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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

FOLLOW-UP MISSION

TO

SWEDEN

Stockholm, Sweden

25 April – 3 May 2016

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA
Integrated Regulatory Review Service
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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
FOLLOW-UP REPORT TO
SWEDEN

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Mission date:	*25 April – 3 May 2016*
Regulatory body:	*Swedish Radiation Safety Authority (SSM)*
Location:	*Stockholm, Sweden*
Organized by:	*IAEA*

IRRS REVIEW TEAM	
SCHWARZ Georg	Team Leader (Switzerland)
KOKAJKO Lawrence	Deputy Team Leader (USA)
CORTES Alejandro	Reviewer (Mexico)
JANSEN Rob	Reviewer (the Netherlands)
MADDEN Jack	Reviewer (Ireland)
MARKKANEN Mika	Reviewer (Finland)
MCCARTIN Timothy	Reviewer (USA)
RAHMAN Muhammad	Reviewer (Pakistan)
SENIOR David	Reviewer (UK)
MAGRUDER Stewart	Team Coordinator (IAEA)
AL KHATIBEH Ahmad	Deputy Team Coordinator (IAEA)
REBIKOVA Olga	Administrative Assistant (IAEA)

The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

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 25 April to 3 May 2016 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The mission took place at SSM Headquarters in Stockholm. The purpose of the peer review was to review the Swedish regulatory framework for nuclear and radiation safety.

The review compared the Swedish regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Swedish counterparts in the areas covered by the IRRS.

The IRRS team consisted of 9 senior regulatory experts from 8 IAEA Member States, 2 IAEA staff members and 1 IAEA administrative assistant. The IRRS team carried out the review in the areas covered by the main mission in 2012 excluding the lessons learned from the TEPCO Fukushima Daiichi accident.

The IRRS review addressed the full scope of regulated facilities and activities.

The mission included interviews and discussions with SSM staff, representatives from the Ministry of Environment and Energy, Ministry of Education and Research, Ministry of Justice, Ministry of Finance, Swedish Customs, Swedish Civil Contingencies Agency, County Administrative Board of Uppsala and Vattenfall AB.

SSM provided the IRRS team with advance reference material and documentation including the follow-up report. Throughout the mission, the IRRS team was extended full cooperation in regulatory and technical areas by all parties; in particular, the staff of SSM provided the fullest practicable assistance and demonstrated extensive openness and transparency.

Since the initial mission in 2012, there was a significant change concerning the Swedish energy policy. The new Government elected in 2014 decided to develop a new energy policy that would be sustainable over the long term. The Government’s goals are the replacement of nuclear power by renewable energy, greater energy efficiency, and Sweden's eventually reaching 100 per cent renewable energy sources. In 2015 Vattenfall communicated that it had postponed its plans to prepare for the construction of new nuclear power plants.

This change was considered during the follow-up review e.g. causing new challenges for SSM:

- The decline in electricity prices presents an economic challenge for the utilities in Sweden. The challenge for SSM is to ensure that the economic pressure on the industry does not have a negative effect on nuclear safety.
- As a reaction to the changed economic environment, the Swedish nuclear industry announced that they intended to prematurely cease the operation of four reactors. The challenge for SSM is preparing for the regulation of large-scale decommissioning.

The IRRS team noted that the recommendations and suggestions from the 2012 IRRS mission have been considered systematically. Significant progress has been made in most areas. Specifically, 20 out of 22 recommendations and all 17 suggestions were closed. During the follow-up mission, the IRRS team developed 4 new suggestions and identified 2 new good practices.

The IRRS team made the following general observations of progress made by Sweden since the 2012 IRRS mission:

- Sweden has systematically and comprehensively addressed the findings of the 2012 IRRS mission and has demonstrated commendable performance in improving the regulatory system for nuclear safety.
- The Government and SSM embarked on comprehensive projects to address the EU Directives and EU Basic Safety Standards, IRRS 2012 Mission findings and other identified changes to the nuclear and radiation protection legal and regulatory framework.

- SSM has developed a well-defined set of criteria for assessing the risks involved in different types of uses of radiation sources.

The IRRS team identified new findings warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system:

- SSM should complete a comprehensive resource and competence assessment, based on a strategic review, which incorporates the Swedish nuclear industry's perspective.
- SSM should consider making key management system process documentation easily available to the applicants, licensees and other interested parties.
- The Government should consider expanding the scope of the national emergency response plan for management of nuclear accidents to include radiological emergencies based on a thorough threat/hazard assessment.

The IRRS team findings are summarized in Appendices IV and V.

A joint IAEA and SSM press conference took place at the end of the mission during which an IAEA press release was issued.

I. INTRODUCTION

At the request of the Government of Sweden, an international team of senior safety experts met representatives of SSM from 25 April to 3 May 2016 to conduct an IRRS follow-up mission. The purpose of the peer review was to review the Swedish regulatory framework for nuclear and radiation safety. The follow-up mission was formally requested by the Government of Sweden in March 2014. A preparatory mission was conducted 28 to 29 September 2015 at SSM Headquarters in Stockholm to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities regulated by SSM and selected safety aspects.

The IRRS review team consisted of 9 senior regulatory experts from 8 IAEA Member States, 1 IAEA staff members and 1 IAEA administrative assistant. The IRRS review team carried out the review in the areas covered by the main mission in 2012 excluding the lessons learned from the TEPCO Fukushima Daiichi accident.

SSM prepared a national follow-up report addressing the findings of the main mission. The results of Sweden's follow-up report and supporting documentation were provided to the team as advance reference material (ARM) for the mission. During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from SSM, Ministry of the Environment and Energy, Ministry of Education and Research, Ministry of Justice, Ministry of Finance, Swedish Customs, Swedish Civil Contingencies Agency and County Administrative Board of Uppsala.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the Swedish radiation and nuclear safety regulatory framework and activities to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by SSM. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in Sweden and other Member States from the knowledge gained and experiences shared between SSM and IRRS reviewers and through the evaluation of the effectiveness of the Swedish regulatory framework for nuclear and radiation safety and its good practices.

The key objectives of this mission were to enhance nuclear and radiation safety, as well as emergency preparedness and response:

- Providing Sweden and SSM with a review of its regulatory programme relating to nuclear and radiation safety, and emergency preparedness in view of the progress made since the initial mission;
- Providing Sweden and SSM with an objective evaluation of its nuclear and radiation safety, as well as emergency preparedness and response regulatory activities with respect to IAEA safety standards;
- Contributing to the harmonization of regulatory approaches among IAEA Member States;
- Promoting the sharing of experience and exchange of lessons learned;
- Providing reviewers from IAEA Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own fields;
- Providing key SSM staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing Sweden and SSM with recommendations and suggestions for improvement; and
- Providing other States with information regarding good practices identified in the course of the review.

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 IRRS follow-up mission was conducted from 28 to 29 September 2015. The preparatory meeting was carried out by the appointed Team Leader Mr Georg Schwarz, Deputy Team Leader Mr Lawrence Kokajko and the IRRS IAEA team representatives, Ms Adriana Nicic and Mr Ahmad Al Khatibeh.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of SSM represented by Mr Fredrik Hassel, SSM Deputy Director General, other senior management and staff. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

- Nuclear power plants;
- Fuel cycle facilities;
- Waste facilities;
- Radiation sources facilities;
- Decommissioning;
- Transport;
- Patient protection;
- Occupational radiation protection;
- Public and environmental exposure control;
- Waste management (policy and strategy, predisposal and disposal);

Mr Hassel made presentations on the national context, the current status of SSM and the progress made by SSM since the original mission of 2012.

IAEA staff presented the IRRS principles, process and methodology of conducting a follow-up IRRS mission. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Sweden in April-May 2016.

The proposed IRRS review team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS review team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer identification, lodging and transport arrangements were also addressed.

The SSM Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Ms Anna Franzén.

SSM provided the IAEA (and the review team) with the advance reference material for the review at the end of February 2016. In preparation for the mission, the IAEA review team members conducted a review of the ARM and provided their initial review comments to the IAEA Team Coordinator prior to the follow-up mission.

B) REFERENCE FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

An opening IRRS review team meeting was conducted on Monday, 25 April 2016, in Stockholm by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. They also presented the agenda for the mission.

The Liaison Officer was present at the initial IRRS review team meeting on Monday afternoon, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The reviewers also reported their first impressions of the ARM and provided the Team Leader with slides for his presentation at the entrance meeting.

The IRRS entrance meeting was held on Tuesday, 26 April 2016, with the participation of SSM senior management and staff and representatives from the Ministry of the Environment and Energy. Opening remarks were made by Mr Mats Persson, Director General of SSM, Mr Stewart Magruder, IRRS Team Coordinator and Mr Georg Schwarz, IRRS Team Leader who made a presentation highlighting the expectations of the mission and initial impressions on the ARM. Mr Björn Dufva, Deputy Director General of Ministry of the Environment and Energy gave an overview of the Swedish context and changes in Swedish Politics and Mr Mats Persson addressed SSM activities and the SSM response to the 2012 mission findings.

During the mission, a review was conducted for all the review areas with the objective of reviewing the Government and SSM's response to the recommendations and suggestions identified during the original mission. The review was conducted through meetings, interviews and discussions regarding the national practices and activities.

The IRRS review team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Tuesday, 3 May 2016 where the IRRS Team Leader Mr Georg Schwarz presented the results of the follow-up mission highlighting the main findings. This was followed by the statement by Mr Mats Persson in response to the Team Leader's presentation. Closing remarks were made by Mr Ahmad Al Khatibeh.

A joint IAEA and SSM press conference took place at the end of the mission during which an IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

New Governmental Energy Policy

After the 2014 election, the Government was formed by a coalition of the Social Democratic Party and Swedish Green Party. The new Prime Minister announced that the Government had made an invitation to the parties in Parliament to participate in a special energy commission. The aim of the energy policy commission, formally appointed in March 2015, was to reach an energy policy agreement that would be sustainable over the long term (2050 perspective). The long-term vision of the Government is an energy system based entirely on renewable energy sources.

In the Government Budget Bill for 2015, the Government stated that it planned to adopt a holistic approach to the government-owned enterprise Vattenfall and its management with the aim of making it a leader in transitioning the energy mix towards a higher proportion of renewable energy sources. Further, the Government stated that Vattenfall had terminated its plans to prepare for the construction of new nuclear power plants.

New plans for the Swedish nuclear energy industry

In autumn 2015 the respective owners and majority shareholders of Ringhals and Oskarshamn announced that they intended to cease the operation of four reactors – two at each plant – and earlier than planned for economic reasons. This was a decision taken due to several reasons affecting the economy including low electricity price, increased safety demands, and the tax on thermal power output. One reactor at Oskarshamn would be immediately removed from production. The other reactors will be subject to a phased shut down by 2020.

Regulation in a declining economic environment

The price of electricity in Sweden has declined by 65% since 2010. The decline in electricity prices presents an economic challenge for the nuclear utilities in Sweden. The challenge for SSM is to ensure that the economic pressure on the industry does not have a negative effect on nuclear safety.

