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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

SWEDEN

Stockholm, Sweden

6 to 17 February 2012

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

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Mission date: *6 to 17 February 2012*
Regulatory body: *SWEDISH RADIATION SAFETY AUTHORITY - SSM*
Location: *SSM HQ in Stockholm (Solna), SWEDEN*
Organized by: *International Atomic Energy Agency (IAEA)*

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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.

CONTENT

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 6 to 17 February 2012 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at the headquarters of SSM in Stockholm.

The purpose of this IRRS mission was to review the effectiveness of the Swedish framework for safety within the competence of SSM. Special attention was given to the review of the regulatory implications of the TEPCO-Fukushima Dai-ichi accident within the Swedish framework for 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 as an opportunity to exchange information and experience between the IRRS review team members and the SSM counterparts in the areas covered by the IRRS.

The IRRS Review team consisted of 18 senior regulatory experts from 16 IAEA Member States, 5 IAEA staff members and an IAEA administrative assistant. The IRRS Review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection; environmental monitoring; control of radioactive discharges and materials for clearance; control of chronic exposure and remediation; waste management; control of medical exposure and transport.

The IRRS mission also included the following regulatory policy issues for discussion: Supervisory strategies; competence at SSM; and response to the TEPCO-Fukushima Dai-ichi accident. The IRRS review addressed all facilities and activities regulated by SSM including ten nuclear power units, fuel fabrications facility, spent fuel and waste management facilities and users of radioactive sources.

The mission included observations of regulatory activities and a series of interviews and discussions with SSM staff and other organizations to help assess the effectiveness of the regulatory system. These activities included observations of inspections and/or surveillance visits to Forsmarks Kraftgrupp AB (Nuclear Power Plant), Westinghouse Electric Sweden AB (fuel factory), Svensk Kärnbränsleförsörjning (SKB), Clab (intermediate storage facility for spent fuel), Uppsala University hospital, Karolinska Institutet (Positron Emission Tomography (PET) cyclotron), Studsvik Nuclear AB and AB SVAFO. Throughout the review of the various areas and policy issues, special consideration was given to the regulatory implications of the TEPCO-Fukushima Dai-ichi accident. The IRRS team members observed the working practices during inspections carried out by SSM, including discussions with the licensee personnel and management. In addition the IRRS team observed an emergency exercise which was conducted with representatives from multiple organizations, government and industry.

SSM provided the IRRS review team with advanced reference material and documentation including the results of its self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS Review team was extended full cooperation in its review of regulatory, technical and policy issues by all parties. The staff of SSM was very open and candid in their discussions and provided the fullest practicable assistance.

The IRRS review team identified a number of good practices and made recommendations and suggestions where improvements will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards.

The main observations of the IRRS Review team were the following:

- SSM operates as an independent regulator in an open and transparent manner with well-organized regulatory processes.
- SSM is a continuously learning organization that is receptive to feedback from interested parties.
- SSM responded promptly and communicated effectively following the TEPCO Fukushima Dai-ichi accident.

Among the strengths/good practices identified by the IRRS review team are the following:

- The formation of SSM by the merger of SKI and SSI was successfully conducted
- SSM's management system is process-oriented, comprehensive, user-friendly and contributes to staff efficiency and effectiveness in conducting regulatory supervision
- The nuclear power plants refurbishment program as required by SSM enhanced safety
- Sweden's regulatory framework for high-level waste disposal is comprehensive and technically sound

The IRRS Review team identified issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system.

- A strategy should be developed to assure Sweden's regulatory framework (legislation, regulations and guides) is consistent with IAEA Safety Standards. Regulations and guides (General Advice) do not cover all topics as required.
- SSM's internal guidance to its staff regarding its regulatory practices should be standardized.
- SSM should evaluate its staffing and competence needs and request appropriate resources from the government.
- The inspection programme in many technical areas needed strengthening.

The IRRS Review team findings are summarized in Appendices V and VI.

A press conference was conducted at the end of the mission, and an IAEA press release was issued.

I. INTRODUCTION

At the request of the Government of Sweden, an international peer review team of senior safety experts met representatives of the Swedish Nuclear Safety Authority (SSM) from 6 to 17 February 2012, to conduct an Integrated Regulatory Review Service (IRRS) Mission. The purpose of the review was to review the Swedish regulatory framework for nuclear and radiation safety.

The review mission was formally requested by SSM in February 2009. A preparatory mission was conducted 6-7 October 2011 at SSM Headquarters in Stockholm to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the areas regulated by SSM and selected safety aspects.

The IRRS review team consisted of 18 senior regulatory experts from 16 IAEA Member States, 5 IAEA staff members and an IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection; environmental monitoring; control of radioactive discharges and materials for clearance; waste management; control of medical exposure and transport. Special attention was given to the regulatory implications of the TEPCO-Fukushima Dai-ichi accident in the Swedish framework for safety.

In addition, several policy issues were discussed including: response to the TEPCO-Fukushima Dai-ichi accident; supervisory strategies, and competence at SSM.

SSM conducted a self-assessment in preparation for the mission. The results of its self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from SSM as well as external organizations and performed direct observation of SSM working practices during inspections. Meetings with other organizations involved in the national regulatory infrastructure for safety were also organized, including the Ministry of the Environment and other authorities responsible for emergency preparedness (representatives of Federal Authorities, county administrative boards and municipalities).

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Swedish nuclear and radiation protection 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 including ten operating nuclear power reactors; two shutdown power reactors, 1 prototype, 2 research reactors and one former nuclear fuel cycle facility undergoing decommissioning; one fuel fabrication facility; one waste facility; one final storage depository for low and intermediate waste; one central spent fuel storage facility; four shallow land burials and other users and uses of radioactive sources (medical, dental, industrial, cyclotrons, irradiators, etc.). 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 by SSM and the IRRS reviewers and through the evaluation of the effectiveness of the Swedish nuclear regulatory framework and its good practices.

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

- ✓ Providing SSM, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against IAEA safety standards;
- ✓ Providing Sweden (SSM) with a review of its regulatory programme and policy issues relating to nuclear safety, radiation protection and emergency preparedness;
- ✓ Providing Sweden (SSM) with an objective evaluation of its nuclear safety, radiation protection and 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 (SSM) with recommendations and suggestions for improvement;
- ✓ 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 authorities, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 6 to 7 October 2011. 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, Mr David Graves, Mr Ahmad Al Khatibeh, and Mr Peter Zombori.

The IRRS mission preparatory team conducted extensive discussions regarding regulatory programmes and policy issues with the senior management of SSM represented by Ms Ann-Louise Eksborg, SSM Director General, and 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 mission:

- Nuclear power plants
- Waste facilities
- Decommissioning
- Occupational radiation protection
- Control of radioactive discharges and materials for clearance
- Environmental monitoring
- Control of chronic exposures (radon, NORM and past activities) and remediation
- Waste management (policy and strategy, predisposal and disposal)
- Transport
- Medical exposure
- Regulatory implications of the TEPCO Fukushima Dai-ichi accident
- Other users and uses of radioactive sources
- Selected policy issues

Ms Eksborg and other SSM staff made comprehensive presentations on the current status of SSM, and the self-assessment results to date. IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Sweden in February 2012.

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, counterpart and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

SSM provided IAEA (and the review team) with the advance reference material for the review, including the self-assessment results, through an external webpage dedicated to IRRS preparation. In advance off the mission, the IAEA review team members conducted a review of the advance reference material and provided their initial review comments to the IAEA Coordinator prior to the commencement of the IRRS mission.

The SSM Liaison Officers for the preparatory meeting and the IRRS mission were Ms Elisabeth Öhlen, Mr Ingemar Lund and Mr Anders Hallman.

B) REFERENCE FOR THE REVIEW

The latest, 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 VIII.

C) CONDUCT OF THE REVIEW

An opening IRRS Review team meeting was conducted on Sunday, 5th February, 2012 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.

In addition, the IAEA Team Coordinator and Review Area Facilitator presented the expectations regarding the new module on the IRRS "Regulatory implications from TEPCO-Fukushima Dai-ichi Accident" to be applied.

The Liaison Officers were present at the opening IRRS Review team meeting, in accordance with the IRRS guidelines, and presented the agenda for the mission. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 6th February 2012, with the participation of SSM senior management and staff. Opening remarks were made by Mr Georg Schwarz, the IRRS Team Leader. Ms Ann-Louise Eksborg, SSM Director General, and other SSM staff gave an overview of SSM status and activities. Mr Björn Dufva from the Ministry of the Environment also gave a presentation on the Ministry activities related to SSM.

During the mission, a systematic review was conducted for all the review areas with the objective of providing SSM with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations 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 Friday 17th February 2012. The opening remarks at the exit meeting were presented by Ms A-L. Eksborg and Mr Björn Dufva from the Ministry of the Environment, and was followed by IRRS Team Leader Mr G. Schwarz, who presented the results of the mission. Closing remarks were made by Mr Jim Lyons, IAEA, Director, Division of Nuclear Installation Safety.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY

Sweden has a structured and mature legislative and regulatory framework for the peaceful use of nuclear energy and providing protection against ionising radiation. The overall purpose or goal of the Swedish Government's Environmental Policy is to hand on to the next generation, a society in which the major environmental challenges facing Sweden are properly managed. To attain this goal, the Government has established national Environmental Quality Objectives (EQO's) across sixteen areas that have been adopted by the Swedish Parliament.

One of the Environmental Quality Objectives is stated to be the achievement of "A Safe Radiation Environment" and requires human health and biological diversity to be protected against the harmful effects of radiation. In Sweden, policies and strategies for safety are mainly expressed through legislative measures and through assignments and instructions to the various regulatory Authorities.

The policies and strategy which establishes the legal framework for nuclear and radiation safety are stated in the following legal acts:

- Nuclear Activities Act (1984:3),
- Radiation Protection Act (1988:220),
- Environmental Code (1998:808),
- Act on Financial Measures for the Management of Waste Products from Nuclear Activities (2006:647)
- Nuclear Liability Act (1968:45)

The Swedish Government's environmental policy clearly states a long term commitment to nuclear and radiation safety and is promulgated through its Environmental Quality Objectives. The government has identified safety principles in the acts which are based on the 10 IAEA Fundamental Safety Principles.

The IRRS team has concluded that the Swedish national policy and strategy for nuclear and radiation safety generally meets the IAEA requirements.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Swedish Parliament is the highest political decision-making body in the country and puts in place the Acts governing nuclear and radiation safety. The Swedish Government has the overall responsibility for the Environmental Quality Objectives and for the implementation of the associated legislation enacted by the Parliament. The Government decides upon and defines the operational requirements for the various Authorities. This is put in place through the issuing of Annual Appropriation Directives and by Ordinances containing instructions to the Authorities and discharges the responsibilities associated with the specific acts. The Appropriation Directives set out the goals an Authority is to deliver through its operations, the financial arrangements the Authority has at its disposal and how the finances are to be allocated between the different regulatory activities. Ordinances are also issued by the Government and contain various general administrative provisions, duties and tasks that relate to how the Authority is to carry out its work.

The legal framework in the field of nuclear safety is the Nuclear Activities Act (1984:3), which aims to maintain safety in the operation, waste management and decommissioning and dismantling of nuclear facilities.

The legal framework in the field of Radiation Protection and Safety is the Radiation Protection Act (SFS 1988:220), Radiation Protection Ordinance (1988:293) and Ordinance with instructions for the Swedish

Radiation Safety Authority (2008:452) which aim to protect people, animals and the environment from the harmful effects of radiation.

The provisions of the Nuclear Activities Act and Radiation Protection Act provide for the general principles of the regulatory regime. The acts are supplemented by a number of ordinances and other secondary legislation containing more detailed provisions concerning nuclear safety and radiation protection.

In connection with the forming of a the new Swedish Radiation Safety Authority (see 1.3) the Minister of the Environment (with delegation from the Government) appointed a Committee of Inquiry with the remit to examine the possibility of harmonising the legislation relating to activities in the field of nuclear safety and radiation protection. The need to simplify and streamline the legislation on nuclear operations and other practices involving radiation has long been discussed and the IRRS team welcomes the plan to complete this work.

The Committee of Inquiry's focus was defined to examine the feasibility of merging the provisions of the Nuclear Activities Act (1984:3) and the Radiation Protection Act (1988:220) into a single law. The aim is to simplify the structure and formulation of the provisions and make them more effective without thereby jeopardizing public requirements regarding nuclear safety and radiation protection. The current parallel application of the Environmental Code, the Nuclear Activities Act and the Radiation Protection Act results in a 'dual' licensing process with significant overlapping of the regulatory processes and the issuing of two permits with similar legal requirements.

The IRRS team has concluded that greater framework alignment is desirable to avoid possible confusion of legal requirements and improve the efficiency of the regulatory process. The plans in place for the consolidation of the legislation into a single Act are being progressed and the government has recently completed an extensive consultation. It was stated that the revised legislation could at the earliest be laid in Parliament via a Bill in March 2013. Following further parliamentary and legal processes the new legislation would then come into force in 2015 at the earliest. The IRRS team noted that a considerable number of consultation responses were received and would encourage the government to deal with the legislative process as a priority.

The IAEA safety requirements place requirements on the government and the regulatory body to promulgate laws and statutes to establish a comprehensive harmonised and hierarchical framework for safety. In this respect the Government and SSM are required to take a strategic view to maintaining legislation that ensures a robust and up to date framework for safety including associated regulations and guidance is always in place.

In Sweden the nuclear safety and radiation protection licensing requirements are defined within the Environmental Code, the Nuclear Activities Act and the Radiation Protection Act. It is important that this legislation covers the entire range of nuclear facilities and activities from radiation sources to the nuclear power programme and meets International requirements. It is therefore recommended that a strategically focussed process is established by Government and SSM to ensure this is achieved.

