IAEA-NS-IRRS-2022/11

ORIGINAL: English

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

SWEDEN

Stockholm, Sweden

14 to 25 November 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Strål säkerhets myndigheten

Swedish Radiation Safety Authority

IAEA

Integrated Regulatory Review Service

IRRS

Integrated
Regulatory
Review Service

IAEA | IRRS

REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
SWEDEN

Integrated Regulatory Review Service

IAEA IRRS

REPORT OF THE INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO SWEDEN

Mission dates:	*14 to 25 November 2022*
Regulatory body visited:	*Swedish Radiation Safety Authority (SSM)*
Location:	*Stockholm, Sweden*
Regulated facilities, activities, and exposure situations in the mission scope:	*nuclear power plants, fuel cycle facilities, radiation sources applications, waste management facilities, emergency preparedness and response, transport, decommissioning, occupational exposure, medical exposure, public exposure and environmental monitoring, interfaces with nuclear security*
Organized by:	*IAEA*

IRRS REVIEW TEAM	
MORRIS Scott	Team Leader (United States)
BERNIER Frédéric	Reviewer (Belgium)
BRANDIŠAUSKAS Dainius	Reviewer (Lithuania)
FREMOUT An	Reviewer (Belgium)
HANNESSON Haraldur	Reviewer (Denmark)
ILYAS Mohammad	Reviewer (Pakistan)
INVERSO Tara	Reviewer (United States)
JANŽEKOVIČ Helena	Reviewer (Slovenia)
JUAN Pierre	Reviewer (France)
KRS Petr	Reviewer (Czech Republic)
LES GIL Cristina	Reviewer (Spain)
MAZUR Anna	Reviewer (Canada)
MULLER Alan	Reviewer (South Africa)
NILSSON Hugo	Reviewer (Switzerland)
PREDA Stefania	Reviewer (Romania)
POLETTO Geronimo	Reviewer (Argentina)
REICHE Ingo	Reviewer (Germany)
URQUHART Donald	Reviewer (United Kingdom)
VAN CALOEN Cédric	Observer (Belgium)
JUBIN Jean Rene	IAEA Team Coordinator
HAILU Teodros	IAEA Deputy Team Coordinator
DANI Mario	IAEA Administrative Assistant

IAEA-2022

The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

CONTENTS

EXECUTIVE SUMMARY

At the request of the Government of Sweden, an international team of senior safety experts formed by the International Atomic Energy Agency (IAEA) met with representatives of the Swedish Radiation Safety Authority (SSM) from 14 to 25 November 2022 to conduct an Integrated Regulatory Review Service (IRRS) initial mission as part of its second IRRS cycle. The IRRS team also met with representatives of: Sweden's Ministry of Environment to review the responsibilities and functions of the Government and Swedish Civil Contingencies Agency (MSB) the authority for regulation of off-site emergency preparedness and response involving nuclear and non-nuclear facilities. The IRRS team consisted of 18 experts from 16 IAEA Member States, 2 IAEA staff members, 1 IAEA administrative assistant and 1 observer.

The primary purpose of the mission was to review the Swedish governmental, legal, and regulatory framework for nuclear and radiation safety within the competence of SSM against the IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources as international benchmarks for safety. The mission was also used to exchange information and experience between the IRRS team members and their Swedish counterparts in the areas covered by the IRRS, as well as the national regulatory implications of the COVID-19 pandemic.

In preparation for the IRRS mission, Sweden conducted a thorough self-assessment and prepared a preliminary action plan to address areas identified for improvement. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material (ARM) prior to conduct of the mission.

The IRRS team reviewed the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body (SSM); management system of SSM; activities of SSM including authorization, review and assessment, inspection, and enforcement; development and content of regulations and guides; and emergency preparedness and response. The scope of authorized facilities and activities included nuclear power plants; fuel cycle facilities; radiation sources facilities and activities; occupational radiation protection; control of medical, public and environmental exposure; transport of radioactive material; waste management facilities; decommissioning; and interfaces with nuclear security. The IRRS mission also included a policy discussion on the challenges facing SSM in the context of possible new builds (and new technologies).

The IRRS mission was conducted about six months prior to an Integrated Review Service for Radioactive Waste and Spent Fuel, Decommissioning and Remediation (ARTEMIS) mission currently scheduled for April 2023. As such, the IRRS team did not review provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel as these activities will be covered by the upcoming ARTEMIS mission.

The IRRS team conducted interviews and discussions with the SSM staff. Members of the IRRS team also observed regulatory oversight activities at an operating nuclear power plant (NPP), an NPP under decommissioning, a nuclear fuel factory, a radioactive waste management facility, a laboratory, and a hospital. These visits included discussions with management and staff of the facilities. A meeting was also held with senior management from OKG NPP, Ringhals NPP and the Swedish state utility Vattenfall which owns a major part of both Forsmark and Ringhals NPP.

The IRRS team concluded that Sweden has a comprehensive regulatory framework for nuclear and radiation safety covering the full range of facilities, activities, and exposure situations. SSM is a competent, independent regulator whose staff are committed to deliver SSM's statutory obligations effectively.

The IRRS team appreciated the outstanding efforts of SSM staff regarding their engagement in this extensive international peer review. This active participation enabled the IRRS team to develop a broad

understanding of Sweden's regulatory framework which resulted in the identification of one good practice and several areas of good performance. Continuing these activities, along with the consideration of several recommendations and suggestions offered by the IRRS team, should further enhance nuclear and radiation safety throughout the country.

In 2021, SSM underwent a very significant organizational change. The organizational structure was shifted from a "functional" approach to a "process approach." The IRRS team noted that this change has resulted in uncertainties among staff, as many staff members have been moved to new organizational units according to their individual competence and the needs of the new organization. SSM management recognizes that this is ongoing challenge and that full implementation of the new organization will take additional time.

The IRRS team identified a good practice regarding supervision and optimisation of patient dosimetry through the development and use of the DosReg web-based portal. A particularly noteworthy aspect of DosReg is that exposure data and typical doses for various medical procedures are made available to any interested party, including the public.

Areas of good performance include:

- The proactive approach to inform and influence public awareness of safety measures;
- Transparent decision-making for licensing via open court hearings;
- The digitisation of processes to facilitate source registration by applicants and authorised users;
- The oversight of the licensees though annual integrated safety assessments and identifying crosscutting issues.

In the spirit of continuous improvement, the IRRS mission report includes a number of recommendations and suggestions intended to improve the Swedish regulatory infrastructure and practices on matters of nuclear and radiation safety.

The IRRS team considers that Sweden's main challenge is the lack of a sufficient number of qualified SSM staff in certain key functional areas, challenging the authority to regulate safety in some areas. These areas include review and assessment, authorization of facilities and activities, and regulatory oversight of radioactive waste disposal.

In addition, the IRRS team concluded that the following actions, if addressed by the Government and SSM, would further enhance the overall effectiveness of the regulatory system:

Government:

- Issue a comprehensive National strategy for competence that addresses current and future needs, particularly given the recent political development regarding support for new nuclear power;
- Enhance coordination between SSM and other national authorities having responsibilities for safety (e.g., distribution of iodine thyroid blocking agents);
- Develop generic justification for radiological activities;
- Ensure expert services related to actual and expected future radiation risks to public health are provided in the event of a nuclear or radiological emergency;
- Apply optimization of safety measures that account for security related to transports of nuclear material, and enhancing the system of nuclear material accounting and control.

SSM:

- Close gaps in regulatory oversight, including certain requirements, authorization processes and supervisory activities;

- Formally document several regulatory and internal processes and simplify the management system;
- Enhance coordination between different SSM organizational units;
- Develop a process to search for and manage disused and orphan sources;
- Continue to foster a culture for safety in a more systematic and formal manner.

The IRRS team was aided by the full support and cooperation of all parties in the regulatory, technical, and policy issue discussions which were conducted in a very open, transparent and frank manner throughout the mission. IAEA considers invitations of full scope international peer reviews to be a sign of openness, transparency, and commitment to continuous improvement.

The IAEA issued a press release upon conclusion of the mission.

I. INTRODUCTION

At the request of the Government of Sweden, an international team of senior safety experts met representatives of the Swedish Radiation Safety Authority (SSM) from 14 to 25 November 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review Sweden's governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Sweden in January 2018. A preparatory meeting was conducted 26 - 27 April 2022 at SSM in Stockholm to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Sweden and their related safety aspects and to agree the scope of the IRRS mission.

This mission was organized back-to-back to an Integrated Review Service for Radioactive Waste and Spent Fuel, Decommissioning and Remediation (ARTEMIS) mission scheduled for 16 - 27 April 2023. To avoid unnecessary duplications between the IRRS and the ARTEMIS missions, the preparation and conduct of the IRRS mission were carried out in a coordinated manner with the ARTEMIS mission. Thus, the provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel, subject of Section 1.7, are to be reviewed by the upcoming ARTEMIS mission.

The IRRS team consisted of 18 senior regulatory experts from 16 IAEA Member States, 2 IAEA staff members, 1 IAEA administrative assistant and 1 observer. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; nuclear power plants, fuel cycle facilities, radiation sources facilities and activities, occupational radiation protection, control of medical exposure, public exposure control, transport of radioactive material, waste management facilities; decommissioning; and interfaces with nuclear security. In addition, a policy issue on challenges of the regulatory body in the context of possible new builds (and new technologies) was discussed.

SSM conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of SSM's self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Sweden advance reference material, conduct of interviews with management and staff from SSM and direct observation of SSM's regulatory activities at regulated facilities. Meetings with the Ministry of Environment were also organized.

All through the mission the IRRS team received excellent support and cooperation from SSM.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Sweden's nuclear and radiation safety governmental, legal and regulatory framework and activities against the relevant IAEA safety standards to report on the effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities, activities and exposure situations regulated in Sweden with the exception of research reactors since there are no operational research reactors in Sweden. It is expected that the mission will facilitate regulatory improvements in Sweden and other Member States, utilising the knowledge gained and experiences shared between SSM and IRRS team and the evaluation of the Sweden regulatory infrastructure for nuclear and radiation safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA safety standards;

k) providing feedback on the use and application IAEA safety standards;

l) providing feedback on the regulatory implications of pandemic situations.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Sweden, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 26 to 27 April 2022. The preparatory meeting was carried out by the appointed Team Leader Mr Scott Morris, Deputy Team Leader Mr Mika Markkanen and the IAEA representatives, Mr Jean Rene Jubin and Mr Teodros Hailu.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of SSM represented by Ms Nina Cromnier, Director General of SSM, and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities, activities and exposure situations would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA Safety Requirements and compatibility with the respective Safety Guides:

- Nuclear power plants;
- Fuel cycle facilities;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public exposure control;
- Waste management facilities;
- Interfaces with nuclear security; and
- Selected policy issue.

Ms Nina Cromnier made presentations on the national context, and the current status of SSM. Mr Daniel Kjellin presented the self-assessment progress at the date of the preparatory meeting.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Sweden in November 2022.

The proposed composition of the IRRS team was discussed. Logistics including meeting and workplaces, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The SSM Liaison Officer for the IRRS mission was confirmed as Ms Anna Franzén as Liaison Officer, and Ms Åsa Zazzi as Deputy Liaison Officer.

SSM provided IAEA with the advance reference material (ARM) for the review at the beginning of September 2022. In preparation for the mission, the IAEA review team members reviewed the ARM and provided their initial impressions to the IAEA Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday 13 November 2022 in Haymarket Hotel, directed by the IRRS Team Leader and the IRRS IAEA Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the IRRS team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officers were present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday 14 November 2022, with the participation of SSM senior management and staff. Opening remarks were made by Ms Charlotta Fred, Head of Chemicals Division at the Ministry of Environment and Mr Scott Morris, IRRS Team Leader. Ms Nina Cromnier, Director General of the Swedish Radiation Safety Authority gave an overview of the Sweden context, SSM activities and the action plan prepared as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for all review areas within the agreed scope with the objective of providing Sweden and SSM with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations of regulatory practices.

The IRRS team performed its review according to the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday 25 November 2022. The opening remarks at the exit meeting were made by Mr Daniel Kjellin, SSM Project Manager for the IRRS mission to Sweden and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Scott Morris. Remarks in response to mission findings were made by Mr Daniel Westlén, State Secretary to Minister for Climate and the Environment and by Ms Nina Cromnier, Director General of the Swedish Radiation Safety Authority. Closing remarks were made by Ms Lydie Evrard, IAEA Deputy Director General and Head of the Nuclear Safety and Security Department.

An IAEA press release was issued at the end of the mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Sweden has established a strong governmental, legal and regulatory framework for safety that defines and allocates responsibilities for nuclear and radiation safety. Sweden's policy and strategy for nuclear safety and radiation protection are 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)

Nuclear safety and radiation protection are considered part of the larger policy on environmental protection, the overarching goal of which is to pass on to the next generation a society in which all the major environmental problems facing Sweden have been solved. A safe radiation environment is one of the sixteen Environmental Quality Objectives set out in furtherance of this goal.

The fundamental principles relating to nuclear safety and radiation protection that make up the national policy include that the operator of a nuclear facility has strict, unlimited liability for radiological damage, that the operator is also obliged to ensure that financial security is provided for damage at a level that varies depending on the facility, that licensees are required to pay fees that cover costs for the management and disposal of spent fuel and radioactive waste from nuclear activities, and that facilities and activities that give rise to radiation risks are justified only if shown to yield an overall benefit. Legislation requires that people and the environment, present and future, must be protected against radiation risks, that protection against the harmful effects of ionising radiation must be optimised to provide the highest level of safety that can reasonably be achieved, and that measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm. Further, all practical efforts must be made to prevent and mitigate nuclear or radiation accidents, and the prime responsibility for safety rests with the person or organization responsible for facilities and activities that give rise to radiation risks.

All Euratom Directives and binding international agreements relating to radiation safety have been implemented in Swedish legislation. The application of a graded approach is achieved primarily through underlying regulations and regulatory practice which 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, the Swedish Radiation Safety Authority (SSM), allocates resources in support 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

Sweden has established a governmental, legal and regulatory framework for safety that defines and allocates responsibilities for nuclear and radiation safety. The Swedish parliament (The Riksdag) is responsible for enacting primary legislation, that is then implemented by the Government. The Government directs the work of governmental agencies via appropriations directives and Ordinances. 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 (ANA) and the Radiation Protection Act (RPA) are the primary legislative instruments that establish safety principles for the protection of people and the environment regarding nuclear safety and radiation protection in Sweden. This primary legislation also establishes obligations and requirements relating to authorization as well as general obligations on authorized parties, including legal responsibility for safety, requirements for periodic safety reviews and responsibilities for nuclear security and nuclear materials safeguards. SSM, as the responsible regulatory authority for radiation safety under the ANA and RPA, has extensive legal powers to enforce the regulations and its decisions. Underlying Ordinances establish provisions relating to processes and responsibilities for licensing, authorisation, review, evaluation, inspection, enforcement and appeals.

The Government maintains the framework for safety through international cooperation, implementing European Union (EU) directives, and peer-reviews. SSM has been mandated to monitor developments in international recommendations, and to report back to the government. SSM also cooperates internationally. The Government has an established procedure for handling the implementation of EU directives.

SSM has identified a delay in remediating a matter impacting the effectiveness of the regulatory framework. Sweden's framework for safety includes the specification of offences with corresponding penalties. However, the RPA, which entered into force on 1 June 2018, contains shortcomings in the penal provisions in that certain violations of the Act are not subject to criminal penalties. The same applies to violations of SSM regulations. At the government's direction, SSM submitted proposals to remedy the RPA and the Radiation Protection Ordinance in March 2019. At the same time, other proposals were made regarding how to introduce penalty fees in the field of radiation protection. These proposals have not yet been adopted in Swedish legislation, with the result that the path to prosecuting non-compliance is impeded.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is currently no penalty for non-compliance with (some) provisions of the RPA and with the regulations under the RPA, which poses a risk to the effectiveness of the regulatory framework and the ability of SSM to enforce compliance with its legislation in some cases.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *…* *(18) The specification of offences and the corresponding penalties;"*
R1	**Recommendation: The Government should amend the legislation to address the gaps in penalties for failure to comply with requirements of the RPA.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Swedish Government has established SSM as the responsible regulatory authority for nuclear safety and radiation protection under the ANA and RPA. The overall mission and responsibilities of SSM are defined in the Ordinance with Instructions for SSM, with additional legal provisions relating to its mandate and authority specified in the Nuclear Activities Ordinance and the Radiation Protection Ordinance. 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 facilities and activities. SSM is also authorised to issue authorizations under the RPA for facilities and activities that are not encompassed by the ANA. SSM is empowered under the ANA and the RPA 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 Ordinances to issue specific conditions relating to the operation of a facility or the conduct of an activity.

Swedish law provides for the independence of regulatory decision-making of administrative authorities: according to the Swedish constitution, an individual minister may not interfere in a specific case handled by an administrative authority. In terms of the exercise of its authority and its decision making relating to the application of laws and regulations, therefore, it can be said that SSM is independent of Ministerial review.

Under the legislative framework, permitting of nuclear activities and facilities are required under both environmental legislation and nuclear or radiation protection legislation. For some permits issued under the ANA, it is the government, not SSM, that makes the initial licensing decision. Before the government makes its decision, however, SSM must provide a statement on the application concerned to the government for its consideration. The IRRS team understood the government attaches great importance to SSM input, as the expert authority on these issues, when it makes its decision. Furthermore, when the government renders its decision, the government must have legal grounds for its decision and justify its conclusion. This decision of government can be subject to a judicial review by the Supreme Administrative Court to examine whether the government decision violates the law.

When the government issues a licence for a nuclear facility, there is a long-established practice of giving SSM the mandate to independently take responsibility for the "step-wise" review process that follows. This process involves safety assessments and the imposition of specific conditions upon the licensee. The step-wise review and approval process is established by a detailed procedure managed by SSM for all stages of a nuclear facility life cycle. Approval by SSM is needed before each step can begin. These steps are facility (a) construction, (b) initial test operation, (c) full operation, (d) certain licensable changes, and (e) decommissioning. A licensee may not proceed to the next stage of the cycle without the prior approval of SSM. It is through this process that expert opinion on nuclear safety is assured. These decisions of SSM are independent decisions that the government must not interfere with. Ultimately it is SSM that is responsible for verifying (through supervision) that the facility meets the established safety requirements.

Given the above, the IRRS team noted that SSM retains the ability to act independently of government in the interests of nuclear safety, regardless of whether government is the authority issuing the initial nuclear facility licence. The IRRS team was informed that a 2019 inquiry report proposed that the step-wise review process of nuclear activities or facilities be codified in the ANA. The Government is currently reviewing the proposal within the Government Offices but as of now has not rendered a decision. The IRRS team observed that Sweden's codification of the step-wise program would ensure the involvement of SSM in the authorization of nuclear facilities and could improve clarity.

SSM is required to submit annual reports and financial statements to the Government, which summarise major results, effects, revenues and costs of its activities. The reports also include key indicators on staffing and competence management to be followed-up by the Government, including a formal dialogue between the Director General and the respective Ministry at the State secretary level. The Swedish National Audit Office, under the auspices of the parliament, has the ability to scrutinize the government authorities to ensure their compliance with directives, rules and regulations. The last audit of SSM took place in 2017.

Resourcing of SSM is accomplished through a process that involves feedback from SSM to the government. Sources of funding include direct grants from the annual state budget, fees recovered by the state from licensee payments, fees paid to SSM for licensing activities, 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. 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 consider the financial statements and proposed budgets submitted annually by SSM. The budget for the new year takes into account resource needs, previous years' regulatory activities, and the fees paid by industry. When tasked with new responsibilities, SSM expects to receive a corresponding allocation of funding in the annual appropriations directive to cover expenditures. Direct funding from the national budget is earmarked for research activities, bilateral and other international support activities, work related to control activities relating to orphan sources and naturally occurring radioactive material (NORM). SSM is also responsible for regulating non-ionising radiation.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Prime legal responsibility for safety is assigned within the RPA and the ANA to the person or organization responsible for a facility or an activity. Any authorized party must ensure that its contractors and any sub-contractors retain personnel with appropriate qualifications to fulfil the licence holder's obligations with respect to safety while performing work.

SSM is designated as the regulatory body with authority to require that these responsibilities are fulfilled, and that compliance is demonstrated. SSM is authorized 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, fail to comply with SSM's instructions or prohibitions, or violate regulations or any licence conditions that have been stipulated with regard to the fulfilment of responsibility for safety.

1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

The Swedish Government provides for coordination of the regulatory functions of different administrative authorities by way of Ordinances and annual appropriation directives. Ordinances specify the duties of the administrative authorities through general instructions, and appropriations directives specify the authorities' budgets and can provide operational directions for specific tasks and areas of responsibility. The Ordinances under the ANA and RPA establish SSM as having the lead regulatory role with respect to nuclear safety and radiation protection. The Environmental Supervision Ordinance identifies SSM as having supervisory responsibility for radiation safety with respect to activities that are subject to permitting under the Environmental Code, where these activities relate to operations also covered by the ANA or the RPA.

In some cases, multiple authorities have a role in regulating a particular matter. For example, SSM, the National Board of Health and Welfare, the Swedish Medical Products Agency, the Social Insurance Agency, the Health and Social Care Inspectorate, the Ethical review authority, and the Swedish Authority for Health Technology Assessment (HTA) all have a role in regulating medical exposure by ensuring the safety of patients undergoing medical exposures. The IRRS team understood that for the most part roles in this area have been delegated effectively to the administrative authorities; however, there is at least one instance of a gap in delegation, as described below. Recommendation R30 in section 9.9. addresses this issue.

The instructions provided by the Government to the different administrative authorities may include instructions to collaborate. Also, the general Government Agency Ordinance relating to the responsibilities of central administrative authorities requires that authorities work in cooperation with each other where necessary to the advantage of individuals and the state as a whole. The IRRS team learned that while cooperation between administrative authorities is in most cases informal, it generally works well. Relationships are maintained and meetings are held to discuss issues of mutual interest and where instructions have been given to more than one authority to be involved in a particular matter. In one specific case, that of radon, the Radiation Protection Ordinance required SSM to develop a plan to define

coordination with other administrative authorities. A National Action Plan was completed in 2018 with other authorities as directed; under the plan, SSM is responsible for organizing meetings, which it has consistently done.

The IRRS team learned that, in some cases, the lack of effective coordination between authorities means important information is not being considered in a comprehensive way. For example, in the context of non-radiological impacts for nuclear facilities not under SSM's responsibility (chemical, emergency preparedness or workers), the regulations state that management system of operators must integrate all risks. However, various authorities do not communicate and share information on assessment and limits. Some authorities receive reports; for example, non-radiological release reports are sent to county administrative boards, but these reports are not necessarily shared in a way that the IRRS team considered sufficient to provide for a holistic, or cumulative, understanding of risk. The concern about relationships between authorities applies in the authorization process context as well, especially in terms of cumulative risk understanding of issues such as environmental and emergency preparedness issues.

To ensure continuity of cooperation into the future and ensure strong knowledge management between authorities involved in safety regulation, especially when multiple agencies are involved in the regulation of a single matter, cooperation and coordination should be formalized.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In most cases where cooperation between administrative authorities is called for, while collaboration is currently taking place, there are no formal arrangements to help ensure consistency of effective coordination.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:…* *(3)Applications of radiation in medicine, industry and research;…* *This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience.*
S1	**Suggestion: SSM should consider establishing formal arrangements for coordination with other administrative authorities having responsibilities for safety.**

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

The RPA and the Radiation Protection Ordinance include provisions aimed at reducing radiation risks associated with unregulated sources. There are also provisions in the Environmental Code and the Civil Protection Act (CPA) concerning responsibility for environmental damage, including that of radioactive contamination.

SSM has a number of responsibilities aimed at preventing these radiation risks, including responsibility for ensuring the recovery and control of orphan sources. SSM must keep records and make assessments of risks

of activities undertaken in Sweden dealing with NORM, and SSM must also ensure that there is a national monitoring program for ionizing radiation that can determine where there may be exposure situations and whether protective measures should be taken. Under the Environmental Enforcement Ordinance (2011:13), SSM is responsible for advising local and regional authorities about radiologically contaminated sites. In accordance with the obligation under the Radiation Protection Ordinance, in 2018 SSM developed a National Action Plan on radon safety with other relevant authorities.

Those who use and maintain sealed radiation sources are obligated under the law to take steps to minimize the risk that those sources fall outside regulatory control, and anyone finding an orphaned source is obligated to notify SSM. The municipalities establish response plans for non-nuclear activities, which include unregulated risks.

1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL

The provisions for the decommissioning of facilities and the management of radioactive waste and of spent fuel are to be reviewed by the upcoming IAEA ARTEMIS mission, which is scheduled for conduct in 2023.

1.8. COMPETENCE FOR SAFETY

The Government provides for building and maintaining the competence of all parties that have responsibilities in relation to the safety of facilities and activities. The Government has done so in part by providing basic funding for universities, higher education and research institutions. It has also appointed SSM as the responsible authority for building and maintaining the competence that is needed for nuclear safety and radiation protection. The Government has established legal obligations relating to competence for safety on persons carrying out activities with ionising radiation and licence holders for nuclear activities; parties are also responsible for ensuring that adequate financial, administrative and human resources are available 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 ANA 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.

According to regulations set by SSM, those responsible for a facility or activity involving ionising radiation shall ensure that those who work in the installation or activity have the necessary competence and are generally suitable to carry out work tasks that are important for radiological protection or nuclear safety. Required competencies, as well as those available to the business, must be systematically identified and documented. Training and any other measures must be taken to achieve and maintain the necessary skills. The operators must have access to a radiation protection expert function that is appropriate to the nature and scope of the activity, and who reports to senior management. The expert with this function must meet criteria established by SSM. SSM's regulations also stipulate the need for a radiation protection manager at all nuclear facilities; this manager must ensure that all personnel with access to active areas of the facility have received appropriate and up-to-date training. SSM inspects and verifies responsible persons' fulfilment of these legal requirements relating to competence management and skills development.

The Government's responsibility for funding basic university training is supplemented by research funding provided via SSM's annual budget; nuclear power plant licensees and Westinghouse Electric Sweden AB also provide funding. 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.

The IRRS team understood that Sweden has experienced at least a decade of contraction in the nuclear power industry, stemming in large part from political decisions to move away from nuclear electricity

generation in Sweden. This decision resulted in a focus on disposal and decommissioning rather than on developing new technology. Sweden has seen a decline in student applications in university programs related to nuclear, and the programs themselves have become less active, receiving less funding. Encouraged in part by previous IRRS missions to Sweden, progress has been made on considering and supporting the provision of skills and competence in the country.

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 enhanced training programmes with particular importance to nuclear safety and radiation protection. Since this proposal, there 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 cooperation 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.

In February 2022, SSM provided a new report relating to progress in the development of national competencies, setting out and recommending a proposal with 21 priorities for building competence throughout the country. SSM received broad input for the proposal, from approximately 40 entities or organizations. The report emphasizes the need for increases in research funding, and both research and knowledge management at the national and international levels. It also highlights the need for stronger national coordination between different authorities and research funders, the National Research Council, the Energy Agency and SSM, and greater coordination between universities and between universities and these authorities. SSM also noted the importance of cooperation between these entities and industry, in order to address the need for competency in the field of radiation protection and nuclear safety in a concerted and coordinated manner. SSM has noted that while it can do much with increased funding to tackle national competency issues, to be fully effective SSM needs to work together with other entities both in Sweden and abroad.

Given very recent political changes and indications that the government's policy on nuclear is changing in support of new nuclear electricity generation, the needs for competence in nuclear could very well soon grow substantially and rapidly.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM's proposal for the national strategy for competence, not yet adopted by the Government, does not anymore consider the most recent political development on nuclear power in Sweden.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 11 states that** *"Competence for safety - The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para. 2.34 states that** *"As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available."*
(3)	**BASIS: GSR Part 1 (Rev. 1) para. 2.35 states that** *"The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety. Competence shall be built, in the context of the regulatory framework for safety, by such means as: — Technical training; — Learning through academic institutions and other learning centres; — Research and development work."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R2	**Recommendation: The Government should adopt a national strategy for competence addressing current and future needs, considering the recent political development on nuclear power in Sweden.**

1.9. PROVISION OF TECHNICAL SERVICES

The Swedish government has made provisions for technical services related to personal dosimetry, environmental monitoring and the calibration of equipment. When appropriate and necessary, SSM proposes measures to monitor, evaluate and report on environmental objectives, and it may consult with the Swedish Environmental Protection Agency. As part of its responsibility for environmental goals, SSM assesses the radiation risk for the population as a whole and for specific groups. SSM maintains a national register of the radiation doses received by workers in connection with occupational exposure. SSM is designated by the Government to be the National Metrology Laboratory for ionizing radiation, which, among other tasks, calibrates radiation measuring devices. Services for personal dosimetry are provided by four hospitals, three nuclear facilities and two private company, all of which are sanctioned by SSM.

1.10. SUMMARY

Sweden has established a governmental, legal and regulatory framework for safety, and has an independent regulatory body. Responsibility for safety has been assigned, and compliance with regulations can be enforced. Sweden provides for coordination between administrative authorities with responsibilities for safety within the regulatory framework and has mechanisms for reducing the risks associated with unregulated sources of radiation. Much has been done to ensure that the competence of all parties that have responsibilities in relation to safety is maintained. The IRRS team identified the following items for improvement to the legislative and regulatory framework for safety:

- certain highlighted legislative amendments to resolve enforcement gaps;
- formalization of cooperation between administrative authorities with responsibilities for safety;
- a re-evaluation of the proposal for the national initiative to secure the long-term provision of skills in the field of radiation safety and action on implementation of the initiative.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Sweden is a contracting party to relevant international treaties and conventions that establish common obligations and mechanisms for ensuring safety in the utilization of nuclear energy and radiation applications for peaceful purposes as well as for an effective coordinated international response to a nuclear or radiological emergency. These include the Convention on Nuclear Safety; the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management; the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency; and the Convention on Early Notification of a Nuclear Accident.

Sweden has formally committed to implementation of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and the two supplementary guides namely the Guidance on the Import and Export of Radioactive Sources; and the Management of Disused Radioactive Sources.

The IRRS team was informed that SSM continuously monitors the publication of IAEA safety standards, which provide the basis for SSM regulations. SSM has included a process in its management system to assure that SSM regulations are compatible with the IAEA safety standards. However, IRRS team noted that international experience is not systematically considered in relation to development of regulations. Suggestion S15 in Section 9.1. addresses this issue.

