implementation of the existing legal and regulatory framework. Where appropriate, SSM may make necessary changes to its own regulations, within the terms of its mandate. Otherwise, reporting to the Ministry of the Environment, SSM may raise before Government issues relating to, e.g. the implementation of new standards or a need for clarification with regard to existing legal and regulatory provisions.

SSM is also responsible to Government for arranging and co-ordinating self-assessment and international peer review in accordance with the Article 8e(1) of Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations and Article 14(3) of Council Directive 2011/70/Euratom of

19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

### **1.3 Establishment of a Regulatory Body and its Independence**

#### ***Related to GSR Part 1 (Rev. 1): Requirements 3 and 4, and GSR Part 3: Requirement 2***

According to the Swedish constitution, administrative authorities are independent in its regulatory decision-making within the legislation and statutes laid down by the Government. An individual minister is not allowed to 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 Swedish Government has established SSM as the responsible regulatory authority for radiation safety under the Act on Nuclear Activities and Radiation Protection Act. The overall mission and responsibilities of SSM are defined in the Ordinance with Instructions for SSM (2008:452), with additional legal provisions relating to its mandate and authority specified in the Nuclear Activities Ordinance (1984:14) and the Radiation Protection Ordinance (2018:506). This includes, inter alia, the authority to issue regulations concerning nuclear safety and activities with ionising radiation and the mandate to act as the supervisory authority for nuclear facilities and activities as well as other activities with ionising radiation. SSM is also authorised to issue licences under the Radiation Protection Act for facilities and activities that are not encompassed by the Act on Nuclear Activities.

SSM's authority to issue licences is otherwise constrained by primary legislation. A separate licence under the Radiation Protection Act is not required for activities encompassed by the Act on Nuclear Activities. However, licence applications according to the Act on Nuclear Activities are first processed by SSM before being forwarded to the Government for a licensing decision, except in cases where limited quantities of nuclear material are involved. Furthermore, the Environmental Code requires that the Government first tests, according to the principles enshrined in the Code, the admissibility of any activity requiring a Government licence under the Act on Nuclear Activities before corresponding licences under both laws can be granted. After a licence under the Act on Nuclear Activities is granted, usually, it will be under the condition that staged authorisations from SSM are subsequently required in relation to construction, commissioning and normal operation of the facility, a so-called step-wise review process.

In addition to the mandate and authority noted above, SSM is fully empowered under the Act on Nuclear Activities and the Radiation Protection Act to request information, to gain access to facilities and to issue prohibitions and injunctions, combined with financial penalties where appropriate, on matters relating to nuclear safety and radiation protection. SSM is also empowered by these Acts and by related Ordinances to issue conditions relating to the operation of a facility or establishment.

The Swedish Government issues objectives and appropriation directives to SSM annually according to an overall budget set out by the Riksdag. The budget for SSM is approximately 520 million SEK to cover wages, rents, repayments and other management costs, which supports a total staff of approximately 300 employees. Annual appropriations take into account the financial statements and proposed budgets submitted

every year by the Authority. Sources of funding include direct grants from the annual state budget, fees recovered by the state from licensee payments, fees paid to SSM relating to licensing work, and reimbursements from the Nuclear Waste Fund for regulatory activities related to the disposal of spent fuel and nuclear waste as well as supervision of nuclear decommissioning. Direct funding from the national budget is earmarked for research activities, bilateral and other international support activities, work related to non-ionising radiation and control activities relating to orphan sources and naturally occurring radioactive material (NORM).

Funding provided to SSM for research (approximately 80 million SEK per year) is, according to the Ordinance with Instructions for SSM, a mechanism for the Government to support SSM in developing national competence of importance for the fields of radiation protection and nuclear safety. This, in turn, is designed to ensure that SSM has the knowledge and tools needed to carry out effective regulatory review and supervisory activities. Even resources from the Nuclear Waste Fund (approximately 9 million SEK per year) are used by SSM to fund scientific research relevant to regulatory work and support competence building. Professional development and competence building of current staff is included in the “other management costs” associated with SSM’s annual operational budget.

The Ordinance with Instructions for SSM requires that SSM should have permanent advisory committees on reactor safety and on the safe management of spent fuel and radioactive waste. Their members are appointed by SSM’s Director General and represent other independent institutions with relevant competences. In addition, SSM has a permanent advisory committee on research to ensure the scientific quality in SSM’s funding of external research projects.

SSM is established as a central administrative authority under the auspices of the Ministry of the Environment, with a Director General that is exclusively responsible to the Government according to principles laid down in the Government Agency Ordinance (2007:515). The Swedish Constitution (in the form of a fundamental law known as the Instrument of Government) protects SSM and other administrative authorities from ministerial governance, which is to say that they are ostensibly autonomous in terms of the exercise of their authority as well as in their decision making relating to the application of laws and regulations. Neither individual ministers, nor the Government at national or local level, are permitted to interfere with specific cases handled by SSM. There is also a functional separation between SSM’s reporting via the Ministry of the Environment, which determines the Authority’s budget and overall objectives, and the main objects of its regulatory supervision, which fall under the responsibility of other departments of the Government.

The Director General of SSM is supported by an advisory council consisting of a maximum of ten members appointed by the Government; this typically comprises members of the Riksdag, high-level agency officials or representatives of interest groups. In addition to providing advice, the council serves to provide public insight into the Authority’s activities.

## **1.4 Responsibility for Safety and Compliance with Regulations**

*Related to GSR Part 1 (Rev. 1): Requirement 5*

### ***GSR Part 2: Requirement 1***

#### ***Related to GSR Part 1 (Rev. 1): Requirements 5 and 6***

Sweden meets the expectations of this safety requirement through the wording of specific provisions in the Radiation Protection Act and the Act on Nuclear Activities. In particular, the provisions specify that:

- A person carrying out an activity with ionising radiation shall, to the extent necessary with respect to the nature of activity and circumstances in which it is conducted:
  - take measures and precautions to prevent or hinder damage to human health and the environment;
  - verify and maintain radiation protection in those places where radiation may occur;
  - properly maintain relevant technical devices as well as radiation measurement and protection equipment;
  - ensure that anyone who works in the business and may be exposed to ionising radiation has knowledge and understanding of the circumstances in which the work is undertaken, including relevant regulations and the risks involved, as well as the competence needed for radiation protection to function satisfactorily.
- Anyone who conducts, or has conducted, an activity with ionising radiation is responsible for ensuring that all associated radioactive waste is managed and, if necessary, disposed of in a manner acceptable from the perspective of radiation protection. This may involve the transfer of responsibility of such wastes to an authorised waste management organisation.
- The licence holder for a nuclear activity is responsible for the safety of that activity and for any measures necessary to maintain safety in operations, as well as with respect to safe management of nuclear wastes and decommissioning and dismantling of facilities.
- The licence holder for a nuclear activity must ensure that contractors and any sub-contractors have personnel with appropriate qualifications to fulfil the licence holder's obligations with respect to safety in respect of the work they are commissioned to undertake.

SSM is designated as the regulatory body under the Radiation Protection Act and the Act on Nuclear Activities with authorisation to require that these responsibilities are fulfilled and that compliance is demonstrated.

SSM is fully empowered under the Radiation Protection Act and the Act on Nuclear Activities to request information, to gain access to facilities and to issue prohibitions and injunctions, combined with financial penalties where appropriate, on matters relating to nuclear safety and radiation protection, with the aim of ensuring compliance with legal and regulatory requirements. It is punishable to conduct business without the necessary permits, to fail to follow SSM's instructions or prohibitions, or to violate regulations or any licence conditions that have been stipulated with regard to the fulfilment of responsibility for safety.

The stipulation of prime responsibility for the protection of human health and the environment, regardless of compliance with specific regulations and requirements, is made through instruments of primary legislation. General provisions under Chapter 2 of the Environmental Code (including, but not restricted to, activities involving ionising radiation) oblige anyone who conducts, or intends to conduct, an activity or take an

action, to be responsible for acquiring the knowledge necessary to protect human health and the environment from harm. More specifically, Chapter 3 of the Radiation Protection Act obliges persons carrying out activities with ionising radiation to take measures and precautions “as necessary” to prevent or hinder damage to human health and the environment, regardless of compliance with more specific regulations or other requirements established by SSM. Regarding nuclear activities, Section 10 of the Act on Nuclear Activities establishes general legal obligations on licence holders to “continuously and systematically” evaluate and, so far as is possible and reasonable, improve the safety of their activities and facilities, taking into account experience from operations (including related experience elsewhere) as well as advances in science and technology. Furthermore, Section 10a formally requires licensees to carry out periodic safety reviews of their facilities, with the prescribed aim of verifying that these general obligations, in addition to all other applicable legal and regulatory requirements, have been and will continue to be fulfilled.

## **1.5 Coordination of Authorities with Responsibilities for Safety within the Regulatory Framework**

### ***Related to GSR Part 1 (Rev. 1): Requirement 7***

The Swedish Government meets the requirement for effective coordination of the regulatory functions of different administrative authorities through the collective responsibility and decision making of the cabinet. This includes general instructions specifying the duties of individual authorities (expressed in separate government Ordinances for each authority) and annual appropriation directives (*regleringsbrev*), which specify the individual authorities’ budgets and provide operative directions relating to specific tasks and areas of responsibility. The latter may include, for example, specific instructions relating to collaboration should this be required. Furthermore, the general Government Agency Ordinance (2007:515) relating to the responsibilities of central administrative authorities requires (Section 6) that the Agencies shall work in cooperation with each other where necessary to the advantage of individuals and the state as a whole.

The Ordinances under the Act on Nuclear Activities and Radiation Protection Act establishes SSM as having the lead regulatory role with respect to nuclear safety and radiation protection. Furthermore, the Environmental Supervision Ordinance (2011:13) identifies SSM as having supervisory responsibility for radiation safety in respect of activities that are subject to permitting under the Environmental Code, where these activities relate to operations also covered by the Act on Nuclear Activities or the Radiation Protection Act. Fulfilment of SSM’s mandate requires cooperation with a range of other authorities and agencies, including:

- The Swedish Environmental Protection Agency on matters relating to national Environmental Quality Objectives as well as the implementation of Sweden’s obligations relating to under the Espoo Convention on environmental impact assessment in a transboundary context.
- The Swedish Civil Contingencies Agency (MSB) on matters relating to building civil capacity for emergency preparedness, including with regard to transport.
- The Swedish Work Environment Authority with regard to health and safety of workers.
- The National Debt Office on matters relating to cost estimates undertaken by licensees for nuclear decommissioning and waste management and matters relating to liability and compensation for radiological accidents.

- The County Administrative Boards in relation to the process of Environmental Impact Assessment for new facilities, as well as emergency planning and preparedness in relation to accidents involving release of radioactivity.
- The Swedish Meteorological and Hydrological Institute (SMHI) on matters related to emergency planning and preparedness in relation to accidents involving release of radioactivity.
- The Swedish National Grid with regard to questions of energy supply and protection from non-ionising radiation in relation to electricity transmission.
- The Police Authority in respect of potential criminal activity, as well as the supervision of road transport.
- The Swedish Customs Service on matters relating to the import and export of radioactive materials.
- The Swedish Transport Agency in relation to the supervision of transport of radioactive substances by rail, sea and air.
- The Coast Guard with respect to certain aspects of marine transport and handling of goods in port areas.

## 1.6 System for Protective Actions to Reduce Existing or Unregulated Radiation Risk

*Related to GSR Part 1 (Rev. 1): Requirement 9*

*GSR Part 3: Requirement 2, paragraph 2.26 and Requirements 47-49*

The Government has established an effective system for protective actions to reduce undue radiation risks associated with unregulated sources through provisions made in the Radiation Protection Act and supporting Radiation Protection Ordinance. In addition, certain provisions of the Environmental Code and the Civil Protection Act relate to responsibility for the remediation of all forms of environmental damage, including radioactive contamination. The system includes the following elements:

- Legal responsibilities placed on licence holders and practices subject to notification seek to minimise the potential for sealed radiation sources to fall outside of regulatory control.
- The finder of an orphan source is required to notify SSM immediately.
- SSM is responsible for the control and recovery of orphan sources, with financial resources for management and disposal being provided by the Government if a responsible owner cannot be identified.
- Where possible, recovered sources are submitted by SSM to Cyclife Sweden AB for treatment, conditioning and storage, pending final disposal.
- SSM is responsible for maintaining up-to-date records of activities in Sweden that handle NORM, and for assessing whether such activities may give rise to non-negligible exposures to employees or members of the public.
- SSM is also responsible for ensuring that there is an up-to-date national monitoring program for ionising radiation, and for identifying and evaluating any existing exposure situations where protective measures may be necessary.
- SSM has a supervisory responsibility under the Environmental Enforcement Ordinance for advising local and regional authorities on radiologically contaminated sites.

- For legacy situations, where no party can be identified as responsible for remediation of contaminated sites, the state has allocated funds under the administration of the Swedish Environmental Protection Agency.

A number of orphan sources are recovered each year but to date, no orphan high activity sealed sources have been found. The Government has also funded SSM to conduct a specific campaign (between 2016 and 2018) aimed at the collection, treatment and storage of radiation sources from disused industrial smoke detectors that had been incorrectly delivered to local recycling centres.

Legacy wastes from historic nuclear activities are managed by a not-for-profit company financed by the commercial reactor licensees.

As the designated responsible authority for protective actions against radiation risks associated with unregulated sources and contamination from past activities or events, SSM applies the principles of justification and optimisation as established in the Radiation Protection Act. This means that there is no difference in the optimisation of protection in relation to the management of orphan sealed sources, once they have been discovered, compared with other sealed sources. NORM, as well as contamination from past activities or events (for which SSM has a designated role as supervisory authority), is managed as an existing exposure situation, with associated requirements on the justification of protective actions and optimisation of radiation protection.

SSM meets the expectations of the IAEA Safety Requirements in respect of providing inputs to protective action through its designated role under Radiation Protection and Environmental legislation noted above. SSM has, for example, established regulatory requirements and criteria for the management of a disused uranium extraction facility and its ultimate release from regulatory control as a licensed nuclear site. Advice was also provided by SSM to the regional authority (the County Administrative Board) in relation to restrictions on future land use for parts of the industrial area. The National Food Administration continues to provide advice to the public in relation to the consumption of wild foods and game in areas that remain contaminated as a result of the Chernobyl accident. SSM has produced regulations relating to the management of contaminated ash (containing NORM or Chernobyl fallout) from the use of peat and wood as industrial fuels. SSM nevertheless considers that there is potential for improvement as regards coordination between administrative authorities and regulatory leadership on actions plans relating to elevated exposures to naturally occurring radionuclides (such as radon) in homes and workplaces.

## **1.7 Provisions for Decommissioning of Facilities and the Management of Radioactive Waste and of Spent Fuel**

*Related to GSR Part 1 (Rev. 1): Requirement 10*

*GSR Part 3: Requirements 2 and 31*

*GSR Part 5: Requirements 1, 2 and 6*

*SSR Part 5: Requirement 1*

*GSR Part 6: Requirements 4 and 5*

Sweden meets IAEA's expectations regarding provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste, and the safe management of spent fuel through specific provisions of primary legislation that relate to responsibilities for radioactive waste management. Under the Radiation Protection Act,

the operator of a facility where activities with ionising radiation have ceased shall undertake the measures necessary to release any contaminated structures and areas from regulatory control. Licensees under the Act on Nuclear Activities bear responsibility for the safe decommissioning and dismantling of their facilities, under the supervision of SSM.

The licence holder for a nuclear activity, and the operator of any activity involving ionising radiation, is responsible for the safe management and disposal of spent fuel and radioactive waste from their activities. The licensees of nuclear power plants bear responsibility for developing and implementing a programme for the safe management and final disposal of spent nuclear fuel and radioactive waste from the nuclear power plants. The programme developed by the licensees and their implementing organisation, The Swedish Nuclear Fuel and Waste Management Company (SKB), takes account of the diversity between different types of waste and their radiological characteristics. Furthermore, it is expected that this programme should also accommodate the disposal of radioactive wastes from other activities, where specific disposal measures are required. The state bears ultimate responsibility for the final management of spent nuclear fuel and radioactive waste, in the event that a licensee is unable to fulfil their obligations.

In accordance with Article 12 of Council Directive 2011/70/Euratom, the Government has assigned responsibility to SSM for ensuring that there is a current national plan for the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent nuclear fuel.

The legal framework in Sweden distinguishes between landfill facilities for short-lived, low-level wastes and geological disposal facilities for more active types of waste. The former have been developed on existing nuclear sites, and their final closure will be associated with the completion of licensed activities on the site. At such a time, the licensee has to apply to SSM for the clearance and release of remaining building structures and the area I. If it is deemed appropriate, this may be coupled with advice to the regional authority (the County Administrative Board) with regard to restrictions on future land use in the vicinity of the landfill. Closure of geological disposal facilities requires permission from the Government in accordance with the Act on Nuclear Activities, whereupon specific conditions will be set for releasing the operator from its responsibilities as a licensee. At this point responsibility for the geological repository and the waste that it contains will pass to the state and the Government can then instruct one or more authorities to take any institutional control measures that may be deemed necessary at that time.

Specific arrangements for the funding of decommissioning and nuclear waste management are defined in the Act on Financial Measures for the Management of Residual Products from Nuclear Activities. Costs for the management and disposal of spent nuclear fuel and radioactive waste from NPPs shall be covered by revenues from the production of energy that has given rise to these costs. Cost estimates are reviewed every three years by the Swedish National Debt Office, which then proposes to the Government the scale of the fees to be paid by licensees into the Nuclear Waste Fund, together with the required financial guarantees. These obligations remain in force until all necessary measures have been performed, even if the licence for the nuclear activity is no longer valid. Producers of radioactive waste other than NPPs shall provide financial securities for the waste management costs and any recovery measures that the activity may incur.

The Act on Nuclear Activities requires the utilities that operate nuclear power reactors, in cooperation, to develop and implement a programme for safe management and disposal of spent nuclear fuel and nuclear waste and for safe decommissioning of nuclear power plants, which includes the Research, Development and Demonstration ('RD&D programme') that is necessary for the programme. Every three years, on the behalf of the operators, SKB submits a report on this programme to the regulatory authority for review. SSM invites a large number of interested parties to comment on the report. The report is to include an overview of all measures that may be necessary and must specify the actions to be taken within a period of at least six years. Based on SSM's review recommendations, the Government approves or rejects the general direction of the continued programme. In connection with the decision, the Government may also issue conditions on the content of future research and development work.

The Swedish government commissioned from SSM in 2021 a report with analysis of the current division of responsibilities for certain historic wastes from both nuclear and non-nuclear activities and the extent to which the costs for their final management fall on different actors (SSM2021-3243). This matter is currently being prepared by the Government Offices.

## **1.8 Competence for Safety**

### ***Related to GSR Part 1 (Rev. 1): Requirement 11***

The Swedish Government makes provision for building and maintaining the competence of all parties that have responsibilities in relation to the safety of facilities and activities in three main ways:

- By establishing legal obligations relating to competence for safety on persons carrying out activities with ionising radiation and licence holders for nuclear activities.
- By providing basic funding for universities, higher education and research institutions.
- By appointing SSM as the responsible authority for building and maintaining the competence that is needed today and in the future for nuclear safety and radiation protection, including taking the initiative for necessary research and education as well as external analysis and development needs. In particular, SSM has been required through its appropriation directives to undertake investigation and analysis of long-term competence needs and progress with strategic initiatives on competence and research management.

Legal obligations regarding competence that concern parties responsible for a facility or activity are linked to the question of prime responsibility for safety. They are expressed in general terms in the Environmental Code (responsibility to acquire the knowledge necessary to protect human health and the environment from harm), and more specifically with regard to the need for appropriate qualifications for radiation protection and nuclear safety in the Radiation Protection Act and the Act on Nuclear Activities. Parties are also responsible for ensuring there are financial, administrative and human resources sufficient to fulfil legal obligations or those arising from regulations or decisions issued under the legislation. Particular obligations on nuclear power plant licensees are also prescribed under the Act on Nuclear Activities for establishing a programme for the comprehensive research and development activities and other measures necessary for the safe

decommissioning of their installations and the safe management and disposal of spent fuel and nuclear waste.

Funding provided to SSM for research (approximately 80 million SEK per year) is, according to the Ordinance with Instructions for SSM, a mechanism for the Government to support SSM in developing national competence of importance for the fields of radiation protection and nuclear safety. This, in turn, is designed to ensure that SSM has the knowledge and tools needed to carry out effective regulatory review and supervisory activities. Even resources from the Nuclear Waste Fund (approximately 9 million SEK per year) are used by SSM to fund scientific research relevant to regulatory work and support competence building.

The Government's responsibility for funding of basic university training is supplemented by research funding provided via SSM's annual budget, as well as by sponsorship from nuclear power plant licensees and Westinghouse Electric Sweden AB. On the basis of this support, the universities have established the Swedish Centre for Nuclear Technology (SKC) and the Centre for Radiation Protection Research (CRPR). Training provided via these research programmes benefits the competence of both operators and SSM.

SSM has carried out a series of investigations on behalf of the Government over the last decade relating to competence development and research management for radiation protection and nuclear safety. In September 2018, SSM submitted a report on national long-term competence needs in the field of radiation safety, making suggestions regarding improved coordination of knowledge management, strengthened funding of critical core research environments and training programmes with particular importance to nuclear safety and radiation protection. One result of this has been a substantial increase in research funding via SSM into the SKC, as well as new additional funding from the Swedish Research Council and the Swedish Foundation for Strategic Research. A national platform for co-operation and coordination on issues relating to competence building and research management, involving representatives from industry, universities, public authorities and the healthcare community, was established in 2017. The platform is chaired and administered by SSM.

More recently (February 2022), SSM has within its assignment from the Government, completed a new report relating to progress in the development of national competences. The report notes challenges with respect to recruitment relating to the use of radiological equipment in the medical field, where demand for competent personnel is expected to increase nationally, while funding for training is primarily administered by authorities at a regional level. The assessment also confirms a continued need for a strengthened national governance and for more concerted strategic actions in relation to competence and research management in the field of radiation protection and nuclear safety.

The Swedish government has mandated SSM to establish specific regulatory requirements with respect to the general provisions of primary legislation regarding competence in radiation protection and nuclear safety matters, including the competence of contractors working at the facilities. According to these regulations (Chapter 3 SSM's regulations (SSMFS 2018:1) concerning basic provisions for licensable activities involving ionising radiation), those responsible for an activity with ionising radiation shall ensure that those who work in the business have the necessary competence and are generally suitable to carry out work tasks that are important for radiation safety. Required competences, as well as those available to the business, shall be systematically identified

and documented. Training and any other measures shall be taken to achieve and maintain the necessary skills. The business must have access to a radiation protection expert function that is appropriate to the nature and scope of the activity, and reports to senior management. The expert with this function must meet criteria established by SSM and shall be approved by the authority.

For nuclear facilities, SSM's regulations identify the central role played by the radiation protection manager (*strålskyddsföreståndare*) at the facility and their responsibility for ensuring that competence and resource issues relating to radiation protection are monitored (SSMFS 2008:24). Among their identified roles, the radiation protection manager ensures that all personnel with access to active areas of the facility have received appropriate training and that such training is regularly updated. The radiation protection manager and their deputy must be approved by SSM.

The Swedish Government's overall approach to equipping SSM with sufficient resources to fulfil its statutory obligations provides the means for the Authority to establish budgets for, inter alia, the recruitment and retention of employees, the procurement of expert support services, and the training and competence development of staff. SSM has no specific government-appointed Technical Support Organisation (TSO); instead, the Authority has two departments serving as an in-house TSO providing expertise to the rest of the organisation within the areas of radiation protection, environmental assessment and plant safety assessment. Furthermore, the Authority supports research projects and positions at Swedish universities, as well as procuring necessary specialist expertise for analysis where this is required. The annual budget supports SSM's internal training programs, Competent Employee and Competent Supervision, to support the discharge of its responsibilities, while time is set aside each year for every employee to participate in these and other activities relating to skills development. By Government instruction, the Director General appoints members of permanent advisory committees to support the Authority on reactor safety, as well as on the safe management of spent fuel and radioactive waste. SSM also has a permanent advisory committee on research, with the aim of ensuring the scientific quality of its external research projects.

SSM's supervisory role under its mandate from Government includes inspection of operators' compliance with requirements specified in primary legislation, relevant regulations and decisions made with the support of legislation. This naturally includes inspection of responsible person's fulfilment of requirements related to competence management and skills development in relation to employees and the procurement of support services, as part of its focus on human factors engineering (*människa, teknik, organisation*). SSM conducts inspections with a periodicity determined by its risk-informed inspection programme and periodically summarises findings relating to all aspects of compliance in an overall assessment of radiation safety (Integrated safety assessment (SSV) - *samlad strålsäkerhetsvärdering*), either for individual licensees (in the case of nuclear licensees or other major installations) or on a branch basis (for smaller-scale activities involving ionising radiation). Verification and approval of technical competences (as noted above) is also an integral part of SSM's authorisation process for activities and facilities.

## **1.9 Provision of Technical Services**

*Related to GSR Part 1 (Rev. 1): Requirement 13  
GSR Part 3: Requirement 2, paragraph 2.23*

The Swedish Government has assigned to SSM responsibility through its Ordinance with Instructions to SSM covering coordination of environmental monitoring of radioactivity and reporting on the environmental quality objective of a safe radiation environment. The national monitoring network consists of 28 monitoring stations for external gamma dose, while there is a denser network of 30 monitoring stations in each of the three counties where nuclear power plants are located. SSM also conducts environmental sampling and measurements, partly at its own radioanalytical laboratory, partly through procurement of the services of other organisations.

The Swedish Government has no need to make provision for personal dosimetry services. Services for personal dosimetry are provided commercially by private companies or within the organisations responsible for facilities and activities (e.g. major nuclear facilities, hospitals). Whole body counting systems are in operation at the majority of nuclear facilities and some other institutions. SSM maintains a national register of the doses received by workers in connection with activities involving radiation.

SSM is designated by the Government as the National Metrology Laboratory (*Riksmätplats*) for measurements of ionising radiation. The Laboratory calibrates instruments and provides Sweden with traceability for measurements of the dosimetric quantities. Personal dosimeters used by category A workers (expected to receive an annual radiation dose of more than 6 mSv) must be approved by SSM according to a process established in SSM's regulations.

## 1.10 Conclusions

Sweden has established a clear and efficient framework for safety. Swedish legislation states the responsibilities of parties carrying out activities involving radioactive materials and also establishes SSM as an effective independent regulatory body. The conclusion of the self-assessment is that it shows good overall compliance with the requirements formulated in the IAEA's standards.

Sweden meets all requirements in GRS Part 1 (Rev. 1). The outstanding recommendation from 2012 and 2016 regarding national competence supply is included in ongoing strategic activities. A development takes place continuously, which means that Sweden, based on identified conclusions, has landed in some appropriate recommendations and actions.

Sweden has a well-established system or plans for the safe management of radioactive waste from most of the nuclear area. Corresponding requirements for common solutions for disposal and final repository do not exist for radioactive waste originating from non-nuclear activities. Responsibility for the safe handling and, if necessary, disposal of radioactive waste from non-nuclear activities, undertaken in accordance the Radiation Protection Act, lies with those authorised to carry out the activities.

A fundamental idea in the "Swedish waste system" is that the authorised actors should resolve their obligations themselves through commercial solutions. However, there is currently only one company in Sweden, Cyclife Sweden AB, which has the skills and resources necessary to treat and store radioactive waste from non-nuclear waste producers. Furthermore, there is only one company, SKB, which is authorised to dispose of radioactive waste, whether from nuclear or non-nuclear waste producers. Neither Cyclife

nor SKB are legally obliged to provide management and disposal services for all non-nuclear waste.

There remain uncertainties with regard to the actors' ability to fulfil their long-term responsibility for all low- and intermediate-level radioactive waste that arises in society. This is particularly the case for certain novel and problematic wastes, as well as for activities that are projected to continue long into the future, where the route for final disposal, and associated costs, may be uncertain.

Sweden has a need for long-term sustainable solutions for the management of non-nuclear-related radioactive waste.

# Module 2: Global Nuclear Safety Regime

## 2.1 International Obligations and Arrangements for International Cooperation

### *Related to GSR Part 1 (Rev. 1): Requirement 14*

The Swedish Government fulfils its international obligations by being contracting party to conventions and participating in peer reviews and other relevant arenas to promote international cooperation to enhance safety globally. The execution of Sweden's international affairs in the fields of safety and security is delegated to SSM to a large extent.

According to the Ordinance with Instructions to SSM (2008:452) the Authority shall promote radiation safety in society and in its activities work towards strengthening radiation safety internationally.

Within SSM, the department of International Policies and Co-operation coordinates the international obligations and activities. The main guideline for this work is SSM's Policy for EU and International Assignments (STYR2020-10). The policy outlines objectives and priorities for the Authority's international work. A strategy for international cooperation will be developed during 2022.

As a member of the European Union, Sweden is obliged to implement the EU legislation including the Nuclear Safety Directive, Radioactive Waste and Spent Fuel management Directive and the Basic Safety Standards (BSS) Directive. In this respect, Sweden collaborates with other EU members in various expert groups.

Sweden participates in several initiatives to enhance nuclear safety and radiation protection internationally, including research programs and collaborations. According to the Ordinance (2008:452 section 13), SSM shall, within its area of operation, participate in the work pursued by the Swedish Government within the European Union and internationally. Additionally, SSM participates in the International Nuclear Regulators Association (INRA), which is a worldwide network for nuclear regulators. SSM also participates in the Western European Regulators Association (WENRA) and Heads of the European Radiological Protection Competent Authorities (HERCA), which are collaborations between European regulators in the areas of nuclear safety and radiation protection, respectively. Furthermore, SSM is part of the Nordic network between radiation safety authorities.

### International Conventions

Sweden is contracting party to the following conventions related to areas within the IRRS scope:

- Convention on Nuclear Safety (CNS)
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (JC)
- Convention on Early Notification of a Nuclear Accident

- Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency
- Convention on Physical Protection of Nuclear Material and its amendment (A/CPPNM)
- Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)
- Convention on the Protection of the Marine Environment of the Baltic Sea Area (HELCOM)
- Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (London Convention)
- Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (London Protocol)
- Convention on access to information, public participation in decision-making and access to justice in environmental matters (Aarhus-convention)
- Convention on Environmental Impact Assessment in a Transboundary Context (Espoo-convention)
- Radiation Protection Convention (convention concerning the protection of workers against ionising radiation), ILO

Furthermore, Sweden is a contracting party to the following treaties related to areas within the IRRS scope:

- Treaty on the Non-Proliferation of Nuclear Weapons (NPT)
- EURATOM

SSM is obliged to participate at all safeguard inspections conducted in Sweden by the IAEA (governmental decision M2009/147/Mk). Since 2015 the IAEA have conducted 30-50 inspections per year in Sweden.

### Codes of Conduct

The Swedish Government has made political commitment to the Code of Conduct<sup>1</sup> on the Safety and Security of Radioactive Sources (IAEA/CODEOC/2004) and the two supplementary guides, the Guidance on the Import and Export of Radioactive Sources (IAEA/CODEOC/IMO-EXP/2012) and the Guidance on the Management of Disused Radioactive Sources (IAEA/CODEOC/MGT-DRS/2018). The Code of Conduct and its supplementary guidance are non-legally binding. However, by the undertaking Sweden ensures State adherence to the Code of Conduct and this requires the regulatory authority to take the Code of Conduct into account when reviewing and revising regulations.

SSM regularly participates in the information sharing process on the Code of Conduct organised by the IAEA.

### IAEA safety standards

SSM and the Government continuously monitor the publication of IAEA safety standards. When developing SSM regulations, requirements and guides, the IAEA safety

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<sup>1</sup> [www.iaea.org/topics/codes-of-conduct](http://www.iaea.org/topics/codes-of-conduct)

standards are one of the main bases and SSM participates actively in the IAEA safety standards commission (CSS) and its committees (NUSSC, WASSC, RASSC, TRANSSC, EPRESC and NSGC). Representatives from Sweden also participate in the development of the IAEA Safety Standards and Guides on other levels in the IAEA system.

It should be noted that in some cases, the transposition of Euratom Directives indirectly requires consideration of IAEA standards.

### International Peer Reviews

Sweden regularly requests international peer review services. The latest IRRS mission to Sweden was conducted in 2012 with follow-up in 2016. The Swedish Government has requested an ARTEMIS mission in 2023. This will be the first ARTEMIS conducted in Sweden. In 2012, an IPPAS mission was conducted in Sweden with follow-up 2016. In addition, an number of missions have been hosted by the licensees; SALTO missions have been performed at all NPPs in operation, OSART missions have been performed to all NPPs, Knowledge Management Assist Visit (KMAV) to Ringhals NPP and WANO peer review missions at all NPPs. Ringhals unit 1 and 2 have preliminary dates for a IAEA Independent Safety Culture Assessment (ISCA) scheduled in the fall of 2022.

The experience gained through missions carried out in Sweden are used by Swedish experts when they participate in and contribute to assignments in other states. Experts from SSM, as well as from Swedish licensees, regularly take part in IAEA service missions such as IRRS, ARTEMIS, IPPAS, OSART, ORPAS, SALTO and OSART missions in other IAEA member states. For the past ten years, SSM has participated in a number of IRRS missions and their follow-ups. SSM is committed to participating in approximately 10 missions yearly, mainly IRRS but also other missions on request and in discussion with the IAEA.

SSM hosted a five-day IRRS training course for the Nordic countries in February 2018, with 23 experts participating from SSM. The training was organised and conducted by the IAEA at the offices of SSM. The programme was organised in the form of a fictitious mission with 33 persons participating in the training.

### Non-proliferation and control of nuclear material

Sweden has offered through the Member State Support Programme to the IAEA, several training courses for IAEA inspectors at Swedish nuclear facilities. This includes courses in spent fuel verification, verification of bulk handling facilities as well as field courses in satellite analysis.

### Nuclear Energy Agency

Sweden has been a member of the Nuclear Energy Agency since its formation in 1958. SSM is actively taking part in committees and working groups with the aim of fostering international co-operation in nuclear safety and radiation protection. Through participation in the Committee on the Safety of Nuclear Installations, SSM contributes to international exchange of technical information, to the promotion of collaboration between organisations involved in safety research, to the exchange of operating

experience, and to the establishment of joint research programmes. Through participation in the Committee on Nuclear Regulatory Activities, SSM takes active part in cooperation amongst member countries on key regulatory issues, including feedback of experience from events and safety improving measures.

Sweden promotes international cooperation in fuel safety research by hosting the OECD/NEA SCIP Joint Project (Studsvik Cladding Integrity Project).

## ICRP

The International Commission on Radiological Protection was founded in 1928 with Sweden being one of the co-founders. For decades, the Swedish Authority frequently occupied posts such as ICRP chair or technical secretary. While the Authority is not influential in the same sense as before, Sweden continues to support ICRP financially, thus recognising ICRP's decisive role in forming the international system of radiation protection. SSM participates to the extent possible in ICRP's open consultations, workshops and symposiums in order to enhance radiation protection both on the international and national level.

## UNSCEAR

Sweden is a member of United Nations Scientific Committee on the effects of Atomic Radiation (UNSCEAR) since 1955 and participates actively in the work. Sweden contributes to the surveys performed by UNSCEAR on medical, occupational and public exposure. This includes reporting of exposure data as well as taking active part in the UNSCEAR evaluation of levels and trends of radiation exposure and their effects and risks to human health and to the environment.

## Support programs to former Soviet Union member states in Eastern Europe

Since the early 1990's, Sweden has been actively engaged in international efforts to strengthen and assist regulators in former Soviet Union member states in eastern Europe, in order to ensure that radioactive and nuclear materials, as well as facilities and installations, are kept safe and secure. Over time, these efforts have grown into long-standing bilateral and multilateral engagements covering training in the nuclear security and non-proliferation area, environmental monitoring, cooperation on nuclear safety, decommissioning and waste management, and more. Sweden has ceased all support programs to Russia and Belarus since February 28 due to the Russian invasion of Ukraine. Sweden is still engaged in bilateral projects in Ukraine, Moldova and Georgia. These collaborations are conducted under several international frameworks, established at UN or EU level, but also within the Nordic cooperation and bilateral agreements, with the overarching aim to strengthen the radiation safety and security globally.

## Bilateral and multilateral agreements

Sweden is part to formal bilateral and multilateral agreements as listed below (for more details see STYR 2011-102). Sweden has ceased all cooperation with Russia and Belarus since February 28.

*Australian Safeguards and Non-Proliferation Office, Australia*

Administrative arrangements on conditions and controls for nuclear transfers for peaceful purposes.

*Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), Australia*

Exchange of technical information and cooperation in radiation protection and nuclear safety.

*Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (BMU), Germany*

Agreement on division of responsibilities for regulations regarding security of transboundary shipments of nuclear fuel

*Canadian Nuclear Safety Commission (CNSC), Canada*

Cooperation and exchange of information in nuclear regulatory matters.

*Nuclear Regulatory Authority (NRA), Japan*

Memorandum of understanding for information exchange.

*State Nuclear Power Safety Inspectorate (VATESI), Lithuania*

Agreement on early notification of nuclear and radiological emergencies

*The State Committee for the Supervision of Nuclear and Radiation Safety, Russia*

Agreement on guidelines for early exchange of information regarding nuclear facilities

*The State Committee for the Utilisation of Atomic Energy, Russia*

Agreement on security requirements for transboundary shipments of nuclear fuel

*State Enterprise National Nuclear Energy Generation Company (Energoatom), Ukraine*

International cooperation program, the agreement ended 2021, but work on renewing the agreement has started.

*State Nuclear Regulatory Inspectorate of Ukraine*

Agreement on co-operation in the field of nuclear safety and radiation safety.

*Environmental Protection Agency (EPA), USA*

Memorandum of understanding on exchange of information on radiation protection, especially with regards to environmental regulations and radioactive waste

*Nuclear Regulatory Commission (USNRC), USA*

Agreement for exchange of technical information and cooperation in the regulation of nuclear safety

*Department of Energy of the United States of America (DOE), USA*

Statement of intent regarding emergency nuclear and radiological incident response and management capabilities

*Office for Nuclear Regulation (ONR), Great Britain*

Arrangements for the exchange of information and co-operation in the area of regulation of safe nuclear energy use for peaceful purposes.

*Joint Stock Company “Rosenergoatom”, Russia*  
Agreement on Project co-operation.

*The Legal Entity of Public Law, Radiation Safety Agency of Georgia*  
Memorandum of understanding for cooperation in Nuclear and Radiation Safety and Security matters.

*Rosatom, Russia*  
Protocol on implementation of actions following from obligations agreed between Sweden and Russia regarding early notification of nuclear safety and emergencies, and on information exchange regarding nuclear installations.

*Autorité de Sureté Nucléaire (ASN), France*  
Framework for co-operation on Nuclear Safety and Radiation Protection Regulation.

*State Agency of Ukraine on Exclusion zone management (SAUZEM), Ukraine*  
Agreement on Co-operation in the Field of Nuclear Safety and Radiation Protection.

*Nuclear Safety and Security Commission (NSSC), South Korea*  
Memorandum of understanding for cooperation and exchange of information in nuclear regulatory matters.

*Women in Nuclear, Ukraine*  
Agreement on Co-operation.

*Euratom and Ukraine*  
Agreement on early exchange of information regarding nuclear facilities and nuclear accidents

*Statement on Nuclear Safety and Security Cooperation between Norway, Ukraine and Sweden*  
The Norwegian Radiation Protection Authority, the State Nuclear Regulatory Inspectorate (SNRIU) of Ukraine and SSM

*Memorandum of Understanding on Cooperation and Information exchange*  
SSM (Sweden), NRPA (Norway), STUK (Finland), and the Ministry for Emergency Situations of the Republic of Belarus.

*Cooperation regarding exchange of information and assistance between Nordic authorities in nuclear or radiological incidents and emergencies*  
Cooperation regarding exchange of information and assistance between Nordic authorities in nuclear or radiological incidents and emergencies. Danish Emergency Management Agency (Denmark), National Institute of Radiation Hygiene (SIS, Denmark), Radiation and Nuclear Safety Authority (Finland), Geislavarnir Ríkisins (GR, Iceland), Norwegian Radiation Protection Authority (NRPA, Norway)

*ESARDA, The European Safeguards Research and Development Association, agreement*  
(JRC Ref. No. 22613-2004-12 SONEN ISP BE).

## 2.2 Sharing Operating and Regulatory Experience

*Related to GSR Part 1 (Rev. 1): Requirement 15*

### Event reporting, analysis and dissemination of operating and regulatory experience

All unplanned events of radiological importance shall be reported to SSM according to the Radiation Protection Ordinance (2018:506 Chapter 8 Section 9). SSM is obliged to disseminate lessons learned from such events to licensees and to manufacturer and suppliers of radiation sources (2018:506 Chapter 6 Section 9).

SSM's regulations concerning basic provisions, Chapter 2 Section 16 SSMFS 2018:1 require licensees to establish processes within their management system for appropriate dissemination of lessons learned in other organisations. If the licensees do not implement lessons learned, SSM notifies the licensee, and requires measures to be taken as appropriate. In addition, Chapter 2, Sections 5 and 20 SSMFS-D, contain more detailed requirements for NPP's in operation.