The IRRS team found that the legislation is currently in need of updating and this is delaying the development of regulations and guidance that are important to regulating nuclear safety and radiation protection. SSM has recently completed a review of the legislation and proposed changes required to Government but it is not clear that a robust process exists to secure the required changes and when they will be completed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Paragraph 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal, and regulatory framework for safety."*
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.**

Currently SSM can only complete inspections of activities on a licensed site or facility. It is vital to nuclear safety that the regulatory body can complete its assessment and inspection of plant and equipment provided to the Authorised Party by suppliers working in the nuclear supply chain. The IRRS team identified that SSM does not have the legal authority to inspect supply chain organisations and operations at the supplier premises. It is recommended that the government ensures SSM is legally entitled to conduct inspections of suppliers. This requirement will become even more important with the proposal for new nuclear reactor build.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Paragraph 2.5 (9) states that** *"The framework for safety shall set out provision for 'The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations…."*
(2)	**BASIS: GSR Part 1 Paragraph 2.13 (b) states that** *"The regulatory body shall be conferred with the legal authority to require an authorised party or an applicant …. to provide access, solely or together with the authorised party or applicant for making inspections on the premises of any designer, supplier, manufacturer, constructor, contractor or operating organisation associated with the authorised party."*
R2	**Recommendation: Government should ensure that SSM is legally entitled to conduct inspections of suppliers.**

Accreditation inspections for nuclear safety related plant/equipment are completed by 'Third Party' organisations on nuclear licensed sites. These activities are important to the safety justification made for operations on the licenced sites. The IRRS team found that the legal basis for 'Third Party' accreditation inspections is established in Swedish law and reflected in the framework for safety including SSM's regulations.

1.3. ESTABLISHMENT OF A REGULATORY BODY

There are a number of Authorities/Agencies responsible for implementing the Government's nuclear safety and radiation safety policies and strategies:

- **The Swedish Radiation Safety Authority (SSM)**
- **The National Council for Nuclear Waste**
- **The Environmental Objectives Council**
- **The Swedish Environmental Protection Agency**
- **The Swedish Civil Contingencies Agency**

- **The Swedish Work Environment Authority**
- **Swedish National Board of Housing, Building and Planning**
- **The National Board of Health and Welfare**
- **National Food Agency**
- **The Medical Products Agency**
- **The County Administrative Boards**

The Swedish Radiation Safety Authority (SSM) was established in 2008 through the merger of the former Swedish Nuclear Power Inspectorate (SKI) and the Swedish Radiation Protection Authority (SSI). The legislation that SKI and SSI worked to was carried forward into the new SSM Authority.

In the current legal framework the Swedish Radiation Safety Authority (SSM) is established as the regulatory body and Administrative Authority reporting to the Ministry of Environment with responsibility for discharging the Acts on nuclear activities and radiation protection.

Ordinance (2008:452) authorises SSM to issue regulations covering nuclear safety and radiation protection. SSM is also responsible for conducting supervision at nuclear facilities and to ensure that licensees comply with applicable laws and regulations. The Director General of SSM is ultimately responsible to the Swedish Government for regulating nuclear and radiation safety.

The IRRS team concludes that the government has established a regulatory body that meets the requirement of IAEA GSR Part 1.

1.4. INDEPENDENCE OF THE REGULATORY BODY

SSM is an Authority established under Swedish law that is legally and functionally independent.

SSM host government department is the Ministry of Environment which has no role in sponsoring or supporting the nuclear industry. The IRRS team noted the responsibilities for nuclear regulation and the promotion and use of nuclear energy are clearly separated within the Swedish Government Ministries.

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. In addition, there are provisions in the Administrative Procedure Act that stipulate a person suspected of not being independent may not participate in a regulatory decision. This arrangement is effective in clearly maintaining SSM's independence.

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 Ministry of the Environment, and the Ministry uses SSM as a "Competent Authority" in light of its technical expertise and governmental status to advise on licencing matters. The IRRS team has concluded the process to issue nuclear site licenses does not challenge the independence of the regulatory body.

The Director General of SSM is appointed by the Government for a period of (normally) six years. While SSM has no formal oversight board, the Director General is responsible for its operations and reports its activities directly to the Government.

The IRRS team has concluded that the requirement for the independence of the regulatory body is satisfied.

1.5. PRIME RESPONSIBILITY FOR SAFETY

Section 10 of the Nuclear Activities Act assigns the obligation and responsibility to take all measures necessary to maintain safety to the license holder of a nuclear activity. This obligation applies not only to

the actual operation, but also includes the decommissioning of the facility and the disposal of the resulting radioactive waste. The obligation to decommission the facility and to dispose the radioactive waste remains with the licensee/operator even if its permit has been revoked. Also under the statutory provisions for liability payments in the event of a nuclear accident, the responsibilities for the licensee's and government are clear.

Section 16 of the same Act states that the supervision of compliance is exercised by the supervisory authority appointed by the Government. It also specifies that the supervisory authority may decide on necessary enforcement measures.

In addition, Section 17 of the Nuclear Activities Act states the obligation for the licensees to provide supervisory authorities with any type of information necessary to check the compliance with the regulatory requirements and grant access to the facilities to supervisory authorities.

The Radiation Protection Act contains equivalent rules for activities involving radiation safety.

1.6. COMPLIANCE AND RESPONSIBILITY FOR SAFETY

As mentioned in section 1.5, the Nuclear Activities Act (Section 10) and the Radiation Protection Act (Section 6) state that the licence holder is responsible for the safety of the activity. When a permit is issued various obligations take effect. Neither of the Acts relieves the licensee from its prime responsibility for safety.

The responsibility for safety remains with the licensee, even if it chooses to call upon third parties. The licensee can delegate tasks, but not its prime responsibility for safety. The licensee is responsible for verifying that products and services supplied to it by third parties, employees and contractors comply with applicable law.

The IRRS team concludes that the Swedish legal framework provides for assuring that compliance with regulations and requirements does not relieve authorised parties of their prime responsibility for safety.

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

The Government's legislation clearly defines the duties and responsibilities of the various authorities having responsibilities for safety. The legislation adopted by Parliament and Government puts in place systems within the Government Offices with the aim to counteract conflicting rules or rules that give rise to inconsistent effects. All the Ministries have the opportunity to provide comments on various legislative proposals before they become agreed proposals. The Government collectively makes decisions; this implies that no individual Minister can make a decision on new legislation. In addition, and with regard to all legislation there is a system of referrals, which reduces the risk for legislation coming into use that is inappropriate or inadequate. There is also a dedicated Authority – the Regulation Council - which reviews all proposed legislation in terms of its impact on individuals and businesses.

SSM is the main regulatory body regarding nuclear safety and radiation protection in Sweden. There are other authorities that are responsible for different aspects of radiation protection and nuclear safety (see 1.2) and in accordance with the Authority Ordinance (2007:515) an Authority is obliged to cooperate with other Authorities when this is mandated.

The IRRS team has concluded that the Government meets the IAEA requirement for the coordination of different authorities operating within the nuclear regulatory framework.

1.8. COMPETENCE FOR SAFETY

The main legislation for regulating nuclear and radiation safety contains expectations for those with responsibility for safety to secure and maintain adequate competences. The Nuclear Activities Act states that the licensee for nuclear activities is obliged to have an organisation with adequate human resources. The Environmental Code (1998:808) states that anyone who conducts or intends to engage in an activity or take a measure shall acquire the necessary knowledge with regard to the nature and extent of the activity or the measure in order to protect human health and the environment against damage or harm. Furthermore, according to the Radiation Protection Act anyone responsible for a practice involving radiation shall ensure that the person engaged in the activity has the necessary qualifications and knowledge about radiation protection. The government has appointed SSM to supervise the licensees' compliance to the requirements.

The academic institutions are a source of specialists to the nuclear sector and in Sweden the Government is responsible for funding of basic university training. SSM has completed projects to survey the availability of graduate/post graduate courses and research capability across the Swedish academic sector. For example experimental research within safety and radiation protection is performed at Chalmers University, Royal Institute of Technology, Uppsala University, Stockholm University and Lund University. The Government has, through SSM funding, established centres concerning safety and radiation protection. One is the SKC (Swedish Centre for Nuclear Technology) at the Royal Institute of Technology and CRPR (Centre for Radiation Protection Research) at Stockholm University. SKC provides long-term support to securing knowledge and competence development for the Swedish nuclear technology programs as a basis for providing resources to the Swedish nuclear industry and its regulators.

SSM has also conducted a review of nuclear sector related competence at a national level in Sweden as part of a review covering all activities related to radiation protection and administrative tasks. The education and research resources within the academic sector were evaluated across 35 institutions in higher education and 20 institutions from the academic sector. SSM concluded for the short term that the education needed for specific nuclear related fields within Sweden is broad and the number of students within the nuclear field is at present adequate. However for the medium and longer term the position is not clear and it is clear that if there was a decision to develop new Nuclear Power Plants the provision would not be adequate and significantly more capability would be required. Additionally the IRRS team noted there are currently no requirements on the minimum education and training levels for personnel engaged in medical radiation exposure such as medical radiation technologists and nurses.

The team has concluded that the Government needs to take action at a national level in Sweden to meet the IAEA requirement to ensure all parties have access to competent staff to ensure the continued safety of nuclear facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Paragraph 2.21 states that** *"The government shall ensure that requirements are established for: (a) education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.*"
(2)	**BASIS: GSR Part 1 Paragraph 2.34 states that** *"As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
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.**

1.9. PROVISION OF TECHNICAL SERVICES

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

The IRRS team has concluded that the Government meets the IAEA requirement for the provision of technical services in the areas of nuclear safety and radiation protection.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

Sweden is a contracting party to all of the relevant conventions expected for a country operating nuclear power plants, including nuclear safety, emergency preparedness and response, nuclear liability, spent nuclear fuel, radioactive waste and physical protection.

Sweden has formally committed to implementation of the Code of Conduct on the Safety and Security of Radioactive Sources and the Supplementary Guidance on the Import and Export of Radioactive Sources.

SSM staff is familiar with IAEA safety standards. While no specific administrative requirements exist within its administrative processes, SSM staff have participated in the development of IAEA safety standards through participation in various Safety Standards Committees, consultancy meetings for development of safety standards, and participation in IAEA safety review missions where IAEA safety standards are used as the basis for the review.

SSM has frequently participated in various peer review activities. Operational Safety Review Team (OSART) missions have been conducted at all Swedish reactor facilities. SSM has also provided staff to participate in OSART missions to other member state nuclear facilities. Swedish utilities are members of the World Association of Nuclear Operators (WANO), and have requested and been subject to WANO peer reviews. In addition to requesting this IRRS mission, SSM staff have participated in a number of IRRS missions in other member states.

Sweden participates in numerous bilateral (15) and multilateral (2) international agreements regarding cooperation on matters of nuclear safety and/or radiation protection. Management System document 102, "Policy for International Agreements," provides the internal SSM guidance for concluding international agreements. SSM has the authority to arrange bilateral agreements with other nations as long as the activities fall under SSM's areas of work. Additionally, SSM is a member of the Organisation for Economic Cooperation and Development/Nuclear Energy Agency (OECD/NEA) and actively participates in various working groups and nuclear and radiation safety initiatives.

As a recent example of international outreach, SSM issued a survey to certain elements of the international community to assess the licensing challenges associated with regulatory oversight of management systems, operations, and safety culture at nuclear power plants. This survey also requested information regarding major plant modifications, power up-rate and life extension programs, and construction and commissioning programs for new nuclear power plants. This survey seeks to understand the regulatory approaches used in various countries. This study is a follow-up to a previous survey conducted in 2002 and 2003, and is indicative of SSM's desire to learn from the international community.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Nuclear facilities are required to report to SSM events and conditions important to safety in accordance with Chapter 7 of the Swedish Radiation Safety Authority Regulatory Code (SSMFS 2008:1). Guidance regarding classification is contained in Appendix 1 to SSMFS 2008:1. Procedure 151 in SMM's Management System describes in detail the process for evaluating the events reported from nuclear power plants. The tasked group reviews the analysis and the conclusions of the licensee, informs the relevant parts of SSM organization and gives recommendations to the organization about actions that should be taken. Based on the judgement of the Director, Nuclear Power Plant Safety Department, the results of this evaluation may be disseminated to other facilities. SSM does not typically disseminate lessons learned from NPPs (or other nuclear facilities or activities) to other licensees. It is considered the responsibility of the license holder to disseminate lessons learned to other facilities and to retrieve information regarding

operational events and lessons learned from the OECD/NEA Incident Report System or other sources.

In any case, all NPP licensees have access to all events reported to SSM. However, there is no similar formal guidance for evaluating events reported from fuel cycle facilities or other users of radioactive materials. Areas specifically identified included decommissioning, radioactive source usage, and transport of radioactive materials.

SSMFS 2008:1, Chapter 2, requires that nuclear facilities provide that "efficient procedures should be in place for continuous experience feedback within the nuclear activity", and "The continuous analysis and evaluation of facility safety should particularly take into account technical and organisational experience from one's own activity, from similar facilities, results from safety analyses and results from research and development projects".

For non-nuclear sites (i.e. activities licensed under the Radiation Protection Act) unplanned events with radiological importance have to be reported to SSM. Also according to the Radiation Protection Ordinance (1988:293) (§15) all events which are of importance from a radiological point of view shall be reported to SSM. The reports are analysed by SSM and if deemed of interest for others it is published on the SSM web site. However, this procedure is not included in SSM's management system.

SSM participates in several information sharing networks (e.g. the European ALARA Network (EAN), the Nordic Society for Radiation Protection (NSFS), the International Radiation Protection Association (IRPA)). These networks provide forums for the dissemination of good ALARA practice and lessons learned concerning radiation protection.

SSM conducts periodic meetings with the nuclear industry related to radiation protection issues. SSM management also meets with management of licensees for nuclear facilities on a regular basis. Meetings with nuclear power plant management organizations takes place on a yearly basis while meetings with management of fuel cycle facilities takes place every two years.

For many activities, there is a requirement to share information within SSM on the results. However, the guidance to use that information as input to review the activity for improvement from the information provided is not clearly articulated.

Both the Swedish Radiation Safety Authority Regulatory Code and the Act on Radiation Protection (SFS 1988:220) require that licensees take appropriate corrective actions for events and identified conditions. However, there is no formalized process for making information of lessons learned available to others, except as information given as feedback to licensees from inspections and reviews of licensees' activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Requirement 15, states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body, and other relevant authorities."*
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.**

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Government's requirements for SSM are defined in the Ordinance (SFS 2008:452) and an Annual Appropriation Directive. The Director General of SSM is usually appointed for a period of six years and is exclusively accountable to the government for all the activities of the Authority.