SSM participates in the development of IAEA safety standards as well as for exchange of regulatory experience. SSM also contributes actively to the IAEA Commission on Safety Standards and its committees, namely: Nuclear Safety Standards Committee (NUSSC); Radioactive Waste Safety Standards Committee (WASSC); Radiation Safety Standards Committee (RASSC); Transport Safety Standards Committee (TRANSSC); Emergency Preparedness and Response Standards Committee (EPReSC); and Nuclear Security Guidance Committee (NSGC).

Sweden has hosted several international peer review services. A full scope IRRS mission to Sweden was conducted in 2012 with a follow-up in 2016. An IPPAS mission was also conducted in Sweden in 2012 with follow-up in 2016. In addition to this current IRRS mission (2022), the Swedish Government has requested an ARTEMIS mission which is planned for 2023. In addition, a number of international appraisal missions have been hosted by the licensees such as SALTO at all Swedish NPPs in operation, OSART to all NPPs, Knowledge Management Assist Visit (KMAV) to Ringhals NPP and WANO peer review missions at all NPPs.

Experts from SSM also take part in different IAEA service missions hosted by other IAEA member states.

Sweden has developed and maintains numerous bilateral cooperation agreements with other countries, including Australia, Finland, France, Germany, Georgia, Great Britain, Canada, Japan, Lithuania, Norway, Ukraine and USA.

Sweden is also engaged in bilateral projects in several Eastern European countries. These collaborations are conducted under several international frameworks, established at the UN or EU level, but also within the Nordic cooperation and bilateral agreements, with the overarching aim to strengthen nuclear and radiation safety, and security globally.

Sweden also works with a number of international organizations and takes part in working groups and committees important for enhancing harmonized approaches for safety as well as for exchange of regulatory and operating experience. These include European Nuclear Safety Regulators Group (ENSREG), Western European Nuclear Regulators Association (WENRA), Heads of European Radiation Protection Competent Authorities (HERCA), World Association of Nuclear Operators (WANO), United Nations Scientific Committee on the effects of Atomic Radiation (UNSCEAR), and the International Commission on

Radiological Protection (ICRP). SSM's DG is also the chairperson of HERCA. In addition, Sweden is a member of the Organisation for Economic Cooperation and Development/Nuclear Energy Agency (OECD/NEA) and actively participates in committees and various working groups with the aim of fostering international cooperation in nuclear safety and radiation protection.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

All events and conditions in Sweden that are important to safety are required to be reported to SSM in accordance with Swedish legislation. Detailed reporting requirements for nuclear power plants in operation as well as for other nuclear facilities are defined in SSM‘s regulation SSMFS 2021:6 (previously referred to as SSMFS-D) and SSMFS 2008 :1.

The process for analysis of the reported events for nuclear power plants in operation is described in an SSM management system procedure. The SSM staff reviews the analyses and conclusions provided by the licensee, informs relevant divisions and departments within SSM, and makes recommendations regarding actions that should be taken. Selected events at foreign nuclear power plants are also reviewed. SSM's ”operating experience and event review team” (ASK - analys av störning vid elproducerande kärnkraftverk) regularly communicates with the Licensees on issues regarding events and operating experience. If the ASK group find it relevant, it can recommend to managers that SSM should send information notices to, or in some cases demand actions from the licensees due to the actual operating experience. Pursuant to provisions set forth in the aforementioned management system procedure, events reported to SSM must also be assessed against the Joint IAEA and Nuclear Energy Agency of the Organisation for Economic Cooperation and Development (OECD/NEA) International Reporting System for Operating Experience (IRS) reporting guidelines and, if deemed necessary, be reported to IRS. As for events at nuclear facilities, the reporting process to international event reporting networks, e.g. Fuel Incident Notification and Analysis System (FINAS), jointly operated by the IAEA and the OECD/NEA, is not formalised.

All unplanned events of radiological importance at licensed non-nuclear facilities and activities are reported to SSM in accordance with the Radiation Protection Ordinance. Lessons learned from such events are disseminated by SSM to licensees and to manufacturers and suppliers of radiation sources in line with the provisions set in RPO. The IRRS team was informed that this is done by providing annual reports and on a case-by-case basis by sending the relevant information to the concerned parties.

The process for reporting and analysing events, and the dissemination of lessons learned, for medical and dental practises is described in the SSM`s process management tool. However, for other practises similar processes and routines are under development.

SSM management conducts meetings with the licensees for nuclear facilities on a regular basis. The frequency for conducting meetings with nuclear power plant management is on annual basis while meetings with management of licensees for fuel cycle facilities are conducted on biennial basis. A system for regular meetings with the nuclear industry related to radiation protection matters is also in place.

For many activities, SSM has a requirement for its staff to share information within the organization on the lessons learned. SSM has included in its action plan the development of procedures for sharing lessons learned in relevant areas as well as overarching process for making information of lessons learned available to other national and international stakeholders.

2.3. SUMMARY

The Government and SSM fulfil their international obligations and actively participate in the relevant international arrangements, including international peer reviews.

A system is in place for use and dissemination of international operating and regulatory experience that contributes to safety. However, the process of operating and regulatory experience feedback could be improved by developing or amending procedures in relevant areas.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

SSM has experienced a number of significant changes in the past five years. In 2017, the Swedish Government relocated SSM's headquarters to the city of Katrineholm, situated about 120 kilometers southwest of Stockholm. The IRRS team was informed that the relocation led to some staff departing the authority. In 2022, SSM had approximately 50 employees with positions at the Katrineholm office. In addition, SSM has opened a small branch office in Gothenburg.

In 2020, SSM management adopted new strategic objectives for the period 2021-2025. These include SSM´s role in public administration, its internal leadership and working environment, as well as its emergency preparedness capabilities and the external perception of SSM as "a world class radiation safety Authority."

In 2021, SSM underwent a very significant organizational change. The organizational structure was shifted from a "competence oriented" approach to a "task-oriented approach." The IRRS team noted that the change initially resulted in uncertainties among staff, as many staff members have been relocated according to their competence and the needs of the new organization. There are still some uncertainties among staff in certain parts of the organisation. The IRRS team was informed that staff preferences regarding relocation within the organization were sought; however, the IRRS team also learned that the reorganization led to some staff leaving SSM.

The established organisational structure of SSM is stated in the Rules of Procedure for the Swedish Radiation Safety Authority (STYR2012-27). The organisational structure separates the authority´s regulatory decision-making with respect to policies and regulations, inspection and enforcement and its licensing and authorisation work into three separate divisions to ensure "internal independence". The IRRS team was informed that there is a longstanding approach in Swedish administration to separate development and funding tasks from implementing tasks in all government authorities. The resources have been distributed accordingly, including for technical areas where resources are currently limited. Two departments (Radiation Protection and Environmental Assessment and Plant Safety Assessment) within the Division for Regulation and Knowledge Management act as the internal technical support organization (TSO) supporting the other divisions and departments with some technical and radiological assessments when needed, which are not part of the normal competency need of that Division. The Rules of Procedure describes the internal delegation of certain decision-making powers from the Director General to Directors, department heads and case handlers.

The IRRS team observed that cooperation, communication and exchange of expertise between experts located in the different divisions has been adversely affected by the new organisational structure, as it is designed to ensure internal independence between the divisions. The IRRS team is of the view that it is important that exchange between inspectors that have extensive knowledge of the facilities and activities they inspect and the authorizing staff who may need to amend licence conditions is fluid and effective. Furthermore, it is also important for staff developing regulations to be able to incorporate the experience of inspectors enforcing those regulations. Similarly, the IRRS team observed that there is a need for inspectors to coordinate with authorizing staff to ensure that they are aware of changes that can affect inspection activities in order to be able to properly inspect facilities and check compliance with licences. The dispersion of expertise in a few domains can be challenging when there is not enough staff within the new departments to maintain sufficient expertise within these fields. This might be a particular challenge in fields with rapidly evolving technologies, such as within the medical field. The IRRS team also noted that the SSM management system does not clearly define documented interface arrangements among different divisions and departments.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current level of interaction and interfaces between different organizational units (divisions and departments) involved in implementing the core functions of SSM poses challenges for SSM and is not clearly described in the management system.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 16 states that** *"The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."*
(2)	**BASIS: GSG-12 para. 4.58 states that** *"Irrespective of the organizational structure selected, attention should be paid to the distribution of expertise and required competences in organizational units and to the integration and interaction of the technical and administrative units involved in implementing the core functions and supporting functions. However, the regulatory body should use an interdisciplinary approach to the oversight concept, enabling a systemic approach in which all aspects relevant to safety are adequately considered with respect to human, technical and organizational factors and their interactions."*
(3)	**BASIS: GSG-12 para. 4.61 states that** *"The roles, responsibilities and lines of communication of organizational units, managers and staff should be clearly defined and assigned, in accordance with the organizational structure, to allow for the effective and efficient implementation of the core functions and supporting functions."*
(4)	**BASIS: GSR Part 2 para. 4.11 states that** *"The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system."*
S2	**Suggestion: SSM should consider further defining and establishing appropriate interaction and interfaces between its organizational units (divisions and departments). This should be clearly established in the management system and communicated to all stakeholders.**

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

SSM is independent in its decision making, organisational matters and the use of resources allocated for different purposes and is functionally separated from entities having responsibilities or interests that could unduly influence its decision-making. According to the Swedish constitution, administrative authorities are independent in their regulatory decision making within the legislation and statutes established by the Government. The Government or an individual minister is not allowed to interfere in a specific case handled by an administrative authority. SSM reports to the Ministry of the Environment, which is not involved in the promotion or utilization of nuclear energy.

SSM's supervisory areas are well defined in the Swedish legal framework. SSM has extensive powers of intervention, from a remark to prohibition of an ongoing activity. None of these interventions (enforcement actions) contain limitations as to which action the authority may choose or when. Economic considerations are not relevant when the authority chooses whether to act against a licensee. If necessary, from a nuclear safety or radiation protection point of view, SSM intervenes regardless of the costs to the authorized party. SSM also has the authority to impose new conditions on licensed activities. If such a condition is not fulfilled, the activity may not be allowed to continue. There is no cost limitation for this kind of condition.

Sweden's Administrative Procedure Act (APA) sets out public administration provisions on issues of conflict of interest. SSM employees and advisors to SSM are disqualified from taking part in proceedings on behalf of the Authority in a way that may affect the Authority's decision-making. According to the

Secondary Employment and Conflicts of Interest steering document, any member of staff who is aware of circumstances that may constitute a conflict of interest has to report this immediately to his or her nearest manager. The Authority shall examine and decide on the matter as soon as possible.

According to SSM's internal steering document on integrity and credibility aspects of recruitment, a withdrawal or waiting period is required before a newly-recruited employee is allowed to participate in regulatory activities and decisions that may pose a conflict of interest from the perspective of integrity and effective independence. The length of the waiting period must be assessed taking into account the role and task of the employee in his or her previous employment. Matters of integrity and trust in the regulatory authority are particularly important when recruiting managers. Decisions on waiting periods are taken by the recruiting manager and must be formally documented.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

SSM has approximately 300 employees. Approximately half of the employees have a technical or natural science background. The IRRS team noted, however, that there are relatively few qualified staff to support certain regulatory functions, e.g., radiation protection, export control, material clearance, waste disposal, inspections, and transport. Some critical positions have only one qualified expert. In some areas it was noted that there is an insufficient number of inspectors with relevant technical knowledge. The IRRS team considered such experience important in the technical discussions between inspectors and facility staff to ensure constructive liaison on safety related issues and in-depth technical dialogue between experts. The IRRS team noted that the staff turnover rate has risen significantly in SSM since the IRRS mission in 2012. The IRRS team was informed that this is a normal turnover rate in comparison with other governmental agencies in Sweden. Nevertheless, the IRRS team considered the turnover rate to be high in comparison to other similar nuclear and radiation safety authorities in other countries and considers it a possible risk for staffing of critical positions within SSM. The IRRS team considered the availability of relevant categories of staff particularly important in light of the proposed plans of the Swedish government to further expand its nuclear program.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are relatively few qualified staff to support certain regulatory functions within SSM.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	**BASIS: GSG-12 para. 6.4 states that** *"In addition to depending on the employment of sufficient staff with suitable qualifications and expertise, the effectiveness of the regulatory body will also depend on the status of its staff in comparison with those of the authorized parties and other involved organizations. Staff of the regulatory body should be appointed at such grades and with such salaries and conditions of service as would facilitate their interactions with authorized parties and reinforce the independence and authority of the regulatory body staff in conducting their work."*
(3)	**BASIS: GSR Part 1 (Rev. 1) para. 4.22 states that** *"The obtaining of advice and assistance does not relieve the regulatory body of its assigned responsibilities. The regulatory body shall have adequate core competence to make informed decisions. In making decisions, the regulatory body shall have the necessary means to assess advice provided by advisory bodies and information submitted by authorized parties and applicants."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R3	**Recommendation: SSM should ensure that there are sufficient qualified staff to fulfil all its statutory and regulatory functions.**

SSM has a process document with procedures for recruitment of qualified competent staff, for skills development and the maintaining and preserving of staff competence by being an attractive and stimulating workplace, as well as for the transfer of knowledge for departing staff.

SSM's human resources planning consists of several integrated planning documents as part of the Authority´s competence management process, including work planning and allocation of resources and strategic long-term budget proposals. Through individual performance appraisals, SSM managers systematically follow-up on staff competence and development needs in order to ensure that employees possess the right skills to carry out their duties and to achieve the objectives of the Authority within their operating area.

The IRRS team noted, however, that SSM does not have a complete understanding of its current and future competence needs. SSM has acknowledged this challenge and is currently performing a competence analysis to ensure that the Authority is adequately staffed and that there is necessary competence based on the respective divisions' and departments' assignments. The competence analysis is based on the prevailing situation before the parliamentary elections in September 2022 after which Sweden decided to expand its nuclear power program. The IRRS team was informed that SSM senior management will ensure that possible new challenges posed to the Authority after this decision will be properly reflected in their competence analysis. The competence analysis will define and influence SSM's human resources planning over the next 4-5 years. The IRRS team is of the view that SSM would benefit from continuing the systematic resource planning addressing especially long-term needs. This issue is covered in section 4.4.

SSM has established a competence transfer concept to compensate for staff attrition (e.g., retirements), and to bolster competence currently held by only one employee or a few employees. 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. Another option occasionally applied by SSM is to rehire retired employees on short-term contracts in order to both maintain the continued case handling and support the transfer of knowledge to remaining and newly hired employees.

SSM´s programme for new staff contains the important elements of the Authority´s regulatory responsibilities and the Swedish public administration core values of democracy, legality, objectivity, free formation of opinion and access to public records and respect for equality. All managers participate in a leadership programme that consists of four days of training and follow-up training during the year. SSM explained that in addition leaders are trained twice a year. A specific internal training programme for future leaders has been set up in order to foster good leadership and secure a consistent management of the Authority´s regulatory functions. A more specific internal training program called "Competent supervision" addresses in detail SSM´s regulatory processes and supervisory procedures. The 6-module programme is carried out twice per year and includes training on SSM's supervisory practices, norms, values, legal bases, etc. The IRRS team was informed that a new module regarding security, security protection and physical protection is currently being implemented. Further, the need for specific technical training decided in the yearly appraisal between individual staff members and their head of department. However, the IRRS team noted that there is no systematic approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *There is a need for systematic training and retraining in technical areas that are needed to deliver SSM's regulatory functions.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
S3	**Suggestion: SSM should consider further strengthening individual training programmes to focus on systematic training and retraining in technical areas that are needed to deliver its regulatory functions.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

By Government instruction, SSM is supported by permanent advisory committees on reactor safety and on the safe management of spent fuel and radioactive waste. The members are appointed by the Director General and represent other national or international authorities and independent institutions with relevant competences. The committees provide advice to SSM on important regulatory issues. SSM is further supported by a transparency council consisting of a maximum of ten members appointed by the Government. The council advises the Director General in transparency matters and ensures public insight in relation to the Authority's activities. By Government instruction, SSM also has a permanent advisory committee on research to ensure the scientific quality in SSM´s funding of external research projects.

SSM can also call upon external expert advice on a consulting basis, in particular as an input of expertise in its review and assessment work to support regulatory licensing and supervisory decisions. The internal procedures for acquiring consulting services are part of the Authority´s procurement process.

All external experts, consultants and researchers, as well as advisory and scientific committees, serve as advisory bodies only. SSM uses the external experts´ services and advice as an input in its own review and assessment work and takes full responsibility for its own independent and informed regulatory decisions.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

SSM´s procedures for supervisory activities include provisions for formal communication with authorized parties and applicants in major licensing reviews. For example, SSM must communicate observations from inspections and assessments to ensure correctness in the basis for regulatory decisions and enforcement actions. All SSM supervisory reports and decisions are communicated to the authorized party or applicant and are made publicly available (unless containing security sensitive information). An integrated safety assessment report is communicated annually for each major facility under SSM's supervision, comprising the results of all inspections and nuclear safety and radiation protection assessments. The report is presented to the authorized party at a top-level management meeting between the Authority and the license holder. Included in the meeting agenda is an oral feedback and discussion on safety performance, leadership for safety and the effectiveness of the licensee´s safety improvements.

SSM also facilitates regular joint safety management meetings with the chief safety officers of the nuclear license holders in order to communicate changes in regulations and the work of SSM, and to follow-up on and discuss safety improvement experiences at the facilities. Information meetings with branch industry organizations also take place as appropriate.

Prior to making regulatory decisions, SSM informs the party concerned of all material relevant to the decision and provides the party an opportunity to comment, within a specified period. SSM is required to

demonstrate in its decisions how regulations have been applied and to justify its decisions. SSM maintains an internal procedure that provides instructions for decision making, including the content and format of SSM decisions, in order to ensure that the justification for a decision is adequately documented.

To ensure the professional and constructive liaison between SSM and authorized parties, a non-residential, supervisory facility coordinator is formally appointed for each major facility licensee. The coordinator maintains regular contact with the licensee and has knowledge of the operation, organisation, design of the facility, and an overview of all supervisory activities carried out by the SSM. The coordinator receives and manages periodic reports, reports on radiation protection and nuclear safety events, notifications of plant modifications and coordinates with and continuously informs other departments at SSM as appropriate. The liaison between SSM and the authorized parties for nuclear facilities, as facilitated by the facility coordinator, is in part informal with frequent, daily or weekly, contacts for the sharing of information and updates on operations. All contacts and meetings are formally documented and as such are traceable and open to the public (unless containing security sensitive information). SSM has requirements for the rotation of individual inspectors between the different licence holders within suitable intervals. The length for a supervisory facility coordinator is limited to four years for a specific license holder.

The IRRS team met representatives from several different authorized parties. These meetings provided an opportunity to the IRRS review team to discuss the interactions of authorized parties with SSM, including their comments on SSM's activities and decisions. While confirming that there is a good level of relationship with SSM in general, representatives of the authorized parties expressed the view that more extensive coordination with SSM management, greater involvement on site by SSM inspectors, and more technical and in-depth inspections/reviews by SSM would help foster better safety and better focus on continuous improvement of safety. The IRRS team noted that there are two members of the SSM senior management group with a technical background.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

SSM is required to ensure good public management in terms of legality, objectivity and proportionality, and to be objective and impartial in its regulatory activities. SSM's supervisory processes for inspection, review and assessment and enforcement are well established.

SSM has documented procedures for assessment and reporting on compliance during supervision activities, on the appropriate enforcement measures (including sanctions) to be applied when compliance assessments result in identified deficiencies, considering the safety implications of these deficiencies. Criteria for assessments of compliance with safety requirements and on judging safety deficiencies and their safety implications are provided.

Basic principles for the allocation of responsibilities and delegated decision making, as well as more specific rules for review and decision making within SSM are documented as well. Decisions are to be handled uniformly and the overall competence of SSM is to be utilized to create the basis for the decision. Depending on the nature of the matter and the decision level within the organisation, a consultation between the concerned division directors or department heads is required before a decision is made. During the preparation of a case and prior to decision-making, the case is also reviewed by one of the Authority´s legal advisors.

3.7. SAFETY RELATED RECORDS

Archiving of records is undertaken independently by both SSM and its licensees. SSM regularly verifies that the requirements for documentation and archiving are met by operators.

According to the Freedom of the Press Act, all documents either received by or produced by an authority are considered to be official documents (limited only by certain aspects of secrecy); SSM has an obligation to register all official documents in the authority's diary without delay. The diary constitutes the authority's

central and comprehensive system for registering official documents. Each document in the same case gets its own document number. SSM has an electronic document and case management system – SSM360 – where SSM registers and stores the public and internal documents. This includes identifying, classifying, storing, securing, retrieving, tracking and preserving records. SSM has a process for filing and archiving.

According to regulations, those who conduct nuclear activities must keep an orderly and listed archive of such documentation that concerns the activities from a radiation protection point of view. A licensee is obliged to archive documentation until completion of the decommissioning or until closure of the installation. All documentation must be provided to SSM after decommissioning or after closure of the installation. The archive must contain, for example, applications and permit documents, design conditions and facility descriptions, event registrations, contingency plans, emission samples and measurement results, waste documentation, and information on personal doses. The archive must be well maintained and, when the activity ceases, a list of the archive must be submitted to SSM.

SSM regulations require 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 ongoing. When the nuclear facility is decommissioned, this information must be documented and compiled in a report submitted to SSM. For activities with ionizing radiation, there are provisions on documentation in SSMFS 2018:1. These regulations require that results from monitoring of emissions, radioactive waste that has arisen in the facility and information on personal doses must be documented and preserved.

The IRRS team concluded that there are sufficient provisions in the Swedish regulatory framework to ensure that adequate records and inventories related to the safety of facilities and activities are established and maintained. The team noted that SSM has not reviewed the completeness of the safety related records and has not developed procedures for how such records are established, developed and managed. This issue was identified in SSM's action plan provided to the IRRS team with the Advance Reference Material. The IRRS team encourages SSM to continue this effort and, in particular, establish well-defined retention periods for relevant records.

<table>
<tr><th colspan="2">RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</th></tr>
<tr><td colspan="2">Observation: SSM has not reviewed the completeness of their safety related records and has not developed procedures for how such records are managed.</td></tr>
<tr><td>(1)</td><td>BASIS: GSR Part 1 (Rev. 1) para. 4.63 states that "The regulatory body shall make provision for establishing and maintaining the following main registers and inventories:
Registers of sealed radioactive sources and radiation generators;
Records of doses from occupational exposure;
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 material to the environment;
Inventories of radioactive waste and of spent fuel"</td></tr>
<tr><td>S4</td><td>Suggestion: SSM should consider reviewing the completeness of the safety related records kept at SSM and developing procedures for how such records are managed, including defining retention periods.</td></tr>
</table>

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

SSM is required to contribute to public insight into all activities that are covered by the authority's responsibilities. To guarantee an open society with access to information about the work of government and its agencies, the principle of public access to official documents has been incorporated into Swedish law. This principle establishes the general public the right to read official documents submitted to or drawn up by the authorities. All documents received or dispatched, letters, decisions and reports are official documents and must be made available.

SSM´s website is an important tool for communicating with the public and other interested parties. The website includes descriptions of SSM's work, such as supervision in connection with modernisation work and power uprates, the repository for spent fuel, etc. All Director General decisions affecting third parties are published on the external website and often communicated by means of a news item on the website. The news is accompanied with a copy of the decision or report. When appropriate, press releases are also distributed. In addition, SSM´s web registry enables the publication of virtually all decisions, injunctions and reports on its public website.

In accordance with the SSM's 2021-2025 strategic objectives, a new communication policy and strategy is under development. Having identified its relevant stakeholders, through this new policy SSM aims is to communicate with the general public and other stakeholders the radiation risks associated with facilities and activities, and to actively influence behaviour in a safety-oriented way. For example, the SSM website includes information and related advice regarding how individuals can protect themselves from the sun's harmful ultraviolet (UV) rays. The IRRS team concluded this proactive approach to inform and influence public safety-culture an area of good performance.

Changes or additions to SSM´s regulatory requirements are undertaken through 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 authorized parties and other interested parties, and quality assurance in the final preparation for decision-making. Consultations are made public on SSM´s website and stakeholders also receive pertinent documents by e-mail.

Local safety committees have been established near five of the Swedish nuclear facilities. These committees are required by law to obtain information regarding radiation safety work that has been performed at the nuclear facility for which it has been designated. For the local safety committees to obtain information and compile material for the public, licensees of the facilities are obliged to provide as complete information as possible. Licensees are required to provide the safety committee full insight into the radiation safety work at the facility. By request of the committee, the licensees must also provide all available information and the documents needed for the committee to fulfil its legal obligations. The licensees are also obligated to give the committee access to facilities or places, if necessary, for the committee to verify that information and access is in accordance with current safety and security requirements. A licensee that does not comply with a local safety committee´s request, or provides incorrect information, is liable to a fine or maximum six months imprisonment. SSM participates at least once per year in meetings convened by the local safety committees. For special issues, such as the deep geologic waste repository, SSM also participates proactively in information sessions organised by municipal authorities in order to meet the public in person to answer questions.

Communication with the neighbouring countries is well established at many levels. There is a strong tradition for close cooperation among the Nordic countries. For example, within the framework of communication, SSM participates in the Nordic Public Communication Group together with the safety authorities from Denmark, Norway and Finland.

3.9. POLICY DISCUSSION

Challenges of the regulatory body in the context of possible new builds (and new technologies)

In August 2022, the Swedish Government required SSM to explore the necessary conditions for continued operation of existing nuclear power plants (NPPs), as well as to identify necessary changes to the legal framework and other issues that could affect potential new builds of NPPs, including small modular reactors (SMRs). At the time of the mission, formal parliamentary budget decision regarding regulatory activities in relation to new builds was expected in December 2022.

Sweden expressed interest in focused discussions on the following topics:

- Competence-related challenges of regulating existing and expected facilities and activities concurrent with new nuclear power facilities;
- Generic type-approvals for new reactors;
- Consideration of reviews and assessments already conducted by other regulatory bodies;
- Experiences with "First of A Kind" licensing.

The policy discussion highlighted the following key items:

- It is key to get a firm governmental commitment and a clear National Nuclear Energy Policy before initiating time- and resource-consuming regulatory development activities to support new builds.
- Regulatory bodies should not underestimate the degree of external pressure likely to be experienced when the decision to proceed with new builds is made.
- The regulatory development activities necessary to support licensing and operation of new builds should not adversely affect the ongoing regulation of other licensed activities and facilities. The funding mechanism for resources needed to support regulatory development activities of new builds should be secured as a near-term priority.
- Proper organizational arrangements, including development and acquisition of necessary staff resources and competence are essential. This challenge is magnified given competition for these same resources from applicants and operators. Partnerships with universities and the industry could be beneficial.
- From a public acceptance perspective, some countries expanding their nuclear power programme often plan new builds on existing nuclear power sites.
- The development of a regulatory framework for new technology is a significant challenge; adopting a technology neutral approach is advisable.
- Prioritization of the use of proven technologies (e.g., light water reactors) may help to facilitate the relative near-term implementation of new power programme.
- International cooperation, bilateral or multilateral, is beneficial if not essential. Leveraging work already completed by other regulatory bodies could provide significant safety- and cost-related benefits for regulating new builds.
- Preliminary regulatory reviews of the nuclear safety features associated with new technologies and associated innovations is essential. These features include the use of passive versus automatic shutdown and cooling systems, the application of control systems, and the consideration of human and organizational factors.

3.10. SUMMARY

The Swedish legal framework provides for the independence of SSM in the performance of its regulatory functions.

The current level of interaction and interfaces between different organizational units (divisions and departments) involved in implementing the core functions of SSM poses challenges for SSM and is not clearly described in the management system.

There are relatively few qualified staff to support certain regulatory functions within SSM.

SSM has the ability to mandate external support organizations as needed, and, based on its internal competence, can act as an intelligent customer. The relationship of SSM and its established advisory bodies is described clearly and does not compromise SSM's ability to evaluate and decide on safety relevant topics independently.

The relationship between SSM and its authorized parties is established with formal and informal channels of communication. While confirming that the relationship with SSM in general is frank, open and transparent, the IRRS team noted in interviews with representatives of the authorized parties that there is a wish for more extensive coordination with SSM management and more technical and in-depth inspections/reviews by SSM to help foster safety and better focus on continuous improvement of safety.

The SSM regulatory process is a formal process with several different instruments that are used to ensure that the process is implemented consistently and with management control, which ensures the stability and consistency of SSM's regulatory control.

In general, there appear to be sufficient provisions in the Swedish regulatory framework to ensure that adequate records and inventories related to the safety of facilities and activities are established and maintained. The IRRS team concluded that SSM should continue reviewing the completeness of the safety related records kept at SSM and establish corresponding routines regarding their management and retention periods.

SSM's communication work is generally comprehensive, transparent and proactive. The IRRS team considered SSM's work in communicating and influencing public behaviour related to safety an area of good performance.

4. MANAGEMENT OF THE REGULATORY BODY

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

All SSM activities are governed by the Authority´s management system, where the Rules of Procedure (STYR2012-27) constitute a top-level document that describes the organisation and the responsibilities of the different divisions and departments; senior management; managers and employees. The responsibilities regarding safety are clearly described in the Rules of Procedure where it is stated that all managers should take "clear leadership on safety issues on the basis of a holistic approach to safety." By setting clear responsibilities, SSM management has established clear expectations regarding safety for the employees.

All decisions are based on the SSM´s organizational values and operating policy, founded on radiation safety, as described in the Decision-making procedure (STYR2012-28). SSM´s management policy (STYR2011-71) is a top-level internal steering document that 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, roles and responsibilities, core organisational values, a commitment to a strong safety culture and leadership for safety. It also describes the integrated management system. The management system has also been designed to support and promote a culture in which issues with an impact on radiation safety are given the attention and priority that their importance requires. Safety is the overriding priority in SSM´s Vision. SSM´s Management policy includes influencing the behaviour of its stakeholders in the field of radiation safety. All employees are responsible for constantly working to strengthen the SSM's organizational culture, including safety culture.

In 2020, SSM management issued new strategic objectives for the period 2021-2025 that focus on internal leadership and working environment. 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 established to foster good leadership and secure a consistent management of the Authority´s regulatory functions.

All managers conduct yearly performance appraisals with employees in part to develop individual competencies in safety. 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.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The Authority´s main goal is the protection of people and environment from harmful effects from ionizing and non-ionizing radiation. Senior management of SSM is responsible for the performance of the regulatory body as well as for the management system. This includes issues of safety and security in nuclear and other operations as well as issues of nuclear non-proliferation. The Authority´s daily operations are governed by SSM's management system.