Chapter 3 Sections 18-19 in SSMFS 2018:1 specifically requires licensees to take appropriate corrective actions in order to prevent the reoccurrence of safety significant events. Furthermore, Chapter 9, Sections 1-3 in SSMFS-D requires the NPP in operation to report these actions to the regulatory authority.

SSM use the International Nuclear Event Scale for the classification of nuclear and radiological events and has a designated INES National Officer. SSM share information on events rated at Level 2 and above and other events attracting international public interest through the Nuclear Events Web-based System (NEWS).

### Nuclear facilities

All licensees have to report to SSM events and conditions, which are of importance to safety. For nuclear power plants in operation reporting is done according to Chapter 9, Sections 1-3 in SSMFS-D and for other nuclear facilities, according to Chapter 7, Sections 1-3 in SSMFS 2008:1. Further, the events have to be classified by the licensee according to Appendix 1 in SSMFS-D or to Appendix 1 in SSMFS 2008:1, respectively. The report shall include the safety significance of the event and a root cause analysis. SSM receives about 200 event reports from the nuclear facilities each year.

The process used for analysis of the reported events for nuclear power plants in operation is described in a documented routine in SSM's Management System (STYR2011-151). The analysis group meets biweekly and involves participants from different fields of expertise. The analyses are mainly dealing with operational experience, but regulatory implications of the events are also handled. The group reviews the analysis and the conclusions of the licensee, informs relevant parts of SSM organisation and gives recommendations to the organisation about actions that should be taken. Selected international events are also handled by the group, which decides if SSM should send information notices or in some cases demand actions from the licensees due to the actual

operating experience. Some of the national events are selected to be reported to the international OECD/NEA IRS system.

Regarding international events, SSM participates in international meetings and conferences in order to gain and share information. SSM representatives participate in IAEA meetings at all levels and in OECD/NEA activities, in particular in Working Group on Operating Experience (WGOE). Sharing of information also takes place by providing and extracting data from IAEA and NEA databases or event reporting networks. One important element in all these forums is to share experiences and lessons learned as well as to disseminate good practices from national experiences.

The accident in Fukushima Dai-ichi in 2011 can be mentioned as an example of how international experience have made a large impact in terms of actions that have been completed by the licensees. However, there are other examples of minor safety significance experiences, which have been shared as an information notice to the licensees, for example a trend of events all caused by degraded diodes. Until then, the licensees had not looked at the diode as being a component with ageing issues. An event at Ringhals 2 in 2014, Corrosion in the Bottom Steel Liner of the Containment, can be mentioned as another example. The information on this event was disseminated nationally and internationally, and all Swedish licensees were asked to report to SSM on the situation in the plants in light of the incident in Ringhals.

Chapter 2 Sections 18-19 in SSMFS 2018:1 specifically requires licensees of nuclear facilities to take appropriate corrective actions in order to prevent the reoccurrence of safety significant events. The regulations also require licensees to report these actions to the regulatory authority, with reporting procedures according to Chapter 9, Sections 1-3 in SSMFS-D.

SSM disseminates lessons learned from operation of NPP's within the organisation – and internationally as member of OECD/NEA IRS system and the OECD/NEA CNRA working group on operating experience. Furthermore, the licensees themselves are responsible for disseminating lessons learned and they all have access to the OECD/NEA IRS system. The licensees have their own organisations for handling lessons learned by national and international organisations.

SSM management meets with the management groups of the licensees for nuclear facilities on a regular basis. Meetings with nuclear power plant management groups take place on a yearly basis while meetings with management of licensees for fuel cycle facilities take place every two years.

There is also a system established for regular meetings with the nuclear industry related to radiation protection matters. These meetings are important for exchange of information between involved parties and an important channel for dissemination of feedback of experience and lessons learned. SSM and the Swedish NPPs are members of the Information System on Occupational Exposure (ISOE) and the licensees share dose reduction information, operational experience and information to improve the optimisation of radiological protection at nuclear power plants.

## Non-nuclear facilities and activities

All unplanned events reported to SSM are analysed within a designated analysis-group and published on the SSM web site if judged to be of interest for others. The process for reporting and analysis of events and the dissemination of lessons learned for medical and dental practises is described in STYR2011-166. However, for other practises similar processes and routines are under development.

SSM used to arrange meetings with the medical physicists community, where almost all licensees were represented. Unplanned events were usually one of the topics, with respect to the procedures and handling (criteria for reporting, investigation of what happened) rather than the presentation of real cases. Examples of the latter are the serious incidences that occurred in France in radiation therapy in the early 2000's, which were presented at the national conference on patient safety arranged by the public health care providers.

SSM is represented in the European ALARA Network (EAN), which is an effective forum for the dissemination of good ALARA practice and lesson learned concerning radiation protection.

## International cooperation

SSM devotes a considerable portion of its resources to participation in international meetings and conferences in order to gain and share information. SSM representatives participate in e.g. IAEA meetings at all levels and in OECD/NEA activities. One important element in all these forums is to share experiences and disseminate any good practices from national experiences.

Other important forums for experience feed-back activities are the International Nuclear Regulators Association (INRA), the recurrent review processes under the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management as well as various forums within the European Union, e.g. the work performed in ENSREG (European Nuclear Safety Regulator group). It is also worth mentioning the work performed within the Article 31-expert group (including subgroups) under the Euratom Treaty. Based on feedback of experience the group contributes to the development of EU directives and recommendations within specific areas of responsibility of the Authority. Sharing of experience and best practices is also an essential part of the work in regulator networks such as WENRA (Western European Nuclear Regulators' Association), HERCA (Heads of European Radiation Protection Competent Authorities) and the Nordic cooperation in radiation safety.

The department of International Policies and Co-operation, consisting of a number of Senior Advisors, is responsible for the coordination of SSM's international co-operation. The senior advisors evaluate the overall effects of international cooperation, based on input from the organisation. They also coordinate SSM's international work and constitute the prime contact point with some major international bodies, for example IAEA, EU, and OECD/NEA.

SSM's management system contain a number of documents that support international cooperation. Exchange of information and lessons learned play an important role and are

a prerequisite for the authority work in the international field, see for example the following documents:

- STYR2020-10 Policy for EU and International Assignment
- STYR2011-143 International meetings including a list of participation in international activities. Activities are classified according to their formal importance and the list is used for prioritising purposes. It gives an indication of the extent of SSM participation in international activities. The list is reviewed and up-dated on a yearly basis.
- STYR2011-64 Convention Assignments
- STYR2011-102 International Agreements

### SSM's structure for lessons learned

SSM's management system does not contain any specific process for improving processes, practices or requirements. Instead, there are in most processes/documents a specific element addressing feedback of experience and lessons learned from that particular process. However, there is a specific process (STYR2011-42) governing internal audits. The main objective with this process is to verify that the management system is appropriate, and strive for continuous improvements. In addition, every process owner is responsible for handling deviations and suggestions from users.

In addition, the procedure for international meetings (STYR2011-143) requires SSM staff to summarise participation in international meetings in travel reports and make them available to others. The document also contains guidance on feed-back of experience from SSM representatives' participation in international activities.

There is no formalised overarching process for making information of lessons learned available to other national and international stakeholders. However, in some areas, such as NPP, medical and dental practices more detailed routines exist. For 2022 and onwards there is a plan to review the main processes in order to further enhance and develop procedures. This include clear steps for gathering and dissemination of lessons learned.

## 2.3 Conclusions

Sweden has signed and ratified a number of convention and treaties. SSM's work in the field of international cooperation is based on the Ordinance (2008:452) with Instructions for SSM, which stipulates that the Authority shall work towards strengthening radiation safety internationally. As a result, SSM has signed bilateral co-operation and information exchange agreements with several countries and SSM participates actively at various levels in the international arena. Furthermore, routines governing SSM's participation in international work have been drawn up and the prerequisites for responsibility have been defined.

Internationally, experience is shared both by means of reporting to various databases as well as through various international meetings and conferences. Information to licensees is provided as necessary and usually in connection with meetings or surveillance inspections. There is no formalised process for making information about lessons learned available to others, except as information given as feedback to licensees from inspections

and reviews of licensees' activities. The quality of safety work could be improved if a more strategic and systematic approach was applied. SSM should consider strengthening its routines for the dissemination of international experience and reports in Sweden.

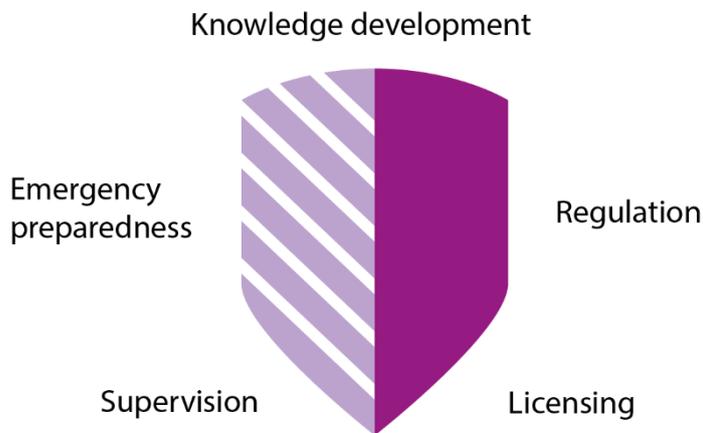
The conclusion of the self-assessment is that it shows good compliance overall with the requirements formulated in the IAEA's standards.

# Module 3: Responsibilities and Functions of the Regulatory Body

## 3.1 Organisational Structure of the Regulatory Body and Allocation of Resources

### *Related to GSR Part 1 (Rev. 1): Requirement 16*

SSM's organisational structure is derived from its roles and responsibilities as assigned by the Government, see Figure 4 and Figure 5. The organisational structure effectively separates the Authority's regulatory decision-making with respect to policies and regulations, inspection and enforcement and its licensing and authorisation work in three separate divisions.



*Figure 4 – SSM's mission and areas of responsibility within radiation safety*

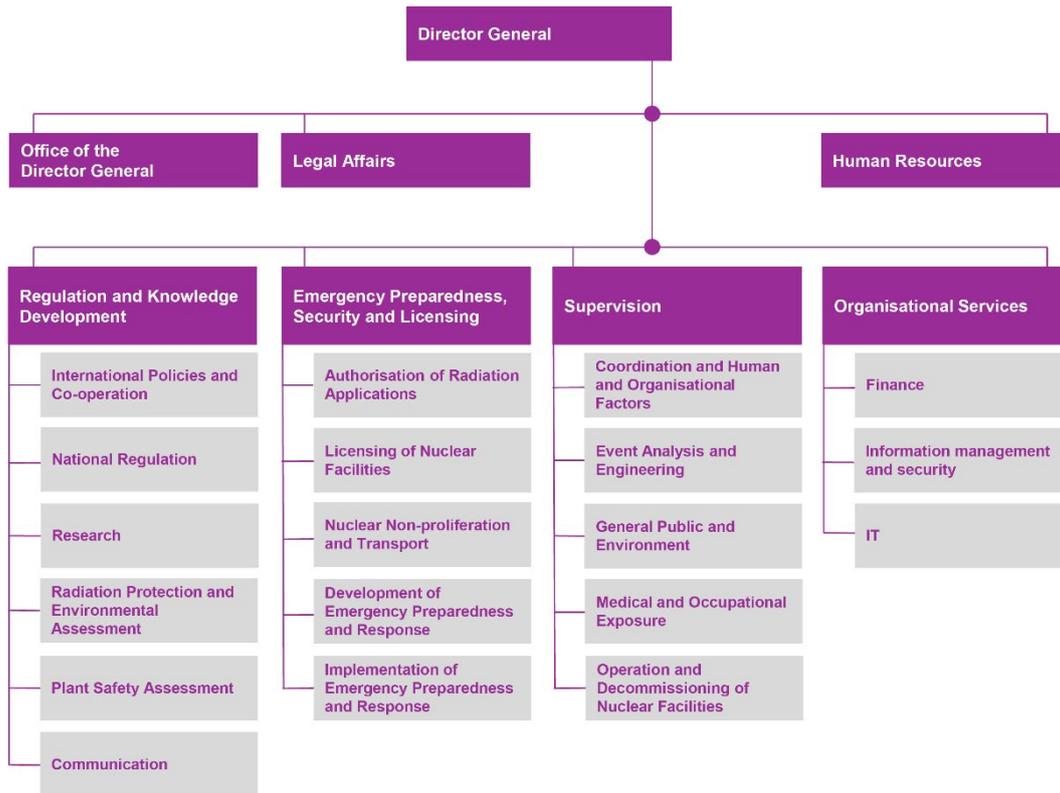


Figure 5 – SSM’s organisation

SSM has established a regulatory framework, which enable it to discharge its responsibilities and perform its functions effectively in a manner commensurate with the radiation risks associated with facilities and activities. SSM is independent on its organisational matters and the use of resources allocated for different purposes. This includes the yearly programme of work as well as the competence management and training necessary to fulfil SSM’s statutory obligations as the regulatory body in nuclear safety, security and radiation protection.

The organisational structure of SSM is appropriate for addressing the radiation risks associated with facilities and activities (STYR2012-27 Rules of Procedure). The division responsible for policies and regulation is independent from the Authority’s inspection and licensing activities, enabling an independent assessment of regulatory requirements commensurate with the radiation risks of the regulated facilities and activities. Specifically, the organisational structure enables a coordinated inspection and enforcement process that encompasses all types of facilities and activities with radiation risks, enabling a concerted approach of risk informed inspection planning and in applying a graded approach based on risk and the fulfilment of regulatory requirements important to safety. The division for licensing activities apply a graded approach based on the regulatory requirements for licensing, authorisation and notifications of facilities and activities with radiation. Many of the decisions made by SSM must be prepared in accordance with the decision-making procedure, STYR2012-28.

## **3.2 Effective Independence in the Performance of Regulatory Functions**

### ***Related to GSR Part 1 (Rev. 1): Requirement 17***

The Swedish Radiation Safety Authority, SSM, performs its functions in a manner that does not compromise its independence as the regulatory body in nuclear safety and radiation protection. SSM has established internal procedures and organisational values in place to achieve independence in the Authority's decision-making.

A strong safety culture within the regulator also aims at maintaining independency. The ability of SSM to emphasize its key values; credibility, integrity and openness are valuable factors to strengthen the safety culture.

SSM's safety culture is characterised by e.g. that safety is part of the leadership, individual responsibility, a culture that promotes safety, open communication, holistic view, continuous improvement, learning and self-assessment.

The Swedish Radiation Safety Authority (SSM) has established rules for new staff members recruited from authorised parties or other organisations affiliated with the nuclear sector or activities with radiation that aims to maintain the independence of SSM as the regulatory body in nuclear safety and radiation protection. Matters of integrity and trust in the regulatory authority are particularly important when recruiting managers. SSM has also established rules for side-line activities.

Furthermore, SSM has established introduction programs for new staff as well as a more specific internal training program called "Competent supervision" which addresses training and learning of regulatory aspects and safety considerations of an effectively independent regulatory body, including SSM's commitment to a strong safety culture and leadership for safety.

SSM's organisational structure effectively separates the Authority's regulatory decision-making with respect to policies and regulations, inspection and enforcement and its licensing and authorisation work in three separate and independent divisions.

SSM has documented (STYR2011-71) its fundamental values in the form of Vision and Mission statements, strategic objectives, SSM's roles and responsibilities, core organisational values, commitment to a strong safety culture and leadership for safety. It also describes the integrated management system.

SSM has extensive powers of intervention, from a remark to prohibition of an activity to continue.

## **3.3 Staffing and Competence of the Regulatory Body**

### ***Related to GSR Part 1 (Rev. 1): Requirement 18***

The Swedish Radiation Safety Authority, SSM, employs a sufficient number of qualified and competent staff, commensurate with the nature and number of facilities and activities to be regulated, to carry out its functions and to discharge its responsibilities as regulatory body in nuclear safety, security, safeguards and radiation protection.

SSM has the authority to structure its organisation and manage its available resources in accordance with the funding and conditions provided by the Government. This includes SSM's yearly programme of work as well as the competence management and training necessary to ensure the appropriate and adequate resources for its work.

SSM's human resources planning is comprehensive and consists of several integrated planning documents as part of the Authority's competence management process, process for work planning and allocation of resources and the strategic long-term budgetary planning of SSM.

Through individual performance appraisals, SSM managers systematically follow-up on staff competence and development needs in order to ensure that employees have the right skills to carry out their duties and to achieve the objectives of the Authority within their operating area. The internal procedures include a requirement for a documented education and development plan for each employee, based on a competence gap analysis comparing the employee's skills today with the Authority's competence needs in the short and long term.

SSM has established a strategy to compensate for the departure of qualified staff with e.g. routines to identify what skills are the most important to strengthen in the short and long term when a vacancy arises. Furthermore, when employees with single or unique skills are close to retirement, the strategy is to recruit in advance in order to create an opportunity for the transfer of knowledge and job introduction. Another option occasionally applied by the Authority is to rehire retired employees on short time contracts in order to both maintain the continued case handling and support the transfer of knowledge to remaining and newly recruited employees.

### **3.4 Liaison with Advisory Bodies and Support Organisations**

#### ***Related to GSR Part 1 (Rev. 1): Requirement 20***

Sweden has no external Technical Support Organisation (TSO) within nuclear safety and radiation protection. However, SSM have since of June 1 2021 established two departments, *Radiation Protection and Environmental Assessment* and *Plant Safety Assessment*, at the *Regulation and Knowledge Development Division*. These two departments serve as an in-house TSO function providing expertise to the rest of the organisation in various topics (STYR2012-27). Furthermore, SSM has adequate arrangements for obtaining technical or other expert professional advice or services as necessary, in support of its regulatory functions.

SSM initiate research, training and studies as needed, conduct external analyses and develop the regulatory activities. SSM's research funding is used to finance basic and applied research in order to develop national competences in radiation protection and nuclear safety as well as to support and ensure that SSM has the knowledge and tools needed to carry out effective regulatory review and supervisory activities. SSM's Policy for funding research (STYR2020-9) provides an overall objective and basis for prioritisation on which research projects shall contribute new knowledge on key issues in the fulfilment of SSM's roles and responsibilities as assigned by the Government, i.e. knowledge management, policies and regulations, inspection and enforcement, licensing and emergency preparedness.

SSM extensively calls upon external expert advice on a consultancy basis, in particular as an input of knowledge in its review and assessment work that support regulatory licensing and supervisory decisions. The internal procedures for acquiring consulting services are part of the Authority's support process (procurement). There is also provisions to ensure that the advice provided is independent and conflicts of interest avoided. SSM manages conflicts of interest in connection with the use of external advisory support with procedures for the disqualification of external experts and advisors from taking part in proceedings in a way that may lead to biased decision-making by the Authority.

SSM is supported by permanent advisory committees on Reactor safety, on the Safe management of spent fuel and radioactive waste and on Research and development. Members are appointed by SSM's Director General and represent other national or international authorities and independent institutions with relevant competences. SSM has also established additional scientific advisory committees with experts that provide essential outside technical support in specific areas of expertise such as UV, electromagnetic fields, and the use of ionising radiation in oncology. The scientific committee members are recognised independent experts in their respective fields.

The permanent committees provide advice to SSM prior to key regulatory decision-making. There are rules of procedure in place for all the advisory and scientific committees and a declaration of no conflict of interest is mandatory for committee members.

### **3.5 Liaison between the Regulatory Body and Authorised Parties**

#### ***Related to GSR Part 1 (Rev. 1): Requirement 21***

SSM's key values *credibility*, *integrity* and *openness* guide the Authority in all its action. The aim is to instil confidence and legitimacy with all stakeholders when SSM exercises its regulatory authority.

Specific provisions are given for the content and format of SSM decisions in order to ensure that the justification for a decision contain sufficient information to enable the party concerned to understand the reasoning of the Authority. SSM has internal procedures on how to assess and report authorised parties' compliance with requirements in relation to laws, ordinances, regulations and license conditions during supervision. The procedures also set out provisions on the appropriate enforcement measures, including sanctions, to be used where compliance assessments result in identified deficiencies, taking into account the safety implications of these deficiencies.

Before making a decision on a matter, SSM informs the party concerned of all material relevant to the decision and give the party the opportunity to comment on it within a specified period of time. The decision contains a justification that specifies the regulations applied and the circumstances that have been decisive for SSM's position in the matter. In notifying the decision, the receiving party is informed to the full content of the decision in a timely manner. If the party is offered the opportunity to appeal against the decision, then he or she is also informed of the procedures.

### 3.6 Stability and Consistency of Regulatory Control

#### *Related to GSR Part 1 (Rev. 1): Requirement 22*

Sweden meets the expectations of the IAEA safety requirements on stability and consistency of regulatory control.

SSM has established internal procedures necessary to ensure that the Authority's regulatory control is stable and consistent. SSM's integrated management system ensures that SSM staff operate professionally and consistently within its remit in relation to safety. The management system provides a systematic and structured approach to continuous improvements of processes with the aim of achieving the objectives by developing operations and render them more efficient. A more detailed description of SSM's management system is provided in the answers to questions in Module 4.

SSM has policies and procedures for regulatory supervision that ensures the grounds for good public management in terms of legality, objectivity and proportionality in order to be objective and impartial in our regulatory activities. The procedure for the exercise of supervision (STYR2017-16) gives an overview of the Authority's supervisory processes for inspection, review and assessment and enforcement. In addition to the internal general requirement on reporting deviations and possibilities for improvement in the management system, there is a specific requirement to document experiences from supervisory activities as a basis for continuous improvements of SSM's processes.

SSM has procedures on how to assess and report the authorised parties' compliance with requirements in relation to laws, ordinances, regulations and license conditions during supervision. SSM decide on appropriate enforcement measures, including sanctions, against the authorised party when non-compliances is identified, taking into account the safety implications of the non-compliance. There are procedures that specifically provide criteria for the assessments of compliance with safety requirements and on judging safety deficiencies and their safety implications.

SSM has risk-informed supervision programs for the long-term effective and consistent inspection and review and assessment of all activities with radiation. The programs take into account the nature and number of facilities and activities to be regulated, the radiation risks associated with the facilities and activities and the applicable regulatory requirements to be fulfilled.

On a yearly basis, an integrated safety assessment report is provided for each major facility under SSM's supervision, comprising the results of all inspections and reviews and all nuclear safety and radiation protection assessments. The report includes an analysis of safety trends and consistency in the licensee's compliance to requirements. The report is presented to the authorised party at a top-level management meeting. Included in the meeting agenda is an oral feedback and discussion on the licensees' safety performance and leadership for safety but also on the effectiveness and consistency of the Authority's supervision as a feedback for continuous improvement.

The formal processes and procedures in the SSM management system include the criteria for safety assessments that form the basis for documented regulatory decisions. The information is made known to the concerned authorised parties and to applicants for licenses as appropriate.

SSM has got a formal process for decision-making that prevent subjectivity in decision-making by individual staff members.

Before a matter is decided, the case must be comprehensively prepared. Decisions are handled uniformly and the overall competence of the Authority are used to create the basis for the decision. Regardless of who will make the decision, a case handler always considers whether other parts of the Authority are concerned or whether other competences would constitute a valuable addition to the preparation of the decision. A case handler does not dismiss other departments that declares an interest in participating in the preparation of a case. Depending on the nature of the matter and the decision level within the organisation, a consultation between the concerned division or department heads is required before a decision is made. During the preparation of a case and prior to decision-making, one of the Authority's legal advisors shall also formally review the case.

SSM manages the risks associated with making modifications to its established practices through a structured organisation of its management system with delegated roles and responsibilities as process owners and leaders for the different core processes. Changes in SSM procedures for supervision, licensing and decision-making in exercising public authority are prepared in a systematic manner in consultation with the concerned operational departments. Modifications in SSM's internal procedures that effect the work of authorised parties are communicated routinely with these parties. The process owner, that is also a member of the Authority's management group, formally decide on changes in established practises.

Changes to SSM's regulatory requirements follows a specific process that is subject to justification and evaluation of its contribution to safety, a thorough systematic preparation with legal support and internal consultations, consultation with authorised parties, often in several steps, consultation with other interested parties and quality assurance in the final preparation for decision-making. A consequence analysis is performed when deciding on changes in Authority regulations. It has to be clear that the changes are justified from the perspective of enhancement of safety, taking into account applicants' and authorised parties' ability to maintain and improve safety as required and the changes being reasonably achievable from a technical, operational and cost effective point of view.

### **3.7 Safety Related Records**

#### ***Related to GSR Part 1 (Rev. 1): Requirement 35***

SSM has got documents that assign responsibilities for establishing, maintaining and retrieving adequate records. All SSM regulatory activities are documented and registered in the Authority's case directory and document software system. The information is generally available to SSM staff and the public, unless the information is confidential. Documents or other types of information are stored according to the Swedish National Archive's regulations.

The registers and inventories are established and covers the following topics:

- Registers of sealed radioactive sources and radiation generators
- Records of occupational doses
- Records relating to the safety of facilities and activities

- Records that might be necessary for the shutdown and decommissioning (or closure) of facilities
- Records of events, including non-routine releases of radioactive substances to the environment
- Records of discharge data from nuclear facilities and records of concentration data in environmental media surrounding the nuclear facilities
- Inventories of radioactive waste and of spent fuel.

The records contain e.g. application and permit documents, design conditions and facility descriptions, event registration, contingency plans, emission samples and measurement results, waste documentation and information on personal doses. The records must be well cared for and when the activity ceases, a list of the records must be submitted to SSM.

SSMFS-D and SSMFS 2008:1 requires that those who conduct nuclear activities must establish and maintain registers of all nuclear waste that has arisen in the activity. Furthermore, technical plant documentation and safety reports as well as documentation of the operating activities must be preserved for as long as the activities are conducted. When the nuclear facility is decommissioned, this must be documented and compiled in a report that must be submitted to SSM.

For other activities with ionising radiation, there are provisions on documentation in SSMFS 2018:1. These regulations requires that results from monitoring of emissions, radioactive waste that has arisen in the business and information on personal doses must be documented and preserved.

The requirements for documentation and archiving directed at the licensees are independent of the archiving that takes place at SSM. Within the framework of the Authority's supervision of the operators, SSM regularly checks that the requirements for documentation and archiving are met.

### **3.8 Communication and Consultation with Interested Parties**

*Related to GSR Part 1 (Rev. 1): Requirement 36  
GSR Part 2: Requirement 5*

Sweden has established requirements that the public should have insight and the opportunity to be consulted in the municipalities where authorised facilities are located through local safety committees, Ordinance (2007:1054) with instructions for local safety committees at nuclear facilities.

The Swedish Radiation Safety Authority participates at least once per year in meetings convened by the local safety committees. These committees comprise local politicians tasked with monitoring safety work at the local nuclear facility and reporting this to the public.

For special issues, such as the repository, SSM participates proactively in information sessions organised by municipal authorities in order to meet the public face to face and answer their questions.

SSM's website is an important tool for communication to the public and other interested parties. Internet news items are published in condensed form at the website. This is also a format for descriptions of the Authority's work, such as supervision in connection with modernisation work and power upgrades, the repository for spent fuel, etc. Another example is that SSM has made environmental data available to the public<sup>2</sup>.

All decisions towards a third party made by the Director General are published on the external website and usually communicated by means of a news item on the website. The news includes a copy of the decision or report. When required, press releases are also distributed. In addition to this, SSM's web registry enables the publication of virtually all decisions, injunctions and reports on our public website.

SSM has several meetings with officers at the Ministry of the Environment, and they are always informed by e-mail or phone prior to all publication of news items and press releases.

Furthermore, SSM has meetings on a regular basis with radiation protection supervisors, radiation safety experts, medical physics and other expert functions.

New requirements or oversight resulting in changes in SSM's regulatory requirements follow a specific process that is subject to justification and evaluation of its contribution to safety, a thorough systematic preparation with legal support and internal consultations, consultation with authorised parties, often in several steps, consultation with other interested parties and quality assurance in the final preparation for decision-making. Consultations are made public at SSM's website and stakeholders also receive the documents by e-mail.

In the strategic objectives, SSM has goals that includes Communication, for example to build up an information service that is tasked with answering the public's questions regarding radiation safety.

Up to today, SSM has published 22 podcasts on the external website. It is a collection of several parts of SSM's operations, ranging from Radon to decommissioning nuclear reactors. Areas that have been highlighted so far are UV radiation, Safety culture, Radiation safety at nuclear power plants, X-rays, Cosmetic laser treatment, Research in radiation safety, Radioecology, Independent core cooling, Fukushima, Chernobyl, Skin cancer, Meltdown and Sievert.

When developing web services, such as the web registry, or when adapting the website, the Authority usually uses a reference group comprising the public, special interest groups and licensees who have an opportunity to submit viewpoints during the work process. The regulations and general advice issued by SSM are always published on SSM's public website.

### **3.9 Conclusions**

Sweden meets the expectations of the IAEA safety requirements on organisational structure of the regulatory body and allocation of resources.

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<sup>2</sup> [www.stralsakerhetsmyndigheten.se/omraden/miljoovervakning/sokbara-miljodata/miljodatabasen](http://www.stralsakerhetsmyndigheten.se/omraden/miljoovervakning/sokbara-miljodata/miljodatabasen)

Sweden meets the expectations of the IAEA safety requirements on effective independence in the performance of regulatory functions.

SSM annually requests funds from the government. The request is based on experiences gained from previous years, environmental scanning and the ambitions that the Authority has for the coming years regarding its regulatory responsibilities and functions in different areas.

SSM should continue its work to strengthen the culture for safety.

# Module 4: Management System of the Regulatory Body

## 4.1 Responsibility and Leadership for Safety

### *Related to GSR Part 2: Requirement 2*

The senior management demonstrate leadership for safety and commitment to safety. The management has made a number of strategic decisions in recent years to promote the mission on safety.

SSM decided on a new organisational structure in June 2021. In the preparatory work preceding the organisational change, security issues have been central. Physical security and information security are highly important and the responsibility is placed close to the top management. Protective security has been separated from these issues but is also placed centrally in the organisation. The responsibility for the Authority's cultural issues, including safety culture, has been centralised, where the HR-function has the overall responsibility. The HR-function is placed close to the top management, in order to gain strength in the development work.

The new organisational structure is appropriate for addressing the radiation risks associated with facilities and activities. The division responsible for policies and regulation is independent from the Authority's inspection and licensing activities, enabling an independent assessment of regulatory requirements commensurate with the radiation risks of the regulated facilities and activities.

All SSM's activities are governed by the Authority's management system, where the Rules of Procedure (STYR2012-27) constitute a top-level document. SSM's Rules of procedure lay down the organisational structure of SSM and the basic principles for the allocation of responsibilities and delegated decision-making. The Rules of Procedure describe SSM's organisation and the responsibilities of the different departments and divisions. The Rules of Procedure describe in detail the responsibilities of each employee and manager. There are clear responsibilities regarding safety. The Rules of Procedure state that all managers should take "clear leadership on safety issues on the basis of a holistic approach to safety". By setting clear responsibilities, the management has also set clear expectations regarding safety for the employees. The need for interaction between people and different parts of the organisation is stated in the Rules of Procedure.

According to the Decision-making procedure (STYR2012-28) all decisions should be governed by SSM's key values and operational policy and be based on radiation safety.

In case of a divergent point of view regarding legal certainty or another significant reason the point of view can be noted in the decision protocol, though this right of the employees should be used in a restrained manner. (STYR2012-28). This is based on Swedish law (Section 30 Administrative Procedure Act (2017:900)).

SSM's Management policy (STYR2011-71) is a top level internal steering document, which refers to the Authority's mandate and assignment by the Government. It establishes SSM's fundamental values in the form of Vision and Mission statements, strategic objectives, SSM's roles and responsibilities, core organisational values,

commitment to a strong safety culture and leadership for safety. It also describes the integrated management system. According to the Management Policy (STYR2011-71), the management system has been designed to ensure that radiation safety requirements are fulfilled in coordination with other operational requirements. The management system has also been designed to support and promote a culture whereby issues with an impact on radiation safety are given the attention and priority that their importance requires.

Safety is an overriding priority in SSM's Vision: A society safe from the harmful effects of radiation.

In 2020, the management decided on new Strategic objectives for the period 2021-2025. These include SSM's role in public administration, our internal leadership and working environment as well as emergency preparedness capabilities and the external perception of SSM as "a world class radiation safety Authority". These objectives further emphasise and aim to strengthen SSM's role and responsibilities with regard to the Swedish public administration key values of democracy, legality, objectivity, free formation of opinion and access to public records and respect for equality.

According to SSM's Management policy, the radiation safety perspective must guide the activities and decisions at all levels of the organisation. In doing so, SSM complies with relevant laws and other provisions.

SSM's Management policy includes influencing the behaviour of our stakeholders in the field of radiation safety. We therefore need to be aware of the impact of our safety culture on those in which we are responsible to authorise and supervise. The Authority's priorities and the employees' actions in relation to our stakeholders are crucial for how the Authority's long-term goals are achieved. It also creates conditions for the licensees to assume their radiation safety responsibility. All employees are responsible for, based on SSM's key values, constantly working to strengthen our culture, including safety culture.

SSM's Safety culture is characterised by:

- safety is clearly part of the Authority's leadership
- all employees of the Authority have an individual responsibility for behaviours that affect safety
- a culture that promotes safety, facilitates cooperation and open communication
- the Authority has a holistic view of radiation safety
- continuous improvement, learning and self-evaluation at all levels of the organisation.

A basic competence profile and performance expectations for all staff at SSM, including managers, is given in the Employee policy (STYR2011-95). The policy has a clear starting point in the public administration values and has a clear link to the Authority's model for training of leaders, "Developing Leadership". A specific internal training program for future leaders has been set up in order to foster good leadership and secure a consistent management of the Authority's regulatory functions.

According to the Employee policy an employee at SSM shall:

- strive to understand role, assignment and how to solve tasks in relation to the Authority's entire assignment
- take responsibility for assignments
- share experiences and knowledge both internally and externally

- be involved in planning and implementation in the business
- contribute to creating acceptance for decisions made
- actively seek information and take responsibility for the whole, i.e. both own development and development of activities
- adapt to changing circumstances
- make contacts, participates in networks and represents SSM in a way that creates trust in the Authority
- act in accordance with our values, our policies and decisions
- contribute to a good working climate and collaborates with others
- be sensitive, respects the skills, ideas and views of others
- ask and give feedback in a constructive way, with the best interests of the activities in mind
- show good judgment and high safety awareness

A manager at SSM shall, according to the employee policy:

- interpret the Authority’s assignment and what it means for its own operations
- guide employees' understanding of the tasks in the overall context
- take responsibility for planning, control and priorities
- ensure competence and staffing in the short and long term by developing my employees
- be clear in the continuous feedback to the employees, takes the necessary measures and makes the necessary decisions
- clarify and communicate a common goal for activities based on SSM’s mission and values
- have good external monitoring and the ability to translate this into activity development
- encourage continuous improvement, learning and self-esteem

All managers conduct yearly performance appraisal with employees to develop them in safety, among other things. All employees at SSM are responsible for working and acting in accordance with SSM’s common values and employee policy. Everyone must also take individual responsibility for behaviours that affect safety.

SSM managers systematically follow-up on staff competence and development needs in order to ensure that employees have the right skills and attitude to carry out their duties and to achieve the objectives of the Authority within their operating area. The internal procedures include a development plan for each employee. Salary appraisal is carried out once a year and focuses on the employee’s skills and productivity and emphasises safety and work environment.

## **4.2 Management for Safety**

***Related to GSR Part 1 (Rev. 1): Requirement 19 and GSR Part 2: Requirements 3, 4 and 5***

SSM meets the expectations of the IAEA safety requirements of having an integrated management system that is aligned with its safety goals. Top management is responsible for the regulator’s performance as well as for the management system.

The main goal is to protect people and the environment from harmful effects from ionising and non-ionising radiation, now and in the future. This includes issues of safety and security in nuclear and other operations as well as issues of nuclear non-proliferation. The Authority’s operations are governed by its management system.

The management system includes specific procedures for the Authority’s decision making in exercising public Authority. The management system includes a steering document with specific procedures for the Authority’s decision making. The structured internal delegation of certain decision-making powers from the Director General, to the Directors, department heads and case handlers is described in the Rules of procedure.

In the Rules of procedure, it is also stated that all managers are expected to establish/develop necessary steering documents and keep them up to date. There is also an expectation on continuous improvement.

SSM’s Management policy is a top-level internal steering document, which refers to the Authority’s mandate and assignment by the Government. It establishes SSM’s fundamental values in the form of Vision and Mission statements, strategic objectives, SSM’s roles and responsibilities, core organisational values, commitment to a strong safety culture and leadership for safety. It also describes the integrated management system.

SSM has established a vision of SSM’s operation “a society safe from harmful effects of radiation”. SSM works proactively and preventively in order to protect people and the environment from the undesirable effects of radiation, now and in the future.

Safety goals are established at various levels at SSM. Goals, strategies, plans and objectives are developed based on the strategic objectives for the period 2021-2025, in which safety is incorporated (The Roadmap for the Strategic Objectives (SSM2021-8026-1) is attached as appendix to the Initial Action Plan).



Figure 6 - SSM's strategic objectives

The strategic objectives for the period of 2021-2025, see Figure 6, control all operation of the Authority. In the yearly planning process the strategic objectives are the foundation

for developing yearly objectives and actions at different departments and divisions of the Authority.

All decisions follow the routines for decision making, which emphasise that all decisions at SSM should be guided by the Authority's fundamental values and policy of operation and based on radiation safety perspective. Furthermore, all matters should be processed as simple, fast and cost effective as possible without compromising safety. It is also emphasised in the Management policy that the radiation safety perspective should be regarded in all operation and decision making at all levels at SSM.

SSM's management has established goals, strategies, plans, objectives and a road map for the organisation on an overall strategic level. The Authority now needs to prioritise and carry out the quality project that is included as part of the strategic road map.

### **4.3 The Management System**

#### ***Related to GSR Part 2: Requirements 6, 7 and 8***

SSM has an integrated management system that describes how we control, implement, follow up and improve our activities.

The management system can be viewed as a structure of processes that together create an overall picture of the activities. The Authority's management system contains the steering documents that create the conditions for the Authority to achieve the objectives of the activity and fulfil the requirements of the Government Authority Ordinance (2007:515) on internal leadership and control. The management system supports a systematic and effective approach and good administration.

The management system is designed to ensure that radiation safety requirements are fulfilled in coordination with other operational requirements. The management system is also designed to support and promote a culture whereby issues with an impact on radiation safety are given the attention and priority that their importance requires.

In addition to the top level document in the management system, SSM has a process map over existing processes. This is visualised and made available for all staff in a specific application. In the application, there are descriptions of each step in the processes including who should be involved, what is expected and associated document for further instructions when available.

The management system is open and accessible to all employees.

The management system is improved continuously to meet the results of the management reviews of the management system. Process owners and process leaders evaluate the expediency of the processes yearly, in order to identify what needs to be improved.

The safety goals of the Authority are incorporated in the strategic objectives. The vision of a society safe from the harmful effects of radiation is also expressed as the output of the overall process map as well as that all decisions at SSM should be guided by the Authority's fundamental values and policy of operation, and based on a radiation safety perspective.

SSM manages the risks associated with making modifications to its established practices through a structured organisation of its management system with delegated roles and responsibilities as process owners and leaders for the different core processes.

SSM has established a model for risk managing and risk analysis (STYR2011-160 and STYR2012-2). This should be conducted when projects start, when changes are made in established practises and when developing or purchasing IT-systems. Risk analyses should also be made before decision on organisational changes in order to ensure that the new organisation does not entail significant implications for safety.

SSM has established a process for internal consultations before decision making as well as a process for handling oversight results. Any oversight resulting in changes in SSM's regulatory requirements shall follow a specific process, including consultation with authorised parties as well as other interested parties. A consequence analysis is formally required to ensure that the changes are justified from the perspective of enhancement of safety, taking into account applicants' and authorised parties' ability to maintain and improve safety.

SSM's management system establishes that safety culture is an important part of the Authority (Management policy (STYR2011-71)). The safety culture at SSM is characterised by that safety is clearly a part of the Authority's leadership. Furthermore, all employees have an individual responsibility to strengthen the safety culture and to act according to safety. It is also characterised by a culture that promotes safety and facilitates cooperation and open communication, and that the Authority has a holistic approach to radiation safety as well as continuous improvement, learning and self-evaluation at all levels of the organisation.

SSM's decisions are based on the key values, and with radiation safety in mind. All decisions shall be prepared as broadly as possible. Before a case is decided, it must be prepared as comprehensively as possible. The Authority's collective competence shall be used to create a basis for the decision. Decisions must be formulated in an appropriate and uniform manner and handled uniformly. The guidelines for this preparation procedure aim to create conditions for the quality of the Authority's decisions to be the highest possible. If a case concerns several departments within the Authority, the preparatory work must be conducted from an inter-authority perspective. Cases of inter-authority and/or fundamental significance must be dealt with by the senior management team before they are decided.