SSM was established in 2008 and took over the responsibility from the two former authorities, the Swedish Nuclear Power Inspectorate (SKI) and the Swedish Radiation Protection Authority (SSI). The main driver for the merger was to strengthen and reinforce the supervision of both nuclear and non-nuclear activities, relating to nuclear safety and radiation protection. There was also a general ambition by the government to make civil service more efficient by reducing the number of administrative authorities.

The transition to the new regulatory body involved bringing together two authorities that worked closely together prior to the merger but with different legislation, regulations, cultures and office locations. There was also a climate of some resistance to the change from staff within the respective authorities. SSM management set up the organisational change project with a clear strategy to deliver the transition and the transformation utilising external expertise but always retaining clear ownership and control of the process. A baseline assessment of the organisation culture was completed at the start of the organisational change process and revisited regularly to monitor a number of key indicators. The leadership team proactively communicated with the organisation during the change process, encouraging staff to provide their views and feedback and maintaining a listening attitude. The SSM management team was thorough in responding to all the feedback from staff and explained the change process in the context of the benefits to be realised. The merger has been welcomed by the authorised and interested parties we have spoken to during the mission who commented positively on the improved regulatory integration.

The IRRS team concluded that this improvement has strengthened nuclear and radiation safety regulation, and the change process was well managed by SSM.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Paragraph 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively."*
GP1	**Good Practice: The transition of two regulatory bodies into the Swedish Radiation Safety Authority (SSM) organisation represented a considerable achievement. The organisational change management process adopted by the SSM leadership and management team brought about an integration of regulatory functions.**

SSM has an Advisory Council with a maximum of ten members who are appointed by the government. The members are usually Members of the Parliament, Agency Officials or Independent Experts or Non-Governmental Organisations (NGO's). The functions of the council are to advise the Director General and to ensure public transparency (insight) in the authority's activities but it has no decision-making powers. This type of advisory board is a common feature in the Swedish governmental system and is considered to be an example of the Swedish democratic process. The council has the remit to alert the government if it suspects irregularities within SSM. In the instruction to SSM the government also states that SSM shall

also organise and run five advisory boards (see 3.4). The role of the Advisory Boards is to give advice in the framework of their expertise.

The funding of SSM is a two-step process structure where the first stage is to provide SSM with funds through the annual budgeting process in the Parliament. In a subsequent Government decision the funding is allocated into separate sub-funds that are then instructed through directions to SSM.

SSM's regulatory intervention planning and allocation of resources is only partly based on the radiation risk of facilities and activities. As 85% of SSM's regulatory activities are indirectly financed by supervision fees, SSM is required by the government to allocate resources directly on the basis of the sector fee income. The IRRS team has noted therefore that SSM only provides a partial grading approach in its allocation of resources commensurate with the safety assessment outcomes and radiation risks.

On an annual basis SSM submits to Government a proposal for the levels of regulatory supervision fee. The proposal is based on the forecast level of supervision identified by SSM and reflects a graded approach. SSM receives an annual appropriation from the Government that is mainly financed by fees from licence holders. SSM has flexibility to allocate the appropriation as required within the planning year. However the total spending for SSM over a longer accounting period (i.e. five years) must match the fees paid by licensees.

The organisation of SSM is set out in the "Rules of Procedure of the Swedish Radiation Authority". This document also comprises the defined responsibilities of the departments, sections and managers as well as the decision-making procedures. SSM has allocated the different tasks into areas of operation. The platform for this division is the Government's governance of the Authority through the Ordinance with instructions for the Swedish Radiation Safety Authority (2008:452). The areas of operation are described in the steering document "Management of the Swedish Radiation Authority" (STYR2011-71).

As for all Swedish authorities, SSM issues an annual report to the Government summarising its major deliverables, performance indicators, issues, revenues and costs. The Government carries out follow-up work and evaluates the authority´s operations based on this report. In addition, SSM submits an annual report to the Government on the status and management of nuclear safety and radiation protection at the Swedish nuclear plants and other facilities and areas. The report summarises major findings and conclusions on operational experience, regulatory inspections and reviews: technical safety status, radiation protection work, environmental impact, waste management, emergency preparedness as well as organisational matters, safety culture, physical protection and safeguards.

The team concludes that SSM meets the requirements of the IAEA in respect to organisation structures and the management processes for its resources.

3.2. EFFECTIVE INDEPENDENCE DURING CONDUCT OF REGULATORY ACTIVITIES

All Swedish administrative authorities are traditionally very independent. Governmental decisions are always taken collectively by ministers and an individual minister cannot therefore interfere in a specific matter being handled by an administrative authority.

Control of the SSM staff to ensure that it remains independent is accomplished the Administrative Procedure Act which is regulating the disqualifying of staff members from decision making. The same Act is also the legal basis for the reporting requirements on the share holdings of SSMs senior management.

The requirements on SSM for openness and provision of information services to the public, politicians and media are very high. Swedish official documents are public unless a decision is made to classify them according to the Public Access to Information and Secrecy Act.

It was noted that due to limited financial resources SSM collaborates with the nuclear industry in the field of expensive research projects. Given the size of the country and its nuclear industry, this issue seems difficult to avoid and as the collaboration is always made transparent by SSM, we have concluded that there is no conflict evident at the present time. Nevertheless, SSM should remain vigilant on this issue.

The team concludes that the regulatory body meets the IAEA safety requirements for effective independence.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The Swedish Government requires all authorities, including SSM, to submit budget forecasts on an annual basis. The requests are processed by the Government and subsequently agreed by the Parliament. The forecasts have to also contain a three year forward projection of budget requirements to enable Government to plan for any future significant changes in the Authority's requirements.

Following agreement by Parliament the Government provides SSM with resources through a resourcing arrangement comprising:

- Granting direct government funds to SSM
- Agreeing the fees that should be paid by licensees to finance the Government Funds (fees paid direct to the state).
- Agreeing the fees to directly finance licensing processes conducted by SSM (fees paid direct to SSM).
- Granting contributions from the spent nuclear fuel management fund to SSM.

It was noted that the Director General of SSM is entitled to employ the staff needed to conduct the tasks given by Government within the annual financial limits and the arrangements allow some in year flexibility. It was also noted that a forward projection of financing requirements for a three year period is part of the process and a feature that may become more important if regulatory activity increases for example as a result of possible new power reactor build.

In comparison with many other nuclear safety regulatory bodies worldwide the number of regulatory staff in SSM is small given the scope of its responsibilities and the size of the nuclear program in Sweden. However, it is noted that in Sweden the legislation and regulatory approach very clearly places the responsibility for safety with the licensees and therefore the regulator does not prescribe how operations are to be conducted through extensive regulations and interventions that would require a much larger number of regulatory staff.

The current staffing and competence levels in the regulatory body are still in part influenced by the government's previous nuclear policy. The Swedish nuclear power industry was established in the period from 1970 through to the early 1980's when 12 nuclear power plants were constructed and brought into service. This was followed by a long period of operational stability within a political nuclear policy environment that required closure of the power plants by 2010. This created a situation where the operating lives of the power reactors were relatively short and limited attention being given to plant life extension, power upgrade, ageing considerations etc. The demands on the regulatory body were therefore limited to the supervision of routine matters which required limited resource in SKI.

Following a change to the nuclear policy in Sweden, the Government requirement to close the nuclear power plants was lifted. This decision required a significant change to SSM's regulatory strategy with a much greater emphasis on maintenance, plant ageing considerations; periodic safety review and power upgrade requests from the licensees. The resources and competences required to deliver a new regulatory strategy were assessed at the time and resulted in an increase to the number of specialist and inspection staff.

SSM currently has (Feb 2012) 280 staff. The Department of Nuclear Power Plant Safety has a staff of 72 working on the supervision of nuclear safety and radiation protection at the 10 operating nuclear power reactors. The Department of Radioactive Materials has 65 staff working on waste management, spent fuels mainly working with inspections of non-power producing nuclear installations including decommissioning, financial issues, nuclear security, non-proliferation, transport activities, radioactive wastes and discharge authorisations from non-nuclear facilities, and with planned or existing off-site spent fuel and waste management facilities - including final repositories. The Department of Radiation Protection has 65 staff working on national emergency preparedness activities, environmental monitoring issues, laboratory measurements, calibrations and use of radiation sources, x-ray equipment related to the operation of the Swedish nuclear facilities.

The IRRS team noted that in 2010, SSM completed a comprehensive review of its current and future resourcing arrangements. The survey identified 59 areas of expertise, including management skills and methodology skills. SSM has put in place a systematic approach to the analysis of competence needs and this is described within the competence process of the management system. The process consists of the following four steps: skills analysis, skills planning, implementation and evaluation. In support of this skills analysis, SSM has a model that describes five different dimensions of competence through a process described as a 'Competence Wheel'. The SSM strategy for addressing competency requirements includes focused recruitment, training and development programs, staff retention measures and knowledge management activities (see also Module 4). Competency profiles for managers, internal auditors, and inspectors (Supervisory core process) have been completed and need to be extended to all key roles in the organisation. The focus to date has been on closing competence gaps for inspectors where a training and development program is being further developed and deployed. There is currently no mandatory training programme, including refresher training, and this should be put in place for all the various technical specialist roles. An example of this requirement is highlighted within the Inspection Module (Ref: Paragraph 7.2.4).

In some technical/specialist areas we found that SSM has only one member of staff covering a key position and shortfalls in many others that include:

- Severe Accident Analysis
- Criticality Safety
- Instrumentation and Control
- PWR Operation
- Electrical Systems
- Probabilistic Safety Analysis
- Maintenance and Testing
- Civil Engineering/Mining Specialists
- Dosimetry

There is also a concern that the current resource levels are limiting important regulatory functions and for example these include:

- supervision inspections
- back-fitting modification assessment work on ageing power plant
- emergency preparedness
- licencing requests including those for radioactive waste disposal
- transport
- revision of existing and production of new regulations

The IRRS team recommends that SSM needs to complete more inspections in all areas of operation in order to meet the IAEA Safety Standards. This, taken together with the rather small competence base in some of the areas and the extensive development of the Swedish nuclear program, as described above, leads the IRRS-team to draw the conclusion that SSM's staffing is too small in number when compared to international practice in the field of nuclear regulation.

The IRRS team also suggests that SSM's resourcing levels will be further challenged with the possibility of new nuclear reactor build in Sweden. The current arrangements only allow SSM to secure additional funding and resources once a new build application is made by the developer and this will not allow SSM enough time to recruit and train the necessary staff to complete its regulatory functions in a timely way.

SSM management recognises the challenges it faces in the area of technical specialist competence and the IRRS team concludes that SSM should complete and implement its planned strategy for securing the required resources for all key positions within the regulatory programmes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 Paragraph 4.3 states that** *"Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained."*
(2)	**BASIS: GS-R-3 Paragraph 4.4 states that** *"Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives."*
(3)	**BASIS: GSR Part 3 Paragraph 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."*
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.**

SSM has developed a strong Man Technology Organization (MTO) specialist regulatory competence comprising psychologists with an in depth experience of safety.

The MTO specialists look at matters such as the working environment, safety culture, human reliability, organisational issues, leadership and management, event reporting and learning from experience and have provided training in this area to a wide range of SSM inspectors. The training equips inspection teams to assess MTO matters in their routine compliance and supervision inspections at licensee sites in order to capture important MTO safety performance information.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: IAEA GSR Part 1, Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and number of facilities and activities to be regulated to perform its functions and discharge its responsibilities."*
GP2	**Good Practice: SSM has developed a strong Man-Technology-Organisation (MTO) specialist regulatory competence and provided training in this area to a wide range of its inspectors. The training equips inspection teams to assess MTO matters in their routine compliance and supervision inspections at licensee sites in order to capture important MTO safety performance information.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

To support the authority in its work, SSM has four scientific or expert boards which can be consulted:

- The Advisory board on research assists the Authority with the horizon scanning, analysis and evaluation of its research and development activities.
- The Advisory board for Reactor Safety is to support the authority with advice and feedback prior to the Authority's decisions, and to give advice on matters related to nuclear safety.
- The Advisory board for questions about radioactive waste and spent nuclear fuel gives advice on matters relating to waste management, rules and regulations and provides advice on major decisions and opinions.
- The Council on Radiation Oncology advises on issues of radiation oncology and provides the authority with advice on questions of justification, optimization, risk assessment and risk management in medical radiotherapy.

With the exception of the Council of Radiation Oncology all the advisory boards are stipulated in the Ordinance of instructions for SSM. Although not mandatory, SSM usually requests the relevant advisory board(s) to complete a review for important regulatory decisions.

The IRRS review team met with a member of the Advisory Board for questions about radioactive waste and spent nuclear fuel. This Advisory Board is comprised of eight positions (currently 1 position is vacant) including 2 members from outside Sweden. The Chairman of this Advisory Board is from SSM. The Advisory Board agenda is proposed by SSM and meetings occur approximately twice a year but there is flexibility in convening meetings based on the need to address specific questions. The Advisory Board results are provided as recommendations to SSM (e.g., .approaches for regulations and guidance for disposal of spent nuclear fuel). The IRRS team concluded the advisory board was providing relevant support to assist SSM in its regulatory activities.

The IRRS team also met with the Reactor Safety Committee (RSN). It was noted that RSN considers that SSM is contributing to the enhancement of reactor safety and "SSM makes a difference to nuclear safety in Sweden". SSM values and gives due consideration to the advice provided by RSN. RSN commented

that SSM could be more mindful in its reports and documentation to avoid excessively elaborate scientific language and to communicate clearly with its target audiences.

In Sweden there is no Technical Support Organization, however SSM has funding for research and support to its regulatory activities and can contract laboratories and consultants for specific technical advice when needed. Specialist inputs received in this way are always reviewed by SSM staff and any associated regulatory decisions are always taken by the regulatory body.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

SSM regularly communicates at levels with its major licensees. In additional to the senior management level meetings, there are special meetings dedicated to safety management. In these meetings current nuclear safety and safety culture issues as well as possible problems in the regulator/licensee relationship are discussed in order that they can be addressed at an early stage. Furthermore, expert discussions on specific topics such as severe accidents, the SSM research program in nuclear safety and radiation protection are organised regularly by SSM for the attention of the major licensees.