National Waste Management Policy and Strategy Plan

The first version of the National Waste Management Policy and Plan was published at the time of the establishment of SSM. During the IRRS Mission in 2012 the team suggested consideration should be given to a new responsibility within the planned review of the policy in 2013.

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S17	**Suggestion: The government should consider assigning SSM to review and integrate the national waste management policy and strategy plan.**

Changes since the initial IRRS mission

Suggestion 17: The IRRS team found that through an amendment made to the Ordinance (2008:452) with instructions to SSM, the SSM is now responsible for maintaining an up-to-date national plan for the management of spent fuel and radioactive waste. The latest National Plan on Waste Management was published as SSM Report 2015:32 in 2015.

Status of the finding in the initial mission

Suggestion 17 is closed. The Government assigned SSM the responsibility to maintain and update the national waste management policy and strategic plan.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

International & European Framework Changes

In addition to the findings relating to the Framework for Safety arising from the 2012 IRRS Mission, the Government and SSM are addressing the requirements of the latest EU Directives relating to nuclear and radiation safety. The EU amended the EU nuclear safety directive (2014/87/EURATOM) in 2014 on the basis of the lessons learned from Fukushima nuclear accident, the safety requirements of the IAEA and WENRA and stress tests completed across Europe in 2011/12. EU member states are required to adopt the requirements and demonstrate compliance with the revised Directive by August 2017. Regarding radiation protection the EU radiation protection directive (EU BSS – 2013/59/EURATOM) came into force in February 2014 and EU member states are required to adopt these requirements and demonstrate compliance by February 2018. In Sweden the Government gave SSM the task to propose necessary legislative changes in order to implement the EU Directives on nuclear safety and radiation protection, IRRS 2012 Mission findings and other identified changes to legislation and regulations. The IRRS team noted that this is a significant and resource intensive effort and that both the Government and SSM are giving this a high priority to complete the project by February 2018.

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R1	**Recommendation: The government and SSM should establish a strategically focused process to ensure the regulatory framework is made up to date and appropriate for the regulation of facilities and activities. This should include maintaining compliance with IAEA Standards.**
R2	**Recommendation: Government should ensure that SSM is legally entitled to conduct inspections of suppliers.**

Changes since the initial IRRS mission

Recommendation 1: At the time of the 2012 Mission, the IRRS team found that the nuclear regulatory Legislation and Regulations were in need of updating. The Government gave SSM the task to review and revise both the Nuclear Activities and Radiation Protection Acts in order to address the 2012 IRRS mission recommendations, and suggest necessary legislative changes in order to implement the latest European Union Directives (Nuclear Safety & Radiation Protection). SSM was proposing, at the time of the 2012 IRRS Mission, to streamline the legislation to secure more efficient and effective regulation of a new build programme for nuclear power plants. However, given the changed nuclear energy policy in Sweden, there is no longer an intention to merge the Nuclear Activities and Radiation Protection Acts. The IRRS team accepts that the Acts can co-exist and operate effectively in parallel.

The work to review and revise the legislation and regulations is a large project in cooperation between the Government and SSM. Considerable progress has been made since the 2012 IRRS mission, and SSM has made the project a high priority and committed significant resources (3500 staff days in the year 2016). The IRRS team noted that good progress was being made with drafts of both Acts, both of which are now issued and currently subject to an external consultation process. It was also noted that SSM during the drafting stage of the project was holding frequent meetings with licensee staff to review the proposed changes and ensure open and transparent communication. A further element of the project is the Government's review of legislation relating to the financing arrangements for decommissioning and waste management. Another Bill is to be provided to the Parliament in 2017 covering these arrangements. The IRRS team thinks this will assist in meeting the international expectations and obligations for decommissioning.

There remains a considerable amount of work to complete by February 2018. The IRRS team found that the work is being completed through comprehensive project management arrangements with a defined scope, plan, and dedicated resources to ensure delivery by the scheduled completion date.

Recommendation 2: The IRRS team found that SSM has proposed to the Government an amendment to the Nuclear Activities Act (SFS 1984:3) to enable the SSM to complete inspections and supervision activities at supplier's premises. The proposed changes were submitted to the Government, and made public, in November 2015. The approach of the Government is to complete the necessary legislative changes in parallel with transposition of the changed nuclear safety directive (2014/87/EURATOM). The planned implementation date for the amendment to the Act is August 2017 and given the progress to date and the project management arrangements in place the IRRS team has confidence that the work should be completed on time.

Status of the finding in the initial mission

Recommendation 1 is closed on the basis of progress made and confidence in effective completion. Good progress is being made by the Government and SSM in reviewing and revising the legislation and regulations and there is confidence that the projects will meet the target completion date of February 2018.

Recommendation 2 is closed on the basis of progress made and confidence in effective completion. There is confidence in the Government process to implement the necessary changes in legislation to enable SSM to complete inspections and supervision activities at supplier's premises. This is expected to be completed by February 2018.

1.3. ESTABLISHMENT OF A REGULATORY BODY

There were no findings in this area in the initial IRRS mission.

1.4. INDEPENDENCE OF THE REGULATORY BODY

Government relationship to the Regulatory Body

After the 2014 election, the new Government decided to reorganise the Government Ministries. It now consists of 11 Ministries with a total of 23 Ministers.

The newly formed Ministry of the Environment and Energy is responsible for the Government's environmental, energy, and climate policy. It works, inter alia, on issues concerning radiation safety and is the host government department of SSM. Unlike to the situation during the IRRS mission in 2012, the responsibility for nuclear regulation and the promotion and use of nuclear energy is not assigned to two different Government Ministries any longer.

The IRRS team was informed that nuclear regulation and the promotion of nuclear energy are the responsibility of two different Ministers that reside in the same Government Ministry. The Minister of Environment and the Minister of Energy act independently from each other.

SSM performs its regulatory work autonomously and independently. The Government has substantial scope for steering the operations of Authorities such as SSM, but it has no power to intervene in SSM's decision-making regarding matters relating to the application of the nuclear safety or radiation protection law or in discharging its authority. While SSM is an independent regulator, it does not have the final decision-making authority for issuing a license for a nuclear facility. This authority rests with the Government.

All governmental matters are decided during Cabinet meetings. This means that the Government takes decisions collectively. This is the case for all matters to be decided by the Government, including issuing of licenses and reconsideration of a decision taken by SSM.

The IRRS team has concluded that the independence of the regulatory body was not negatively influenced by the reorganisation of the Government Ministries.

There were no findings in this area in the initial IRRS mission.

1.5. PRIME RESPONSIBILITY FOR SAFETY

There were no findings in this area in the initial IRRS mission.

1.6. COMPLIANCE AND RESPONSIBILITY FOR SAFETY

There were no findings in this area in the initial IRRS mission.

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

There were no findings in this area in the initial IRRS mission.

1.8. COMPETENCE FOR SAFETY

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R3	**Recommendation: The Government should make provisions to maintain competence for nuclear safety and radiation protection on a national level such that it is ensured that all parties have access to competent staff to ensure continued safety.**

Changes since the initial IRRS mission

Recommendation 3: Since the IRRS mission in 2012 there has been considerable Government Political and Policy change in relation to the Swedish energy sector. The context of this recommendation has therefore changed from addressing the needs of a nuclear sector with new nuclear power plant build to a situation of maintaining sufficient competent and experienced staff to ensure high standards of nuclear safety and radiological protection for existing operations and decommissioning.

The IRRS team learned from the Government and SSM that there had been a decline in the number students opting to complete nuclear technology-related university courses and academic research projects. SSM also advised that it had prepared and submitted a report to Government (October 2015) highlighting the need to maintain appropriate levels of research and education programmes in the fields of nuclear safety and radiation protection.

The IRRS team noted that the Government had acknowledged, but had not yet responded to SSM's report. In subsequent discussions, the Government stated that it was currently too early to intervene as there was not a sufficient understanding at the national level regarding the industry's overall future nuclear skills requirements and the academic sector's capability to meet the demand.

Status of the finding in the initial mission

Recommendation 3 remains open. The decision for making provisions to maintain competence for nuclear safety and radiation protection on a national level has not been taken by the Government.

1.9. PROVISION OF TECHNICAL SERVICES

There were no findings in this area in the initial IRRS mission.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

There were no findings in this area in the initial IRRS mission.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R4	**Recommendation: SSM should systematically evaluate operational experience from non-nuclear facilities and radiation protection events and activities, and should establish and implement guidance for the dissemination of all significant operating experience lessons learned to all relevant authorized parties.**

Changes since the initial IRRS mission

Recommendation 4: Since the IRRS mission in 2012, the status and progress of evaluating operational experience for a number of regulatory functions and activities has improved. It was noted that the evaluation of operational experience is most mature for nuclear power plants, and that this has been further developed and improved since the IRRS mission in 2012. In order to improve the evaluation of operational experience of non-nuclear facilities and radiation protection events and activities, SSM implemented several measures. These measures include improving the dissemination incident reports, exchanging information between the regulatory authority, the licensees, and other national and international organisations, and making more information on events available on the SSM's website.

Specifically:

- discussion of the reports on safety related events for activities involving medical exposures and decision on the continued regulatory approach on a weekly basis;
- participation of SSM in the IAEA work of the Fuel Incident Notification and Analysis System (FINAS), a web-based system for the exchange of lessons learned from operating experience gained in fuel cycle facilities;
- feedback regarding evaluated information on incidents or accidents to the Class 7 Transport Community through participation in regular meetings of Safety Advisors; and,
- a procedure for handling reports from licensees includes deciding on how to disseminate the reports. This includes guidance on the management and assessment of incident reports in health and dental care, and the management of events in other practices and industries and research.

Although there have been several new initiatives and various measures taken in Sweden to improve the evaluation of operational experience from non-nuclear facilities and radiation protection events, SSM concluded in its self-assessment that further work is required. Therefore, it is appropriate that Recommendation 4 remains open.

Status of the finding in the initial mission

Recommendation 4 remains open. SSM has neither conducted the evaluation of operational experience from non-nuclear facilities and radiation protection events and activities using a systematic approach nor provided guidance on the dissemination of information from events and the lessons learned to all relevant authorized parties.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

Regulatory Body Organizational Changes

There have been several significant organizational changes at SSM since the initial IRRS mission in 2012. These include the appointment of a new Director General and the reorganisation of SSM's support functions.

The Swedish Government appointed Mr Mats Persson as Director General of SSM on 13 September 2012. This appointment was originally for the period 17 September 2012 to 31 July 2016. On 5 February 2016, the Government issued the decision to extend Mr Persson's appointment to mid-2018.

In 2013 a reorganisation of SSM's support departments was implemented. The goal for this reorganization was to reduce the number of management layers and to increase SSM's efficiency.

Prior to the reorganization, the management system, legal matters, research, safety culture and fundamental values were driven and managed by the staff of the Director General. The reorganization reassigned most of the Director General's staff to a new Development Department, which is in charge of legal matters, research, communication and analyses and methodology. The previous communication department became a section within the Development Department.

The Administration department name was changed to the Organisational Services Department and was tasked with responsibility for SSM's management system. Finally, International Affairs were coalesced in a small secretariat that answers directly to the Deputy Director General.

There were no findings in this area in the initial IRRS mission.