According to the Decision-making Procedure (STYR2012-28), the heads of the departments (according to their assigned responsibility in the organisation) are responsible for each matter being sufficiently handled before decision-making. This responsibility includes sufficient consultation. Before matters are decided, internal consultations should be made to ensure that different perspectives are handled in a proper way. The administrative officer who handles the matter should report any divergent point of view to the responsible head. Any conflict that cannot be solved at a lower level should be raised to a higher level in the organisation. In the final preparation before decision, the Office of legal affairs also carries out a quality assurance.

In case of a divergent point of view regarding legal certainty or another significant reason the point of view can be noted in the decision protocol, though this right of the employees

should be used in a restrained manner. This is based on Swedish law. (Section 30 Administrative Procedure Act (2017:900))

One of the main purposes with the new organisational structure, established in June 2021, was to reduce the risk of conflicts of interest that may arise from the Authority's various roles - regulation, licensing and supervisory activities.

In the preparatory work preceding the organisational change, security issues have been central. Physical security and information security are highly important and the responsibility is placed close to the top management. Protective security has been separated from these issues but is also placed centrally in the organisation. The responsibility for the Authority's cultural issues has been centralised, where the HR-function has the overall responsibility. The HR-function is placed close to the top management, in order to gain strength in the development work.

SSM's organisational structure, Figure 5, is appropriate for addressing the radiation risks associated with facilities and activities. The division responsible for policies and regulation is independent from the Authority's inspection and licensing activities, enabling an independent assessment of regulatory requirements commensurate with the radiation risks of the regulated facilities and activities.

Specifically, the organisational structure enables a coordinated inspection and enforcement process that encompasses all types of facilities and activities with radiation risks, enabling a concerted approach of risk informed inspection planning and in applying a graded approach based on risk and the fulfilment of regulatory requirements important for safety. The division for licensing activities apply a graded approach based on the regulatory requirements for licensing, authorisation and notifications of facilities and activities with radiation.

The management has revised a number of top-level internal steering documents in the light of the new organisation. The update includes for example the Rules of Procedure (STYR2012-27), the Decision-making procedure (STYR2012-28) and the Management policy (STYR2011-71).

With the new organisation, there will be improved opportunities to collaborate in supervision, which is part of having a good safety culture. This means that co-planning and having a holistic perspective on supervision in all areas is possible to a greater extent e.g. prioritisations of the supervision can be based more clearly on a risk assessment and on a holistic view among all regulatory areas.

However, there is a need to further develop the structure, the processes and the steering documents in the management system so that it is up to date and appropriate. This work forms part of the roadmap towards the strategic objectives.

## Graded approach

The management system is developed and applied using a graded approach in several different ways.

According to top-level steering document in the management system, there are specific procedures for the Authority's internal delegation of decision-making. The structured

internal delegation of certain decision making powers from the Director General, to Directors, department heads and case handlers, is an example on applying an organisational graded approach based on the risks associated with regulated facilities and activities with radiation.

The new organisational structure enables a coordinated inspection and enforcement process that encompasses all types of facilities and activities with radiation risks, enabling a concerted approach of risk informed inspection planning and in applying a graded approach based on risk and the fulfilment of regulatory requirements important for safety. The division for licensing of activities apply a graded approach based on the regulatory requirements for licensing, authorisation and notifications of facilities and activities with radiation.

SSM's regulations and guides are kept consistent and comprehensive, and provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with the graded approach.

Graded approach is applied at different levels in the legal framework. For small amounts of radioactive material and for certain measures services, only notification or registration is applied (instead of a permit requirement) according to the Ordinance for Nuclear Activities. Graded approach is applied based on the nature, scope and potential risks of the activity. Graded approach is also applied in SSM's set of regulations (SSMFS). In addition, in each SSMFS regulation, SSM may decide in individual cases on exemptions from parts of requirements or entire requirements.

## Regulatory documentation

The management system is documented mainly through processes and links to steering documents in a digital process management tool (where the processes are both documented and illustrated).

The controlling of documentation in the management system is on an overall level described in a steering document (STYR2011-32 Document governance). The protection of the documented information is based on a classification for information security. The specified classification of a matter controls security measures and handling of the matter. The classification structure of information protection consists of four levels: green for basic handling, yellow for extended handling, pink for higher security and red for very high security. These levels are based on demands of confidentiality, accuracy and availability. Within the digital system for managing matters, records and archiving (SSM360) documents classified as green or yellow are handled (when preparing, reviewing, revising and approving documents) according to the authorisation given by SSM's active directory, which is based on the mandates according to Rules of Procedure.

The type of records used depend on the process applied. Processes are specified in the management system through the digital process tool Ps, in the process maps or steering documents. The records produced are reachable through SSM360. Some records, i.e. risk

analyses and objectives are controlled and handled in the digital tool for planning and follow up.

## **4.4 Management of Resources**

### ***Related to GSR Part 2: Requirement 9***

SSM managers systematically follow-up on staff competence and development needs through individual performance appraisals in order to ensure that employees have the right skills to carry out their duties and to achieve the objectives of the Authority within their operating area. The internal procedures include a development plan for each employee, based on a competence gap analysis comparing the employee's skills today with the Authority's competence needs in the short and long term.

SSM uses a systematic planning and follow-up process for work planning and allocation of resources. SSM management allocates employees to the planned regulatory activities in a step-wise prioritisation process for the following budget year. Re-budgeting and prioritisation during a budget year is done in a follow-up process with current and more systematic tertiary reviews of human resources needs and adjustments as appropriate. All planning and allocation of resources is documented in the Authority's activities and resources planning system.

SSM's introduction program for new staff contains the important elements of the Authority's regulatory responsibilities and the Swedish public administration key values of democracy, legality, objectivity, free formation of opinion and access to public records and respect for equality.

A basic competence profile and performance expectations for all staff at SSM, including managers, are given in the Employee policy. The policy has a clear starting point in the public administration values and has a clear link to the Authority's model for training of leaders, "Developing Leadership". A specific internal training program for future leaders has been set up in order to foster good leadership and secure a consistent management of the Authority's regulatory functions.

The requirements for individuals at all levels are specified and training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence.

When employees with single or unique skills are close to retirement, the strategy is to recruit in advance in order to create an opportunity for the transfer of knowledge.

SSM managers systematically follow-up on staff competence and development needs in order to ensure that employees have the right skills to carry out their duties and to achieve the objectives of the Authority within their operating area.

The recruitment process is well established at SSM with a recruitment strategy, routines to support the hiring departments and the Human Resources secretariat, a specialised computer tool and a communication platform. When a vacancy arises, an inventory is initiated to identify what skills are the most important to strengthen in the short and long term. The senior management team is involved in both replacements and extended recruitments in order to ensure that available financial resources are used in a sustainable way for the most important competence needs of the Authority in the short and long term.

It is important to ensure that the new organisation (June 2021) is adequately staffed and that there is relevant competence based on the respective division and department assignments.

## 4.5 Management of Processes and Activities

### *Related to GSR Part 2: Requirements 10 and 11*

The new SSM organisational structure is appropriate for addressing the radiation risks associated with facilities and activities. The division responsible for policies and regulation is independent from the Authority's inspection and licensing activities, enabling an independent assessment of regulatory requirements commensurate with the radiation risks of the regulated facilities and activities.

Specifically, the organisational structure enables a coordinated inspection and enforcement process that encompasses all types of facilities and activities with radiation risks, enabling a concerted approach of risk informed inspection planning and in applying a graded approach based on risk and the fulfilment of regulatory requirements important for safety. The division for licensing of activities apply a graded approach based on the regulatory requirements for licensing, authorisation and notifications of facilities and activities with radiation.

The management of SSM is controlled in a process-based approach, see Figure 7. There are eight core processes aimed at achieving SSM's vision: *A society safe from the harmful effects of radiation*. The core processes are controlled by the management process and supported by seven supporting processes. The processes are documented and illustrated in a digital process tool called Ps. A supporting internal council with the heads of departments discusses and solves issues about interfaces between the management process, core and supporting processes. Each process should be reviewed by a process team and approved by the process owner before use.

The management system is improved continuously to meet the results of the management reviews of the management system. Process owners and process leaders evaluate the expediency of the processes yearly, in order to identify what needs to be improved. All employees have the possibility to address any proposals or needs of improvements.

The management system is described in the Rules of Procedure (STYR2012-27) and in more detail in Management Policy (STYR2011-71). The processes are described in the digital process tool, with reference to related governing documents.

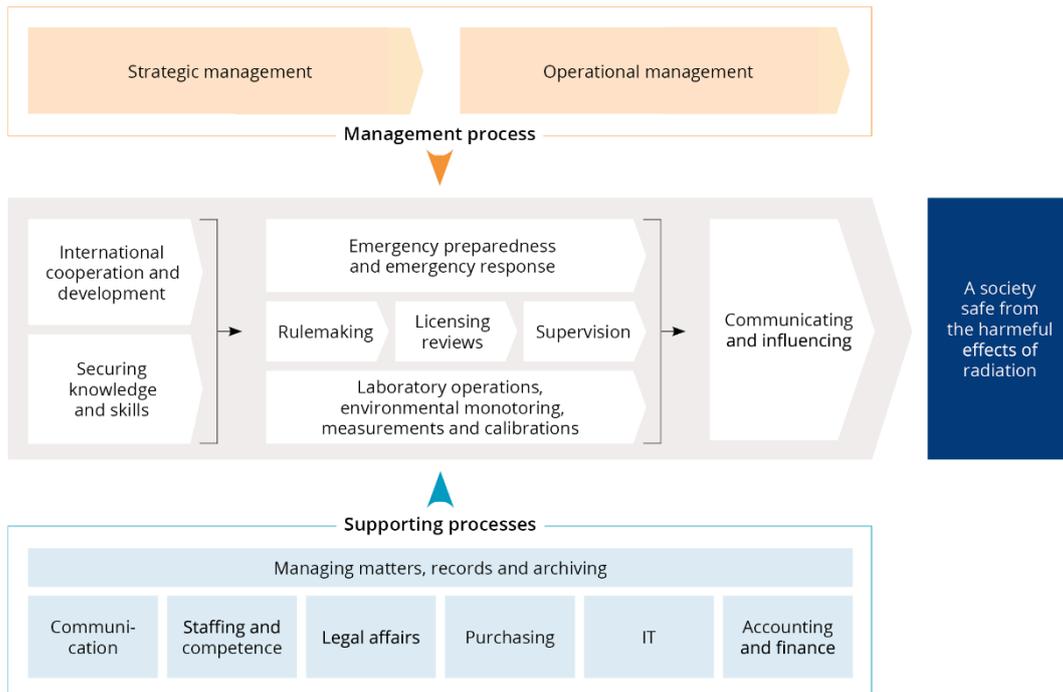


Figure 7 - SSM's overarching process map

## Intelligent customer

Swedish authorities are in general strictly ruled by common agreements between the state and different suppliers according to the Swedish Public Procurement Act (SFS 2016:1145), which is largely based on the EU Directive 2014/24/EU concerning public procurement. Most of the purchased goods is procured according to a list of these common agreements; the Authority has in this case small opportunities to make changes. The Authority has established a process for procurement (purchasing).

Whenever SSM uses external resources for conducting the mission of radiation safety, the Authority retains the responsibility for safety. When the contracting regards protection security the Authority has specific agreements with the contractor. Those agreements specify how the contractors should meet the demands of protecting security.

## 4.6 Culture for Safety

**Related to GSR Part 1 (Rev. 1): Requirement 19 (para 4.15.)**  
**GSR Part 2: Requirement 12**

SSM managers systematically follow-up on staff competence and development needs in individual performance appraisals, in order to ensure that employees have the right skills and attitude to carry out their duties and to achieve the objectives of the Authority within their operating area. The internal procedures include a development plan for each employee. All employees of SSM are regularly trained on security matters.

In the performance appraisal, we also discuss safety culture with the employees in order to increase the Acceptance by employees of personal accountability for their attitudes and

conduct with regard to safety. Salary appraisal is carried out once a year and also focus on the employee's skills and productivity and emphasises safety and work environment.

SSM's introduction program and a clear employee policy (see Module 4.1) assists SSM as an organisation to foster a strong safety culture.

In 2016, SSM adopted the NEA five principles that supports the safety culture of an effective nuclear regulator and included them in the management system. The management system as such is however not fully functional in practice.

## **4.7 Measurement, Assessment and Improvement**

### ***Related to GSR Part 2: Requirements 13 and 14***

The effectiveness of the management system is evaluated in order to identify opportunities for improvement of the management system. The evaluations are conducted by the senior management group.

One key element in terms of the effectiveness is the follow up of the goals and objectives. Another key element in the monitoring is the self-assessment of each process that is conducted every year by the process owners and process leaders. These assessments, which are done by inputs from employees working within the process, include assessment of the expediency and effectiveness of each process.

According to the requirements in the Ordinance (2009:907) on environmental management in government agencies, SSM conducts internal audits regarding the environmental management system at SSM.

An annual self-assessment of compliance of the regulatory requirements concerning the Authority is conducted by the senior managers, initiated and supported by Legal Affairs. The self-assessment follows a plan for the years 2019-2021.

Every year different kinds of audits are carried out in order to verify that the management is functioning in a proper way. For instance, SSM (as well as other Swedish national authorities) is annually reviewed by the Swedish National Audit Office.

Another independent audit is carried out of the work at the National Metrology Laboratory for ionising radiation. Every 3-4 years the laboratory is audited by Swedac, the Swedish Board for Technical Accreditation, in regards to the international laboratory standard ISO/IEC 17025. The laboratory also conducts annual internal audits in respect to the same standard, and every four years the laboratory contracts a third party for an internal audit with an external assessor.

SSM needs to review the structure and maintenance of the management system. The system is complex and partially incomplete. The management system needs to be simplified and improved. There is a need to further develop the structure, the processes and the steering documents in the management system so that it is up to date and appropriate. This work forms part of the roadmap towards the strategic objectives.

## Review of the management system

Senior management regularly commission assessments of leadership for safety and of safety culture. From 2015 to 2018 SSM carried out several activities aiming for a strengthened safety culture. During 2015 SSM had several management meetings on the topic, initiated work on how to better include safety culture in the management system and initiated the work with a safety culture assessment/evaluation. This evaluation was carried out by an external party.

The self-assessment of leadership for safety and of safety culture includes assessment at all organisational levels and for all functions in the organisation. Such self-assessment makes use of recognised experts in the assessment of leadership and of safety culture.

All managers undergo the leadership programme “UL”, which consists of four days of training and follow-up training during the year. This programme is coordinated to our employee policy and it helps our leaders to foster and sustain a strong safety culture and to guide the employees in our mission and values.

## 4.8 Conclusions

Sweden meets the requirements on the management system for the regulatory body. SSM’s senior management demonstrates leadership for safety and establishes goals, strategies, plans and objectives with safety as an overriding priority. SSM has an integrated and documented management system that is continuously developed and improved.

However, SSM will continue its ongoing work to clarify, simplify and develop the integrated management system. In addition to this, SSM will review and further develop the structure, the processes and the steering documents of the management system. Furthermore, senior management will strive to further improve managers’ communicative leadership, including safety culture issues, as well as work to clarify and strengthen a good organisational culture.

# Module 5: Authorisation

## 5.1 Generic Issues

*Related to GSR Part 1 (Rev. 1): Requirement 4, paragraph 2.12; Requirements 23 and 24*

*GSR Part 3: Requirements 6, 7, 8 and 13*

*GSR Part 4: Requirement 21*

The national legal framework in Sweden provides a system of licensing and prohibition of nuclear installations without a licence.

Authorisation of activities involving ionising radiation is regulated through three legal and regulatory regimes addressing activities involving radiation, nuclear activities, and environmental aspects, respectively. The main acts and ordinances are:

- The Act (1984:3) on Nuclear Activities
- The Nuclear Activities Ordinance (1984:14)
- The Radiation Protection Act (2018:396)
- The Radiation Protection Ordinance (2018:506)
- The Environmental Code (1998:808)
- The Ordinance (2008:463) on certain fees to SSM

In general, activities licensed under the Radiation Protection Act do not need a license under the Act on Nuclear Activities and vice versa. Instead, the Radiation Protection Act and the Radiation Protection Ordinance enables SSM to issue conditions for activities licensed under the Act on Nuclear Activities. Correspondingly, the Nuclear Activities Ordinance enables SSM to impose license conditions necessary from a radiation protection point of view.

SSM is authorised in accordance with the Radiation Protection Act and the associated Ordinance to issue regulations for activities involving ionising radiation. In addition, SSM is authorised in accordance with the Nuclear Activities Ordinance to issue regulations on measures to maintain and improve safety and security of nuclear activities. SSM has issued regulations in SSMFS 2018:1 concerning basic provisions for all licensed activities involving ionising radiation and in SSMFS 2008:1 concerning safety in all nuclear facilities except shallow land disposals, respectively. These level 1 regulations are further specified and detailed in level 2 and level 3 regulations, as explained in Module 8. SSM reviews licence applications against applicable requirements, as described in Module 6.

The concept of graded approach is implemented from the ordinances issued by the Government, through SSM's regulations and processes.

Ordinance (2008:463) on certain fees to SSM regulates fees a licensee or license applicant has to pay to SSM for certain activities, applications and reviews. For example, a party that applies for a license in accordance with Sections 5 or 5a (Act on (1984:3) Nuclear Activities) has to pay the fee (Section 4 2008:463) that is specified (Section 5 2008:463) for the particular category of facility or activity. The fee should cover SSM's

costs for the associated regulatory activities and should thus be regarded as an indicator on the importance and thoroughness expected of the review, i.e. graded approach.

The requirements on implementation of reasonably practicable safety improvements to existing nuclear installations (Article 8a 2.(b) 2014/87/Euratom) was incorporated into national law (Section 4 and 10 of 1984:3) in 2017 (prop 2016/17:157). This clarifies the licensee responsibility to continuously evaluate and implement reasonably and practicable improvements to safety.

The regulations that SSM issue, and the process applied for authorisation (Ps and STYR2011-131) both use a graded approach. To mention one key aspect with respect to graded approach in SSM's regulations, the portal sections cover the basic safety provisions for construction and operation of an NPP (Chapter 2 Sections 1-5 SSMFS-K) and state that,

- the defence-in-depth concept shall be applied with particular consideration of site, construction, operation and all sources of radioactive material that will be handled
- the defence-in-depth shall consist of multiple and independent layers, five layers in total
- events with a low impact on radiation safety and with a large probability of occurrence, shall not yield large consequences, whereas
- events with an (detrimental) impact on radiation safety and with potentially large consequences, shall have a very low probability of occurrence, and
- actions taken to reduce the risks associated with a facility or activity on the radiation safety shall be optimised as far as reasonably practicable with respect to existing technology, economy and societal factors.

Requirements on safety in nuclear facilities are applied with due regard to the specificities of the facility in question (graded approach) (Chapter 2 SSMFS 2008:1). The scope and detail of the Safety Assessment Report (SAR) should reflect the facility's complexity and associated risks (general advice to Chapter 4 Section 2 SSMFS 2008:1). As part of SAR, deterministic and probabilistic methods are used to grade risks and determine the overall strengths and weaknesses of the facility. These constitute the basis for a safety assessment on how the facility meets the requirements on protection of people and environment.

For activities and facilities licenced according to the process map in the digital process tool, there are several instructions addressing a specific facility or activity, enabling a graded approach. However, a distinct example of graded approach is the decision to authorise some activities under the Radiation Protection Act (2018:396) through a notification process according to SSMFS 2018:2. Parties that are subject to the notification process do not have to provide any safety assessment or other documentation (except registration of the radiation sources), upon notification. This decision is based on a risk analysis performed by SSM as part of the preparatory work in writing SSMFS 2018:2, see Notification process below.

## Licensing of nuclear activities

Licensing of nuclear activities is governed by several acts having different purposes. This also involves a number of authorities. Licence matters under the Act on Nuclear

Activities are decided by the Government or in some cases by SSM (as authorised in the Nuclear Activities Ordinance). In cases where the decision is made by the Government, SSM act as a drafting authority. If the activity requires a license under the Environmental Code, the Land and Environmental Court act as a drafting authority with SSM as a referral body and the Government decides on permissibility. Furthermore, a nuclear activity must be approved in accordance with aspects of nuclear safety and radiation protection to ensure the protection of human health and the environment. Lastly, licensing conditions are issued under the various acts by the authorities responsible. New nuclear installations and major modifications of existing installations that are subject to authorisation must be considered under both the Act on Nuclear Activities and the Environmental Code.

As stipulated by the procedure for applications (Chapter 5 1984:3), a licence application must be submitted to SSM (Section 24 1984:14), which processes the matter under the Act on Nuclear Activities and to the Land and the Environment Court, which processes the matter under the Environmental Code. Applications are to be accompanied by an environmental impact assessment under Chapter 6 of the Environmental Code. Figure 8 below provides a schematic illustration of the licensing process for new nuclear installations included in SSM's steering document "*Preparation of licences and review of licence conditions concerning nuclear installations and other complex installations where radiation is used*" (Appendix 1, STYR2011-131).

It should be noted that the preparation and review of an application, according to the Environmental Code, as well as the issuing of a licence and conditions, take place in open court hearings at the Land and Environment Court. At these hearings, all interested parties may attend and comment, including the relevant authorities. The applicant must provide an oral presentation with a description of all relevant aspects of the matter. Questions may be submitted during the proceedings.

SSM's process for licence applications includes review and assessment to check whether the application complies with applicable requirements on nuclear safety and radiation protection to ensure the protection of human health and the environment. If SSM finds that it provides an adequate demonstration of safety for the planned nuclear activity or facility SSM will propose that the Government grants a licence under the Act on Nuclear Activities and proposes licence conditions. SSM shall propose license conditions that enable a continued step-wise review process until the date planned for regular operation. One or more of the following licence conditions are to be proposed:

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

Following a Government decision to grant a licence, SSM authorises according to the licence conditions that the Government have issued in a step-wise process, see Figure 9. SSM decides at each stage if the licensee is allowed to proceed to the next step.

It should also be noted that for all nuclear installations in operation in Sweden, the operating licence is granted with an indefinite term. This means that the operation of a nuclear installation is allowed as long as the licensee meets the requirements set by the

applicable laws, government ordinances, regulation of the nuclear regulatory authority, and conditions imposed by the initial licence.

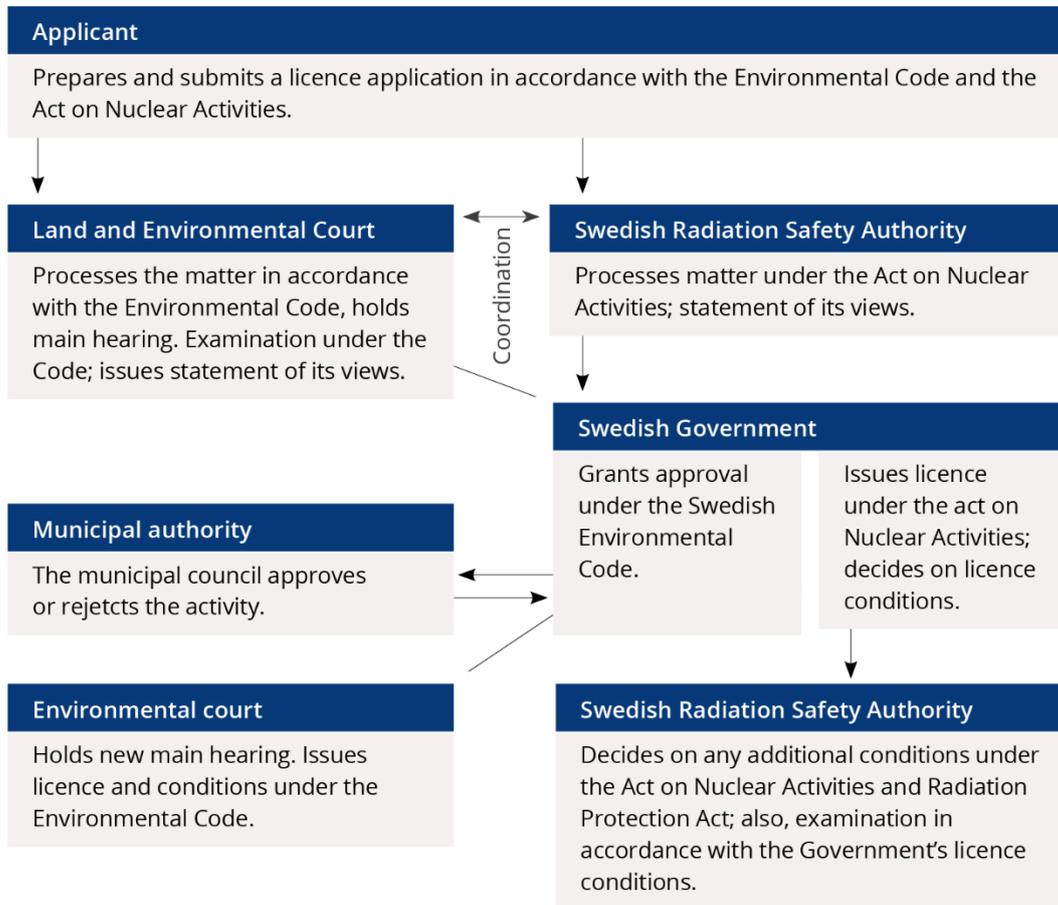


Figure 8 - Overview of the licensing process for a new nuclear installation (Figure 1 STYR2011-131)

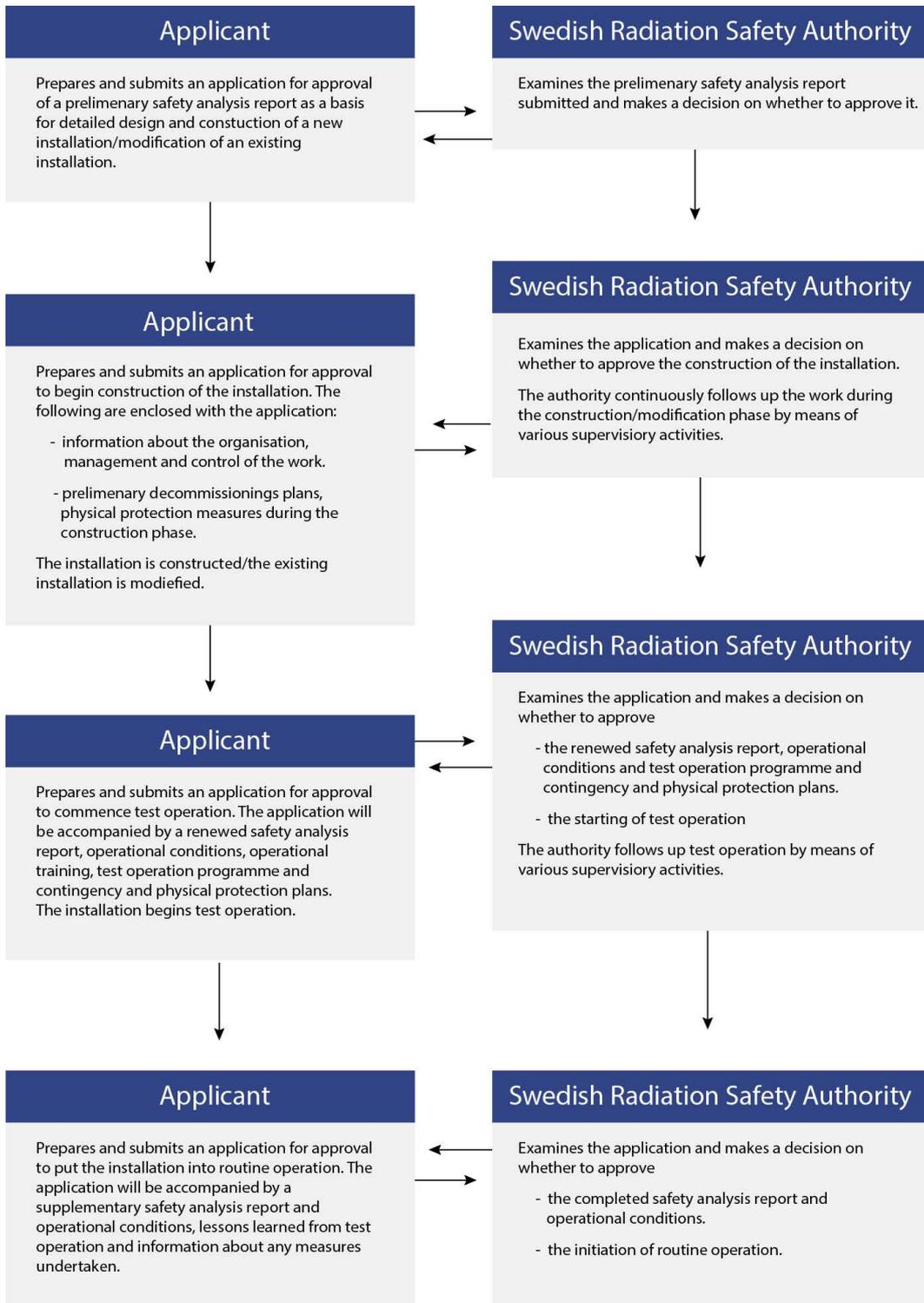


Figure 9 - Schematic illustration of the process of multi-stage review against regulations and licence conditions – new installations and licensable modifications of existing installations for nuclear activities and for complex non-nuclear activities involving ionising radiation (Figure 4, STYR2011-131)

For certain nuclear facilities and activities SSM has the mandate to issue licences, including the transport of nuclear material and nuclear waste, as well as activities involving the handling, as well as the import of, limited quantities of nuclear material or nuclear waste (Sections 16-19 in the Nuclear Activities Ordinance).

## Licensing under the Radiation Protection Act

Licenses are issued for a limited time (Chapter 6 Section 20 Radiation Protection Act). However, some licenses in the field of medical exposure were issued prior to the requirement regarding limitations in time. The license states the activities that are permissible (Chapter 1 Section 7 Radiation Protection Act and Sections 1-2 Act on Nuclear Activities). Any other activities that are to be undertaken requires a new licence or a licence modification, subject to the authorisation procedure. When the period of validity is about to expire, the licensee must apply for renewal or terminate the licence by notifying SSM. Renewal of a licence follows the same procedure as the initial authorisation. SSM has not established a procedure for suspension or revocation of licences under the Radiation Protection Act.

A prerequisite for a license is the approval of one or more Radiation Protection Experts (Chapter 3 Section 12 SSMFS 2018:1). For nuclear facilities SSM has also issued requirements regarding the approval of a Radiation Protection Manager (SSMFS 2008:24).

The authorisation of transboundary shipments of radioactive waste and spent fuel is regulated in accordance with the Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel (SSMFS 2009:1).

## Notification process

SSM has the mandate to replace licensing review under the Radiation Protection Act with approval by notification (Chapter 5 Section 3 Radiation Protection Ordinance). The Authority also has the mandate to issue regulations for exemption from authorisation under the Radiation Protection Act for radioactive material and technical equipment generating ionising radiation, and for clearance of materials, building structures and areas that may be contaminated through activities with ionising radiation (Chapter 7 Section 1 Radiation Protection Ordinance).

The Act on Nuclear Activities provides for approval by a notification process for certain research and development activities and for manufacturing, import and export of nuclear equipment (Sections 7a-d Act on Nuclear Activities). Exemptions from the general licensing requirement in the Act or for approval by a notification process, regarding management of small amounts of nuclear material or nuclear waste, and certain nuclear equipment containing nuclear material are given in Sections 4-15 a in the Nuclear Activities Ordinance.

Activities involving ionising radiation, subject to notification requirements in accordance with the Radiation Protection Act, are defined in Chapter 1 SSMFS 2018:2 concerning notifiable activities, e.g. dental intra-oral X-ray, some applications in veterinary medicine and technical equipment for measurements and analysis.

Radioactive material and technical equipment generating ionising radiation subject to exemption in accordance with the Radiation Protection Act, are defined in Chapter 2 SSMFS 2018:3 concerning exemptions from the Radiation Protection Act and concerning

the clearance of materials, building structures and sites. These regulations also define under which conditions materials, building structures and areas that may be contaminated through activities with ionising radiation, can be subject to clearance (Chapter 3 SSMFS 2018:3).

In the individual cases, SSM is authorised to grant an exemption from the Radiation Protection Act regarding radioactive material, technical devices containing radioactive material or generating radiation and medical check-up. An exemption may be combined with conditions and must not entail an unacceptable risk of exposing people or the environment to any harmful effects of radiation (Chapter 7 Section 5 Radiation Protection Ordinance). If necessary from a radiation protection point of view, SSM is allowed in the individual case, to decide that an activity is not allowed without a license, or that an exempt activity is not allowed without a licence or notification (Chapter 5 Section 5 Radiation Protection Ordinance). SSM has as part of the preparatory work in the development of SSMFS 2018:2 performed a risk analysis (document 15-429) regarding authorisation by notification. In this process, SSM adopted six criteria that has to be met for notification to be sufficient as authorisation for a specific facility or activity (document 15-2224):

1. The radiation protection is largely ensured by the design of premises and choice of equipment. For radioactive substances this means that no or only negligible release/discharges can occur
2. The execution does not vary significantly but is standardised and routine
3. Descriptions of how to perform the activities are easy to follow
4. The extent of necessary radiation protection training for staff is relatively small
5. There is a history of few problems with radiation safety, such as few serious incidents
6. The radiation protection is to a large extent independent of human misconduct.

SSM considers, if all the criteria above is met, that it is improbable with occupational effective doses above 1 mSv/year, and public effective doses above 0.1 mSv/year and thus authorisation through notification might be considered. As mentioned above facilities or activities that are subject to the notification process is stated in chapter 1 SSMFS 2018:2.

### SSM's authorisation process

SSM's authorisation process is part of SSM's management system, which is described in the digital process tool, Module 4. The authorisation process consists of a licensing process and a notification process. The current description in the digital process tool does not include the notification process and the description of the licensing process does not include all types of licensing. The long-term goal for the authorisation process is to include licensing of all activities in one or more process maps in the digital process tool.

For the notification process, SSM provides an electronic service (SIWA) for parties to register their possession of radiation sources and equipment. SIWA is under development in order to extend its functionality, for example allowing parties to change and add information in the register. In addition, SSM has decided on developing an electronic service for the licensing process (SIWAT). This project is in the start-up phase.

The process for licensing review of complex facilities, such as nuclear reactors, large accelerator facilities, cyclotrons for production of radiopharmaceuticals and proton therapy facilities is described in a steering document “Preparation of licences and review of licence conditions concerning nuclear installations and other complex installations where radiation is used” (STYR2011-131). The process follows a stepwise approach, based on experience from complex assessments e.g. thermal power upgrades of nuclear reactors and the European Spallation Source (ESS) facility.

Each application or notification including all official documents are registered as a matter in SSM360, and given individual reference numbers. The matter is closed when a decision has been formalised (STYR2012-28) and dispatched, i.e. to approve or to deny the current application or notification. SSM’s decision is often based on a supervision (review and assessment) report that is included in the matter.

A prerequisite for SSM to review applications for modifications to the license for nuclear facilities is that the licensee has performed a safety review of the supplied documents, as described in Module 6.2.

The identified parties (national and international) that should be notified during different stages of SSM’s review of a licence application (5.5 STYR2011-131) include:

- Other authorities whose pronouncement should be considered,
- The formalities on interactions with the public with respect to the environmental impact assessment,
- The formalised sharing of certain information between the Sweden, Denmark, Finland and Norway,
- Sharing of information with the Swedish Environmental Protection Agency so that they may fulfil their international obligations, and
- Reporting to EC with respect to Article 37 Euratom.

## Competence available within SSM

There are three departments within SSM’s *Emergency Preparedness, Security and Licensing Division* that are dedicated to authorisation;

- *Authorisation of Radiation Applications* with thirteen analysts,
- *Licensing of Nuclear Facilities* currently with eleven analysts, and
- *Nuclear non-proliferation and Transport*, with three inspectors that authorise transport activities

There is also competence available within SSM’s *Regulation and Knowledge Management Division*.

## 5.2 Authorisation - Nuclear Power Plants

*Related to SSR-2/1: paragraph 2.17*

*SSR-2/2: Requirements 4, 6, 7, 11, 25, 26 and 31*

*NS-R-3*

### **GSG-13**

As described under generic issues, the Government grants the license to operate a nuclear facility based on the respective pronouncements of the Land and Environmental Court and SSM.

The operating licence specifies the authorised activities but is not limited in time. Licensees must apply for licence modifications or amendments if they are planning for nuclear activities outside the licence conditions. SSM's process (STYR2011-131) for the review of licence applications stipulates a review conducted in several successive steps. This is necessary in view of the complexity of the facilities and the reviews that need to be made at different stages from a radiation safety point of view.

The Government may grant an operating licence to a new NPP only if it replaces an existing reactor that has been in operation after 31 May 2005 and will be permanently shut down once the new reactor commence commercial operation (Chapter 17 Section 6 a Environmental Code). Furthermore, the new NPP must be on the same site as the one it replaces. This means that siting in Sweden with respect to NPP is limited to Simpevarp Site (OKG), Väröbacka site (RAB) and Forsmark site (FKA) and the number of operating NPPs is limited to ten reactors.

For NPPs, the operating license normally defines the maximum allowable thermal power during operation. Over time, specific license conditions and new requirements have served as a driving force in the safety improvements and modernisation of nuclear facilities. For example, all NPPs in Sweden had to be equipped with a Filtered Containment Venting (FCV) system in the 1980s. SSM and its predecessor SKI have developed new regulations and issued orders for Swedish NPPs and required extensive back-fitting of the NPPs in operation. For example, SSMFS 2008:17 required new systems to avoid Common Cause Failure. Another example is SSM's decision SSM2012-3022-16 on conditions for independent core cooling system (ICCS), as described in Background.

Changes to an operating NPP that does not affect the licence, for example the back-fitting of some SSCs or organisational changes is handled in SSM's processes for review and assessment, Module 6. The responsibility for safety of licenced nuclear activities (Section 10 Act on Nuclear Activities), applies regardless of whether a licence has expired or not (Section 14 Act on Nuclear Activities). SSM carries out supervision of the licensed facilities and activities Module 6, Module 7 and may at any time decide on the suspension of activities and/or the undertaking of certain activities (Section 18 Act on Nuclear Activities), see Module 8. The licensee is required to assess continuously all aspects of safety and to conduct periodic safety reviews (PSR) at least every ten years (Sections 10 and 10 a Act on Nuclear Activities), see Module 6. The license covers also decommissioning of the facility, see Module 5.7.

SSMFS-A, SSMFS-D and SSMFS-K are applicable for an operating NPP until all nuclear fuel has been removed from site (Chapter 1 Section 1 SSMFS-A, -D and -K). There are further requirements on formal approval before decommissioning is allowed to commence as explained in Module 5.7 decommissioning activities.

### **5.3 Authorisation - Research Reactors**

Out of scope. There are no research reactors in Sweden.

## **5.4 Authorisation - Fuel Cycle Facilities**

*Related to NS-R-5, paragraphs 2.9 – 2.15, 3.6– 3.10 and 4.1 – 4.5  
NS-R-3  
GSG-13*

The authorisation of fuel cycle facilities follows the approach described in Module 5.2.

## **5.5 Authorisation - Radioactive Waste Management Facilities**

*Related to GSR Part 5: Requirements 3 and 4  
SSR-5: Requirements 2, and 12 - 19*

The authorisation of radioactive waste management facilities follows the approach described in Module 5.2.

Specific requirements that are reviewed in the authorisation of radioactive waste management facilities and geological repositories are found in:

- SSMFS 2008:21 concerning safety in connection with the disposal of nuclear material and nuclear waste,
- SSMFS 2008:37 concerning the protection of human health and the environment in connection with the final management of spent nuclear fuel and nuclear waste.

The most recent and extensive authorisation of a radioactive waste management facility in Sweden is the final geological repository for spent fuel (SFK) to be sited in Forsmark.

In addition to regulations concerning safety in nuclear facilities, the safety analyses for geological waste disposals must also comprise features, events and processes that can lead to the dispersion of radioactive substances after closure. Such analyses must be made before repository construction, before repository operation and before repository closure (Section 9 SSMFS 2008:21). Prior to repository closure, the safety analysis report is to be renewed and will be reviewed and approved by SSM (Chapter 4 Section 3 SSMFS 2008:1).

Shallow land burial facilities are used in Sweden for disposal of very low-level radioactive waste (VLLW) from nuclear activities. Shallow land burials are licenced under both the Act (1984:3) on Nuclear Activities and the Environmental Code (1998:808). In the Nuclear Activities Ordinance (1984:14), SSM is given the mandate to licence shallow land burials up to a specified inventory limit of 10 TBq, of which a maximum of 10 GBq may consist of alpha emitting substances (Section 16 in the Nuclear Activities Ordinance). A shallow land burial must be approved under the Environmental Code (1998:808) since it is defined as an environmentally hazardous activity. The Land and Environment Court can issue such a licence, including licence conditions, without an approval by the Government. Similar to other repositories for nuclear waste, applications are to be filed to SSM and the Court respectively.