The formal mechanisms of communication include consultation with the licensees in the preparation of permits and guidelines. Further the licensees are given the opportunity to comment the factual circumstances emerging during an inspection or review. In this way SSM tries to maintain transparency towards authorized parties which give them the opportunity to respond if they believe certain facts are wrong. If the comments are relevant SSM makes an adjustment. SSM is the sole responsible for assessing the facts.

Relations between SSM and the operators seem to be open and frank; they apparently work together in a professional and respectful way. Nevertheless, since the former SKI and SSI were merged, SSM emphasises on a clear definition of the role of each party. In accordance with its corporate key values "Openness" and "Integrity" SSM increased the information of the public and reduced its responsiveness with regard to industry requests.

With respect to the operational business of interested parties there is feedback from operators including licensees that SSM does not always have sufficient resources to complete the required regulatory activities in a timely way. SSM should consider in its future resourcing requests and management processes the operational perspective of the site licensees, including on-going periodic safety review/improvement programmes/power upgrading projects and possible applications for new reactor build, while at the same time ensuring that safety is not compromised.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 paragraph 3.6 states that** *"The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties while at the same time ensuring that safety is not compromised."*
(2)	**BASIS: GS-R-3 paragraph 3.6 states that** *"Stakeholder means an interested party – with an interest or concern in ensuring the success of an organisation, business system etc."*
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.**

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

In general terms, SSM assures that regulatory control is both stable and consistent. The core processes to assure this are Authorization, Review and Assessment and Supervision. These processes are described in various documents that state the methods and processes to be followed. The results of this leads to regulatory decisions designed to enhance safety, and may also be used as an input to the integrated safety assessment.

To assure consistency, SSM may meet with industry representatives and other interested parties as a part of the regulatory development process. Seminars may be held to inform and describe the regulatory body´s interpretation of a revised or new requirement. Additionally, SSM has a process for feedback after inspections or other supervision activities. The performance of SSM is evaluated by both internal and external audits and the results are reported to the Director General. Deviations from the outlined policies and procedures are addressed.

Decisions taken by SSM are structured in its archives and document management system. In the current SSM activity plan, the Department for Nuclear Power Plant Safety was assigned to develop a regulatory database which would collect SSM´s decisions, licensing conditions and findings towards nuclear facilities and in this way facilitate uniform application of current rules. When the database is operational, the ability to assure regulatory consistency will be enhanced.

Sweden's public access policy gives the public (including foreign citizens) the right to examine SSM's public documents. This transparency allows any interested party to take part in various SSM´s processes. SSM communicates its observations that are made after a regulatory activity to the licensees and the general public. Such observations are communicated through multiple channels; such as, sending letters with information on regulations, sending instructions to the licensees and holding meetings, seminars and training courses.

However, while SSM appears to be faithful to its process for regulatory development, there is a concern, supported by statements from licensees and regulatory staff, that formal and specific guidance is needed on regulatory topics, functions and activities associated with its regulatory responsibilities; and further, not all material used by SSM staff is available as an official guidance document. This could lead to inconsistent application of regulations, and a less stable, predictable and consistent regulatory approach. Such material would be useful to all licensees and interested parties and communicated to them in advance. SSM should consider providing technical guidance for review and assessment to assure consistency in the review outcome and harmonization of review processes. Examples of such material would include internal procedures and other formal guidance documentation to review and assess applications for authorization and to assure that inspections are conducted in a consistent manner. Specific details in this respect are provided in various modules.

SSM should have a strategy for completing the development and implementation of procedures and other formal guidance documentation to further clarify roles and responsibilities, define tasks associated with key operational (regulatory program) processes, develop technical criteria, and other associated information. This strategy should also include completing the designation and training of process owners, and expanding the uptake of its robust document management and retrieval system in order to provide assurance that applicable process guidance and instruction material will be developed and available to staff whenever and wherever needed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: IAEA GSR Part 1, Requirement 22 states that** *"Stability and consistency of regulatory control, states, "The regulatory body shall ensure that regulatory control is stable and consistent."*
(2)	**BASIS: GSR Part 1 Paragraph 4.27 states that** *"The regulatory body shall emphasize the continuous enhancement of safety as a general objective. However, it shall also recognize the risks associated with making modifications to well established practices."*
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.**

3.7. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

SSM has chosen the values Integrity, Reliability and Openness as key words to characterise how it conducts its day to day work:

- Integrity means that SSM staff upholds its independence and base decisions on facts.
- Reliability means that SSM's work is conducted by employees who are competent, objective and impartial.
- Openness means that SSM is transparent to the outside world: clearly and actively providing information about its activities.

The three values are communicated broadly to the SSM stakeholders with the purpose of confirming the way the authority conducts its mission. SSM believes that an open dialog based on a mutual understanding of the different roles in combination with transparency is the best way to reach mutual understanding and respect. In SSM´s decision-making process the licensee is given the opportunity to comment on the factual circumstances emerging during an inspection or review, with the same principle applying to major permit applications. In this way SSM tries to maintain transparency towards authorised parties which give them the opportunity to respond if they believe certain facts are wrong. However it was noted in our discussions that some licensees do not share the view that SSM always provides appropriate notice of an intention to publish information of interest to the company and that the industry needs to move towards greater openness and transparency. These observations demonstrate the need for an improved dialogue.

For major licensees, mainly NPP´s and other large holders of facilities SSM has developed different levels of communication on a regular basis such as senior management meetings and safety management meetings with the nuclear industry. Meetings with other industrial organisations within the nuclear sector supply chain also take place.

We noted that Communications has been made a priority in SSM with a team of 9 staff dedicated to the function dealing with both internal and external matters. A layered approach is taken to communicating key messages with staff at all levels involved in the process. A particular success has been the involvement of specialists/experts who received media training and have become accomplished at getting complex arguments across to a wide range of audiences using appropriate levels of detail and language. This was a particular success during the Fukushima event when SSM were in demand to provide an expert interpretation of the events in Japan.

In respect of moving with the times and being able to communicate with all sectors of society, SSM primarily uses the internet web as its primary communication vehicle but has experimented with the use of social media such as 'Facebook' and 'Twitter'. The experience to date suggests that such methods of communication are effective for the younger age groups in society and can be used to good effect. SSM has a communications strategy that was developed shortly after the merger of SKI and SSI in 2008 and is accepted to be in urgent need of updating.

SSM monitors how well it is communicating by the public by reviewing the press and the Internet. Meetings with different stakeholders on nuclear safety and radiation protection related topics also enable SSM to collect opinions. SSM also carries out surveys, which are becoming more routine, to determine how the regulatory authority is perceived by the public. It was noted that SSM has not asked the licensee community what its views are on its communication effectiveness and this is something that could be considered to help identify areas for improvement.

The team concluded that SSM's approach to communications was working well with some good practices and plans to improve the function further.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Requirement 36 states that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."*
(2)	**BASIS: IAEA GSR Part 1 Paragraph 4.67 states that** *"The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities."*
GP3	**Good Practice: The Communications function in SSM was working well with evidence of some good practices and plans to further improve the area. In particular the training and briefing of specialists/experts to communicate complex regulatory and technical arguments on Television and Radio proved to be very effective. The use of social media to target specific groups in society and inform the public on some key health and safety information is working well and should be considered for deployment across a wider range of SSM's regulatory business.**

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

Introduction

The IAEA safety requirements publication GS-R-3 entitled *The Management System for Facilities and Activities* defines the requirements for establishing, implementing, assessing and continually improving management systems designed to integrate safety, health, environmental, security, quality and economic aspects. By following the integrated approach defined in GS-R-3 the organization has assurance that safety is properly taken into account in all activities in the protection of people and the environment. The requirements of GS-R-3 are applicable to management systems for nuclear facilities and activities and the regulation thereof. GS-R-3 is consistent with the on-going evolution and advancement of the family of ISO international standards and builds upon experiences of Member States.

Background

The overriding safety objective of the Swedish Radiation Safety Authority (SSM) is to "strive to prevent and to protect man and the environment from harmful effects of radiation, in present time and in the future." As part of a planned transition to a new organization, previous management systems developed by SKI and SSI have been consolidated into a single integrated management system consistent with GS-R-3 safety requirements. The focus to date has been on the creation of a SSM-specific culture and identity which includes developing and strengthening the underlying infrastructure for its management system.

Noteworthy elements of the SSM management system

Management system infrastructure

The application of the management system is evident through four integrated components which collectively provide valuable capabilities and information to assist in day-to-day management of the organization – i) a planning tool (Sinus) for regulatory and improvement activities which includes operating resource requirements and enables follow-up and reporting; ii) a process model illustrating the SSM suite of steering, strategy, procedure and other guidance documentation, iii) a document and record management system (SSM360) for storing, retrieving and archiving documents and records; and iv) a finance and resourcing system (Agresso) for assigning, tracking and reporting resources (funds and time). While Sinus and Agresso share the same IT structure, further work remains in improving the integration of all component systems in terms of content/information shared and the manner in which it is shared.

Engagement of Senior Management and Staff

Management engagement and strong staff involvement are critical elements for the successful development, implementation, and improvement of a management system. SSM management commitment is outlined in the key strategy document - "*Management of the Swedish Radiation Safety Authority" STYR2011-71.* Management's decision to obtain certification in ISO international standards is a testament to its commitment to lead by example – demonstrating to staff, industry and other stakeholders that SSM itself is open to review and certification. Senior Management works collaboratively with staff to develop, implement, improve and communicate the management system. Elements of management reviews are completed throughout the year as part of on-going management discussions. Collectively these reviews verify that the management system remains effective and suitable for the organization although SSM remains challenged in being able to fully demonstrate its effectiveness. Discussions and decisions concerning the management system are documented, shared with staff and posted to the intranet. Three senior positions in the DG Staff are assigned full time to improving overall organizational development, including the management system.

Senior Management is actively involved in determining priorities for all improvements. Managers at all levels communicate important discussions, information, and decisions that are of common interest to staff. Senior Management works closely with the communications representatives. Regulatory decisions made by the Director General are published on the external web-site.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 Paragraph 2.3 states that** *"The management system shall identify and integrate with the requirements contained within this publication:* - *Any requirements formally agreed with interested parties (also known as 'stakeholders');* - *Requirements from other relevant codes and standards adopted for use by the organization."*
GP4	**Good Practice: SSM's decision to lead by example and demonstrate that it too is open to review and certification in choosing to certify against recognized international and national standards, including ISO 9001 (quality), ISO 14001 (environment), ISO 17025 (laboratory) and AFS 2001:1 (Systematic Work Environment Management).**

Work Environment

Swedish legislation requires employers to provide a safe and satisfactory work environment. SSM decided to certify to the national AFS 2001:1 standard. Management and staff work together to restrict workplace hazards, prevent accidents, and protect the physical and mental health of employees. Workplace assessments are conducted regularly by each section and comprise all physical, psychological and social conditions of importance. The work environment is also an element within scheduled self-assessments (every four (4) months). Identified risks are documented in an action plan, assigned responsibility, monitored and reported. Annual safety inspections are conducted in the laboratories.

Process Management and Document Management / Control

SSM merged the management systems of the predecessor SKI and SSI as part of developing a SSM-specific culture and identity. SSM recognizes the importance of documenting management decisions and direction and capturing and retaining resident knowledge to strengthen its regulatory program today and into the future. Significant progress has been made in developing steering documents which cover a range of strategy, policy, process, and procedure level guidance. The two core processes of "Supervision" and "Assess Applications/Authorization" receive focused attention for clarifying roles, responsibilities, accountabilities and associated tasks and for identifying competency requirements and associated training. An interactive process model highlighting the sequence and interaction of all key processes has been developed, validated and posted to the internal website. Component sub-process information and associated guidance material can be readily accessed by way of the process model, dedicated intranet pages and a robust document management system.

Responsibility for the overall development and improvement of the management system rests with the DG staff while managers are responsible at the process level. SSM is challenged in getting all managers to fulfil their responsibility with respect to overseeing the implementation, evaluation and control of processes within their respective area(s) of responsibility. While an interim process manager has been assigned for the Supervisory process and work is proceeding well, the absence of assigned process ownership for the remaining key processes puts SSM at risk of being able to close remaining gaps (in guidance documentation, competencies and training, and understanding of process/procedure effectiveness) in a timely manner.

The *Rules of Procedure for the Swedish Radiation Safety Authority* regulates the governance and organizational structure of SSM and also sets the decision-making procedures. This document is considered the top document in the document hierarchy. The comprehensive set of steering documents describes how SSM fulfils its mandate and associated safety objectives and goals across its defined areas of operation.

SSM recently implemented a robust document storage and retrieval system and documented an accompanying process on how internal documents and records are to be produced, updated, approved, published, filed and destroyed. Official documents are managed in accordance with Swedish National Archive regulations and the Public Access to Information and Secrecy Act. All registered documents include required metadata elements (document number, regulatory activity area, process, sub-process, etc.) in order to facilitate storage and retrieval and to provide assurance that users can retrieve the appropriate documents as required at point of use. Managers are delegated responsibility for ensuring approved procedures are followed and that the documentation adheres to format requirements. Internal audits have been used as a means to verify consistency in application.

Uptake in usage of the document management system continues to grow throughout the organization. However, procedures for document management are not always adhered to. As a consequence, access to guidance documents previous decisions and other background material may be limited or in fact restricted. This introduces risk into the regulatory program should staff not be aware of or not be able to access applicable decisions, direction or guidance whenever and/or wherever needed. Furthermore, useful management information for formulating and/or revising its regulatory program may not fully leveraged.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 Paragraph 2.8 states that "***The documentation of the management system shall include the following: …* - *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;* - *A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved."*
(2)	**BASIS: GS-R-3 Paragraph 2.10 states that** *"The documentation of the management system shall reflect:* - *The characteristics of the organization and its activities;* - *The complexities of processes and their interactions."*
GP5	**Good Practice: SSM has taken a creative approach in how it chose to increase awareness of its key processes, reinforce their relative placement and interconnectedness, and provide a direct and simple means to access required guidance documents – SSM has developed, validated and posted an interactive process model to its intranet. This interactive tool represents one of many ways for staff to quickly gain access to the appropriate guidance documents and information for key processes.**
(1)	**BASIS: GS-R-3 Paragraph 2.8 states that** *"The documentation of the management system shall include the following: …* - *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;* - *A description of the processes and supporting information that explain how work is*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	to be prepared, reviewed, carried out, recorded, assessed and improved."
(2)	**BASIS: GS-R-3 Paragraph 2.9 states that** *"The documentation of the management system shall be developed to be understandable to those who use it. Documents shall be readable, readily identifiable and available at the point of use."*
(3)	**BASIS: GS-R-3 Paragraph 2.10 states that** *"The documentation of the management system shall reflect:* - *The characteristics of the organization and its activities;* - *The complexities of processes and their interactions."*
(4)	**BASIS: GS-R-3 Paragraph 5.21 states that** *"Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable."*
(5)	**BASIS: GS-R-3 Paragraph 5.22 states that** *"Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organization. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record."*
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.**

Measurement, Assessment and Improvement

Although SSM deploys a comprehensive and structured approach for identifying and applying the suite of applicable corporate objectives, goals, performance indicators/measures and targets, SSM is challenged in demonstrating the effectiveness and efficiency of the management system and of its component processes.