3.2. EFFECTIVE INDEPENDENCE DURING CONDUCT OF REGULATORY ACTIVITIES

There were no findings in this area in the initial IRRS mission.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S1	**Suggestion: SSM should consider completing and implementing its planned strategy for managing and maintaining the required staff competences, knowledge and training for all key positions within its regulatory programmes, and in particular for technical (specialist) staff. This should include the development of role profiles together with an appropriate but mandatory training programme that includes retaining valuable corporate knowledge.**
R5	**Recommendation: Government should increase the financial resources allocated to SSM in order to fulfil its regulatory responsibilities and shortfalls in the areas of supervision inspections, back fitting safety assessment and dealing with licencing requests. This should be based on a resource assessment of SSM.**

Changes since the initial IRRS mission

Suggestion 1: The IRRS team found that SSM has put in place a comprehensive staff competency mapping process. SSM has a clear picture of the capability available and where there are gaps. The approach to professional development complements the competency mapping by providing the means to enhance employee skills and improve capability. In addition, the new induction programme for all staff represents a significant improvement and includes a mentoring element.

Recommendation 5: Since the IRRS mission in 2012, SSM presented a number of requests to Government for additional budget resources, including the post Fukushima stress test activity and

emergency planning and response. The IRRS team found that the Government agreed to most of the annual requests from SSM for additional financial resources, including those for inspections and back fitting safety assessment. It was noted that the regulatory body has increased its staff by approximately 10%.

At the time of IRRS mission in 2012, SSM was anticipating a significant increase in demand for its regulatory services due to the proposal for nuclear power plant new build. The Government responded to this situation by agreeing to a 100 MSEK new build licensing fee to cover SSM's regulatory costs. Following a change in Government energy policy and falling electricity prices, nuclear power plant new build in Sweden is no longer anticipated and SSM has modified its future resourcing requirements accordingly.

The follow up mission concluded that the Government has agreed to most of SSM's requests for additional budget/resource and the recommendation can be closed. However, it was established that SSM had not assessed its long term resource and competence requirements and, given the upcoming focus on decommissioning activities, a new Suggestion (SF1) is proposed.

Status of the finding in the initial mission

Suggestion 1 is closed. SSM provided evidence that demonstrates it has an effective process for managing and maintaining the required staff competences, knowledge and training for key positions within its regulatory organisation.

Recommendation 5 is closed. The Government has agreed to most of the annual requests from SSM for additional financial resources, including those for inspections and back fitting safety assessment. However, the IRRS team found that SSM has not comprehensively assessed its long term resource needs, and a new Suggestion is proposed.

FOLLOW-UP Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IRRS team found that SSM has not assessed its long term resource needs.*	
(1)	**BASIS: GSR Part 1 Para 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions".*
(2)	**BASIS: GSR Part 1 Para 4.12 states that** *"The human resources plan for the regulatory body ... shall include the strategy to compensate for the departure of qualified staff".*
SF1	**Suggestion: SSM should complete a comprehensive resource and competence assessment, based on a strategic review, that incorporates the Swedish nuclear industry's perspective.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There were no findings in this area in the initial IRRS mission.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S2	**Suggestion: SSM should consider the operational perspective of the licensees in its future resourcing requests and management processes while at the same time ensuring that safety is not compromised for the periodic safety review related improvement programmes, power upgrading projects and possible new nuclear reactor build.**

Changes since the initial IRRS mission

Suggestion 2: This Suggestion relates to the nuclear industry operational perspective and SSM's interpretation and understanding of the Industry's needs. During the IRRS mission in 2012, there was a view from some licensees that SSM did not always deal with regulatory requests efficiently and that resource constraints may be an issue.

In late 2014, SSM conducted a survey amongst licensees and received over 800 responses. The purpose of the survey was to establish the licensee's opinions on the responsiveness and quality of the regulatory authority's interactions and interventions. Although confidence in the regulatory authority was shown, there was a common opinion that SSM did not handle regulatory activities in a timely way and that the regulatory framework should be improved. This aligned with the perspective of the IRRS mission in 2012. SSM confirmed that the survey would be repeated on a regular basis.

The IRRS team established that SSM had responded to the survey feedback. Senior management addressed the issues raised and made it a priority to improve SSM operating processes and culture. In autumn 2015, SSM completed a study with the aim of increasing the efficiency of the licensing process and improving staff competence and capability. The outcome of this work is now being implemented through the 'ETTAN' (Swedish acronym for e-Government, supervision, licensing, work environment and satisfied customers) project that is expected to deliver annual efficiency savings of 15 full time equivalent staff by 2018. It was also noted that SSM had successfully secured additional resources (3 MSEK) from the Government which was used to increase its work on the regulation of Periodic Safety Review submissions. Overall, the IRRS team found that SSM had made significant improvements towards understanding the licensees' operational perspective and responding to their needs.

Status of the finding in the initial mission

Suggestion 2 is closed. SSM has made significant improvements towards understanding licensees' operational perspectives and responding to their needs.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R6	**Recommendation: SSM should provide formal and specific internal guidance on appropriate regulatory topics, functions and activities associated with its regulatory review and inspection responsibilities. Such internal guidance should address those technical issues associated with regulatory review and inspection, and it should be made available to the applicants, licensees and other interested parties.**

Changes since the initial IRRS mission

Recommendation 6: The IRRS team was informed that since the IRRS mission in 2012, SSM reviewed its need for internal guidance specific to regulatory review and inspection activities and identified gaps. Work is in progress to establish new or revised internal guidance documents. They include, among others:

- Examination of Periodic Safety Reviews which licensees must report at least every ten years (STYR2011-123)
- Review of applications and supporting documents regarding increases of reactor thermal power (STYR2011-176)
- Execution of integrated annual safety assessment based on all information from related supervision activities (STYR2011-122 and STYR2014-42)
- Follow-up and evaluation of events that occur in the facilities including how licensees respond to these events and other operating experience (STYR2011-151)

Additionally, templates were developed to achieve consistent and uniform supervisory instructions. These templates specify what to include in specific supervisory instructions, including the regulations and guides to be considered, competence required, and the scope and focus of the task.

Work is in progress on other specific instructions that follow the model templates. Examples for such instructions are:

- Review of fuel designs
- Review of deterministic safety analysis
- Review of probabilistic safety analysis
- Supervision of trial operation after power increases and major modernization of facilities
- Supervision of management systems

Other specific instructions are also planned to be developed or revised by 2018. Upon completion, SSM will adopt an appropriate set of formal and specific guidance on regulatory topics, functions, and activities associated with SSM's regulatory responsibilities. The implementation includes completing the designation and training of process owners and expanding its document management and retrieval system.

Ensuring stability and consistency of regulatory control includes the application of pre-established principles and associated criteria on which regulatory actions are based. These criteria can be partially found in the above mentioned internal guidance documents and templates as well as in the key management system process documentation. SSM should consider making key management system process documentation available to the applicants, licensees, and other interested parties.

Status of the finding in the initial mission

Recommendation 6 is closed on the basis of progress made and confidence in effective completion. Formal and specific internal guidance on appropriate regulatory topics, functions, and activities associated with SSM's regulatory review and inspection responsibilities were established or revised. SSM plans to complete this work within 2 years.

However, the internal guidance documents, particularly the key management system process documentation, have not been made easily available to the applicants, licensees, and other interested parties.

FOLLOW-UP Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The internal guidance documents, particularly the key management system process documentation, has not been made available to the applicants, licensees and other interested parties.*	
(1)	**BASIS: GSR part 1 Requirement 22 Para. 4.26 states that** *"…In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based."*
SF2	**Suggestion: SSM should consider making key management system process documentation available to the applicants, licensees and other interested parties.**

3.7. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

There were no findings in this area in the initial IRRS mission.

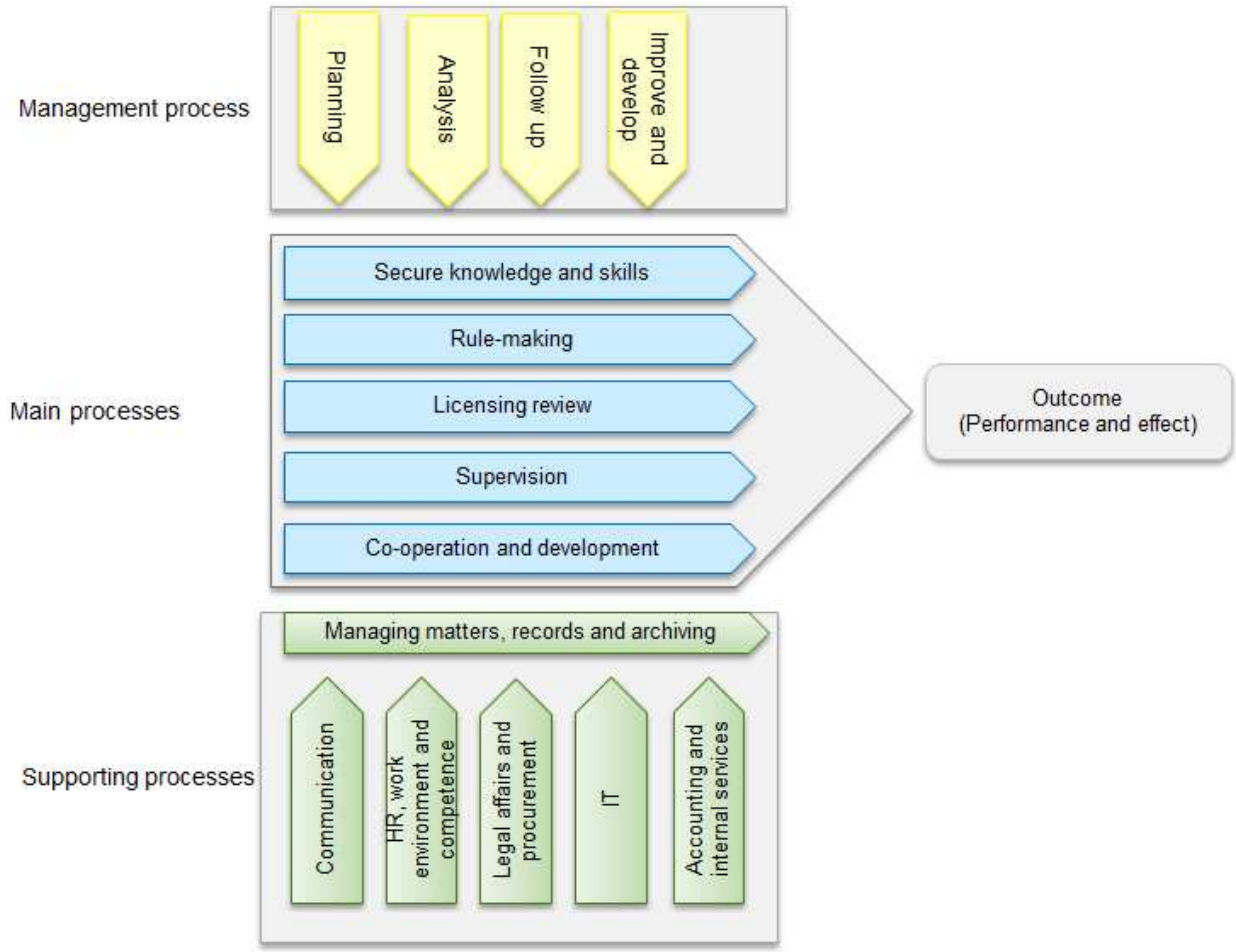
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R7	**Recommendation: SSM should develop and implement a strategy to i) complete the designation and training of process owners, and ii) expand the uptake of its robust document management and retrieval system (to a level where its critical mass is assured) in order to provide assurance that applicable process guidance, instruction material, and/or records will be readable, readily identifiable, and available at the point of use.**

Changes since the initial IRRS mission

The IRRS team found that SSM made considerable progress regarding this recommendation through increasing its attention on continuous process improvements. SSM developed a new process map to more accurately and easily reflect management system processes, products, and outcomes (see Figure below).