The SSM has established a vision of SSM's operation as "a society safe from harmful effects of radiation." 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 SSM´s management has established goals, strategies, plans, objectives and a "road map" for the organization on an overall strategic level. However, the IRRS team noted that SSM needs to continue prioritizing the objectives included in the strategic road map. This issue was identified in the SSM's action plan provided to the IRRS team with the Advance Reference Material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM needs to continue prioritizing the objectives that are included as part of the strategic road map.*	
(1)	**BASIS: GS-G 3.1 para. 2.5 states that** *"In an integrated management system, all goals, strategies, plans and objectives of an organization should be considered in a coherent manner". This implies:* - *Identifying their interdependences and their potential to impact on each other;* - *Assigning priorities to the goals, strategies, plans and objectives;* - *Establishing procedures to ensure that these priorities are respected in decision making."*
S5	**Suggestion: SSM should consider further prioritizing the objectives included in the strategic road map.**

4.3. THE MANAGEMENT SYSTEM

SSM initiated a significant organizational change and implemented a new organization in June 2021. SSM assessed appropriately the risks associated with: work conditions; project implementation; and operation of the SSM. The IRRS team concluded that competence management and business continuity had been effectively covered by the risk assessments conducted in preparation of this change. On the other hand, the IRRS team was informed that SSM did not assess specifically the risks associated with the potential degradation of safety culture since SSM had not identified any significant risks in this regard which were not already captured in the other risk assessments. Considering the multiple impacts at organizational and individual levels, this modification may have affected the culture as whole, in particular the culture for safety of SSM. Due to the role and responsibilities of SSM as regulatory body, this issue should have deserved an ad-hoc risk assessment in order to identify preventive measures to anticipate any potential degradation of the SSM's culture for safety, during and after the transition period which may last several years.

The management has revised a number of top-level internal steering documents in the light of the new organization. The steering documents describe the responsibilities and functioning of different divisions and departments of SSM. The IRRS team observed that documentation of the management system is not user friendly, is complex and incomplete. The IRRS team concluded that the documentation structure needs to be reviewed in the light of new organization and further developed, as appropriate. The maintenance of the management system should be also strengthened in order to keep it up to date and fit for purpose. This issue was identified in the SSM's action plan provided to the IRRS team with the Advance Reference Material. Furthermore, the overall responsibility for establishing, applying, sustaining and continuously improving the management system is not clearly described in the rules of procedures.

The SSM Rules of Procedure describes the functioning of different councils and committees of SSM. The supporting structure (Process council, Council and team) for the management system is complicated and could be simplified. The IRRS team noted that SSM does not have a specific process to manage and review organizational changes.

After developing the new organization, SSM introduced a new type of steering document (i.e., "Strategy") and accordingly reflected such in its Rules of Procedure. In 2017, SSM also developed the steering document "Document Governance (STYR2011-32)" which provides an overview of the various documents handled by the Authority. This document has defined three types of documents. The IRRS team noticed that the new type of steering document "Strategy" is not reflected in the Document Governance. Further,

the IRRS team was informed that policy documents serve as the top-level steering document; however, the Document Governance reflects "policy" as the second level.

The IRRS team noted that the Department for Information Management and Security is responsible to archive and record management. SSM has a plan reflecting different types of management system records along with their location, retention time, etc. SSM ensures that the records are readable for the duration of the retention times specified for each record in the plan. However, the IRRS team observed that SSM has not documented a process that describes types of records, their categorization, retention and disposal of records they produce.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The management system documentation is complex, inconsistent and incomplete.*	
(1)	**BASIS: GSR Part 2 Requirement 8 states that** *"The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use".*
(2)	**BASIS: GS-G 3.1 para. 2.45 states that** *"The management system should be described by a set of documents that establish the overall controls and measures to be developed and applied by an organization to achieve its goals".*
(3)	**BASIS: GS-G 3.1 para. 2.46 states that** *"The documentation of the management system should be appropriate to the organization and to the work that it performs and should be readily understandable to users".*
R4	**Recommendation: SSM should finalize the review and revision of the overall structure of the management system documentation to ensure consistency, clarity and completeness.**
Observation: *SSM does not have a process to manage and review organizational changes.*	
(1)	**BASIS: GS-G 3.1 para. 5.61 states that** *"Senior management should develop a specific process to manage and review organizational changes. The process should ensure that there is no degradation in the safety culture of the organization".*
S6	**Suggestion: SSM should consider developing a specific process to manage and review organizational changes.**
Observation: *SSM does not have a process that describes the different types of the management system records generated, their categorization, retention time and disposal.*	
(1)	**BASIS: GSR Part 2 para. 4.20 states that** *"Documentation of the management system: Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and with the obligations for knowledge management of the organization."*
(2)	**BASIS: GS-G 3.1 para. 5.42 states that** *"Records should be categorized according to the needs of the organization and the necessary retention period of the records". Annex II and III provide guidance on retention periods and storage for records".*
(3)	**BASIS: GS-G 3.1 para. 5.49 states that** *"Senior management should identify who is responsible for the transfer or disposal of records. Records should be categorized and retained for the retention period specified by the organization. After the retention period specified for a record has elapsed, the record can be disposed of. This should be done by, or with the agreement of, the organization".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R5	**Recommendation: SSM should establish a process for the management system records that reflects all types of records generated, and their categorization, retention time and disposal.**

4.4. MANAGEMENT OF RESOURCES

The SSM´s human resources (HR) planning documents for competence management, work planning, resource allocation, and budget development are incorporated into the Authority´s management system, though not in an integrated manner.

Through individual performance appraisals, SSM managers systematically follow-up on staff competence and development needs to ensure that employees have the skills necessary to carry out their duties and to achieve the objectives of the agency within their functional area. For work planning and allocation of resources, SSM uses a systematic planning and follow-up process.

A basic competence profile and performance expectations for all staff at SSM, including managers, are provided in the Employee policy. The recruitment process is well established with a recruitment strategy, routines to support the hiring divisions and the secretariat for human resources, a specialized computer tool and a communication platform. When employees with unique skills are close to retirement, the strategy is to recruit in advance in order to create an opportunity for the transfer of knowledge.

The IRRS team noted that the secretariat for Human Resources is currently conducting competence analyses to identify gaps in existing staff competencies relative to SSM's needs. These analyses are expected to be presented to senior management in late December. SSM has also established recruitment profiles when recruiting new staff.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

SSM has management, core and support processes that are documented and illustrated in a digital process tool. A supporting internal council consisting of the SSM division directors discusses and resolves interface issues between the different processes. Each process has a designated process owner, is reviewed by a process leader with support from process teams and approved by the process owner before use.

The IRRS team was informed that SSM has defined process owners and process leaders for all processes. The steering document for process roles at the SSM (STYR2017-10) describes the tasks of the process forum, process councils, process owners, process leaders and process teams in detail. The assessment of processes is carried out on annual basis by process owners and process leaders to identify needed improvements.

4.6. CULTURE FOR SAFETY

In 2016, SSM adopted the five principles set up in the OECD/NEA publication on "The Safety Culture of an Effective Nuclear Regulatory Body" to characterise the culture for safety intended to be fostered and supported within the organization. The principles of safety culture are documented in the management policy, highlighting the importance of strong leadership, clear accountability, cooperation and open communication, using a comprehensive and systemic approach to safety, as well as continuously learning and improving performance at all levels of the organization. As it was described to the IRRS team, the management system is not fully functional in practice and additional work is needed to develop and implement documented provisions to foster and support a culture for safety as part of the overall organizational culture of SSM. This issue was identified in the SSM's action plan provided to the IRRS

team with the Advance Reference Material. Furthermore, SSM identified the need to further integrate the safety culture with the authority's overall work developing leadership and the organizational culture.

In SSM's Rules of Procedure, the responsibility to promote and support the organizational culture, as well as the culture for safety, is assigned to the secretariat for Human Resources. However, the IRRS team was informed that there is currently no expertise for safety culture in the secretariat for Human Resources. There is however considerable qualified competence in leadership development and development of organisational culture as a whole.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The necessary provisions and competences to foster and support a culture for safety in the organization are not fully in place in the management system.*	
(1)	**BASIS: GSR Part 2 Requirement 9 states that** *"Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them".*
(2)	**BASIS: GSR Part 2 Requirement 12 states that** *"Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture."*
(3)	**BASIS: GSR Part 2 para. 4.24 states that** *"Competences to be sustained in-house by the organization shall include: competences for leadership at all management levels; competences for fostering and sustaining a strong safety culture; and expertise to understand technical, human and organizational aspects relating to the facility or the activity in order to ensure safety."*
(4)	**BASIS: GSG 12 para. 3.9 states that** *"The regulatory body should establish and maintain a programme to develop, foster and evaluate its safety culture. Such a programme should include safety culture self-assessments, workshops and seminars for defining improvement programmes, as well as training and support."*
R6	**Recommendation: SSM should establish necessary provisions in the management system and competences to foster and support a culture for safety in the organization.**

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Self-assessments are conducted every year by process owners, process leaders and with support from process review teams, as defined in SSM's Rules of Procedure. However, there are no specific procedures that describe how self-assessments are to be performed. The Management Policy also provides descriptions for independent assessment and management system review. However, the IRRS team noted that the description for the conduct of self-assessments is not provided in the policy.

SSM also conducts independent assessment (internal audits) of its processes. The responsibility for coordination of internal audits is assigned to the Division for Organisational Services. Internal audit teams at SSM consist of staff selected from across the organization. However, the IRRS team noted that the audit process is not clearly reflected in the Management Policy and is also not in line with the steering document STYR2011-42 (Internal Audits).

SSM has prepared a 4-year programme (2020-2023) for auditing processes in accordance with Internal Audit Steering Document. This document refers to ISO 9001-2015 and ISO 19011-2002 as the standard and guidance for the quality management system. However, the IRRS team was informed that the audit programme was discontinued in mid-2020 and is still on hold. SSM staff explained that this hold was due to COVID-19 pandemic and the reorganization in 2021. The IRRS team also noted that the internal audit

process does not reflect the provisions of relevant IAEA safety standards for auditing the management system. However, the IRRS team was informed that individuals who conduct audits are not involved in assessing their own work.

The senior management group conducts the review of the management system in accordance with the Management Policy which provides the overarching requirements for the conduct of the management system review. However, the IRRS team noted that the frequency of conducting management system reviews is not defined. Furthermore, there is no specific document defining the detailed process for conducting such reviews.

Between 2015 and 2018, SSM carried out several activities aimed at strengthening safety culture. During 2015, SSM conducted several management meetings on the topic, initiated work on how to better include safety culture in its management system, and performed a safety culture assessment. This evaluation was carried out by an external entity.

The IRRS team observed that SSM does not have a specific programme for conducting safety culture self-assessment (SCSA) with a clearly defined methodology, scope, frequency and general conduct of such self-assessments.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM has neither requirements in its management policy nor a documented process for conducting self-assessments.*	
(1)	**BASIS: GSR Part 2 para. 4.11 states that** *"The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system".*
(2)	**BASIS: GSR Part 2 para. 4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization".*
(3)	**BASIS: GSG 12 para. 5.4 states that** *"The integrated management system of the regulatory body is required to clearly specify its organizational structure, resources and processes".*
R7	**Recommendation: SSM should establish requirements for conducting self-assessments in its management policy and develop a documented process.**
Observation: *SSM is currently not conducting internal audits. Furthermore, there are two documents, the management policy and the steering document, that govern the process, which are not in line with each other.*	
(1)	**BASIS: GSR Part 2 para. 6.4 states that** *"Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any resulting significant changes shall be analysed for their implications for safety"*
(2)	**BASIS: GSR Part 2 para. 4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization".*
(3)	**BASIS: GS-G 3.1 para. 2.46 states that** *"The documentation of the management system should be appropriate to the organization and to the work that it performs and should be readily understandable to users".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(4)	**BASIS: GSG 12 para. 5.4 states that** *"The integrated management system of the regulatory body is required to clearly specify its organizational structure, resources and processes".*
R8	**Recommendation: SSM should conduct internal audits according to a well-defined process. The management policy and steering document should be aligned accordingly.**
Observation: *SSM has not established a fully documented process for conducting periodic reviews of the management system.*	
(1)	**BASIS: GSR Part 2 para. 6.6 states that** *"Senior management shall conduct a review of the management system at planned intervals to confirm its suitability and effectiveness, and its ability to enable the objectives of the organization to be accomplished, with account taken of new requirements and changes in the organization".*
(2)	**BASIS: GS-G 3.1 para. 6.46 states that** *"The frequency of review should be determined by the needs of the organization. Inputs to the review process should result in outputs that provide data for use in planning for improvements in the performance of the organization".*
(3)	**BASIS: GSR Part 2 para. 4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization".*
(4)	**BASIS: GSG 12 para. 5.4 states that** *"The integrated management system of the regulatory body is required to clearly specify its organizational structure, resources and processes".*
R9	**Recommendation: SSM should establish a documented process for conducting periodic reviews of the management system.**
Observation: *SSM's management system does not contain provisions to conduct Safety Culture Self-Assessments (SCSA). SSM does not conduct structured SCSA.*	
(1)	**BASIS: GSR Part 2 Requirement 14 states that** *"Measurement, assessment and improvement of leadership for safety and of safety culture. Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization".*
(2)	**BASIS: GSR Part 2 para. 6.9 states that** *"Senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels and for all functions in the organization. Senior management shall ensure that such self-assessment makes use of recognized experts in the assessment of leadership and of safety culture".*
R10	**Recommendation: SSM should develop the methods for Safety Culture Self-Assessments (SCSA) and establish related provisions in the management system.**

4.8. SUMMARY

SSM maintains a strong commitment to continuous improvement of its management system. Senior management recognizes the importance of implementing an effective management system to ensure fulfilment of duties assigned to each division and department within the Authority.

Senior management at SSM has established a vision of the Authority's mission to protect people and the environment from the undesirable effects of radiation. Safety is an overriding priority in SSM´s Vision: "A society safe from the harmful effects of radiation". Goals, strategies, plans and objectives are developed based on the strategic objectives for the period 2021-2025. SSM has developed a road map containing

numerous actions to achieve SSM's strategic objectives. SSM's activities are controlled through a process-based approach. SSM completed a major reorganization in June 2021. SSM evaluates the effectiveness of its management system to identify opportunities for improvement.

There are areas for improvement concerning the comprehensiveness of the existing management system, including the review of the overall structure of management system, the development and implementation of steering documents, the self- and independent assessments of management system, and safety culture.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Authorisation of facilities and activities is defined in the legislation through a series of acts and ordinances, the most prominent being the RPA, ANA and the Environmental Code. These acts and related ordinances prescribe the requirements for the need to hold appropriate authorisations before conducting such activities.

Activities and facilities are typically authorized under the RPA or ANA, but not both. Facilities that are authorized under the ANA are regarded as environmentally hazardous and therefore needs to be licensed according to the Environment Code. The Land and Environmental Code issues the license according to the Environmental Code. Licensing for non-nuclear radiation activities requiring a licence under the RPA, only those that are considered to be environmentally hazardous, as outlined in the Environmental Code, require a licence from the Land and Environment Court.

Whilst SSM and the Land and Environment Court are intrinsically involved in the administration of licences for nuclear facilities, approval by giving permission under the Swedish environmental code and the issuing of a licence for a nuclear facility under the ANA are roles reserved principally for government.

However, the decision of the government is supported by recommendations from both the Land and Environmental Court and SSM, which can subsequently determine the need for additional conditions under the Environmental Code, ANA, or RPA.

However, for some other nuclear facilities and activities, SSM has the authority to issue licences. For the facilities that SSM can issue a license according to ANA, there is no requirement for permission by the government, and the Land and Environmental Court can issue a license according to the environmental code without filing an application to the government.

As a basis for all licences for a nuclear facility, an Environmental Impact Assessment (EIA) should be produced by the applicant according to the requirements in the environmental code. The EIA will provide a basis for the license application to the ANA and the environmental code and should address the potential harmful effects to the public and the environment by the proposed activity, including issues relating to ionizing radiation. The applicant is required to engage with a range of stakeholders through a consultation procedure during the delivery of such assessments.

Licences issued in relation to nuclear installations are, in most instances, granted for an indefinite term, thereby allowing the licensee to continue to operate so long as statutory requirements relating to nuclear and radiological safety continue to be met. Authorizations issued under the RPA are time limited, although any such licences for relevant undertakings (typically relating to medical exposures) issued prior to the current RPA do not have a time limit.

For authorizations issued under the RPA that are time limited, the authorized parties must either seek renewal or revocation of the licence by SSM. Whilst SSM has a procedure for licence renewal, it does not have a process for the revocation of licences.

To ensure that licensees do not overlook the need to seek renewal or request the revocation of licenses, SSM maintains a register and sends reminders to licensees a few months before expiry and a last reminder a month before expiry.

If the appropriate renewal or revocation request action is not taken in a timely manner, appropriate enforcement action is taken by SSM such as an injunction, penalty or prosecution depending on the circumstances.

According to the RPA, the holder of a radiation source or device is responsible for its safety, including in the event that a licence expires.

Applications for authorizations of nuclear or radiological activities that could be environmentally hazardous, are also administered by the Land and Environmental Court under the auspices of the Environmental Code. The preparation and review of an application, and the decision-making relating to the issuing of a licence and licence conditions takes place in open court hearings, and any interested parties can attend such hearings, can offer comments and, by so doing, are allowed to participate, offer comments, be consulted and achieve transparency as regards proceedings. This is acknowledged as an area of good performance.

For nuclear and 'complex' non-nuclear activities, SSM applies a staged process of approval for the various stages of pre-construction, construction, commissioning, and operation of such facilities.

SSM is authorized by legislation (RPA) to approve some lower hazardous activities by a notification process in accordance with a graded approach to authorisation.

The legislation includes provisions for the granting of exemptions from the RPA by SSM, which allows some discretion as to when such exemptions may be appropriate or when licensing or notification may be required.

Authorization processes conducted by SSM are defined, for the most part, in its management system. However, the description of licensing processes within SSM's management system is not yet sufficiently comprehensive (i.e. it does not include all types of licensing, with revocation of licenses and the notifications process being examples). This has also been identified in SSM's action plan. The IRRS team was informed that as SSM progresses the digitisation of its authorisation and wider processes, there is a plan to include all licensing approaches (including the suspension or revocation of licences under the RPA) within the new digital processing tool.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM's management system is not sufficiently comprehensive regarding authorization, eg the notification and revocation processes are not defined.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.17 states that** *"The management system shall specify, in a coherent manner, the planned and systematic actions necessary to provide confidence that the statutory obligations placed on the regulatory body are being fulfilled."*
R11	**Recommendation: SSM should review its authorization processes to ensure that they include clear, documented and consistent processes for all types of authorization, including the notification and revocation processes.**

SSM has undertaken significant work to digitise some of its regulatory processes, representing a significant commitment to modernisation. The web application (SIWA) allows holders of notifiable activities to register the radioactive sources and radiation generating equipment in their possession. SSM intends to complement this with an e-service portal for licensing processes in order to automate part of the process of licence application and management of information by the licensees (SIWAT), which is currently under development. Collectively, these digitisation improvements are viewed as highly beneficial in allowing simple access to a comprehensive and current suite of authorisation processes and to make it simple for source registration and for applicants to seek authorisations. This is acknowledged as an area of good performance.

The IRRS team noted the lack of capacity and resilience of some technical areas to deliver authorisations for licensing of nuclear facilities, nuclear non-proliferation and transport. At present, for these three authorisation activities, there are only 13, 11 and 3 full time equivalents (FTE) of analyst effort available respectively, although there is an intent to increase this by 2 FTEs in the next year. The authorisation analysts are required not only to implement SSMs licensing process, including authorization of NPPs and

Geological Disposal Facility (GDF) authorisation, but also have important functions in Periodic Safety Reviews, review of the R&D-programme submitted by SKB/NPP and clearance activities (each of which requires the involvement of difference disciplines). In addition, a significant number of specialist technical competences appear to be dependent on one staff member or very small numbers of staff (e.g. regulation and approvals relating to "class 7" transport, control and instrumentation, electrical engineering, construction engineering, hydrogeology/rock mechanics, corrosion, transport authorization, criticality specialists, export control, authorisation for medical and industrial applications etc). Whilst SSM has a mechanism whereby the staff responsible for the authorisation process can and are required to seek specialist resources from other teams, there is no clear mechanism to ensure that they will be given appropriate priority or that significant fluctuations in workload are reflected in planning. The IRRS team was informed that there are instances where insufficient resources have been made available at the time at which they were needed, resulting in unpredictable delays to authorisation process timescales. In addition, there is little evidence of capability resilience, generally, as regards loss of staff through illness, resignation or retirements. There is some planning for succession, although it appears to be inconsistent. The IRRS team was informed that there are also challenges around developing resources and skills necessary, in advance, to prepare to authorise potentially novel SMR and new medical technologies. Whilst there are early activities already underway in this respect as regards SMRs, there is a need for SSM preparedness in terms of resources or skills in this respect.

Overall, from a capability, capacity and resilience perspective, the IRRS team noted that the lack of capacity and resilience in the breadth of technical areas and expertise in SSM involved in making authorisation decisions relating to nuclear activities could be a potential challenge to SSM to be able to discharge some of its statutory authorisation duties both currently or should staff become unavailable for any reason.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The small number of dedicated analysts and the lack of capacity of some other specialist staff available are not sufficient to continuously deliver the authorization of nuclear facilities, nuclear non-proliferation, and transport in a timely manner, whilst accommodating retirements, resignations and illnesses etc.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
R12	**Recommendation: SSM should ensure sufficient resources are available to deliver its authorization responsibilities in a timely manner, whilst accommodating retirements, resignations and illnesses etc.**

In addition to the licensing and exemption arrangements provided in legislation, SSM has the mandate to replace a licensing review under the RPA with 'approval by notification' (i.e. as a proportionate means of authorisation of some lower hazard radiation sources – e.g. some dental/veterinary applications of radiation; research and development activities; small amounts of radioactive waste; manufacturing, and import and export of specified nuclear equipment).

An applicant for a licence to conduct an activity needs to submit a demonstration of safety to SSM in order to receive authorisation and to demonstrate that there is provision for authorisations to be obtained at different stages in the lifetime of a facility. These submissions are assessed by SSM to ensure that they are adequate for patient, public and worker safety, and protection of the environment.

SSM has arrangements for appeals by licensees, NGOs and others. If the appeal is done under the ANA, the appeal is referred to the government, with no further right of appeal. However, individuals can also appeal under the Environment Code and RPA, for which further appeals may be possible.

Government decisions cannot be appealed, although challenges of adherence to legal processes are permitted.

The appropriateness of both qualifications and practical experience of Radiation Protection Experts (RPE) is approved as part of the authorization process of the facility or activity, or by other means.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

There is a statutory obligation under the ANA for those who wish to operate a nuclear power plant to have safety and environmental licences granted by the government. The process by which such licences are obtained is, overall, clear and robust.

Where there are changes to licence activities that are outwith that justified within the existing licence and associated regulations/conditions, the licensee must apply for a licence modification or amendment. SSM will only consider such applications if the licensee has already performed an independent safety review of the documents supplied.

Whilst there is a steering document regarding the content of licensing applications for nuclear facilities applicants, there is an increasing demand for further and clearer guidance on form and content of such applications. There is a high level of commitment within SSM to deliver this, and the IRRS team welcomes this and encourages timely progress to be made.

The independence of such licensee internal reviews is overseen by SSM, which examines the output of the independent review process. The IRRS team noted that SSM observes, in practice, clear evidence of an independent challenge culture by the content of the independent assurance reports that it examines.

The licensing for new nuclear power plants in Sweden is restricted, by legislation, to replacement of reactors must be located to one of the three sites with reactors in operation after 31 May 2005and only on the sites where a nuclear power reactor has been in operation after 31 May 2005.

In the granting of such safety and environmental licences, and for other nuclear facilities for which licensing is not the responsibility of SSM, SSM and the Land and Environmental Court act as ‘drafting authorities’ for government. The duty for government to issue such licenses is stated in the ANA and it is not, therefore, a statutory function of SSM. The authorities are required to provide recommendations to government on acceptability based on safety and environmental considerations.

The IRRS team was informed that the views expressed by the regulators are not binding on government as such, which could potentially lead to a situation where government decides to license nuclear facilities against the advice of SSM as the nuclear and radiological safety regulator (reference is made to section 1.3.)

However, usually, the government defines a licence condition requiring the licensee to seek SSM authorisation to construct, commission and operate a nuclear facility. Should government decide not to do so, SSM has the power to issue conditions with regards to safety to the licensee to that same effect. Similar conditions can also be applied under the Environmental Code.

After licence is issued by the government, SSM authorises each stage of the life cycle of the nuclear reactor. By this mechanism, SSM is able to ensure the safety of such facilities in an objective and independent manner.

SSM retains the ability to act independently of government in the interests of nuclear safety, regardless of whether government issues the initial nuclear facility licence.

However, the IRRS team noted that there seems to be a lack of precise clarity over the details of these legalities, recognising that it is a complex concept to articulate.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM is an independent regulator and retains the legal ability to act independently of the Government. However, SSM's independence and ability to ensure safe reactor design, construction and operation, in any instances where it could be possible for Government to grant a licence that acts counter to SSM's advice would benefit from clarification.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 4 states that** *"The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."*
(2)	**BASIS: GSR Part 2 Requirement 8 states that** *"The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use."*
S7	**Suggestion: SSM should consider clearly articulating the basis of its independence in instances where it could be possible for Government to grant a licence counter to SSM advice.**

SSM has the legal authority to issue regulations and to define conditions necessary to ensure the maintenance and continual improvement of safety of nuclear facilities. Failure to comply with such regulations or conditions provides grounds for the government, or SSM as appropriate, to revoke the licence or to suspend activities.

As licences to operate nuclear power plants are not time-limited, licensees are required, at least every 10 years, to perform a periodic safety review to demonstrate that the plant remains safe to operate for its next period of operation. This is subject to appropriate regulatory oversight and assessment.

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

The general requirements, processes and arrangements for authorization of fuel cycle facilities (i.e. fuel fabrication, interim spent fuel storage, and fuel and materials testing) are the same as those described in section 5.1 above and are similar to those described in section 5.2. The only difference is that there is no restriction for the siting of fuel cycle facilities as exists for NPP facilities.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The NPP operators have formed the jointly owned subsidiary Swedish Nuclear Fuel and Waste Management Company (SKB) to develop a solution for their needs as regards a geological disposal for spent nuclear fuel and for low- and intermediate level radioactive wastes.

With regards to the repository for spent nuclear fuel, SKB conducted the siting programme, guided by conditions set by government. SKB has responsibility for producing the necessary documentation required for a licence application, including the Environmental Impact Assessment (EIA). The authorisation process for licensing of geological waste disposals includes, e.g. the potential dispersion of radioactive substances after closure and risks associated with intrusion into the repository. The licensee is required to document the safety of geological disposals prior to their construction, during operation and before closure.

SKB has been given the responsibility by the NPPs for the safe siting and construction of the geological disposal facilities, but should it fail to provide an appropriate solution, the responsibility returns to the NPP licensees. Whilst responsibility for the safety of operation rests with SKB, the responsibility for accurately declaring the waste consigned to such a repository rests with all licensees.

A governmental licensing decision is required for closure of a geological disposal and for enabling conditions to be defined that ultimately lead to the acceptance of responsibility for the closed facility by the State.

Throughout the life cycle of disposal facilities, SSM performs regulatory oversight to ensure that all relevant obligations, requirements and licence conditions are met.

Smaller radioactive waste management facilities, e.g. shallow land burials with limited activity content and with the NPP as the license holder have been approved by both SSM and the Land and Environmental Court under their appropriate respective safety and environmental regulatory frameworks. SSM has also approved that temporary waste storages have been constructed on existing nuclear sites. .

According to issued regulations, licensees are able to perform clearance of materials containing very low level of radioactivity for which the potential for harmful exposures to members of the public is minimal. For materials with at higher content, SSM may approve conditions for specific clearance.

SSM considers the effect of climate change in relation to authorisation of waste facilities, although specific procedures for such have not been developed.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

An authorization is required for the operation of radiation source facilities and for conduct of activities with radiation sources. There are provisions for exemption from regulatory control for very low hazard sources, and clearance criteria have been defined in most cases. However, the IRRS team was informed that these don't exist for sealed sources.

A list of activities that are authorized by notification is set out in regulations, based on a generic risk analysis conducted by SSM. The applicant provides basic data related to the activity and technical data of the source and the practice. Applicants for notification are not required to provide safety related documentation to SSM. SSM has developed a web-based tool where an applicant can notify SSM and receive authorization without any additional review or assessment by SSM of the information delivered. The IRRS team was informed that SSM does not routinely review the information received, to consider safety implications of lots of radioactive sources at a single location.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The current "authorisation by notification" process is based on a generic risk assessment. SSM does not review the information provided to verify that the notified activity falls within the generic risk assessment, nor does SSM assess the safety implications of large-scale inventories of notified radioactive sources held at a single location.*	
(1)	**BASIS: GSR Part 3 para 3.7 states that** *"Any person or organisation intending to carry out any of the actions specified in paragraph 3.5 shall submit a notification to the regulatory body off such an intention. Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible. Notification is required for consumer products only with respect to manufacture, maintenance, import, export, provision, distribution and, in some cases, disposal."*
(2)	**BASIS: GSG-13 para 3.91 states that** *"… The regulatory body should use the information received in the notification process to update the register of sources, facilities and activities and to decide on the level of regulatory control to be applied. The notification should be reviewed and, if necessary, the regulatory body should inform the person or organisation as to what further regulatory interactions will be required."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R13	**Recommendation: SSM should establish a proportionate verification process for authorization by notification to ensure that the notified practice falls within generic safety assessment, including the cumulative impact of multiple radioactive sources.**

SSM also issues export and import licences. SSM has prepared a list of forms to be used by applicants for application for licence. The forms guide an applicant to provide SSM with the necessary information. The IRRS team noted that some forms do not include all necessary safety related information, e.g. management of discharges when unsealed sources are handled and management of storage of sources. In addition, the set of specific forms does not cover all regulated facilities and activities, e.g. no specific form for more complex facilities. SSM has also identified this issue in its action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM has issued, for selected practices using radiation sources, a specific form to be used by a licence applicant. However, the form does not include all necessary safety related information and the set of the specific forms do not cover all types of facilities and activities.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process"*
R14	**Recommendation: SSM should revise its guidance on the format and content of the documents to be submitted by an applicant, in support of an application for a licence, for all radiation sources facilities and activities.**

The review and assessment of license applications is conducted by staff working within SSM's Department for Authorization of Radiation Applications in the Division for Emergency Preparedness, Security and Licensing. Although, in general, the responsibilities for authorization related to radiation sources facilities and activities are well defined, the responsibilities for some specific authorizations such as the use of radiation sources in nuclear facilities and applications associated with the use of depleted uranium are not elaborated. Recommendation R3 in section 3.1 addresses this issue.