Outcome objectives are assigned by the DG and other levels of management in relation to planned impact on nuclear safety, radiation protection and the environment. The objectives, goals and associated planned activities are entered into the planning tool (Sinus). Progress is reported and discussed throughout the year and summarized in the Authority's annual report. Sinus provides powerful search, tracking and reporting capabilities to aid management in developing and adjusting planned regulatory programs/activities. Performance against plan in terms of activities completed (or not) and effort expended to date is discussed at senior management meetings every four (4) months on a scheduled basis and on an ad hoc basis as needed.

The Swedish National Audit Office annual audits often include an assessment of the effectiveness of the SSM management system. Other national authorities audit/review SSM as appropriate. External audits are conducted for ISO and AFS 2001:1 recertification. Internal audits leverage the availability of trained internal staff (on loan to DG Staff). The entire management system is reviewed over a three (3) year period.

Managers are delegated responsibility for the self-assessment and improvement of their own area. Self-assessments are conducted three (3) times per year and provide input into scheduled discussions with the Director General. Opportunities for improvement are identified and added to the departments' operation plan for action and follow-up. Staff feedback is valued by management. Staff surveys conducted at the time of the creation of the Authority informed management direction during the merger. In 2010, a comprehensive staff survey was conducted covering leadership, diversity, satisfaction, etc. Employees were briefed prior to the survey and staff participation was a commendable 80%. The structure of the survey allowed for inter-authority comparisons and SSM scored very well. Upon receipt of the findings, the DG held an all-staff informal 'chat' to present the aggregate results, planned management actions, and expectations going forward. Formal action plans were developed at all levels of the organization and progress tracked in the planning tool. SSM is currently piloting a more dynamic and individual-oriented survey tool called "Health Watch". The new survey was positioned relative to previous surveys and actions that remained outstanding. Almost one-third of the employees are involved in the pilot. An initial baseline comprehensive survey received more than 85% participation. The on-going (much shorter) survey takes less than a minute to complete and is completed at least bi-weekly (some complete it daily). Feedback to the employee is immediate. Aggregate results are made available to management bi-weekly for appropriate action. The survey tool has recently been evaluated and given a good result. It has been decided that all employees shall use this survey tool.

Non-conformances identified during daily activities and/or audits and reviews are documented and entered into Sinus for monitoring and follow-up. The responsible manager oversees the completion of the appropriate action and is responsible for evaluating its outcome(s). Major non-conformances can result in a formal DG assignment. SSM plans to introduce its risk management model into the forthcoming 2012 planning exercise as a means to reduce the number of non-conformances in regulatory activities. Information about planned corrective actions is shared and posted on the internal website.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 paragraph 3.9 states that** *"Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed"*
(2)	**BASIS: GS-R-3 paragraph 3.12 states that** *"Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved."*
(3)	**BASIS: GS-R-3 paragraph 3.13 states that** *"An individual reporting directly to senior management shall have specific responsibility and authority for:* - *Coordinating the development and implementation of the management system, and its assessment and continual improvement;* - *Reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement;* - *Resolving any potential conflicts between requirements and within the processes of the management system."*
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.**

Resource Management and Knowledge Management

Senior Management assigns the necessary resources by way of the annual planning process. Resource allocation is based on identified needs and the extent of funding provided by the government. To date, sufficient resources have been made available to establish, implement, assess and continually improve the management system. Supplementary resources were made available at the time the Authority was created.

Changing demographics and the rapid pace of advancement in technology make the effective management of knowledge critical to all organizations. SSM currently deploys an unstructured approach to capture, codify, share and retain technical knowledge. The most common activity is the codification of corporate history, management decisions and direction, and guidance in the form of strategy, steering, policy, process and procedure documents. Technical staff participates in the development of competency profiles for their area of expertise. To date, competency profiles for the positions of managers, internal auditors, and inspectors have been defined. SSM encourages senior staff members to bring more junior staff with them when attending international conferences, workshops and meetings. All employees are required to write trip reports and at times provide a presentation. Technical seminars are held when appropriate interest or need is identified. SSM is also considering reintroducing a formal mentoring and 'tutoring' program and its 'Management Succession Program' where selected employees contributed a few days a month over a nine (9) month period to learn from experts from other areas of the organization. Information systems such as the document management system are leveraged to store, manage and share pertinent knowledge.

Management of Organizational Change

Swedish regulations outline employer obligations with respect to organizational change. At SSM, the Director General sets priorities for improvement and development work and takes decisions on all important organizational changes. Management works collaboratively with staff and the unions to manage organizational change. The DG regularly visits the different areas of SSM and also holds all-staff meetings. These opportunities are often used to inform staff of planned direction and to obtain staff input. Staff feedback is valued and used to inform and shape the direction of the organizational change. For changes on a larger scale, employees are informed beforehand, a risk and consequence analysis completed, and the planned path forward openly discussed with staff.

Stakeholder needs and expectations

SSM works well with its stakeholders and has a good understanding of the varying needs and expectations. Stakeholder groups such as the public, municipalities, and industry are consulted regularly during the execution of the regulatory program. The public has access to all SSM documents unless they are classified as Secret or higher. Arrangements are made for the public to obtain immediate access to the documents on-site at SSM. The SSM planning process leverages environmental scans involving many stakeholder groups. Targeted actions to address stakeholder needs and expectations do not compromise regulatory functions and SSM responsibilities for safety.

Safety Culture

As shown throughout this report, there is clear evidence that safety is a priority within the SSM regulatory approach which is built upon the core values of Integrity, Reliability, and Openness. However, the manner in which SSM addresses its safety culture within the management system is neither integrated nor comprehensive. Examples of actions to date to improve the common understanding of safety culture include scheduled self-assessments and management system reviews, the involvement of participant departments in the development of the routine for regulatory supervision, and the offering of seminars and education opportunities, including a seminar specifically on safety culture. Nevertheless, to assure that all staff give appropriate attention to safety culture in their roles and tasks, SSM should integrate safety

culture in a more comprehensive manner within the management system. This will assure a common understanding of the key aspects of safety culture across the organization, support staff in conducting regulatory tasks taking into account all possible interactions, and reinforce the importance of a learning and questioning attitude.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-3 paragraph 2.8 states** *"The management system shall be used to promote and support a strong safety culture by:* - *Ensuring a common understanding of the key aspects of safety culture within the organization;* - *Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;* - *Reinforcing a learning and questioning attitude at all levels of the organization;* - *Providing the means by which the organization continually seeks to develop and improve its safety culture."*
S4	**Suggestion: SSM should consider addressing safety culture in its management system in a more comprehensive and integrated manner.**

5. AUTHORIZATION

5.1. GENERAL

This section reviews authorizations for nuclear facilities and activities using the requirements of GSR Part 1 and the associated guides as the basis. The review focuses on those authorization aspects that are part of SSM's responsibilities.

Nuclear activities require a license under the Act on Nuclear Activities (1984:3) and in certain cases under the Environmental Code. Other activities than nuclear, in which ionizing radiation occurs, are governed by the Radiation Protection Act (1988:220).

5.2. NUCLEAR FACILITIES

In general the government decides on licensing for nuclear facilities. Other nuclear activities and activities with radiation covered by the Radiation Protection Act are subject to authorization by SSM. Some nuclear facilities also require a permit under the Environmental Code. No facilities are exempted from regulatory authorization. There are some activities, radioactive substances and devices containing a radioactive substance that are exempted from authorization requirements, according to the Ordinance on Nuclear Activities (1984:14) and Ordinance on Radiation Protection (1988:293).

The applications notified to SSM are reviewed and assessed based on regulations formulated by SSM and according to the processes described in the following documents:

a) Internal system document "Review" (STYR2011-124).
b) Internal system document "Licensing work and examination of licence conditions as regards nuclear facilities and other complex installations where radiation is used" (STYR2011-131).
c) Internal system document "Licensing work and examination of licence conditions as regards power up-rates of nuclear power plants" (STYR2011-154).

The licensing process differs depending on whether it is larger facilities or less complex activities that are to be assessed. Larger facilities are associated with more complex systems and greater radiological risks, while for less complex activities it is the opposite. These differences are reflected in the demands made on applicants for both the licensing process and license.

Applications for new nuclear power plants, other nuclear facilities and major modifications of operating plants, such as power up-rates, must be examined both under the Act on Nuclear Activities and the Environmental Code. According to the application procedure, an application for a permit is submitted to SSM, which prepares the case under the Act on Nuclear Activities, and to the Land and Environment Court, which prepares the case under the Environmental Code. An application for a license to construct, possess or operate a nuclear installation contains an Environmental Impact Assessment (EIA), an initial preliminary safety analysis report (PSAR) along with technical and other statements of the proposed plant and its operation. SSM assesses whether the plant is likely to be located, designed and operated in such a way that the safety and radiation protection requirements and the requirements for security and safeguards are met.

The court prepares the case in accordance with the provisions of Chapter 22 in the Environmental Code. The basis is General rules of consideration under Chapter 2, Environmental Code, the submitted EIA, drawings and technical descriptions of site conditions, production volume or other similar data and the use of raw materials, other inputs and topics like energy use.

Both SSM and the Land and Environment Court give their opinions to the Government, who decides on permissibility according to Chapter 17 of the Environmental Code, and for a decision for a permit under the Act on Nuclear Activities (design, construction, commissioning and operation).

The authorization by the Government includes the following licensing conditions to allow continued stepwise examination until the proposed plant can be put into routine operation:

- The licensee may not begin construction of the nuclear power plant without SSM approval,
- the nuclear power plant may not be taken into commissioning phase including trial operation without being approved by SSM, and
- the nuclear power plant may not be taken into routine operation without being approved by SSM.

The team observed that the legal and regulatory framework does not categorically establish responsibility for institutional control and for the termination of the licence. The legal and regulatory infrastructure on authorization process include provisions for formal public participation during the preparation of the factual basis for the governmental license decisions and decisions of environmental court but not in subsequent authorization stages.

The content of information for safety analysis reports of nuclear facilities is briefly described in Appendix 2 of SSM regulations, SSMFS 2008:1. The contents are suitable for nuclear reactors and are applied to other nuclear fuel cycle facilities with some changes as discussed and agreed upon between SSM and the applicant. However, the regulations do not provide specific guidance on the format of safety analysis report.

The authorization of nuclear power plants issued by the Government includes generic licence conditions setting e.g. the maximum thermal output. For other nuclear facilities the license conditions vary.

SSM regulation SSMFS 2008:32 contains provisions concerning the competence of operations personnel at nuclear reactors and perform inspections to verify that the provisions are met by licensees in authorizing their operators. SSM does not itself grant authorizations to operating personnel of nuclear reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 23 states that** *"Authorization by the regulatory body shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."*
R8	**Recommendation: The government should establish responsibility for institutional control and for procedures for the termination of the license.**
(1)	**BASIS: SSG 12 Paragraph 2.42 states that** *"The public should be given an opportunity to present their views during certain steps of the licensing process, where appropriate."*
S5	**Suggestion: SSM may consider including public participation in a formal way in all stages of its licensing and authorization process.**

5.3. INDUSTRIAL, MEDICAL AND RESEARCH RADIATION FACILITIES

Legal and organizational aspects

According to Section 20 of the Radiation Protection Act (1988:220) all facilities and activities with radiation sources shall be authorized unless otherwise exempted. Exemptions are prescribed in Section 2 of the Radiation Safety Ordinance (2008:45). Authorization is by licensing only.

Regulations specify the requirements for obtaining a license for certain practices. These include:

- SSMFS: 2008:9 dealing with the Control of High-Activity Sealed Radioactive sources, and
- SSMFS: 2008:10 dealing with import and export, as well as, reporting of radioactive substances.

Section 26 of the Radiation Protection Act authorizes SSM to issue conditions to the license. SSM has in use practice specific sets of standard license conditions which are attached to the license.

Different departments and sections of SSM issue authorizations for the use of radiation sources and for the import or export of radioactive sources. Industrial and research facilities are authorized by the Occupational Practices and Work Activities Section; medical facilities are authorized by the Medical Exposures Section; and radiation sources in nuclear facilities are authorized by the Radiation Protection Section. In addition, Control and Protection Section authorize the import and export of Category I and II sources, as prescribed in the Regulation SSMFS: 2008:9.

In some cases there is no internal guidance which would clearly define the authorization regimes regarding specific activities or types of licensees.

Section 42 of the Radiation Protection Act provides a mechanism by which regulatory decisions could be appealed to an administrative court.

Authorization of use of radiation sources

In case of industrial or research applications, usually one license is issued covering all different practices, facilities and sources of one company. Whenever new sources are acquired or transferred from the licensee, SSM has to be notified and the license amended accordingly.

Public medical institutions are licensed at a county level, but separately for different types of practices, namely diagnostic radiology, nuclear medicine and radiotherapy, and irrespective of the number of facilities and sources within one county. Every county has a radiation protection organization which covers all the public medical facilities and activities within the county. The counties provide once a year a report regarding their practices to SSM, which also includes the source inventory. SSM shall be notified separately only when introducing a new or modifying and existing treatment room for radio-therapy.