Recommendation 7: SSM completed the designation and training of process owners. Furthermore, it started significant modifications to its document management and retrieval system to ensure that applicable process guidance, instruction material, and/or records are (or will be) readable, readily identifiable and available at the point of use. For example, all internal regulatory documents are on its document management system and are available electronically on its network to all employees, and employees are trained in its use.

Additionally, SSM commenced the ETTAN Planning Directive, which amongst other initiatives, will further develop, improve, and enhance accessibility to SSM's digital documentation system.

According to SSM, this project may produce an annual efficiency improvement of about 15 full-time equivalent staff. While this enhancement is underway, SSM informed the IRRS team that the nomination of the project leader was delayed. Most of the additional work will be performed in 2016 and 2017, with the goal of completion by 2018. Feedback on the new system will also begin in 2018.

Finally, SSM sought third party verification (certification) of its management systems and processes and is using the results of this review to implement further improvements.

Status of the finding in the initial mission

Recommendation 7 is closed on the basis of progress made and confidence in effective completion. SSM undertook significant work to train process owners and to enhance and expand its document management retrieval system to ensure that it is readable, readily identifiable, and available at the point of use. The work is expected to be completed by 2018.

4.2. MANAGEMENT RESPONSIBILITY

There were no findings in this area in the initial IRRS mission.

Since the initial IRRS mission in 2012, SSM reorganized from a designated Director General staff with overall responsibility for the management system to a structure with two new departments; i.e., the Development Department and the Organizational Services Department. Both of these departments have responsibilities to ensure there is an effective and functional SSM management system, particularly in regard to the recommendation related to document management and retrieval noted above. The IRRS team noted that working across organizational boundaries is essential to success together with having clearly defined roles, responsibilities, and expectations.

FOLLOW-UP Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Development Department and Organizational Services Department both have responsibilities to assure an effective and functional SSM management system.*	
(1)	**BASIS: GS-R-3, paragraph 3.5 states that,** "S*enior management shall ensure that it is clear when, how and by whom decisions are to be made within the management system".*
(2)	**BASIS: GS-R-3, paragraph 5.5 states that,** *"The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities"*
SF3	**Suggestion: SSM should consider reviewing its roles, responsibilities, and expectations of its departments to assure clarity and to consider methods to assure effective cross organizational boundary communication that enable effective implementation of its management system components.**

4.3. RESOURCE MANAGEMENT

There were no findings in this area in the initial IRRS mission.

4.4. PROCESS IMPLEMENTATION

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S3	**Suggestion: SSM should consider developing and implementing a strategy to improve their ability to follow-up, evaluate and demonstrate the effectiveness, efficiency and overall performance of the management system and component key operational processes.**

Changes since the initial IRRS mission

Suggestion 3: The IRRS team found that SSM took steps to develop and implement a strategy to improve its ability to follow-up, evaluate, and demonstrate the effectiveness, efficiency, and overall performance of the management system and key operational processes. Notably, SSM modified its mission statement in 2014 to declare in STYR 2011-71, Management of the Swedish Radiation Safety Authority, "We have a systematic and structured approach to continual improvements to our processes in order to develop our operations, render them more efficient and achieve our objectives."

Additionally, SSM updated its guidance (STYR 2011-71), Management of the Swedish Radiation Safety Authority, to identify long-term objectives, output objectives, and improvement objectives, which translate to defined performance indicators across a spectrum of activities that are monitored every four months and annually. The Rules of Procedure for SSM (STYR 2012-27) requires such an evaluation and assigns delivery responsibilities.

Planning and follow-up is required by another procedure (STYR 2011-98), translating to management performance indicators (doc. no. 16-611), which has been in place since 2014, and is required to be documented and appropriately assessed periodically (doc. no. 16-1418). Management engagement and oversight is routine.

SSM encourages employees to suggest improvements, and process owners are required to address the feedback which may lead to additional improvements.

Finally, SSM sought third party verification (certification) of its management systems and processes and is using the results of this review to implement further improvements.

Status of the finding in the initial mission

Suggestion 3 is closed. SSM took appropriate steps to develop and implement procedures and tools to evaluate and demonstrate that its management system and its processes are both effective and efficacious.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S4	**Suggestion: SSM should consider addressing safety culture in its management system in a more comprehensive and integrated manner**

Changes since the initial IRRS mission

Suggestion 4: The IRRS team found that significant progress was made by SSM in addressing safety culture in its management system through adopting a more comprehensive and integrated approach. SSM updated its process, Management of the Swedish Radiation Safety Authority (STYR2011-71), to emphasize the importance of a good safety culture, recognizing that sustaining it is a continual process. In light of this, the Man-Technology-Organization section was given overall responsibility for promoting safety culture within SSM.

To assist in reinforcing safety culture, numerous training sessions are held for new and existing employees on a routine basis, emphasizing both the employee's role as well as management's role. Further, procedures, such as STYR 2011-95, Employee Policy, and STYR 2011-97, Supervisory Policy, were revised to underpin the training sessions. Safety Culture is also part of the SSM's Strategic Plan for Work in 2016 (doc. no.14-3752), and it will be updated annually. Additionally, SSM remains engaged with the international community to learn from others and adopt best practices. Recently, SSM participated in the NEA/CNRA Special Task Group for the development of the green booklet on the safety culture for effective regulatory bodies, which was published in 2016.

External experts were contracted to conduct an assessment of the regulatory body's safety culture in 2015 with the aim of establishing a baseline for further comparisons. This assessment is expected to be followed up in two years by another external assessment to ascertain if improvements were achieved in understanding the importance of the regulator's safety culture, and the values, attitudes,

and commitment to safety. While it was anticipated that the results of this external review would be ready for review by the time of the IRRS follow-up mission, the results were delayed until May 2016. Hence, this attribute for assessing internal safety culture could not be evaluated by SSM or the IRRS Team. The IRRS team does recognize that performing an external assessment of its safety culture is strong evidence of SSM's commitment to a good internal safety culture.

Status of the finding in the initial mission

Suggestion 4 is closed on the basis of progress made and confidence in effective completion. Significant work was completed to address safety culture in its management system in a more comprehensive and integrated manner. An assessment by external experts on SSM's internal safety culture is ongoing and is expected to be finished by May 2016.

5. AUTHORIZATION

5.1. GENERAL

There were no findings in this area in the initial IRRS mission.

5.2. NUCLEAR FACILITIES

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R8	**Recommendation: The government should establish responsibility for institutional control and for procedures for the termination of the license.**
S5	**Suggestion: SSM may consider including public participation in a formal way in all stages of its licensing and authorization process.**

Changes since the initial IRRS mission

Recommendation 8: SSM has examined the transfer of responsibility from the licensee to the State regarding the waste repository after its closure and has concluded that there are several Government and Parliament Statements from 1980 – 2005 on the State's ultimate responsibility, including the ratification of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

The State's ultimate responsibility is also stated in the current Swedish National Plan for spent fuel and radioactive waste management "Safe and responsible management of spent fuel and radioactive waste in Sweden" (SSM report no 2015:32) submitted by the Government to the European Commission as required by the Council Directive 2011/70/EURATOM. This clarifies that the State has the responsibility for institutional control.

The Act on Nuclear Activities (1984:3) Sections 14 and 15 prescribe responsibilities in case a license is revoked or expired but it does not consider the termination of a license in general. SSM has identified the different phases and conditions for terminating a license and has concluded that a procedure exists even though that it is not currently formalized as a separate provision in the legislation.

However, at the current phase of the overall process, the issue of termination of a license (which will take place in the 2070's at the earliest) is to be considered more as a matter of responsibility than as a current formalized regulatory process. Considering the overall State responsibility discussed above, the terms and conditions to terminate a licence would likely be developed in an appropriate time frame consistent with the closure of the facilities.

Suggestion 5: The legal and regulatory infrastructure in Sweden includes provisions for formal public participation during the preparation of governmental decisions on licensing decisions and decisions of the environmental court but not in subsequent authorization stages.

SSM has considered the suggestion to include public participation also in the subsequent phases of authorization but has concluded that the current arrangements in place are sufficient and appropriate and there is no need for further measures in this regard.

In particular, the current arrangements include the following mechanisms for public participation during the subsequent authorization phases:

- There is a consultation procedure as part of the Authority's reviews of R&D Programmes and Plan Cost Estimates. Further, local safety boards have an important role in outreach activities.
- The role of local safety boards is to enable insight into safety and radiation protection matters at the facilities in addition to emergency response planning, as well as communicating these areas to the general public. These boards have been set up by the Act on Nuclear Activities (1984:3) and the Government ordinance (2007:1054) in

municipalities that have nuclear power plants for the purpose of giving the public insight into nuclear activities and to provide them with information about these operations. The local safety boards have an important role for public participation in all licensing steps while new nuclear facilities are being planned, constructed and commissioned.

- The Swedish right of public access to official records not only gives the public and mass media the right to gain insight into SSM's organisation and its work, but also the right to access the Authority's official documents, provided they are not subject to secrecy under the Swedish Public Access to Information and Secrecy Act (SFS 2009:400). SSM's online register (e-registry), which contains details about the Authority's registered items of business, is accessible from SSM's public website. All reports issued by SSM may be ordered. Most of them are downloadable from the SSM website.

The IRRS team concurs with SSM's conclusion on this matter.

Status of the findings in the initial mission.

Recommendation 8 is closed. The Swedish National Plan for spent fuel and radioactive waste management clarifies that the State has the responsibility for institutional control and procedures for the termination of the licence.

Suggestion 5 is closed. SSM has considered the suggestion but concluded that the existing arrangements are sufficient.

5.3. INDUSTRIAL, MEDICAL AND RESEARCH RADIATION FACILITIES

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R9	**Recommendation: The government should establish a national strategy and system for gaining and regaining control over orphan sources including for providing rapid response when orphan sources are discovered.**
S6	**Suggestion: SSM should consider cross-checking information from suppliers of radioactive source transfers to individual licensees against the information received from the licensees.**

Changes since the initial IRRS mission

Recommendation 9: The Government has taken several actions to improve the management of orphan sources including the assignment of responsibility for the management of orphan sources to SSM (Ordinance 2008:452) and the allocation of funds to SSM for managing orphan sources through the Environmental Protection Agency's funds for contaminated sites clean-up (2016). SSM has established new internal procedures "Management of orphan sources" (STYR2016-2) and has also addressed orphan sources in its emergency plan (STYR2011-54) and the action checklist for officers on duty (STYR2011-53).