Requirements related to modification of a radiation sources facility or activity as well as requirements related to closure are established in legislation.

In the licensing of radiation sources facilities and activities, the applicant is required to provide information on a radiation protection expert who provides advice on safety measures. Such expert may be a staff member, who can also act as a radiation protection officer, or a service provider outside the applicant's organization. For practices that are authorized by notification, there is no requirement for radiation protection experts. SSM regulations do not require the designation of a radiation protection officer, which might create a potential risk that oversight of safety measures is not conducted on a regular basis, especially in those facilities and activities where the radiation protection expert is not a staff member of the facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM regulations do not require designation of a radiation protection officer for a facility or activity, which might create a potential risk that oversight of safety measures is not conducted regularly.*	
(1)	**BASIS: GSR Part 3 para. 3.94 states that** *"Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate: …*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(e) Shall designate, as appropriate, a radiation protection officer in accordance with criteria established by the regulatory body."
(2)	**BASIS: GSR Part 3 para. 3.96 states that** *"Registrants and licensees, in cooperation with employers where appropriate, shall establish, maintain and keep under review a programme for workplace monitoring under the supervision of a radiation protection officer or qualified expert."*
(3)	**BASIS: GSG-7, para 9.49. states that** *"A radiation protection officer should be appointed, when required by the regulatory body, to oversee the application of the relevant regulatory requirements and compliance."*
S8	**Suggestion: SSM should consider requiring the designation of a radiation protection officer for radiation sources facilities or activities to ensure safety measures are implemented on a regular basis.**

SSM has conducted some activities to ensure the safety and security of disused sources and orphan sources. The IRRS team was informed that SSM has a database of all cases in which the existence of orphan sources has been reported over the last fifteen years. SSM has a continuous service for reporting such sources. Whilst it conducts activities to prevent the creation of orphan sources, the IRRS team noted that the arrangements for management of disused sources and discovered orphan sources are not formalized. Adequate regulatory oversight of the storage of discovered orphan sources is not clearly established. The IRRS team was informed that specific campaigns to identify orphan sources have not been conducted for the last ten years.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The arrangements for management of disused sources or discovered orphan sources are not formalized in the SSM management system. Additionally, there is a need to improve the regulatory oversight on the storage of newly discovered orphan sources including establishing a search programme.*	
(1)	**BASIS: GSR Part 3 para. 2.26 states that** *"The government shall ensure that arrangements are in place for regaining control over radioactive sources that have been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorization."*
(2)	**BASIS: Code of Conduct on the Safety and Security of Radioactive Sources para. 22 (3) states that** *"Every State should ensure that the regulatory body established by its legislation has the authority to:…* *(b) ensures that arrangements are made for the safe management and secure protection of radioactive sources, including financial provisions where appropriate, once they have become disused;* *(k) ensure that corrective actions are taken when a radioactive source is in an unsafe or non-secure condition; ensure that, where disused sources are stored for extended periods of time, the facilities in which they are stored are fit for that purpose."*
(3)	**BASIS: SSG-19 para. II.50 22 states that** *"Routine searches for sources are generally passive searches. However, routine searches can also be conducted in an active manner. An example of how this might be done is as follows: In the course of a routine inspection of an authorized user's premises, some additional time could be spent walking through storage areas or basements with a radiation detector in order to see if there might be other sources present, of which perhaps even the user is unaware."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R15	**Recommendation: SSM should ensure that disused sources and newly discovered orphan sources are subject to proper management, including their safe storage. SSM should also develop a programme for search of orphan sources.**

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The Environmental Code, RPA, the ANA, the RPO and the Nuclear Activities Ordinance (NAO) are applicable during decommissioning of licensed activities. In addition to this legislation, SSM's regulations and licence conditions establish more detailed requirements regarding decommissioning. Authorisation to start decommissioning is also dependent on the European Commission's approval of a submission under Article 37 of the Euratom treaty.

The ANA places responsibility for decommissioning of nuclear installations on the licence holder. This responsibility remains until all activities at the facility have ceased and all nuclear material and nuclear waste have been placed into a final disposal facility. Responsibility for nuclear wastes emplaced the disposal facility remain with the waste generator until the facility has been sealed. Under the operational licence, SSM is required to approve the safety assessment for dismantling and demolition, and in the case of nuclear reactors the permission of the Environment Court is required prior to the transition from routine operations to decommissioning and dismantling of NPPs, since this is considered to be a significant change of use in terms of the environmentally hazardous activities it entails. For other nuclear facilities there is a possibility of a simpler process involving "change" that does not require issuing a new licence... The IRRS team was informed that this requires an EIA to be prepared and approved.

Decommissioning is an obligation on the licensee by the general license issued under the RPA. The RPA requires that, where activities involving ionising radiation are discontinued or relocated, the licensee must take necessary measures to enable building structures and areas that may have been contaminated to be cleared as soon as reasonably possible. Additionally, although there is no requirement for specific authorisation for decommissioning in the case of non-nuclear facilities, all such facilities are required to be already licensed.

Given that operating licences under the RPA for non-nuclear activities usually are time limited, should the license expire prior to or during decommissioning, the licensee is required to seek renewal or revocation of the licence. SSM may subsequently choose to limit the activities under the new license to decommission (e.g. remove the licence to conduct other operations, that would be available under the previous licence), but continuing decommissioning without a valid licence is an offence.

Once decommissioning is complete and clearance has been achieved and verified by SSM, the licensee's responsibility for this aspect of their licence obligations can be considered to be discharged. Obligations relating to the safe management of wastes remain, however, until release from regulatory control of the facilities in which they have been disposed or responsibility for the waste has been transferred to another party.

5.7. AUTHORIZATION OF TRANSPORT

SSM is appointed as competent authority for the transport of radioactive material by the Ordinance on Transport of Dangerous Goods. Under the dangerous goods regulations referred to in the Ordinance of Transport of Dangerous Goods, SSM is assigned to do all authorizations required in SSR-6.

For the most common types of authorizations, internal guidelines have been established (i.e. for approval of package designs including validation of foreign package design approvals and for approval of transport under special arrangement). These guidelines set up the general process for these types of authorizations.

The content of approval certificates issued by SSM is consistent with the applicable requirements of SSR-6.

In addition to the authorizations required by SSR-6 and the dangerous goods regulations, in Sweden, licensing is required for any transport of radioactive material in amounts that are not exempt from SSR-6. These licences are issued by SSM in accordance with the RPA and ANA. Furthermore, SSM approves transboundary shipments of radioactive material and waste.

The transport group, within the Department for Nuclear Non-proliferation and Transport of SSM, is responsible for all the above-mentioned authorizations, including review and assessment for these authorizations. The same people are responsible for inspecting the transport of radioactive material. With the currently small number of three persons, the extent of the review for authorization as well as the frequency of inspections is limited by the capabilities of the group, rather than to what is considered necessary. Additionally, it is a challenge for SSM to ensure consistency in the expert knowledge required for the complex regulatory work within the area of transport including the approval of package designs and shipments with only three persons. The IRRS team noted that there is a need for SSM to ensure that there are sufficient staff available for authorization including review and assessment and for inspection for transport, with competences covering all areas of the assessments and inspections necessary. This issue was identified in the SSM's action plan provided to the IRRS team with the Advance Reference Material. Recommendation R4 in section 3.3 addresses this issue.

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

Protection of workers against ionizing radiation and responsibilities for occupational exposures are addressed in the RPA, RPO and SSMFS 2018:1. The ANA, SSMFS 2021:6, SSMFS 2018:2, SSMFS 2018:6 and SSMFS 2018:7 also establish responsibilities for the protection of workers in nuclear and non-nuclear installations. The regulations establish organizational, procedural, and technical requirements for control of occupational exposures, which include designation of controlled and supervised areas, provision for suitable and adequate personal protective equipment for workers, and requirements regarding assessment of radiation exposures to workers.

The RPO establishes requirements for optimization of protection and safety of occupational exposures.

Dose limits are established in the RPO. For occupationally exposed workers above the age of 18, the annual dose limits established in the RPO are an effective dose of 20 mSv, an equivalent dose of 20 mSv to the lens of the eye, an equivalent dose of 500 mSv to the extremities and equivalent dose of 500 mSv to the skin as an average over 1 square centimetre regardless of the surface area exposed. Employment of persons under the age of 18 is prohibited, according to the RPA, if annual doses exceed 1 mSv or such persons may have to participate in nuclear or radiological emergency.

The RPO requires that dose constraints are established as appropriate by the licensee for optimization and for protection and safety.

SSMFS 2018:1 includes provisions for occupationally exposed workers to be classified as Category A and B workers depending on the anticipated annual doses they may receive, in line with the designation of the controlled and supervised areas. Workers who might receive an annual dose above 6 mSv are designated Category A workers, whilst occupationally exposed workers who might receive an annual dose above 1 mSv but not more than 6 mSv are grouped as Category B workers.

According to SSMFS 2018:1, radiation doses for Category A workers should be determined through individual monitoring, using appropriate approved dosimetry; the doses of Category B workers should be monitored through measurements, calculations or assessments to such an extent that it is possible to demonstrate that the classification in category B is correct.

Dosimetry service providers are approved by SSM with the duration of validity of the approval being for two years (SSMFS 2018:9). SSMFS 2018:1 requires the employee or licensee to maintain occupational exposure records.

SSM maintains the National Dose Registry.

SSM does not have internal guidance or an established mechanism for verifying that the classification of radiation workers is in accordance with the regulations.

Authorized parties are responsible for the classification of the workers. For example, regarding nuclear facilities, individual monitoring for category A and B workers is provided and doses for category A and B are recorded in the National Dose Registry.

Regulations (SSMFS 2018:1) require the licensee to involve a radiation protection expert function as regard the application of regulatory requirements for the protection of workers, the general public and the environment from exposure to ionising radiation. The radiation protection expert function needs approval from SSM as an element of the licensing process.

Information and training of personnel as regards radiation protection is provided by the licensee for nuclear facilities (SSMFS 2018:1) and non-nuclear facilities, specific to the type of work and the environment within which the work is to be performed. Records on training of personnel are maintained in nuclear facilities.

According to the Radiation Protection Act, the licensee employing pregnant or breast-feeding workers must ensure that any exposure to ionising radiations, to the foetus and mother respectively, is restricted to that to which members of the general public are limited.

SSM has produced a national action plan for the management of radon risk in workplaces.

Reference levels for the aircrew and space crew due to cosmic radiation are established under the SSMFS 2018:11 regulation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM does not have internal guidance establishing the mechanism for verifying that classification of occupationally exposed workers is in accordance with the regulations.*	
(1)	**BASIS: GSR Part 3 para. 3.73 states that** *"The regulatory body shall be responsible, as appropriate, for: …* *(b) Review of monitoring programmes of registrants and licensees, which shall be adequate to ensure that the requirements with regard to occupational exposure in planned exposure situations are fulfilled;…* *(d) Review of periodic reports on occupational exposure (including results of monitoring programmes and dose assessments) submitted by employers, registrants and licensees;…* *(f) Verification of compliance of an authorized practice with the requirements on the control of occupational exposure."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body."*
S9	**Suggestion: SSM should consider developing internal guidance and establishing a mechanism for verification of the appropriateness of the licensee's classification of radiation workers.**

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

There are requirements for the licensing of a range of medical applications including complex dental procedures, medical X-ray diagnosis, guidance or interventional radiology, radiotherapy, and nuclear medicine, with such facilities being licensed under SSMFS 2018:1. Dental practices that only involve intraoral devices are activities authorized by notification under the SSMFS 2018:2.

The licensing process requires that the regulator reviews the applicants' activity scope, the justification, the organisation, management and control of the activities, equipment and premises, training, safety, physical protection of the radiation sources, waste and decommissioning plans, and protection of patients and workers. Internal templates for review and assessment of the license applications exist for each main type of application. As there is no framework for generic justification (cf. section 9.9), the justification of the types of practices rests solely with the licensees.

If legal requirements are met, SSM issues a licence with a 5-year period of validity. However, licences issued before 2010 are not time limited.

The approach to SSM's authorization process for medical and dental exposures accords with the principles of a graded approach.

Recommendation R13 in section 5.1., addressing the need for ensuring capacity and resilience of technical resources to deliver authorisations in a timely manner, applies also for the domain of medical exposures.

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

For all types of practices, the authorization of potential public exposures is included in the overall authorization process. Before a licence is issued, the applicant must perform an assessment of the potential exposures to the public and the environment. This assessment must include calculations of radiation doses to the public and has to be transparent and kept up to date for the lifetime of the activity.

Licensees are required to operate within dose constraints to the public not exceeding 0.1 mSv per year, within which radiation exposures must be optimised.

There are requirements to restrict members of the public from places where activities involving ionising radiation are being conducted and where members of the public are allowed access, that they must be informed of the risks involved and the precautions to be taken.

5.11. SUMMARY

The statutory framework for authorizations is generally robust, consistent and comprehensive, and the radiological safety and environmental regulators are acting, overall, in accordance with (and delivering their responsibilities under) national legal framework relating to safety and environmental protection.

There is clear evidence of use of a graded approach to ensure that the level of regulatory authorization and oversight is consistent and proportionate to the level of nuclear or radiological risk in specific cases. However, some authorization processes were not clearly defined within SSM's management system.

The process of authorization by notification appears to be, in effect, a passive registration system. Whilst this is not unreasonable, this arrangement is predicated on a generic risk assessment.

The number of analysts available to deliver the licensing of nuclear facilities and of nuclear non-proliferation and transport appear to be small, especially in light of the breadth of skills and technical expertise necessary to make such licensing decisions. In particular, these numbers and those in some other key specialist areas are such that a small number of leavers, sick or otherwise unavailable staff could adversely affect the ability of SSM to discharge elements of its statutory function.

Overall, and notwithstanding the recommendations made in this report, it is evident that the Swedish processes for authorisation of relevant facilities and activities are robust, mature, well-managed and in general overall accordance with IAEA safety standards.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The legal framework for nuclear and radiation safety designates SSM as the organization responsible for review and assessment of relevant safety information to determine whether facilities, activities, and exposure situations comply with regulatory requirements and authorization conditions. The national legal framework describes responsibilities and requirements for performing regulatory review and assessment. SSM has several internal steering documents to guide its staff in the review and assessment process. The content, scope, and frequency of review and assessment activities are generally conducted using a graded approach.

For facilities and activities (with the exception of radiation sources facilities and activities related), SSM conducts review and assessment over the lifetime of the facility or duration of the activity. SSM verifies that licensees conduct periodic safety reviews; manage deviations and events, periodic reporting, and observed deficiencies; and report principal modifications, as required. SSM reviews these activities annually for NPPs and on a longer periodicity for other facilities and activities, based on a graded approach. In 2021, 87 notifications were provided by nuclear power plants and SSM conducted a review of 31 of them. In addition, 114 notifications were submitted by all other types of nuclear facilities and SSM conducted a review of 35.

In addition to these activities, SSM develops an annual supervisory programme that establishes review and assessment plans based on inputs received in the prior year. SSM prepares an annual plan based on concerns raised in previous assessments, results of the integrated safety assessments, and events at facilities. Supervisors from various organizations within SSM conduct workshops to aide in the prioritization of the planned activities, for effective spread across the facilities and activities. If SSM identifies a non-compliance with regulations, they assess the radiation safety significance of the deficiency. SSM takes that into account when conducting the prioritization.

Although SSM conducts this prioritization, which supports graded approach to review and assessment, a detailed process for using risk-information to consistently develop a graded approach does not exist within internal guidance. Lacking internal guidance and criteria, SSM relies only on expert judgment, which could create inconsistency across managers and staff, as well as knowledge management challenges. This issue was identified in the SSM's action plan provided to the IRRS team with the Advance Reference Material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM does not have detailed internal procedures on consideration of a graded approach to the regulatory review and assessment activities. The implementation of a graded approach is only based on expert judgment of the safety significance of the activity and the type of facility, considering factors such as risk information. This is a particular challenge in the area of Integrated Safety Assessment (ISA), where no procedure exists to describe the purpose.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.40 states that** *"The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process (…) The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSG-13 para. 2.8 states that** *"The main factor to take into consideration in the application of a graded approach is that the application of the regulatory functions should be consistent with the magnitude of the possible radiation risks arising from the facility or activity. The approach should take into account any exposures to radiation, and discharges or releases of radioactive substances in normal operation, anticipated operational occurrences and accident conditions, as well as the possibility of events with a very low probability of occurrence, without neglecting very low probability events with potentially high consequences…"*
(3)	**BASIS: GSG-13 para. 3.161 states that** *"In order to provide assurance that all topics significant to safety will be covered consistently with submissions for similar facilities or activities, review and assessment should be carried out by means of a systematic and formalized process implemented through specific procedures."*
S10	**Suggestion: SSM should consider developing internal procedures for review and assessment, including a procedure on the conduct of Integrated Safety Assessments, to provide assurance that the depth and scope is commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.**

SSM utilizes an IT tool called PS to manage review and assessment. PS contains a flow chart for all required steps of the process, including relevant internal guidance. To document its decisions, SSM utilizes an IT tool called SSM360, which includes all final reports on review and assessment, as well as the initial notification from licensees (where applicable) and supporting documentation. The information within SSM360 is publicly available. Information related to supervision activities is entered and maintained in another IT tool, TILLDA, which has the capability to filter data for further analysis. Use of these tools significantly aids in the consistency of review and assessment.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

In SSM, 67 staff members (including 6 managers) in the supervision division have review and assessment and inspection responsibilities. New staff receive training on how to conduct review and assessment activities.

SSM has no external Technical Support Organization (TSO). However, in June 2021, SSM established two departments, Radiation Protection and Environmental Assessment and Plant Safety Assessment, in the Division for Regulation and Knowledge Development. These departments serve as an in-house TSO and provide expertise on a variety of regulatory functions.

SSM has identified that it is lacking competencies within the supervision division. Accordingly, it has increased its staffing plan in some areas and is actively hiring to fill the new positions. In the interim, the review and assessment staff is relying on other divisions that have competency. The IRRS team noted that in the longer-term additional technical competencies in some specific fields will be necessary to effectively meet review and assessment objectives.

If necessary, SSM is able to obtain assistance from external entities, though that is uncommon. SSM also has funding for external research and development, which can be used to complement its review and assessment activities. SSM also utilizes an advisory body of external experts, which meets twice per year. SSM collaborates with international organizations for benchmarking and sharing best practices in some subject areas but could strengthen international cooperation in the area of waste management facilities.

Review and assessment of radiation sources facilities and activities is conducted only when authorization is issued, normally every five years. The details are described in 6.5.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

SSM maintains regulations and guides for safety assessment and analyses by the authorized parties.

If SSM identifies a need for information not contained in an application, SSM contacts the applicants to obtain the additional information. The ANA establishes that authorized parties must provide SSM with the necessary information and documents required for the supervision.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

SSM's supervisory programme for nuclear facilities is divided into six fundamental areas: management and control; safety analysis; design; facility status; operation; and environmental impact. The depth and scope of the review is commensurate with the radiation risks associated with the facility or activity in accordance with the graded approach. SSM utilizes standing groups of experts, e.g. the Notification Processing Group (ABG), to make a first assessment and screening of all notifications. The ABG, in conjunction with assigned site coordinators within SSM, verifies the completeness of the submittals.

SSM communicates with authorized parties as needed throughout the review and assessment process, and occasionally prior to planned submittals. Internal to SSM, communication between the review and assessment function and the inspection function is sufficient because both functions exist within the same division. For each NPP and site facility, SSM conducts a weekly meeting to facilitate communications across divisions.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

SSM reviews activities as divided into sub-processes for review and assessment: periodic safety reviews (PSR); deviations and events; periodic reporting; principal modifications and others. SSM has an annual supervision plan, supplemented by a supervision program which consists of a fixed part, "base review," and a flexible part, "need-based review." The supervisory programme covers a period of 10 years and has 38 supervisory groups. Depending on their risk importance, the supervisory groups occur in the programme every third, fifth or seventh year.

Licensees conduct periodic safety reviews with a maximum interval of every 10 years. The operating licenses for the currently operating NPPs do not specify a time limit for their validity. The periodic safety reviews must consider: the conditions under which the activity is conducted; how systems structures and components are affected by operation and aging; experiences from operating the facility and from the operation of similar facilities; developments in science and technology. The PSR includes an analysis of how the requirements of the ANA, the Environmental Code and the RPA, and the regulations and conditions imposed under those laws are met with regard to safety and radiation protection. The PSR must also include an analysis and statement on how the conditions for these rules will be met until the next PSR is conducted.

Integrated safety assessments (ISA) are conducted annually for each licensee, based mainly on a review of information contained in TILLDA for each facility. An overall professional judgement is made according to four levels: "unacceptable, acceptable, satisfactory, and good." The report links final conclusions and assessment to information, observations, and findings obtained throughout the year. The suggestion in Section 6.1 aims to enhance the ISA process in SSM by clearly describing how the graded approach is used in determining ISA conclusions and ensuring consistency across facilities and time. The IRRS team learned that SSM is planning to develop formal guidance for conducting ISAs. As of the date of this report, work has not yet begun.

Licensees are required to notify SSM of all technical and organizational modifications to a facility, which can affect conditions specified in the safety report. The ABG reviews each report to make a first assessment and screening of notifications and makes a recommendation to division management. Similarly, licensees report events and conditions that have occurred or deficiencies in design, assessment, or operation. The licensee notifies SSM in the daily report sent to SSM and produces a licensee event report (LER) within a

specified time limit. An interdisciplinary group reviews all LERs. All LERs since 1972 are maintained in a database. This information is used as input to supervisory programmes and part of ISAs. The interdisciplinary group issues a yearly report covering trends from the last five years.

Reviews may be conducted of activities reported to SSM or initiated by SSM for other reasons. For modifications, the licensee is required to develop a plan to demonstrate the safety benefit of the modification.

SSM does not license the operating personnel of the nuclear power plants. However, SSM conducts an inspection of operating personnel competencies at least every 5 years. In the interim, SSM gathers observations continually as part of routine activities. If a lack of competency is identified, SSM can issue an Order to enhance competence.

SSM documents the reviews and shares the reports with the licensee, as well as archives the reports within SSM360. The reports provide clarity on what has been reviewed, the results of the reviews and a determination of whether requirements are met. A decision on supervisory measures is then made. The decision describes the relevant requirements.

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

The review and assessment of license applications for fuel cycle facilities follows the general approach described for other nuclear facilities such as NPPs, but their periodicities differ: PSR is performed every 10 years; ISA is performed every two years; and General Safety Review (ABG Group) is performed every second week to assess principal notifications at the supervision level and if needed.

Moreover, every safety notification provided to SSM is reviewed by both, an internal and external committee. As required by SSM, the licensee reviews and assesses the FINAS event database for operational feedback experience of fuel cycle facilities. Some reports that contain operating experience are sent to the different departments of SSM supervisory division. SSM reviews these reports and sends comments to operators in the area of radiation protection, release to the environment, and waste management.

SSM regulations for nuclear facilities state that the management system of operators must integrate all risks. Considerations on the necessary coordination between the different authorities to get a general overview of the risks are discussed in module 1.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Review and assessment of waste management facilities is covered by the specific supervisory programme of SSM. Review and assessment of waste management facilities is performed as described in Section 6.1 of this report. For waste management facilities, with the exception of shallow land burial facilities, the periodic safety review as well as the review of principal modifications follows the procedure for NPP (see Section 6.2).

The main purpose of SSM´s review and assessment for waste management facilities is that the licensee complies with applicable legal and regulatory requirements by reviewing licensee documentation submitted to SSM. In addition to the generic requirements for nuclear and radiation facilities, compliance with specific requirements related to waste management facilities within several guidance documents is verified.

In its review of geological disposal facilities, SSM addresses operational aspects as well as the aspects related to post-closure safety. The assessment evaluates exposures due to the expected evolution of the repository, as well as scenarios with a lower probability. The review and assessment addresses the management of uncertainties in relation to the performance of the safety analysis.

SSM and its predecessors have implemented research programmes aimed at developing in-house competences and tools in the field of geological disposal. The research has been carried out by the authority's personnel and through a network of external experts via a number of international initiatives. These activities were important to support SSM's regulatory functions during the pre-licensing and authorization phase. Although SSM is still involved in international projects like the DECOVALEX international project on thermo-hydro-mechanical-chemical (THMC) processes, the IRRS team observed that SSM has no strategic plan for required research and international activities to support the ongoing regulatory review processes. There is a need maintaining competence in multidisciplinary fields considering the long period of time covered by the licence of geological disposal during which review and assessment will have to be continued.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no long-term strategic plan regarding in-house competences related to radioactive waste disposal, to ensure that capabilities are available for independent assessment when needed and to undertake international cooperation.*	
(1)	**BASIS: SSR-5 para. 3.9 states that** *"The regulatory body … has to maintain competent staff, to acquire capabilities for independent assessment and to undertake international cooperation, as necessary, to fulfil its regulatory functions."*
(2)	**BASIS: SSG-14 para. 3.7 states that** *"The regulatory body has to arrange for independent research and assessments, and has to participate in international cooperation as necessary in order to carry out its regulatory functions."*
R16	**Recommendation: SSM should ensure the availability of competences related to radioactive waste disposal and capabilities to maintain independent assessment and to undertake international cooperation.**

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

SSM conducts review and assessment of documentation provided for notifications and license applications of radiation sources facilities and activities.

Once a practice is authorized, review and assessment is conducted only in case of modifications, incident or accident, or when a new authorization is needed (i.e., five years). However, SSM does not have procedures prescribing criteria for review and assessment and information that is necessary to be provided by an applicant (e.g. information on financial guaranty for management of disused sources and on sufficient competence of workers dealing with radiation sources). This issue was identified in the SSM's action plan provided to the IRRS team with the Advance Reference Material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM does not have a procedure for review and assessment of the information provided by an applicant for authorization of radiation sources facilities and activities in accordance with the criteria stipulated in regulations and guides.*	
(1)	**BASIS: GSR Part 2 para. 4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R17	**Recommendation: SSM should develop a procedure for consistency in review and assessment of information provided by an applicant for authorization of radiation sources facilities and activities.**

Review and assessment are conducted by dedicated SSM staff members who, as a rule, have a technical background and are trained and retrained in legislative matters. However, the IRRS team observed that technical competence of the SSM staff conducting review and assessment of specific complex facilities using radiation sources, such as unsealed sources, could be strengthened. Suggestion S2 in section 3.3 addresses this issue.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Prior to starting an activity, a documented plan for decommissioning the activity is required to be compiled by the licensee. This plan should describe the objectives and time schedule for decommissioning, how decommissioning is to be carried out, and how radioactive materials and radioactive waste are to be managed. The plan should be based on an assessment of various decommissioning approaches appropriate to the nature and scope of the activity. SSM verifies that the plan fulfils the regulatory requirements. SSM regulations require that licensees keep the plan up-to-date while the decommissioning activity is in progress and completed.

In the case of nuclear installations other than nuclear power plants, principal changes to the plan should be reported to SSM. The plan should be resubmitted to SSM as part of the periodic safety review. For other types of installation, there is no requirement for SSM to approve the updated plans, although the plans must be made available on request for SSM inspection.

Licensees of nuclear facilities are required to identify and analyse any decommissioning events and conditions that have an impact on radiation safety before starting an activity. The consequences of decommissioning for radiation protection of the general public and the environment should be assessed and documented. The assessment should be carried out before the activity commences and cover the period while the facility and activity is being decommissioned and beyond. The assessment should be kept up-to-date. A safety analysis report is required to be submitted to SSM for review.

There is not yet a requirement that describes the contents of the final decommissioning report in detail, although overall requirements are specified in SSM's general regulation SSMFS 2018:1. . However, SSM is currently developing a new regulation, incorporating feedback from licensees that are undergoing the decommissioning process. Currently only two nuclear licensees, both on the site of the former Ranstad uranium ore facility, have reached the final step of decommissioning.

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

SSM is responsible for review and assessment required for issuing the authorizations described in SSR-6, including the approval of design of transport packages and special form radioactive material and the approval of shipments. SSM has prepared internal guidelines for assessment and review of package design and transport under special arrangement. The results of the review are documented in SSM360.

The acceptance criteria for the review and assessment for approvals according to SSR-6 are set by the dangerous goods transport regulations. SSM's internal guidelines reflect these requirements. However, the internal guidelines do not specify the different technical assessments to be carried out: mechanical, thermal, activity release, radiation protection, criticality safety. The IRRS team noted that SSM would benefit from including in the internal guidelines specific guidance for the technical assessments and regarding the required competence of the reviewers of the different technical areas. For reviews of criticality safety,

currently an external consultant is available. Assessment in all other areas is currently handled in the transport group of SSM. SSM has just three staff for this activity and competence is mostly concentrated in the area of radiation protection. For validation of foreign package design approvals, SSM significantly relies on the assessment done in the country of origin. For assessment of Swedish designs for packages and special form radioactive material, the transport group within the Department for Nuclear Non-proliferation and Transport of SSM would benefit from increasing staffing and competence in all areas required for the review. Recommendation R4 in section 3.3. addresses this issue.

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

Review and assessment of occupational exposures is performed together with the review and assessment of radiation sources facilities and activities. For nuclear activities and facilities, occupational exposure is included in the PSR and ISA.

SSM regulations require that licensees report annually on doses to workers at nuclear facilities and this information is reviewed by SSM. SSM regulations require licensees to report incidents and accidents with impact on safety and SSM investigates these reports in a systematic manner.

In the National Dose Registry, an investigation level of 6 mSv/year has been established by SSM for $H_p(10)$. Licensees are required to investigate if an event led to the dose exceeding the investigation level and to inform the provider of the health surveillance service for the worker and report the findings to SSM.

Reports of all types of incidents and accidents, and reports regarding potentially exceeded dose limits for occupational exposure from all type of facilities and activities, are considered by SSM in the establishment of the annual supervision plan for review and assessment. SSM uses a survey method for its review of compliance with regulations requirements regarding radiation protection program for non-nuclear facilities.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

SSM performs review and assessment of information relevant to medical exposures in the licensing process and through annual reports, incident reports, and reporting of typical doses for a fixed set of clinical procedures. Templates for the review and assessment of license applications are used and a graded approach is applied.

According to the RPA, the responsibility for generic (level 2) justification rests solely with the licensee. During inspections, SSM verifies that local procedures cover the level 2 justification as well as the individual (level 3) justification including the adherence to national or local reference guidelines.

During inspections, SSM also verifies that procedures for optimization are implemented.