The way by which private medical facilities are licensed is based on their size. In case of "a small company", a facility is licensed separately and they shall notify SSM of each source transaction separately. In case of "a large company" having many facilities, only one license is issued which covers all medical facilities it operates in Sweden. In this case, no notifications on each source transaction are required but a yearly report of their practices which includes the source inventory. There is no guidance or procedures in place which would define what a small or large facility is.

Dentists who use intra-oral x-ray devices do not need an individual license. Where any other types of dental x-ray machines are used, such as a panoramic device, a license shall be applied.

Application forms for a license and corresponding instructions are available on the SSM website. However, there is no guidance on the level of detail of information, for example of practical radiation safety arrangements in place, of what is to be submitted when applying for an authorization, except references to the existing regulations.

A license is usually issued for a fixed period of 5 years. Most licenses with unlimited duration have been issued before SSM was established in 2008. If there is a significant change in the practice, the license will be amended accordingly. However, there is no formal process for amending or renewing a license.

Import and export of radioactive sources

A separate license identifying each individual source is required for import or export of Category I and II sources, as defined by Regulation 2008:10. The Category I in the regulation corresponds to the Category I in the IAEA Safety Guide RS-G-1.9 on the Categorization of Radioactive Sources. However, Category II in the regulation covers HASS-sources, as proscribed in Council Directive 2003/122/Euratom, and thus covers all RS-G-1.9 Category II sources but also some others.

SSM seems to follow, in practice, the IAEA Guidance on the Import and Export of Radioactive Sources. However, there is no requirement either in the regulations or in SSM internal guidance which would prescribe that the IAEA guidance must be followed. In the case of source transfer within the EU, provisions of the Council Regulation 1493/93/Euratom are followed.

A general import license is required for import of any other radioactive sealed sources than Category I or II sources. Most of the facilities having a license for the use of radioactive sources have also a general license to import sources. The Team also noticed that in some cases general import authorizations were granted together with the authorization for use, even where the applicant has not applied for a general import authorization.

Register of licenses and sources

SSM maintains a register of licensees and the sources they hold. The main source of information for the source registry is license applications (new users of sources) or notifications received from licensees (sources have been acquired or transferred to someone else).

In case of Category 1 and 2 sources, source identifiers are included (source ID given by SSM and serial number given by the manufacturer). For all other sources only the radionuclide and activity is stored, as well as, some general information of the device in which the source is placed. If a source capsule is changed, no notification needs to be made to SSM provided that the new source has the same radionuclide and nominal activity as the original one. No information is entered to the register about sources with activity less than 500 MBq.

Licensees importing radioactive sources shall report to SSM names and license numbers of entities to whom they have delivered sources, as well as, the total number of sources and the sum activity of sources delivered. There is no procedure in place to cross-check this source delivery data with the notifications received from licensees taking the corresponding sources in use.

A backup copy of the register is taken automatically on a daily bases. However, there are no clearly defined procedures on who updates the database and when.

Orphan Sources

If an orphan source is discovered in a condition deemed unsafe, it would be considered as an emergency situation and first responders will ensure immediate safety of the source. SSM would provide the necessary expert advice in radiation safety matters. However there is currently no strategy and system for gaining control of orphan sources.

Information on sources that could have potential trans-boundary effects is shared with the relevant state bilaterally and information would be provided to the different international systems including through the IAEA illicit trafficking database (ITDB). There is an initiative to issue regulatory requirements on practical monitoring arrangements by customs at boarders.

SSM has provided training and exercises in radiation safety to specific members of customs personnel, police and fire brigade occasionally for several years.

In the text above, there are some observations with regard to establishing and implementing written guidance and internal procedures. Recommendation in this regard is provided in Part 3.6 of this report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: Code of Conduct on the Safety and Security of Radioactive Sources paragraph 8 (c, d) states that** *"Every State should have in place an effective national legislative and regulatory system of control over the management and protection of radioactive sources. Such a system should:* *(c); include national strategies for gaining or regaining control over orphan sources (d);provide for rapid response for the purpose of regaining control over orphan sources…"*
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.**
(1)	**BASIS: Code of Conduct Paragraph 8(b) states that** *"Every State should have in place an effective national legislative and regulatory system of control over the management and protection of radioactive sources. Such a system should minimize the likelihood of a loss of control."*
S6	**Suggestion: SSM should consider cross-checking information from suppliers of radioactive source transfers to individual licensees against the information received from the licensees.**

6. REVIEW AND ASSESSMENT

6.1. GENERAL

SSM performs review and assessment of licensing submissions, modifications, periodic safety review reports, reports submitted by licensees during regulatory supervision activities and the documents submitted by the licensees as a result of particular requirements imposed by the Government or the Authority. The review work is governed by acts, ordinances, SSM's regulations and internal documents. The aim of review is to verify whether the legal and regulatory requirements are fulfilled.
The results of SSM's reviews and assessments are documented in review reports. These reports shall include clear information on what has been reviewed, by whom and in what respects, the results of reviews and clear assessment whether relevant requirements are met.

6.2. NUCLEAR FACILITIES

Regulations concerning safety of nuclear facilities (SSMFS 2008:01) establish requirements for SSM review of licensee's documents. Application of the graded approach is not clearly defined in the regulations and internal documents issued by SSM. The information provided in the regulations is equally applicable for all nuclear facilities without any categorization or exemptions. During discussion SSM explained that they apply graded approach during their supervision activities such as to the level of details required for various types of nuclear facilities. The desire for a graded approach is also identified by the industry during their meeting with IRRS team.

SSM has identified seventeen areas for regulatory supervision (inspections as well as review and assessments) which in the opinion of IRRS team can be a good instrument to apply in a graded manner to various installations and activities depending on the risks associated.

The review and assessment process of SSM is mainly based on administrative guidance provided in the regulations and internal documents, however, technical guidance such as those that may lead to providing the basis for acceptance of the documents are not addressed in these documents. As a result the quality of review is mainly dependent on the expertise of individual reviewer whereas consistency in review outcome and harmonization in review process is difficult to ascertain.

SSM review and assessment during licensing comprises four stages. Stage 1 focuses on review and evaluation of basic design criteria presented in the Preliminary Safety Analysis Report (PSAR) for the facility to verify that all applicable SSM requirements have been identified, interpreted and translated into design requirements. In stage 2 of the review, an evaluation of applicant's organizational, human and administrative capacity is performed. This stage also includes the examination of documents describing security measures during construction phase and preliminary plans for the future decommissioning of the plant. Review at stage 3 comprises an evaluation of renewed safety analysis report (SAR) reflecting the as built or modified plant. During this stage SSM also reviews and assesses proposed operational conditions in technical specifications, test program, security measures, operator's training program and instructions providing guidance for operational staff. In stage 4 of the review, the SAR, operational conditions in technical specifications and instructions that have been supplemented with experience from the test operation is evaluated.

During plant operation phase, SSM conducts periodic safety review every ten years to determine that the plant meets the new safety requirements and practices. In addition, SSM also performs annual integrated safety assessment by combining the outcome of regulatory supervision activities. Continuous improvement process is well established in the regulations for periodic safety reviews and is applied during the review. In other review processes of SSM, e.g. the annual integrated safety assessment, the

process of continuous improvement is not explicitly specified in the regulations but is applied during the assessment.

The regulations require that all technical and organizational modifications to a facility, which can affect the conditions specified in the safety report as well as principal modifications in the safety report, shall be reviewed by the licensee. The licensee safety review in accordance with the provisions of the regulations in SSMFS 2008:1 shall be performed in order to verify that applicable safety aspects have been taken into account and that applicable safety requirements with respect to the design, performance and organization of the facility are met. Before modifications may be implemented, SSM shall be notified of the modifications.

SSM has established a standing group of experts (Notification Processing Group, ABG, (STYR2011-111) that meets once every week to make a first assessment and screening of all notifications. The group makes one of the following proposals to the department management meeting (Dep. of Nuclear Power Plant Safety and Radioactive Materials) regarding each notification:

- No further action is needed by SSM
- Require the applicant to postpone the implementation of the modification until the notification meets the expected quality
- SSM should review the notification in specified aspects
- The proposed modification shall not be allowed until SSM has reviewed the documentation further.

For this first assessment, a set of criteria has been developed on the safety significance of the notification, other relevant circumstances, and the degree of confidence SSM has in the independent safety review process of the licensee. For instance, if a notification has to do with new or complex technology, is of high safety significance or if confidence is low, there is a high probability that a notification will be reviewed further. The department head makes the final decision whether to review or not.

It is the opinion of IRRS team that the regulations issued by SSM do not establish clear technical and safety relevant requirements for regulatory approval of modifications. A recommendation in this regard is given under module 9 of this report.

In 2004 there was a major revision of the nuclear safety regulations when SKI issued set of goal based regulations for operating nuclear reactors. The revision included refurbishment requirements to be carried out until the end of 2012. In 2006 SKI reviewed refurbishment programs proposed by the nuclear power licensees. The programs contained safety improvement measures consisting of:

- improvement of physical and functional separation of safety control systems,
- diversification of safety functions,
- extra accident management measures, and
- withstanding local dynamic effects from pipe ruptures and external events (e.g. earth quakes).

The costs of the safety measures added up to 3 – 5 billion SEK per unit.

The program is on-going. It is expected that the plants will fully comply with regulation SSMFS 2008:17 by the end of year 2015.

It is the opinion of the IRRS-team that this refurbishment program brings the NPP’s in Sweden to a high international safety level. Therefore the team regards the refurbishment program as a good practice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Paragraph 4.43 states that** *"The regulatory body shall assess all radiation risks associated with normal operation, anticipated operational occurrences and accident conditions, prior to operation of the facility or conduct of the activity, and* ***periodically*** *throughout the lifetime of the facility or the duration of the activity, to determine whether radiation risks are as low as reasonably achievable."*
GP6	**Good Practice: The NPPs refurbishment program as required by SSM is a good practice.**

6.3. INDUSTRIAL, MEDICAL AND RESEARCH RADIATION FACILITIES

Forms for application for a license and corresponding filling instructions are available on the SSM website. However, there is no guidance on the level of detail of information, for example of practical radiation safety arrangements in place, of what is to be submitted when applying for an authorization.

There exist some written procedures (routine document) for reviewing and assessing applications for authorizations; however, there is no common written procedure as to ensure that the review and assessment of the application would be done in the different sections issuing authorizations in a coherent manner.

In most cases, licenses are renewed without any actual review or assessment if the licensee indicates that there is no change in the practice.

Industrial and research radiation facilities

The review and assessment is in most cases limited to checking that information requested in the forms is filled in. These include essentially information on the applicant and the sources to be employed. SSM assumes that licensees follow the requirements given in the regulations and license conditions.

In addition, as most industrial facilities are never inspected (see par. 7.1 below), there are currently no mechanisms in place to verify whether an individual licensee complies with regulatory requirements and conditions of the license.

Medical facilities

In case of public health care units, the licensee can take into operation any new radiation device or radioactive sources without any notification to SSM and thus without any review and assessment by SSM. The licensee shall prepare an annual report of its activities to SSM by the end of March the following year. However, there are no written procedures in place how the annual report shall be reviewed and assessed.

In case where a new nuclear medicine or radiotherapy department is to be established, SSM shall be notified in advance and it will review and assess radiation safety features of the facility in advance such as the placement within a building, shielding of the room and safety systems in place.

In the text above, there are some observations with regard to establishing and implementing written internal procedures. Recommendation in this regard is provided in Section 3.6 of this report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 25 states that** *"The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization."*
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.**

7. INSPECTION

7.1. GENERAL

In Sweden, the Act on Nuclear Activities (1984:3) and the Radiation Protection Act (1988:220) stipulate that the Government or the public authority may issue regulations concerning measures necessary in order to prevent the effects in all the malfunction of equipment, improper handling, sabotage or other circumstances that could result in a radiological accident.

Section 16 of the Nuclear Activity Act states that supervision of compliance with this act and with conditions and regulations that have been issued under the act, together with monitoring and control of disposal, are exercised by the public authority appointed by the Government. SSM's document, STYR2011-71, "Management of the Swedish Radiation Safety Authority" describes its mandate for supervision to verify that radiation safety is being maintained and improved by parties carrying out an activity. SSM carries out this task by imposing requirements, monitoring compliance with requirements, promoting radiation safety and taking actions when deficiencies are discovered. The "Supervisory Policy", STYR2011-97, prescribes the responsibility and the basic principles for supervision. SSM is responsible for the inspection of the nuclear power plants and other nuclear facilities and carries out three different types of inspections: compliance inspections, surveillance inspections and rapid investigations.

It is clearly stated in the Nuclear Activities Act (1984:3) and in the Radiation Protection Act that the inspection activity of SSM does not diminish the full and unshared responsibility of the licensee.

In addition to the three types of inspections mentioned above, SSM has the mandate to perform unannounced inspections in all types of supervisory areas. In practice, however, this is only done in the field of non-proliferation.

SSM has 10 human factors experts who have responsibility and conduct supervision in areas such as management, organization, management systems, working conditions, competence, skills and staffing, suitability, safety, management of safety, MTO perspective on plant modifications and control rooms, etc. The authority is trained by the MTO section so that all employees can see and recognize indications of a lack of safety culture. This is collected continuously and systematically in any enforcement action made at nuclear power plants in reviews and in all types of inspections. In that way, the authority has the possibility to follow the progress of the licensees and detect at an early stage any plant showing signs of lacking safety culture.

SSM-inspectors stressed that they are convinced that inspection from the MTO-perspective contributes essentially to their supervision on the nuclear facilities. The IRRS team is positively intrigued by this SSM-approach and announced that this issue deserves an IRRS follow-up.

Compliance inspection at nuclear power plants usually carried out by technical and human factors experts in teams in order to get an integrated evaluation of technical issues, management system and organizations aspects that also provide SSM with a good view of the safety culture at the facility.