With the funds allocated, SSM has made a contract with Studsvik Nuclear AB for the practical physical management of orphan sources (SSM2015-1890). In addition, SSM has conducted different types of campaigns regarding identification and recovery of possible orphan sources e.g. in hospitals, scrap yards and steel mills.

The allocation of responsibility to SSM as the body responsible for managing orphan sources (Ordinance 2008: 452) and the new internal document "Management of Orphan Sources (STYR2016-2)" supported by other SSM internal documents provide a national strategy for gaining control of orphan sources and subsequent rapid response when orphan sources are discovered.

The IRRS team concurs with SSM's conclusion on this matter.

Suggestion 6: SSM has taken alternate measures for implementation of the suggestion as such to ensure the accuracy of the source inventories maintained by the licensees and SSM. This has been done by establishing a process where the licensees are sent annually an extract of the SSM register of

their sources record with a request to check the correctness of the source specific data. In addition, SSM has established a process to check that both the supplier and the consignee of a source are appropriately authorized.

Based on a graded approach to regulatory control, SSM tracks individually only high-activity (as defined by the EU HASS Directive) sealed sources (which is sufficient in accordance with the Code of Conduct on the Safety and Security of Radioactive Sources) which makes the suggested cross-checking for all sealed sources practically impossible. However, the IRRS team considered the measures taken by SSM are sufficient to meet the intent of the suggestion.

Status of the finding in the initial mission

Recommendation 9 is closed. SSM was assigned the responsibility for managing orphan sources and issued STYR2016-2, "Management of Orphan Sources". This procedure is supported by other internal documents and forms a national strategy for gaining control of orphan sources.

Suggestion 6 is closed. SSM has established alternative measures to meet the intent of the suggestion i.e. to ensure the accuracy of source inventories maintained by the licensees and the SSM.

5.4. TRANSPORT

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R16	**Recommendation: SSM should only use Special Arrangements as defined in TS-R-1.**

Changes since the initial IRRS mission

Recommendation 16: SSM has established new internal guidance STYR2012-6 to address the management of applications for Special Arrangements. This guidance requires compensatory safety measures in case of special arrangements as defined in TS-R-1.

Status of the finding in the initial mission

Recommendation 16 is closed. SSM established guidance, STYR2012-6, on the review of applications for Special Arrangements as defined in TS-R-1.

6. REVIEW AND ASSESSMENT

6.1. GENERAL

There were no findings in this area in the initial IRRS mission.

6.2. NUCLEAR FACILITIES

There were no findings in this area in the initial IRRS mission.

6.3. INDUSTRIAL, MEDICAL AND RESEARCH RADIATION FACILITIES

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R10	**Recommendation: SSM should thoroughly review and assess if the safety of facilities and activities involving radiation sources comply with regulatory requirements before granting a license. The review and assessment should be commensurate with radiation risks of the facilities and activities.**

Changes since the initial IRRS mission

Recommendation 10: SSM has updated its licencing review and assessment processes for industrial and research uses of radiation (procedure STYR2013-40) and for medical uses of radiation (procedure STYR2015-9).

The new processes are following a graded approach by defining the information to be reviewed based on the type of practice and risks involved. In addition, the review is now periodic i.e. a review is conducted again at license renewal.

The IRRS team was informed that SSM intends to further elaborate the application of a graded approach by introducing registration as a form of authorization when establishing new SSM regulations as part of the regulation update project expected to be completed by February 2018.

Status of the finding in the initial mission

Recommendation 10 is closed. SSM updated its review and assessment processes to provide for a graded approach.

7. INSPECTION

7.1. GENERAL

The IRRS team found that SSM performs systematic and thorough assessment of risks involved in different types of uses of radiation sources.

The assessment is based on a risk model comprising a comprehensive set of assessment criteria considering different radiological consequences (public, worker and patient health, effect on environment and infrastructure), as well as, other consequences such as cost and societal trust in operations with radiation or the supervision of such operations. Also the probability of events is considered.

The results of the assessment are being used for strategic planning for the different regulatory control processes including inspections and enforcement.

FOLLOW-UP Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The risk model used by the SSM for assessing risks involved in different types of uses of radiation sources utilises a comprehensive and well defined set of assessment criteria.*	
GPF1	**Good Practice: SSM has developed a comprehensive and well defined set of criteria for assessing the risks involved in different types of uses of radiation sources.**

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R11	**Recommendation: SSM should carry out more inspections in the areas of transport, industrial, medical and research radiation facilities.**
R12	**Recommendation: SSM should carry out more unannounced inspections in all facilities.**
R13	**Recommendation: SSM's regulatory inspection should incorporate monitoring, measuring and direct observation of the on-site operations.**
R14	**Recommendation: The inspection program in the areas of fuel cycle and waste facilities, transport, industrial, medical and research radiation facilities should be prepared in accordance with a systematic graded approach.**

Changes since the initial IRRS mission

Recommendation 11: Based on the established inspection strategy (see Recommendation 14), inspections of some practices are conducted based on "sampled supervision". These include e.g. most common uses of radiation sources in industry. In these cases, the objective is not to focus on one individual licensee but to monitor the general state of safety and compliance with regulatory requirements in different types of practices and to identify possible tendencies requiring further attention.

As part of the overall strategy of implementing a graded approach, the number of inspections for some types of practices is still very small and many facilities are never inspected. The IRRS team was informed that the number of inspections, as such, does not prescribe details of the overall coverage of safety because one inspection might just cover either one small facility or, it could cover a very large activity comprising multiple facilities under the same licence.

The IRRS team was also informed that many of the facilities under "sampled supervision" will be made subject to registration instead of licensing as part of the regulations update project expected to be completed in February 2018. This will significantly lower the number of licensees which currently

are not inspected. However, the yearly inspection plan developed up to 2018, shows that the number of inspections was increased.

Recommendation 12: The IRRS team found that SSM has included unannounced inspections in the internal guidance document STYR 2011-106, "Compliance inspections". Unannounced inspections are addressed in the inspection programmes established for different types of practices and facilities (doc. no. 15-1224, 15-932, 15-1244 and 16-714). SSM provided several examples of the conduct of unannounced inspections in various types of facilities.

Recommendation 13: The IRRS team found that SSM has now included in its inspection programmes specific instructions on performing monitoring, measuring and direct observation of the on-site operations as part of regulatory inspections. The inspection programmes are documented in doc number 16-714 (Nuclear Power Plants), doc number 16-452 (Nuclear Facilities and safe management of radioactive waste), doc number 15-1224 (Medical uses of radiation) and doc number 15-932 (Products and Services).

Recommendation 14: The IRRS team found that SSM has established inspection strategies for different types of practices and facilities based on consideration of the:

- results of systematic risk assessment;
- experiences from previous inspections and other regulatory processes;
- possibilities to use other SSM processes to influence the licensees to the same effect; and,
- effective use of resources.

Based on these considerations, SSM has established an overall inspection programme (STYR2016-6) and specific long term inspection programmes for different types of practices and facilities (doc. no. 15-1224, 15-932, 15-1244 and 16-714) which are then used for annual inspection planning. This approach provides a systematic way to establish inspection programmes in accordance with a graded approach.

Status of the finding in the initial mission

Recommendation 11 is closed. SSM has established new inspection strategies for different types of practices and facilities. The inspection programmes vary based on the selected strategy for a certain type of activity.

Recommendation 12 is closed. SSM has included in its inspection programmes unannounced inspections.

Recommendation 13 is closed. SSM included in its inspection programmes instructions on performing monitoring, measuring and direct observation of the on-site operations.

Recommendation 14 is closed. SSM established inspection strategies and programmes for different types of practices in accordance with a systematic graded approach.

7.2. NUCLEAR POWER PLANTS, FUEL CYCLE AND WASTE MANAGEMENT FACILITIES

There were no findings in this area in the initial IRRS mission.

7.3. INDUSTRIAL, MEDICAL AND RESEARCH RADIATION FACILITIES

There were no findings in this area in the initial IRRS mission.

8. ENFORCEMENT

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S7	**Suggestion: SSM should consider monitoring the implementation status of corrective actions of licensees.**

Changes since the initial IRRS mission

Suggestion 7: The IRRS team found that SSM has developed and implemented the so called "Tillda" database for monitoring the implementation status of corrective actions.

The findings from an inspection or a review are registered in the database by the responsible staff member the so called "leader of the activity". Any injunction and the deadline for corrective actions are also registered. When the deadline has been reached, the "leader of the activity" is prompted by the system and has to register the licensee's documentation of the corrective actions taken.

The administrator of "Tillda" checks the database and reminds SSM staff who have not yet taken action. There is also a possibility for the SSM management to check any backlog in the system.

The IRRS team was informed that the "leader of the activity" is normally the inspector who has been responsible for conducting the inspection. In the case of nuclear facilities, the facility co-ordinator (as defined by the internal steering document STYR2014-13) has the role to oversee SSM's supervision work.

The internal steering document STYR2011-87 (as updated in 2016) defines deficiencies for which a senior legal adviser should be contacted regarding any further measures. Under STYR2012-27 a decision regarding an injunction must be reported to the legal services section of SSM who also maintains an archive of all injunctions. The legal services section will monitor follow-ups of injunctions issued and take the necessary steps to ensure uniformity and timely action.

Status of the finding in the initial mission

Suggestion 7 is closed. SSM established processes, including an electronic system, for monitoring the implementation status of the corrective actions of licensees.

9. REGULATIONS AND GUIDES

9.1. GENERAL

There were no findings in this area in the initial IRRS mission.

9.2. PROCESS FOR DEVELOPING REGULATIONS AND GUIDES

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S8	**Suggestion: SSM should consider ensuring that the "General advice" for radiation protection is kept up to date.**

Changes since the initial IRRS mission

Suggestion 8: The IRRS team found that SSM revised the internal regulatory document STYR2011-51, describing the process to create or modify regulations and general advice. Since 2012, the General Advice SSMFS 2008:42 on specification of equipment performance for X-ray diagnostics was suspended. Updates will be part of the ongoing regulation update projects.

The IRRS team was informed that SSM implemented an annual review process to evaluate the need for administrative changes and important or urgent updates in the content of the existing regulations. These reviews will also incorporate feedback from regulatory activities (supervision and licensing) to improve the explanatory guidance that is under development. The IRRS team noted that a comprehensive review will be completed covering the entire regulatory framework at least every five years. SSM will implement this systematic approach upon completion of the regulation update projects.

Status of the finding in the initial mission

Suggestion 8 is closed on the basis of progress made and confidence in effective completion. The "General advice" for radiation protection is being revised within the scope of the regulation upgrade project that is expected to be completed by February 2018.

9.3. EXISTING REGULATIONS AND GUIDES

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R19	**Recommendation: SSM should make explicit in the regulations the principle for minimizing the amount of waste produced in non-nuclear practice.**

Changes since the initial IRRS mission

Recommendation 19: The IRRS team found that the minimization principle for waste produced in non-nuclear practice is addressed in the draft amendment of the Radiation Protection Act (Chapter 4, Section 13) stating, "The party conducting an activity involving ionising radiation is required to limit the generation of radioactive waste in its operation as far as reasonably practicable". This change is included in the scope of the regulations upgrade project, which is expected to be completed by February 2018.