## **5.6 Authorisation - Radiation Sources Facilities and Activities**

*Related to GSR Part 1 (Rev. 1): Requirements 23 and 24  
GSR Part 3: Requirements 6, 7 and 8*

There are regulatory requirements to register radiation sources or radiation generators at the regulatory body. Chapter 6 Section 1 in SSMFS 2018:1 states that "A notification for registration shall be made on a form provided by SSM and include the information specified therein." Chapter 1 SSMFS 2018:2 describes what activities and practises are due to notification. Chapter 2 Section 2 SSMFS 2018:2 requires that "A notification pursuant to Section 1(1) shall include the information requested by the Authority in accordance with a stipulated form."

## 5.7 Authorisation - Decommissioning Activities

### *Related to GSR Part 6*

The decommissioning of a nuclear facility is covered by the operational licence. However, it is required that the safety assessment for dismantling and demolition is approved by the regulatory body before dismantling and demolition activities are commenced (Chapter 9 Section 7 SSMFS 2008:1). For nuclear power plants the transition from normal operation to decommissioning and dismantling, requires permit from the Land and Environment Court according to The Environmental Code (1998:808). Decommissioning activities at the nuclear reactors from the time the nuclear facility has been permanently shut down until all nuclear material and other radioactive material have been permanently removed are considered as environmentally dangerous activities and also require a permit according to The Environmental Code (1998:808) (Chapter 22 Section 1).

For facilities other than nuclear, no authorisation by the regulatory body is required in order to start decommissioning activities. If SSM regards that such an authorisation is necessary, e.g. for the European Spallation Source, this will be regulated by issuing licence conditions (Chapter 6 Section 21 in the Radiation Protection Act and Chapter 5 Section 1 in the Radiation Protection Ordinance).

All licence holders are also required to have an updated safety assessment, decommissioning plan and waste management plan (Chapter 2 Section 1, Chapter 5 Sections 9 and 14 SSMFS 2018:1).

For all activities with ionising radiation (facilities and activities) before they are being decommissioned, the events and conditions that are not negligible from the point of view of protection and safety must be identified and assessed (Chapter 2 Section 1 SSMFS 2018:1). However, it is not required to report these assessments to the Authority.

According to the Environmental Supervision Ordinance (2011:13), the Land and Environmental Court has to approve that the licensee may start the transition phase, with removal of spent nuclear fuel as the main activity, as well as the start dismantling and demolition on the basis of an Environmental Impact Assessment (Section 22 in the Environmental Impact Assessment Ordinance (2013:251)). The European Commission (EC) has to state its opinion on the report according to article 37 of the Euratom treaty. Article 37 reporting must be submitted to SSM at least one year before dismantling and demolition is planned to commence (Chapter 9 Section 6 SSMFS 2008:1). Finally, SSM decides on the clearance of the remaining building structures and areas upon application by the licensee (Chapter 3 SSMFS 2018:3).

## 5.8 Authorisation - Transport Activities

### *Related to SSR-6*

SSM is the competent authority for the transport of radioactive substances (Ordinance (2006:311) on Transport of Dangerous Goods, Sections 7:1 and 18). According to the Ordinance (1984:14) on Nuclear Activities, Section 20 and according to the Radiation Protection Ordinance (2018:506), Chapter 5, Section 1, SSM deals with matters relating to safety conditions in accordance with the Act (1984:3) on Nuclear Activities, Section 8 and in accordance with the Radiation Protection Act (2018:396), Chapter 6, Section 20. The approval process or the validation certificate, as applicable, follows the general procedure approved and established in accordance with the Authority's approval process. The flow of this procedure is described in Ps, and the approval process regarding transport is described in detail in SARIS Module 6 for review and assessment.

Approvals are issued in accordance with paragraphs 832-839 of IAEA SSR-6, which have been incorporated into Swedish modal legislations (Regulations on transport of dangerous goods by road ADR-S 2021 (MSBFS 2020:9), railway RID-S 2021(MSBFS 2020:10), sea IMDG-code (TSFS 2015:66) and air ICAO-TI (LFS 2007:23; from May 17th 2021 TSFS 2021:30).

The recognition of foreign approvals is carried out in accordance with Swedish transport legislation, which incorporates the provisions of IAEA SSR-6. In addition, internal instruction documents have been developed to describe methods and facilitate approvals, e.g. STYR2012-6 "Approval for the transport of dangerous goods class 7, special arrangement" and STYR2011-182 "Review and assessment of transport packages".

## 5.9 Authorisation - Occupational Exposure

### *Related to GSR Part 3: Requirements 12, 19-21, 23-25, 28 and 52 describe and demonstrate implementation in the authorisation process:*

The following authorisation is part of this sub section:

#### *Licencing:*

- Veterinary medical radiology
- Industrial radiography
- Accelerators, above 1 MeV
- Research and industry
- Professional Trade - Service and Maintenance, and
- High Activity Sealed Sources (HASS)

#### *Notification:*

- Veterinary medical radiology: stationary x-ray devices with locked beam direction <150 kV and dental x-ray diagnostic using intra-oral image receptor
- Technical devices for measuring, control, analysis and laboratory use
- Cabinet X-ray
- Sealed sources (excluding HASS)
- Unsealed sources, up to a certain activity, and
- Professional Trade – Market and Demonstration

In the licensing of Medical exposure, occupational exposure is included, therefore this is described in Module 5.10 (Medical exposure).

There are also specific activities and appointments that need *approval* by SSM:

- Dosimetry services for category A workers, and
- RPE (Radiation Protection Expert).

The authorisation of occupational exposure follows the approach described in Module 5.1 and parts of Module 5.2.

For a number of practices and activities that require a licence according to the Radiation Protection Act (2018:396), SSM has issued complementary and more specific regulations: SSM's regulation (SSMFS 2018:5) concerning medical exposures, SSM's regulation (SSMFS 2018:6) concerning industrial radiography and SSM's regulation (SSMFS 2018:7) concerning licensable veterinary activities.

In terms of occupational exposure, notification is applied for activities described in SSMFS 2018:2, in which it is considered unlikely that the effective dose to a worker is exceeding 1 millisievert per year. Activities (beside dental intra-oral X-ray which is described in Module 5.8 Medical exposure) subjected to notification requirements are defined in SSMFS 2018:2 (Chapter 1 Sections 3-7 and 10). These activities consist of veterinary X-ray diagnostics, cabinet X-ray equipment, technical devices for measurement, control, analysis and laboratory use, sealed radiation sources with an activity less than HASS, open radiation sources with an activity level not exceeding one hundred times the activity values set out in Annex 1 in SSMFS 2018:2 and professional trade with radiation sources. Notification is done in SIWA.

According to SSMFS 2018:9, the application for approval of dosimetry service must include a description of the quality management system. The quality management system is required to correspond to the principles in ISO 9000 series (Section 4 SSMFS 2018:9). For approval, the dosimeter system also have to meet a number of performance requirements (Section 2 SSMFS 2018:9).

An approval is valid for two years (Section 7 SSMFS 2018:9). There's a template for a letter to the company, containing information regarding measures required to renew the approval, stored in SSM360 (18-2552). Changes of the dosimeter systems that are included in the approval must not be made without SSM's consent (Section 6 SSMFS 2018:9). When renewing the approval, the main focus is on changes that have taken place since the latest approval (STYR2011-146).

A list of approved dosimetry service providers including parameters for each dosimeter system is published and kept up to date on SSM's website (<https://www.stralsakerhetsmyndigheten.se/att-arbeta-stralsakert/godkanda-persondosimetritjanster/>).

## 5.10 Authorisation - Medical Exposure

***Related to GSR Part 3: for Requirements 34-36, 39 and 42 describe and demonstrate implementation in the authorisation process:***

Medical exposures require a licence according to chapter 6 section 1 in the Radiation Protection Act (2018:396). Requirements for medical exposure for licensed activities are stated in the Radiation Protection Act (2018:396), the Radiation Protection Ordinance (2018:506) and in SSMFS 2018:1. Complementary and more specific regulations regarding different areas in medical exposures are stated in SSMFS 2018:5.

Dental intra-oral X-ray is the only medical exposure activity subject to notification. Notification is done in SIWA, an electronic service for parties to register their possession of radiation sources and equipment. Regulations and general advice regarding dental X-ray diagnostic using intra-oral image receptor are found in chapter 1 section 2, chapters 2 and 3 SSMFS 2018:2.

The licencing of medical exposures follows the process described under generic issues (Module 5.1). Applicants are required to submit information about the practice involving medical exposure they plan to carry out. SSM has published application instructions on the web site for several activities and facilities, which cover requirements regarding medical exposure. There are also specific report templates (in SSM360) for the review and assessment of medical facilities and activities:

- Template for review and assessment of medical radiology (X-ray equipment)
- Template for review and assessment of nuclear medicine (open and sealed sources)
- Template for review and assessment of radiation therapy (linear particle accelerator (LINAC) and HASS)
- Template for review and assessment of dental radiology (X-ray equipment)

The templates cover the requirements that must be complied with in order to be granted an authorisation.

During the review, SSM verifies that the applicant has submitted all the information requested in the application form, including mandatory attachments. SSM reviews the information and makes assessments whether or not the medical exposure is deemed to be justified (all applicants registered as a caregiver are deemed to be justified, level 1 justification) and whether the applicant has the capacity and ability to comply with the requirements. According to the Patient Safety Act (Chapter 3 Sections 1-5 SFS 2010:659), caregivers are obliged to report new health and medical care activities to Health and Social Care Inspectorate who is responsible for the caregiver register. If the applicants is registered as a caregiver and is deemed to have the capacity and ability to comply with the requirements a license will be issued. These licenses issued by SSM has a limited authorisation period of five years. After five year the licensees has to apply for a renewal. However, some old licenses are unlimited in time.

## **5.11 Authorisation - Public Exposure**

***Related to GSR Part 3: Requirements 12, 29-30, 33, 45 and 47 describe and demonstrate implementation in the authorisation process:***

The authorisation of public exposure applies to all licensees and are included in the licensing process described in Module 5.1, for both nuclear activities, medical exposure and other activities involving ionising radiation.

Concerning the demonstration of safety and public exposure, it is stated that the impact of an activity from a radiation protection point of view on the public and the environment needs to be assessed and documented based on the nature and scope of the activity (Chapter 5 Section 1 SSMFS 2018:1). The evaluation is to be carried out before the operation is allowed to commence, including the time when the operations are ongoing, discontinued and the time thereafter, and is required to refer to the release of radioactive substances into the environment and other exposure to ionising radiation from the operation. The evaluation must be kept up to date.

Radiation doses to the public are to be calculated with an appropriate method depending on the nature and scope of the activity and by applying the concept of *representative person*. (Chapter 5 Sections 2-3 SSMFS 2018:1). The method must be transparent, verified, and validated and reasonably conservative. Radiation doses should be calculated to the age categories 0-5, 6-15, and 16-70 years and dose coefficients recommended by ICRP for inhalation and intake is to be applied.

In terms of public exposure, notification is applied for activities described in SSMFS 2018:2, in which it is considered unlikely that a person in the general public could receive an effective dose exceeding 0.1 mSv/yr.

In accordance to the Radiation Protection Act (2018:396) and the associated Ordinance, SSM may issue further regulations on authorisation or notification for activities, which are carried out in environment with ionising radiation (Chapter 6 Section 7 in the Radiation Protection Act and Chapter 5 Section 7 in the Radiation Protection Ordinance).

## 5.12 Conclusions

The overall conclusion is that there are legal and regulatory requirements for the authorisation in Sweden. The requirements allow SSM to specify the conditions necessary for safety. There is a process for exemption and approval by notification for certain activities. There are a requirements for applicants of nuclear activities to conduct safety assessment and submit a demonstration of safety in support of the application for authorisation of a facility or an activity.

# Module 6: Review and Assessment

## 6.1 Generic issues

### Management of Review and Assessment

*Related to GSR Part 1 (Rev. 1): Requirements 25 and 26, paragraphs 4.40 – 4.48  
GSR Part 3 Requirement 13  
GSR Part 4 (Rev. 1): Requirements 1 – 4*

SSM performs review and assessment of relevant radiation safety information to determine whether facilities, activities and exposure situations comply with regulatory requirements and conditions specified in the authorisation. SSM is responsible for performing reviews and assessments prior to authorisation and again over the lifetime of the facility or the duration of the activity until decommissioning is completed, as specified in acts, ordinances and regulations promulgated by SSM or in the authorisation process, see also Module 5.

The purpose of the review and assessment is to check whether the legal and regulatory requirements are met. The content, scope and frequency of review and assessment activities are commensurate with the radiation risks and societal concern associated with the reviewed facility or activity, in accordance with a graded approach. The review and assessment is documented in a review report. SSM records the results and decisions deriving from review and assessments and takes appropriate action, including enforcement action, as necessary.

SSM has an established formal process containing generic steps for review and assessment activities, see Figure 10. The process begins with the initiation and preparation phases, in which the objectives of the review and assessment activity are defined and competent resources are allocated for the assignment. A review plan is produced containing identified governing, regulatory documents and assessment criteria that are derived from relevant standards or from other supporting material. In the following phase, assessment of compliance with applicable requirements is performed in accordance with steering document (STYR2011-87) and documented in a report. The review includes external technical or other professional support and views from other authorities as needed. The preliminary results are consulted and quality is controlled according to the SSM management system prior to approval of the report. The process is adjusted depending on the scope and purpose of the review and assessment to cover all regulated facilities and activities. Specified guidance on how to perform review and assessment in authorisation and in supervision over a lifetime of a facility and duration of an activity is given in SSM's process management tool and in other supporting documentation. These generic steps are applied also to authorisation and inspection processes, see Module 5 and Module 7 respectively.



Figure 10 – Generic steps for Review and Assessment activities

SSM uses the word “supervision” as the common term for review and assessment and inspection activities over the lifetime of a facility or the duration of an activity. An overview of the supervisory processes is presented below.

## Supervisory processes

SSM’s supervisory activities follow a number of formal processes that are described in SSM’s process management tool and in the steering document “Process: Exercising supervision” (STYR2017-16). For the purpose of this report, the supervisory processes are sorted under the two overarching processes “Review and assessment”, which is described in this chapter and “Inspection”, which is described in Module 7, see Figure 11.

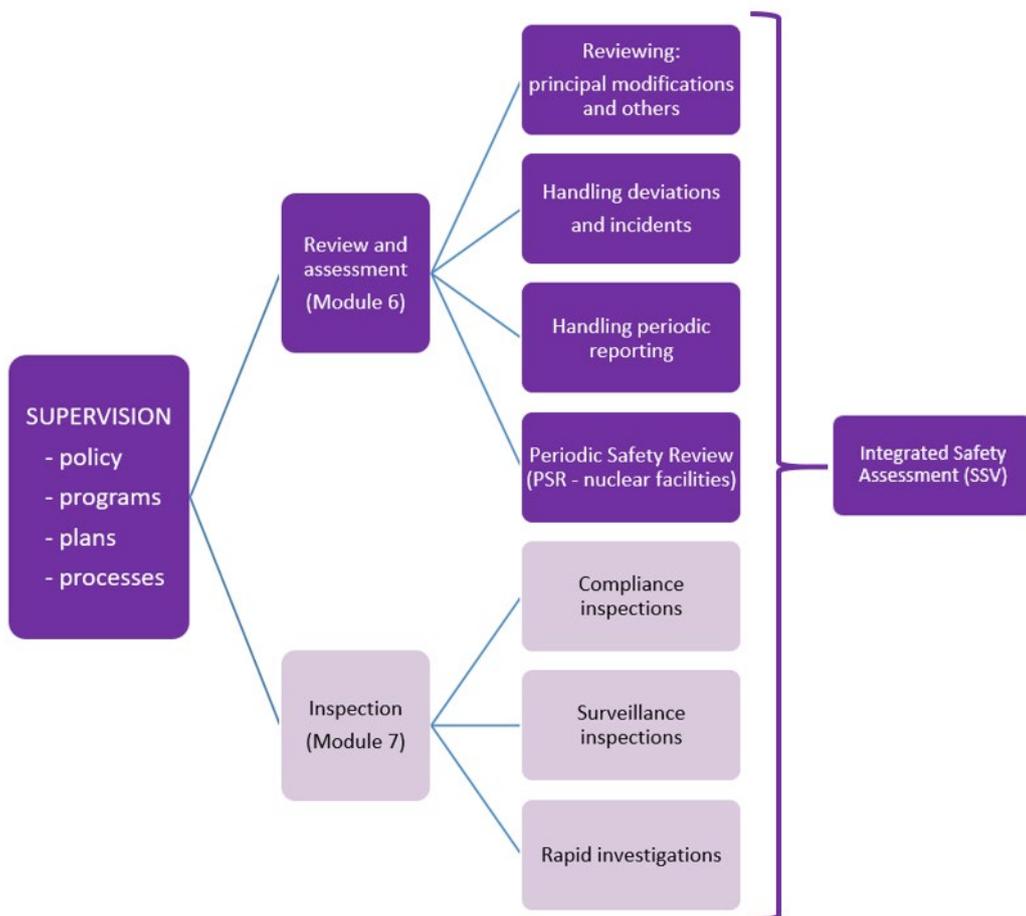


Figure 11 - Supervisory process ("Review and Assessment" and "Inspection")

## Supervisory policy and programmes

SSM has adopted a supervisory policy that applies to all supervision (inspections, reviews and assessments) conducted by the Authority (STYR2011-97). The policy states that SSM must compile a comprehensive supervisory plan based on an investigation of the

need for supervision in the Authority's entire area of operation. A supervisory plan is developed annually based on four supervisory programmes that aims to clarify overall supervision needs and priorities in relevant areas.

Supervisory programs for relevant supervisory areas are developed according to a steering document (STYR2016-4) to ensure that all regulated facilities and activities and all aspects relevant to safety are reviewed and assessed over their lifetime:

1. Nuclear power plants in operation (20-2694),
2. Nuclear facilities and safe management of radioactive waste (incl. decommissioning) (20-1941),
3. Health and medical services (15-1224), and
4. Products, services and natural radiation aspects (19-1151).

The supervisory programs consists of both recurrent periodical supervision as well as more demand-based supervision, which is defined on a yearly basis depending on results from supervision activities, identified areas where supervision is regarded as necessary for a specific area, major modifications, technical and organisational and other identified needs. The programs cover not only review and assessment activities but also activities related to authorisation (see Module 5) and to inspection (see Module 7).

## Organisation and Technical Resources for Review and Assessment

***Related to GSR Part 1 (Rev. 1): Requirement 4, paragraph 2.8; Requirement 11, paragraphs 2.34 – 2.38; Requirement 15, paragraphs 3.3 – 3.5; Requirement 16, paragraph 4.4 – 4.5; Requirement 17, paragraph 4.6; Requirement 18, paragraphs 4.11 – 4.13 and Requirement 20, paragraphs 4.18 – 4.22***

The organisation, staffing and competence management of SSM is described in Module 3.

Review and assessment activities prior to authorisation are directed by the *Emergency Preparedness, Security and Licensing Division*, which has two departments dedicated to authorisation and licensing for various facilities and activities, *Authorisation of Radiation Applications* and *Licensing of Nuclear Facilities*, see also Module 5.

The *Supervision Division* directs review and assessment and other supervisory activities over the lifetime of the facility or the duration of the activity, see also Module 7. The *Supervision Division* is divided into five departments covering different supervisory areas, *Coordination and Human and Organisational Factors*, *Event Analysis and Engineering*, *General Public and Environment*, *Medical and Occupational Exposure* and *Operation and Decommissioning of Nuclear Facilities*. Supervision is also conducted by the two departments *Nuclear Non-proliferation and Transport* and *Development of Emergency Preparedness and Response* (security) at the *Division of Emergency Preparedness, Security and Licensing*.

In both cases above, review and assessment activities are supported as needed by analysts and specialists from the *Regulation and Knowledge Development Division*, in particular by the three departments *Plant Safety Assessment*, *Radiation Protection and Environmental Assessment* and *Research*. Additionally, there are arrangements for obtaining technical or other expert professional advice or services from external sources in support of review and assessment activities as described in Module 3.4.

## Bases for Review and Assessment

***Related to GSR Part 1 (Rev. 1): Requirements 23 and 24, paragraphs 4.33 – 4.34; Requirements 25 and 26, paragraphs 4.40 – 4.41  
GSR Part 4 (Rev. 1): Requirements 14 – 15***

SSM conducts supervision (inspections, reviews and assessments) in accordance with

- the Act (1984:3) on Nuclear Activities and the Nuclear Activities Ordinance (1984:14),
- the Radiation Protection Act (2018:396) and the Radiation Protection Ordinance (2018:506),
- the Environmental Code and the Environmental Supervision Ordinance (2011:13),
- the Act on the control of dual-use items and of technical assistance (2000:1064) and the Ordinance on the control of dual-use items and of technical assistance (2000:1217),
- the Act on Transport of Dangerous Goods (2006:263) and the Ordinance on Transport of Dangerous Goods (2006:311),
- the Ordinance on market surveillance of goods and other related supervision (2014:1039),
- the Product Safety Act (2004:451) and the Product Safety Ordinance (2004:469),
- the Act on liability and compensation for radiological accidents (2010:950) and the Ordinance on liability and compensation for radiological accidents (from the date of their entry into force),
- the Protective Security Act (2018:585) and the Protective Security Ordinance (2018:658) (as of the date on which the amendments to the Ordinance enter into force), and
- the Ordinance with instructions for SSM (2008:452).

The following regulations and guidance is relevant for safety assessment and for deterministic and probabilistic safety analysis by the licensees:

- SSM's regulations (SSMFS 2018:1) concerning basic provisions for licensable activities involving ionising radiation
- SSM's regulations (SSMFS-A) concerning the assessment and presentation of radiation safety for nuclear power plants
- SSM's regulations (SSMFS 2008:1) concerning safety at nuclear installations
- SSM's regulations (SSMFS-KÄKA) concerning management of radioactive waste from nuclear facilities

The updated regulations promulgated by SSM in recent years are developed with reference to the IAEA safety standard and other relevant international standards, see also Module 9. The regulations for safety assessment and safety analysis are developed with reference to, e.g. IAEA GSR Part 4, IAEA SSG - 61, IAEA SSR -2/2 and WENRA SRL.

An authorised party must provide the Authority with information and documents needed for supervision upon request (chapter 8, section 4 in the Radiation Protection Act (2018:396). In addition, SSM has the right to access facilities where activities with ionising radiation are carried out (chapter 8 section 11 in the Radiation Protection Act (2018:396)). According to Section 17 of the Act (1984:3) on Nuclear Activities, the

licensee shall provide SSM with information and documents as needed for supervision, as well as give access to any facility or location where nuclear activities are performed so that investigation and sampling can be performed as deemed necessary.

According to Section 16 a of the Act (1984:3) on Nuclear Activities the licensee of nuclear activities shall provide the opportunity for the regulatory body to observe and review how the requirements are complied with in respect of tasks performed by suppliers or their subcontractors or other contractors. Reviews and other supervisory activities are important parts in assessing compliance with the legislation, regulations and conditions over the lifetime of the facility or duration of the activity.

A graded approach is implemented in the regulations promulgated by SSM, which is based on the nature, scope and potential risks of the activity or facility. The supervisory programs are based on the steering document (STYR2016-4), in which it is stated that the supervision performed by SSM shall be effective, risk- and knowledge-based, as well as adapted to the various facilities and activities.

## Performance of Review and Assessment

***Related to GSR Part 1 (Rev. 1): Requirements 25 and 26, paragraphs 4.43 – 4.48  
GSR Part 4: Requirements 2 – 21***

The depth and scope of SSM's review and assessment of a facility, activity or exposure situation is commensurate with the radiation risks and societal concern associated with the facility, activity or exposure situation in accordance with a graded approach.

SSM reviews and assesses the radiation risks associated with normal operation, anticipated operational occurrences and accidents, including possible events with a very low probability of occurrence. Reviews and assessments are made prior to operation of the facility or conduct of the activity as well as during authorisation, and periodically throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable. Any proposed modification that might significantly affect the safety of a facility or activity is subject to a review and assessment by SSM. SSM reviews and assesses all aspects related to radiation safety for the facility or activity. SSM documents and records the results and decisions deriving from reviews and assessments, and takes appropriate action (including enforcement action) as necessary.

SSM verifies the comprehensiveness, scope and quality of incoming radiation safety assessments by performing an initial review of the quality of the submitted documentation with respect to the accuracy, completeness, traceability and transparency.

SSM has methods to ensure that any reasonably practicable safety improvements identified in reviews and assessments are implemented in a timely manner. All review and other supervisory activities that comprises a control against requirements shall result in a decision with regards to the findings. Depending on the findings, the decision can result in various measures (STYR2011-87). The licensee should be ordered to take action if a deficiency is of moderate or major importance to radiation safety, is complex or needs to be addressed immediately. A regulatory injunction is mandatory for the licensee to follow and to carry out the actions stated. It may involve direct physical measures, such as re-designs, carry out analyses or provide a remedial action programme. A regulatory order lets the activity continue, but the specified actions or measures shall be taken within a specified time, a conditional fine may also be included in the regulatory order. Non-compliance with a regulatory order is punishable. The licensee has to inform SSM how

the order is handled. SSM follows up on the licensee's progress by conducting review and assessment or other supervisory activities, e.g. inspections. Documented results from inspections, e.g. assessed requirements, identified deficiencies and issues, serve as input for Integrated Safety Assessments (SSV), which are performed regularly based on results from previous supervision (inspections, reviews and assessments), see also Module 6.2.

## 6.2 Review and Assessment - Nuclear Power Plants

*Related to almost all requirements listed in subchapter 6.1*

The review and assessment of license applications for nuclear power plants (e.g. power uprate and facility modifications due to upgraded operating conditions) follows the method described in Module 5.

### Supervisory program for nuclear power plants in operation

The supervisory program for nuclear power plants in operation (20-2694) over duration of the activity has been revised in recent years to provide better alignment with international best practice (SSG-25, IAEA GS-G-1.3, IAEA GS-G-1.3). The aim is to achieve a better overview, assuring alignment with regulations and introducing a higher degree of risk-information in the frequency and scope of supervisory program. The program entails considerable changes to the planning, implementation, and follow-ups of supervision.

The supervisory program (20-2694) is divided into six fundamental areas:

- Management and control
- Safety analysis
- Design
- Facility status
- Operation
- Environmental impact

#### *Supervisory groups for nuclear power plants*

The recurrent periodical part of the supervisory program for nuclear power plants covers a period of 10 years and describes which supervisory groups that are assessed each year for nuclear power plants in operation. There are 37 supervisory groups at the moment, further development of the program might change the number of groups (20-2694):

1. Safety management, including communication, safety culture
2. Management system, including document management
3. Organisation, Organisational changes, including operational changes
4. Information security, IT security, archive management
5. Supplier management, purchasing – both goods and services
6. Skills, staffing, staff management, recruitment
7. Training, simulator, re-training, exercises
8. Experience feedback – both internal and external
9. Internal reviews
10. Safety review

11. Self-assessment, self-evaluations, safety programmes
12. Incident management and incident investigations
13. Safety analyses
14. - Deleted
15. SAR – Safety Assessment Report (design, content and topicality)
16. Operational Limits and Conditions (design, content and topicality)
17. Facilities register
18. Plant modifications (temporary and permanent), component replacements
19. Nuclear fuel, criticality safety measures
20. Maintenance, maintenance plan, FU, AU
21. Ageing management and Ageing management programmes
22. Environmental qualification, Qualification, Requalification
23. In-service inspection
24. Function checks, functional testing
25. Operation of the facility, including Revision
26. Severe accident management including emergency response organisation
27. Operational conditions (procedures, instructions, operator aids), operational procedures
28. Verification of readiness for operation
29. Work at the facility (work licences, occupational radiation dose, housekeeping, etc.)
30. Protection of workers
31. ALARA programme
32. Chemistry programme
33. Physical protection, access control
34. Release of radioactive substances
35. Environmental monitoring
36. Non-proliferation control
37. (Handling of radioactive materials and waste)
38. (Emergency preparedness)

The supervisory groups occur in the program every third, fifth or seventh year based on the risk importance for each group. At those time intervals, the group as a whole is assessed. Hence, the programme covers each group (and requirement) at least once over a period of 10 years. For each supervisory group, supporting documentation is provided that describes the content of each group, its scope and requirements and necessary supervisory (inspections, reviews and assessments) activities to ensure enough information for the assessment of the supervision group according to the periodicity of the programme (20-2694).

## Demand-based supervision

Another important part of the supervisory program is the demand-based supervision that is defined on a yearly basis and described in an annual supervision plan. It differs from year to year depending on:

- Results from integrated safety assessments
- Results from inspections

- Identified areas where supervision is seen as necessary from e.g. events or concerns of both national or international origin
- Major ongoing changes, technical or organisational at the licensee
- Other identified needs.

There is also a possibility for SSM to carry out supervisory activities more rapidly if e.g. an event has occurred that needs more immediate attention.

Information from the “demand based” supervisory activities are also used when assessing the different supervisory groups and, if enough information is available, the demand based supervision can also replace some of the recurrent activities.

## Review and assessment processes

Based on the supervisory program, SSM uses a number of approaches for the review and assessment of nuclear facilities and activities during their lifetime:

### Review of principal modifications (ABG)

- Licensees of nuclear facilities are required to notify SSM of all planned technical and organisational modifications at the facility or activity, which may affect the conditions specified in the safety report as well as the resulting revisions to the safety report. The licensee shall perform a radiation safety audit in accordance with the provisions of the regulations prior to submission in which the licensee reviews and ensures that applicable radiation safety aspects are taken into account. All submitted notifications are handled by a standing group of experts (Notification Processing Group, ABG (STYR2011-111)). The group is established by SSM in order to make a first assessment and screening of all notifications based on a set of criteria that describes the radiation safety significance of each notification. The group meets biweekly and gives a recommendation to the division management regarding each notification. The division head makes the final decision on whether notifications are subject to reviewing or not.

### Follow-up of deviations and incidents

- Licensees must report any deviation or incident to SSM, in accordance with current regulations. SSM’s handling of the reported issues varies depending on the facility and the nature of the deviation or incident.

### Review of periodic reports

- The licensees are required to submit annual reports describing, for instance, the operation from a safety perspective, discharges of radioactive substances to the environment, radiation protection work with regard to employees and the radioactive waste management. The required reports are listed in SSM’s steering document STYR2011-153. SSM decides on which reports to review and assess following the formal process described in SSM’s digital process tool.

### Periodic Safety Review (PSR)

- SSM ensures that authorised parties routinely evaluate operating experience and perform comprehensive safety reviews of nuclear facilities, in the form of a PSR as required by Section 10 a of the Act (1984:3) on Nuclear Activities. The purpose of the PSR is to have the licence holder re-assess, verify and continuously improve the safety of its nuclear installations. The PSR is to be reported to SSM together with identified measures documented in an action plan. The PSR report and the action plan is reviewed by SSM in accordance with a steering document (STYR2011-123) in order to verify that the PSR report fulfils

the applicable requirements. SSM also assesses the potential of the action plan to lead to fulfilment of the requirements concerning maintenance and improvement of the safety and radiation protection of the facility. SSM ensures that any reasonably practicable safety improvement identified in the review are implemented in a timely manner, by issuing a decision and a command, which is also followed up by supervision six months later.

#### **Integrated Safety Assessment (SSV)**

- SSM’s integrated safety assessments (SSV) comprise nuclear safety and radiation protection assessments of the nuclear facilities under SSM’s supervision. SSVs are performed annually for NPPs. Based on all supervision activities (compliance inspections, surveillance inspections, reviews, authority decisions and other relevant information and evaluations), a general appraisal is made of the nuclear safety, radiation protection and non-proliferation control status of the facility in relation to relevant requirements. In the assessment, previous information and conclusions are included in order to identify trends that are difficult to detect in a short-term perspective. The SSV reports for NPPs are approved by SSM’s Director General and presented at top-level management meetings with the licensees.

#### **Related activities**

- If SSM deems it necessary, it is possible to initiate review and assessment of any matter related to safety, radiation protection, security or nuclear non-proliferation.
- The processes “Securing skills and competence”, “International cooperation and development cooperation” and “Measurement activities, environmental surveillance and measurement assignments” provide conditions for conducting supervision and licensing review with well-supported decisions that are perceived as adding value (STYR2011-71).

### **Radiation safety audit**

Radiation safety audit is a tool with which the licensee review and ensures that applicable radiation safety aspects are taken into account, and that applicable statutory requirements for radiation safety for the design and operation of the nuclear reactor are met. For notifications from nuclear facilities and activities (Appendix 4 SSMFS-D), the subject of the notification shall undergo a radiation safety audit prior to submission to SSM (Chapter 6 SSMFS-A). The radiation safety audit consists of both a primary (Section 3 Chapter 6 SSMFS-A) and an independent radiation safety audit (Section 4 Chapter 6 SSMFS-A). The requirements of the latter function is stipulated in provision (Section 3 Chapter 2 SSMFS-D) and its purpose is to ensure a control function, independent from the rest of the organisation, with sufficient means to monitor, review and enhance the radiation safety at the nuclear power plant.

## **6.3 Review and Assessment - Research Reactors**

Out of scope. There are no research reactors in Sweden.

## 6.4 Review and Assessment - Fuel Cycle Facilities

### *Related to NS-R-5, paragraph 3.9*

The review and assessment of license applications for fuel cycle facilities follows the method described in Chapter 5. The review and assessment over the lifetime of a fuel cycle facilities follows the approaches described in Module 6.2:

- Periodic Safety Review (PSR)
- Review of principal modifications (ABG)
- Integrated Safety Assessment (SSV)
- Operating experience and event follow up
- Review of required reports
- Related activities

The periodical supervisory program for Fuel Cycle Facilities is included in the supervisory program Nuclear facilities and safe management of radioactive waste (incl. decommissioning) (20-1941). The supervisory program is developed from the supervisory program for nuclear power plants in operation (20-2694) and describes how SSM plans to implement supervision in the area: "Radiation-safe Nuclear Facilities and radiation-safe management of radioactive waste".

The supervisory programme consists of both recurrent periodical supervision activities as well as more demand-based supervision. The programme consists of 23 supervisory areas to be covered within a ten-year cycle:

1. Safety management, Safety culture
2. Management System
3. Organisation and Organisational Change
4. IT-Security and archiving
5. Procurement
6. Competence and staffing, Education and training
7. Experience feedback
8. Internal audits
9. Safety review
10. Internal control and safety program
11. Event analysis and root cause analysis
12. Safety analysis
13. Safety Assessment Report, Technical specifications
14. Maintenance program, aging management, environmental qualification, surveillance program, functional testing
15. Facility modifications
16. Criticality safety
17. Operations
18. Instructions for operation, Plant control and surveillance
19. Work conditions inside the facility, protection of workers, ALARA-program
20. Discharges of radioactive substances, Environmental monitoring
21. Non-proliferation management
22. Radioactive waste management
23. Emergency preparedness and response

The frequency of supervisory activities at a fuel cycle facility is determined by the emergency preparedness category (SSM2018-3446-1) of the facility and on the risks of

the facility in relation to the 23 supervisory areas. The supervision groups occur in the program every fourth, sixth or eighth year for facilities with an emergency preparedness category 2; and every fifth, seventh and ninth year for facilities in category 3. A graded approach is applied also for the Integrated Safety Assessment (SSV) of nuclear facilities other than NPP's. For these facilities the SSV is performed every second or third year depending on the licensee's risk category.

The supervisory programme is mostly focused in verifying that the authorised party is in compliance with regulatory requirements. It is also possible to verify compliance with the conditions specified in the authorisation but this is normally performed in an indirect way by controlling compliance with the Safety Assessment Report. The planning of supervisory activities to verify compliance with authorisation conditions is less systematic than for compliance with regulatory requirements.

The demand-based supervision in the programme is defined on a yearly basis and is described in an annual supervision plan. It differs from year to year depending on factors like ongoing modifications (technical or organisational), results from previous inspections or results from the integrated safety assessment. The integrated safety assessments are usually performed every second year for fuel cycle facilities and are based on all compliance inspections, surveillance inspections, reviews, authority decisions and other relevant information performed by SSM during the period.

## Safety review

According to Chapter 4, Section 3 SSMFS 2008:1, a safety review shall be carried out by the licensee in order to check that applicable safety aspects of modifications are taken into account and that applicable safety requirements for the design, function, organisation and operation of the installation are met. The review shall be carried out in a comprehensive and systematic manner and be documented.

The safety review shall be carried out in two steps. The first step, the primary safety review, shall be carried out within the parts of the installation's organisation that are responsible for the issue. The second step, the independent safety review, shall be carried out within a dedicated review function which shall be independent of the parts of the organisation responsible for the matter.

### **6.5 Review and Assessment - Waste Management Facilities**

#### ***Related to GSR Part 5: Requirements 13 – 16, SSR-5: Requirements 11 – 14***

Review and assessment of waste management facilities is covered by the supervisory program Nuclear facilities and safe management of radioactive waste (incl. decommissioning) (20-1941), see also Module 6.4.

In addition to the existing waste management facilities, four major waste management and geological disposal facilities are foreseen to be designed, sited, constructed and licensed in the future. A plant for encapsulation of spent nuclear fuel, a disposal facility for spent fuel, a disposal facility for long-lived low and intermediate level waste, and an extension of the SFR facility for waste from decommissioning are planned and additional land burials may be constructed. The review and assessment of license applications for waste management facilities is described in Chapter 5.

For waste management facilities in general, with the exception of shallow land burial facilities, the periodic safety review as well as principal modifications follows the procedure described in Module 6.2.

Requirements regarding the management of radioactive waste from nuclear activities are stipulated by several SSM regulations. The regulations include requirements for, among others, the following:

- A documented plan for management of radioactive waste, showing how and when the waste is to be managed (chapter 5 section 9 SSMFS 2018:1)
- Plans for safe on-site handling, and continued management of nuclear material and nuclear waste shall be described in the safety analysis report of the facility (chapter 4, section 2 SSMFS 2008:1).
- Measures for the management of nuclear waste shall be planned in a systematic manner so that relevant aspects are taken into account and weighed from a holistic approach to management. (chapter 2, section 2 SSMFS-KÄKA).
- When designing and operating a facility concerning space for storage, the need to inspect the stored radioactive waste and spent nuclear fuel must be met as well as the need for extra space for moving radioactive materials (chapter 6, section 2 SSMFS 2008:1).
- Waste management plans. The plans shall for example take into account amounts of different categories of the radioactive material and processing and storage of the radioactive material (chapter 2, section 5 SSMFS-KÄKA).
- Only packages approved by SSM may be stored for more than three years or transported to a geological repository (such as the SFR facility) for disposal (chapter 4, section 3 SSMFS-KÄKA). Such approval, which is given to different waste type descriptions, are based on an evaluation that the waste packages will comply with the waste acceptance criteria for disposal.
- An up-to-date inventory of on- and off-site radioactive waste produced from operations or decommissioning of the facility (chapter 5, sections 1–3 SSMFS-KÄKA).
- Waste acceptance criteria must be derived based on the properties of the radioactive material that can be received for processing, storage or disposal. The waste acceptance criteria are to form part of the safety analysis report (chapter 6, section 11 SSMFS 2008:1).
- Procedures must also be in place for management of radioactive waste that does not meet the waste acceptance criteria so that measures that can be undertaken have been prepared (chapter 3, section 6 SSMFS-KÄKA).

In the review of geological disposal facilities SSM addresses both operational aspects as well as the aspects related to post-closure safety. The regulatory requirements specifically related to post-closure safety are specified in two regulations issued by SSM (SSMFS 2008:37 and SSMFS 2008:21). In these regulations the risk-based criteria for geological disposal facilities are established together with requirements concerning optimisation and the use of BAT (Best Available Technology), requirements regarding the natural and technical barriers, as well as requirements regarding the safety assessment of the repository. The assessment should evaluate exposures both due to the expected evolution of the repository, as well as scenarios with a lower probability. The identified scenarios should be motivated. The review and assessment of a geological repository always need to address uncertainties

concerning the initial state and the long-term evolution of the repository as a basis for evaluating the consequences on human health and the environment.

## Safety review

The requirement for safety review described in Module 6.4 (Chapter 4, Section 3 SSMFS 2008:1) also applies to waste management facilities, see above.

## 6.6 Review and Assessment - Radiation Sources Facilities and Activities

*Related to GSR Part 1 (Rev. 1): Requirements 23, 25 and 26  
GSR Part 3: Requirements 10 - 13*

Radiation sources are covered by the supervisory programme Products, services and natural radiation aspects (19-1151), which applies to supervision of licensees within the following fields:

- Accelerators
- High Activity Sealed Sources (HASS)
- Industrial radiography
- Unsealed sources
- Installation and maintenance
- Veterinary medicine
- Other practices requiring a license

Review and assessment of information relevant to safety for radiation sources facilities and activities are performed in connection with license applications, annual reports, and incident reports and through supervision. The review and assessment of radiation sources facilities and activities are performed combined with review and assessment of occupational exposure and, if relevant, medical exposure and public exposure.

Review and assessment of radiation sources facilities and activities in connection with licensing follows SSM's general process for licensing review (see description in Module 5)

Over the lifetime of non-nuclear facilities and activities, review and assessment is performed of e.g.