Through its web-application, DosReg, SSM collects data on patient doses in radiology and administered activities in nuclear medicine. This data is used to establish national diagnostic reference levels; the reference levels are used in the licensee's optimisation process. The yearly reporting of the number of procedures in radiology and nuclear medicine is also integrated in this tool. This data allows SSM to identify trends in the use of radiopharmaceuticals in nuclear medicine, x-ray procedures and types of equipment. Most data contained in the system is publicly available. This includes typical doses for a set of procedures including clinical indications as defined in SSMFS 2018:5, with information on the hospital and type of equipment. DosReg is therefore not only a tool for SSM to establish diagnostic reference levels (DRL) and to perform general oversight of patient doses and use of equipment and radiopharmaceuticals, it is also a comprehensive tool for licensees to help them in the optimization process. Further, it allows any interested party, including the general public, to benchmark relevant information on patient dosimetry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM's DosReg web-application is a very comprehensive tool for patient dosimetry. It is readily available for licensees to use in the optimisation of medical exposures to patients. The data is publicly accessible and allows any interested party to find relevant benchmarks for patient dosimetry.*	
(1)	**BASIS: GSR Part 3 para. 3.168 states that** *"Registrants and licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:* *a) For diagnostic radiological procedures, typical doses to patients for common procedures;* *b) For image guided interventional procedures, typical doses to patients;* *c) For therapeutic radiological procedures, absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner;* *d) For therapeutic radiological procedures with unsealed sources, typical absorbed doses to patients."*
(2)	**BASIS: GSR Part 3 para. 3.169 states that** *"Registrants and licensees shall ensure that:* *a) Local assessments, on the basis of the measurements required in para. 3.168, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established (para. 3.148).* *b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:* *i. Typical doses or activities exceed the relevant diagnostic reference level; or* *ii. Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient."*
GP1	**Good Practice: The DosReg portal is a very comprehensive tool for supervision and optimisation of patient dosimetry, both for licensees and for SSM. Additionally, the data on hospitals, equipment and typical doses for procedures, including clinical indication, being open access, allows any interested party to find relevant benchmarks for patient dosimetry.**

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

In applications for and renewal of licenses, the applicant and licensee are required to document the potential public and environmental exposures. The government has assigned SSM the task of identifying and evaluating existing exposure situations. The IRRS team was informed that SSM has evaluated and identified the existing exposure situations in Sweden. The evaluation determined that the following areas are of concern and should be addressed in more detail: radon in indoor air, gamma radiation from building materials in existing buildings, self-harvested food containing Cs-137 originating from the Chernobyl accident and drinking water from private wells containing naturally occurring radionuclides. Reference values have been established for radon in indoor air and for gamma radiation from building materials, but have not been established for self-harvested food containing Cs-137 or drinking water from private wells containing naturally occurring radionuclides. The government has also assigned SSM the task of

establishing protection strategies for those identified existing exposure situations. While SSM is in the process of doing so, this work is not yet completed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The government assigned SSM the task of identifying and evaluating existing exposure situations. SSM's work to establish protection strategies is in progress. Reference values have not yet been established for all existing exposure situations.*	
(1)	**BASIS: GSR Part 3 para. 5.4 states that** *"The regulatory body or other relevant authority assigned to establish a protection strategy for an existing exposure situation shall ensure that it specifies:* *a) The objectives to be achieved by means of the protection strategy;* *b) Appropriate reference levels."*
R18	**Recommendation: SSM should establish protection strategies and reference values for all existing exposure situations.**

The IRRS team was informed that SSM has evaluated the potential risk of discharges to the environment and identified the licensees that must perform source and environmental monitoring. This is being performed by the licensees and the results are reported to SSM for regulatory review. SSM does perform inspections and does perform occasional measurements of samples provided by the licensee, but SSM has not made provision for an independent monitoring of discharges and of the environment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM has not established provisions to conduct independent monitoring of discharges and of the environment.*	
(1)	**BASIS: GSR Part 3 para. 3.135 states that** *"The regulatory body shall be responsible, as appropriate for:* *… (c) Making provisions for an independent monitoring programme. …*
R19	**Recommendation: SSM should make provisions for independent monitoring of discharges and of the environment.**

6.11. SUMMARY

The legal basis and management processes for the Swedish regulatory review and assessment of nuclear facilities and activities is well established. SSM is committed to performing comprehensive review and assessment that meets IAEA expectations.

Some opportunities for improvement exist, such as developing internal guidance to describe how to incorporate a graded approach into review and assessment, which would reduce reliance on expert judgment. In the area of public exposure, SSM should establish reference levels and protection strategies for identified existing exposure situations of concern and make provisions for source monitoring and environmental monitoring to enable independent review and assessment of licensee monitoring.

There are two areas for improvement related to radiation sources, facilities, and activities, namely a need to establish procedure for review and assessment and to enhance technical competence of SSM staff regarding review and assessment of complex facilities with radiation sources.

The DosReg application for patient dosimetry is a good practice.

7. INSPECTION

7.1. GENERIC ISSUES

The Swedish legal framework provides SSM with the authority to enter and perform supervision in all the installations and activities under its responsibility. SSM conducts inspections to verify compliance with regulatory requirements and license conditions. Its inspection activities are carried out, except for transport and physical protection (security), by the Division for Supervision, which includes the departments of:

- Coordination and Human and Organizational Factors (12 people)
- Event analysis and Engineering (14 people)
- General public and environment (12 people)
- Medical and occupational exposure (14 people)
- Operation and decommissioning of nuclear facilities (12 people)

Inspection for transport is carried out by the transport group in the nuclear non-proliferation and transport department on the emergency preparedness, security and licensing division. Inspection for physical protection is performed under the department for Implementation of Emergency Preparedness and Response.

All inspectors are involved in the SSM supervision process, which includes review and assessment, and inspection. SSM has the authority to perform supervision in all the installations and activities under its regulatory responsibility. The respective Supervisory programmes are included in a range of steering documents, programmes and plans.

The SSM supervisory policy is established in the Steering document STYR2011-97. The Supervisory programme is stipulated under STYR2016-4, which establishes the purposes of planned supervision, the obligation to develop supervisory programmes, and the general requirements for the development of these programmes (i.e. objectives, allocation of resources, strategy, responsibilities and the need to keep these updated). All the Supervisory programmes are linked to SSM360. STYR2011-87 states how to assess compliance with requirements during supervision activities and the different type of decisions available to inspectors after supervision. SSM can, as appropriate, also initiate a process of intensified supervision under STYR2012-115.

The periodicity and the scope of the supervisory activities are based on assessments of radiological risk. The supervisory programmes cover each license requirement at least once over a period of ten years. The programmes cover not only inspections but also activities related to review and assessment. There are supervisory programmes for nuclear power plants in operation; nuclear facilities and safe management of radioactive waste; health and medical services; and products, services and natural radiation aspects.

Except for radiation sources facilities and activities, the supervisory programme includes basic and additional inspections on site, and allows for both announced and unannounced. However, in practice very few unannounced inspections are performed. These are neither included in SSMs supervision programmes nor its annual inspection plans.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM's supervision programmes and annual inspection plans do not include unannounced inspections.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R20	**Recommendation: SSM should include unannounced inspections in their supervision programmes and annual inspection plans.**

SSM performs reactive inspections (called rapid inspections) after events happen in facilities and activities within its regulatory responsibility. However, SSM does not have any established criteria to determine when rapid inspections should be performed and how such inspections are to be performed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no procedure for decision making on reactive inspections (rapid inspections) after an event; and no written criteria to decide when a reactive inspection needs to be done, in accordance with a graded approach.*	
(1)	**BASIS: GSG 13 regarding requirement 29 of GSR Part.1 Requirement 29, para. 3.221 states that** *"(b) Carrying out reactive inspections, as appropriate, in response to events."*
(2)	**BASIS: GSG 13 regarding requirement 29 of GSR Part.1 Requirement 29, para. 3.244 states that** *"… a pre-established, graded approach to responding to special circumstances will assist in determining the appropriate level of resources for use in reactive inspections".*
S11	**Suggestion: SSM should consider establishing a procedure and developing criteria for when and how a reactive inspection should be undertaken in accordance with a graded approach.**

SSM has not developed inspection procedures for each supervision programme. SSM has a generic process description and requires that, by way of preparation, inspectors consider: the supervision annual plans, the flow chart describing the supervision process, and the "support package" for the group under supervision, which includes all the guidance necessary to perform the supervision on that group.

Not all the items in SSM's supervision programmes, such as physical protection, emergency preparedness and transport, have correspondent "support package" as guidance supporting the inspectors in planning and performing the inspection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no "support package" (as guidance) for inspectors relating to physical protection, emergency preparedness and transport supervisory programmes for nuclear facilities.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body."*
(2)	**BASIS: GSG-13 para. 3.232 states that** *"For verification of the overall performance of the authorized party, inspections of adequate depth should be conducted in a wide range of subject areas and at appropriate intervals. Each planned inspection should have objectives that have previously been specified by the regulatory body to serve to the extent practicable as guidance for inspectors."*
R21	**Recommendation: SSM should develop guidance for conducting inspections in the areas of physical protection, emergency preparedness and transport.**

7.2. INSPECTION OF NUCLEAR POWER PLANTS

The document 20-2694 (issued in 2020) describes the supervisory programme for "Supervisory area 1: NPP in operation." The document describes the basic supervision and the need-based supervision. The need-based supervision is based on a needs assessment based on for example the integrated safety assessment, events etc. The document provides examples of when inspection (compliance and surveillance) can be used. The NPP's supervisor programme considers six functional areas (namely safety management including management system, radiation safety analysis, design, plant/facility status, prerequisites for operations and environmental impact) and 38 supervision groups to be undertaken at a frequency of 3, 5 or 7-years depending on the group, which fulfils the overall objective of completing the entire supervision program on NPP every ten years. Each supervision group has, or is completing, its own "support package" to guide inspectors in performing the supervision. Each includes requirements, general advice, guidance text and other assessment criteria. SSM has a matrix-table matching requirements versus supervision groups for NPPs.

The ISAs are performed under expert judgement and SSM has identified that there is not yet a complete alignment between the supervisory program (6 functional areas, 38 supervisory groups) and the ISA (17 areas). This issue was identified in the SSM's action plan provided to the IRRS team with the Advance Reference Material.

The ISA considers the complete set of outcomes and findings resulting from the supervision process on each NPP, that must be included in TILLDA databases (review and assessment, and inspections), concluding on the necessity for needs-based inspections and other additional actions. There are no steering/directing documents as to how the ISA should be carried out. Suggestion S9 in section 6.1.1 addresses this issue.

There are no resident inspectors assigned to Swedish NPPs, although there is one site coordinator per NPP site. They act as focal points and coordinators for SSM at each of these NPP. They discuss their most relevant information with other respective contacts point at the NPP, on a weekly basis. That includes discussion of relevant information on SSM inspection's findings, and the subsequent actions taken by the licensee. The site inspectors are then responsible for preparing and updating the annual inspection plan for their respective NPP.

Regarding the inspection types, unannounced inspections are not included in document 20-2694 even though they are occasionally undertaken. The IRRS team has identified that, since 2019, SSM has performed 2 unannounced inspections in Forsmark and in Oskarshamn respectively, both in 2020. As SSM does not have resident inspectors at the NNP, some aspects of daily work and control room activities, shift handovers (specially out of working times), surveillance test of very low frequency etc, are not adequately covered under announced inspections. Recommendation R21 in Section 7.1 addresses this issue.

In 2022, SSM has performed and reported 49 inspections to the date in the Swedish NPP (12 compliance, 37 surveillance), 91 in 2021 (16 compliance, 75 surveillance), and 106 in 2020 (28 compliance, 78 surveillance).

There is no clear or obvious link between the 38 supervision's groups under document 20-2694 and the regulatory inspection areas described in GSG-13, annex IV for NPP under operation. As regards refueling outages, the IRRS team has identified that to perform an inspection during outages is only required under supervision group 29 (work in controlled area), but not under the supervision group 25 (operational management), where control room operations are included. SSM performs one inspection per outage per unit including, as a minimum, involvement of experts from the Department for Medical and Occupational Exposure, who are responsible for supervision groups 29, 30 and 31. The inspection includes plant walk-downs, inspection of areas not accessible during normal operation, and interviews on site. The IRRS team has identified that often but not always, experts from other departments pertaining to the Division for

Supervision are participating in the inspection team. Consequently, some aspects of performance relating to operation under refueling outages (as indicated in annex IV) are not inspected every time (shifts turnovers, status of control room, surveillance test only performed during outages etc).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Inspections of control room activities, shift turnovers, surveillance tests performed during outages, operating configurations of systems important to safety etc, are not performed at every refuelling outage.*	
(1)	**BASIS: GSG-13 para. 3.271 states that** *"Examples of where such surveillance may be useful include the following: (a) Workplaces; (b) Transfer of jobs between persons; (c) Radiation protection arrangements including boundaries of controlled areas; (d) Items important to safety for the facility or activity; (e) Fire barriers; (f) Housekeeping; (g) The presence of management; (h) Internal and external interfaces and communications; (i) Arrangements for emergency preparedness and response."*
(2)	**BASIS: GSG-13 para. 3.259 states that** *"This Safety Guide covers a wide range of types of facility and activity, and it is not possible to provide details of specific areas that would be subject to inspection at each lifetime stage for each type of facility and activity. The degree to which the areas should be considered will depend on the nature of the facility or activity and the risks associated with it. Major inspection areas for nuclear facilities are listed in Appendix IV"*
S12	**Suggestion: SSM should consider expanding the scope of its NPP refuelling outage inspection activities and revising the refuelling outages guidance accordingly.**

After the re-organization of SSM, the division now acts independently from the other divisions, being responsible for the development and fulfilment of the supervisory programmes and annual supervision plans. The division for supervision sometimes needs some support from experts of the division for Regulation and Knowledge Development (regarding structural integrity, as for example).

The need for Supervision division to interact and get support from the other divisions; to improve the links and connections between analysis, licensing and supervision functions in order to improve the integrated safety assessment; the high turnover of supervision staff as a weakness; and need for training and retraining of inspectors have been identified by the IRRS team and the first two issues have been identified in SSM's action plan provided to the IRRS team with the Advance Reference Material. Recommendations R3 and R4, as well as Suggestion S2 in module 3 address this issue.

The process for supervision, including inspection, is described in an internal flow chart. The inspection findings (good practices and deviations) are communicated to the licensee at the exit meeting, and the inspection reports, after an internal independent review, are sent to the licensee. SSM classifies deviations as being of minor, moderate or major importance and there are not established quantitative criteria regarding the risk impact to the plant to categorize the inspections findings, in accordance with a graded approach. This issue was identified in the SSM's action plan provided to the IRRS team with the Advance Reference Material. The IRRS team encourages SSM to establish quantitative criteria based on the risk impact to the safety of the nuclear power plant to perform the assessment of deviations, in accordance with a graded approach.

The SSM programme on inspection gives a strong commitment to supervision of safety management, including management systems being a "core area" under the supervisory program. SSM has allocated significant resources to this (11 of 67 people in the division are experts on human factors), and the yearly ISA allows SSM to identify crosscutting aspects related to management, control and governance, clearly focused on making the licensees primarily responsible for safety. The IRRS team acknowledged this as an area of good performance.

SITE VISIT

The IRRS team observed an inspection at Forsmark nuclear power plant and attended part of a 'management of safety' inspection. Specifically, the purpose of the inspection was to check effectiveness of corrective measures adopted by the NPP in safety management in response to SSM findings from previous regulatory oversight. This included unclear interfaces between different organizational units, unclear division of responsibilities, decisions being delayed, management system being ineffective in some areas, lack of governance in different projects operated by the plant, etc. The IRRS team observed the entrance meeting and four interviews of plant managers at different levels, including the plant safety manager. The inspection was conducted in Swedish but the IRRS team received a very good summary of discussions at the end from SSM's members. This inspection was planned for three days. The exit meeting was planned to be held five days later through video link. The SSM team was led by a human factors specialist with three other participating inspectors (the site coordinator and event analysis and human factors inspectors). The IRRS team observed that SSM and the licensee exchanged opinions freely with very good communication being maintained throughout the interview. Afterwards, the IRRS team interviewed the licensee without the presence of the SSM (head of the safety and quality department, head of engineering department and operations manager of Unit 2 being interviewed). The licensee managers confirmed the good relationships with SSM in general, and their commitment to solve in a timely manner the inputs and findings coming from SSM's supervision, including them under their internal corrective action programme. However, the plant managers also expressed the view that more extensive coordination between them and SSM management, greater involvement on site by SSM inspectors and more technical and in-depth inspections/reviews by SSM would help foster better safety and better focus on continuous improvement of safety.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

The general requirements, process and arrangements for inspection of fuel cycle facilities are mainly the same as those described in section 7.1 above.

The supervision programme for FCFs is based on:

- Basic supervision over 23 supervisory areas that are completed every 10 years (separated into three groups, i.e. P1 to 3 based on risk. Each group has a defined periodicity of 4, 6 or 8 years.
- Needs driven supervision determined on a yearly basis.

An annual steering document describes the supervision programme based on these two types of supervisions. It details the topics of inspections but doesn't give the number of inspections, which is defined in another document provided to the licensees. A minimum number of inspections may be set for the different levels of facilities in the guidance for inspectors. In 2021, 6 basic inspections and 9 needs-driven inspections were carried out on the Westinghouse facility.

In 2019, a working group defined a supervisory programme for non NPP facilities based on the NPP programme. It defined areas in accordance with a graded approach, developing 23 supervisory programme areas out of the 38 NPP supervisory programmes. This programme for non NPP facilities has not been reviewed and this graded process approach, whilst based on experience, is not consistently documented.

The periodicity of supervision defined for certain areas, such as for radiation protection, where extra basic inspections have been added, is not followed by SSM. Some areas under the responsibility of SSM are not covered by the FCF supervision programme, such as transport (transport department), chemistry programmes, and physical protection which are, however, considered in the NPP programme. Moreover, there is no specific guidance for inspectors, especially for some areas that cover a large scope of safety issues, such as maintenance programmes, ageing management, environmental qualification, surveillance programmes and functional testing. These relate to different areas of the NPP programme. Support packages

for inspectors for the supervision programme of non NPP facilities are not yet fully developed. A matrix-table relating requirements and criteria from regulation that have to be inspected and supervision areas has been developed for NPP programme but doesn't exist for non NPP facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A new supervision programme for non NPP facilities has been implemented without any further assessment of where to focus the work and guidance for inspectors. Moreover, some areas under the responsibility of SSM are not covered by the FCF supervision programme, such as Chemistry and Physical protection.*	
(1)	**BASIS: GSR Part 1 (rev. 1) para. 4.52 states that** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 (rev. 1) para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body."*
(3)	**BASIS: GSG-13 para. 3.232 states that** *"For verification of the overall performance of the authorized party, inspections of adequate depth should be conducted in a wide range of subject areas and at appropriate intervals. Each planned inspection should have objectives that have previously been specified by the regulatory body to serve to the extent practicable as guidance for inspectors."*
R22	**Recommendation: SSM should enhance the supervision programme for fuel cycle facilities in order to cover all regulated areas and to determine the associated frequencies in accordance with a graded approach.**

Internal transports are included in the Supervisory area: "Handling of radioactive materials and waste". There is no support package for transportation inspection yet.

It is noted that there have been no unannounced inspections since 2018. Recommendation R21 in section 7.1 addresses this issue.

Inspection findings are managed and followed-up using the TILLDA supervisory database.

The IRRS team visited the Westinghouse fuel manufacturing site in Västerås to observe an inspection relating to embedding of learning from operational feedback experience. The licensee was provided with an early copy of the agenda.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

Inspections of waste management facilities are performed in accordance with SSM's Supervisory policy and processes. The inspection effort for the supervision of waste management facilities is adequate.

SSM has site coordinator inspectors for waste management facilities. The site coordinator is the point of contact between the regulator and licensee. They coordinate the inspection activities of the site for which they are responsible.

The supervisory program for Waste Management Facilities is defined annually and focuses on compliance with regulatory requirements and license conditions. The main purpose of the supervisory programme for waste management facilities is to verify the licensee´s compliance with applicable legal and regulatory requirements.

The IRRS team accompanied four SSM inspectors during an inspection of the Ågesta NPP (which operated from 1964 to 1974). Dismantling started in 2020. The IRRS team was informed that some of the radioactive waste generated by the decommissioning will be placed in interim storage at the Studsvik site until the appropriate geological disposal for long lived waste has been authorised and taken into operation (i.e. anticipated in the 2050s).

The inspection observed by the IRRS team was related to transport activities (see section 7.7) and the management of radioactive waste. For the radioactive waste management part, the inspection focused on the competence and training of the persons working at the facility, the records and documentation of the waste and the database management system. The IRRS team was able to observe good preparation for the inspection and the inspectors' interaction during the inspection. The facility's staff showed a constructive dialogue, which helped enhance relationships between the licensee and SSM. The discussions between the regulator and the licensee reflected the good technical knowledge of the SSM inspectors. The role of the site coordinator appeared essential to ensure continuity and consistency between the inspections.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

SSM performs inspections in all areas of its competence and has full access to facilities to conduct inspections. SSM's planned inspections are announced well before the inspection date, with a pre-inspection meeting taking place with the relevant representatives of the operator. Basically all SSM's inspections are announced and the IRRS team was informed that non-announced inspections are seldom performed. Recommendation R21 in section 7.1 addresses this issue.

During 2021, SSM conducted twelve medical inspections and 40 industrial and veterinary medicine inspections. However, due to the pandemic, data on inspections performed in 2021 are not representative. The actual operators to be inspected are not defined in Annual plans for inspections. For 2022, altogether about 57 inspections have been planned. The IRRS team was informed that inspection of radiation sources facilities and activities is based on non-documented risk assessments of practices using a graded approach. The IRRS team noted that there is no stipulated frequency of inspections for radiation sources, facilities and activities of SSM's inspection programme. The annual inspection plan does not include inspections of medical cyclotron facilities, temporary storages of sources including disused sources and orphan sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM does not stipulate the frequency of inspections for radiation sources facilities and activities. The SSM inspection programme does not include inspections of temporary storage of disused and orphan sources.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para.4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
R23	**Recommendation: SSM should revise its inspection programme for radiation sources facilities and activities in accordance with a graded approach. The programme should stipulate the frequency of inspections and cover temporary storage of disused and orphan sources.**

SSM empowers its staff to perform inspections, which are organized and coordinated through the Division for Supervision. Inspections are delivered by nine inspectors who also inspect non-ionizing radiation areas. Six inspectors are dedicated to inspection of medical facilities, and three to industrial and research respectively. The inspectors are mainly medical physicists or engineers. The IRRS team noted that there is no systematic documented technical training and retraining of inspectors. Suggestion S2 in section 3.3 addresses this issue. However, the IRRS team was informed that inspections are always conducted by two inspectors, usually one senior inspector and a less experienced staff member in order to benefit from sharing experience.

Inspectors are using checklists to prepare for and conduct inspections. The IRRS team noted that the number of checklists were limited, and inspectors do not have a procedure for performing visual observation or sampling. They also do not use passive dosimeters during inspection and the IRRS team was informed that the number of electronic dosimeters available in SSM is limited. The inspection reports are presented to the inspected operator. Reports are documented. However, the IRRS team noted that there is no procedure in place for follow-up of corrective actions required by SSM inspectors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM does not have comprehensive procedures and checklists for all facilities and activities and regulated areas. SSM does not have a procedure for follow-up of corrective actions required to be addressed by an operator.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para.4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body."*
(2)	**BASIS: GSR Part 2 para.4.28 states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation."*
R24	**Recommendation: SSM should develop a complete set of procedures and checklists for all areas and types of inspections of radiation sources facilities and activities. SSM should develop a procedure for follow-up of required corrective actions for radiation sources facilities and activities.**

The IRRS team noted that SSM inspectors do not perform any measurements or confirmatory tests during inspection of radiation sources facilities or activities for independent verification of the operator's safety measures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM does not perform independent measurements or confirmatory tests when inspecting radiation sources facilities or activities.*	
(1)	**BASIS: GSG-13, para 3.268 states that** *"The inspection procedures of the regulatory body should incorporate and use a variety of methods, as follows:…* *(d) Confirmatory tests and measurements.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S13	**Suggestion: SSM should consider introducing verification measurements and confirmatory tests when conducting inspections of radiation sources facilities and activities.**

The IRRS team also observed an inspection of Gems Pet Systems AB, Uppsala. The IRRS team observed that well prepared interviews were conducted by the inspector as well as good cooperation between the operator and SSM. Well-prepared entrance and exit interviews were conducted as well as interviews with workers when visiting laboratories and other premises. In the discussion with facility representatives, it was outlined that this was the first inspection for about 13 years, but noted good cooperation with SSM whenever needed. The licensee expressed a need for more guidance from the regulator on management of radioactive waste under temporary storage. Recommendation R28 in section 9.1. addresses this issue.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

Inspections of decommissioning facilities are performed in accordance with SSM's supervisory policy and processes. The inspection effort to deliver the supervision of decommissioning activities is adequate.

The inspection plan for decommissioning is defined on a yearly basis and focuses on monitoring compliance with regulatory requirements and license conditions.

The main purpose of SSM´s inspections during decommissioning is to verify the licensee´s compliance with applicable legal and regulatory requirements. SSM's inspection focuses on operation of dismantling and demolition equipment; waste characterization; sorting, handling and clearance of materials; radiation protection; and monitoring of authorized releases of radioactive substances to the environment. A number of aspects are subject to regular supervision (e.g. the management system, the operational activities, procedures and records, competence of staff and safety culture).

Through application of a graded approach, SSM's inspections during the decommissioning of non-nuclear facilities cover the same areas as during the decommissioning of nuclear facilities.

The radiological end-state of the facility is verified by SSM during the authorization for clearance of the remaining building structures and areas.

7.7. INSPECTION OF TRANSPORT

SSM inspects the transport of radioactive material. Each year, SSM creates a plan for announced inspections to facilities that act as a consignor, consignee or shipper of radioactive material (e.g. nuclear facilities, hospitals, radiographers) and for "common inspections" of the transport practice together with other relevant authorities. This planning is done considering the risks associated with different kinds of transport, experience from previous inspections as well as international experience, but not reflected in some steering document ("supervision programme"). The inspections in facilities (1-2 per year) are focused on an audit of the management system of the facility for the transport of radioactive material, including its implementation. The common inspections (8-10 per year) look at the shipments themselves: in harbours, airports, goods terminals, on road and rail. They are carried out in cooperation with the coast guard, police, Swedish Civil Contingencies Agency (MSB) and the Transport Agency. Additionally, there is surveillance done in some facilities to establish whether further inspections are necessary.

The planned inspections are well prepared, including the assessment of documents requested before the inspection and creation of a detailed plan for the inspection. The inspections are carried out in accordance with that plan and with IAEA standards and guides.

Inspection for transport is delivered entirely by the transport group (3 people) in the Department for Nuclear Non-Proliferation and Transport of the Division for Emergency Preparedness, Security and Licensing. The frequency of inspections is adjusted to the number of available inspectors. No long-term written supervision program has been created for transport, although inspections are planned on an annual basis. Manufacturers of packages are currently not inspected, although SSM informed the IRRS team of their intention to inspect a manufacturer of special form radioactive material next year. The frequency of inspections to sites handling radioactive material is too small comparing to the high number of activities related to transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM has not developed a supervision programme for the transport of radioactive material.*	
(1)	**BASIS: GSR Part 1 para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach".*
R25	**Recommendation: SSM should develop the supervision programme for the transport of radioactive material.**

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

SSM carries out inspections of nuclear and non-nuclear facilities regarding occupational exposure.

During the compliance inspection the authorized party is required to provide information on the number of workers in the facility, on the doses received by workers in the facility, on procedures for establishing dose constraints, on the classification of work areas and the warnings signs on such areas, on the provision of personal protective equipment, on the training of workers, on the information provided to female workers, and on the records of accidents and incidents.

The observations made during the inspection in relation to occupational radiation protection are included in the inspection report that is provided to the authorized party.

SSM has the expertise to take measurements of the radiation levels in the controlled and supervised areas, although this is not done in practice. Suggestion S12 in section 7.5. addresses this issue.

SSM inspectors are considered as visitors during the inspection and the radiation doses to visitors are measured in controlled area where exposure to ionizing radiation may occur according to the SSM regulation (SSMFS 2018:1) by using a dosimeter of an instant reading type with an alarm function.

Reference levels for radon are established in the RPO 2018:506 and SSM has elaborated in the National action plan for management of radon risks in workplaces. However, verification of radon in workplaces is not currently included in the inspection programme of SSM. This issue was identified in the SSM's action plan provided to the IRRS team with the Advance Reference Material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *Verification of the radon level in workplaces is not included in the inspection programme.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 para. 5.27 states that** *"The regulatory body or other relevant authority shall establish a strategy for protection against exposure due to 222Rn in workplaces, including the establishment of an appropriate reference level for 222Rn. The reference level for Rn-222 shall be set at a value that does not exceed an annual average activity concentration of Rn-222 of 1000 Bq/m3, with account taken of the prevailing social and economic circumstances."*
S14	**Suggestion: SSM should consider including verification of the radon level in workplaces in its inspection programme.**

7.9. INSPECTION OF MEDICAL EXPOSURE

SSM has a supervisory programme for medical facilities (15-1224) that covers medical exposures as well as occupational exposures, radioactive waste and security aspects with respect to HASS in the healthcare sector.

A graded approach is adopted on the basis of a risk analysis for activities involving ionising radiation in medical facilities (15-273).

During compliance inspections, all procedures of the licensee as required by the regulations are reviewed and, through interviews and site visits, the inspector verifies whether these are understood and applied by the relevant health professionals. More focused thematic inspections are also performed.

The inspection programme does not cover licensees for which the risk has been assessed as low in the risk analysis. In total, only 10 to 15 inspections per year are performed in medical facilities, mainly in radiotherapy departments and some radiology departments. SSM does not have an inspector for nuclear medicine since more than one year. SSM should review its inspection programme to revise the frequency of inspections for medical exposure considering the number of medical facilities in Sweden. Recommendation R24 in section 7.5. addresses this issue. The IRRS team noted that there is a need for increasing the number of SSM's inspectors for medical facilities. Recommendation R4 in section 3.3. addresses this issue.

7.10. INSPECTION OF PUBLIC EXPOSURE

Inspections of public exposures from non-nuclear authorized parties are integrated in the SSM inspection programmes and are included in annual inspection plans.

SSM performs specific inspections, with focus on public exposures, on NPPs and other nuclear facilities. The frequency varies, but the IRRS team was informed that these are done at least every 7 years per facility and that SSM also meets with the licensees in between inspections to discuss and assess status and performance. Additionally, SSM annually receives information, including data from nuclear facilities on discharges and environmental monitoring and these are used to prepare the inspections on public exposures.