Status of the finding in the initial mission

Recommendation 19 is closed on the basis of progress made and confidence in effective completion. A specific requirement on the minimizing the amount of waste has been included in to the draft Radiation Protection Act expected to be completed in February 2018.

9.4. REVIEW OF THE REGULATIONS AND GUIDES

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R15	**Recommendation: Based on the results of the review of the current regulations and general advice (Requirement 1 in Module 1) SSM should develop a consistent and more comprehensive set of regulations and general advice.**
S9	**Suggestion: SSM should consider elaborating the regulations "SSMFS" and related "General advice" guidance to cover the issues identified as missing in the current regulatory requirements and guides.**

Changes since the initial IRRS mission

Recommendation 15: The IRRS team found that SSM commenced a project in 2013 dealing with regulations and general advice for nuclear activities. Another project was established in 2014 to deal with activities involving radiation, including medical applications. SSM presented a new structure for the regulations describing the three levels of regulatory control under the law and ordinances and that all SSM regulations will be included in that new structure. SSM had decided to create supporting documents describing the rationale behind the regulations and will include formal interpretations of the regulatory sections.

Both projects use IAEA standards and good practices of other countries as input and will also be used to implement the WENRA Safety Reference Levels, the European Directive for Nuclear Safety and the Basic Safety Standards. The projects are expected to be completed by February 2018.

SSM presented the status and planning of the project to the IRRS team. The IRRS team noted that the planned human resources for implementing the projects until 2018 amount to10-15 fte/year. It was also noted that some revisions to regulations were prioritised for later review because of resource limitations of the licensees, who are consulted to review proposals of the revised regulations.

SSM explained to the IRRS team that the updated regulations for decommissioning will be ready for the forthcoming decommissioning projects resulting from the announced closure of four nuclear power plants in the next several years. SSM has also informed the IRRS team that decommissioning is not a new regulatory activity since SSM gained previous experience with decommissioning of research reactors and NPP's and has an established decommissioning licensing approach, which includes preparation of an Environmental Impact Assessment.

The IRRS team concludes that the ongoing regulation update projects will provide for a consistent and comprehensive set of regulations that will enhance the stability and consistency of the Swedish regulatory framework. The regulation update projects are carried out using an integrated approach and are taking into account international standards and good practices. The comprehensiveness and the expediency by which the update projects are carried out are commended by the IRRS team.

Suggestion 9: The IRRS team found that SSM is elaborating the regulations "SSMFS" and related "General advice" guidance within the scope of the ongoing regulation update projects expected to be completed in February 2018.

Status of the finding in the initial mission

Recommendation 15 is closed on the basis of progress made and confidence in effective completion. A consistent and more comprehensive set of regulations and general advice is being developed as part of the regulations update projects and is expected to be completed in February 2018.

Suggestion 9 is closed on the basis of progress made and confidence in effective completion. SSM is elaborating the regulations "SSMFS" and related "General advice" guidance as part of the regulations update projects and is expected to be completed in February 2018.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The comprehensiveness and the expediency by which the ongoing regulation update projects are carried out using an integrated approach and taking into account international standards and good practices are commended.*	
(1)	**BASIS: GSR part 1 Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.*
GPF2	**Good Practice: SSM's prompt and integrated approach to establish a consistent and comprehensive regulation taking into account international standards and good practices.**

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. BASIC RESPONSIBILITIES

There were no findings in this area in the initial IRRS mission.

10.2. FUNCTIONAL REQUIREMENTS

There were no findings in this area in the initial IRRS mission.

10.3. REQUIREMENTS FOR INFRASTRUCTURE

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R17	**Recommendation: The Government should consider establishing a government level coordination body (committee, board etc.) that would be responsible for the coordination of the national efforts to cope with the longer term consequences of a severe emergency. A national radiation emergency response plan, which would describe the responsibilities and concepts of operation of this governmental body and the other response organizations, should also be drafted.**
S10	**Suggestion: SSM should consider developing on-line, real-time access to NPPs operational and safety parameters.**
R18	**Recommendation: SSM and other relevant authorities should control the inadvertent and illicit trafficking of radioactive material through the national borders**

Changes since the initial IRRS mission

Recommendation 17: The IRRS team found that a national emergency response plan for management of nuclear accidents (the plan) was reported to the Government on 31 January 2015. In addition, the IRRS team found that the Government established a coordination body responsible for the coordination of the national efforts to cope with the longer term consequences of a severe emergency, as stated in the plan. The Government fulfilled the establishment of a government level coordination body.

The plan was developed within the scope of a Government assignment dated 2014-01-23. The assignment was addressed to the Swedish Civil Contingencies Agency (MSB) and others regarding preparedness for radiological and nuclear events. The work was carried out within the framework of applicable laws and responsibilities and resulted in the plan for handling of both short and long term consequences of a nuclear accident. The plan was reported to the Government on 31 January 2015.

The plan describes the legal bases, authorities involved in the response of a nuclear accident and the responsibilities of these authorities. The plan also governs national coordination, describes how the relevant authorities work together, outlines the available resources at national level and how they are requested and coordinated. International support is also described in the plan. In this document, the different authorities responsible for responding to a nuclear emergency situation are referred to, making the organization of responsibilities more transparent. In addition to the plan, there is a national action plan for improvements in emergency preparedness work.

The plan, however, does not take into consideration radiological emergencies based on a threat/hazard assessment, even though SSM stated the methodology, roles and assignments of the plan would be applicable to these emergencies. No threat/hazard assessment was considered to implement a graded approach to establishing and maintaining adequate arrangements as a basis to determine further development of the plan, taking into consideration GS-R-2 (or the more recent GSR Part 7

"Preparedness and Response for a Nuclear or Radiological Emergency"). The IRRS team therefore concludes that a further suggestion (SF4) is warranted.

Suggestion 10: The IRRS team found that a Memorandum of Understanding (MoU) regarding electronic transmission of parameters was signed by the Director General of SSM and the managing directors of Swedish nuclear power plants (NPPs) in the autumn of 2012. A more detailed MoU was signed by the same parties in the summer of 2014. In the latter MoU, work was divided into four phases with a timeframe for completion as follows:

- Phase 1: To have an agreement regarding which process parameters should be available online at SSM's emergency response centre. This phase has been successfully concluded in accordance with the scheduled plan.
- Phase 2: To develop a common standard for visualizing the process parameters in an online tool and trends. This phase has been successfully concluded in accordance with the scheduled plan.
- Phase 3: To use the online visualization tool together with transmission of the process parameters. This phase is on schedule.
- Phase 4: To feed the online visualization tool with process parameters for educational and training purposes. This phase is on schedule and out of the scope of the basis of the suggestion.

There is also a specification of the requirements for the first three phases, including an agreement on those process parameters that should be available online, at SSM's emergency response centre.

SSM has furthermore proposed to the Government to amend the Act on Nuclear Activities to include a requirement on the licensee of a nuclear power plant to transfer the relevant process parameters from the reactor to SSM in the event of an emergency.

SSM has taken the necessary steps to develop and operate a system for online, real-time access to the NPPs' operational and safety parameters in the event of an emergency to enable giving the necessary calculations and proper advice on protective actions in a timely manner. The new system is expected to be in full operation in 2018.

Recommendation 18: The IRRS team found that the Swedish Government mandated SSM and Swedish Customs, in consultation with the National Food Agency, Swedish Board of Agriculture and other relevant authorities, to carry out a review of the capabilities of the controls of radioactive materials at Swedish borders.

The current situation is that Swedish Customs has the following capabilities for detection of radioactive and nuclear materials:

- Border units with chemical, biological, radioactive, nuclear and explosives emergency response capabilities (three mobile units),
- Scanner teams (three mobile units with hand instruments), and
- Temporary capacity (personnel rapidly trained for a particular event).

Resources are available for radioactive and nuclear materials checking when specific information is received on suspected radioactive contamination of goods. In these cases, a barrier is set up in Swedish Customs' data system (TDS) for goods from a particular sender abroad or for certain recipients in Sweden.

Checking also takes place for containers or other cargo shipped by carriers for reasons other than related to radioactive or nuclear materials supplied to Customs' inspection site in the Skandia port in Gothenburg. SSM has established cooperation with Customs and police personnel to conduct targeted transport inspections at ports of entry and to give support in case further information is needed.

Export control of goods to the United States is performed within the framework of the Container Security Initiative using fixed detection equipment for radioactive and nuclear materials, using portal monitors in the Skandia port of Gothenburg.

Status of the finding in the initial mission

Recommendation 17 is closed. A national emergency response plan for management of nuclear accidents was reported to the Government on 31 January 2015, establishing a national coordination body and describing how the relevant authorities work together. However, the plan does not take into account radiological emergencies based on a threat/hazard assessment.

Suggestion 10 is closed on the basis of progress made and confidence in effective completion. The new system for online, real-time access to the NPPs' operational and safety parameters is expected to be in full operation in 2018.

Recommendation 18 is closed. Swedish Customs has developed adequate capabilities for detection of radioactive and nuclear materials and has established cooperation with SSM.

FOLLOW-UP Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The national emergency response plan for management of nuclear accidents does not take into account radiological emergencies based on threat/hazard assessment.*	
(1)	**BASIS: GS-R-2, Paragraph 5.10, states that -** *Arrangements for the co-ordination of emergency response and protocols for operational interfaces between operators and local, regional and national governments shall be developed, as applicable. These arrangements shall include the organizations responsible for emergency services and for response to conventional emergencies. The arrangements shall be clearly documented and this documentation shall be made available to all relevant parties.*
(2)	**BASIS: GS-R-2, Paragraph 3.7, states that -** *Threat categories are used in this Safety Requirements publication to implement a graded approach to establishing and maintaining adequate arrangements for preparedness and response by establishing requirements that are commensurate with the potential magnitude and nature of the hazard as identified in a threat assessment.*
SF4	**Suggestion: The Government should consider expanding the scope of the national emergency response plan for management of nuclear accidents to take into consideration arrangements for responding to radiological emergencies, based on threat/hazard assessment.**

11. RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING, OCCUPATIONAL, PUBLIC AND ENVIRONMENTAL EXPOSURE CONTROL

11.1. OCCUPATIONAL RADIATION PROTECTION

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S11	**Suggestion: SSM should consider inviting an IAEA mission on Occupational Radiation Protection Appraisal Service (ORPAS), in order to assess the level of compliance of the new harmonized regulations with the IAEA Standards regarding the protection and safety of occupationally exposed workers.**
S12	**Suggestion: SSM should consider clarifying the conditions when personal dosimeters have to be used in accordance with the SSM internal rules concerning categorisation of SSM staff members.**
S13	**Suggestion: SSM should consider checking, within a defined period of time, the implementation by all licensees of a radiation protection programme.**

Changes since the initial IRRS mission

Suggestion 11: SSM is currently working on the transposition of the European Union Basic Safety Standards Directive 2013 into Swedish legislation and regulations which is part of the ongoing regulation update project. SSM will begin using the new legislation and regulations on supervision following the transposition date of February 2018.