- Notifications of changes regarding radiation sources,
- Annual reporting regarding medical exposures performed within nuclear medicine and diagnostic radiology,
- Reported events and circumstances involving radiation sources in health and medical services,
- Annual reporting from licensees in industrial radiography regarding accidents and incidents
- Clearance of facilities with activities which have lead, or could have lead to contamination or activation,
- Reporting regarding potentially exceeded dose limits for occupational exposure.

Additionally, SSM has the option to initiate investigations or finance research activities to support review and assessment activities, if deemed necessary.

Activities with radiation sources have been divided into activities that require a license and notifiable activities that only need to be notified for registration (1 chap. SSMFS 2018:2). Practices with notifiable activities are found in the following areas:

- Veterinary medicine (fixed equipment)
- Cabinet X-rays, XRFs
- Equipment with sealed sources (category 4 and 5), e.g. level gauges
- Unsealed sources
- Trade with radiation sources or radiation generators

## 6.7 Review and Assessment - Decommissioning Activities

### *Related to GSR Part 6: paragraph 3.3*

Nuclear activities and non-nuclear activities with ionising radiation are subject to requirements in the Radiation Protection Act (2018:396). In chapter 1, section 7 of this Act it is stated what is included in the term activities with ionising radiation. In chapter 5, section 4 of the same act it is stated that the party conducting the activity, when the activity with radiation is about to be moved or decommissioned shall take measures as soon as possible and applicable in order to radiologically clear areas and buildings that might have been radiologically contaminated from the activity. In chapter 5, section 9 of the same act it is stated that the relevant authority is allowed to give out more detailed requirements and regulations with respect to decommissioning.

SSM regulates decommissioning in SSMFS 2018:1. In chapter 5, section 14 in SSMFS 2018:1 it is stated that before starting an activity, a documented plan for decommissioning the activity shall be compiled.

During the dismantling and demolition phase the licensee of nuclear activities and facilities is required to submit more detailed descriptions of “work packages” (decommissioning activities) before the work is initiated, as stated in chapter 9, section 8 of SSMFS 2018:1. All submissions are handled by the Notification Processing Group, ABG (STYR2011-111), see also Module 6.2.

SSM follows the ongoing decommissioning through supervisory activities such as reviews and inspections and through regular communication between SSM and the licensee. The licensee is also obliged to submit weekly reports and a set of yearly reports to SSM according to requirements in SSM’s regulations. Decommissioning activities are also included in the Integrated Safety Assessment (SSV), see also Module 6.2.

For decommissioning of nuclear facilities, SSM has developed a general programme for base supervision, which is covered by the supervisory programme Nuclear facilities and safe management of radioactive waste (incl. decommissioning) (20-1941). The programme addresses supervision of different activities recurring at different intervals depending on their respective importance to radiation safety. Since SSM consider decommissioning to be a non-routine activity limited in time, adaptations for supervision of decommissioning are made in accordance with importance to safety. However, a number of aspects are continually supervised, e.g., Structures, systems and components

and materials important to safety, Management systems, Operational activities and procedures, Records of operational activities and results of monitoring, Liaison with contractors and other service providers, Competence of staff, and Safety culture.

SSM has set up additional license conditions for authorisation regarding decommissioning of nuclear reactors (SSM2016-5866-26). In every authorisation for decommissioning of a nuclear reactor, references are made to each of the general conditions of authorisation that are applied for that specific reactor.

When the dismantling and demolition of a nuclear facility is authorised by SSM, the dismantling and demolition activities are gathered into so-called work packages. SSM is notified before the licensee commences with these work packages. Based on the submitted detailed documentation, SSM assesses the need and form for supervisory activities with regard to each work package, i.e. review of the documentation complemented by onsite (surveillance) inspections.

### Safety review

The requirement for safety review described in Module 6.4 (Chapter 4, Section 3 SSMFS 2008:1) also applies to decommissioning of nuclear facilities, see above.

## **6.8 Review and Assessment - Transport Activities**

### *Related to SSR 6*

Transport activities are covered by the supervisory programme Products, services and natural radiation aspects (19-1151).

SSM performs review and assessment of relevant information for determining whether the applicant for authorisation or the authorised party complies with applicable regulatory requirements. SSM is the competent authority for matters relating to the transport of radioactive substances (Transport of Dangerous Goods Ordinance (SFS 2006:311), Section 7 item 1 and Section 18). According to Swedish legislation (Radiation Protection Act (2018:396) Chapter 1 Section 1 and Chapter 6 Sections, 1, 9 and 20 and the Act (1984:3) on Nuclear Activities Sections 1, 5 and 8) the transport of radioactive material is equated to an ionising radiation activity or nuclear activity and therefore a license is required. SSM's review and assessment of transport-related activities or facilities is based on SSM's regulations (SSMFS 2018:1, Chapter 5).

### Transboundary Shipment of radioactive waste and spent fuel

In the licencing process according to applications according to the Council directive 2006/117/Euratom SSM considers the answers from the other Competent Authorities involved. All countries involved must consent to the shipments before the authorisation by SSM. After authorisation of transboundary shipments according to the Directive, SSM conducts a kind of inspection. By the specific standard documents containing information regarding date of dispatch and date of receipt, SSM supervises that the applicants stay within given authorisation.

## 6.9 Review and Assessment - Occupational Exposure

*Related to GSR Part 3: Requirements 19, 20, and 24 and demonstrate implementation in the review and assessment process:*

Occupational exposure is included in all four supervisory programmes listed in Module 6.1.1. For nuclear activities and facilities, occupational exposure is included in the review and assessment of the periodic safety review (PSR) and the integrated safety assessment (SSV), see also Module 6.2. Occupational exposure to radon is not yet included in any of the supervisory programmes.

Occupational exposure is regulated specifically in chapter 4 in the Radiation Protection Act. General requirements on justification Sections 1-4 in chapter 3 of the Act and optimisation of radiation protection is given in 5-7 chapter 3 of the Act. Dose limits for occupational exposure is given in chapter 2 in the Radiation Protection Ordinance. In chapter 3 section 1 of the Ordinance requirements for dose restrictions to be used as tools for optimisation for planned exposure situation, are set. For emergency exposure situations, requirements for dose restrictions are given in 3 chapter section 9 of the Ordinance.

Occupational exposure is reported for category A workers (expected annual radiation dose more than 6 mSv) to the Swedish dose registry (Svedos), administrated by SSM. If the reported dose is above a certain level, the licensee is contacted and asked to investigate and report to SSM including measures to prevent it from happening again. Doses to workers at nuclear facilities shall be reported to SSM annually (Section 33, SSMFS 2008:26 and Chapter 9 Section 4, SSMFS-D). Work tasks expected to exceed 0.1 mansievert shall be reported to SSM in advance (chapter 4, section 4 SSMFS 2021-D).

Events of significance from a radiation point of view shall according to the Radiation Protection Ordinance (2018:506) be reported to SSM. If a dose limit is suspected to have been exceeded, SSM shall be contacted immediately according to Chapter 8 Section 9 Radiation Protection Ordinance (2018:506). SSM reviews such reports and conduct necessary actions depending on the content. For industrial radiography activities, unplanned events must be compiled and reported to SSM annually (chapter 2 section 3 SSMFS 2018:6).

## 6.10 Review and Assessment - Medical Exposure

*Related to GSR Part 3: Requirements 37, 38, and 43 demonstrate implementation in the review and assessment process:*

SSM performs review and assessment of information relevant to safety for Medical Exposure in connection with license applications, annual reports, reported typical doses and incident reports. Regarding license applications, SSM applies a graded approach commensurate with the radiation risks associated with the exposure. Those medical exposures that only requires notification has a simplified regulatory framework and review and assessment is performed to a lesser extent.

Medical exposures are covered by the supervisory programme for Health and medical services (15-1224). The programme is based on a risk analysis for practices involving ionising radiation in health and medical services (15-273). The purpose of the supervisory

program is to establish a risk-based supervision that focuses on the areas in the healthcare sector that entail the potentially greatest radiation safety risks for patients, staff and the general public. The program sets out how the supervision should be conducted and which supervision methods should be applied (inspections, audits and handling and evaluation of reports) in order for the supervision to be in commensurate with the risks associated with the exposure.

## Justification

According to chapter 3 section 2 in the Radiation Protection Act the responsibility for ensuring that a radiological procedure (level 2) is justified rest solely on the licensee. There is no national framework to ensure that all new classes or types of practice resulting in exposure to ionising radiation are justified. SSM has in a joint statement with the Nordic Radiation Protection Authorities recommended an integration of justification of new types of practices involving medical exposure into the assessments of new health technologies (HTA). SSM verifies during inspections that there is local procedures for introducing new radiological procedures and that the procedures covers justification on level 2.

SSM verifies that there are procedures for justification (level 3) during licensing review. SSM also verifies that there is evidence of justification through inspections or review and assessment activities with specific focus on justification. SSM reviews, as part of inspection, whether procedures for evaluation of justification during processing of referral are in place. There is no single set of national referral guidelines available. However, there are about 31 standardised care processes and 52 care national or regional programs for cancer care. These processes and care program includes recommended imaging at suspicion of cancer, before treatment and for follow-up after treatment. The National Board of Health and Welfare have also issued several national guidelines (where imaging guidelines are included) for different diseases e.g. cardiovascular diseases, musculo-skeletal disorders and epilepsy. At inspections SSM review whether procedures adhere to the guidelines of the relevant national professional societies. It is assessed whether procedures for processing of referrals includes consultation between practitioner and referrer, where relevant, taking into account the appropriateness of referral, urgency of the procedure as well as the medical history of the individual patient.

## Optimisation

As part of inspections, SSM assesses whether procedures for optimisation of medical procedures are implemented, e.g. through regular reviews of protocols for examinations and use of relevant treatment planning for therapeutic procedures. For assessment of optimisation of protocols for examinations SSM assess during inspections that the radiological medical practitioner, the medical physicist expert and other personnel who work with medical exposures or support measures participate actively in the optimisation process to the extent required from a radiation protection point of view. SSM verifies during inspections if an individual planning of the radiation dose precedes therapeutic procedures and if the dose plans are approved in a forum consisting of a radiological medical practitioner, a medical physicist and persons with such additional competences and skill that might be needed.

SSM collects data on measured patient doses/administered doses from all relevant institutions/departments and provides diagnostic reference levels for use in application of

optimising measures locally. The licensee should at least every third year or when any major changes have been done report typical doses to SSM. For this issue SSM have developed a web-based tool (DosReg) for radiological departments to report typical doses to the Authority and to be used as a supporting tool when optimising examination protocols. With DosReg, a radiological department is able to compare their own typical doses with other radiological departments in Sweden. They also receive a real time evaluation of how they perform in relation to national diagnostic reference levels (NDRL). When comparing their own reported typical doses with others performing the same examinations it is possible to access other radiological departments' clinical examination protocol as well as the brand and model of their equipment. DosReg handles six different modalities: Computer tomography, Nuclear medicine, Mammography, Interventional procedures, Conventional radiology and CBCT dental. Reported typical doses will be the ground to set new or updated NDRLs, which Sweden have decided to do at least every fifth year for both adults and paediatric patients. DosReg also makes it possible for SSM to overlook trends within radiology, and monitor if the licensee is performing optimisation of examination protocols. If the typical dose exceeds the upper diagnostic reference level or below the lower diagnostic reference level, the cause of this should be investigated. If the investigation shows that the examination is not optimised, measures must be taken to optimise radiation protection. The local use of diagnostic reference levels is reviewed and assessed, often as part of inspection routines.

### Quality assurance

SSM verifies that there are procedures for quality assurance and procedures for quality control of sources and equipment during licensing review. During inspections quality assurance documents, procedures for quality control of sources and equipment and documentation over performed controls and calibrations is addressed.

### Radiological review

The licensees are required to systematically and regularly review the implementation and effectiveness of the management system. Results of internal audits and other reviews, e.g. reviews of patient dosimetry, are assessed during inspections. Annually, SSM also requests and reviews a sample of safety assessment for patient safety from the licensee (chapter 5 section 13 in SSMFS 2018:5). The safety assessment must state:

1. How the systematic radiation protection work has been conducted during the last year
2. What measures that have been taken to maintain and develop the safety, and
3. What results that have been achieved in the radiation protection work.

### Unintended and accidental medical exposures

The licensee is obliged to investigate incidents relevant to radiation protection that has taken place and to take necessary measures to minimise the risk of the incident being repeated. The investigation shall identify any shortcomings in operations and include:

1. the sequence of events characterising the causes
2. any radiation doses,

3. actual and potential consequences; and
4. measures taken (Chapter 3 Section 18 in SSMFS 2018:1)

A written report including what measures that has been taken has to be sent to SSM (chapter 3 Section 10 in SSMFS 2018:5). A specific working group (on SSM) with competence in x-ray diagnostics, interventions, nuclear medicine, radiation therapy and human-technology-organisation reviews the report to evaluate if the measures are adequate and in commensurate with the radiation risks. Any deficiencies results in enforcements actions where the licensee is required to take corrective actions.

## **6.11 Review and Assessment - Public Exposure**

***Related to GSR Part 3: Requirements 29, 32, 33, 47, 49, 50 and 51 demonstrate implementation in the review and assessment process:***

Public exposure is regulated specifically in chapter 5 of the Radiation Protection Act. General requirements on justification 1-4 in chapter 3 of the Act and optimisation of radiation protection is given in section 5-7 chapter 3 of the Act. Dose limits for public exposure is given in chapter 2 in the Radiation Protection Ordinance. In section 1, chapter 3 of the Ordinance requirements for dose constraints to be used as tools for optimisation for planned exposure situation, are given. For emergency exposure situations, requirements for dose restrictions are given in section 3, chapter 3 of the Ordinance.

All unplanned events with relevance for radiation safety shall be investigated, according to Chapter 3, Section 18 SSMFS 2018:1. The investigation includes an assessment of the event including occupational exposure and actual as well as potential consequences. The investigation shall identify the cause to the event and also measures taken to prevent new events.

Review and assessment activities include e.g. review of ALARA-programs, results of dose monitoring as well as review of work procedures and education of personal and public exposure.

## **6.12 Conclusions**

The overall conclusion is that Sweden meets the expectations. SSM performs review and assessment of relevant radiation safety information, according to a formal process described in the digital process tool, in order to determine whether the applicant for authorisation or the authorised party complies with applicable regulatory requirements.

# Module 7: Inspection

## 7.1 Generic issues

*Related to GSR Part 1 (Rev. 1): Requirements 27 – 29, paragraphs 4.50 and 4.53*

### Supervisory processes

SSM's supervision consists of activities within "Review and assessment", which is described in Chapter 6 and "Inspection", which is described in this chapter. The supervisory processes can be sorted as depicted in Figure 12. The supervisory processes are described in SSM's process management tool and in the steering document "Process: Exercising supervision" (STYR2017-16).

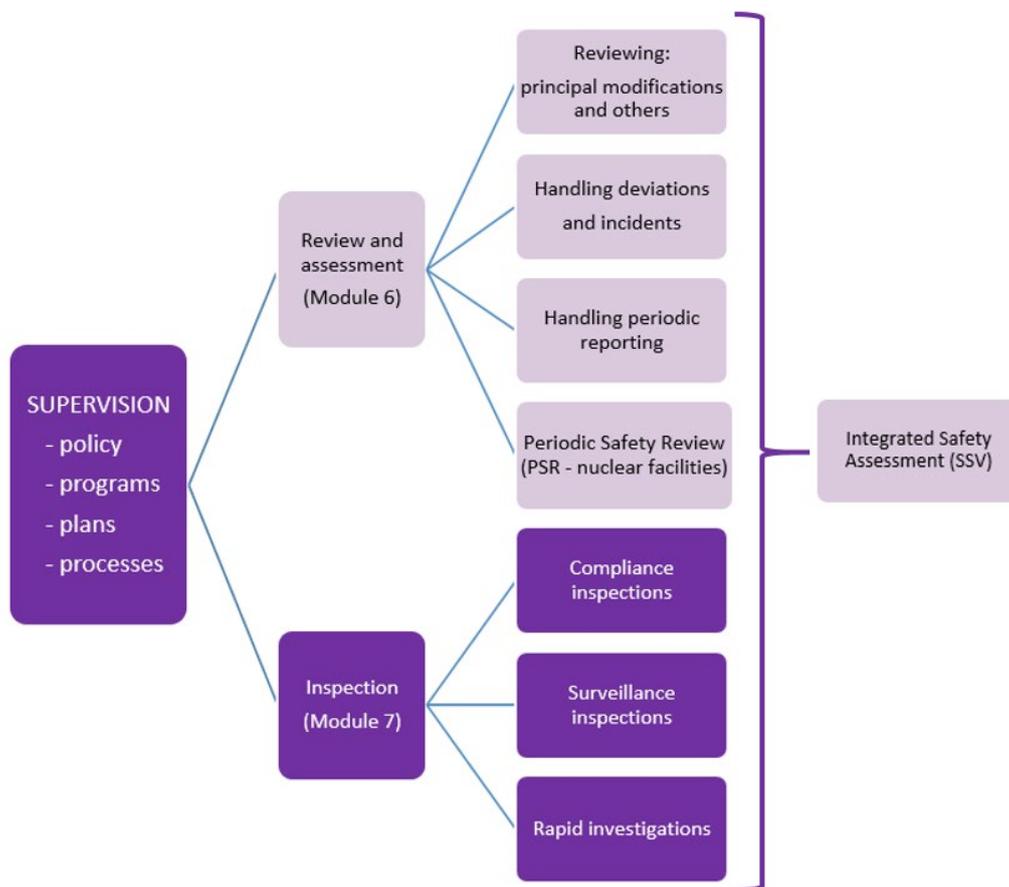


Figure 12 - Supervisory process ("Review and Assessment" and "Inspection")

SSM carries out inspections of facilities, activities and exposure situations to check whether the licensees comply with the regulatory requirements and with the conditions specified in the license. This is done through control of the inspected party taking its defined responsibility. Deviations are resolved through decisions on enforcement actions involving necessary corrective actions or prohibition, see also Module 8. SSM does not suggest specific actions regarding solutions to be taken by the licensee in order to handle

non-compliance from regulation. This is to ensure that regulatory inspections do not diminish the authorised party's prime responsibility for radiation safety.

There are laws and ordinances in place that give SSM the necessary authority to carry out inspections in all areas relevant to radiation safety. The licensees are required to provide site access for the regulator to conduct investigations or testing as needed. According to Swedish legislation, SSM has the mandate to conduct inspections. Several laws and ordinances give SSM all necessary authority for carrying out supervision. The main acts and ordinances are:

- The Act (1984:3) on Nuclear Activities sections 16, 16 a and 17
- The Radiation Protection Act (2018:396) chapter 8, sections 1-5, 8-9 and 11-12
- The Nuclear Activities Ordinance (1984:14) sections 21-22
- The Radiation Protection Ordinance (2018:506) chapter 8, sections 1-15
- The Environmental Code (1998:808) chapter 26, section 3

### Supervisory programs

Inspections are included as regulatory activities in the supervisory programs, which are described also in Module 6. There are four supervisory programs covering relevant aspects of:

1. Nuclear power plants in operation (20-2694),
2. Nuclear facilities and safe management of radioactive waste (incl. decommissioning) (20-1941),
3. Health and medical services (15-1224), and
4. Products, services and natural radiation aspects (19-1151).

However, supervision of radon at workplaces is not yet included in the relevant supervisory program.

SSM's supervisory programmes for NPPs and nuclear facilities were fundamentally revised to provide better overview, assure complete alignment with regulations, and introduce a higher degree of risk-information in the frequency and scope of supervision. The new supervisory programme for NPPs was tested in 2017, and formally introduced in 2018 and for the remaining nuclear facilities the program was tested 2019 and introduced formally in 2020. The programmes entails considerable changes to the planning, implementation, and follow-up of supervision. The supervisory programmes are now structured into two basic parts, baseline supervision and demand-based supervision.

Inspections of facilities and activities include baseline and demand based inspections on site, both announced and unannounced. The periodicity and the scope of the supervisory activities are based on assessments of risks and needs, which means that risks and possible negative consequences (short and long term) serves as basis for SSM's priorities. The supervisory programmes cover each requirement at least once over a period of 10 years. The programs cover not only inspections but also activities related to authorisation (see Module 5) and to review and assessment (see Module 6).

SSM has decided on a supervisory policy (STYR2011-97) to develop a comprehensive supervisory plan based on an investigation of the need for supervision in the Authority's entire area of operation. The supervisory plan shall describe how resources have been

balanced and allocated. The supervisory plan shall provide options for event-based inspections. The Director General shall make the final decision regarding the supervision plan. At present, SSM does not have a specific comprehensive supervisory plan as described above. However, work is currently in progress.

### Annual supervisory plans

SSM decides on annual supervision plans with activities based on the supervisory programmes. Supervisory activities shall be planned based on a graded approach according to risk and necessity, and short and long-term potential consequences of deficiencies shall be taken into account. Unspecified activities are given room in the plans in order for SSM to be prepared for unforeseen supervisory needs. SSM's supervision requires different strategies and approaches in the different supervisory areas. There are large differences between operators, spanning from NPPs to hospitals and smaller companies that use radiation sources in their operations. SSM adjusts the supervision accordingly. To achieve an effective supervision in total, the level of attention from the regulator must correspond to the risk and other needs associated with the each operation.

### Competent supervision

SSM has established an internal development programme "Competent Supervision" in order to achieve a common approach to supervision, and to ensure that supervisory work is conducted consistently and effectively (STYR2011-171). The purpose of the development program is that employees who exercise supervision have the knowledge and ability to check that the licensees comply with current requirements and that they take responsibility for radiation safety. The development efforts aim to develop the supervisory role through knowledge acquisition and discussion and create a common view of how the supervisory work is to be conducted within the Authority. The program covers the parts of the exercise of supervision that are common to the various areas of supervision. Inspectors are required to have basic training in supervision and knowledge of the legal basis. Previous participation as observer during an inspection is expected before active participation as an inspector.

### Inspection types and procedures

SSM carries out three types of inspections of facilities and activities on site:

- **Compliance inspections** serve as a planned and systematic way for SSM to analyse and assess whether the licensee in charge of the activity complies with applicable legislation, regulations and conditions relating to the operation and to the license. The compliance inspection shall be documented in a report that forms the basis for a decision after supervision.
- **Surveillance inspections** are exercised in order to gather knowledge of the activities conducted by licensees through observations linked to the requirements of the activity, as well as to exchange information with the licensee. A surveillance inspection takes place through continuous monitoring of licensee activities. The results are used to disseminate information within SSM and to plan additional supervisory measures. An additional purpose is to give response on SSM's observations to the party carrying out an activity. The results of the

surveillance inspection shall be documented in a report that forms the basis for a decision after supervision.

- **Rapid investigation** is a procedure to perform a surveillance inspection without prior planning. Rapid investigations are conducted on a short notice when an event has occurred or a circumstance has been discovered, for which SSM requires additional information to come to a decision on supervisory measures. The aim of a rapid investigation is for SSM to gain a quick and independent interpretation of the event or circumstance that has been discovered.

SSM has established formal processes for inspection activities (compliance inspections, surveillance inspections and rapid investigations), see Figure 13. All three processes contain generic steps, which are described in SSM's process management tool, see also Module 4. In the *initiation step*, a decision is made on the aim, focus and limitations of the specific activity. An inspection team with competent resources are allocated for the activity in the annual planning of supervisory activities, including a lead for the inspection. Rapid investigations are triggered by reported events from the licensees. The *preparation step* includes development of a plan for the activity. This stage involves examination of the need for reference reports to be requested from the licensee before a pre-announced visit and reviewed prior to the site visit. The content of preparatory meeting with the licensee is also drafted. For compliance inspections, requirements and assessment criteria are identified, as well as relevant reference cases to verify compliance. The *execution step* begins with a start-up meeting on site at which the purpose of the activity and the schedule for the visit is presented to the participants. Notes taken during interviews and walk-downs are added to the draft report. Preliminary results and conclusions are presented to the licensee at an exit-meeting, which also contains a preliminary assessment of compliance with requirements at a compliance inspection. The licensee is given the opportunity to comment on the observations drafted in the report before the conduction of SSM's internal quality control and finalisation of the report. In the *decision step*, assessments of compliance are made in relation to laws, regulations, legislation or conditions for the licensee and documented in the report (STYR2011-87). Non-compliance is subject to enforcement measures, see Module 8, which are followed up later through additional supervisory activities. In the *final step*, all relevant material is archived, results and conclusions are recorded and feedback of experiences from the inspection team is collected and recorded.



Figure 13 - Generic steps for inspection activities

Documented results from inspections, e.g. assessed requirements, identified deficiencies and issues, serve as input for Integrated Safety Assessments (SSV), see Module 6. Surveillance inspections may serve as preparation for authorisation (see Module 5) and other review and assessment activities (see Module 6).

### Intensified supervision

SSM can perform so-called intensified supervision (STYR2012-115). The use of intensified supervision is decided by the Director General and is applied when the Authority is dissatisfied with the safety performance of a licensee. Intensified supervision can also be applied to other special safety reasons, e.g. during test operations after a large

plant modification. The intensified supervision regime means that more inspections are done and particular progress reporting is required from the licensee.

## 7.2 Inspection - Nuclear Power Plants

### *Related to GSR Part 1 (Rev. 1): Requirements 27 – 29*

SSM's supervisory activities for nuclear power plants involve all three inspection types mentioned in the previous section and follow the procedure described above. The supervision program consists of both recurrent periodical supervision activities as well as more demand-based supervision. The different areas of supervision are divided into 37 supervision groups covering all regulatory requirements for nuclear power plants in operation. The baseline activities are outlined in the supervisory programme for nuclear power plants (20-2694), see also Chapter 6. For each supervisory group of the program, supporting documentation is provided that describes the content of each group, its scope and requirements and necessary supervisory (inspections, reviews and assessments) activities to ensure enough information for the assessment of the supervision group according to the periodicity of the program.

Integrated safety assessments (SSV) are performed annually for NPPs and are based on all compliance inspections, surveillance inspections, reviews, authority decisions and other relevant information performed by SSM during the period, see also Module 6.

There are 25 inspectors available for NPP inspection, of which 4 inspectors with focus on nuclear security.

### Site coordinators

SSM has a designated site coordinator for each nuclear power plant, who coordinates all supervisory activities towards the site. The site coordinator also serves as the point of contact between regulator and licensee. SSM has no inspectors residing on the NPP sites.

### Recurrent surveillance and monitoring

SSM carries out surveillance inspections to gather information on safety problems and overall activities at the plants. Normally these surveillance inspections include three or four annual meetings with each reactor operations management, two annual meetings with the safety department, one inspection at each power plant, and yearly meetings to review safety and internal audit programmes. Some inspections are made in connection with events, to follow up organisational change, and relating to other current issues, such as findings from earlier inspections. In many cases, these inspections focus on non-technical issues, such as safety management and safety culture. Preparation and documentation of surveillance inspections are simplified in comparison with compliance inspections, but the 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.

## Strengthened supervision due to shutdown decisions

SSM has notified licensees of strengthened supervision in response to decisions from owners on final shutdown of nuclear reactors (e.g. SSM2015-2569 and SSM2015-4483). Strengthened supervision implies that SSM increases its inspection activities in order to ensure that the licensee takes necessary actions for maintaining safety during the remaining time of operation. The increased inspection activities focus on e.g. organisation, management, governance, competence and staffing as well as decommissioning planning.

## 7.3 Inspection - Research Reactors

Out of scope. There are no research reactors in Sweden.

## 7.4 Inspection - Fuel Cycle Facilities

*Related to NS-R-5, paragraphs 3.11 – 3.12*

Figure 3 on page 10 shows the locations of the fuel cycle facilities in Sweden.

Inspections of fuel cycle facilities are performed in accordance with SSM's process for supervision and inspections described in 7.1. There are in total 6 inspectors with focus on fuel cycle facilities.

SSM applies a supervisory program (20-1941) for fuel cycle facilities, together with other nuclear facilities. The supervisory program describes how SSM plans to implement supervision in the area "Nuclear facilities and safe management of radioactive waste". The supervision program consists of both recurrent periodical supervision activities as well as more demand-based supervision. The different areas of supervision have been divided into 23 supervision groups covering all regulatory requirements, see also Module 6.

The supervision program is mostly focused in verifying that the authorised party is in compliance with regulatory requirements. It is also possible to verify compliance with the conditions specified in the authorisation but this is normally performed in an indirect way by controlling compliance with the Safety Assessment Report. The planning of supervisory activities to verify compliance with authorisation conditions is less systematic than for compliance with regulatory requirements.

The demand-based supervision in the programme is defined on a yearly basis and is described in an annual supervision plan. It differs from year to year depending on factors like ongoing modifications (technical or organisational), results from previous inspections or results from the integrated safety assessment. Integrated safety assessments are usually performed every second year for fuel cycle facilities and are based on all compliance inspections, surveillance inspections, reviews, authority decisions and other relevant information performed by SSM during the period, see also Module 6.

Unannounced inspections have been performed in limited extent the last years, but one example is unannounced inspections of documented register of waste "*Inspection of waste registers, internal transports and controlled area at Clab*" (SSM2018-4056-2).

As described in Module 7.2, the role of site coordinator is in place for fuel cycle facilities as well, to coordinate all supervisory activities towards the site. The site coordinator also serves as the point of contact between regulator and licensee.

## 7.5 Inspection - Waste Management Facilities

*Related to GSR Part 5: paragraphs 4.22, 5.14, 5.15, 5.20  
SSR-5: paragraphs 3.15, 3.48, 5.19*

Figure 3 on page 10 shows the locations of the waste management facilities in Sweden.

Inspections of waste management facilities are performed in accordance with SSM's process for supervision and inspections described in 7.1. There are in total 5 inspectors with focus on supervision of waste management facilities.

SSM have site coordinator inspectors for waste management facilities, as described under Module 7.2. The role of the site coordinator is among other things to coordinate all regulatory supervision towards the site and also serve as the point of contact between regulator and licensee.

SSM applies a supervisory program (20-1941) for Waste Management Facilities, together with other nuclear facilities. The supervisory program describes how SSM plans to implement supervision in the area "Radiation-safe Nuclear Facilities and radiation-safe management of radioactive waste".

The supervision program consists of both recurrent periodical supervision activities as well as more demand-based supervision. The different areas of supervision have been divided into 23 different supervision groups covering all regulatory requirements. Those groups were distributed into 3 categories (P1, P2 and P3) based on a judgement of their risks. The supervision activities for the three risk categories waste management facilities are planned with a frequency of every 5, 7 and 9 years respectively. Hence, the programme covers each group (and requirement) at least once over a period of 10 years.

The supervision program is mostly focused on controlling that the authorised party is in compliance with regulatory requirements. It is also possible to control compliance with the conditions specified in the authorisation but this is normally performed in an indirect way by controlling compliance with the Safety Assessment Report. The planning of supervisory activities to verify compliance with authorisation conditions is less systematic than for compliance with regulatory requirements.

The demand-based supervision in the programme is defined on a yearly basis and is described in an annual supervision plan. It differs from year to year depending on factors like ongoing modifications (technical or organisational), results from previous inspections or results from the integrated safety assessment. Integrated safety assessments (SSV) are usually performed every third year for waste management facilities and are based on all compliance inspections, surveillance inspections, reviews, authority decisions and other relevant information performed by SSM during the period, see also Module 6.

## **7.6 Inspection - Radiation Sources Facilities and Activities**

### ***Related to GSR Part 1 (Rev. 1): Requirements 27 – 29 and GSR Part 3: Requirement 3***

Inspections of radiation sources facilities and activities are performed in accordance with SSM's process for supervision and inspections described in 7.1. There are in total 3 inspectors with focus on radiation sources facilities and activities.

Unannounced inspections may be considered. However, in reality, such inspections have not been performed within this supervision area during the last years. If performed, the inspections may cover all applicable requirements or only requirements within a specific area. Reactive inspections are used e.g. as a result of an unplanned event or if other circumstances in particular justify an inspection e.g. suspicion of non-compliance. Such inspections are rare, but occasionally performed. The inspection may cover all applicable requirements or only within a specific area, for example requirements connected to the reason for the inspection. Neither unannounced inspections nor reactive inspections are part of the planned inspection programmes.

SSM has a specific supervision program for supervision within the following fields for practices requiring a license (15-165):

- Accelerators
- High Activity Sealed Sources (HASS)
- Industrial radiography
- Unsealed sources
- Installation and maintenance
- Veterinary medicine
- Other practices requiring a license

In the supervision programme, each field is briefly described regarding number of licence holders, what their main occupations are and SSM's planned frequency for inspections. The planned frequency for inspections, normally between five and ten years, is based on radiation safety assessments for the area in question. The programme, which is updated on a yearly basis, also states how many license holders SSM plan to inspect within each field per year during the 5 years to come. In addition to the supervision programme, SSM has inspection plans for each type of radiation source within the different fields in the supervision program. The inspection plans include more detailed information about the inspections planned for the current year.

There are also inspection plans, similar to those for licence holders, for practices that are subject to notification/registration according to SSMFS 2018:2. These inspection plans cover the following areas:

- Veterinary medicine (19-31)
- Industry (X-ray) (19-25)
- Industry (sealed sources) (18-105)

During inspections of radiation sources facilities and activities all applicable requirements, or only a set of requirements are in the scope for the inspections.

The supervision programme for medical exposure, 15-1224 2021 Supervision Programme for health and medical services, covers radiation sources used in health and medical services (for more information see “Medical Exposure”).

## **7.7 Inspection - Decommissioning Activities**

*Related to GSR Part 6: paragraph 8.5*

Figure 3 on page 10 shows the locations of the nuclear facilities under decommissioning in Sweden.

Inspections of decommissioning activities are performed in accordance with SSM’s process for supervision and inspections described in 7.1. There are in total 7 inspectors with focus on decommissioning of nuclear facilities.

As described in Module 7.2, the role of site coordinator is in place for nuclear facilities under decommissioning as well to coordinates all supervisory activities towards the site. The site coordinator also serves as the point of contact between regulator and licensee.

SSM has developed a general programme for periodical supervision for decommissioning with supervision of different activities recurring at different intervals depending on their respective importance radiation safety. Since SSM performs reviews of D&D-SAR (dismantling and demolition), see also Modules 5 and 6, with its supporting documents, SSM considers decommissioning to be a non-routine activity limited in time, and adaptations of supervision of decommissioning are made in accordance with importance to radiation safety. A number of aspects are continually supervised during decommissioning, e.g., Structures, systems and components and materials important to safety, Management systems, Operational activities and procedures, Records of operational activities and results of monitoring, Liaison with contractors and other service providers, Competence of staff, and Safety culture. Frequency of these inspections are one to two times every seven years.

When the dismantling and demolition of a nuclear facility is authorised by SSM, the dismantling and demolition activities are gathered into so-called work packages. SSM is notified before the licensee commences with these work packages. Based on the submitted detailed documentation, SSM assesses the need and form for supervisory activities with regard to each work package, i.e. review of the documentation complemented by onsite (surveillance) inspections. Furthermore, SSM performs inspections as a response to unexpected events or incidents, depending on their importance to (nuclear-)safety or radiation protection.

## **7.8 Inspection - Transport Activities**

*Related to SSR-6: paragraphs 302, 306, 503,582, 801 and Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52*

Inspection of the transport of radioactive substances are performed in accordance with SSM’s process for supervision and inspections described in 7.1.

There are in total 5 inspectors with focus on transport of radioactive substances and transboundary shipments. Three of these inspectors are focusing on transport of radioactive substances and two on transboundary shipments.

SSM regularly carries out inspections in cooperation with other supervisory authorities with similar tasks, in the area of the transport of radioactive material (dangerous goods, class 7), in order to control compliance with the regulations, to strengthen the work on radiation safety and to harmonise the supervisory evaluations in radiation matters. The area of responsibility of each supervisory authority involved is clearly indicated in Section 10 of the Transport of Dangerous Goods Ordinance (2006:311).

For transboundary shipments of radioactive waste and spent fuel, SSM is obliged to perform inspections to verify that the authorised party is in compliance with the regulatory requirements according to Ordinance of Nuclear Activities (1984:14). It is stated that imported radioactive waste and spent fuel must be returned to the country of origin within three years with exception if it has been decided for final disposal by the Swedish Government or if the radioactive waste can be cleared.

After authorisation of transboundary shipments according to the Council directive 2006/117/Euratom (the Directive), SSM conducts inspection. By the specific standard documents (decided in the Commission decision of the 5 March 2008 (2008/312/Euratom)) containing information regarding date of dispatch and date of receipt, SSM supervises that the applicants stay within given authorisation. A compliance inspection or a surveillance inspection can be carried out in conjunction with an applicant applying for a new authorisation or if the applicant has remarks from earlier permits or applications. Further, a compliance inspection or a surveillance inspection can also be carried out due to neglect concerning the standard documents. Control of the standard documents concerning dispatch and date of receipt of the radioactive waste or spent fuel are supervised when received from the applicant or consignee.

## **7.9 Inspection - Occupational Exposure**

*Related to GSR Part 3: Requirements 19-24, 27, 28 and 52. Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52*

Inspections of occupational exposure are performed in accordance with SSM's process for supervision and inspections described in Module 7.1. There are in total 8 inspectors (one vacancy) with focus on occupational exposure (inspectors of occupational exposure within health and medical services not included, see Module 7.10). Five of these inspectors are focusing on occupational exposure (supervision area 1 and 2) at nuclear facilities and three inspectors are focusing on occupational exposure due to activities with radiation sources (supervision area 4) e.g. research, industry and veterinary.

During inspections of occupational exposure, the use of dose constraints and goals for the optimisation of protection is reviewed as well as application of radiation protection in practice i.e. time, distance and personal protective equipment. During inspections the classification of areas in controlled and supervised areas as well as classification of staff is reviewed. Inspections usually covers review of programmes for monitoring of doses to staff and its relation to established dose constraints and goals for optimisation. Doses to

staff is also monitored through the national dose registry (Svedos), which is managed by SSM.

## Research, industry and veterinary

For supervision area 4 SSM has specific inspection plans for the different types of radiation sources within the different fields. The inspection plans are reviewed on a yearly basis. Focus for the inspections may therefore vary from year to year. It may cover all applicable requirements (within areas as organisation, management system, competence of staff, occupational exposure, radiation sources, transport, public exposure etc.) or only requirements within a specific area.

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## Health and medical services

Occupational exposure in health and medical services due to medical exposures is covered by the same supervision programme as medical exposure (supervision area 3) (15-1224). The programme (introduced in Module 6.1.1) covers medical exposures as well as occupational exposure, radioactive waste and security aspects related to high activity sealed sources within the healthcare sector. Inspections form the basis of the supervisory activities, while different types of review and assessments (described in Module 6.9) serves as a complement to inspections. The supervision programme states that the need for supervision depends on the radiation risk of the activity in question. According to the supervision programme, the inspections of occupational exposure in health and medical services, will focus on occupational exposure in medical radiology (interventional radiology) and nuclear medicine. Inspection of occupational exposure is less prioritised in dental radiology and radiotherapy where the exposure risks are generally lower.

## Nuclear facilities

Occupational exposure at nuclear facilities is included in the supervision program for nuclear power plants (20-2694) and for other nuclear facilities (20-1941) respectively (supervision area 1 and 2). The supervision programme consists of both recurrent periodical supervision activities as well as more demand-based supervision.

The supervision programs contain 38 supervision groups. Three of them with a specific focus on occupational exposure. These groups are:

- Work in the facility (doses to workers, work permits, planning, housekeeping)
- ALARA-programmes. (the process of optimisation, use of company indicators and goals, dose constraints)
- Protection of workers (Electronic dosimetry, internal/external dosimetry etc.)

A risk based approach has been applied to decide the frequency for each group. The sub-group *Work in the facility* is conducted every five years and *Protection of workers* and *ALARA-programmes* every seven years.

## Radon

Regarding inspections of radon in workplaces, SSM does not have a finalised supervision programme in place; it is under preparation and the process has been struggling with problems with finances. However, there are regulations involving radon at workplaces in place. There is also an agreement that occupational exposure of workers due to radon at workplaces should be included in all the inspection programmes and reviewed in connection with the regular inspections of these facilities. The General Public and Environment department at the Division for Supervision conducts inspections of workplaces where radon exposure can be a significant problem, e.g. mines.

## 7.10 Inspection - Medical Exposure

***Related to GSR Part 3: Requirements 34-40 and Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52***

Inspections of medical exposure are performed in accordance with SSM's process for supervision and inspections described in 7.1. There are in total 7 inspectors (one vacancy) with focus on medical exposure. These inspectors also covers occupational exposure within health and medical services. Three inspectors are focusing on medical radiology, two inspectors are focusing on radiotherapy, one inspector is focusing on dental radiology and one inspector (vacant) is focusing on nuclear medicine. All the inspectors have long experience of clinical work within their respective field and are either medical physicists (4), radiographer (1) or dental hygienists (1).

SSM has a supervision program for health and medical services (15-1224) that is introduced in 6.1.1. The supervision program for health and medical services covers medical exposures as well as occupational exposure, radioactive waste and security aspects related to high activity sealed sources within the healthcare sector. The supervision program provides an overall description, and the scope, of activities involving ionising radiation in health and medical services.