The IRRS team accompanied SSM on an inspection at a nuclear facility where the focus was on public exposures and environmental monitoring. There were two inspectors from SSM performing the inspection, which was very thorough, with physical inspection of the premises and individual interviews of persons with different responsibilities in the organization, including laboratory operators and management. The inspectors focused on the licensee's environmental monitoring programme, including technical details, staffing, management etc. The inspectors were competent and provided guidance without compromising their independence and authority as inspectors.

7.11. SUMMARY

The inspection process for nuclear facilities, transport, medical exposures and the protection of exposed workers, the public and the environment during the use of radioactive materials is described in the SSM management system, which needs to be fully implemented.

Unannounced inspections are not included in the supervisory programmes and inspection annual plans. The SSM inspection programme neither include the frequency of inspections for radiation sources facilities and activities nor inspection of temporary storages of disused and orphan sources.

SSM is performing reactive inspections, but SSM does not have any process or guidance to decide when and how to perform them.

Some of the "support packages" for inspectors, used as guidance to perform inspections under each supervision group, are either under development or not developed yet. The procedures and checklists for conducing specific inspections of radiation sources facilities and activities should be completed.

SSM should reinforce the competencies within its supervision division to ensure the availability of the necessary knowledge to perform their responsibilities in an effective and efficient way, and the training and retraining of inspectors on technical matters should be improved.

Regarding inspection on NPP, SSM should consider reinforcing the inspection activities during refuelling outages and developing quantitative criteria to categorize the inspections findings.

The SSM programme on inspection gives a strong commitment to supervision of safety management, clearly focused on making the authorized parties primarily responsible for safety. The IRRS team acknowledged this as an area of good performance.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The Act on Nuclear Activities (ANA), the Radiation Protection Act (RPA) and the Environmental Code provide SSM with the legal authority to enforce the regulations and its decisions. However, there is currently no penalty for non-compliance with (some) provisions of the RPA and with the regulations under the RPA, which poses a risk to the effectiveness of the regulatory framework and the ability of SSM to enforce compliance with its legislation in some cases. The IRRS team noted that work is ongoing to correct this omission. In the meantime, a limited possibility to overcome this problem is to use instead SSM regulations linked to relevant paragraphs of the RPA to build the legal case in the event of non-compliances. Recommendation R1 in section 1.3. addresses this issue.

An overarching principle for enforcement, as expressed in the Administrative Procedure Act, is that a measure shall not be more far-reaching and burdensome than needed to obtain its objectives. Based on this legislation, SSM has established an enforcement policy which is implemented through the recently revised internal document STYR2011-87.

Enforcement actions by SSM, which are used in accordance with a graded approach, include remarks in inspection reports, injunctions, prohibitions to continue the operation, revocation of licence and implementation of corrective actions at the expense of the licensee. Injunctions and prohibitions may include a conditional fine for non-compliance.

In specific cases defined in the legislation, SSM has to involve the office of public prosecutor in the enforcement process. The interface between the public prosecutor and the regulatory body is clearly defined. There is provision for certain flexibility for SSM to decide between SSM enforcement and prosecution in cases of lower importance.

Enforcement actions taken by both SSM and the public prosecutor focus mainly on organisations, rather than individuals. In recent years, SSM has put emphasis on promoting high levels of safety management at nuclear facilities, including the capacity of licence holders to analyse root cause and correct the non-conformances themselves. Such measures show that safety culture concept is considered in the area of enforcement in Sweden.

The licensee has in all cases the right to appeal any enforcement decision made by SSM or the public prosecutor. Recently, a high ratio of appeals cases had been successfully defended by SSM

SSM STYR2011-87 and internal document 20-2447 contain basic criteria and guidance for different enforcement mechanisms used by SSM. Templates are also available for SSM staff, including for the four most frequent cases associated with injunction.

8.2. ENFORCEMENT IMPLEMENTATIONS

Practically in all areas regulated by SSM, the most common enforcement action is to make a remark in an inspection report. The second most frequent enforcement action is to issue an injunction. SSM issues about 30-40 injunctions annually. The licensee is required to inform SSM when the corrective action is completed. SSM can also check the effectiveness of the corrective action during inspections, however this is not done systematically.

The follow-up of corrective actions is the responsibility of a SSM inspector who is usually the inspection leader. For nuclear facilities, the findings stemming from an inspection or a regulatory review and assessment are recorded in a database. The database is used to monitor the implementation status of corrective actions. For other regulated areas, tailored tools, such as spreadsheets with deadlines, are used by different SSM departments to facilitate the monitoring and follow-up of corrective actions.

The IRRS team was informed that an SSM inspector can take immediate on-site enforcement action where safety so necessitates. This power is conferred by ANA and RPA to SSM then delegated to the inspectors by the Rules of Procedure of SSM. Such a decision made by the inspector shall be reviewed by the Director General as soon as possible.

The most important enforcement actions taken by SSM are published on the SSM website and in the annual reports. Stakeholders interested can get more information on enforcement actions in accordance with the Law on Free Access to Public Information and send requests to SSM.

Training in the area of enforcement is done through a specific module of the SSM standard training programme. Enforcement aspects are also covered somehow in other modules of the SSM training programme such as the supervision and inspection module.

The IRRS team reviewed sample enforcement cases of different level and related to different facilities and activities.

8.3. SUMMARY

A comprehensive enforcement regime is in place in Sweden. However, the RPA revision from 2018 does not provide the authority to use penalties to enforce (some) parts of RPA and regulations under the RPA. This power will be restored through legislative change to the RPA that is in progress at the moment.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Swedish legislative and regulatory framework for nuclear and radiation safety is established in the Act of Nuclear Activities (1984:3) (ANA) and the Radiation Protection Act (2018:396) (RPA), and their ordinances: the Nuclear Activities Ordinance (1984:14) and the Radiation Protection Ordinance (2018:506). These documents establish the areas related to safety on which the Government or SSM may issue regulations as necessary. The legal framework on safety of the transport of radioactive material is also set by the Act and Ordinance on Transport of Dangerous Goods, specified by the dangerous goods transport regulations issued by Swedish Transport Agency and the Swedish Civil Contingencies Agency (MSB).

SSM can issue general advices and guides as necessary.

As described by its management system, SSM issues regulations for facilities and practices under its regulatory control. The type of authorization i.e., licensing and notification, to be issued for a facility or an activity is selected in consideration of its complexity and risk in accordance with a graded approach.

Regulations for facilities that are required to be licensed are structured in different levels. The first level provides general regulatory requirements that shall be observed by any licensee; the second level provides specific requirements for a particular type of facility or activity; and the third level consists of compliance requirements concerning technical aspects as well as specific aspects of radiation safety.

A well-defined steering document (or procedure), STYR2011-51, established under SSM Management system, describes how new regulations are developed and how they can be amended or repealed. This steering document includes a requirement to perform an analysis and prepare a report where several matters have to be assessed before drafting a regulation.

STYR2011-51 also indicates how internal and external consultation is implemented. The goal of this provision is that the intent and impact of a new or amended regulation is fully considered and understood by a broad range of identified stakeholders. This consultation process provides an opportunity for them to offer comments, objections and suggestions. The IRRS team had the opportunity to review the result of recent public consultations on new regulations.

General advice is a guidance tool described as non-binding, but consists of general recommendations for a preferred manner to comply with regulations, ordinances or laws. The IRRS team was explained that general advices are of dual nature. SSM used to issue general advices containing virtually binding requisites for an approved manner of implementation for compliance. This point of view is inconsistent with the advisory nature that a guide should have, opposed to that of a regulation. SSM has identified this situation and when a regulation is developed or reviewed, applicable existing general advices are incorporated as requirements, when so considered, or otherwise moved to guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *"General Advice" issued by SSM is a guidance document and therefore is not legally binding, however, it includes some requirements.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
(2)	**BASIS: GSG-13 para. 3.12 states that** *"[…] The principal purpose of establishing a system of regulations is to codify safety requirements of general applicability that require mandatory compliance by all authorized parties. […]".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSG-13 para. 3.19 states that** *"Guides are advisory in nature; they should allow the authorized party flexibility in applying new technologies and developing new procedures to enhance safety. […]".*
S15	**Suggestion: SSM should consider finalizing the separation of requirements from the guidance documentation and revising the implementation of the "General Advice" to better distinguish requirements from guidance.**

SSM issues guides to provide explanations, background, criteria and advice on how to comply with regulatory requirements. The guides are developed according to the same procedure, STYR2011-51 despite this document is only intended for the development of regulations. SSM is aware of this gap and is currently revising this procedure, in order to expand its scope to include the development of guides. The IRRS team encouraged SSM to expedite this revision to adopt a consistent and systematic manner to develop guides.

SSM maintains an up-to-date website where the SSM regulations and guides are published, in order for the public to have full access to the regulatory framework.

SSM's management system requires all regulations to be reviewed every five years to identify if a regulation needs to be revised or perhaps repealed. This review process is regularly conducted by SSM on all existing regulations. The IRRS team identified that, even though existing regulations are periodically revised, the full set of regulations is not systematically assessed. Thus, gaps within the regulatory framework and needs for new regulations could go unnoticed. This could lead to a situation where significant developments on international standards or feedback from relevant experience are not systematically identified as triggers for the development of new regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM has no provisions for conducting systematic assessments of comprehensiveness of its full set of regulations.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
(2)	**BASIS: GSR Part 1 (Rev. 1) para. 4.62 states that** *"[…] The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage […]"*
R26	**Recommendation: SSM should establish provisions for conducting systematic assessments of its full set of regulations, in order to ensure that regulations are comprehensive.**

Within the steering document STYR2011-51, international regulatory experience is not systematically considered as a source of information for reviewing regulations. SSM has identified this shortcoming within this steering document, and others as well, and will work on the preparation of a plan of amendment of them to include proper consideration of international regulatory experience when developing or amending regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *SSM has no provisions for systematic consideration of international regulatory experience as trigger for and input to the development and amendment of its regulations.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 3.3 states that** *"The reporting of operating experience and regulatory experience has led to significant corrective actions […] as well as changes to regulatory requirements and modifications to regulatory practices."*
(2)	**BASIS: GSG 13 para. 3.11 states that** *"[…] The regulatory body should establish a process for the development of regulations and guides. This process should ensure that the regulations and guides:[…]* *f) Take into account internationally agreed standards and feedback gained from related experience; [...]"*
S16	**Suggestion: SSM should consider revising its procedure for development and amendment of regulations to systematically consider international regulatory experience.**

SSM's regulatory framework has been recently modified in some areas, replacing previous regulations with new, updated ones. In this regard, SSM has identified that extensive work on the development of second and third level regulations is not yet complete. Moreover, SSM has various projects underway for updating regulations and guidance for other facilities and activities. The number of regulations in line to be updated or revised is substantial. The IRRS team was of the view that the resources allocated to the development of regulations are too limited and should be increased, in order to be in position to complete the remaining work in a timely manner. Recommendation R4 in section 3.3. addresses this issue.

It has been identified that, while the diversity of facilities and activities with radiation sources is large, there is a lack of regulation and guides for specific practices, e.g., the use of nuclear gauges. In addition, some of the regulations and guides already published do not specify criteria to be used, e.g., criteria for reporting accidental or unintended exposures in the medical field. A lack of criteria has been noted in SSM's action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM regulations and guides specifying the criteria for the safe operation of facilities and conducting activities with radiation sources do not cover all facilities and activities. SSM has not issued guidance on the content of safety assessments for radiation sources facilities and activities.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
	BASIS: GSR Part 1 (Rev. 1) para. 4.62 states that *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."*
R27	**Recommendation: SSM should further develop their regulations and guides specifying the criteria for the safe operation of facilities and conducting activities with radiation sources to cover all facilities and activities. SSM should develop a guide on the content of safety assessments of radiation sources facilities and activities.**

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

Safety requirements for NPPs are written in a number of regulations that cover the three different levels described in section 9.1. These regulations have been recently developed and have replaced a larger number of previous regulations. Transitory provisions have been included within the new regulations in order to allow the licence holders to implement the requirements according to a gradual schedule.

Requirements in these regulations generally cover IAEA Specific Safety Requirements, established by SSR-2/1 and SSR-2/2. They address essential topics such as fundamental safety functions, defence in depth, design, operation, staffing and emergency preparedness.

Level 1 general requirements which are also applicable to other licensed facilities, are described in regulation SSMFS 2018:1. Overarching requirements related to defence in depth, classification of events, organizational matters, conditions to workers and public, are expressed in that requirement.

Level 2, more detailed, specific requirements for NPPs are established in three recently produced regulations, which have replaced ten older regulations:

- SSMFS 2021:4 (previously referred as SSMFS-K): on design, construction and commissioning of nuclear power plants;
- SSMFS 2021:5 (previously referred as SSMFS-A): on assessment and review of radiation safety for nuclear power plants; and
- SSMFS 2021:6 (previously referred as SSMFS-D): on operation of nuclear power plants.

Level 3 regulations for NPPs cover certain specific compliance subjects, such as requirements for mechanical components (SSMFS 2008:13) or nuclear waste management (SSMFS 2021:7, previously referred as SSMFS-KÄKA). These regulations have only been developed for specific areas or components where the need for detailed requirements has been identified.

Detailed guides have been developed simultaneously with the regulations. These guides provide explanations, background, and criteria for the requirements expressed in the regulations, as well as advice for compliance with them.

It should be noted that specific regulations for NPPs, described above as level 2 regulations, explicitly identify the scope of application to cover only light-water reactors. In this regard, regulations for NPPs do not provide flexibility to allow application for alternate technologies. SSM recognizes this situation and express that if a sudden need would arise for authorization of NPPs of a different technology, the establishment of regulatory requirements would be done by setting licensing conditions as necessary. Nonetheless, the government has already commissioned SSM to review the applicability of its regulatory framework over other technologies, and resulting needs for amendments.

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

SSM has issued regulations applicable to fuel cycle facilities. The general requirements, processes and arrangements for regulations of fuel cycle facilities are the same as those described in section 9.1.

For the graded approach consideration and risk evaluation, three groups of nuclear facilities are identified, considering source terms and possible release. The FCF belong to level 2 group.

New regulation has been implemented for NPP’s since 2021. The new level 2 regulation specific for FCF is expected to be ready in the 2023/2024. Every requirement within should be accompanied with guidance. Basically, there will be three sections of requirements: design, construction and commissioning, review and assessment of radiation safety, and operation in accordance with those of new NPP regulations. In the meantime, applicable regulation has been updated to remove NPP references.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Generic requirements for nuclear and radiation facilities apply to waste management facilities. Additionally, specific requirements concerning management of radioactive waste from nuclear facilities are provided in the SSMFS 2021:7 (referred to as a draft in background material as SSMFS-KÄKA) regulation.

The regulatory framework requires a waste management plan for generated radioactive waste showing how and when the waste must be managed. The plan must be based on an assessment of different ways of managing the waste and be kept up to date. Radioactive waste with different characteristics must be separated as far as is reasonably practicable when it is generated and subsequently kept separate. The characteristics of the waste must be determined in an appropriate manner. The waste shall then be managed in accordance with its characteristics and how it is to be disposed of. The regulatory framework includes requirements for a site evaluation to the extent that is appropriate for the potential hazards presented by a facility or activity. SSMFS 2018:1 covers events and conditions that have an impact on radiation safety must be identified and assessed before starting an activity. The consequences for the general public and the environment have to be assessed and documented on the basis of the nature and scope of the activity. The assessment shall be carried out before the activity commences, cover the period while the activity is in operation, is decommissioned and beyond, and cover the release of radioactive substances to the environment and other exposure to ionising radiation from the activity. The assessment shall be kept up-to-date.

The IRRS team observed that there are several radioactive waste storages relating to activities licensed under RPA that are not specifically covered by the existing licence. This is because, for some types of waste (e.g. for C-14, activated copper coils and some liquid wastes), no suitable waste routes have yet been identified. **This issue is to be further reviewed by the upcoming ARTEMIS mission.**

SSM does not have a mandate to issue regulations prescribing requirements for pre-licensing activities, but when becoming a licensee, the applicant must show an ability to fulfil all relevant requirements.

Specific regulations are in place concerning the post-closure safety of geological disposal (SSMFS 2008:37 and SSMFS 2008:21). These regulations broadly cover the IAEA safety standards but some issues are not explicitly mentioned, such as the consideration of isolation as a safety function or the way to apply certain safety principles to long term safety. SSM is aware of this and is already in the process of updating these regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Regulations relating to long-term safety of the disposal of radioactive waste are not fully in line with IAEA safety requirements (e.g., the requirements for the various stages of the licensing process; isolation as a safety function; on how optimization and defence in depth principles are applied to the long-term safety; and the monitoring programme.)*	
(1)	**BASIS: SSR-5 Requirement 2 states that** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."*
(2)	**BASIS: SSR-5 Requirement 4 states that** *"Importance of safety in the process of development and operation of a disposal facility Throughout the process of development and operation of a disposal facility for radioactive waste, an understanding of the relevance and the implications for safety of the available options for the facility shall be developed by the operator. This is for the purpose of providing an optimized level of safety in the operational stage and after closure."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: SSR-5 Requirement 7 states that** *"The host environment shall be selected, the engineered barriers of the disposal facility shall be designed and the facility shall be operated to ensure that safety is provided by means of multiple safety functions. Containment and isolation of the waste shall be provided by means of a number of physical barriers of the disposal system. The performance of these physical barriers shall be achieved by means of diverse physical and chemical processes together with various operational controls. The capability of the individual barriers and controls together with that of the overall disposal system to perform as assumed in the safety case shall be demonstrated. The overall performance of the disposal system shall not be unduly dependent on a single safety function."*
(4)	**BASIS: SSR-5 Requirement 21 states that** *"A programme of monitoring shall be carried out prior to, and during, the construction and operation of a disposal facility and after its closure, if this is part of the safety case. This programme shall be designed to collect and update information necessary for the purposes of protection and safety. Information shall be obtained to confirm the conditions necessary for the safety of workers and members of the public and protection of the environment during the period of operation of the facility. Monitoring shall also be carried out to confirm the absence of any conditions that could affect the safety of the facility after closure."*
R28	**Recommendation: SSM should update the regulation related to disposal of radioactive waste to be fully in line with IAEA safety requirements.**

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

SSM published several general regulations related to radiation sources facilities and activities and SSM issued a limited set of guides on conducting specific practices with radiation sources, namely medical exposure, industrial radiography and licensable veterinary medicine. Two handbooks, on industrial radiography and for veterinary medicine were also prepared. The IRRS team noted that a set of practice specific regulations and guides to be used by operators when implementing safety principles is quite limited, considering the large diversity of practices with radiation sources in the country including management of disused and orphan sources. Because there is a lack of practice-specific regulations and guides, there are no clear criteria to be used by SSM when conducting its regulatory functions regarding such practices. In particular, SSM already noted a need for establishing criteria for review and assessment and for a guide on the content of safety assessments for radiation sources, facilities in activities to be sent by an applicant for licensee. Recommendation 28 in section 9.1. addresses this issue.

Regulations and guides are prepared by SSM staff in cooperation with stakeholders. The IRRS team noted the lack of a plan for needed new or amended regulations and guides as well as a lack of sufficient number of specialists with technical competences required for the preparation of practice specific regulations and guides. Recommendation R4 in section 3.3. addresses this issue.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

SSM has the mandate to issue regulations containing detailed provisions on nuclear safety, security, and radiation protection including requirements for decommissioning of facilities, planning for and conduction of decommissioning, protection of workers, the public and the environment during decommissioning, and clearance of materials, building structures, and areas.

These requirements are stated in SSM's regulations, especially SSMFS 2018:1, SSMFS 2008:1, and SSMFS 2018:3, and are in line with IAEA standards.

Additionally, SSM is also mandated to issue additional licence conditions for decommissioning activities under the provisions of the Radiation Protection Act (2018:396) or the Act on Nuclear Activities (1984:3).

The IRRS team concluded that SSM is complying with the requirements on Regulations and Guides of decommissioning activities.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

Regarding the regulations for the safe transport of radioactive material in Sweden, the Ordinance on Transport of Dangerous Goods points to the international modal regulations for the transport of dangerous goods, which in turn are based on SSR-6:

- Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);
- Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) (Appendix C to the Convention concerning International Carriage by Rail (COTIF));
- Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI); and
- International Maritime Code for Dangerous Goods (IMDG-Code).

This ordinance also sets the responsibilities for establishing dangerous goods transport regulations for Sweden: The Swedish Transport Agency for air and water modes and the Swedish Civil Contingencies Agency (MSB) for road and rail. These authorities have issued regulations prescribing the application of the mentioned international codes to the Swedish territory:

- MSBFS 2020:9 - Swedish Civil Contingencies Agency regulations on the transport of dangerous goods by road and off-road (ADR-S);
- MSBFS 2020:10 - Swedish Civil Contingencies Agency regulations on the transport of dangerous goods by railway (RID-S 2021);
- TSFS 2022:52 – The Swedish Transport Agency’s regulations on transport on water of packaged dangerous goods (IMDG-code); and
- TSFS 2021:30 - The Swedish Transport Agency's regulations on the transport of dangerous goods by air.

All modes of transport are covered by the above-mentioned regulations. Therefore, the regulations established for the safe transport of radioactive material in Sweden are in line with the IAEA transport regulations SSR-6 (Rev. 1).

In Sweden the transport of dangerous goods on inland waterways is in general regulated by applying the IMDG code. In certain areas of sea coast and inland waterways, instead of the IMDG code ADR may be applied, with additional conditions, as stated in the Swedish Transport Agency's regulations and general advice (TSFS 2019:39) on the transport of packaged dangerous goods on water in traffic areas D and E including on inland waterways.

SSM uses IAEA safety guides for the application of these transport regulations.

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The RPA and SSM´s regulations concerning licensable activities regulate various responsibilities of regulatory body, employers, registrants and licensees with regards to occupational exposure in planned as well as in existing exposure situations.

SSM is the regulatory body responsible for the supervision of occupational exposures for all types of facilities.

Radiation Protection Ordinance (2018:506) establishes requirements for dose limits, for the optimized protection of workers and requires the setting of dose constraints as appropriate.

SSM regulations SSMFS 2018:1 establishes requirements for arrangements under the radiation protection programme, assessment of occupational exposure, instruction and training of workers.

Regulation SSMFS 2018:1 requires the employee or licensee to provide, at the request of any worker, information about the worker's individual radiation doses and the supporting material used to determine these.

SSM has not issued guidance for keeping records by the employer or authorized party on all data needed to assess individual dose for workers for whom the assessment of the occupational exposure of workers is not conducted by individual monitoring.

Radiation Protection Act (2018:396) establishes requirements for protection of pregnant or breast-feeding workers and under-age workers.

Requirements for the protection of aircrew occupationally exposed to cosmic radiation are prescribed in the SSMFS 2018:11.

Reference levels for the protection of workers in cases where they are exposed to radon are established in the Radiation Protection Ordinance (2018:506). The value set for the Rn-222 reference level is 200 Bq/m^3 according to the Radiation Protection Ordinance (2018:506), which complies with the IAEA GSR Part 3 safety standards that require reference level for Rn-222 to be set at a value that does not exceed an annual average activity concentration of Rn-222 of 1000 Bq/m^3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM has not issued guidance on keeping records by the employer or licensee on all data needed to assess individual dose for workers for whom the assessment of the occupational exposure of workers is not conducted by individual monitoring .*	
(1)	**BASIS: GSR Part 3 para. 3.73 states that** *"The regulatory body shall be responsible, as appropriate, for:* *(a) Establishment and enforcement of requirements for the monitoring, recording and control of occupational exposures in planned exposure situations in accordance with the requirements of these Standards; …* *(e) Provision for maintaining exposure records and results of the assessment of doses from occupational exposure;* *(f) Verification of compliance of an authorized practice with the requirements on the control of occupational exposure."*
(2)	**BASIS: GSR Part 3 para. 3.101 states that** *"For any worker who regularly works in a supervised area or who enters a controlled area only occasionally, the occupational exposure shall be assessed on the basis of the results of workplace monitoring or individual monitoring, as appropriate."*
(3)	**BASIS: GSR Part 3 para. 3.104 states that** *"Records of occupational exposure for each worker shall be maintained during and after the worker's working life, at least until the former worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure."*
S17	**Suggestion: SSM should consider establishing record keeping guidance on all data needed to assess individual doses for workers for whom the assessment of the occupational exposure of workers is not conducted by individual monitoring.**

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The legal basis for medical exposures is established by the Health and Medical Service Act (2017:30), specifying the responsibility of the counties with regard to the organization and planning of health care, and by the Radiation Protection Act (2018:396), specifying the responsibilities of parties conducting activities involving ionising radiation.

The requirements are further detailed in the Radiation Protection Ordinance (2018:506), the SSM Regulations SSMFS 2018:1 on licensable activities, SSMFS 2018:2 on notifiable activities and SSMFS 2018:5 on medical exposures.

Some aspects have been attributed by the Government to other authorities, e.g. the National Board of Health and Welfare approves screening programmes for asymptomatic individuals and the Ethical Review Authority should establish dose constraints for volunteers. SSM is not always consulted in this process and is not always informed about the approach taken by other authorities. SSM meets regularly with the Ministry of Environment but there is no direct contact with the Ministry of Social Affairs. Formalising cooperation between SSM and the relevant authorities involved in health care could improve this situation. Suggestion S1 in section 1.5. addresses this issue.

Health professionals, including doctors, nurses, radiographers and medical physicists, are recognized by the National Board of Health and Welfare. Curricula for training are established by the Swedish Higher Education Authority. SSM is not involved in the setting up of the curricula nor in the recognition process. SSMFS 2018:5 requires that employees involved in medical exposures of children, health screening programmes or high dose procedures undergo a special training.

The responsibility to ensure that there are sufficient medical and paramedical personnel available and that only persons with the necessary knowledge of the activity, the risks associated to it and the competence in radiation protection are involved, lies with the care provider (the licensee/registrant). These are not necessarily recognised health professionals.

The care provider should assign certain expert functions: the leading radiological practitioner (RaLF) with overall responsibility for justification, the medical physics expert (MPE) with overall responsibility for optimisation of radiation protection of patients, and the radiation protection expert (RPE) with overall responsibility for occupational exposure, protection of members of the public and the environment. These expert functions should consist of recognised health professionals with competence and experience in accordance with SSM regulation 2018:5 on medical exposure.

The RPA requires the authorized party to ensure that the radiological method is justified (level 2 justification) and that each individual medical exposure is justified (level 3 justification). There is however no general framework for generic justification to ensure that all existing and new classes or types of practice resulting in exposure to ionising radiation are justified. Justification rests solely on the licensee. In a position paper, the Nordic Radiation Protection Authorities recommend the integration of level 2 justification into established methods for assessments of new health technologies as one approach to strengthen the justification process. HTA organisations exist in Sweden both on the national level (Swedish Agency for Health Technology Assessment and Assessment of Social Services) and at the regional level. Licensees who want to introduce new practices can address an assessment request to one of these organisations. However, this is not a regulatory requirement. New radiopharmaceuticals are evaluated and approved by the Swedish Medical Products Agency, which is the competent authority for medical devices and medicines. The effectiveness and radiation protection for patients is taken into account in the assessment, but occupational exposures are not taken into account. Screening programmes for asymptomatic individuals are approved by the National Board for Health and Welfare. SSM is not consulted in this process.

SSM has made a proposal for establishing a section in the new Radiation Protection Ordinance that the National Board of Health and Welfare should be responsible for assessing whether new methods involving

medical exposure are justified before they may be used generally. After submission of the draft regulation to the ministry of environment, the National Board of Health and Welfare rejected the proposal. However, the National Board of Health and Welfare agreed that there is a need to assess new methods involving medical exposure to ionising radiation at national level. Therefore, efforts on creating the framework for generic justification on a national level still need to be continued.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no national framework for generic justification of all new classes or types of practice resulting in exposure to ionising radiation.*	
(1)	**BASIS: GSR Part 3 para. 3.56 states that** *"Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments."*
R29	**Recommendation: The Government should ensure that generic justification of radiological procedures is carried out by the relevant authorities in conjunction with appropriate professional bodies.**

Referral criteria do exist on a national level but only for cancer and a small set of other pathologies. For other pathologies, referral criteria are provided at a regional level or even at licensee level.

Procedures for the individual justification of medical exposures are defined at the level of the licensee by the health care provider with support from the leading radiological practitioner (RaLF).

Optimisation of medical exposures is the responsibility of the MPE. SSMFS 2018:5 defines the scope and the aspects of the optimisation process, including the design considerations, the operational considerations, calibration, patient dosimetry, quality assurance and dose constraints. Diagnostic reference levels (DRL) have been set for a number of clinical procedures including relevant clinical indications. Dose constraints have been set for carers and comforters. The Swedish Ethical Review Authority is the competent authority for setting dose constraints for volunteers participating in research. This is done on a case-by-case basis. SSM has no view on whether relevant recommendations such as ICRP 62 are used in this process.

Special provisions on medical exposure of pregnant and breast-feeding patients are in place, as well as criteria for the release of patients who underwent a treatment with radioactive substances.

Procedures to minimise the likelihood of unintended and accidental exposures as well as on the notification of unintended and accidental exposures which implied or could have implied serious injury, have to be developed by the licensee. A guidance document gives more information on this notification but is still not very specific on the types of events to notify. This lack of specificity was confirmed by the licensee during the site visit. Recommendation R28 in section 9.1. addresses this issue.

Requirements on record keeping and periodic radiological review at medical radiological facilities is in place. However, no retention periods are set.

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The RPA provides general requirements for the exposures of the general public and the environment to ionising radiation. More detailed regulations exist on how to protect the public and the environment against ionising radiation. Example of such requirements are:

- Entities must be licensed to discharge radioactive materials into the environment (SSMFS 2018:1). This license to discharge is incorporated in the overall license of the facility;

- Assessments of consequences of an activity on the general public and the environment shall be carried out before the activity begins, it shall cover the period while the activity is in progress, is decommissioned and beyond, and cover the release of radioactive substances to the environment and other exposure to ionizing radiation from the activity (SSMFS 2018:1);
- Licensees are required to perform source monitoring of their discharges and document their monitoring method and radiation doses to the general public (SSMFS 2018:1 and, for nuclear facilities, SSMFS 2008:23, SSMFS 2021:6 previously referred as SSMFS-D and SSM2019-6915-60);
- Regulation for clearance and exemption is well established (SSMFS 2018:3); and
- Requirement for establishing strategies for protection of the public against existing exposure situations (SFS 2018:506)

9.11. SUMMARY

The regulatory framework covers all areas regulated by SSM, although some gaps have been identified. The existing regulations and guides reflect the IAEA safety standards and other relevant international requirements. Regulations provide varied level of detailed requirements and associated criteria.