With regard to the significant changes that will occur as part of the ongoing regulation update project SSM came to the conclusion that there is limited added value in having an ORPAS mission at this time. Once the new legislation and regulations have been in use for some period of time, a decision will then be taken on a possible new IAEA mission.

Suggestion 12: The IRRS team found that revisions to SSM internal steering document STYR 2011-6 clarify how personal dosimeters should be used in accordance with SSM rules concerning categorization of staff members.

Work at SSM which comes under the scope of radiation protection includes its own activities with ionising radiation (SSM Laboratories), emergency preparedness work with radiation sources and inspectors involved in supervision work.

All SSM staff that spend time in environments with ionising radiation are categorised, and the categorisation is conducted by the responsible Section Head in consultation with the Radiation Protection Expert (RPE).

Categorisation of staff takes into account the annual work plan for staff, internal and external exposures and is based on dose reports, measurements and/or calculations of actual and expected doses. All categorisations are reviewed annually or as required, and all decisions are recorded in SSM document management system.

Suggestion 13: The IRRS team found that the term “radiation protection programme” is not used in Swedish regulations, but the elements of such programmes are covered by the licence requirements imposed on licensees, e.g. categorization of staff and areas, education, training, area monitoring, dosimeters, etc.

New procedures have been introduced to review more information in relation to the elements of the radiation protection programmes at the licence application stage. Licensing in the area of products and services and the review of elements of the radiation protection programme at the application stage is performed in accordance with the procedure described in steering document STYR2013-40. Regarding licensing in the area of medical exposure, reviews of the elements of the radiation protection programme are performed at the application stage according to procedures described in steering document STYR2015-9.

The majority of licenses in the areas of medical exposure and products and services (industry and research) are renewed at 5 year intervals and a review of the elements of the radiation protection programme forms part of the licence renewal process.

The implementation of elements of the radiation protection programmes by licensees is also checked as part of risk informed inspections. In the area of medical exposures, licensees are inspected according to a 5-year plan and these inspections include checking on the implementation of these elements.

During 2015, fifty parties that were granted licences in the area of products and services during the period July 2013-June 2014 underwent compliance inspections, and these inspections included checking on the implementation of the elements of the radiation protection programmes.

Status of the finding in the initial mission

Suggestion 11 is closed. SSM considered the suggestion and concluded that there was limited added value in an ORPAS Mission due to significant changes that will occur as part of the ongoing regulation update project.

Suggestion 12 is closed. SSM revised the steering document STYR2011-6 which clarifies the use of personal dosimeters.

Suggestion 13 is closed. SSM introduced procedures to review the elements of radiation protection programmes at the application stage and at licence renewal. The implementation of these elements is checked as part of risk informed inspections.

11.2. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE AND ENVIRONMENTAL MONITORING

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S14	**Suggestion: SSM should consider ensuring that the registrants and licensees verify the adequacy of assumptions used in site specific dose assessment models.**
S15	**Suggestion: SSM should consider extending the national gamma monitoring system for gamma monitoring stations near nuclear facilities.**

Changes since the initial IRRS mission

Suggestion 14: The IRRS team found that since 2011, the Swedish nuclear industry carried out a common project whose purpose is to evaluate and develop site-specific dose assessment models. The industry will present its updated dose assessment models to SSM in 2016.

SSM described its review plan for PREDO (PREdiction of DOses from normal releases of radionuclides to the environment) to the IRRS team. The SSM review plan provides the elements for a detailed evaluation of the assumptions used in site specific dose assessments models, including, but not limited to, the adequacy of support for parameters and models, consideration of uncertainties, and exposure pathway parameters. SSM is prepared to conduct independent calculations to assist its review of the licensees' verification of the adequacy of the assumptions used in the updated dose assessment models.

Suggestion 15: The IRRS team found that SSM and the County Administrative Boards of Halland, Kalmar and Uppsala have worked together in a joint project to install a system for online monitoring of ambient dose equivalent rates around the Swedish nuclear power plants. The overall aim of the project is to improve the potential to detect, verify, monitor and map a release from a nuclear power plant in the event of a nuclear accident.

The measurement stations are designed to measure ambient dose equivalent rate and are also equipped with rain sensors. The stations are powered by solar panels and equipped with battery backup and were found to function acceptably during the previous winter. Data from the measurement stations are transmitted to a central server application at SSM via the Swedish national Tetra network (Rakel).

The IRRS team also observed a real-time demonstration of the measurement data being collected at the monitoring stations.

This program will add 90 additional monitoring stations to the national gamma monitoring system. The measurement data will be available on the SSM website and will also be delivered to the European Radiological Data Exchange Platform (EURDEP).

Status of the finding in the initial mission

Suggestion 14 is closed on the basis of progress made and confidence in effective completion. SSM has put in place a detailed review plan to evaluate the adequacy of assumptions used in site-specific dose assessment models. SSM will initiate its review on receipt of the models from the licensees.

Suggestion 15 is closed. SSM and the County Administrative Boards installed a system for online monitoring of ambient dose equivalent rate around the three Swedish nuclear power plants.

11.3. CONTROL OF CHRONIC EXPOSURES (RADON, NORM AND PAST ACTIVITIES) AND REMEDIATION

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S16	**Suggestion: The government should consider ensuring that radiological impacts are given higher priority in the process of the identification of a contaminated area for remediation.**

Changes since the initial IRRS mission

Suggestion 16: The IRRS team found that the Government made an amendment on May 8, 2013 to the Environmental Supervision Ordinance (2011:13) stating that SSM shall provide for the supervisory guidance in matters relating to "the pollution damage and other environmental damage in accordance with Chapter 10 of the Environmental Code, caused by radioactive substances" based on a SSM memorandum (doc. No 12-2056, dated 19.10.2012) and a following letter to the Government (SSM 2013-441, dated January 2013).

Further, SSM has made a survey of older facilities where radioactive substances have been stored and handled (SSM report 2013:23, July 2013) which provides for an inventory of historical sites. This report now serves as a basis for the local authorities for considering the need for remedial action and comparing these needs with other sites with different types of hazardous contamination. However, no area has yet been identified for remediation in respect of radiation substances.

Status of the finding in the initial mission

Suggestion 16 is closed. With an amendment to the Environmental Supervision Ordinance (2011:13), the Government assigned SSM the mandate to provide supervisory guidance regarding contaminated sites.

11.4. WASTE MANAGEMENT

Suggestion 17: see Chapter 1.1

11.5. MEDICAL EXPOSURE

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R20	**Recommendation: SSM should cooperate with the National Board of Health and Welfare to ensure that the requirements regarding referring medical practitioners are consistent.**

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R21	**Recommendation: SSM and the relevant parties should ensure that generic justification of procedures is carried out by the relevant health authorities in conjunction with appropriate professional bodies.**
R22	**Recommendation: The government should ensure that requirements are in place for education, training, qualification and competence in protection and safety of all health professionals with responsibilities for medical exposure.**

Changes since the initial IRRS mission

Recommendation 20: The IRRS team found that SSM proposed a new regulation (SSM2013-286-75) on medical exposures regarding medical referrals. The proposed regulation confers the responsibility to make medical referrals to the licensed medical professionals specified by the National Board of Health and Welfare. Thus, this proposed regulation eliminates any inconsistency between SSM regulations and the requirements of the National Board of Health and Welfare regarding medical referrals. This proposal is part of the ongoing regulation update project expected to be completed in February 2018.

Recommendation 21: The IRRS team found that since 2012, SSM was tasked by the Government to review and assess the situation in Sweden in relation to the justification of new methods involving medical exposures. SSM consulted with relevant interested parties and proposed a new ordinance concerning radiation protection SSM2014-1921-14 which will mandate the National Board of Health and Welfare to judge on the justification of new methods involving medical exposures before they are generally used.

This proposal is sent to interested parties for comments and forms part of the transposition of the EU Basic Safety Standards Directive 2013 which is part of the ongoing regulation update project expected to be completed in February 2018.

Recommendation 22: The IRRS team found that SSM was tasked by the Government to review and assess the issue of education, training, qualifications and competence in radiation protection of all health professionals with responsibilities for medical exposure.

In 2014, SSM commissioned a report, "education and expertise in radiation protection of the various functions involved in or affecting medical exposures". This report looked at the education for all licensed professionals with connections to medical exposures i.e. doctors, specialised doctors, medical physicists, radiographers, nurses, dentists, specialised dentists and dental hygienists. On the basis of this report, SSM proposed an ordinance concerning an amendment to the Higher Education Ordinance (193:100) regarding health professionals with responsibility for medical exposures.

Through this proposal, core learning outcomes for the radiation protection knowledge to be acquired in connection with the area of medical exposure must be stated in the examination descriptions/syllabi for dentists, medical doctors and dental hygienists. The core learning outcomes will shape the syllabi of institutions of higher education. These outcomes will also be covered by the quality evaluation performed by the Swedish Higher Education Authority, UKÄ.

This proposal forms part of the transposition of the EU Basic Safety Standards Directive 2013 which is part of the ongoing regulation update project expected to be completed in February 2018.

Status of the finding in the initial mission

Recommendation 20 is closed on the basis of progress made and confidence in effective completion. Requirements regarding medical referrals that are consistent with those of the National Board of Health and Welfare are being revised as part of the regulations update project expected to be completed in February 2018.

Recommendation 21 is closed on the basis of progress made and confidence in effective completion. SSM has proposed that the responsibility for the justification of new methods involving

medical exposure is assigned to the National Board of Health and Welfare as part of the regulation update project expected to be completed in February 2018.

Recommendation 22 is closed on the basis of progress made and confidence in effective completion. SSM proposed an amendment to the Higher Education Ordinance (1993:100) regarding health professionals with responsibility for medical exposures as part of the regulation update project expected to be completed in February 2018.