Medical exposures are carried out by approximately:

- 89 licensees in medical radiology
- 23 licensees in nuclear medicine
- 26 licensees in radiotherapy
- 713 licensees in dental radiology (panoramic or cone beam computed tomography)
- 1200 notified activities in dental radiology (intraoral radiography)

Inspections form the basis of the supervisory activities, while different types of review and assessments (described in Module 6.10) serves as a complement to inspections. The supervision programme states that the need for supervision depends on the radiation risk of the activity in question. Radiation risks related to medical exposures in medical radiology, nuclear medicine, radiotherapy and dental radiology have been identified at an overall level. The identified risks, together with experience from supervision (inspection results, integrated safety assessments and unplanned events), form the basis for the risk and needs-based supervision to be carried out for medical exposures. As a result, from the risk analysis SSM concludes that it is not an effective use of resources to include all licensees within medical exposures in an inspection programme. Hence, the inspection

programme does not cover licensees with less extensive activities where radiation doses are low. These licensees require other forms of review and assessment to ensure that the activities are carried out in accordance with the regulatory framework. For these licensees, regulatory control consists largely of the review and assessment carried out in connection with the authorisation and renewals of permits every 5 years (see 5.10 and 6.10). Licensees who are not covered by the inspection programme may of course still be eligible for reactive inspections e.g. as a result of an unplanned event or if other circumstances in particular justify an inspection. According to the supervision programme, the inspections of medical exposure will focus on the following areas:

### Medical radiology

Inspections focus particular on licensees who are engaged in either activities involving CT scans or interventional radiology. This means that the supervision programme covers 35 licensees in medical radiology (All licensees engaged in CT scans, mammography or interventional radiology). The main focus of the inspections in medical radiology should be on verifying the existence of procedures for justification, including access to referral guidelines for medical imaging, taking into account the radiation doses, and ensuring that systematic optimisation of protection is carried out. In regards to inspection of optimisation the application of typical doses to be compared with diagnostics reference levels is investigated as well as the systematic co-operation between radiologists, medical physicist, radiographers and other personnel involved in medical exposures. The licensee should at least every third year, or when any major changes have been done, report typical doses for a variety of examinations to SSM. For this purpose SSM have developed a web-based tool (DosReg). By using DosReg SSM can monitor compliance with the requirement regarding application of diagnostic reference levels and thus ensure that the licensees works with optimisation.

### Nuclear medicine

The number of licensees (approximately 23) is such that all licensees should be covered by SSM's supervision programme. From a risk perspective, the activities of licensees are relatively similar, which further justifies the inclusion of all licensees in the inspection programme. The main focus of the inspections in nuclear medicine should be on the review of procedures for verifying patients' identity, possible pregnancy and breastfeeding, as well as procedures to ensure that the amount of activity to be administered is correct, as well as that the equipment is checked to an appropriate extent and perform as intended.

### Radiotherapy

18 licensees, of which eight also include brachytherapy, conducts external radiotherapy (Grenz ray therapy for skin disorders not included). There is one proton therapy facility (The Skandion Clinic) and one Gamma Knife® in Sweden. The number of licensees is such that all licensees should be covered by SSM's inspection programme. From a risk perspective, the activities of licensees are relatively similar, which further justifies the inclusion of all licensees in the inspection programme. During inspections, the entire patient's treatment chain is reviewed, from the referral (justification) to the delivered radiation dose (optimisation).

## Dental radiology

The very large number of licensees and notifiable activities, combined with the fact that the activities are spread throughout the country and the relatively low radiation doses, means that regular inspections are, in practical terms, unrealistic to carry out. Instead, supervision should be exercised primarily through review and assessment in connection with authorisation and communication efforts. To the extent that inspections are carried out, inspections should focus on large trend-setting licensees. SSM has identified 27 licensees within dental radiology with a business of such an extent that they may be relevant for inspections. The current objective is to inspect one major licensee per year and a couple of minor licensees. Inspections of dental radiology should focus on procedures for justification, working methods and patient flow at the clinics in question. The inspections should also include a review of the licensees control programme for dental equipment (radiation sources) so that the equipment meets radiation protection requirements and that radiation protection is otherwise optimised so that patients are exposed to as low radiation doses as possible.

Education and competence is always part of the scope of the inspections since the right competence and sufficient training is key to carrying out medical exposures in a “radiation safe” manner.

A compilation of performed inspections of medical exposures exists (15-1523).

## 7.11 Inspection - Public Exposure

***Related to GSR Part 3: Requirements 27-31, 33 and 47 and demonstrate implementation in the inspection process***

Inspections of public exposure are performed in accordance with SSM’s process for supervision and inspections described in 7.1. There are in total 4 inspectors with focus on public exposure.

## Nuclear power plants and nuclear facilities

Regular inspections are performed by SSM in accordance to the supervision programs (20-2694, 20-1941) for these facilities. Reactive inspections are also performed usually as a result of unplanned events or if a facility is reporting abnormal discharges or malfunctioning monitoring systems for a prolonged period. Inspections are performed in order to ensure compliance with regulations concerning potential exposure of the public from normal operation. These inspections focuses on 1) abatement techniques 2) measurement and monitoring of emissions, and 3) monitoring of radioactive substances in the surrounding environment. In addition, SSM performs control measurements.

## Transport

Issues regarding public exposure are addressed in accordance with applicable legal requirements in this area.

## Radon

SSM does not perform supervision of public exposure to radon. SSM's role concerning supervision of radon exposure to the public is to give guidance regarding supervision of radon exposure to the local authorities (municipality) who perform the supervision.

### **7.12 Conclusions**

Sweden meets the expectations of the IAEA safety requirements for inspections. SSM has a mandate to conduct inspection in all areas that are covered by SSM's supervision. SSM verify that the licensees follow laws and regulations by performing independent inspections of facilities, activities and exposure situations.

# Module 8: Enforcement

## 8.1 Enforcement Policy and Process

*Related to GSR Part 1 (Rev. 1): Requirements 30 and 31, paragraphs 4.54, 4.57 – 4.60*

In accordance with the Act on Nuclear Activities, the Radiation Protection Act and the Environmental Code, SSM has extensive legal powers to enforce the regulations and its decisions. The following actions can be taken: remark, injunction, and prohibition to continue the operation before taking actions, revocation of license and correction at the expense of the licensee. Injunctions and prohibitions can be combined with a conditional fine. An assessment of the significance of deficiencies must be made in relation to the regulatory requirements. The purpose of the assessment is to determine which actions are required, to what extent and when in time.

### Enforcement policy

According to SSM's internal steering document (STYR2011-87) Assessment of compliance with requirements during regulatory supervision, requirements must be assessed as fulfilled, partially fulfilled or not fulfilled. For requirements that are fulfilled, any areas for improvement and good practice are identified. If requirements are not fulfilled, an assessment must be made if a notification of prosecution is to be actualised. An assessment of the radiation safety significance of any deficiencies must be made. The assessment of the shortcomings is specified as small, moderate or large significance. Both real consequences and potential consequences are considered. Potential consequences refer to consequences that have not yet had any significance for radiation safety but may have it, in the short or long term. For example, it can be insufficient instructions, inadequate management functions or insufficient competence of staff. The consequences (real and potential) are set in relation to the principles of radiation safety applicable to the current supervisory action.

According to the Act on Nuclear Activities and the Radiation Protection Act, SSM can enforce regulatory requirements. Section 17 of the Act on Nuclear Activities and Chapter 8 Sections 4 and 11 of the Radiation Protection Act stipulates that a licensee has to provide SSM with all information, documentation and access to installations that are needed for the regulatory supervision. If necessary, the Police Authority shall provide the assistance needed for the supervision.

Section 18 of the Act on Nuclear Activities and Chapter 8 Sections 6–9 of the Radiation Protection Act states that the supervisory authority may decide on necessary measures and also impose upon the licensee the orders and prohibitions that are necessary in individual cases to ensure that the Act, or regulations or conditions that have been issued under the Act, are observed. If a party does not implement a measure imposed upon it under the Act or in accordance with regulations or conditions that have been issued under the Act or according to an order by the supervisory authority, the authority may arrange for the measure to be implemented at the party's own cost.

According to Section 25 of the Act on Nuclear Activities, Section 22 a of the Nuclear Activities Ordinance (1984:14) and Chapter 9 of the Radiation Protection Act, it is a criminal offence to violate the Act as well as conditions or regulations issued with

support of the Act. If the Authority has reason to suspect that non-compliance has occurred, the Authority must always consider reporting to police or prosecutor.

## Enforcement powers

Normally, SSM uses a scale of supervisory measures in cases where the licensees deviate from the regulations. The legal basis is described above. The different sanctions are:

### **Issuing a remark on issues to be corrected by the licensee**

Any identified deficiencies that have not prompted an order, areas for improvement or good practices are stated in the supervision report. These observations are taken into account by the licensee.

**Decision on the order to adopt measures** If a deficiency is of moderate or great importance for radiation safety, is complex or need to be remedied immediately, the licensee is ordered to adopt measures within a specified time period. Examples of actions could be to take concrete physical measures, such as renovations, produce certain types of analyses or report action programs. The operation is allowed to continue. A conditional fine may also be included in the regulatory order.

### **Suspension of operations, if necessary with a conditional fine**

If a licensee breaches a regulation or a condition, it means that the operation is not allowed. SSM is then obliged to decide on whether the operation shall be stopped immediately and not restarted until the licensee yet again meets the regulation or condition. A prohibition means, depending on how it is formulated, that the operation of all or parts of the operation must cease. A prohibition is normally linked to a need for actions. The prohibition must be limited in time, either until these actions have been taken or measures implemented and until SSM has approved the continuation of the operation. A prohibition can be combined with a monetary fine if deemed necessary for the prohibition to be complied with.

### **Revoking a licence**

A licence can be revoked by the authority which issued the licence (SSM or the government) if any of the conditions specified in the legislation for revocation are met. Revocation of a permit is a far-reaching measure and means that the operator must apply for and obtain a completely new permit in order to resume operations.

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

### **Adjustment of the supervision - intensified supervision**

Adjustment of the supervision in the form of e.g. intensified supervision (internal decision) means that SSM for a limited time intensifies the supervision of a licensee. The intensified supervision may cover all or parts of the operation. Adjusted supervision is normally combined with decisions on measures and reports to SSM. The reasons for applying adjusted supervision are that SSM makes the assessment that it exists shortcomings in the operation that are so serious in nature or extensive that SSM must question the operator's ability to uphold long-term radiation safety.

### **Temporary care (Radiation Protection Act)**

If it is necessary while waiting for an order to be complied with, SSM may decide on managing a radioactive material or a technical device containing a radioactive material or which is capable of emitting radiation.

#### **Sealment (Radiation Protection Act)**

SSM may decide to seal properties, buildings, premises and other facilities where activities with ionising radiation are conducted. Also technical devices which contain a radioactive substance or which can generate radiation may be sealed. Sealment may take place if necessary to prevent illegal use.

#### **Correction at the licensee's expense**

If a licensee does not take action required by law or by order, SSM may carry out the measure. Because the responsibility for the operation always lies with the licensee, correction shall only be carried out when all other possibilities have been exhausted.

#### **Refer suspected cases of criminal violations to a public prosecutor**

If SSM has reason to suspect that a violation of a penalty provision has occurred, the Authority shall always consider whether a report of suspected criminal violations shall be filed to a public prosecutor.

#### **Impose additional licensing conditions**

SSM's supervision may indicate that additional licensing conditions are necessary. Licensing conditions should be of a more long-term character than orders.

## **8.2 Enforcement Implementations**

### ***Related to GSR Part 1 (Rev. 1): Requirement 31, paragraphs 4.55 – 4.56***

Normally sufficient enforcement measures emerge during the supervision. After the supervision has ended, the supervisory report is completed. The report contains observations and deficiencies in relation to regulatory requirements. Based on the conclusions of the report, an appropriate enforcement action is presented to the managers concerned. After consultation with a legal adviser regarding the decision, the manager approves both the report and the decision. The supervisory report identifies deficiencies in relation to regulatory requirements. After the supervision has ended, the report and the decision – which is a result of the report – are sent to the licensee at the same time. In some cases – due to delays regarding the decision – the report could be sent first.

When the licensee submits documentation, which contains information on how the licensee has implemented corrective actions, SSM makes an initial assessment whether the corrective actions are sufficient. In some cases a more, thorough assessment in relation to regulatory requirements is necessary. The assessment could result in two alternative measures. If the corrective actions are sufficient, the licensee will get feedback and case is closed. If the assessment results in the conclusion that identified deficiencies are not handled, the licensee will get feedback that SSM requires further information and the case is open until the licensee is able to present sufficient corrective actions. Through this process, the inspector consults with the managers concerned and when necessary, also with legal officers.

The inspector is responsible for following up the enforcement implementation, see above. If necessary, legal competence is involved. Decisions on prohibitions and orders where an immediate decision is required for reasons of radiation safety may be delegated to the

administrative officer according to SSM's Rules of Procedure. This is typically items discovered during ongoing supervision that cannot wait. If necessary, SSM orders the licensee to take corrective measures at a specific date. As shown above, SSM has a wide range of enforcement actions at its disposal.

If the licensee complies with regulatory framework but unforeseen risks are identified and those are not addressed in regulations, it can be handled by additional licensing conditions. Possibly, it can also be handled as adjusted supervision.

All employees at SSM engaged in supervision are obliged to take part in education regarding the steering document STYR2011-87 on compliance and supervisory activities during supervision. According to STYR2011-171 on competence profile and development programme for supervisors this will take place during the first year as employed at SSM.

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### **8.3 Conclusions**

Sweden meets the expectations of the IAEA safety requirements for enforcement. Through STYR2011-87 an enforcement policy at SSM has been established and implemented for responding to non-compliance with regulatory requirements or with any conditions specified in the authorisation, in accordance with a graded approach.

If deficiencies or other risks are identified in the supervisory mission, SSM has a process for requiring corrective actions by the licensees. Those actions are assessed and form the basis for the continued handling by SSM.

# Module 9: Regulations and Guides

## 9.1 Generic issues

*Related to GSR Part 1 (Rev. 1): Requirements 32 – 34, paragraphs 4.61 – 4.62  
GSR Part 3: Requirement 3*

SSM has a comprehensive authorisation to decide on regulations for nuclear activities and activities with ionising radiation. The mandate emanates from the Riksdag (Swedish parliament) and is primarily found in the Nuclear Activities Ordinance (1984:14) and the Radiation Protection Ordinance (2018:506) decided by the Government. SSM can also decide on general advice and guidelines and for this no special authorisation is needed. The hierarchy in Swedish legislation is shown in Figure 14.

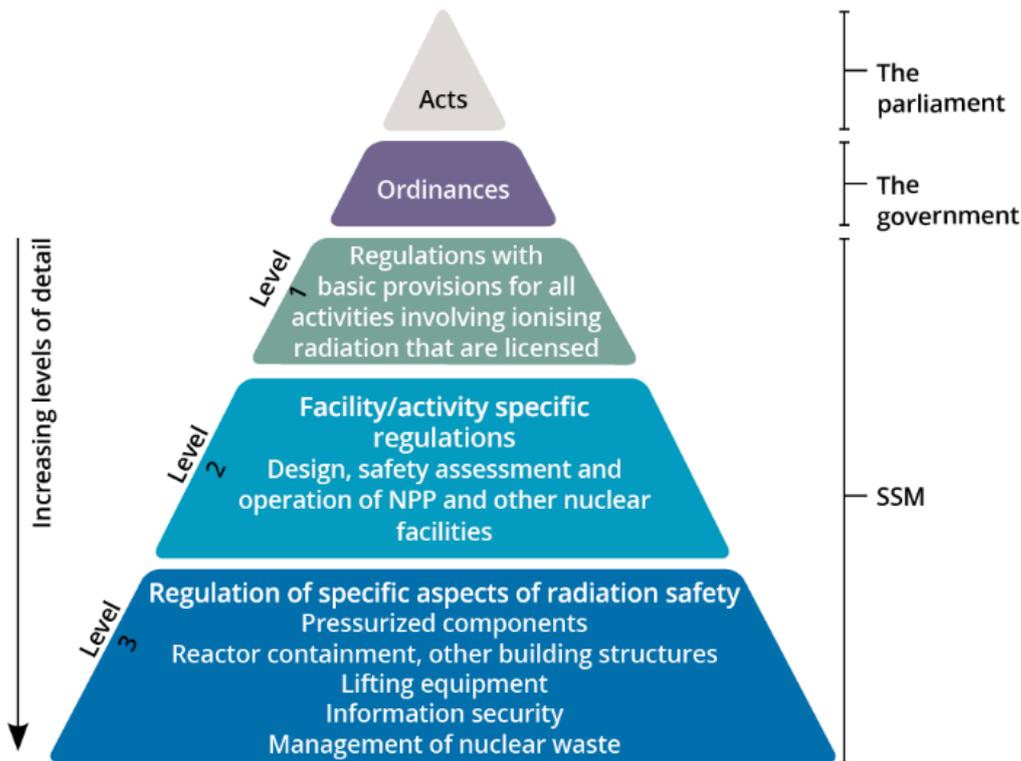


Figure 14 - Hierarchy of Swedish legislation and the regulatory framework

A major update of SSM’s regulations began in 2012. The new integrated regulations consider all aspects of radiation safety for different phases of the facility or the activity, see Figure 15.

		Traditional way of regulating in Sweden			
		Nuclear safety	Radiation protection	Nuclear security	Non-proliferation control
New integrated regulation	Design and construction	X	X	X	X
	Analysis and assessment	X	X	X	X
	Operation	X	X	X	X
	Decommissioning	X	X	X	X

Figure 15 - Regulations of various aspects of radiation safety in Sweden: traditional approach (vertical) and new approach (horizontal).

SSM has a routine for working with regulations. The routine is documented in the internal governing document STYR2011-51 on the process of developing regulations. In the following, it is described how the routine is to be applied.

According to the routine, the Authority should evaluate existing regulations, general advice and guides continuously and assess whether the regulations should continue to apply in their current form or whether they need to be revised for some reason or perhaps even repealed.

The reason for revising regulations may be new experiences gained from supervision, updated international recommendations, new practice, or new or revised national legislation which requires adjustments in SSMFS.

The evaluation should be done at least every five years or more often if necessary. The General Counsel is responsible for regulations, and monitors that evaluations take place with the support of the analysts at the National Regulation department. The evaluation shall be documented in a review report which shall contain a summary of what has emerged and a proposal for a decision regarding the regulations.

The regulatory work is, after the assessment has shown the need for a revision or new regulations, conducted in 13 main steps, including drafting, internal and external consultations, impact assessment, DG (Director General) decision and printing permit and publication of the decided regulations. The department for National Regulation has started a development work to gather experience continuously on the use of regulations, as well as to develop the process for revision and production of new regulations. For internal purposes there is a specific function on SSM's intranet where employees can submit feedback.

According to the Radiation Protection Act (2018:396) all activities and practices with ionising radiation are due to licensing. In order to apply a graded approach, the Radiation Protection Act allows also the establishment of requirements for activities and practices with ionising radiation that are due to registration only. SSM has done risk assessments for different activities and practices in order to classify them as due to licensing, due to registration only or exempted from licensing and registration.

SSM's regulations for activities and facilities that are due to licensing, cover aspects of radiation safety for all facilities, activities and practices using ionising radiation. The regulations also take into account different phases of the lifetime of a nuclear facility and different main types of specific activities and design aspects. Moreover, the regulations are structured in three levels, namely:

1. The first level represents requirements that must be observed by any party that has a licence for activities involving ionising radiation;
2. The second level is facility/activity/practice specific requirements; and
3. The third level consists of requirements concerning technical aspects as well as specific aspects of radiation safety.

Based primarily on the Act on Nuclear Activities, the Nuclear Activities Ordinance, the Radiation Protection Act, and the Radiation Protection Ordinance, the coordinated and integrated regulation is realised by bringing together existing provisions regarding the different protection aspects relevant to each phase, and by developing and supplementing these provisions based on new IAEA standards as well as WENRA documents.

Since June 2018, the regulations (SSMFS 2018:1) on basic provisions for licensed activities with ionising radiation contain general and common provisions that facilities, premises and places where activities are conducted must be designed so that exposure of workers to ionising radiation and dissipation of radioactive substances can be limited and measured. These regulations also contain provisions that before an activity is commenced, during the time it is conducted and when it is discontinued, events and conditions that are important for radiation safety must be identified and evaluated.

SSM promulgates regulations, general advice and guidance to regulations.

What characterises a regulation is that it is binding (*shall*-statements) and that it has general applicability. A regulation thus differs from an administrative decision or a license condition that only applies to the person to whom the decision or condition is addressed.

What characterises general advice is that it is not binding either on individuals or on authorities, but instead consists of such general recommendations on the application of a constitution (law, ordinance or regulation) that states how someone *should* act most appropriately in a certain situation.

What characterises a guide (including guidance for application, background and motives for regulations) is that it places the regulations in a context and develops how the provisions are intended to be applied and how one *can* do to meet the requirements that are set.

Sweden has specified handbooks for a few appointed practices (e.g. small animal veterinary, horse X-ray, industrial radiography, pregnant women, mammography screening) to even further give guidance on application.

According to section 4 of the Ordinance (2007:1244) on impact assessment in the regulatory process, an authority deciding on regulations or general advice, must as early as possible

1. investigate the cost impact and other consequences of the regulations or general guidelines to the extent necessary in the individual case and document the investigation in an impact assessment, and
2. give governmental authorities, municipalities, regions, organisations, the business community and others significantly affected by the costs or otherwise, an opportunity to comment on the issue and on the impact assessment.

According to (STYR2011-51), the developing process shall be communicated internally and externally. For this purpose, a communication plan must be prepared for various communication efforts. The extent of communication efforts are decided within each project for development of new or revised regulation.

Before SSM decides new or revised regulations, the proposal is sent for consideration to the relevant bodies. These referral bodies may include affected licensees, central government agencies, special interest groups, local government authorities or other bodies whose activities may be affected by the proposals. This process provides valuable feedback and allows SSM to gauge the level of support it is likely to receive. If a number of referral bodies respond unfavourably to the recommendations, SSM may try to find an alternative solution.

Draft regulations can be submitted in up to four steps:

- a first internal consultation within SSM,
- a first not formal consultation to the relevant licensees,
- a combined second internal and not formal consultation, and
- a formal consultation to relevant licensees, other Swedish authorities and other stakeholders.

If needed, SSM arranges information and consultation meetings in order to tell and explain more about the proposal. During the consultation period, SSM is always available for questions.

Several of the proposed regulations are also notified to the European Commission in accordance with the Euratom treaty or EU directives before they are decided.

When the consultation period is over, the comments received are evaluated and compiled. If possible, comments are incorporated into the proposed regulation.

Regulations are available online at <https://www.stralsakerhetsmyndigheten.se/regler/>

Most regulations are also available in printed form and are distributed to stakeholders for a fee.

To strengthen the work regarding regulations, further development of the internal governing document (STYR2011-51), the related work processes and process-map in the digital process tool is ongoing.

## 9.2 Regulations and Guides for NPPs

### *Related to SSR-2/1 and SSR-2/2*

The regulations and licence conditions cover the regulatory supervision of the entire life-cycle of nuclear power plants, see also Modules 5.2, 6.2 and 7.2.

Level 1 regulations for NPPs are set out in SSMFS 2018:1. These include overarching requirements regarding e.g. identification and assessment of events and conditions relevant for radiation safety, and applications of defence in depth. There are also requirements on leadership, management and culture for safety, measures and design for protection of workers, public and the environment as well as on waste management and on plans for decommissioning.

Level 2 regulations for NPPs are

- SSMFS-K on design, construction and commissioning of nuclear power plants, i.e. specifying requirements on application of defence in depth, fundamental safety functions to be fulfilled in events and conditions in event class H1–H5 (representing plant states)
- SSMFS-A on safety assessment and analysis, incl. analysis of postulated initiating events, review and reporting of NPP as built and operated including OLCs, safety report, assessment and reporting of modifications, periodic safety review etc.

- SSMFS-D on operation, incl. organisation, competence and staffing, training, monitoring and evaluation of safety performance, operating procedures, maintenance etc.

Level 3 regulations for NPPs are

- SSMFS 2008:13 on mechanical components, incl. specific provisions for testing, surveillance, inspection
- SSMFS-KÄKA on nuclear waste management

There are also specific conditions. One example is independent core cooling system (ICCS) as a condition to continue operation of NPPs after 2020 (SSM2012-3022), see also Module 5.2. Other examples are the additional licence conditions for decommissioning of NPPs (SSM2016-5866-26), see also Module 5.7.

### **9.3 Regulations and Guides for Research Reactors**

Out of scope. There are no research reactors in Sweden.

### **9.4 Regulations and Guides for Fuel Cycle Facilities**

*Related to NS-R-5*

Similar to the development of level 2 regulations for NPPs, development for other nuclear facilities is ongoing, including regulations for fuel cycle facilities. Regulations in SSMFS 2018:1 and elsewhere are currently applicable to fuel cycle facilities as described below for waste management facilities in Module 9.5.

### **9.5 Regulations and Guides for Waste Management Facilities**

*Related to GSR Part 5: Requirements 2, 6, 8, 9, 10, 11 and 12  
SSR-5: Requirements 5, 7, 10, 15, 19, 20, 22 and 26*

SSM's regulations concerning safety at nuclear installations (SSMFS 2008:1); These regulations apply to measures required to maintain safety at nuclear installations during the construction, possession and operation, including operation during decommissioning, in order to prevent radiological emergencies and the unauthorised handling of nuclear material or nuclear waste as far as is reasonably practicable, observing the best available technology. The regulations also apply to certain measures for maintaining and developing radiation protection at nuclear installations. The regulations include provisions on technical, organisational and administrative measures.

SSM's regulations concerning physical protection of nuclear installations (SSMFS 2008:12); these regulations apply to measures required to protect nuclear installations against malicious acts. The regulations include provisions on technical, organisational and administrative measures.

SSM's regulations concerning mechanical components at certain nuclear facilities (SSMFS 2008:13); these regulations apply to the design, construction and in-service inspection of mechanical components belonging to the primary system or containment barrier, or comprising part of safety, operating and auxiliary systems of (among others)

facilities for storage or other handling of spent nuclear fuel. The regulations apply to technical and administrative measures.

SSM's regulations on protection of human health and the environment in connection with discharges of radioactive substances from certain nuclear facilities (SSMFS 2008:23); these regulations apply to facilities for storage or other handling of used nuclear fuel and facilities for storage, treatment or final disposal of nuclear substances or nuclear waste for which the Government has granted licences under the Act (1984:3) on Nuclear Activities. These regulations apply to all discharges of radioactive substances from nuclear facilities that are directly related to normal operating conditions at the respective facility.

SSM's regulations on radiation protection managers at nuclear facilities (SSMFS 2008:24); these regulations apply to radiation protection work at nuclear facilities.

SSM's regulations on radiation protection of individuals exposed to ionising radiation at nuclear facilities (SSMFS 2008:26); these regulations are applicable to radiation protection of individuals at nuclear facilities.

SSM's regulations concerning archiving at nuclear installations (SSMFS 2008:38); these regulations are applicable to the archiving of documentation created and received in the context of activities at nuclear installations.

SSM's regulations concerning emergency preparedness at nuclear installations (SSMFS 2014:2); these regulations apply to emergency response activities at nuclear installations classified by SSM as emergency preparedness category 1, 2 or 3.

SSM's regulations concerning basic provisions for licensable activities involving ionising radiation (SSMFS 2018:1); these regulations contain provisions on radiation safety that shall be observed by any party that has a licence for activities involving ionising radiation in accordance with the Radiation Protection Act (2018:396) or nuclear activities under the Act (1984:3) on Nuclear Activities .

SSM's regulations concerning exemptions from the Radiation Protection Act and concerning the clearance of materials, building structures and sites (SSM 2018:3).

SSM's regulations concerning management of radioactive waste from nuclear facilities (SSMFS-KÄKA); these regulations contain provisions on radiation safety in the event of management of radioactive waste from nuclear facilities that must be observed by anyone who has or has had a licence under the Act (1984:3) on Nuclear Activities from the Government for nuclear activities or from SSM for final disposal in the form of shallow land disposal facilities for nuclear waste.

### List of regulations specific for disposal facilities

SSM's regulations concerning safety in connection with the disposal of nuclear material and nuclear waste (SSMFS 2008:21); These regulations apply to facilities for the disposal of nuclear material and nuclear waste (repositories). The regulations do not apply to facilities for landfill disposal of low-level nuclear waste under Section 16 of the Nuclear Activities Ordinance (1984:14).

SSM's regulations concerning the protection of human health and the environment in connection with the final management of spent nuclear fuel and nuclear waste (SSMFS 2008:37); these regulations apply to the final management of spent nuclear fuel and nuclear waste. The regulations do not apply to landfills for low-level nuclear waste in accordance with Section 19 of the Nuclear Activities Ordinance (1984:14).

SSM's decision on conditions for the continued operation of the final repository for low and intermediate level radioactive waste (SSM2021-7569-01); conditions for the continued operation of the final repository for low and intermediate level radioactive waste within the scope of the licence for continued operation and expansion of the facility decided upon by the Government on 22 December 2021 (M2019/01879).

SSM's statement on an application for a licence under the act on nuclear activities for extended activities at SFR (SSM2014-5966-11).

SSM's updated operating conditions for SFR 1 (SSI ref. no. 6222/3744/03).

### Shallow land disposals

SSM's reconsideration of the licence for the shallow land disposal facility for low-level waste at the Forsmark facility (SSM2010/721-54); The Swedish Radiation Safety Authority grants Forsmarks Kraftgrupp AB, FKA a licence to construct, own and operate a shallow land disposal facility at the Forsmark facility, Svalören (property designation: Östhammar, Forsmark 6:5), for low-level operational waste arising from this.

Disposal of waste may take place until 31 December 2040 and must not exceed 17,000 cubic metres. This licence is valid until 31 December 2070, or such later date as SSM may decide.

SSM's licence for a shallow land disposal facility for low-level nuclear waste at Svalören at the Forsmark facility (SSI ref. no. 6221/2530/01).

SSM's updated radiation protection conditions for the shallow land disposal facility at the Oskarshamn nuclear power plant (SSM 2009/4381).

## 9.6 Regulations and Guides for Radiation Sources Applications

### *Related to GSR Part 1 (Rev. 1): Requirements 32-34*

The following regulations cover the regulatory supervision of radiation sources applications:

Chapter 3 section 10 item 2 of the Radiation Protection Act (2018:396) (Maintenance of technical devices).

Chapter 3 sections 13-14 of the Radiation Protection Act (2018:396) (Labelling and information).

Chapter 3 sections 15-16 of the Radiation Protection Act (2018:396) (Functional requirements for technical devices).

Chapter 5 section 2 of the Radiation Protection Act (2018:396) (Rendering technical devices harmless).

Chapter 5 section 6 of the Radiation Protection Ordinance (2018:506) (Obligation to notify of orphan sources).

Chapter 6 of SSMFS 2018:1 concerning basic provisions for licensable activities (Radiation sources intended for exposure).

SSM's regulations (SSMFS 2018:6) concerning industrial radiography.

Chapter 3 of SSMFS 2018:7 concerning licensable veterinary activities.

Chapter 4 of SSMFS 2018:5 concerning medical exposures.

SSM's regulations (SSMFS 2018:2) concerning notifiable activities.

## **9.7 Regulations and Guides for Decommissioning Activities**

### ***Related to GSR Part 6***

The following regulations cover decommissioning:

Section 3 a of the Act (1984:3) on Nuclear Activities (Requirement to prevent a radiological emergency during decommissioning).

Section 10 item 4 of the Act (1984:3) on Nuclear Activities (requirement to decommission and demolish in a safe manner).

Sections 11 and 12 of the Act (1984:3) on Nuclear Activities (requirements concerning the R&D program, including decommissioning related issues).

Chapter 5 section 2 of the Radiation Protection Act (2018:396) (requirement to render technical equipment harmless).

Chapter 5 section 3 of the Radiation Protection Act (management of radioactive waste).

Chapter 5 section 4 of the Radiation Protection Act (clearance of building structures and areas, i.e. requirement concerning "immediate dismantling"); also Chapter 3 section 7 of SSMFS 2018:3 (decontamination of radioactive pollutions/impurities).

Chapter 2 section 1 of SSMFS 2018:1 (identification, assessment and management of incidents and conditions of relevance for (future) decommissioning).

Chapter 5 section 14 of SSMFS 2018:1 (decommissioning plan) also chapter 9 sections 1, 5 and 7 of SSMFS 2008:1 and appendix 5 to SSMFS 2008:1 concerning the content of the decommissioning plan (for NPPs under decommissioning replaced by additional license condition 14.2 and appendix 5 to SSM2016-5866-26).

Chapter 5 section 15 of SSMFS 2018:1 (measures to be taken before decommissioning commences), see also Chapter 5 section 7 of SSMFS-K and Chapter 3 section 1 of

SSMFS 2008:1 (requirement to take future decommissioning into account during construction).

Chapter 3 section 5 SSMFS of 2018:3 (clearance of building structures and areas by SSM's approval).

Chapter 3 section 6 SSMFS of 2018:3 (re-use of building structures without approval of clearance).

Chapter 3 section 16 SSMFS of 2018:3 (clearance levels for building structures).

Chapter 3 section 17 SSMFS of 2018:3 (SSM's approval of clearance levels for areas).

Chapter 3 section 18 of SSMFS 2018:3 (stakeholder involvement before clearance of building structures and areas for restricted use).

Chapter 9 section 2 of SSMFS 2008:1 (overarching decommissioning plan, "decommissioning strategy", for a site containing more than one nuclear facility), see also additional license condition 13 and appendix 4 to SSM2016-5866-26.

Chapter 9 sections 4 and 5 of SSMFS 2008:1 (measures in connection with (planned) permanent shutdown and care and maintenance phase).

Chapter 9 section 6 of SSMFS 2008:1 (report according to article 37 of the Treaty Establishing the European Atomic Energy Community).

Chapter 9 section 7 of SSMFS 2008:1 and additional license conditions 4 and 5 as well as appendices 2 and 3 to SSM2016-5866-26 concerning the approval of the safety analysis report for dismantling and demolition (NoR-SAR), i.e. SSM's authorisation of dismantling and demolition.

Chapter 9 section 8 of SSMFS 2008:1 as well as additional license conditions 27 and 28 and appendices 6 and 7 to SSM2016-5866-26 (content of the work package notification and report).

Additional license conditions 20 – 26 in SSM2016-5866-26 (discharge of radioactive effluents to the environment).

## **9.8 Regulations and Guides for Transport Activities**

### ***Related to SSR-6***

The following regulations cover transport requirements:

Section 5 of the Act (1984:3) on Nuclear Activities on Permit for Nuclear Activities. A Permit is required for Transport of Nuclear Material with special provisions.

Chapter 6 section 1 of the Radiation Protection Act on Permit for Activities concerning Radioactive Material. A Permit is required for Transport of Radioactive Material.

The Act (2006:263) and Ordinance (2006:311) on Transport of Dangerous Goods stipulates the provisions of activities on Transport of Dangerous Goods, listing the Authorities and their activities as well as their authority powers. SSM is authorised to inspect all activities concerning Transport of Radioactive and Nuclear Material.

MSBFS 2020:9, ADR-S 2021 on Transport of Dangerous Goods on Road and in Terrain.

MSBFS 2020:10, RID-S 2021 on Transport of Dangerous Goods on Railway.

TSFS 2015:66, IMDG-code 2020 edition on Transport of Packaged Dangerous Goods by Sea.

TSFS 2009:131, Memorandum of Understanding of Transport of Packaged Dangerous Goods on Ro-ro Ships on the Baltic Sea.

International Convention for Safe Containers, CSC, 1972.

TSFS 2021:30, ICAO-TI edition 2021-2022, Regulations on Transport of Dangerous Goods by Air.

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## **9.9 Regulations and Guides for Occupational Exposure**

### ***Related to GSR Part 3: Requirements 10-12, 19-24, 28 and 52***

The following regulations cover occupational exposure:

The Radiation Protection Act, Radiation Protection Ordinance (2018:506), SSM's regulations (SSMFS 2018:1) concerning basic provisions for licensable activities and SSM's regulations (SSMFS 2018:2) concerning notifiable activities regulates various responsibilities of regulatory body, employers, registrants and licensees with regards to occupational exposure in planned as well as in existing exposure situations

Chapter 3 sections 1-3 of the Radiation Protection Act (justification)

Chapter 3 section 5 of the Radiation Protection Act (optimisation)

Chapter 2 sections 2-5 Radiation Protection Ordinance (2018:506) (dose limits)

Chapter 4 sections 18-28 of SSMFS 2018:1 concerning basic provisions for licensable activities describe the regulations on monitoring and recording of occupational exposure.

Chapter 4 section 15 of the Radiation Protection Act (2018:396) describes the requirements for compliance by workers and cooperation between employers and authorised persons

Chapter 4 of SSMFS 2018:1 concerning basic provisions for licensable activities describe arrangements under radiation protection programme, assessment of occupational exposure and workers' health surveillance.

Regulations describing requirements for information, instruction and training; Chapter 3 section 10 pt. 4 of the Radiation Protection (good knowledge and competence, Chapter 3 sections 10-11 and 13 of SSMFS 2018:1 concerning basic provisions for licensable activities (competence needed for significant tasks) and Chapter 4 sections 13-14 of SSMFS 2018:1 concerning basic provisions for licensable activities (competence in radiation protection).

The following regulations concern exposure at working places due to existing exposure situations; Chapter 4 sections 5, 7-8 and 11 of the Radiation Protection Act (2018:396) concerning exposure of workers, pregnancy and breast-feeding, SSMFS 2018:10 concerning radon at worksites and SSMFS 2018:11 concerning exposure to cosmic radiation in aerospace.

The following requirements specifically protect female and under-age workers; Chapter 4 section 1 of the Radiation Protection Act (2018:396) (under-age workers) and Chapter 4 sections 7-11 of the Radiation Protection Act (2018:396) (female workers).

## **9.10 Regulations and Guides for Medical Exposure**

### *Related to GSR Part 3: Requirements 35-42*

#### **Requirements for education and training of health professionals**

Chapter 3 section 10 item 4 of the Radiation Protection Act (2018:396) states that any party conducting an activity involving ionising radiation, or employing a person to conduct work in such an activity, must ensure that everyone working in the activity has:

- good knowledge of the conditions, terms and regulations under which the activity is conducted,
- knowledge of the risks that may be associated with the activity, and
- the competence necessary for the satisfactory operation of radiation protection.

The care provider (the licensee/registrant) for medical exposures is responsible for planning, controlling and leading the practice so that it comply with proper care. In most cases it is the head at the department, who assign the tasks (e.g. to act as referrer, radiological practitioner or operator) and thus decide who is competent. However, SSMFS 2018:5 requires the licensees to involve certain expert functions in order to conduct medical exposures. These expert functions are:

- Radiological practitioner (RaLF) with overall responsibility for justification assessments and to assist and advice in questions related to medical exposure.
- Medical physics expert (MPE) with overall responsibility for optimisation of radiation protection for patients, questions relating to radiation protection and to assist and advice in questions related to medical exposures.
- Radiation Protection Expert (RPE) with overall responsibility for occupational exposure.

Chapter 3 section 10 of SSMFS 2018:1 requires the licensee to ensure that the workers have the necessary competence for carrying out tasks of relevance for radiation protection purposes. The competence needed in the organisation and the competence available should be identified and documented in a systematic way. If needed, training and education should be carried out or other measures taken, to achieve and maintain competence. Further, in chapter 4 section 13 of SSMFS 2018:1 and chapter 3 section 7 SSMFS 2018:5 it is regulated that the licensee ensures that the workers have the necessary competence to take the relevant protective measures during performance of the activities. In addition chapter 3 section 4 of SSMFS 2018:5 requires that every employee that works with medical exposure concerning children, health screening programmes or medical exposures involving high doses to the patient should undergo special training.

Similar requirements apply for notifiable activities. These requirements can be found in chapter 2 of SSMFS 2018:2.

### Medical exposure and release of patients

Patients to whom a radioactive substance is to be administered for medical exposure and persons who support and comfort the patient outside their professional activity and are deliberately exposed shall be informed of what measures they can take to minimise the radiation dose to other persons. The information shall be adapted to the examination or treatment in question and the circumstances of the patient and the person providing support and comfort (chapter 6 section 5 of SSMFS 2018:5).

Any medical exposure involving the administration of radioactive substances to a patient shall (in accordance with chapter 6 section 3 of SSMFS 2018:5) be planned so that the effective dose to carers and comforters does not exceed 3 millisieverts if the person is aged 18 or over and 15 millisieverts if the person is aged 70 or over. The effective dose to close relatives under the age of 18 should not exceed 1 millisievert and for members of the general public the effective dose should not exceed 0.1 millisieverts.