The IRRS team considered that the number of inspections in transport, industrial, medical and research facilities is low. For example, the inspection plan for industrial facilities in 2012 comprises 21 inspections from about 1500 registered licensees/facilities. SSM doesn't inspect industrial, medical and research facilities and practices involving significant radiation risks during the authorization phase. Most industrial facilities are never inspected. For transport, compliance inspections are carried out by SSM. The overall process is well documented and thorough using check lists that ensure the appropriate weight is given to the correct regulatory requirements. Intervention reports are produced that record the main outcomes of the inspection. The numbers of inspections completed are low (6-8 per year). SSM is aware of this issue and are trying to introduce more inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part Requirement 27 states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."*
(2)	**BASIS: GSR Part 1 Requirement 28 states that** *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
R11	**Recommendation: SSM should carry out more inspections in the areas of transport, industrial, medical and research radiation facilities.**

The Act on Nuclear Activities and the Radiation Protection Act authorize SSM to have the unlimited access to the facilities and documents during the inspection. SSM inspectors often carry out inspections without accompanying licensee. But, unannounced inspections in Sweden are not carried out enough which is in contradiction to the GSR part 1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Sec. 4, Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
R12	**Recommendation: SSM should carry out more unannounced inspections in all facilities.**

The inspection plans are prepared on an annual basis by reflecting previous inspection results and operating experiences. The available experts among relevant departments in SSM are assigned as inspectors and inspections are carried out mainly by reviewing the licensee's management, procedures and by interviewing the licensee's staff at the facilities. SSM's inspections are mostly concentrated on assessing the quality assurance system and interviews but not very much by checking and observing the operations directly on the site, which can lead to a lack of assessing the licensee's capability to maintain a high level of safety. Checking the operations directly on the site can be done by sampling.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 29 Paragraph 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* - *Structures, systems, components and materials important to safety;* - *Management systems;* - *Operational activities and procedures;* - *Records of operational activities and results of monitoring;* - *Liaison with contractors and other service providers;* - *Competence of staff;* - *Safety culture;* - *Liaison with the relevant organization for joint inspections, where necessary..."*
(2)	**BASIS**: **GS-G-1.5 Paragraph 3.63 (d) states that** *"...tests and measurements carried out by the regulatory body should serve as an independent verification of those tests and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	measurements performed by the operator."
R13	**Recommendation: SSM's regulatory inspection should incorporate monitoring, measuring and direct observation of the on-site operations.**

The inspection program for the fuel cycle and waste management facilities, industrial, medical and research radiation facilities and also the transport area is prepared on an annual basis. SSM has not yet implemented systematic risk-based inspection programs and therefore a graded approach is not utilized. Implementation of inspection programs with the systematic graded approach is required to be established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Requirement 29 states that "***Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1, Paragraph 4.50 states that** *"In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
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.**

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

7.2.1 GENERAL

NUCLEAR POWER PLANTS

Ten power reactors are in operation in Sweden : three PWRs and one BWR at Ringhals, three BWRs at Oskarshamn and three BWRs at Forsmark. The IRRS team reviewed SSM's inspection activities for these NPPs with relevant IAEA safety standards and guides.

In SSM, experts from Nuclear Power Plant Safety Department, Radioactive Material Department and Radiation Protection Department carry out inspections. Around 40 experts participated in 22~31 compliance inspections and 81~100 surveillance inspections and 0~1 rapid investigations per year for ten operating reactors during the last three years. SSM covers seventeen different inspection areas which include, inter alia, design and construction of facility, management, competence and staffing of licensee, operation, and maintenance.

Inspections are usually carried out by technicians and human factor experts together in order to improve the efficiency of the inspection and to have a very good view of the safety culture in the organization of the facility.

There are two accredited third party inspection organizations which also carry out inspections for the integrity of some structural and stress-bearing components. These third party organizations make commercial contract and communicate directly with the NPP licensee. It is required to clearly define the

legal position and the role of the "Third Party Inspection Organization" carrying out activities related to nuclear safety and radiation protection. [Detailed information can be found in section 1.2]

FUEL CYCLE AND WASTE MANAGEMENT FACILITIES

The fuel cycle facility under the scope of the IRRS review is the "Westinghouse Sweden AB" fuel factory. This facility uses UF6 to produce fuel pellets, fuel rods and fuel assemblies. In the year 2011, five compliance inspections and twelve surveillance inspections were carried out.

The waste management facilities for treatment, storage and disposal include: Studsvik nuclear AB (waste treatment, material testing), AB SVAFO (waste treatment, decommissioning, interim storage), BKAB (Barsebäck NPP under decommissioning), Clab SKB (spent fuel interim storage) and burial facilities. In the year 2011, 9 compliance inspections and 38 surveillance inspections were carried out for these facilities.

7.2.2 SITE VISITS

The IRRS team visited Forsmark nuclear power plant and attended inspection meetings on the competence of the operators in Forsmark Unit 3. The IRRS team observed the exit meeting and the interview of the Unit 1 and 2 manager. The inspection was conducted in Swedish but the IRRS team had a good translation by a SSM member. This inspection lasted for five days. The SSM team was composed of 2 inspectors (the site inspector and a human factor expert) who had well prepared this inspection with a large list of questions. During the exit meeting, the SSM inspectors presented the results of the inspection to all the staff of the licensee involved in the inspection. The licensee and the inspectors discussed the findings of the inspection. The IRRS team observed that SSM and the licensee exchanged their opinions freely and good communication was maintained. The IRRS team interviewed the head of the safety and environment department of Forsmark NPP, without the presence of SSM. The licensee confirmed the good level of communication with SSM.

The IRRS team visited the Clab facility for storage of spent fuel and HLW. The subject of the inspection was related to human factors and SKB´s increased responsibilities for the operation of Clab. The inspection team was composed by an inspector and three other technical support staff from SSM. The inspection was previously announced to the operator, as interviews with the personnel were planned. The IRRS review team attended the interviews, assisted by a member staff from SSM as the interviews were conducted in Swedish. The inspectors were well prepared with a comprehensive check list of questions and aspects to confirm with the personnel. The interviews were performed in a professional manner that exhibited good listening skills that resulted in good communication environment for obtaining useful information from the site personnel.

The IRRS team observed SSM's compliance inspection at Studsvik's site concerning the implementation of measures required by SSM from previous inspections. The management of the facilities was involved during the whole inspection and was informed about the main conclusions of this inspection directly after the inspection.

Furthermore, the IRRS team visited the Westinghouse fuel factory in Västerås. The subject of the inspection was the safety program of Westinghouse, how it was initiated, follow-up and experience feed-back. The inspection team was composed of two inspectors. The IRRS review team attended a Westinghouse presentation, followed by discussion, interviews with Westinghouse employees and ending with an exit meeting. The inspection was conducted in Swedish and an SSM employee helped the IRRS review team with the translation. The inspectors were well prepared with a list of questions to confirm the impression from the preparations before the inspection. The inspection team had good communication with the licensee and obtained useful information for the exit meeting.

7.2.3 INSPECTION PROGRAM

For nuclear power plants, an inspection plan is prepared annually based on the importance of the area to be inspected, previous inspection results and the planned activities of the facilities. In the planning of inspection, the results of SSM's integrated safety assessment for the utilities are also taken into account.

Inspections are carried out for the seventeen different areas with different frequencies depending on the importance. Three different types of inspections are carried out by SSM: compliance inspection, surveillance inspection and rapid investigation. The compliance inspection is a planned announced inspection to check whether the licensee complies with applicable requirements and conditions related to the operation. The surveillance inspection is also an announced inspection carried out to monitor the licensee's activities and to gather information continuously. The results of surveillance inspections are used to decide if additional supervisory measures are required. The rapid investigation is a reactive inspection which is performed when an event occurred or a particular circumstance is discovered.

For the fuel cycle and the waste management facilities, the inspection programmes are prepared on an annual basis but the frequencies of the inspection items are not systematically defined by the associated risk. Improvement for this process should be considered to ensure that inspection programmes cover adequately all areas of responsibility of the regulatory body with respect to fuel manufacturing, low and intermediate level waste (LILW), from predisposal to disposal. [Detailed information can be found in 7.1].

7.2.4 SCOPE OF INSPECTION

The scope of inspection carried out by SSM is divided into seventeen different areas which correspond to the requirements of SSM's regulation, licensing conditions and regulatory decisions. These seventeen inspection areas are very comprehensive and cover almost all important activities of the licensee, but do not cover the off-site activities of the suppliers of services and products to the licensee. SSM does not have the authority to supervise the off-site activities of the suppliers because there is no rule supporting this supervision. The IAEA Safety Guide GS-G-1.3, "Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body", states that regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility including the activities of suppliers of services and products to the operator. A new rule is needed to allow the supervision of the suppliers to the licensee. [Detailed information can be found in section 1.2]

7.2.5 FEEDBACK OF EXPERIENCE AND GRADED APPROACH

SSM's inspections on nuclear power plants are mostly surveillance and compliance inspections. These two types of inspections are planned inspections in which inspection purposes, schedules and documents to be reviewed are provided to the licensee before the inspection to allow for the necessary arrangements. Including the document review, inspections last several days typically and are carried out by team of inspectors. During the exit meeting, the SSM inspectors presented the results of the inspection to the licensee with the relevant requirements and findings. The discussions with the licensee are reflected in the inspection reports which are finalized by the section head or department head. When a deficiency is found during the inspection, the regulatory decision is made by the section head, department head or director general depending on the severity of the deficiency.

All the finalized compliance inspection reports of a power plant are provided not only to the inspected plant but also to all nuclear power plants in Sweden for feedback. The inspection results are recorded and used in SSM's integrated safety assessment of the utilities. In contrast to the nuclear power plants, inspections of the fuel cycle and waste management facilities do not systematically implement the graded approach reflecting the risk associated.

7.2.6 INSPECTOR TRAINING AND QUALIFICATION

The competence needed for the inspection is described in the compliance inspection document (STYR2011-106). According to this document, the inspection team must consist of two or more persons including the inspection leader, and the inspection team must reflect a sufficient level of knowledge in the area of inspection. It also states that inspectors must have documented competence to perform inspections. But there is no prescribed qualification process in organizing the inspection team for the chosen inspection area. Although most inspectors have participated in at least one course of interview techniques, there is no specific mandatory training program for different technical areas. To maintain the necessary competence in the different technical areas, a technical training and qualification program should be implemented. [Detailed information can be found in section 3.3]

7.3. INDUSTRIAL, MEDICAL AND RESEARCH RADIATION FACILITIES

7.3.1 GENERAL

Section 29 of the Radiation Protection Act provides for supervision (i.e. inspection) of compliance with the Act and with regulations or conditions issued pursuant to it. Section 15 of the Radiation Protection Ordinance defines SSM as the authority which shall conduct supervision.

Most inspections on uses of radiation sources are compliance inspections as prescribed in SSM document STYR2011-106. In case of an accident or incident, rapid investigations are being done to gain independent interpretation of the event. An inspection team comprises always at least two inspectors irrespective of the type of practice and the scope of the inspection. Most inspections are announced. Unannounced inspections have been carried out only in a few exceptional cases. [Detailed information can be found in 7.1].

A comprehensive inspection report is prepared after an inspection and is sent to the licensee for comment before a final approval by the Section Head. Possible non-compliance is addressed in the report.

SSM prepares summary reports based on inspections conducted in a certain specific area of interest (industrial uses), or in a certain county (medical uses). The reports consider also incidents and accidents. The summary reports prescribe findings, levels of compliance with regulatory requirements and license conditions, and lessons learnt from accidents and incidents. The report also provides suggestions for possible future actions for improvement. However, the process by which these suggestions are to be reflected in SSM regulatory activities is not defined. In case of medical uses, findings and conclusions of the report are also presented and discussed in a meeting with representatives of the relevant county. The reports are published and made publicly available on the SSM web site.

7.3.2 SITE VISIT

The IRRS team visited Karolinska University Hospital to observe SSM staff conduct inspection on the Positron Emission Tomography (PET) cyclotron facility. The inspection was conducted by three inspectors from the medical and industrial activities sections of SSM, and its scope was on occupational exposure control. The inspection included areas such as radiation protection organization and competence, QA program, safety systems, monitoring, laboratory practices, and categorization of workers and workplaces.

The inspection started by presentations made on the organizational structure of the PET cyclotron by the facility management, and was followed by a round table discussion/interview with the management and relevant staff. The inspectors then proceeded to the control room inside the PET cyclotron facility to conduct practical observation and assessment of how the staff in the hospital conducts their activities. The inspectors of SSM conducted the inspection in a professional manner and had a cooperative attitude with the concerned staff and management of the PET cyclotron facility.

Following the observation, an exit briefing has been conducted with the management and relevant staff of the PET facility and findings of the inspection was presented and discussed at the exit meeting.

During a site visit, it was observed that SSM inspectors did not have personal dosimeters despite the fact that the inspections were conducted partially within a controlled area where the licensee personnel were required to carry a dosimeter. In addition, the inspectors had no radiation measuring device for performing any independent verifying measurements. When radiation measurement was needed, the inspectors used licensees' survey meter.

In a separate discussion, the licensee representatives expressed a desire for more dialogue with SSM such as through meetings regarding radiation safety and regulatory aspects.

7.3.3 INDUSTRY AND RESEARCH APPLICATIONS

SSM has prepared a long term inspection plan covering years 2012 – 2016. The objective of the plan is to gain a general view on the level of compliance with requirements of a selected group of licensees rather than to verify the status of safety and compliance of each individual licensee. The plan prescribes areas of interest for each year. For example, in 2012 emphasis is on veterinary practices but also some other facilities and activities will be inspected. There is no formal process in place by which the annual areas of interest are being selected. Usually no inspections are conducted as part of the authorization process.

The number of inspections to be carried out is defined in an annual work plan. The plan for 2012 comprises 21 inspections from about 1500 registered licensees/facilities. Detailed practice specific check-lists based directly on articles of relevant regulations seem to be at disposal of the inspectors but there is no internal written procedure in place which would require these check-lists to be used.

7.3.4 MEDICAL APPLICATIONS

The inspections are intended to cover all practices (except intra oral dental practices) at some period of time. All private hospitals have been covered during recent years and now inspections are targeted at public hospitals. The inspections are done systematically in all public hospitals locating in a certain County. Currently inspections cover four to five Counties per year (of the total of 21 counties in Sweden), including follow-up of previous inspections. In addition, inspections of certain thematic areas (such as current radiation safety of the patient in therapy departments) are conducted covering the whole country. Whenever a new therapy or nuclear department is established, inspection is conducted in connection to the authorization.