APPENDIX I: LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
1. **SCHWARZ** Georg	**Eidgenoessisches Nuklearsicherheitsinspektorat (ENSI)**	georg.schwarz@ensi.ch
2. **KOKAJKO** Lawrence	**U.S. Nuclear Regulatory Commission (NRC)**	lawrence.kokajko@nrc.gov
3. **CORTES** Alejandro	**Comision Nacional de Seguridad Nuclear y Salvaguardias (CNSNS)**	acortes@cnsns.gob.mx
4. **JANSEN** Rob	**Authority for Nuclear Safety and Radiation Protection (ANVS)**	rob.jansen@anvs.nl
5. **MADDEN** Jack	**Environmental Protection Agency (EPA)**	j.madden@epa.ie
6. **MARKKANEN** Mika	**Radiation and Nuclear Safety Authority (STUK)**	mika.markkanen@stuk.fi
7. **McCARTIN** Timothy	**U.S. Nuclear Regulatory Commission (NRC)**	timothy.mccartin@nrc.gov
8. **RAHMAN** Muhammad	**Pakistan Nuclear Regulatory Authority (PNRA)**	m.rahman@pnra.org
9. **SENIOR** David	**Office for Nuclear Regulation (ONR)**	david.senior@onr.gsi.gov.uk
IAEA STAFF MEMBERS		
1. **MAGRUDER** Stewart	**Division of Nuclear Installation Safety**	s.magruder@iaea.org
2. **AL KHATIBEH** Ahmad	**Division of Radiation, Transport and Waste Safety**	a.al-khatibeh@iaea.org
3. **REBIKOVA** Olga	**Division of Nuclear Installation Safety**	o.rebikova@iaea.org

APPENDIX II: FOLLOW-UP MISSION PROGRAMME

Time	Sun 24 Apr	Mon 25 Apr (Nordic C Hotel)	Tue 26 Apr	Wed 27 Apr	Thu 28 Apr	Fri 29 Apr	Sat 30 Apr (Nordic C Hotel)	Sun 1 May	Mon 2 May	Tue 3 May
9:00-10:00	Arrival of team members	Arrival of team members	Entrance meeting	Interviews in-group discussions (scheduled)	TM write report / Interviews TBD	Discussion of findings by the Team / Team writes report	Cross reading of the report	Host reads report / TL prepares presentation	General discussion of the draft report with host	Exit meeting
10:00-11:00							Discussion of cross reading results **Submission of Report to IRRS Admin**			
11:00-12:00										
12:00-13:00			Lunch	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch	Press conference
13:00-15:00		Lunch / Team Meeting	Interviews / in-group discussions (scheduled)	TM formulate findings Interviews (TBD)	TM write report	Discussion of findings with counterparts	Detailed Group Review	Host reads report / TL prepares presentation	Submission of the Final Draft	Lunch / Departure of Team Members
15:00-16:00						Team revises report based on discussions	TC drafts Executive Summary / TM finalise the Draft Report	Written comments by the Host	Finalization of press release	
16:00-17:00				**Written preliminary findings delivered**	**Final findings with text delivered**	**Draft report text to TL**		Team meeting for finalisation of the Report		
17:00-18:00			Daily Team Meeting	Daily Team Meeting: Discussion of findings **Submission to IRRS Admin**	Daily Team Meeting: Discussion of findings **Submission to IRRS Admin**	Daily Team Meeting: outcomes of discussion with counterparts **Submission to IRRS Admin**	Detailed Group Review. Discussion of Executive Summary		Free	
18:00-20:00	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Farewell Dinner	
20:00-		Writing of the report	Writing of the report	IRRS Admin compiles/distributes Report	IRRS Admin compiles/distributes Report	IRRS Admin compiles/distributes Report for cross reading	IRRS Admin finalizes Draft Report **Submission of the Draft to the Host**		Free	

APPENDIX III: LIST OF MISSION COUNTERPARTS

Overall coordinators

Mats Persson, Director General
Fredrik Hassel, Deputy Director General
Anna Franzén, Liaison Officer

Modules 1 and 2

Erik Henriksson, Department Director, Organisational Services
Lars Skånberg, Head of Section, Structural Integrity and Event Analysis
Eva Simic, Head of Section, Research
Charlotte Waller-Dahlberg, Head of Section, Legal Services
Pernilla Sandgren, Senior Legal Adviser, Legal Services Section
Susanne Gerland, Senior Legal Adviser, Legal Secretariat, Ministry of the Environment and Energy
Johan Pettersson, Legal Adviser, Legal Secretariat, Ministry of the Environment and Energy
Mats Johnsson, Senior Advisor, Division for Research Policy, Ministry of Education and Research
Björn Dufva, Director, Head of Chemicals Division, Ministry of the Environment and Energy

Module 3

Erik Henriksson, Department Director, Organisational Services
Martin Bengtsson, Human Resources Strategist, HR Section
Björn Hedberg, process owner, regulatory supervision
Stefan Appelgren, Deputy Director, Chemicals Division, Ministry of the Environment and Energy

Module 4

Anneli Hällgren, Director, Development Department
Sophie Ljungberg, Quality Coordinator, Organisational Services Department
Carina Vesterberg, Controller, Organisational Services Department
Anne Edland, Head of Section, Man-Technology-Organisation

Modules 5 and 6

Johan Anderberg, Director, Department of Radioactive Materials
Helene Jönsson, Head of Section, Occupational Practices and Work Activities
Erica Brewitz, Government Specialist, Transport and Waste Section
Ulf Yngvesson, Chief Legal Officer
Henrik Efraimsson, Government Specialist, Transport and Waste Section
Helmuth Zika, Inspector, Transport and Waste Section
Britt-Marie Rolén, Analyst, Transport and Waste Section
Helen Blomberg, Ministry of Environment and Energy

Modules 7 and 8

Michael Knochenhauer, Director, Nuclear Power Plant Safety Department
Anne Edland, Head of Section, Man-Technology-Organisation
Carl Bladh, Inspector, Medical Exposures Section
Helene Jönsson, Head of Section, Occupational Practices and Work Activities

Svante Ernberg, Head of Section, Operation and Decommissioning of Nuclear Facilities
Björn Hedberg, process owner, regulatory supervision
Anna Bärjegård, Analyst, Man-Technology-Organisation Section
Fredrik Hassel, Deputy Director General
Anna Franzén, Development Strategist, Section for Analyses and Methodology

Module 9

Charlotte Waller-Dahlberg, Head of Section, Legal Services
Lars Skånberg, Head of Section, Structural Integrity and Event Analysis
Ulf Yngvesson, Chief Legal Officer
Anders Frank, Inspector, Medical Exposures Section

Module 10

Johan Friberg, Director, Department of Radiation Protection
Catarina Danestig Sjögren, Head of Section, Emergency Preparedness and Response
Erica Brewitz, Senior Specialist, Control and Protection Section
Key Hedström, Director of Legal Affairs, Swedish Civil Contingencies Agency
Cecilia Looström, Swedish Civil Contingencies Agency
Thord Eriksson, Ministry of Justice, Government Offices of Sweden
Richard Vesterberg, Ministry of Justice, Government Offices of Sweden
Stig Husin, County Administrative Board of Uppsala
Fredrik Persson, Swedish Customs

Module 11

Torsten Cederlund, Head of Section, Medical Exposures
Jan Lillhök, Head of Section, Radiation Measurements
Carl-Göran Stålnacke, Inspector, Section for Occupational Practices and Work Activities
Charlotta Fred, Head of Section, Facility Radiation Protection
Karin Aquilonius, Inspector, Section for Facility Radiation Protection
Jan Johansson, Government Specialist, Emergency Preparedness and Response Section
Anders Frank, Inspector, Medical Exposures Section
Anders Wikander, Inspector, Medical Exposures Section

APPENDIX IV: RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE 2012 IRRS MISSION THAT REMAIN OPEN

Section	Module	R/S	Recommendations/Suggestions
1.8	**1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**	**R3**	**Recommendation:** The decision for making provisions to maintain competence for nuclear safety and radiation protection on a national level has not been taken by the Government.
2.2	**2. GLOBAL NUCLEAR SAFETY REGIME**	**R4**	**Recommendation:** SSM has neither conducted the evaluation of operational experience from non-nuclear facilities and radiation protection events and activities using a systematic approach nor provided guidance on the dissemination of information from events and the lessons learned to all relevant authorized parties.

APPENDIX V: RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2016 IRRS FOLLOW-UP MISSION

Section	Module	RF/SF/ GPF	Recommendations, Suggestions or Good Practices
3.3.	3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	SF1	**Suggestion:** SSM should complete a comprehensive resource and competence assessment, based on a strategic review, that incorporates the Swedish nuclear industry's perspective.
3.6.	3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	SF2	**Suggestion:** SSM should consider making key management system process documentation available to the applicants, licensees and other interested parties.
4.2.	4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	SF3	**Suggestion:** SSM should consider reviewing its roles, responsibilities, and expectations of its departments to assure clarity and to consider methods to assure effective cross organizational boundary communication that enable effective implementation of its management system components.
7.1.	7. INSPECTION	GPF1	**Good Practice**: SSM has developed a comprehensive and well defined set of criteria for assessing the risks involved in different types of uses of radiation sources.
9.4.	9. REGULATIONS AND GUIDES	GPF2	**Good Practice:** SSM's prompt and integrated approach to establish a consistent and comprehensive regulation taking into account international standards and good practices.
10.3.	10. EMERGENCY PREPAREDNESS AND RESPONSE	SF4	**Suggestion**: The Government should consider expanding the scope of the national emergency response plan for management of nuclear accidents to take into consideration arrangements for responding to radiological emergencies, based on threat/hazard assessment.

APPENDIX VI: REFERENCE MATERIAL PROVIDED BY SSM

Enactments

- Ordinance with Instructions for the Swedish Radiation Safety Authority
- Radiation Protection Act
- Act on Nuclear Activities
- Environmental Supervision Ordinance (2011:13)
- Excerpt from appropriation directions for the 2016 budget year, with reference to the Swedish Environmental Protection Agency
- SOSFS 2004:11 (M) Provisions on responsibility for letters of referral for patients within health and medical care, dental care, etc.

Internal steering documents

- Management of the Swedish Radiation Safety Authority, STYR2011-71
- Rules of procedure, STYR2011-27
- Decision-making procedure, STYR2011-28
- Career development discussion, STYR2011-33
- Surveillance inspection, STYR2011-107
- Rapid investigation, STYR2011-108
- Reviews, STYR2011-124
- Regulatory work – the process, STYR2011-51
- Competence supply model, STYR2014-41
- Handling of cases relating to orphan sources, STYR2016-2
- Approval of the transports of dangerous goods class 7 according to special arrangements, STYR2012-6
- Planning and follow-up, STYR2011-98
- Supervisory programme, STYR2016-4
- Competence profile and development programme for officers exercising regulatory supervision, STYR2011-171
- Assessment of compliance with requirements during regulatory supervision, STYR2011-87

Other documents

- The Swedish Radiation Safety Authority's input report for Government research policy
- Appendix 1: Individual professional development plan
- Areas of competence for members of staff exercising regulatory supervision
- The ETTAN Directive
- National emergency response plan
- Areas of competence for members of staff exercising regulatory supervision
- Appendix 1: Individual professional development plan
- The Authority's strategy objectives
- External audit, March 2016
- Follow-up report: Swedish Radiation Safety Authority, Four-month period 3, 2015
- Management's follow-up measurements for monthly follow-up 2016, Memorandum 16-611
- Evaluation of process – template

- Copy of 15-2953 on submitting suggested improvements
- Progress report on revision of the Authority's Regulatory Code, Memorandum 16-1239
- Criteria model for risk assessment, 16-1620

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, IAEA, Vienna (2010).
3.	**INTERNATIONAL ATOMIC ENERGY AGENCY** – The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3, IAEA, Vienna (2006).
4.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear and Radiological Emergencies, Safety Requirement Series No. GS-R-2, IAEA, Vienna (2002).
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36.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010)
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38.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)

39.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Spent Nuclear Fuel Specific Safety Guide Series No. SSG-15, IAEA, Vienna (2012)
40.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014)
41.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002)
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56.	**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)
57.	**INTERNATIONAL ATOMIC ENERGY AGENCY** - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX VIII: SSM ORGANIZATIONAL CHART