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### Measures to minimise the likelihood of unintended and accidental exposures

According to chapter 2 section 1 of SSMFS 2018:1 events and conditions that have an impact on radiation safety shall be identified and assessed before starting an activity, while it is in progress and when it is decommissioned. On the basis of the assessment measures shall be implemented to ensure that the activities are carried out in a way that is safe in terms of radiation safety and radiation protection. The assessment shall be documented and kept up-to-date. In chapter 2 section 2 it is further regulated that there shall be a defence in depth system with associated barriers and other obstacles adapted to the activity.

Chapter 4 sections 3-5 of SSMFS 2018:5 regulates acceptance testing, functional testing and performance inspections as well as acceptance criteria for equipment used in medical exposure.

Chapter 8 section 9 of the Radiation Protection Ordinance (2018:506) states that a party conducting an activity involving ionising radiation or in an environment involving ionising radiation must provide the supervisory authority as soon as possible with information about events and conditions in the activity that are of relevance for radiation protection purposes. If there is reason to suspect that a dose limit has been exceeded, the licensee must report this to the supervisory authority immediately. Further requirements on investigation of unintended or accidental medical exposures are found in chapter 3 section 18 of SSMFS 2018:1, chapter 3 section 10 and 11 of SSMFS 2018:5 and chapter 2 section 12 of SSMFS 2018:2 (for notifiable activities).

## Periodic radiological review at medical radiological facilities

Chapter 3 section 13 of SSMFS 2018:5 requires the licensee yearly prepare a safety assessment. The safety assessment must state:

1. How the systematic radiation protection work has been conducted
2. What measures have been taken to maintain and develop the safety, and
3. What results have been achieved in the radiation protection work.

Chapter 3 section 7-8 of SSMFS 2018:1 also requires the licensee to systematically and regularly review the application and effectiveness of the management system. There shall be an audit programme that identifies audit areas on the basis of the importance of the activities and any processes in respect of radiation safety.

In chapter 3 section 12 of SSMFS 2018:5 there are further requirements regarding experience feedback stating that the results of medical exposures carried out shall be reviewed for quality as part of the self-assessment to be carried out in accordance with the National Board of Health and Welfare's provisions on management systems for systematic quality work.

## Justification of medical exposure

Chapter 3 section 1 of the Radiation Protection Act (2018:396) states that it is prohibited to conduct an activity involving ionising radiation that is not justified. Chapter 3 section 2 of the Radiation Protection Act (2018:396) requires the licensee to ensure that the radiological method is justified and that in each individual case before someone is exposed to radiation, it is ensured that the exposure is justified.

Section 3 of the National Board of Health and Welfares requirements (SOSFS 2004:11) on responsibility for referrals of patients in healthcare and dentistry requires the caregiver to make available instructions in writing regarding how referrals should be designed and managed including who is entitled to act as a referrer. Chapter 2 section 1 of SSMFS 2018:5 requires the licensee to make available referral guidelines to those who are entitled to act as referrers. Chapter 2 section 2 of SSMFS 2018:5 further requires the radiological practitioner responsible for the delivery of the medical exposure to, so far as is reasonable and practical, take previous diagnostic information or medical records into account when deciding on the justification of the exposure.

Chapter 2 section 3 of SSMFS 2018:5 states that persons of childbearing age who are to undergo medical exposure shall be asked, where appropriate, whether they are pregnant. If it is not possible to rule out pregnancy in the person to be exposed, the expected radiation dose to the foetus and the urgency of the exposure shall be taken into account when assessing whether the exposure is justified.

Similar requirements for notifiable activities are stated in chapter 3 of SSMFS 2018:2.

## Optimisation of medical exposures

Chapter 3, section 5 of the Radiation Protection Act (2018:396) states the regulatory requirements concerning optimisation of all radiation exposures, including medical exposures. Chapter 2 section 5 of SSMFS 2018:5 states specific requirements concerning optimisation of medical exposures. Chapter 2 section 6 of SSMFS 2018:5 defines the

scope of the optimisation process for medical exposures. It is stated that optimisation shall include selection of equipment, ensuring diagnostic information and treatment outcomes, practical implementation of examination and treatment, quality assurance and evaluation of working methods and associated patient radiation doses. Furthermore the co-operation on the optimisation process concerning the radiological practitioner, medical physicist and other personnel involved in medical exposures or supporting measures is defined in chapter 3 section 8 of SSMFS 2018:5.

It follows from chapter 6 section 1 of SSMFS 2018:5 that as part of the optimisation process, the licensee should compare the measured patient doses to the reference levels defined by the authorities, where available.

Requirements concerning optimisation for notifiable activities are stated in chapter 3 SSMFS 2018:2.

### Specific regulations on medical exposure of pregnant and breast-feeding patients

Persons of childbearing age who are to undergo medical exposure shall be asked, where appropriate, whether they are pregnant. If it is not possible to rule out pregnancy in the person to be exposed, the expected radiation dose to the foetus and the urgency of the exposure shall be taken into account when assessing whether the exposure is justified.

When optimising an exposure in connection with examination or treatment of someone who is pregnant or where pregnancy cannot be excluded, the radiation dose to the foetus shall be taken into account in the planning and implementation so that the radiation dose to the foetus is as low as is reasonably practicable (chapter 2 section 5 of SSMFS 2018:5). In chapter 5 section 2 of SSMFS 2018:5 it is further stated that there shall be written method descriptions based on science and proven experience. These shall include, where applicable, alternative examination and treatment methods for pregnant women that can reduce the radiation dose to the foetus.

Chapter 9, Sections 9 and 10 of SSMFS 2018:5 states that persons of childbearing age who are to undergo nuclear medicine examination or treatment shall be asked whether they are breastfeeding. If the person to be exposed is breastfeeding, the expected radiation dose to the breastfed child and the urgency of the exposure shall be taken into account when assessing whether the exposure is justified. A breastfeeding person who is to undergo a nuclear medicine examination or treatment shall be informed, before the start of the exposure, of the risks that the exposure may involve for the child and be told to stop breastfeeding, where appropriate.

## 9.11 Regulations and Guides for Public Exposure

### *Related to GSR Part 3: Requirements 30-32, 47, 48 and 51*

*The various responsibilities of the relevant parties with regards to public exposure*

The Radiation Protection Act (2018:396)

The Radiation Protection Ordinance (2018:506)

SSM's regulations (SSMFS 2018:1) concerning basic provisions for licensable activities

SSM's regulations (SSMFS 2018:2) concerning notifiable activities

SSM's regulations (SSMFS 2018:3) concerning exemptions from the Radiation Protection Act and concerning the clearance of materials, building structures and sites

### **Radioactive waste management and discharges to the environment by licensees, registrants and suppliers**

Chapter 3 section 9 of the Radiation Protection Act (2018:396) (Waste, releases and environmental protection)

Chapter 5 section 3 of the Radiation Protection Act (2018:396) (Radioactive waste management)

Chapter 5 sections 17-21 of the Radiation Protection Ordinance (2018:506) (on permits for final disposal of radioactive waste abroad or for final disposal of foreign radioactive waste in Sweden)

Chapter 5 sections 7-8 of SSMFS 2018:1 concerning basic provisions for licensable activities (emissions of radioactive substances e.g. to drain)

Chapter 5 sections 9-13 of SSMFS 2018:1 concerning basic provisions for licensable activities (management of radioactive waste)

### **Monitoring and reporting public exposures**

Chapter 5 section 1 of the Radiation Protection Act (2018:396) (monitoring emissions and exposure to the public and the environment)

Chapter 5 sections 2-3 of SSMF2018:1 concerning basic provisions for licensable activities (on the calculation of radiation doses to the public)

### **Requiring justification and optimisation of remedial actions and protective actions**

Chapter 3 section 1 of the Radiation Protection Act (2018:396) (justified practice)

Chapter 3 section 3 of the Radiation Protection Act (2018:396) (justified measures)

Chapter 3 section 5 of the Radiation Protection Act (2018:396) (optimisation).

### **Reference levels for existing exposure situations**

Chapter 3 section 6 of the Radiation Protection Ordinance (2018:506) (reference levels for radon)

Chapter 3 section 7 of the Radiation Protection Ordinance (2018:506) (reference levels for gamma radiation from building materials)

## Exposure due to radon indoors

Chapter 3 section 6 of the Radiation Protection Act (2018:396) on (optimising radiation protection with regard to the radon content in premises accessible to the public)

Chapter 4 sections 7-8 of the Radiation Protection Ordinance (2018:506) (national action plan for managing risks with radon)

Sections 4-5 of SSMFS 2018:10 concerning radon at worksites (notification of activities with a high radon content)

Sections 6-17 of SSMFS 2018:10 concerning radon at worksites (monitoring of elevated radon levels)

Exposure due to radionuclides in commodities Chapter 5 sections 6-7 of the Radiation Protection Act (2018:396) (prohibition of goods containing radioactive material)

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## 9.12 Conclusions

Sweden meets the expectations of the IAEA safety requirements concerning regulations and guides. SSM has carried out an extensive review of the Authority's regulations regarding safety and radiation protection since the previous IRRS mission. SSM has adapted them to modern standards and requirements for consistency and comprehensiveness. Extensive work remains to be done on the development of level 2 and 3 regulations.

SSM's revised regulations specify the principles, requirements for safety upon which its regulatory judgements, decisions and actions are based. SSM is continuing its work to keep the regulations consistent, comprehensive and up-to-date, in accordance with a graded approach.

# Module 10: Emergency Preparedness and Response

This information only concerns the regulatory aspects of emergency preparedness and response (EPR).

## 10.1 Authority and Responsibilities for Regulating on-site EPR of Operating Organisations

*Related to GSR Part 7: Requirements 2, 20 and 25*

*GSR Part 1 (Rev. 1): Requirements 16, 26 and 27*

In Sweden, the state authorities Swedish Civil Contingencies Agency (MSB), Swedish Radiation Safety Authority (SSM), and the County Administrative Boards and municipalities have the authority to regulate the on-site EPR arrangements of operating organisations.

MSB is responsible for matters relating to protection against accidents, emergency preparedness and civil defence, to the extent that no other authority is responsible. The responsibility refers to measures before, during and after an accident, crisis, war or danger of war.

The County Administrative Board is geographically responsible for the county area and the highest civilian total defence authority within the county. They are responsible for the state administration in the county, to the extent that no other authority is responsible for special administrative tasks.

The municipalities are responsible for a large part of the community service that exists where the population live. The municipalities are obliged to have certain activities. It is the municipalities' responsibility to secure the supply of staff and skills in the operations, in both normal and emergency situations.

The emergency planning according to the Civil Protection Act (2003:778) is done according to a graded approach with level division specifying who is in charge of the emergency planning. The three levels represented in the legislation are:

1. The municipality's responsibility; Accident that has consequences for those involved in the accident and the area e.g. a traffic accident, fire.
2. The municipality's responsibility; dangerous activities, Installations/ industry that are not nuclear installations but that can cause emissions that can cause serious damage to people and /or the environment.
3. State responsibility; inter alia accidents at nuclear facilities.

In accordance with the Administrative Procedure Act (2017:900), all authorities shall, within its area of responsibility, cooperate with other authorities. All authorities in Sweden are obliged to make sure that a decision is made. This states that a party that can be affected by an authority's decision shall be heard.

In order to protect people's life and health as well as the environment, a municipality must ensure that measures are taken to prevent fire and other accidents (Civil Protection

Act (2003:778)). According to Civil Protection Ordinance (2003:789), the municipality shall work with preventive work within the municipality and the work shall be summarised in an action program for preventive measures. The municipalities are responsible for the supervision of the operating organisations when it comes to questions regarding the Civil Protection Act (2003:778) and the Civil Protection Ordinance (2003:789).

Through the Civil Protection Act (2003:778) and The Ordinance on Civil Protection (2003:789), the Government has assigned MSB the mandate to issue specific regulations and action plans regarding the municipality's rescue services, which includes resources regarding on-site rescue services.

MSB shall according to the Civil Protection Act (2003:778) perform supervision over the municipalities concerning their supervision of the operating organisations. Furthermore, MSB conducts supervision of the County Administrative Boards concerning planning for rescue services during radioactive release and planning for decontamination.

Through the Nuclear Activities Ordinance (1984:14) and the Radiation Protection Ordinance (2018:506), the Government has assigned SSM the mandate to issue specific regulations and, if needed, licensing conditions for licensees in the fields of nuclear safety and radiation protection (including medical exposure and transportation), and provisions for supervision. The holder of a license in the fields of nuclear safety and radiation protection must ensure that all the necessary measures are taken for maintaining safety in compliance with the regulations and licensing conditions.

In accordance with legal authorisation and the mandate defined by the Government, SSM's supervisory practices include compliance inspections and reviews with respect to requirements found in regulations, licensing conditions and to some extent in regulatory decisions. The ambition is to systematically supervise and monitor developments based on a comprehensive inspection programme. The documented inspection and review findings provide a basis for SSM's integrated evaluation of radiation and nuclear safety on the part of each license. Consequently, SSM conducts supervision on EPR arrangements since a wide range of regulations cover EPR. This supervision covers nuclear facilities, use of radioactive sources in industry and medical exposure, and transportation.

The Supervision division (T) at SSM conducts the supervision of EPR. The division is responsible for the operational supervision according to risk-based supervision plans and programs. The Regulation and Knowledge Development division (N) is responsible for developing legislation, policies, strategies and other steering documents within the framework of SSM's assignment. The Emergency Preparedness, Security and Licensing division (B) is responsible for SSM's work on permit and notification matters as well as the development and implementation of EPR issues.

At SSM, there are developed supervision programs, which covers the supervision of EPR (see IRRS Module 6 Review and assessment, and Module 7 Inspection). These programs describe how the regulations on ERP are to be supervised and how often. The facilities are placed in different emergency preparedness categories 1-3 (SSMFS 2018:1 (Appendix 4)), depending on how much impact the facility can have on people and the environment in the event of a radiological emergency. SSM has classified e.g. the Swedish nuclear

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power plants in emergency preparedness category 1. Regulation and supervision is conducted with a graded approach in relation to the emergency preparedness categories.

As RB for emergency planning of both nuclear and radiological emergencies and supervision of the County Administrative Boards and municipalities, MSB has developed a process on how to supervise the County Administrative Board and the municipality based on a graded approach. The process is described in MSB's *process Tillsyn, Kärnteknisk anläggning* that is described in MSB's internal rules of procedures (MSB ps). MSB has recently been tasked with the responsibility for the supervision of the municipalities emergency planning. The supervision includes for example emergency planning, coordination, emergency organisation, information to the public, decontamination, waste storage, exercises and education.

When MSB and SSM revises or writes new regulations, they must send these for referral to relevant authorities according to Section 26, Administrative Procedure Act (2017:900).

## **10.2 Regulations and Guides on On-Site EPR of Operating Organisations**

*Related to GSR Part 7: Requirements 2 and 8  
GSR Part 1 (Rev. 1): Requirement 2*

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

- Civil Protection Act (2003:778) regarding protection against accidents with serious potential consequences for human health and the environment (on-site and off-site EPR),
- Civil Protection Ordinance (2003:789) regarding protection against accidents with serious potential consequences for human health and the environment (on-site and off-site EPR)
- Act (1984:3) on Nuclear Activities regarding general provisions on emergency response in the event of an accident at the nuclear facility.
- Nuclear Activities Ordinance (1984:14) regarding general provisions on emergency response in the event of an accident at the nuclear facility
- Radiation Protection Act (2018:396) regarding protection of people, animals and the environment from the harmful effects of radiation during an emergency
- Radiation Protection Ordinance (2018:506) regarding reference levels to be applied in the case of a radiological emergency and includes requirements for optimisation.

In line with the IAEA requirements, SSM has established and adopted several regulations, some with guiding text, for EPR of operating organisations to address the emergency arrangements that the operating organisations should put in place and comply with for an effective emergency response on-site. SSM's regulations on on-site emergency preparedness uses the concept of emergency preparedness categories (1, 2, and 3) based on the IAEA's emergency preparedness categories. The regulations involves the application of a graded approach depending on the radiological hazard at the facility.

*The following SSM regulations applies to all activities:*

- SSMFS 2018:1 concerning basic rules for licensed activities involving ionising radiation,

The following regulations only applies to NPPs in operation:

- SSMFS-K concerning construction of nuclear power reactors,
- SSMFS-A concerning the assessment and reporting of radiation safety of nuclear power reactors, and
- SSMFS-D concerning the operations of nuclear power reactors.

The following regulations only applies to nuclear installations where there are no reactors in operation:

- SSMFS 2008:1 concerning safety in nuclear facilities.
- SSMFS 2014:2 concerning emergency preparedness at nuclear facilities (on-site emergency preparedness and response)

According to the Radiation Protection Act (2018:396), the one who is responsible for a measure taken in an existing exposure situation or in connection to an emergency exposure situation, shall ensure that the measure is justified, if it alters the radiation exposure situation. Furthermore, anyone who is responsible for a practice or for a measure that may involve a person being exposed to ionising radiation must optimise radiation protection by, as far as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors, limiting

1. the likelihood of exposure;
2. the number of individuals exposed, and
3. the magnitude of the individual radiation dose.

In regard to emergency services under the Civil Protection Act (2003:778) the state or municipality is responsible for the emergency response to accidents and to the imminent danger of accidents to prevent or limit harm to people, property or the environment.

The Act (1984:3) on Nuclear Activities is clear about the prime responsibility for safety, Section 10 in the Act on Nuclear Activities states that 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 nuclear activities are no longer carried out.

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

Facilities that have an activity that have been classified by the County Administrative Board as a hazardous activity is obliged to analyse the risks that exist within the operating organisation. The owners are also obliged to maintain or pay for preparedness to a reasonable extent according to the Civil Protection Act (2003:778). The municipalities are responsible for interpreting what is meant by a *reasonable extent*.

The municipality must identify the risks that exist within its area and plan the rescue service based on those risks. This shall be done within the framework of the municipality's action program, Civil Protection Act (2003:778). Operating organisations within the municipality shall assist.

SSMFS 2018:1 requires that the licensees must have EPR arrangements that are adapted to its emergency preparedness category (in which the activity is placed in accordance with Section 4). Contingency and crisis management shall be described in an emergency plan that states which preparations that have been made and what crisis management is available to deal with and limit the consequences of a radiological emergency. The emergency plan shall be tested through regular exercises. Experiences from these shall be drawn to improve preparedness and crisis management. The emergency plan shall be kept up to date.

### **10.3 Verifying the Adequacy of On-Site EPR of Operating Organisations**

*Related to GSR Part 7: Requirements 2 and 25  
GSR Part 1 (Rev. 1): Requirements 26-31*

The Act (1984:3) on Nuclear Activities, the Nuclear Activities Ordinance (1984:14), the Radiation Protection Act (2018:396) and the Radiation Protection Ordinance (2018:506) give SSM the mandate to carry out inspections and states that supervision of the operating organisations shall be performed by the RB. SSM verifies continuously on-site EPR planning and arrangements by conducting recurring inspections, reviews and assessment of the nuclear facilities. For new licensees (*placed in emergency preparedness category 1-4*) SSM reviews and approves the operator's emergency plan. For licensees in operation, changes to the emergency plan must be reported to SSM. Furthermore, exercises are followed up in inspections and some evaluations are conducted during the licensees' exercises.

SSM has not established specific guides or checklists for the review or inspection of the EPR activities. The supporting documents are general and applicable to all kinds of reviews and inspections, and criteria for analysing compliance of requirements are established in a plan for each review or inspection.

The municipality will make inspections at the operating organisation to make sure that it complies with the Civil Protection Act (2003:778) when it comes to fire and other accidents. It will also make sure that the risk analysis is up to date so that the on-site and off-site response will not differ.

SSMFS 2008:1 concerning nuclear facilities and SSMFS-A concerning NPPs state that a licensee must perform an overall analysis and assessment of the operating organisation's safety at least every ten years, according to the Act(1984:3) on Nuclear Activities and state how the operating organisation at the time of assessment meets current safety requirements. The licensee shall also analyse if conditions exist for operating the facility in a safe manner until the next assessment, taking into account the development that has taken place in science and technology. The analyses, the assessments and the measures prompted by these shall be documented and reported to SSM.

SSMFS 2008:1 concerning nuclear facilities and SSMFS-A concerning NPPs requires that technical and organisational changes in a facility, which can affect the conditions

specified in the safety report, and principal changes to the safety report shall be safety audited. Before any such changes may be applied, SSM must be notified.

In accordance with the Civil Protection Act (2003:778) all emergency planning must be planned and organised so that the rescue operation can begin within an acceptable time and be carried out in an efficient manner. The municipalities and state authorities that are responsible for activities in accordance with the Civil Protection Act (2003:778), shall coordinate their activities and cooperate with each other and with others affected.

According to the Civil Protection Act (2003:778), the municipalities shall take advantage of the opportunities to utilise each other's resources for rescue services. The rescue service must therefore, in collaboration with relevant authorities and the licensee, develop the emergency planning together, so that each authority or organisation knows how to act during a radiological emergency. The same applies to the County Administrative Board, which must coordinate its planning with the Swedish Police Authority or the municipality so that an accident or emergency can be handled by the off-site emergency authorities. Sweden has tested the collaboration during an exercise in 2019 involving a security event giving rise to a nuclear emergency. Each authority or organisation has a responsibility for making sure that their own part, and their obligation in the national EPR system can be fulfilled, and the basis for this is collaboration.

According to SSMFS-D, there are requirements that the exercise activities for crisis management in radiological emergencies must include exercises carried out in collaboration with relevant actors, such as e.g. the Swedish Police Authority, the Rescue Service, the County Administrative Board or SSM.

It is recommended, generally, that SSM should develop a clearer review and inspection process with guidance on how to carry out reviews and assessments and inspections including development of criteria for assessing compliance with regulatory requirements.

## 10.4 Roles of the RB in a Nuclear or Radiological Emergency

*Related to GSR Part 7: Requirements 2, 20-26*

*GSR Part 1 (Rev. 1): Requirements 3 and 8*

To understand the roles of the RBs in a nuclear or radiological emergency the Swedish system for accidents is described. The Swedish legislation and emergency preparedness is structured in accordance with three principles:

- **The principle of responsibility** – those actors who are responsible for a certain activity under normal circumstances retain this responsibility in the event of societal disruptions. Actors also have a responsibility to act, even in uncertain situations. The expanded principle of responsibility means that the actors are obliged to support and collaborate with each other.
- **The principle of proximity** – societal disruptions are to be managed where they occur and by those actors most closely concerned and responsible.
- **The principle of similarity** – actors are not to make changes to their organisational structure that are more substantial than the situation demands. Accordingly, in the event of societal disruptions, operations are to continue to function as they do under normal circumstances, to the extent possible.

The municipality is the authority closest to the citizens and all accidents occurs within a municipality. Thus, the Swedish legislators have decided that the municipality should

handle all type of accidents except six. For the other six types of accidents the state is responsible. One of these six exceptions is a nuclear accident for which the County Administrative Board is responsible for emergency planning and remediation. The County Administrative Board is the government agency that is in the immediate vicinity to the accident and is the agency that has the closest cooperation with the municipalities within their area.

There are 290 independent municipalities and 21 county administrative boards in Sweden. The municipalities in Sweden are responsible for rescue services during a radiological emergency according to Civil Protection Act (2003:778). The County Administrative Boards are responsible for off-site rescue services during nuclear emergencies, according to the Civil Protection Act (2003:778), and the Civil Protection Ordinance (2003:789).

In the Swedish system, an accident is defined as a sudden event that may cause or causes injury and that requires immediate action. The definition in Swedish legislation of an accident does not take into account why something has happened. It is the consequences of the accident that the emergency preparedness should focus on. This means that it does not matter for the legislators if it is an antagonistic event or an accident (Proposition 1985/86:170).

For the Swedish system for accidents to work, those who are responsible for the emergency planning must coordinate the planning with other agencies and e.g. operating organisations (Civil Protection Act (2003:778)). Those responsible must also ensure that the public is informed of what preparedness there is and how the public is to be warned. This is true regardless of who is responsible for the emergency planning.

Anyone who discovers or otherwise becomes aware that an accident has occurred where there is danger to life, health or the environment is obliged, if possible, to warn people who are in danger and, if necessary, call for help (Civil Protection Act (2003:778)). It does not matter if this is an operating organisation or a person that observes an accident they all have the same obligation. To secure this obligation operating organisations have to prepare and collaborate with the emergency planners.

The municipality is responsible for planning its ability to conduct rescue operation based on the risks that exist within the municipality. These risks can be e.g. transport accidents, industries that have radiation sources, hospitals, etc. The municipality must have a preventive work that prevents an accident from happening, but there must also be an action program for emergency services (Civil Protection Act (2003:778)).

MSB is the RB and can prescribe how emergency planning off-site should be done and has supervisory responsibility for planning (Civil Protection Ordinance (2003:789))

The County Administrative Board shall decide that, if a facility where the operation involves a risk that an accident will cause serious injuries to people or the environment, the facility shall be classed as a hazardous (Civil Protection Ordinance (2003:789)). The operating organisation is required to support the County Administrative Board with information regarding the risk analysis (the Civil Protection Act (2003:778)). To support the decision, the County Administrative Board can use the emergency preparedness categories that SSM has described in SSMFS 2018:1 Appendix 4.

For non-nuclear facilities, if the operating organisation is classed as hazardous in accordance with the Civil Protection Act (2003:778), the Government has decided that the municipality shall establish a specific emergency plan for that facility (the Civil Protection Ordinance (2003:789)). The scope of the emergency plan is to satisfy the safety that the environment requires. The emergency plan must be updated at least every three years or when there is reason to do so due to changed circumstances. Connected to the emergency plan there shall be an exercise plan that clearly shows when, how and what shall be practiced.

MSB is the RB when it comes to emergency preparedness off-site and has supervisory responsibility for the planning (the Civil Protection Ordinance (2003:789)).

Regardless of the type of rescue operation that is conducted, all state authorities and municipalities are obligated to participate in the rescue operation with personnel and property (the Civil Protection Act (2003:778)). Since the municipalities are an important part of the emergency planning, they are also obliged to participate in the planning and exercise of an accident and subsequent remediation (the Civil Protection Act (2003:778)). When an accident has occurred, everyone, including the individual, is obliged to provide information on personnel and property that can be used for rescue operation and decontamination (the Civil Protection Act (2003:778)).

If the accident is not in a nuclear installation, MSB has the right to prioritise and distribute reinforcements (the Civil Protection Act (2003:778)). In order for the County Administrative Board to be able to plan effectively, MSB, together with SSM and county administrative boards, has produced a joint national contingency plan which describes the authorities' support to the county administrative boards (NBP).

General requirements that central governmental agencies shall advise the Government and response organisations in preparing an emergency plan and in the event of a nuclear or radiological emergency are in place in Sweden. General roles and responsibilities for central governmental agencies in response to nuclear or radiological emergencies follow the mandate of each central governmental agencies during normal circumstances. For a selection of central governmental agencies, requirements that are more specific are also in place.

Requirements that central governmental agencies shall provide expert services to the Government and response organisations in preparing an emergency plan and in the event of an emergency are in place in Sweden. However, responsibilities are not clearly allocated with regard to the provision of risk assessments for actual and expected future radiation risks to the population or to specific groups of the population in the event of a nuclear or radiological emergency.

According to the Administrative Procedure Act (2017:900), public authorities are obliged to cooperate with each other within their areas of responsibility. All authorities in Sweden are obliged to make sure that a decision is made according to the Administrative Procedure Act (2017:900). This states that a party that can be affected by an authority's decision shall be heard. According to the Ordinance (2015:1052) on Emergency Preparedness and the Measures to be taken by Designated Authorities in the Event of Heightened Alert, each public authority whose area of responsibility is affected by an emergency, shall take the measures needed to handle the consequences of the emergency. The public authorities shall coordinate and support each other in such a situation.

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The Government appointed a committee to review the responsibilities for Iodine Thyroid Blocking (ITB) in connection to nuclear emergencies (dir. 2019:83). The committee presented a proposal for the future responsibility to procure, store, distribute as well as inform and recommend intake of ITB (SOU 2021:19 A strengthened security of supply for health and medical care). The Government has not yet decided on the proposal from the committee. Meanwhile, the Government tasked the county administrative boards, SSM, MSB to procure, store and distribute ITB (M2020/00729/Ke).

Rescue services during a radiological or nuclear emergency can be headed by a municipality or by the state. Every municipality has appointed a rescue commander according to Act (2003:778). The rescue commander can act as an incident commander or appoint a person having fulfilled the training required by MSB to act as an incident commander according to Act (2003:778). The incident commander has the authority and responsibility to direct and coordinate rescue services according to Act (2003:778). If several municipalities are affected by an emergency, the incident commanders in the affected municipalities shall agree on who should be in charge of rescue services. If they cannot agree, the County Administrative Board has the authority to make this decision according to Act (2003:778). The County Administrative Board can also take over the responsibility for rescue services for large-scale emergencies according to Act (2003:778), and Ordinance (2003:789).

MSB shall support authorities to coordinate their actions during emergencies according to Ordinance (2008:1002) with instructions for the Swedish Civil Contingencies Agency, section 7 and has issued guidance to this end.

Requirements on arrangements for the coordination of ERP between operating organisations and authorities at the local, regional and national levels, including those organisations and authorities responsible for the response to conventional emergencies are clearly regulated.

Requirements on SSM and MSB to develop tools, procedures and criteria for use in the response to a nuclear or radiological emergency are in place. Both authorities provide advice to response organisations in the event of a nuclear or radiological emergency.

According to Ordinance (2008:452) with instructions for SSM, SSM is charged with the responsibility to give advice on radiation protection in connection to nuclear and radiological emergencies. SSM shall also provide technical advice in the event of a nuclear or radiological emergency. Furthermore, SSM shall provide expertise as well as knowledge- and decision support within the area of radiation protection, including, dispersion prognoses, radiation monitoring and radiation protection assessments. SSM shall also maintain and lead an expert response support organisation and have the ability to perform radiation monitoring, sampling and analysis in the field. SSM shall maintain national systems for 24/7 monitoring of radiation levels.

Requirements on all authorities with a role in emergency response to develop an emergency plan in the event of nuclear or radiological emergencies are in place in Sweden. The requirements follow a graded approach, with general requirements for radiological emergencies and more extensive requirements for nuclear emergencies at facilities in emergency preparedness categories I and II. However, the responsibility to maintain a national emergency response plan is not clearly allocated.

General requirements on procedures and analytical tools for the goals of emergency response to be achieved and for the emergency response to be effective are in place in Sweden.

The responsibility for rescue services is regulated in Act (2003:778) and Ordinance (2003:789) as described above. With that responsibility follows that all necessary procedures and analytical tools shall be available in an emergency, either at the municipality or County Administrative Board in question or via supporting governmental agencies such as SSM, MSB and the Swedish Meteorological and Hydrological Institute.

General requirements for testing procedures and analytical tools under simulated emergency conditions for a nuclear or radiological emergency as well as general requirements for validation prior to use and the information on how release assumptions will influence the decision making process are in place in Sweden.

Governmental agencies are responsible for the training and exercise activities necessary for the staff to be able to solve its assignments in emergencies according to Ordinance (2015:1052), section 9. Moreover, the ordinance states in the same section that the agencies are requested to have arrangements in place for training, drills and exercises to be able to fulfil the assignments.

General requirements regarding a plan describing adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation are in place in Sweden. Regulations on the authorities' use of communication systems are in place.

Public authorities' documentation in its crisis management process shall follow normal regulated procedures at Swedish authorities, as specified in the Administrative Procedure Act (2017:900) and in the Archives Act (1990:782).

Requirements on arrangements to ensure that personnel assigned to positions with responsibilities in emergency response undergo specified training are in place in Sweden. Requirements on extensive qualifications are in place for incident commanders in charge of rescue services.

All governmental agencies that have a responsibility within the crisis management system are responsible for ensuring that their staff at the authority receives the training and exercises they need to be able to solve their tasks according to Ordinance (2015:1052). A planned training and exercise activity for the purpose of achieving this goal shall be implemented according to Ordinance (2015:1052).

MSB, together with other authorities, has developed a joint education and exercise strategy in a national strategy for systematic exercise activities – for emergency preparedness and civil defence, MSB report MSB1625 – October 2020. This describes how Sweden will work with follow-up of exercises and how experiences from education and exercise will bring the development of preparedness in a cyclical follow-up. At an overall societal level, MSB shall follow up and evaluate emergency preparedness and assess whether the measures taken have had the desired effect as stated in Ordinance (2008:1002).

All governmental agencies, with personnel and property that may be used in rescue operations according to Act (2003:778), are obliged to participate in planning and exercises according to Ordinance (2003:789).

According to the Ordinance (2015:1052), the responsible authorities listed in the Annex to the Ordinance shall inform MSB about their exercises so that it can be coordinated with the exercise activities that the MSB is planning.

According to the Ordinance (2015:1052), the responsible authorities listed in the Annex to the Ordinance, the County Administrative Boards and other authorities decided by the Government are responsible for planning and become prepared to handle a crisis and resist vulnerabilities.

All municipalities are obliged to participate in the planning and exercises for nuclear emergencies, including and subsequent decontamination, according to Act (2003:778). The municipality's plans for rescue operations for emergencies at non-nuclear practices with ionising radiation if they are classified as dangerous practices according to Act (2003:778), shall be commensurate to the required level of safety off-site according to Act (2003:789). MSB has the mandate to issue regulations on details to the plans according to Act (2003:789).

No regulatory body has been assigned with any responsibility in response to a nuclear or radiological emergency that might compromise or conflict with its responsibility as a regulator.

According to the Act (1984:3) on Nuclear Activities, the responsibility for nuclear safety lies with the licensee for the nuclear facility. This responsibility cannot be delegated. According to SSM's regulation SSMFS 2018:1, concerning basic rules for licensed activities involving ionising radiation, it is stated that the operating organisation has the prime responsibility for safety. This must be included in their integrated management system.

## **10.5 Conclusions**

Sweden meets the expectations of the IAEA safety requirements for Emergency Preparedness and Response in all four core areas: authority and responsibilities for regulating on-site EPR, Regulations and Guides on on-site EPR, verifying the adequacy of on-site EPR, and the roles of the RB in a nuclear or radiological emergency.

# Module 11: Interface with Nuclear Security

## 11.1 Legal Basis

### *Related to GSR Part 1 (Rev. 1): Requirement 12, paragraph 2.39*

Sweden's system of acts, ordinances and regulations may be divided into two main categories. The first category can be referred to as "radiation safety provisions", which derive from the Radiation Protection Act and the Act on Nuclear Activities, and are supplemented by the ordinances and regulations that are appurtenant to these acts. The second category may be referred to as "other national provisions", encompassing all other provisions though which do not belong to the above-mentioned radiation safety provisions. Examples of legislation in the category "other national provisions" include the Protective Security Act (2018:585), Installations Protection Act (2010:305), Act (2006:263) on Transport of Dangerous Goods, Police Act (1984:387), Civil Protection Act (2003:778), and Public Access to Information and Secrecy Act (2009:400).

The Swedish legal framework governing physical protection of nuclear material and nuclear facilities is set up by means of interplay between the radiation safety provisions and other national provisions.

SSM is the main regulatory body regarding nuclear safety and radiation protection in Sweden. Nevertheless there are other authorities that are responsible of different aspects of radiation protection and nuclear safety (radiation safety). According to the Government Agency Ordinance (2007:515) a government agency shall work to take advantage of collaboration through collaboration.

According to Swedish legislation SSM has the mandate to conduct oversight and enforce arrangements for safety, nuclear security and the system of accounting for, and control of nuclear material. There are several laws and ordinances that gives SSM all necessary authority for carrying out supervision. The main acts and ordinances are:

- The Act (1984:3) on Nuclear Activities sections 16, 17, 18,, 22
- The Radiation Protection Act (2018:396) chapter 8, sections 1, 6, 7
- The Nuclear Activities Ordinance (1984:14) sections 2, 3 a, 3 b, 3 d, 15 a, 16, 16 a, 18, 18 a, 19, 19 c, 20, 20 a, 20 b, 21, 22, 24, 25, 27, 28
- The Radiation Protection Ordinance (2018:506) chapter 8, sections 1, 3, 4, 8, 10, 11, 15.

## 11.2 Regulatory Oversight Activities

### *Related to GSR Part 1 (Rev. 1): Requirement 12, paragraphs 2.39 – 2.40*

The Act on Nuclear Activities is the basic law regulating nuclear safety, including nuclear security. It contains basic provisions concerning safety in connection with nuclear activities, and applies to the operation of nuclear power plants (NPP) and other nuclear facilities as well as to the handling of nuclear material and nuclear waste.

Operation of a nuclear facility may only be conducted in accordance with a licence issued under the Act on Nuclear Activities as well as with a licence issued under the Environmental Code. The Act on Nuclear Activities is mainly concerned with issues of nuclear safety and security, while the Environmental Code (1998:808) regulates general aspects of the environment and the possible impacts of “environmentally hazardous activities”, to which nuclear activities are defined as belonging.

According to the Act on Nuclear Activities, such activities shall be conducted so as to meet nuclear safety requirements and fulfil the obligations pursuant to Sweden’s agreements for the purpose of preventing the proliferation of nuclear weapons and unauthorised dealing with nuclear material and spent nuclear fuel. Safety in nuclear activities shall be maintained by taking all measures required to

1. prevent failures or faults in equipment, human errors, sabotage or other circumstances leading to a radiological emergency situation and to restrict and delay release of radioactive substances if an emergency situation does occur,
2. at an early stage of a radiological emergency situation, avoid such emissions of radioactive substances which would require off-site emergency measures but with insufficient time to implement them,
3. avoid such large radioactive releases that would require protective measures that could not be limited in area or time, and
4. prevent unauthorised dealing with nuclear material or nuclear waste

It should be noted that the Act on Nuclear Activities emphasises that nuclear safety should be maintained by taking measures to prevent and mitigate radiological emergencies and prevent unauthorised dealing with nuclear material or nuclear waste. The Act on Nuclear Activities names sabotage as one possible cause for radiological emergencies and thereby indirectly include security measures in safety. This way of regulating security is relatively unique from an international perspective, but is something that SSM has to relate to when developing new regulations. In the early stage of the project to develop new regulations, a decision in principle was taken stating that the aspects of radiation protection, nuclear safety and security to a greater extent than previously should be regulated in an integrated manner and in the contexts where these aspects are concerned, and not in separate regulations. The aim is to establish an improved and more transparent and consistent set of requirements, give a more logic structure, and to improve preconditions for more integrated regulatory supervision.

A safety analysis report shall provide an overall view of how the safety of the facility is arranged in order to protect human health and the environment against radiological accidents and unauthorised handling of nuclear material and nuclear waste. The report shall reflect the facility as it is built, analysed and verified, as well as show how the requirements on its design, function, organisation and activities are met. The safety analysis report shall contain no less than the information specified in Appendix 2 in addition to the Operational Limits and Conditions stipulated in Chapter 5, Section 1 SSMFS-A. Modifications to the facility shall be evaluated on the basis of the conditions specified in the safety analysis report. A preliminary safety analysis report shall be drawn up before a facility may be constructed and, for an existing facility, before major refurbishing or rebuilding work or major modifications are carried out. The safety analysis report shall be updated before trial operation of the facility may commence so that the report reflects the construction of the facility. The safety analysis report shall be supplemented, taking the experiences of such trial operation into account, before the facility is subsequently taken into regular operation. The preliminary safety analysis

report as well as the updated and supplemented safety analysis report in accordance with the second paragraph (chapter 4 section 2 SSMFS 2008:1))

The provision aims at requiring the licensee to have special attention to the fact that measures for radiation protection, nuclear safety and security measures shall interact without adversely affecting each other. In addition, considerations shall be made to achieve a balanced implementation of all aspects of radiation safety. Application of the provision is explained in guidance and examples are given.

For other facilities and activities than nuclear power plants this is explicitly mainly regulated in the regulations on physical protection (SSMFS 2008:12), which is related to the general requirements on safety of nuclear installations in SSMFS 2008:1. For example, the general recommendations to section 1 SSMFS 2008:12 states that the primary purpose of the measures taken to protect nuclear facilities against malicious acts which may lead to radiological emergency situations should be corresponding to the provisions on barriers and defence in depth in chapter 2 section 1 SSMFS 2008:1. Further, the general recommendation states that malicious acts against a nuclear facility should not lead to more severe consequences than failure or faults of structures, systems or components, human errors or external events are expected to lead to. This is the same intention as the more direct provisions on design of nuclear power plants.

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### 11.3 Interface among Authorities

#### *Related to GSR Part 1 (Rev. 1): Requirement 12, paragraphs 2.39 – 2.40*

SSM is the main regulatory body regarding nuclear safety and radiation protection in Sweden. Nevertheless there are other authorities that are responsible of different aspects of radiation protection and nuclear safety (radiation safety). According to the Government Agency Ordinance (2007:515) a government agency shall work to take advantage of benefits that can be gained through collaboration.