Areas of improvement related to radiation sources facilities and activities, and medical exposure were identified. There is a need to develop a complete and comprehensive set of regulations and guides for all radiation sources facilities and activities, and to ensure a sufficient number of specialists with technical competences required for the preparation of needed practice specific regulations and guides; and to create a general framework for generic justification.

The procedure to develop, amend and revise regulations is established and is followed by SSM. Development of guides is not covered by any provision, but the same procedure is used. The IRRS team encouraged SSM to amend this procedure to cover also guides.

An extensive review programme for regulations and guides has been decided by SSM’s management and is currently underway. However, additional resources should be allocated to allow for a timely execution of the review programme.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS

The authority of SSM for regulating the operating organisations' emergency preparedness and response arrangements is stated in the ANA, the ONA, the RPA and the RPO, together with regulations related to nuclear activities and radiation protection. The authority of SSM includes issuance of specific regulations on emergency preparedness and response (EPR) for operating organizations, conduct of inspections, review and assessment, and exercises. SSM ensures that the operator's emergency arrangements are coordinated with those of other organizations and integrated with nuclear security and contingency response plans.

The SSM's resources for EPR have been included in three divisions of SSM. In total twenty-two staff members participate in activities relating to the development or review of regulations, performing reviews and inspections, and participating in exercises involving the operating organisation.

10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS

Responsibilities for operating organisation's EPR are included in the Nuclear and Radiation Protection Acts and Ordinances as well as in five SSM regulations. The regulations cover a wide range of arrangements to be established and implemented to manage nuclear and radiological emergencies and implement a graded approach depending on the Emergency Preparedness Categories (EPC). Regulation SSMFS 2018-1 specifies a requirement for all licensees to provide information to allow SSM to determine the applicable EPC in Sweden, the need for an emergency response plan, testing of emergency response plans through exercises, and updates or improvements of such plans. Regulations SSMFS 2021:4, SSMFS 2021:5, and SSMFS 2021:6 issued in 2021 for design, operation, and assessment of radiation safety for EPC I contain general preparedness requirements and requirements for handling emergency conditions. Regulation SSMFS 2014:2 contains requirements for EPC II and III including the review and approval of emergency response plans, as well as EPR functional and infrastructure requirements.

Licensees are required to take prompt actions to transition from normal operations to operations under emergency conditions and, during the event, maintain effective communications to protect personnel and coordinate with off-site authorities, protect emergency workers and analyse the emergency. The licensee should validate the tools and procedures and must have a quality management programme in place. EPC I facilities should be able to set up a logistics centre in a location distanced from the site to serve as a control point.

According to the Ordinance 2015:1052 and 2003:789 and Regulation MSBFS 2016:7, SSM should conduct a risk and vulnerability analysis associated with facilities and activities. According to SSM 2018:1, SSM shall place facilities and activities in emergency preparedness categories. The IRRS Team was informed that SSM has completed this for all nuclear facilities, but the assessment for all non-nuclear facilities possibly to be placed in EPC III has not yet been completed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM has not assessed all non-nuclear activities and identified which should be placed in EPC III.*	
(1)	**BASIS: GSR Part 7 para. 4.19 states that** *"For the purposes of these safety requirements, assessed hazards are grouped in accordance with the emergency preparedness categories shown in Table 1."*
S18	**Suggestion: SSM should consider completing the assessment for all non-nuclear facilities to identify those that should be placed in EPC III.**

The IRRS team was informed that SSM has included in its annual plans the development of a specific and more detailed regulation for the protection of emergency workers. A draft regulation has already been reviewed by other public authorities and operating organisations.

10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS

SSM requires that the operating organisation's emergency plan be tested through regular exercises which are used to improve (EPR). Some exercises conducted by the operator are observed by SSM, and observations are included in review and inspection programmes. The SSM also participates in large-scale exercises organized by the County Administrative Board every 2 years, and exercise observations are shared amongst all participating parties to improve the on-site and off-site emergency preparedness and response arrangements.

In accordance with Act (1984-3), SSM may decide on the corrective actions required and notify the licensee thereof. SSM ensures through the regulations and supervision that there is integration of on-site emergency arrangements with those of relevant off-site response organizations and with other plans such as security and contingency plans. Sweden exercised a scenario in 2019 during which a nuclear security event triggered the radiological release from an NPP.

The SSM verifies that operating organisations test and validate, prior to use, procedures, and analytical tools under simulated emergency conditions for a nuclear or radiological emergency.

The SSM requires that EPR arrangements for all facilities and activities be described in an EPR plan. For nuclear facilities, the plan is submitted for approval by SSM prior to operations or as part of facility modifications. The IRRS team was informed that for non-nuclear facilities, the EPR plans for radiological emergencies are verified by SSM as part of the licensing application process and SSM may be notified of changes to the plans prior to the expiry of the licenses.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulations do not require non-nuclear facilities to submit changes to radiological emergency response plans to SSM for approval.*	
(1)	**BASIS: GSR Part 7 para. 6.19 states that** *"The operating organization of a facility or for an activity in category I, II, III or IV shall prepare an emergency plan. This emergency plan shall be coordinated with those of all other bodies that have responsibilities in a nuclear or radiological emergency, including public authorities, and shall be submitted to the regulatory body for approval."*
S19	**Suggestion: SSM should consider revising the regulations to include provisions for non-nuclear facilities to submit changes to radiological emergency response plans to SSM for approval.**

Annual plans are prepared for inspection of EPR. The specific areas to be inspected are identified; however, "support packages" similar to those of other inspection areas (which describe the inspection content, applicable requirements, guidance, criteria and checklists) are not yet completed for EPR. Recommendation R22 in section 7.1. addresses this issue.

There are guidance texts for regulations in place for EPC I facilities interpretating the requirements for review and assessment purposes including for EPR. For other EPCs, there are no criteria for the review and assessment of EPR plans or when changes to the plans should be reviewed and approved by SSM. This issue was identified in the SSM's action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SSM does not have internal guidance, checklists or criteria for the review of emergency response plans or changes to such plans to ensure that all relevant emergency preparedness and response aspects are covered.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body."*
R30	**Recommendation: SSM should develop specific, internal guidance, checklists and criteria for the review of emergency response plans.**

10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

The Civil Protection Act (CPA 2003-778) and the Civil Protection Ordinance (CPO 2003-789) assign the Swedish Contingencies Agency (MSB) the authority for regulation of off-site emergency preparedness and response involving nuclear and non-nuclear facilities. MSB's responsibilities and instructions are described in governing documents related to planning, performance, control and improvement. The IRRS team was informed that MSB has a contingency organisation that is available 24/7 and consists of several capacities to fulfil the MSB mission for nuclear and radiological emergencies. MSB has systems for communications, along with IT services and facilities that are regularly tested through emergency exercises.

The authority for performing assessment for actual and expected future radiation health risks in the event of a nuclear or radiological emergency has not been assigned to any public authority in Sweden. This issue was identified in the SSM's action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The responsibility to provide expert services on risk assessment for actual and expected future radiation risks to public health in the event of a nuclear or radiological emergency is not allocated.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 2.24 states that** *"In preparing an emergency plan and in the event of an emergency, the regulatory body shall advise the government and response organizations, and shall provide expert services (e.g. services for radiation monitoring and risk assessment for actual and expected future radiation risks) in accordance with the responsibilities assigned to it [5]."*
R31	**Recommendation: The Government should assign the responsibility to the appropriate regulatory authorities to provide expert services related to actual and expected future radiation risks to public health in the event of a nuclear or radiological emergency.**

SSM is collaborating with MSB, the National Food Agency, Board of Agriculture, and the Swedish Defence Research Agency on decontamination and remediation in the event of a nuclear or radiological emergency. The national expert group of decontamination (NESA) is being coordinated by MSB to collect and share information that will result in a new or revised guideline being developed for decontamination in the event of a nuclear or radiological emergency. Some of the specific guidelines developed so far has been included in large-scale exercises.

According to Ordinance (2008-452), SSM has specific responsibilities regarding response during a nuclear or radiological emergency which includes advising on radiation protection assessments, coordination with a national expert organization, performing radiation measurements and atmospheric dispersion calculations,

and conducting environmental sampling and analyses. The SSM is also responsible for notifying regulatory authorities in neighbouring countries and submitting proposals to the Government on international reviews related to nuclear or radiological emergencies.

Reference levels for nuclear and radiological emergencies are specified in the RPO2018-506. SSM has developed a "Decision Support System for an accident at a Swedish Nuclear Plant" in collaboration with responsible authorities and decision makers. The system contains flow charts for decisions, protective actions, and other actions before, during and after a release of radioactivity from the facility for emergency classes and emergency planning zones. It also includes reference levels, dose criteria, operational intervention levels, termination criteria and evaluation of doses. The IRRS team was informed that the SSM decision support outcome has been adopted by the Country Administrative Board in its response plans and tools.

The SSM has established and maintains a 24/7 system with two persons on standby for the range of potential nuclear or radiological emergencies in Sweden. The SSM has the capability to promptly establish a crisis management function using a phased implementation. Critical positions in the SSM response organization with respect to providing technical advice to public authorities in case of a nuclear or radiological emergency have been identified. A training plan to increase competencies amongst SSM staff has been developed and implemented for the areas of source term verification, radiation protection assessments, and dispersion modelling.

The SSM is Sweden's Competent Authority for IAEA's Conventions on Assistance and Notification in case of a nuclear or radiological emergency. The Swedish Meteorological and Hydrological Institute is Sweden's National Warning Point and contacts SSM and MSB directly in case of nuclear or radiological emergencies. SSM regularly participates in emergency response exercises with other public authorities, operating organisations, the IAEA, the European Union and other Nordic countries, and to test its own emergency response capabilities.

The SSM maintains a national system for 24/7 monitoring of radiation levels in the country through an early warning system consisting of 120 gamma radiation stations. SSM has contracts in place and coordinates with an expert group to perform radiation monitoring, sampling and analysis in the event of a nuclear or radiological emergency.

The SSM has an approved EPR plan (STYR2011-540) for nuclear and radiological emergencies. The plan stipulates SSM's responsibilities, implementation, management, and cooperation as well as logistics and resilience. The plan also refers to role cards, rules and handbooks for areas such as leadership, nuclear analysis, radiological analysis, cooperation, communication and logistics during crisis management.

The SSM has a dedicated emergency response centre at its offices in Stockholm. The SSM has a comprehensive set of radiation measurement instruments, personal protective equipment, communication systems, computers and facilities available for use during emergency response. SSM's communications systems are redundant and encrypted. There is an arrangement in place for SSM staff to transport a spare set of equipment quickly in a nuclear or radiological emergency to an alternate location for the SSM team to fulfil its mandate during the response. Information systems are available in the emergency response centre to interact and cooperate with other stakeholders during a nuclear or radiological emergency.

Sweden has cooperation regarding exchange of information and assistance between Nordic authorities in nuclear or radiological emergencies including with the Emergency Management Agency in Denmark, Danish Health Authority in Denmark, Radiation and Nuclear Safety Authority in Finland, Radiation Safety Authority in Iceland and Norwegian Radiation and Nuclear Safety Authority in Norway.

SSM performed an internal investigation of responsibilities and arrangements for iodine thyroid blocking (ITB) procurement, storage, and distribution following engagement with other public authorities. According to the Swedish Law on Trade of Pharmaceuticals (2009-366) which the IRRS team learned is based on EU

Directive 2001/83/EC relating to medicinal products for human use, organisations responsible for ITB need to have licenses in place to fulfil obligations and expertise associated with pharmaceuticals. However, as yet there is no organization with assigned responsibilities and a license. Following an initiative by SSM, the Government tasked a committee to review the responsibilities for ITB with respect to procurement, storage, distribution and the authority to recommend intake. The committee has made a proposal in line with EU legislation for medical products. As of today, however, the government has not made a decision of the future handling of ITB. In the interim the Government has instructed SSM, MSB and the County Administrative Boards to procure, store and distribute ITB. This issue was identified in the SSM's action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Swedish legislation requires a licence for the provision of iodine thyroid blocking in case of a nuclear and radiological emergency as an urgent protective action. The current interim arrangements for iodine thyroid blocking are being implemented by organizations without such licences.*	
(1)	**BASIS: GSR Part 7 para. 5.38 states that** *"For facilities in category I or II, arrangements shall be made for effectively making decisions on and taking urgent protective actions, early protective actions and other response actions off the site in order to achieve the goals of emergency response, on the basis of a graded approach and in accordance with the protection strategy."*
R32	**Recommendation: The Government should assign the responsibility to the appropriate parties for the procurement, storage, distribution and the authority to recommend intake of iodine thyroid blocking.**

10.5. SUMMARY

SSM has comprehensive arrangements in place to fulfil its response to a nuclear or radiological emergency and to effectively cooperate with national authorities and international organisations.

The existing regulatory framework uses a graded approach in establishing arrangements for preparedness and response to nuclear radiological emergencies and for implementing the IAEA requirements. Nevertheless, some emergency preparedness and response aspects require further development to ensure compliance with the IAEA safety standards, including responsibility for public health risk assessment and ITB.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

The Swedish legal framework for safety, security and safeguards is established through ANA and RPA together with NAO, RPO and other legislation. Together they provide the basis of the regulatory framework for nuclear safety, nuclear security, and safeguards. Swedish legislation defines nuclear safety as encompassing nuclear security.

The SSM is the main authority responsible for safety, security, and safeguards for nuclear and radioactive materials. Its roles and responsibilities are provided in Ordinance (2008:452), the ANA and RPA. There are other authorities that are also responsible of different aspects of radiation protection and nuclear safety, including nuclear security. Swedish legislation defines the legal basis and role of individual authorities having regulatory or other responsibilities and the interface in above areas.

Swedish legislation provides mandates that the SSM conduct the oversight activities and to take enforcement actions in case of non-compliances related to safety, nuclear security, and the system of accounting for and control of nuclear material. There are several laws and ordinances that empowers SSM with all necessary authority to conduct effective oversight activities.

The ANA requires that nuclear activities be conducted in such a way that requirements for safety are met and Sweden's agreements and obligations are fulfilled to prevent nuclear explosions, the proliferation of nuclear weapons, and the unauthorized handling of nuclear materials and nuclear waste consisting of spent nuclear fuel. It also requires that nuclear safety be maintained by taking measures to prevent and mitigate radiological emergencies and prevent illegal handling of nuclear material or nuclear waste.

SSM has developed several regulations, including SSMFS 2008:1, SSMFS 2021:4, and SSMFS 2018:1 that contain the requirements related to integration of measures for safety and security. Regulation SSMFS 2008:1 concerning safety at nuclear installations requires that the design facilitate radiation protection and physical protection. SSMFS 2021:4 concerning the design of nuclear power plants defines the levels of defence in depth, which amongst others, includes the aims to prevent malicious attacks, to detect multi-stage antagonistic threats, deal with antagonistic threats, recover stolen radiation sources, nuclear material and other radioactive substances or mitigate the radiological consequences of stolen radiation sources, nuclear material and other radioactive substances. The very early integration of nuclear safety with nuclear security into the design of a nuclear installation provides an opportunity to address the interface and prevent long term problems.

SSM has identified the gaps in the areas of optimization of safety with respect to security for transports of nuclear material and the system of accounting for, and control of, nuclear material. The IRRS team was informed that the development of corresponding SSM regulation has been initiated regarding transport of nuclear material. The IRRS team concluded that above areas of the legal framework should be improved by developing the corresponding requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no requirements for some aspects of the optimization of safety, taking into account factors relating to a system of accounting for, and control of, nuclear material. There are requirements for optimization of safety, taking into account factors relating to nuclear security, except for transport of nuclear material.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include:*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(a) Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for, and control of, nuclear material being taken into account. …"
R33	**Recommendation: SSM should establish requirements on optimization of safety taking into account security for transports of nuclear material, and system of accounting for, and control of, nuclear material.**

Sweden is a contracting party to the Treaty on Non-Proliferation of Nuclear Weapons (NPT) and the Convention on the Physical Protection of Nuclear Material (CPPNM) and its Amended Convention on Physical Protection of Nuclear Material (CPPNM/A). Sweden has also made a commitment to follow recommendations of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and its two supplementary guides (Guidance on the Import and Export of Radioactive Sources and Guidance on the Management of Disused Radioactive Sources). The RPO and the Ordinance with instruction for SSM 2008:452 establishes SSM as the competent authority to perform these tasks and observe the principles for the control activities in accordance with the Code of Conduct.

11.2. REGULATORY OVERSIGHT ACTIVITIES

Requirements for safety and nuclear security measures are specified in the legislation. The compliance with requirements is verified during the licensing process and through compliance inspections.

The legal framework assigns SSM the responsibility for review and assessment, inspection and enforcement to check and ensure compliance with regulatory requirements.

Security and safety inspections are performed in accordance with approved annual inspection plans and processes. Although, targeted inspections to assure that security measures in place will not cause difficult implementation of mitigation or response action are not performed. During the annual planning, the interface with nuclear security is taken into account and relevant human resources and expertise in both areas are allocated to ensure the interface is duly covered. In this regard, the IRRS team was informed on the lack of resources in the area of physical protection. Recommendation R4 in section 3.3. addresses this issue.

The needed competence is controlled by performing inspection jointly by staff having responsibilities and competences in a separate safety and nuclear security areas. Reactive joint safety-security inspections can be performed in response to events.

The consideration of safety and nuclear security requirements are dealt with by SSM through its review and assessment process. In accordance with SSM management system procedures, the group performing review and assessment consists of representatives from all interested departments to ensure all needed competences are present. SSM management system procedures do not explicitly address interface with nuclear security, therefore potential risk exist that potential interference between safety and nuclear security might be overlooked. SSM should consider ensuring that the interface between safety and security is well documented in its management system to identify potential conflict and ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.

11.3. INTERFACE AMONG AUTHORITIES

SSM is the main regulatory authority responsible for safety, security and safeguards. There are other authorities that are responsible for different aspects of radiation protection and nuclear safety. A number of acts and ordinances describe various provisions to ensure coordination and cooperation among these authorities. Such coordination and cooperation are required by Government Agency Ordinance (2007:515).

One example of corporation between different authorities is the framework of the Cooperation Council against Terrorism.

The Swedish legal and governmental framework includes specific responsibilities for the integration of emergency response arrangements for both safety-related and nuclear security-related incidents. However, SSM has identified the need to further develop the national contingency plan so that it, among other things, will address both nuclear and radiological emergencies and antagonistic events. SSM informed the IRRS team that activities are ongoing in this respect. The team confirmed that integrated nuclear safety and security exercises (triggered by nuclear security events) are performed regularly at nuclear facilities. A large-scale exercise, initiated by nuclear security events, was conducted in 2019 with the involvement of all relevant competent authorities.

11.4. SUMMARY

SSM is the main competent authority responsible for the regulation of safety, security, and safeguards. Swedish legislation clearly defines the duties and responsibilities of the authorities having responsibilities for safety and nuclear security and also contains various provisions to ensure coordination and cooperation among these authorities. SSM ensures the interface with nuclear security is considered during regulatory activities by involving the staff with both competences.

The legal basis for optimization of safety with respect to security for transports of nuclear material and system of accounting for, and control of, nuclear material needs further improvement. Further, the process to assess the interface between nuclear safety and security should be documented in SSM’s management system to ensure that nuclear security measures do not compromise safety and nuclear safety measures do not compromise security.

12. REGULATORY IMPLICATIONS OF PANDEMIC SITUATIONS

Sweden decided to include in the scope of the mission the national regulatory implications of the COVID-19 pandemic with a focus on business continuity to maintain delivery of statutory duties and responsibilities for safety. This section presents relevant feedback and main conclusions drawn by the IRRS team from the discussions and evaluations made in the course of the mission, with the objective to identify ways to strengthen the governmental, legal and regulatory framework for safety.

12.1 GOVERNMENTAL AND LEGAL FRAMEWORK FOR SAFETY

The IRRS team noted that the pandemic-related "lockdown" in Sweden was less restrictive that in most other countries, and as such the level of disruption was correspondingly less. Sweden managed the COVID-19 pandemic without concerns for the maintenance of nuclear and radiation safety.

Overall, the SSM provided sufficient support to the Government. The Ministry of the Environment received regular reports from SSM, and an effective dialogue was maintained. The IRRS team was informed that SSM also collaborated actively with other authorities throughout the pandemic. The Swedish Civil Contingencies Agency (MSB) held national collaboration conferences every week in which SSM participated. In March 2020, SVK (the state-owned enterprise for electricity) initiated a weekly interaction with SSM regarding the status of the country's nuclear power plants.

The war in the Ukraine further exacerbated the challenges experience during the pandemic. Experiencing two crises at the same time resulted in a significant test of the SSM's emergency response capabilities. The EPR procedures were initiated, and were effective, even though some staff were still working remotely.

SSM is not aware of any examples of business closures or bankruptcy's during the pandemic that led to the need for urgent action to prevent radiation sources from becoming out of regulatory control. In general, SSM's role in responding to reports of orphan sources was unaffected.

12.2 REGULATORY FRAMEWORK

SSM established a pandemic plan in 2011. As part of this plan, SSM identified those functions critical for carrying out the authority's regulatory functions, and associated staffing requirements. SSM's pandemic plan included scenarios where 15% of the staff could be absent for an extended period, and up to 50% of the staff unavailable for a shorter period.

SSM updated the plan at the beginning of the COVID-19 pandemic, primarily to include new tools and routines for working and meeting remotely. At the beginning of the pandemic, a dedicated group was established that met regularly to monitor the situation, evaluate the ability of the authority to carry out its mission, assess the status of radiation safety within SSM's area of responsibility, and plan communications.

SSM's activities adhered to the recommendations and general advice from the Public Health Agency of Sweden in order to minimise the spread of COVID-19. In April 2020, SSM directed its employees to work from home in accordance with the Swedish Public Health Agency´s regulations and general advice. Employees with tasks that could not be handled remotely, or could not work at home for other reasons, were permitted to continue working from the SSM office.

When teleworking, SSM staff used encrypted communications. Skype was used as the primary means of internal communication except when working with classified information. Internal information meetings were held regularly to inform staff of the current situation. Management also published information SSM's intranet. In urgent cases, SSM communicated with staff via text messaging (SMS).

The IRRS team was informed that multiple online workshops were held with SSM staff to prepare for the reorganization that was implemented in 2021.

Despite the different arrangements made, the COVID-19 pandemic situation affected the authority's work in several areas. These included, inter alia, the internal audit programme (discontinued in mid-2020) and the work of the self-assessment group (carried out exclusively by virtual means).

In January 2022, the secretariat for Human Resources was designated as the SSM lead for pandemic-related issues. A gradual return of all SSM staff to the office began in February 2022. The Government permitted agencies to offer a one-time payment to their staff to show appreciation for their hard work and dedication throughout the challenges presented by the pandemic.

12.3 REGULATORY FUNCTIONS

The IRRS team was informed that overall, there were no significant changes in performing regulatory functions during the pandemic. Regulatory control was maintained throughout and, when possible, conducted via desktop reviews or remotely. SSM staff continued to work effectively and efficiently, and found ways to discharge its mandate without interruption.

Planned supervision activities were prioritized, and some were paused. While this solution did not negatively affect regulatory oversight, there was recognition that had the pandemic restrictions continued, other measures might have been needed to ensure adequate regulatory oversight.

Authorization

The impact on authorisations was minimal as much of the work that continued during the pandemic was conducted unabated under the various working arrangements available. Fewer applications for authorisation were received than normal, and activities such as site clearances took longer.

No adverse impact on operating nuclear power plants was reported. For radiation sources facilities and activities, authorization-related activities were conducted without any major challenges since the authorization process was already implemented using IT technology before the pandemic began.

There was a short delay in provision of dosimetry services from Landauer in France, but this delay caused minimal disruption to SSM functions.

The primary impact of the COVID-19 pandemic was that several activities were deferred and, therefore, current workloads are now higher than typical levels.

Review and Assessment

A large part of the review and assessment activities had been accomplished while working from home during the early phases of the pandemic. When access resources related to security were needed, SSM staff reported to the SSM offices. In this respect, SSM improved the use of IT tools (e.g., Skype) used by to communicate with the authorized parties. SSM noted that the use of Skype increased the efficiency of routine review and assessment activities and is still leveraged today, as appropriate, to increase the performance of the organization.

Inspection

When the pandemic began the SSM Division of Supervision faced significant challenges because a large part of regulatory oversight is generally conducted in-person.

Virtual inspections were introduced at the early stage of the pandemic using Skype. SSM considered that the use of Skype was useful for presentation of documents and worked quite well for conducting interviews and exchanging information. It also allowed the conduct of inspections even when an inspection team member experienced COVID-19 symptoms. In general, Skype provided a great flexibility to the staff throughout the pandemic.

SSM developed a methodology for the entire organization to support the decision-making process, including whether to postpone an inspection or to replace it with a remote (virtual) inspection. Many supervisory activities had to be re-planned. SSM adapted its supervisory methods to the pandemic situation effectively.

Numerous inspections were carried out remotely. However, SSM's experience showed that certain compliance inspections could not be carried out remotely. As such, in-person inspections were performed when necessary (e.g., inspecting the maintenance records of waste registers, certain decommissioning activities, etc.). It was acknowledged that written text, drawings and pictures cannot fully substitute a physical presence of the inspector on site, including to provide the licensee with clear signals that activities are being effectively regulated. In addition, SSM expressed that inspections need to be based on sampling, observations and walk downs, and virtual meetings are less effective in facilitating a trustful atmosphere. Further, most security-related documents were not available remotely.

Licensees expressed appreciation on the possibility to conduct remote inspections where possible. They also had to adapt their operations in these pandemic circumstances. Their staff who could work from home were asked to do so to reduce the risk of COVID-19 contamination.

The number of inspections of radiation sources facilities and activities in health, industry, research and veterinary fields was reduced when compared to previous years. The health sector was heavily strained with high number of infected patients. SSM considered it inappropriate to place additional burden on the healthcare sector by conducting inspections.

SSM immediately contacted the NPP's licensees to know how they were handling the situation and what actions they were taking from the standpoint of personnel, emergencies preparedness, etc. SSM's site inspectors met weekly with the licensee.

Use of a virtual tool has not been an obstacle for inspected operators or at least this has not been noted by SSM inspectors.

In person inspections conducted during the pandemic were found to be more difficult to conduct than before because of measures taken by licensees to protect people from contracting the COVID-19 virus. In this regard, SSM also provided guidance to inspectors on risk management and how to adapt inspection protocols to minimise the spreading infection risk during on-site inspections. This guidance was developed in taking account of guidance established by the Swedish Public Health Authority.

From a resource management point of view, inspectors not travelling to NPPs saved time and costs, and was environmentally friendly.

12.4 EMERGENCY PREPAREDNESS AND RESPONSE

Swedish Civil Contingencies Agency (MSB) conducted the inspections of the County Administrative Boards according to the frequencies established in the annual plan. During the pandemic, MSB conducted inspections and follow-up activities through virtual meetings. Public agencies with an EPR mandate were required to submit weekly reports to MSB on the pandemic's impact. Reports from SSM on the impact of the pandemic on NPPs were discussed at the MSB weekly public agencies duty officers meeting. MSB required that all public agencies submit a completed questionnaire regarding their capability to handle a crisis situation.

SSM required that the licensees implemented actions to limit the spread of the virus at their sites. Licensees imposed strict measures the personnel such as presenting a negative COVID-19 test upon arrival, and the conduct of rapid virus tests. Licensees were also required to report to SSM the status of the impact of COVID-19 on site operations, including EPR. Some EPR exercises were postponed or altered in scope to reduce the number of staff involved. In addition to in-person inspections, SSM also reviewed and assessed

EPR activities through virtual meetings with the licensees. SSM required that the licensees assess their ability to handle a nuclear or radiological emergency with a reduced on-site staff during the pandemic.