The National Center for Terrorist Threat Assessment is a permanent working group with personnel from the Security Police, National Defence Radio Establishment and the Military Intelligence and Security Service. The centre's task is to make strategic assessments of the terrorist threat against Sweden and Swedish interests in both the short and long term. The business produces strategic analyses of events, trends and external developments related to terrorism that affect Sweden and Swedish interests. The assessments are communicated to the Government Offices and authorities that are part of the Cooperation Council against Terrorism and aim to provide an early warning of changes that may affect the threat to Sweden and Swedish interests and that may require action. SSM, the Police Authority, the Security Police, MSB and Svenska kraftnät (SvK, State owned enterprise for the Swedish national grid for electricity) have jointly agreed to establish a collaboration group to strengthen the protection of nuclear activities and other activities with radioactive substances, as well as transports of radioactive substances, against antagonistic threats. SSM is chairman of the group and takes support from this for threat analyses and in the preparation of changes in DHB. If necessary, other actors are also co-opted to the liaison group, for example the Coast Guard and the Armed Forces. The collaboration group was established on the recommendation of an international review (International Physical Protection Advisory Service, IPPAS) of the Swedish system for physical protection in 2011. The group has also functioned as a steering group for joint exercise activities within e.g. transport of nuclear material and cyber threats. This co-operation group is conducted independently within the framework of the Co-

operation Council against Terrorism, which in turn is a co-operation between fifteen Swedish authorities with the aim of strengthening Sweden's ability to counteract and deal with terrorism.

## **11.4 Conclusions**

Sweden meets the requirement regarding the governmental framework to enable effective interfaces between safety, nuclear security and NMAC. However, the evidence for fulfilment with respect to interfaces with NMAC is indirect in the sense that fulfilment follows as practical consequence rather than as the result of an explicit feature of the framework.

The legal and governmental framework does not include explicit responsibilities for optimisation of safety with respect to NMAC. However, implicitly NMAC related optimisation will be covered by responsibilities for considering the facility or activity as a whole - including NMAC if relevant - when licensees are performing assessment of safety and security.

The legal and governmental framework includes ordinances to SSM that gives SSM the responsibility for oversight and enforcement of arrangements for safety, nuclear security and NMAC.

The legal and governmental framework includes specific responsibilities for the liaison with law enforcement agencies.

The legal and governmental framework includes specific responsibilities for the integration of emergency response arrangements for both safety related and nuclear security related incidents. However, it should be noted that there is an ongoing work within SSM to propose further development of the national contingency plan so that it among other things will include both nuclear and radiological emergencies and antagonistic events.

The legal and governmental framework does include explicit responsibilities for optimisation of safety with respect to security for nuclear facilities. However, the framework does not, to the same level of detail, include such responsibilities for other nuclear activities e.g. external (outside of a facility) transports of nuclear material. Requirements regarding transports of dangerous goods (applicable to transports of nuclear material) does include references to IAEA security guidance. But the content of this guidance has not been implemented explicitly at the regulatory level (as it has been done for nuclear facilities) when it comes to transports of nuclear material.

# Module 13: Regulatory Implications of the Covid-19 Pandemic

## Regulatory arrangements

SSM has collaborated actively with other authorities throughout the pandemic. The Swedish Civil Contingencies Agency (MSB) has held national collaboration conferences every week in which SSM participated. At the initiative of Svenska kraftnät (SvK, State owned enterprise for the Swedish national grid for electricity), a collaboration with SSM commenced every week at the end of March 2020 to create a common picture regarding the situation at nuclear power plants due to covid-19.

In March 2020, SSM decided that business trips shall follow the Swedish Public Health Agency's recommendations and based on conscious, active decisions by the Authority. In April 2020 employees at SSM were told to work from home in accordance with the Swedish Public Health Agency's regulations and general advice on everyone's responsibility to prevent infection by covid-19. Employees with tasks that could not be handled remotely were allowed to work from the office throughout the pandemic. Employees were also allowed to work in the office if they could not work at home due to work environment reasons. A gradual return to the office started in February 2022.

At the beginning of March 2020, SSM's pandemic plan was updated. A pandemic group was activated to take lead and coordinate necessary actions. The group was led by the Director General and the other members were Chief of Staff, Chief Security Officer, Head of HR and Head of Communications.

At the beginning of April 2020, the working methods for the agency's pandemic group were developed. The pandemic group, under the leadership of the Chief Security Officer, met a couple of times a week to develop a common operating picture, assess the organisation's capacity and develop guidelines for continued work and communication efforts. The group continuously collected information from SSM's major licensees, not least the nuclear power plants. In June 2020, the pandemic group's work was transferred to the line organisation and from January 2022 the human resources secretariat was responsible for pandemic issues.

## Pandemic impact on SSM's areas of responsibilities

### Emergency Preparedness

During 2020, SSM developed its ability to work remotely in the crisis organisation and in early April 2020 a policy document for work in the crisis organisation in the event of a risk of the spread of infection was produced.

In the first half of 2021, few or no training and exercise activities requiring physical presence could be carried out. During the autumn, some exercise activities were resumed. Five exercises were carried out with all or part of SSM's emergency organisation. The

pandemic has also led to delays in the delivery of preparedness equipment. However, the main part of the emergency preparedness mission was achieved despite the pandemic.

## Regulation

The Covid-19 pandemic had primarily an impact on international work, while national standardisation work has been completed as planned. Work within the IAEA, the EU, conventions and regional collaborations was carried out through digital meetings. SSM found that the international community adapted to the situation and implemented new digital working methods. In some areas, the transition to digital meeting formats has brought benefits, for example by enabling more participants in training courses and conferences, which has contributed to an increase in expertise. In other areas, there are negative aspects, for example by reducing the opportunities for more developmental work and networking.

## Knowledge development

The pandemic had an impact mainly on communication activities, where training courses and seminars had to be carried out as webinars. A few research projects were delayed. Otherwise, the knowledge development activities were carried out largely according to plan.

## Licensing

In 2021, licensing activities were conducted as planned.

In 2021, the number of licence applications for laser increased compared to 2020, as an effect of the pandemic restrictions that were relaxed in the autumn.

Export control efforts were more difficult as a result of the pandemic. This was due to the fact that licensing also involves supervision activities. Due to the pandemic restrictions, it was not possible to carry out inspections as planned.

## Supervision

For a supervisory authority such as SSM, the pandemic has been a challenge because a large part of the supervision is usually conducted on site with the licensees. Therefore, many supervisory activities had to be re-planned. SSM developed the Authority's supervisory methods and adapted to the pandemic situation.

Inspections were to a large extent carried out remotely. On-site inspections had to be risk assessed and planned to minimize potential spread of infection. The licensees also adapted their operations based on the pandemic. Those who could work from home and on-site actions were taken to ensure distance between people and thereby reduce the spread of infection.

The number of inspections of health, industry, research and veterinary activities was decreased compared to previous years. The health sector was heavily strained with infected patients. SSM considered it inappropriate to place additional burdens on the healthcare sector through inspections.

## **Conclusions**

The pandemic situation has led the Authority to change its way of working in many areas. The assessment is, however, that SSM was able to fulfil its mission without the result being affected in the short term. The Authority learned that, for example, it is possible to conduct significantly more supervision digitally than previously thought. Digital meetings have worked well to conduct both national and international webinars with many attendees.

# Initial Action Plan

This Initial Action Plan (IAP) contains actions necessary with respect to the recommendations from the SARIS Self-Assessment that was performed in preparation for the IRRS mission to Sweden in November 2022.

The actions addresses the Government (2, 3 and 4), Swedish Civil Contingencies Agency (MSB) (6) and SSM (1, 4, 5, 6 and 7). SSM's roadmap for the strategic objectives (SSM2021-8026-1) contains actions that will address several recommendations from the self-assessment, (Actions 8-29). The self-assessment recommendations Actions 30-31 are covered by SSM's Rules of Procedure (STYR2012-27), which was implemented in the new organisation in June 2021. Self-assessment recommendations (A-F) were dismissed after evaluation.

Lastly, a table is provided listing all recommendations from the self assessment and how they are addressed in the IAP.

## Method

The method has been to evaluate whether the recommendations from the self-assessment are taken care of by SSM's existing development work or to assess whether new commitments are needed. SSM's development work is summarized in the Roadmap for the Strategic Objectives (SSM2021-8026-1) which provides measures coupled to the five strategic objectives below labelled as, *Cooperation, World class, Governance, Effective and uniform work* and *Ready when it happens*.

All recommendations from the IRRS self-assessment have been compiled and, if possible, attributed to applicable strategic objectives and SSM's mission. Recommendations that belong to the same *strategic objective* have then been sorted by *mission* and grouped according to common denominators in the following eleven *areas*;

1. Competence
2. Culture (organization, management, communication, safety)
3. Emergency preparedness
4. Quality work, interersted parties
5. Quality work, internal
6. International cooperation
7. New or updated requirements
8. Systematic administration of regulations
9. Risk-informed supervision
10. Strategy and actions with respect to (orphan) sources
11. Systematic analysis of experiences and dissemination of lessons learned

SSM's senior management organized all recommendations into the following categories

- Cat. 0 external parties (e.g. Government) are responsible
- Cat. 1 handled in SSM's roadmap for the strategic objectives
- Cat. 2 to be added as actions in this IAP
- Cat. 3 dismissed

Thereafter, actions are formulated that encompass one or more recommendations from the self-assessment.

## Actions

#	Actions	Org.	References
1	SSM to implement measures in accordance with the <i>Roadmap for the strategic objectives</i> (Appendix 1)	SSM	M4-R4, see Actions 8-29
	<b>Competence</b>		
2	The Government to consider implementation of relevant actions aiming at securing a national long-term provision of skills in the field of radiation safety.	Gov.	M1-R6
	<b>New or updated requirements</b>		
3	The Government to consider clarifying the responsibilities of authorities in identified areas, and in the area of medical exposure consider establishing a framework for generic justification and additional recommendations to national screening programs.	Gov.	M1-R7, M10-R2, M10-R3, M10-R4, MedEx-R2, MedEx-R3
4	The Government and SSM to strive towards a comprehensive national framework for the management of non-nuclear radioactive waste.	Gov. and SSM	M1-R4
5	SSM division N to take initiative together with relevant authorities and professional bodies to establish a national strategy for handling of deceased persons or human remains.	SSM-N	Rad sourc-R7
	<b>Emergency preparedness</b>		
6	MSB to update the national emergency preparedness plan for radiological emergency to include nuclear security related incidents. A prerequisite is that SSM division B will provide MSB with the necessary information.	MSB and SSM-B	M11-R3
	<b>Strategy and actions with respect to orphan sources</b>		
7	SSM division N to take initiative, and involve relevant authorities, to establish a strategy and initiate appropriate actions with respect to orphan sources.	SSM-N	Rad sourc-R6, Rad sourc-R8

## Actions in SSM's roadmap addressing self-assessment recommendations

#	Strategic objectives	Actions from SSM's roadmap	Org.	Areas	References
8	cooperation	Cultural work	SSM	culture	M3-R2, M4-R2, M4-R3
9	cooperation	Management development	SSM	competence	Disp-R2, Disp-R3
10	cooperation	Management team development	SSM	competence	
11	effective and uniform work	Quality work	SSM	competence	
12	world class	Implement the supervisory policy	SSM-T	quality work, internal	M6-R2, M6-R4, M8-R1, M8-R2, M8-R3, M10-R1, Predisp-R4, Predisp-R5
13	governance	Case management processes	SSM-T	quality work, internal	
14	world class	Implement the supervisory policy	SSM-T	risk-informed supervision	M6-R1, M6-R3, M7-R2, M7-R3, FCF-R2, NPP-R3, NPP-R5, Predisp-R7
15	governance	Case management processes	SSM-T	risk-informed supervision	
16	world class	Strategy for public communication	SSM-N	quality work, interested parties	Pub Exp-R3, Pub Exp-R4
17	world class	Clarifying national arenas	SSM	quality work, interested parties	M11-R3, M3-R6, M9-R2, M9-R3, M9-R7 och NPP-R1
18	governance	Case management processes	SSM-B	quality work, internal	M5-R2, M5-R4, Rad Sourc-R9, M9-R4, M9-R8
19	governance	Case management processes	SSM-T	quality work, internal	M6-R5, M7-R5
20	effective and uniform work	Structure for work with the management system	SSM-T	quality work, internal	
21	effective and uniform work	Quality work	SSM	Systematic analysis of experiences and	M2-R2, Rad Sourc-R4

#	Strategic objectives	Actions from SSM's roadmap	Org.	Areas	References
				dissemination of lessons learned	
22	effective and uniform work	Digitalization strategy and IT-strategy	SSM	quality work, internal	M3-R5, Predisp-R6
23	effective and uniform work	Automation and e-services	SSM-B	quality work, interested parties	M5-R1, M5-R3
24	world class	Competence analyses	SSM	competence	M1-R5, M2-R3, M7-R1
25	world class	Competence analyses	SSM	quality work, internal	Transp-R1
26	world class	Strategy for international work	Gov. SSM, coop	competence	M1-R1, M1-R2
27	world class	Objectives and focus for Agenda 2030	SSM	international (cooperation)	M2-R1
28	effective and uniform work	Structure for work with the management system	SSM	quality work, internal	M3-R3, M4-R1, M7-R4
29	governance	Digitalization strategy and IT-strategy	SSM	quality work, interested parties	M3-R4

### Self-assessment recommendations covered by SSM's Rules of Procedure (STYR2012-27)

#	Responsibility	Org.	Group	Reference
30	National regulations	SSM-N	new or updated requirements	MedEx-R1, MedEx-R4, Predisp-R1, Predisp-R2, Predisp-R3, decom-R1, decom-R2, FCF-R1, Disp-R4, M11-R1, M11-R2, Pub Exp-R5, Occ Exp-R1, Rad sourc-R1, Rad sourc-R2, Rad sourc-R3, Rad sourc-R5, Rad sourc-R10, Rad sourc-R11
31	National regulations	SSM-N	systematic administration of regulations	M1-R3, M5-R5, M9-R1, M9-R5, M9-R6, Disp-R1

### Self-assessment recommendations that are dismissed

#	Self-assessment recommendations	References	Comments
A	SSM to allocate funding for independent environmental monitoring program	Pub Exp-R2	Does not follow the basic principle that costs are to be covered by the party causing the pollution
B	On establishment of internal TSO function	M3-R1	Already implemented in SSM's new organisation
C	On continued work in weak competence areas	Pub Exp-R1	Already included in SSM's research strategy
D	On the development of supervisory program and data base (Tillda)	Predisp-R6	Alternative measures covered by roadmap action "Implement the supervisory policy".
E	On graded approach	NPP-R2	Already implemented in the supervisory policy (STYR2011-97).
F	On communication of transitional provisions	NPP-R4	Already communicated to licensees.

## List of SARIS Self-Assessment recommendations

Module	R No.	#IAP
M1 Responsibilities and Functions of the Government	R1	26
	R2	26
	R3	31
	R4	4
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M2 The Global Safety Regime	R1	27
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	R3	24
M3 Responsibilities and Functions of the Regulatory Body	R1	B
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	R3	28
	R4	29
	R5	22
	R6	17
M4 Management System for the Regulatory Body	R1	28
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	R3	8
	R4	1
M5 Authorization	R1	23
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M8 Enforcement	R1	12, 13
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M9 Regulations and Guides	R1	31
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	R3	17
	R4	18
	R5	31
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M10 Basic Primary responsibilities of the regulatory body (RB) in emergency	R1	12, 13
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	R3	3
	R4	3
M11 Interfaces with Nuclear Security	R1	30
	R2	30
	R3	6, 17
Decom Regulation of Decommissioning of Facilities	R1	30
	R2	30
Disp Safety Requirements for Disposal of Radioactive Waste	R1	31
	R2	9, 10, 11
	R3	9, 10, 11
	R4	30
FCF Regulation of Fuel Cycle Facilities	R1	30
	R2	14, 15
MedEx Safety Requirements for Medical Exposure	R1	30
	R2	3
	R3	3
	R4	30
NPP Regulation of Nuclear Power Plants	R1	17
	R2	E
	R3	14, 15
	R4	F
	R5	14, 15
Occ Exp Safety Requirements for Occupational Exposure	R1	30
Pre Disp Safety Requirements for Predisposal Management of Radioactive Waste	R1	30
	R2	30
	R3	30
	R4	12, 13
	R5	12, 13
	R6	D, 22
	R7	14, 15

Module	R No.	#IAP
Pub Exp Safety Requirements for Public Exposure	R1	C
	R2	A
	R3	16
	R4	16
	R5	30
Rad sourc Safety Requirements for Radiation Sources	R1	30
	R2	30
	R3	30
	R4	21
	R5	30
	R6	7
	R7	5
	R8	7
	R9	18
	R10	30
	R11	30
Transp Safety Requirements for Transport of Radioactive Material	R1	25

# References

## Acts

SFS 1984:3	Act (1984:3) on Nuclear Activities
SFS 1984:387	Police Act (1984:387)
SFS 1990:782	The Archives Act (1990:782) <i>(in Swedish only)</i>
SFS 1998:808	Swedish Environmental Code (1998:808)
SFS 2000:140	Act (2000:140) on Inspections under International Agreements for Non-proliferation of Nuclear Weapons
SFS 2003:460	The Act (2003:460) concerning the Ethical Review of Research Involving Humans <i>(in Swedish only)</i>
SFS 2003:778	Civil Protection Act (2003:778)
SFS 2006:263	Act (2006:263) on Transport of Dangerous Goods
SFS 2006:544	Act (2006:544) on municipalities' and regions' measures before and during extraordinary events in peacetime and heightened alert conditions
SFS 2006:647	Act (2006:647) on the Financing of Management of Residual Products from Nuclear Activities
SFS 2006:804	Food Act (2006:804) <i>(in Swedish only)</i>
SFS 2006:1570	Law (2006:1570) on protection against international threats to human health <i>(in Swedish only)</i>
SFS 2009:400	Public Access to Information and Secrecy Act (2009:400) <i>(in Swedish only)</i>
SFS 2010:305	Installations Protection Act (2010:305) <i>(in Swedish only)</i>
SFS 2010:659	Patient Safety Act (2010:659) <i>(in Swedish only)</i>
SFS 2010:950	Act (2010:950) concerning radiological accident liability and compensation
SFS 2017:30	Health and Medical Service Act (2017:30)
SFS 2017:900	Administrative Procedure Act (2017:900)
SFS 2018:396	Radiation Protection Act (2018:396)
SFS 2018:585	Protective Security Act (2018:585) <i>(in Swedish only)</i>

## Ordinances

SFS 1977:1166	Work Environment Ordinance (1977:1166) <i>(in Swedish only)</i>
SFS 1984:14	Nuclear Activities Ordinance (1984:14)
SFS 1994:246	Ordinance (1994:246) on compensation for certain additional costs and losses due to the Chernobyl accident <i>(in Swedish only)</i>

SFS 1998:899	Ordinance concerning environmentally hazardous activities (1998:899) <i>(in Swedish only)</i>
SFS 1998:905	Ordinance (1998:905) on environmental impact assessments
SFS 2000:1217	Ordinance (2000:1217) on the control of dual-use items and of technical assistance
SFS 2001:512	Landfill Ordinance (2001:512)
SFS 2002:375	Ordinance (2002:375) on the Armed Forces' support for civilian activities <i>(in Swedish only)</i>
SFS 2003:396	Ordinance (2003:396) on electronic communications <i>(in Swedish only)</i>
SFS 2003:789	Civil Protection Ordinance (2003:789)
SFS 2006:311	Ordinance (2006:311) on Transport of Dangerous Goods
SFS 2006:637	Ordinance (2006:637) on municipalities 'and regions' measures before and in the event of extraordinary events in peacetime and heightened preparedness <i>(in Swedish only)</i>
SFS 2006:813	Food Ordinance (2006:813) <i>(in Swedish only)</i>
SFS 2006:814	Ordinance (2006:814) on feed and animal by-products <i>(in Swedish only)</i>
SFS 2007:515	Government Authority Ordinance (2007:515)
SFS 2007:913	Ordinance (2007:913) with instructions for the Swedish Work Environment Authority <i>(in Swedish only)</i>
SFS 2007:1054	Ordinance (2007:1054) with instructions for local safety committees at nuclear facilities <i>(in Swedish only)</i>
SFS 2007:1161	Ordinance (2007:1161) with instructions for the Swedish Maritime Administration <i>(in Swedish only)</i>
SFS 2007:1244	Ordinance (2007:1244) on impact assessment in the regulatory process
SFS 2007:1266	Ordinance (2007:1266) with instructions for the Armed Forces <i>(in Swedish only)</i>
SFS 2008:452	Ordinance (2008:452) with instructions for the Swedish Radiation Safety Authority
SFS 2008:463	Ordinance (2008:463) on certain fees to the Swedish Radiation Safety Authority
SFS 2008:1002	Ordinance (2008:1002) with instructions for the Swedish Civil Contingencies Agency
SFS 2009:907	Ordinance (2009:907) on environmental management in government agencies <i>(in Swedish only)</i>
SFS 2009:1395	Ordinance (2009:1395) with instructions for the Sami Parliament <i>(in Swedish only)</i>
SFS 2009:1426	Ordinance (2009:1426) with instructions for the National Food Administration <i>(in Swedish only)</i>

SFS 2009:1464	Ordinance (2009:1464) with instructions for the Swedish Board of Agriculture ( <i>in Swedish only</i> )
SFS 2009:974	Ordinance (2009:974) with instructions for the Swedish Meteorological and Hydrological Institute ( <i>in Swedish only</i> )
SFS 2010:185	Ordinance (2010:185) with instructions for the Swedish Transport Administration ( <i>in Swedish only</i> )
SFS 2011:13	Environmental Supervision Ordinance (2011:13)
SFS 2012:546	Instructions (2012:546) to the Swedish National Board of Housing ( <i>in Swedish only</i> )
SFS 2013:251	Environmental Impact Assessment Ordinance (2013:251)
SFS 2014:1102	Ordinance (2014:1102) with instructions for the Police Authority
SFS 2015:284	Ordinance (2015:284) with instructions for the National Board of Health and Welfare ( <i>in Swedish only</i> )
SFS 2015:1052	The Ordinance (2015:1052) on Emergency Preparedness and the Measures to be taken by Designated Authorities in the Event of Heightened Alert
SFS 2015:1053	The ordinance (2015:1053) on total defense and heightened preparedness ( <i>in Swedish only</i> )
SFS 2016:1332	Ordinance (2016:1332) with instructions for the Swedish Customs ( <i>in Swedish only</i> )
SFS 2017:868	Ordinance (2017:868) containing instructions for county administrative boards
SFS 2017:1179	Ordinance (2017:1179) on Financial Measures for the Management of Residual Products from Nuclear Activities
SFS 2018:506	Radiation Protection Ordinance (2018:506)
SFS 2019:84	Ordinance (2019:84) with instructions for the Coast Guard ( <i>in Swedish only</i> )
SFS 2021:248	Ordinance (2021:248) with instructions for the Swedish Public Health Agency ( <i>in Swedish only</i> )

## Regulations

SSMFS 2008:1	SSM's regulations (SSMFS 2008:1) concerning safety at nuclear installations
SSMFS 2008:3	SSM's regulations (SSMFS 2008:3) concerning non-proliferation control, etc.
SSMFS 2008:12	SSM's regulations (SSMFS 2008:12) concerning physical protection of nuclear installations
SSMFS 2008:13	SSM's regulations (SSMFS 2008:13) concerning mechanical components at certain nuclear facilities
SSMFS 2008:17 (replaced)	SSM's regulations (SSMFS 2008:17) concerning the Design and Construction of Nuclear Power Reactors

SSMFS 2008:21	SSM's regulations (SSMFS 2008:21) concerning safety in connection with the disposal of nuclear material and nuclear waste
SSMFS 2008:23	SSM's regulations (SSMFS 2008:23) on Protection of Human Health and the Environment in connection with Discharges of Radioactive Substances from certain Nuclear Facilities
SSMFS 2008:24	SSM's regulations (SSMFS 2008:24) on radiation protection managers at nuclear facilities ( <i>in Swedish only</i> )
SSMFS 2008:26	SSM's regulations (SSMFS 2008:26) on Radiation Protection of Individuals Exposed to Ionising Radiation at Nuclear Facilities
SSMFS 2008:37	SSM's regulations (SSMFS 2008:37) concerning the Protection of Human Health and the Environment in connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste
SSMFS 2008:38	SSM's regulations (SSMFS 2008:38) concerning archiving at nuclear installations
SSMFS 2008:44	SSM's regulations (SSMFS 2008:44) on smoke detectors that contain radioactive material ( <i>in Swedish only</i> )
SSMFS 2008:47	SSM's regulations (SSMFS 2008:47) on smoke alarms that contain a radiation source with a radioactive substance ( <i>in Swedish only</i> )
SSMFS 2009:1	SSM's regulations (SSMFS 2009:1) concerning the control of transboundary movements of radioactive waste and spent nuclear fuel
SSMFS 2012:2	SSM's regulations (SSMFS 2012:2) on binoculars, bearing compasses and reticle containing tritium. ( <i>in Swedish only</i> )
SSMFS 2012:3	SSM's regulations (SSMFS 2012:3) concerning the handling of contaminated ash
SSMFS 2014:2	SSM's regulations (SSMFS 2014:2) concerning emergency preparedness at nuclear installations
SSMFS 2018:1	SSM's regulations (SSMFS 2018:1) concerning basic provisions for licensable activities involving ionising radiation
SSMFS 2018:2	SSM's regulations (SSMFS 2018:2) concerning notifiable activities
SSMFS 2018:3	SSM's regulations (SSMFS 2018:3) concerning exemptions from the Radiation Protection Act and concerning the clearance of materials, building structures and sites
SSMFS 2018:4	SSM's regulations (SSMFS 2018:4) on naturally occurring radioactive material and building materials ( <i>in Swedish only</i> )
SSMFS 2018:5	SSM's regulations (SSMFS 2018:5) concerning medical exposures
SSMFS 2018:6	SSM's regulations (SSMFS 2018:6) concerning industrial radiography
SSMFS 2018:7	SSM's regulations (SSMFS 2018:7) concerning licensable veterinary activities
SSMFS 2018:9	SSM's regulations (SSMFS 2018:9) concerning approved personal dosimetry services
SSMFS 2018:10	SSM's regulations (SSMFS 2018:10) concerning radon at worksites

SSMFS 2018:11	SSM's regulations (SSMFS 2018:11) on exposure to cosmic radiation in aerospace operations ( <i>in Swedish only</i> )
SSMFS-A	SSM's regulations (SSMFS-A) concerning the assessment and presentation of radiation safety for nuclear power plants – <i>reference version, final version published as SSMFS2021:5</i>
SSMFS-D	SSM's regulations (SSMFS-D) concerning operation of nuclear power plants – <i>reference version, final version published as SSMFS2021:6</i>
SSMFS-K	SSM's regulations (SSMFS-K) concerning the design of nuclear power plants – <i>reference version, final version published as SSMFS2021:4</i>
SSMFS-KÄKA	SSM's regulations (SSMFS-KÄKA) concerning management of radioactive waste from nuclear facilities – <i>reference version, final version published as SSMFS2021:7</i>
HSLF-FS 2016:40	The National Board of Health and Welfare's regulations (HSLF-FS 2016:40) and general advice on record keeping and processing of personal data in health care ( <i>in Swedish only</i> )
LIVSFS 2012:3	The National Food Administration's regulations (LIVSFS 2012:3) on foreign substances in food ( <i>in Swedish only</i> )
MSBFS 2015:5	MSBFS 2015:5 regulations and general advice on municipalities' risk and vulnerability analyses ( <i>in Swedish only</i> )
MSBFS 2016:7	MSBFS 2016:7 regulations and general advice on government agencies' risk and vulnerability analyses ( <i>in Swedish only</i> )
MSBFS 2017:3	MSBFS 2017:3 regulations on information in emergency situations where there is a risk of radiation ( <i>in Swedish only</i> )
MSBFS 2020:9	MSBFS 2020:9 – Swedish Civil Contingencies Agency regulations on the transport of dangerous goods by road and off-road (ADR-S)
MSBFS 2020:10	MSBFS 2020:10 refers to railways ( <i>in Swedish only</i> )
MSBFS 2021:8	MSBFS 2021:8 - on how the municipality is to plan and carry out its supervision in accordance with the Civil Protection Act (2003:778)
SLVFS 2001:30	The National Food Administration regulations (SLVFS 2001:30) on drinking water ( <i>in Swedish only</i> )
SOSFS 1997:14	The Swedish National Board of Health and welfare regulation (SOSFS 1997:14) on delegation of tasks within healthcare and dentistry ( <i>in Swedish only</i> )
SRVFS 2004:9	SRVFS 2004:9 regulations on the authority to be a rescue leader in a municipal rescue service ( <i>in Swedish only</i> )
SRVFS 2007:4	SRVFS 2007:4 general advice and comments on the County Administrative Board's preparedness for decontamination after release of radioactive substances from a nuclear facility ( <i>in Swedish only</i> )
TSFS 2015:66	The Swedish Transport Agency's regulations (TSFS 2015:66) and advice on transport by sea of packaged dangerous goods (IMDG Code)

TSFS 2021:30	The Swedish Transport Agency's regulations (TSFS 2021:30) on the transport of dangerous goods by air
TSFS 2021:69	The Swedish Transport Agency's regulations (TSFS 2021:69) and guide on transport of packaged dangerous goods on Ro-ro ships in the Baltic Sea ( <i>Östersjöavtalet</i> ) ( <i>in Swedish only</i> )

### **Licence conditions, decisions etc.**

13-3735	13-3735 Template: reporting of security incidents by employees
15-2224	15-2224 PM on the obligation to report ( <i>in Swedish only</i> )
15-3444	15-3444 Division of activities for consultation and approval (Notification obligation) ( <i>in Swedish only</i> )
19-1844	19-1844 Template for memo on formal presentation to the Director General
19-2731	19-2731 Legal compliance check 2019-2021
19-2762	19-2762 Review of new equipment
AFS 2018:1	Hygienic limit values (AFS 2018:1) ( <i>in Swedish only</i> )
SOSFS 2004:11	The National Board of Health and Welfare requirements (SOSFS 2004:11) on responsibility for referrals of patients in healthcare and dentistry ( <i>in Swedish only</i> )
SSI dnr 6221/2530/01	Licence for a shallow land disposal facility for low-level nuclear waste at Svalören at the Forsmark facility (SSI ref. no. 6221/2530/01)
SSI dnr 6222/3744/03	Updated operating conditions for SFR 1 (SSI ref. no. 6222/3744/03)
SSM 2009/1210-1	SSM 2009/1210-1 Condition testing and supervision when increasing thermal power in nuclear power reactors ( <i>in Swedish only</i> )
SSM 2009/4381	SSM 2009/4381 Updated radiation protection conditions for the shallow land disposal facility at the Oskarshamn nuclear power plant
SSM 2010/721-54	SSM 2010/721-54 Reconsideration of the licence for the shallow land disposal facility for low level waste at the Forsmark facility
SSM2012-3021-11	SSM2012-3021-11 Forsmarks kraftgrupp AB - Order regarding conditions for independent core cooling ( <i>in Swedish only</i> )
SSM2012-3022-16	SSM2012-3022-16 Conditions for independent core cooling for Oskarshamn 3
SSM2014-127-1	SSM2014-127-1 Review report/plan ESS ( <i>in Swedish only</i> )
SSM2014-127-36	Special conditions for the ESS research facility in Lund (SSM2014-127-36)
SSM2014-5966-11	Statement on an application for a licence under the Act on Nuclear Activities for extended activities at SFR (SSM2014-5966-11)

SSM2016-5866-26	Licence conditions for the decommissioning of nuclear power reactors (SSM2016-5866-26)
SSM2017-2291-5	Decision on licence conditions for the decommissioning of Ringhals 1 (SSM2017-2291-5)
SSM2018-4833-2	SSM2018-4833-2 Approval of equipment that emits parasitic X-rays ( <i>in Swedish only</i> )
SSM2019-3395-2	SSM2019-3395-2 Cyclife conditions ( <i>in Swedish only</i> )
SSM2019-5701-1	SSM2019-5701-1 Order on measures for the disposal of nuclear waste Westinghouse ( <i>in Swedish only</i> )
SSM2019-6915-60	SSM2019-6915-60 Special conditions for the ESS facility in Lund ( <i>in Swedish only</i> )
SSM2019-6915-61	SSM2019-6915-61 Permit for activities with ionising radiation ( <i>in Swedish only</i> )
SSM2019-10024-82	SSM2019-10024-82 Compliance with conditions for operation
SSM2019-10114-1	SSM2019-10114-1 Decision by the Director General – Plan for legal compliance check
SSM2020-1565-1	SSM2020-1565-1 Internal review programme 2020-2023
SSM2020-5189-10	SSM2020-5189-10 Decision on restart of the metal treatment plant ( <i>in Swedish only</i> )
SSM2020-7537-3	SSM2020-7537-3 Appendix 1, Special conditions for the ESS facility in Lund ( <i>in Swedish only</i> )
SSM2021-1033-6	SSM2021-1033-6 Penalty injunction Chalmers ( <i>in Swedish only</i> )
SSM2021-7569-1	SSM2021-7569-1 Decision on conditions for the continued operation of the final repository for low and intermediate level radioactive waste

### **Steering (governance) documents**

STYR2011-2	STYR2011-2 Secondary employment and conflicts of interest
STYR2011-7	STYR2011-7 Emergency response at laboratories
STYR2011-23	STYR2011-23 Archive ( <i>in Swedish only</i> )
STYR2011-32	STYR2011-32 Document governance
STYR2011-33	STYR2011-33 Staff appraisals
STYR2011-42	STYR2011-42 Internal auditing ( <i>in Swedish only</i> )
STYR2011-45	STYR2011-45 Recruitment routine ( <i>in Swedish only</i> )
STYR2011-48	STYR2011-48 Security at the Swedish Radiation Safety Authority
STYR2011-49	STYR2011-49 Pay policy
STYR2011-51	STYR2011-51 Regulatory work – the process
STYR2011-54	STYR2011-54 The Swedish Radiation Safety Authority's emergency response plan for radiological emergencies

STYR2011-64	STYR2011-64 Convention assignments ( <i>in Swedish only</i> )
STYR2011-71	STYR2011-71 Management policy
STYR2011-86	STYR2011-86 Access to installations and activities within the Authority's field of supervision
STYR2011-87	STYR2011-87 Compliance and supervisory activities during supervision
STYR2011-95	STYR2011-95 Employee policy
STYR2011-97	STYR2011-97 Supervisory policy
STYR2011-102	STYR2011-102 International agreements ( <i>in Swedish only</i> )
STYR2011-111	STYR2011-111 Preparation of notifications (ABG - the report processing team)
STYR2011-123	STYR2011-123 Review of safety reviews
STYR2011-129	STYR2011-129 Integrity and credibility aspects of recruitment to the Swedish Radiation Safety Authority
STYR2011-131	STYR2011-131 Preparation of licences and review of licence conditions concerning nuclear installations and other complex installations where radiation is used
STYR2011-138	STYR2011-138 Addressing conflicts of interest when engaging external support
STYR2011-143	STYR2011-143 International meetings including a list of participants in international activities ( <i>in Swedish only</i> )
STYR2011-146	STYR2011-146 Guidance on the approval and supervision of personal dosimetry services
STYR2011-149	STYR2011-149 Safety for workers
STYR2011-151	STYR2011-151 Management of reported deficiencies in barriers and defence in depth systems at nuclear power plants that generate electricity
STYR2011-153	STYR2011-153 Reporting from nuclear power plants in operation and other nuclear facilities ( <i>in Swedish only</i> )
STYR2011-160	STYR2011-160 Risk management at the Swedish Radiation Safety Authority
STYR2011-166	STYR2011-166 Medical and dental practises
STYR2011-171	STYR2011-171 Competence profile and development programme for supervisors
STYR2011-182	STYR2011-182 Examination of package constructions ( <i>in Swedish only</i> )
STYR2012-6	STYR2012-6 Approval for the transport of dangerous goods Class 7 by special arrangement
STYR2012-25	STYR2012-25 Project model for the Swedish Radiation Safety Authority

STYR2012-27	STYR2012-27 The Swedish Radiation Safety Authority's rules of procedure
STYR2012-28	STYR2012-28 Decision-making procedure
STYR2012-115	STYR2012-115 Intensified supervision
STYR2014-41	STYR2014-41 Competence provision process
STYR2015-2	STYR2015-2 Handling of permit applications for exports of nuclear equipment, etc. <i>(in Swedish only)</i>
STYR2016-4	STYR2016-4 Supervisory programme
STYR2017-10	STYR2017-10 Process roles at the Swedish Radiation Safety Authority
STYR2017-16	STYR2017-16 Process: Exercising supervision
STYR2018-1	STYR2018-1 Security and risk analyses when procuring services and system development
STYR2018-6	STYR2018-6 The work of the process council
STYR2019-1	STYR2019-1 Approach and methodology for arranging competence testing and bilateral comparison between laboratories <i>(in Swedish only)</i>
STYR2020-1	STYR2020-1 Filing and archiving at the Swedish Radiation Safety Authority
STYR2020-4	STYR2020-4 Annual risk and opportunity analysis of activities
STYR2020-9	STYR2020-9 Research funding policy
STYR2020-10	STYR2020-10 Policy for EU and international work <i>(in Swedish only)</i>
STYR2020-14	STYR2020-14 The Swedish Radiation Safety Authority's committee for research issues
STYR2021-1	STYR2021-1 Policy against corruption and other irregularities

### **Programs, plans etc.**

15-165	15-165 Overall supervision program within SY <i>(in Swedish only)</i> <i>(superseded by 21-2384)</i>
15-273	15-273 Risk analysis for activities involving ionising radiation in health and medical services
15-429	15-429 Further development of adapted application & risk analyzes <i>(in Swedish only)</i>
15-1224	15-1224 Supervisory programme for health and medical services
19-1151	19-1151 Supervisory programme for the area of operation Products, services and natural radiation aspects <i>(superseded by 21-2384)</i>
20-1941	20-1941 Supervisory programme 2021 for TO2 Nuclear facilities and safe management of radioactive waste
20-2694	20-2694 Supervisory programme for Supervisory area 1 Nuclear power plants in operation, 2020

20-887	20-887 Experience feedback after supervision ( <i>in Swedish only</i> )
21-1282	21-1282 Needs Analysis for Research Funding 2021 from the Department of Nuclear Safety ( <i>in Swedish only</i> )
21-872	21-872 Instructions for applicants - Published on SSM's website ( <i>in Swedish only</i> )
2021:15	2021:15 National Plan - Responsible and safe handling of spent nuclear fuel and radioactive waste in Sweden
AFS 2019:3	Medical checks in working life (AFS 2019:3) ( <i>in Swedish only</i> )
MSB1625	MSB1625 National strategy for systematic exercise activities: for crisis preparedness and civil defense ( <i>in Swedish only</i> )
NV-rapport 5977	Risk assessment of contaminated areas, NV report 5977 ( <i>in Swedish only</i> )
NV-rapport 5978	Choosing a finishing method. NV report 5978 ( <i>in Swedish only</i> )
RIR 2019:30	If the worst were to happen - The state's work to prevent nuclear accidents (RIR 2019:30) ( <i>in Swedish only</i> )
SOU 2021:19	SOU 2021:19 A strengthened security of supply for health and medical care ( <i>in Swedish only</i> )
SSM2015-3257-100	SSM2015-3257-100 Transport flows and doses to staff and the general public during transport of radioactive substances in Sweden (2019) ( <i>in Swedish only</i> )
SSM2015-4192-1	SSM2015-4192-1 Review plan SFR expansion (SFR-U) ( <i>in Swedish only</i> )
SSM2015-4872	SSM2015-4872 ( <i>in Swedish only</i> )
SSM2016-1824-42	SSM2016-1824-42 National action plan for radon ( <i>in Swedish only</i> )
SSM2017-134	SSM2017-134 Government assignment on long-term competence supply ( <i>in Swedish only</i> )
SSM2018-2459	SSM2018-2459 waste register/internal transport AB SVAFO ( <i>in Swedish only</i> )
SSM2018-4056-2	SSM2018-4056-2 Inspection of waste registers, internal transports and controlled area at Clab ( <i>in Swedish only</i> )
SSM2021-8026-1	SSM2021-8026-1 Roadmap for the strategic objectives









The Swedish Radiation Safety Authority has a comprehensive responsibility to ensure that society is safe from the effects of radiation. The Authority works from the effects of radiation. The Authority works to achieve radiation safety in a number of areas: nuclear power, medical care as well as commercial products and services. The Authority also works to achieve protection from natural radiation and to increase the level of radiation safety internationally.

The Swedish Radiation Safety Authority works proactively and preventively to protect people and the environment from the harmful effects of radiation, now and in the future. The Authority issues regulations and supervises compliance, while also supporting research, providing training and information, and issuing advice. Often, activities involving radiation require licences issued by the Authority. The Swedish Radiation Safety Authority maintains emergency preparedness around the clock with the aim of limiting the aftermath of radiation accidents and the unintentional spreading of radioactive substances. The Authority participates in international co-operation in order to promote radiation safety and finances projects aiming to raise the level of radiation safety in certain Eastern European countries.

The Authority reports to the Ministry of the Environment and has around 300 employees with competencies in the fields of engineering, natural and behavioral sciences, law, economics and communications. We have received quality, environmental and working environment certification.

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