Special arrangements for working in the SSM emergency response centre were introduced, such as re-positioning response functions to other rooms, virtual exercising of the response capability and implementing personal protective measures. In 2020, SSM exercised its virtual emergency response capability during an incident that occurred at an NPP in a neighbouring country.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
MORRIS Scott	Nuclear Regulatory Commission (NRC)	scott.morris@nrc.gov
BERNIER Frédéric	Federal Agency for Nuclear Control (FANC)	frederic.bernier@fanc.fgov.be
BRANDIŠAUSKAS Dainius	State Nuclear Power Safety Inspectorate (VATESI)	dainius.brandisauskas@vatesi.lt
FREMOUT An	Federal Agency for Nuclear Control (FANC)	an.fremout@fanc.fgov.be
HANNESSON Haraldur	National Institute of Radiation Protection (SIS)	hah@sis.dk
ILYAS Mohammad	Pakistan Nuclear Regulatory Authority (PNRA)	m.ilyas@pnra.org
INVERSO Tara	Nuclear Regulatory Commission (NRC)	tara.inverso@nrc.gov
JANŽEKOVIČ Helena	Slovenian Nuclear Safety Administration (SNSA)	helena.janzekovic@gov.si
JUAN Pierre	Autorité de Sûreté Nucléaire (ASN)	pierre.juan@asn.fr
KRS Petr	State Office for Nuclear Safety (SUJB, ret.)	pet.kr@seznam.cz
LES GIL Cristina	Nuclear Safety Council (CSN)	clg@csn.es
MAZUR Anna	Canadian Nuclear Safety Commission (CNSC)	anna.mazur@cnsc-ccsn.gc.ca
MULLER Alan	National Nuclear Regulator (NNR)	amuller@nnr.co.za
NILSSON Hugo	Swiss Federal Nuclear Safety Inspectorate (ENSI)	hugo.nilsson@ensi.ch
PREDA Stefania	National Commission for Nuclear Activities Control (CNCAN)	stefania.preda@cncan.ro
POLETTO ANTONACCI Geronimo	Nuclear Regulatory Authority (ARN)	gpoletto@arn.gob.ar
REICHE Ingo	Federal Office for the Safety of Nuclear Waste Management BASE)	ingo.reiche@base.bund.de
URQUHART Donald	Office for Nuclear Regulation (ONR)	donald.urquhart@onr.gov.uk
Observer		
VAN CALOEN Cédric	Federal Agency for Nuclear Control (FANC)	cedric.vancaloen@fanc.fgov.be
IAEA Staff		
JUBIN Jean Rene	Division of Nuclear Installation Safety	j.jubin@iaea.org
HAILU Teodros	Division of Radiation, Transport and Waste Safety	t.hailu@iaea.org
DANI Mario	Division of Nuclear Installation Safety	m.dani@iaea.org
LIAISON OFFICER		
FRANZEN Anna	Swedish Radiation Safety Authority (SSM)	anna.franzen@ssm.se
ZAZZI Åsa	Swedish Radiation Safety Authority (SSM)	asa.zazzi@ssm.se

GROUP PHOTO

APPENDIX II – MISSION PROGRAMME

Initial Mission First Week

<table>
<tr><th>Time</th><th>SAT</th><th>SUN 13.11</th><th>MON</th><th>TUE</th><th>WED</th><th colspan="3">THU</th><th>FRI</th><th>SAT</th><th>SUN</th></tr>
<tr><td>9:00-10:00</td><td rowspan="11">Arrival of Team Members</td><td rowspan="3">Arrival of Team Members</td><td>Entrance Meeting</td><td rowspan="3">Interviews / Visits</td><td rowspan="3">Interviews / Visits</td><td rowspan="3">Interviews Visits</td><td rowspan="3">Coordinator(s) write(s) introductory parts</td><td>Policy[1] Discussion</td><td rowspan="3">• Discussing and improving Draft Report between TM
• TL, DTL, TC and DTC read everything
• Secretariat edits the report:</td><td rowspan="11">Free day, Social Tour
Reading, Cross-reading of the Report by the Team Leads</td></tr>
<tr><td>10:00-11:00</td><td rowspan="2">Interviews</td><td>TM write Report</td></tr>
<tr><td>11:00-12:00</td><td>Drafts sent to Team Leads for review</td></tr>
<tr><td>12:00-13:00</td><td rowspan="2">Lunch with Host</td><td colspan="5">Standing lunch</td></tr>
<tr><td>13:00-13:30</td><td>Lunch</td><td rowspan="4">Interviews / Visits</td><td rowspan="3">Interviews / Visits</td><td rowspan="4">Interviews</td><td rowspan="4">Discussions with Team leads if necessary</td><td rowspan="4">TL and DTL review introductory part</td><td>Team Leads review drafts</td><td>Secretariat edits new draft:
New Draft Report Ready</td></tr>
<tr><td>13:30-15:00</td><td rowspan="3">Interviews</td></tr>
<tr><td>15:00-16:00</td><td rowspan="2">• Welcome
• TM self-intro
• Refresher training

Initial Team Meeting
• Mission logistics (LO)
• Discussion of first impressions
• Closing</td><td>Secretariat edits a draft report

First draft report ready

Cross-reading by TM</td><td rowspan="3">Finalisation of Draft Report (focus on Observation Boxes only)</td></tr>
<tr><td>16:00-17:00</td><td>Written preliminary findings delivered</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td>Daily Team Meeting</td><td>Daily Team Meeting: Discussion of findings (Boxes)</td><td colspan="3">Daily Team Meeting Discussion of Observations (Boxes)</td><td>Daily Team Meeting</td></tr>
<tr><td>18:00-20:00</td><td>Team Dinner</td><td>Dinner</td><td>Dinner</td><td>Dinner</td><td colspan="3">Dinner</td><td>Dinner</td><td>Dinner</td></tr>
<tr><td>20:00-24:00</td><td></td><td>Writing of the report</td><td>Writing of the report</td><td>Daily Team Meeting: Discussion of findings</td><td colspan="3">Writing of the report</td><td>Cross-reading by TM (cont'd)</td><td>Secretariat edits the report</td></tr>
</table>

[1] *Challenges of the regulatory body in the context of possible new builds (and new technologies)*

Initial Mission Second Week

<table>
<tr><th></th><th>MON</th><th colspan="2">TUE</th><th colspan="3">WED</th><th colspan="2">THU</th><th>FRI 25</th></tr>
<tr><td>9:00-10:00</td><td rowspan="2">'Pandemic' Contributions to IAEA

Discussion of Recommendations, Suggestions and Good Practises with Counterparts by module</td><td colspan="2" rowspan="2">Cross-Reading of the Report TL, DTL, TC and DTC read everything
Finalisation</td><td colspan="3">Common read through and finalisation of the Report by the Team (If necessary)</td><td rowspan="2">Host reads Draft Report</td><td></td><td>Submission of the Preliminary Report</td></tr>
<tr><td>10:00-12:00</td><td colspan="3">Submission of the Draft to the Host</td><td>Team discusses the Mission and provides IAEA with feedback</td><td>Exit Meeting
Publication of Press Release</td></tr>
<tr><td>12:00-13:00</td><td>Standing lunch</td><td colspan="2">Standing lunch</td><td colspan="3">Lunch</td><td colspan="2">Standing Lunch</td><td>Lunch</td></tr>
<tr><td>13:00-15:00</td><td>Individual discussions of Recommendations, Suggestions and Good Practises with counterparts</td><td rowspan="3">Discussion of the Report by the Team</td><td rowspan="3">Team Leads prepare Executive Summary and exit presentation</td><td rowspan="3">Host reads Draft Report</td><td rowspan="3">TL finalises Executive Summary and Exit Presentation</td><td rowspan="3">TC Drafts the Press Release</td><td colspan="2">Written comments provided by the Host

Team meeting to discuss and resolve Host comments</td><td rowspan="5">Departure</td></tr>
<tr><td>15:00-17:00</td><td>Updating/finalization of draft report</td><td colspan="2">Plenary (Team + Host) to discuss Host comments and finalize the report</td></tr>
<tr><td>17:00-18:00</td><td>Daily Team Meeting</td><td colspan="2">Briefing of the Senior IAEA Manager; Finalisation of the press release and of the Preliminary Report</td></tr>
<tr><td>18:00-20:00</td><td>Dinner</td><td colspan="2">Dinner</td><td colspan="3">Dinner</td><td colspan="2" rowspan="2">Farewell Dinner</td></tr>
<tr><td>20:00-21:00</td><td rowspan="2">Secretariat updates Report</td><td colspan="2" rowspan="2">Secretariat finalises Report</td><td colspan="3" rowspan="2">Free</td></tr>
<tr><td>21:00-24:00</td><td colspan="2">Free</td></tr>
</table>

APPENDIX III – SITE VISITS

1. Westinghouse Fuel Cycle Facility, Västerås
2. Västmanland Hospital Oncology Department, Västerås
3. Forsmark NPP, Östhammar
4. Cyclife Radioactive Waste Management Facility, Studsvik
5. Gems Pet Systems, Uppsala
6. Ågesta NPP (under decommissioning), Farsta

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Anna Mazur (Canada)	FRED, Charlotta (Head Government offices Chemical Division)	LILJEQUIST, Karin (Government offices chemical division) PETERSSON, Robert (Legal Services at the Ministry of the Environment) GERLAND, Susanne (Deputy Head of the Division for Legal Services at the Ministry of the Environment) GERHARDSSON, Ansi (SSM DG's office)
2.	**THE GLOBAL SAFETY REGIME**		
	Dainius Brandisauskas (Lithuania)	BERGSTRÖM MÖRTBERG, Anna (Head of Department for International Policies and co-operation)	SANDBERG, Nils (International Policies and co-operation)
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Hugo Nilsson (Switzerland)	CROMNIER, Nina (Director General)	TÖRNER, Anna (Head of Division for Regulation and Knowledge Development)
4.	**MANAGEMENT OF THE REGULATORY BODY**		
	Muhammad Ilyas (Pakistan)	GISTORP, Johan (Head of Division for Organisational Services)	WIDE NELSON, Anna Maria (DG's office) BENGTSSON, Martin (Human Resources) JOHANSEN, Pia (Human Resources) EDLAND, Anne (Head of Department for Coordination, Human and Organisational Factors)

	IRRS EXPERTS	Lead Counterpart	Support Staff
			CIVETT, Johanna (Organisational Services) HEDBERG, Björn (Coordination, Human and Organisational Factors) SINDAHL, Tina (Economy)
5.	**AUTHORIZATION**		
	Donald Urquhart (United-Kingdom)	RANLÖF, Lisa (Head of Department for Licensing of Nuclear Facilities) JÖNSSON, Helene (Head of Department for Authorisation of Radiation Applications)	WIEBERT, Anders (Licensing of Nuclear Facilities) OSSIPOVA, Natalia (Authorisation of Radiation Applications)
6.	**REVIEW AND ASSESSMENT**		
	Tara Inverso (United States of America)	HÖGLUND, Erik (Head of Division for Supervision)	HARTMAN PERSSON, Anita (Head of Department for Operation and decommissioning of Nuclear Facilities) HEDBERG, Björn (Coordination, Human and Organisational Factors)
7.	**INSPECTION**		
	Cristina Les Gil (Spain)	EDLAND, Anne (Head of Department for Coordination, Human and Organisational Factors)	LINDSTRÖM, Karin (Coordination, Human and Organisational Factors) CHAIKIAT, Per (Coordination, Human and Organisational Factors)
8.	**ENFORCEMENT**		
	Petr Krs (Czech)	ELOFSSON, Kim (Chief Legal Officer)	HARALDSSON, Anna (Legal Affairs)

	IRRS EXPERTS	Lead Counterpart	Support Staff
9.	**REGULATIONS AND GUIDES**		
	Poletto Gerónimo (Argentina)	OBENIUS-MOWITZ, Aino (National Regulation)	YNGVESSON, Ulf (General Counsel) GUSTAVSSON, Marcus (National Regulation)
10.	**EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS**		
	Alan Muller (South Africa)	FRIBERG, Johan (Head of Division for Emergency Preparedness, Security and Licensing)	DANESTIG SJÖGREN, Catarina (Head of Department for Development of Emergency Preparedness and Response) JOHANSSON, Jan (Development of Emergency Preparedness and Response) *Swedish Civil Contingencies Agency (MSB)* PERBECK, Patrik (MSB Acting Head of Department for emergency services and accident prevention) ASP, Anna (MSB Legal Services) LÖVRUP, Erik (MSB Legal Services) NORLANDER, Peter (MSB Department for emergency services and accident prevention) POSTGÅRD, Pelle (MSB Department for emergency services and accident prevention)
11.	**INTERFACE WITH NUCLEAR SECURITY**		
	Dainius Brandisauskas (Lithuania)	LINDAHL, Pär (Development of Emergency Preparedness and Response)	UNGELL, Mikael (Implementation of Emergency Preparedness and Response)

	IRRS EXPERTS	Lead Counterpart	Support Staff
	Decommissioning and Radioactive waste management facilities		
	Frederic Bernier (Belgium)	EGAN, Michael (Licensing of Nuclear Facilities)	KOZARCANIN, Adnan (Operation and Decommissioning of Nuclear Facilities) EFRAIMSSON, Henrik (Supervision, General Public and Environment) ZAZZI, Åsa (Plant Safety Assessment)
	Fuel Cycle Facilities		
	Pierre Juan (France)	FORSS HADI, Christoffer (Operation and decommissioning of Nuclear Facilities)	BEJARANO, Gabriela (Operation and decommissioning of Nuclear Facilities)
	Medical Exposure		
	An Fremout (Belgium)	BLADH, Carl (acting Head of Department for Radiation Protection and Environmental Assessment)	IDESTRÖM, Lars (Authorisation of Radiation Applications) CEDERLUND, Torsten (Authorisation of Radiation Applications) FRANK, Anders (National Regulation) LAGER, Charlotte (Head of Department for Supervision, Medical and Occupational Exposure)
	Nuclear Power Plants		
	Donald Urquhart (United-Kingdom) Tara Inverso (United States of America) Cristina Les Gil (Spain) Poletto Gerónimo (Argentina)	HANBERG, Jan (Head of Department for Plant Safety Assessment)	WESTERHOLM, Pasi (Supervision, Operation and decommissioning of Nuclear Facilities) LILLHÖK, Sofia (Head of Supervision Event Analysis and Engineering)

	IRRS EXPERTS	Lead Counterpart	Support Staff
	Occupational Exposure		
	Stefania Preda (Romania)	LAGER, Charlotte (Head of Department for Supervision, Medical and Occupational Exposure)	HOFVANDER, Peter (International policies and co-operation) OSSIPOVA, Natalia (Authorisation of Radiation Applications)
	Public Exposure		
	Haraldur Hannesson (Denmak)	HÄGG, Anki (International policies and co-operation)	ANDERSSON, Pål (Radiation Protection and Environmental Assessment)
	Radiation Sources		
	Helena Janzekovic (Slovenia)	ANDERSSON, Tomas (Authorisation of Radiation Applications)	HOLZWARTH, Richard (Medical and Occupational Exposure) FRANK, Anders (National Regulation)
	Transport		
	Ingo Reiche (Germany)	WALLIN, Michael (Nuclear Non-Proliferation and Transport)	KOUFAKIS, Markos (Nuclear Non-Proliferation and Transport)

APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	**R1**	The Government should amend the legislation to address the gaps in penalties for failure to comply with requirements of the RPA.
	S1	SSM should consider establishing formal arrangements for coordination with other administrative authorities having responsibilities for safety.
	R2	The Government should adopt a national strategy for competence addressing current and future needs, considering the recent political development on nuclear power in Sweden.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**S2**	SSM should consider further defining and establishing appropriate interaction and interfaces between its organizational units (divisions and departments). This should be clearly established in the management system and communicated to all stakeholders.
	R3	SSM should ensure that there are sufficient qualified staff to fulfil all its statutory and regulatory functions.
	S3	SSM should consider further strengthening individual training programmes to focus on systematic training and retraining in technical areas that are needed to deliver its regulatory functions.
	S4	SSM should consider reviewing the completeness of the safety related records kept at SSM and developing procedures for how such records are managed, including defining retention periods.
	S5	SSM should consider further prioritizing the objectives included in the strategic road map.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**R4**	SSM should finalize the review and revision of the overall structure of the management system documentation to ensure consistency, clarity and completeness.
	S6	SSM should consider developing a specific process to manage and review organizational changes.
	R5	SSM should establish a process for the management system records that reflects all types of records generated, and their categorization, retention time and disposal.
	R6	SSM should establish necessary provisions in the management system and competences to foster and support a culture for safety in the organization.
	R7	SSM should establish requirements for conducting self-assessments in its management policy and develop a documented process.
	R8	SSM should conduct internal audits according to a well-defined process. The management policy and steering document should be aligned accordingly.
	R9	SSM should establish a documented process for conducting periodic reviews of the management system.
	R10	SSM should develop the methods for Safety Culture Self-Assessments (SCSA) and establish related provisions in the management system.
5. AUTHORIZATION	**R11**	SSM should review its authorization processes to ensure that they include clear, documented and consistent processes for all types of authorization, including the notification and revocation processes.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R12	SSM should ensure sufficient resources are available to deliver its authorization responsibilities in a timely manner, whilst accommodating retirements, resignations and illnesses etc.
	S7	SSM should consider clearly articulating the basis of its independence in instances where it could be possible for Government to grant a licence counter to SSM advice.
	R13	SSM should establish a proportionate verification process for authorization by notification to ensure that the notified practice falls within generic safety assessment, including the cumulative impact of multiple radioactive sources.
	R14	SSM should revise its guidance on the format and content of the documents to be submitted by an applicant, in support of an application for a licence, for all radiation sources facilities and activities.
	S8	SSM should consider requiring the designation of a radiation protection officer for radiation sources facilities or activities to ensure safety measures are implemented on a regular basis.
	R15	SSM should ensure that disused sources and newly discovered orphan sources are subject to proper management, including their safe storage. SSM should also develop a programme for search of orphan sources.
	S9	SSM should consider developing internal guidance and establishing a mechanism for verification of the appropriateness of the licensee's classification of radiation workers.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
6. REVIEW AND ASSESSMENT	**S10**	SSM should consider developing internal procedures for review and assessment, including a procedure on the conduct of Integrated Safety Assessments, to provide assurance that the depth and scope is commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.
	R16	SSM should ensure the availability of competences related to radioactive waste disposal and capabilities to maintain independent assessment and to undertake international cooperation.
	R17	SSM should develop a procedure for consistency in review and assessment of information provided by an applicant for authorization of radiation sources facilities and activities.
	GP1	The DosReg portal is a very comprehensive tool for supervision and optimisation of patient dosimetry, both for licensees and for SSM. Additionally, the data on hospitals, equipment and typical doses for procedures, including clinical indication, being open access, allows any interested party to find relevant benchmarks for patient dosimetry.
	R18	SSM should establish protection strategies and reference values for all existing exposure situations.
	R19	SSM should make provisions for independent monitoring of discharges and of the environment.
7. INSPECTION	**R20**	SSM should include unannounced inspections in their supervision programmes and annual inspection plans.
	S11	SSM should consider establishing a procedure and developing criteria for when and how a reactive inspection should be undertaken in accordance with a graded approach.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R21	SSM should develop guidance for conducting inspections in the areas of physical protection, emergency preparedness and transport.
	S12	SSM should consider expanding the scope of its NPP refuelling outage inspection activities and revising the refuelling outages guidance accordingly.
	R22	SSM should enhance the supervision programme for fuel cycle facilities in order to cover all regulated areas and to determine the associated frequencies in accordance with a graded approach.
	R23	SSM should revise its inspection programme for radiation sources facilities and activities in accordance with a graded approach. The programme should stipulate the frequency of inspections and cover temporary storage of disused and orphan sources.
	R24	SSM should develop a complete set of procedures and checklists for all areas and types of inspections of radiation sources facilities and activities. SSM should develop a procedure for follow-up of required corrective actions for radiation sources facilities and activities.
	S13	SSM should consider introducing verification measurements and confirmatory tests when conducting inspections of radiation sources facilities and activities.
	R25	SSM should develop the supervision programme for the transport of radioactive material.
	S14	SSM should consider including verification of the radon level in workplaces in its inspection programme.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
9. REGULATIONS AND GUIDES	**S15**	SSM should consider finalizing the separation of requirements from the guidance documentation and revising the implementation of the "General Advice" to better distinguish requirements from guidance.
	R26	SSM should establish provisions for conducting systematic assessments of its full set of regulations, in order to ensure that regulations are comprehensive.
	S16	SSM should consider revising its procedure for development and amendment of regulations to systematically consider international regulatory experience.
	R27	SSM should further develop their regulations and guides specifying the criteria for the safe operation of facilities and conducting activities with radiation sources to cover all facilities and activities. SSM should develop a guide on the content of safety assessments of radiation sources facilities and activities.
	R28	SSM should update the regulation related to disposal of radioactive waste to be fully in line with IAEA safety requirements.
	S17	SSM should consider establishing record keeping guidance on all data needed to assess individual doses for workers for whom the assessment of the occupational exposure of workers is not conducted by individual monitoring.
	R29	The Government should ensure that generic justification of radiological procedures is carried out by the relevant authorities in conjunction with appropriate professional bodies.
10. EMERGENCY PREPAREDNESS AND	**S18**	SSM should consider completing the assessment for all non-nuclear facilities to identify those that should be placed in EPC III.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
RESPONSE – REGULATORY ASPECTS	**S19**	SSM should consider revising the regulations to include provisions for non-nuclear facilities to submit changes to radiological emergency response plans to SSM for approval.
	R30	SSM should develop specific, internal guidance, checklists and criteria for the review of emergency response plans.
	R31	The Government should assign the responsibility to the appropriate regulatory authorities to provide expert services related to actual and expected future radiation risks to public health in the event of a nuclear or radiological emergency.
	R32	The Government should assign the responsibility to the appropriate parties for the procurement, storage, distribution and the authority to recommend intake of iodine thyroid blocking.
11. INTERFACE WITH NUCLEAR SECURITY	**R33**	SSM should establish requirements on optimization of safety taking into account security for transports of nuclear material, and system of accounting for, and control of, nuclear material.

APPENDIX VI – COUNTERPART'S REFERENCE MATERIAL USED FOR THE REVIEW

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) *(in Swedish only)*
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 *(in Swedish only)*
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) *(in Swedish only)*
SFS 2006:1570	Law (2006:1570) on protection against international threats to human health *(in Swedish only)*
SFS 2009:400	Public Access to Information and Secrecy Act (2009:400) *(in Swedish only)*
SFS 2010:305	Installations Protection Act (2010:305) *(in Swedish only)*
SFS 2010:659	Patient Safety Act (2010:659) *(in Swedish only)*
SFS 2010:950	Act (2010:950) concerning radiological accident liability and compensation
SFS2016:1145	Public Procurement Act
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) *(in Swedish only)*

Ordinances

SFS 1977:1166	Work Environment Ordinance (1977:1166)
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 *(in Swedish only)*

SFS 1998:899	Ordinance concerning environmentally hazardous activities (1998:899) *(in Swedish only)*
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 *(in Swedish only)*
SFS 2003:396	Ordinance (2003:396) on electronic communications *(in Swedish only)*
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 *(in Swedish only)*
SFS 2006:813	Food Ordinance (2006:813) *(in Swedish only)*
SFS 2006:814	Ordinance (2006:814) on feed and animal by-products *(in Swedish only)*
SFS 2007:515	Government Authority Ordinance (2007:515)
SFS 2007:913	Ordinance (2007:913) with instructions for the Swedish Work Environment Authority *(in Swedish only)*
SFS 2007:1054	Ordinance (2007:1054) with instructions for local safety committees at nuclear facilities *(in Swedish only)*
SFS 2007:1161	Ordinance (2007:1161) with instructions for the Swedish Maritime Administration *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
SFS 2009:1395	Ordinance (2009:1395) with instructions for the Sami Parliament *(in Swedish only)*
SFS 2009:1426	Ordinance (2009:1426) with instructions for the National Food Administration *(in Swedish only)*

SFS 2009:1464	Ordinance (2009:1464) with instructions for the Swedish Board of Agriculture *(in Swedish only)*
SFS 2009:974	Ordinance (2009:974) with instructions for the Swedish Meteorological and Hydrological Institute *(in Swedish only)*
SFS 2010:185	Ordinance (2010:185) with instructions for the Swedish Transport Administration *(in Swedish only)*
SFS 2011:13	Environmental Supervision Ordinance (2011:13)
SFS 2012:546	Instructions (2012:546) to the Swedish National Board of Housing *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
SFS 2016:1332	Ordinance (2016:1332) with instructions for the Swedish Customs *(in Swedish only)*
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 *(in Swedish only)*
SFS 2021:248	Ordinance (2021:248) with instructions for the Swedish Public Health Agency *(in Swedish only)*
SFS2021:667	Amendment to ordinance (2008:452)

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 *(in Swedish only)*
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 *(in Swedish only)*
SSMFS 2008:47	SSM's regulations (SSMFS 2008:47) on smoke alarms that contain a radiation source with a radioactive substance *(in Swedish only)*
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. *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
SSMFS-A	SSM's regulations (SSMFS-A) concerning the assessment and presentation of radiation safety for nuclear power plants – *reference version, final version published as SSMFS2021:5*
SSMFS-D	SSM's regulations (SSMFS-D) concerning operation of nuclear power plants – *reference version, final version published as SSMFS2021:6*
SSMFS-K	SSM's regulations (SSMFS-K) concerning the design of nuclear power plants – *reference version, final version published as SSMFS2021:4*
SSMFS-KÄKA	SSM's regulations (SSMFS-KÄKA) concerning management of radioactive waste from nuclear facilities – *reference version, final version published as SSMFS2021:7*
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 *(in Swedish only)*
LIVSFS 2012:3	The National Food Administration's regulations (LIVSFS 2012:3) on foreign substances in food *(in Swedish only)*
MSBFS 2015:5	MSBFS 2015:5 regulations and general advice on municipalities' risk and vulnerability analyses *(in Swedish only)*
MSBFS 2016:7	MSBFS 2016:7 regulations and general advice on government agencies' risk and vulnerability analyses *(in Swedish only)*
MSBFS 2017:3	MSBFS 2017:3 regulations on information in emergency situations where there is a risk of radiation *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
SOSFS 1997:14	The Swedish National Board of Health and welfare regulation (SOSFS 1997:14) on delegation of tasks within healthcare and dentistry *(in Swedish only)*
SRVFS 2004:9	SRVFS 2004:9 regulations on the authority to be a rescue leader in a municipal rescue service *(in Swedish only)*
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 *(in Swedish only)*
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 (*Östersjöavtalet*) *(in Swedish only)*

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 *(in Swedish only)*
15-3444	15-3444 Division of activities for consultation and approval (Notification obligation) *(in Swedish only)*
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) *(in Swedish only)*
SOSFS 2004:11	The National Board of Health and Welfare requirements (SOSFS 2004:11) on responsibility for referrals of patients in healthcare and dentistry *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
SSM2012-3022-16	SSM2012-3022-16 Conditions for independent core cooling for Oskarshamn 3
SSM2014-127-1	SSM2014-127-1 Review report/plan ESS *(in Swedish only)*
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 *(in Swedish only)*
SSM2019-3395-2	SSM2019-3395-2 Cyclife conditions *(in Swedish only)*
SSM2019-5701-1	SSM2019-5701-1 Order on measures for the disposal of nuclear waste Westinghouse *(in Swedish only)*
SSM2019-6915-60	SSM2019-6915-60 Special conditions for the ESS facility in Lund *(in Swedish only)*
SSM2019-6915-61	SSM2019-6915-61 Permit for activities with ionising radiation *(in Swedish only)*
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 *(in Swedish only)*
SSM2020-7537-3	SSM2020-7537-3 Appendix 1, Special conditions for the ESS facility in Lund *(in Swedish only)*
SSM2021-1033-6	SSM2021-1033-6 Penalty injunction Chalmers *(in Swedish only)*
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 *(in Swedish only)*
STYR2011-32	STYR2011-32 Document governance
STYR2011-33	STYR2011-33 Staff appraisals
STYR2011-42	STYR2011-42 Internal auditing *(in Swedish only)*
STYR2011-45	STYR2011-45 Recruitment routine *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
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. *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)*
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 *(in Swedish only)* (*superseded by 21-2384*)
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 *(in Swedish only)*
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 (*superseded by 21-2384*)
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 *(in Swedish only)*
21-1282	21-1282 Needs Analysis for Research Funding 2021 from the Department of Nuclear Safety *(in Swedish only)*
21-872	21-872 Instructions for applicants - Published on SSM's website *(in Swedish only)*
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) *(in Swedish only)*
MSB1625	MSB1625 National strategy for systematic exercise activities: for crisis preparedness and civil defense *(in Swedish only)*
NV-rapport 5977	Risk assessment of contaminated areas, NV report 5977 *(in Swedish only)*
NV-rapport 5978	Choosing a finishing method. NV report 5978 *(in Swedish only)*
RIR 2019:30	If the worst were to happen - The state's work to prevent nuclear accidents (RIR 2019:30) *(in Swedish only)*
SOU 2021:19	SOU 2021:19 A strengthened security of supply for health and medical care *(in Swedish only)*
SSM2015-3257-100	SSM2015-3257-100 Transport flows and doses to staff and the general public during transport of radioactive substances in Sweden (2019) *(in Swedish only)*
SSM2015-4192-1	SSM2015-4192-1 Review plan SFR expansion (SFR-U) *(in Swedish only)*
SSM2015-4872	SSM2015-4872 *(in Swedish only)*
SSM2016-1824-42	SSM2016-1824-42 National action plan for radon *(in Swedish only)*
SSM2017-134	SSM2017-134 Government assignment on long-term competence supply *(in Swedish only)*
SSM2018-2459	SSM2018-2459 waste register/internal transport AB SVAFO *(in Swedish only)*
SSM2018-4056-2	SSM2018-4056-2 Inspection of waste registers, internal transports and controlled area at Clab *(in Swedish only)*
SSM2021-8026-1	SSM2021-8026-1 Roadmap for the strategic objectives

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Leadership and Management for Safety, General Safety Requirements Part 2, No. GSR Part 2, IAEA, Vienna (2016)
4.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No. GSR Part 3, IAEA, Vienna (2014).
5.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste, General Safety Requirement Series Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Facilities, General Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014)
8.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirement Series No. GSR Part 7, IAEA, Vienna (2015)
9.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Site Evaluation for Nuclear Installations, Specific Safety Requirement Series No. SSR-1, IAEA, Vienna (2003)
10.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Design, Specific Safety Requirements Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Research Reactors, Specific Safety Requirements Series No. SSR-3, IAEA, Vienna (2016)
13.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements Series No. SSR-4, IAEA, Vienna (2017)
14.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Disposal of Radioactive Waste, Specific Safety Requirements Series No. SSR-5, IAEA, Vienna (2011)
15.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018)
16.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
17.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, Safety Guide Series No GSG-2, IAEA, Vienna (2012)
18.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide Series No. GSG-6, IAEA, Vienna (2017).

19.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide Series No. GSG-7 , IAEA, Vienna (2018)
20.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No GSG-9, IAEA, Vienna (2018)
21.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide Series No. GSG-12, IAEA, Vienna (2018).
22.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Functions and Processes of the Regulatory Body for Safety, General Safety Guide Series No. GSG-13, IAEA, Vienna (2018).
23.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
24.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008) (superseded by GSG-16)
25.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
26.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006) (Superseded by SSG-50)
27.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Modifications to Nuclear Power Plants, Safety Guide Series No NS-G-2.3, IAEA, Vienna (2001) (Superseded by SSG-71)
28.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide Series No NS-G-2.8, IAEA, Vienna (2002)
29.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
30.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2008)
31.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Borehole Disposal Facilities for Radioactive Waste, Safety Guide Series No SSG-1, IAEA, Vienna (2009)
32.	**INTERNATIONAL ATOMIC ENERGY AGENCY -** Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
33.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
34.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
35.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
36.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
37.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Spent Nuclear Fuel, Safety Guide Series No SSG-15 (Rev. 1), IAEA, Vienna (2020)

38.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Periodic Safety Review for Nuclear Power Plants, Safety Guide Series No SSG-25, IAEA, Vienna (2013)
39.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26 (Rev. 1), IAEA, Vienna, (2018)
40.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide Series No SSG-40, IAEA, Vienna (2016)
41.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-41, IAEA, Vienna (2016)
42.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No SSG-45, IAEA, Vienna (2019)
43.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-47, IAEA, Vienna (2018)
44.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide Series No SSG-48, IAEA, Vienna (2018)
45.	**INTERNATIONAL ATOMIC ENERGY AGENCY** –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide Series No SSG-49, IAEA, Vienna (2019)
46.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – Operating Experience Feedback for Nuclear Installations, Safety Guide Series No SSG-50, IAEA, Vienna (2019)
47.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Accident Management Programmes for Nuclear Power Plants, Safety Guide Series No SSG-54, IAEA, Vienna (2019)
48.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002) (Superseded by SSG-65)
49.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
50.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna, (2008)
51.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009)
52.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2009 Edition), Safety Guide No TS-G-1.6 (Rev.1), IAEA, Vienna, (2014)
53.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No WS-G-6.1, IAEA, Vienna (2006)
54.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)

APPENDIX VIII – ORGANIZATIONAL CHART