There are some observations with regard to establishing and implementing written internal guidance or procedures. Recommendation in this regard is provided in Part 3.6 of this report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Paragraph 4.51 states that** *"Results of inspections shall be used as feedback information for the regulatory process and shall be provided to the authorized party."*
GP7	**Good Practice: SSM prepares and publishes (and makes publicly available on website) summary reports on inspection findings and incidences in different uses of radioactive sources including suggestions on how to improve level of safety and compliance, with regulatory requirements and license conditions. In case of medical practices in public hospitals, the summary report is discussed with the representatives of the county.**

8. ENFORCEMENT

In accordance with the Act on Nuclear Activities, the Radiation Protection Act and the Environmental Code, SSM has extensive legal powers to enforce the regulations and its decisions. The following actions can be taken: remark, injunction, and prohibition to continue the operation before taking actions, revocation of license and correction at the expense of the licensee. Injunctions and prohibitions can be combined with a conditional fine.

An overarching principle for enforcement, as expressed in chapter 26 section 9 second paragraph of the Environmental Code, is that a measure shall not be more restrictive than necessary. SSM internal document STYR2011-87 prescribes the measures that could be taken based on the degree of severity of the non-compliance. Currently SSM has no formal enforcement policy but it is under development. Also, there are no defined criteria which SSM will use in choosing appropriate enforcement action in different types of cases. Thus SSM makes an assessment of appropriate measures on a case by case basis. The timeframe for corrective action is usually discussed with the licensee.

Depending on the severity of the non-compliance the decision is taken at different hierarchical levels in the SSM organisation (from head of section to the director general). SSM has procedures describing the responsible person for the enforcement decision in accordance with the safety significance.

A matrix (need for improvement vs. safety consequences) is under development for the nuclear power plants in order to make an enforcement decision with a graded approach.

In case of nuclear facilities, the most common action is to make a remark in an inspection report. In addition, SSM makes issues about 30 injunctions per year to the NPPs and other nuclear facilities. The licensee is asked to inform SSM when the corrective action is completed. SSM can also check the effectiveness of the corrective action during the surveillance inspections. However, this is not done systematically.

In case of industrial, research and medical radiation facilities, the most common action is to issue an injunction to take action within a given time frame. Most injunctions are based on inspection findings and are issued following an inspection. Injunctions are submitted to the licensee in a separate letter which is subject to approval by the corresponding Section Head and SSM legal section.

The follow-up of injunctions is the responsibility of an individual inspector (usually inspection leader). Some sections of SSM are using some section level tools facilitating follow-up (e.g. spread sheets where deadlines are recorded), however, there is no formalized process in place for the follow-up.

If actions are not taken within the specified time period, a process to issue a fine can be initiated. Final decision of the payment of the fine is done by the court.

The IRRS team was informed that a SSM inspector has the power to take immediate on-site enforcement action where safety so necessitates. This mandate is conferred by the Act on Nuclear Activities and the Radiation Protection Act and delegated to the individual inspector by chapter four, section 2 of the Rules of Procedure of SSM. Such a decision shall as soon as possible be reviewed by the DG.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Paragraph 4.60 states that** *"Finally, the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions."*
(2)	**BASIS: GSG 1.3 Paragraph 3.1 states that** *"The management within the regulatory body of inspection activities is an important element of the authorization process. Consideration should be given to assigning managerial responsibility to a single individual or organizational unit. These responsibilities should include :* - *ensuring that follow-up actions from inspections, including dissemination of findings, are taken;"*
S7	**Suggestion: SSM should consider monitoring the implementation status of corrective actions of licensees.**

9. REGULATIONS AND GUIDES

9.1. GENERAL

The Nuclear Act, the Radiation Protection Act and the related ordinances establish the framework for the regulatory control of nuclear and radiation safety. The requirements for the licensees or license applicants are further detailed in the legally binding regulations issued by SSM. There regulations are called Strålsäkerhetsmyndighetens föreskrifter (SSMFS). These regulations are in some cases accompanied by guidance on how to meet the requirements in the regulations (General advice). When SSM was established the nuclear safety regulations and radiation safety regulations were merged into a single set of regulations. In 2008 when SSI and SKI were merged 53 SSMFSs were re-issued and some additional regulations have been issued since.

The approaches utilized by the previous regulatory bodies SSI and SKI were different. For radiation protection there are a significant number of guides to the regulations which cover the details of the main activities and practices in Sweden. These guidelines are used to recommend and clarify the implementation of legal requirements and to ensure uniform implementation in practice. Guidelines cover the assessment of facilities, surveillance of operations and some detailed elements. The regulation and the related guidance for nuclear facilities are more general.

At the time of the IRRS mission there were 45 regulations and 21 general advice covering nuclear and radiation safety.

The SSMFSs are numbered with the year and continuous number starting each year from 1. Thus the list is common to all types of facilities and activities. On SSM's web site the regulations are available by user groups such as industry, health care, environment, and emergency preparedness. On the web site the systematic presentation of the regulations based on user groups could be enhanced and more information on the development of the regulations could be presented.

Some of the SSMFS have been translated into English. In the current global stakeholder environment SSM should consider having the unofficial translations of the regulations available in English. This is especially important, as there are international license holders of radioactive sources in Sweden. The translations of regulations provided by the regulatory body diminish the risk for misinterpretation of the requirements by international vendors.

There are two major changes in the regulatory environment having an impact on the regulations: First, on 1 January 2011 Sweden made the decision to allow the new build of nuclear reactors and second, a proposal to combine the Nuclear Activities Act and Radiation Protection Act (SOU 2011:18) was made in February 2011. The current regulations for the nuclear power plants were written from the point of view of operating power plants. There is need in due time for the regulations to cover activities associated with new nuclear power plants.

One of SSM's main priorities for 2012 is the development of the overall strategy and structure for the development and revision of regulations and oversight. The further implementation stages, timelines and resourcing are to be defined after the initial planning. It was noted that the allocation of resources for preparation of the regulatory strategy was presented in the working plan of the legal section. However the allocation of the resources from other technical and specialist sections could not be verified from the SSM planning system (Sinus). This suggests that the initial plans may not be properly resourced and puts additional pressure on already stretched technical and specialist staff.

9.2. PROCESS FOR DEVELOPING REGULATIONS AND GUIDES

The process of developing regulations and guides is one of the core processes of SSM. The regulations are binding documents and they are to be developed according to the Radiation Protection Ordinance (1988:293) including public hearing. STYR2011-51 describes the process of preparing of a SSMFS. The process owner is the head of the legal section. For each of the prepared regulation a project is established. The project activities as well as the duties and responsibilities of the project group and heads of sections are described in the STYR2011-51. There are also instructions how the requirements should be written. The process consists of 16 steps which include internal and external hearings.

The proposal of a new regulation or a modification includes a thorough review of the needs and consequences of the regulation as well as the review of international requirements related to the issue. Technological advances, research and development work, relevant operational lessons learned and institutional knowledge should be taken into account in the new proposal. The report gives good basis for the further activities.

Section 2.2 of STYR2011-51 includes the review of the regulations every 5 years. This process has not been carried out during the existence of SSM due to the fact that the regulatory body was established in 2008. There is a need to clarify the actors and responsibilities of the review process. Revision 3 of STYR2011-51 was under development at the time of IRRS mission. Until now the responsibility for establishing the full set of regulations has been on the technical sections. However SSM has plans to shift this responsibility to the legal section.

The internal process STYR2011-51 is focusing on the preparation of a single regulation, but the annual planning process should have as its objective the development of the set of SSMFSs as a whole. In addition to the existing STYR2011-51 there is a need to expand STYR2011-51 to cover the aspects of developing the SSMFSs. The approach for the five years period for the review of the regulations should include two aspects: First, the set of regulations as a whole and second, the individual regulations. The review of the individual regulations should be included into the annual plans. The IRRS team recognized that some guidance (General advice) in different areas of radiation protection was not up to date.

The IRRS team recognized that there is a need to review the process for preparing regulations and guides and revise the related procedure STYR2011-51.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
S8	**Suggestion: SSM should consider ensuring that the "General advice" for radiation protection is kept up to date.**

In spite of the fact that preparation of the regulations is one of the core processes of SSM it has not been audited internally or externally.

The allocation of resources for preparing regulations in the technical sections for year 2012 is about 3 man-years. At the beginning of the year government appointed more resources for SSM due to potential new build of nuclear energy. This would allow one man-year more for preparing regulations during the year 2012 (see Section 3).

In general the process of developing regulations and guides is well established. Regulations and guides are developed by SSM with respect to the legal system of Sweden for preparation, reviewing, issuing and enforcing. The review process takes into account internationally agreed standards and the feedback of relevant experience. Concerning the implementation of the process there are deficiencies related to overall review of the whole set of regulations. Moreover, no external or internal audits have been conducted regarding the process related to the regulations.

9.3. EXISTING REGULATIONS AND GUIDES

9.3.1 NUCLEAR FACILITIES

Until 1999, there were no general safety regulations for nuclear activities. Instead there were specific individual license conditions in place. In 1999 the first general regulations on nuclear safety came in force by SKI. Regulations regarding radiation protection were already binding in general regulations. After that the regulations were revised as needed. In 2004 there was a major revision of the nuclear safety regulations when SKI also issued a set of goal based regulations for operating nuclear reactors. The revision included modernisation requirements to be carried out until the end of 2012.

SSM has at the time of the IRRS mission a total number of 45 SSMFS and 21 general advice for all the activities it regulates. Of these, 12 SSMFS are related to nuclear facilities, two are related to nuclear reactors, two are related to spent fuel and four are related to the radiation protection of workers and the public.

The basic requirements for the nuclear faculties are presented in the SSMFS's. SSMFS 2008:1 is the main regulation for nuclear facilities and it covers a wide spectrum of issues. Several of the issues are presented in more detail in related regulations such as SSMFS 2008:17 for the design and construction of a nuclear power plant and SSMFS 2008:13 for mechanical components at the nuclear facilities.

At the time of IRRS mission there are plans for generating the revised SSMFS for new reactors (revision of SSMFS 2008:17), fire protection and cranes (SSM 2009/1793). The revision of eight regulations related to nuclear facilities for waste management is in the annual plan for year 2012.

There are two on-going processes related to the review of the SSM regulations: First, SSM has the request from the government to analyse long term aspects of the nuclear safety in Sweden and second, the activities to be carried out due to Fukushima Dai-ichi accident in March 2011. The project established at SSM includes the assessment of the coverage of the current requirements and the assessment of the Swedish oversight strategy. SSM ordered an expert report of the comparison of the Swedish requirements with the new IAEA SSR 2/1(DS414), the Finnish YVL guides, NRC regulations, French regulations and German regulations. The main conclusion of the review is that in general the topics are covered but in several areas more detailed requirements are needed.

Most of the SSMFS have an attachment (General advice) which gives more detailed advice on how to comply with the requirements. The General advice for the nuclear safety regulations are at a high level and it is assumed that the licensee and vendor are competent and well aware of the expectations of the regulator. In the General advice there are references to more detailed guidance such as IAEA safety standards, ASME standards, EN standards or ANSI standards. Also some advice to the licensee is given by delivering SSM internal guidance for review and assessment such as STYR2011-131 (licensing process and content of the license application), STYR2011-159 (control of affluent to air), the SSM Handbook for reviewing PSA or the SSM Handbook for reviewing digital I&C.

The General advice is always given to extend the content of the paragraph in the SSMFS. There is also an expressed need to limit the length of the General advice. In principle the SSM internal documents and Handbooks published as research reports do not have any status in the legal system. Thus the preparation of the regulations and the related guidance makes it challenging to address cross-cutting issues such as

classification of systems, structures and components, plant layout, I&C architecture, PSA and other plant level issues.

SSM should have a clear strategy and process in place to guide the licensee in meeting the regulatory requirements and implement this strategy in a systematic manner. (See module 1 and 3.6)

9.3.2 INDUSTRIAL, MEDICAL AND RESEARCH RADIATION FACILITIES

The system of regulations and guides established is a user friendly system, where the user can find information about safety and radiation protection for their activities. SSM has established a number of regulations and guides which cover in details the main activities and practices in Sweden. The system of regulations is facilitating the licence holder (LH) in the process of preparation for licence application. The system of regulating is enforced by regulations and conditions established on the license and through the inspection process. The main responsibility remains with the user and is the object of control through supervising. Before starting an activity the LH is obliged to complete the entire requirement related to its activity or practice by signing in the application form that he knows the requirement of the regulations.

The fundamental documents governing the regulation of ionizing radiation are:

- SSMFS: 2008:51 Regulations concerning basic provisions for the protection of workers and the general public in practices involving ionizing radiation;
- SSMFS 2008:35, (medical and dental practices);
- SSMFS 2008:25, (industrial radiography);
- SSMFS 2008:27, (practices with accelerators and sealed sources);
- SSMFS 2008:28, (laboratory work with unsealed sources); and
- SSMFS 2008:30, (use of x-rays in veterinary medicine).

The fundamental document governing the system of regulations in radiation protection is SSMFS 2008:51 Regulation “concerning basic provisions for the protection of workers and the general public in practices involving ionizing radiation” and applies to workers and the general public as well as to pregnant women who may be exposed to radiation in their work.

More details on these requirements and their implementation have been reviewed in other modules (SSMFS 2008:35 for medical and dental practices; SSMFS 2008:25 and SSMFS 2008:49 (earlier SSI FS 1989:2) for industrial radiography; SSMFS 2008:27 (earlier SSI FS 2000:9) for practices with accelerators and sealed sources). These regulations apply to practices and ensure that quality assurance programmes and written quality manuals are established.

9.4. REVIEW OF THE REGULATIONS AND GUIDES

The Swedish regulatory framework for nuclear facilities has historically grown upon the practical needs. Although IAEA safety standards and publications are sometimes explicitly referred to in Swedish regulations and guidance, they were not systematically considered when developing draft regulations in the past.

The radiation protection regulations were reviewed against GSR Part 3 (formerly the BSS). The implementation of GSR Part 3 into national legislation is in progress.

Sweden has participated in the Western European Nuclear Regulators Association (WENRA) cooperation and made the comparison of the Swedish regulations to the WENRA reference levels for nuclear power plants and waste management. As a result of this work a plan has been made to address the identified differences. A new version of SSMFS 2008:1 was issued in 2010 which addressed most of the gaps for the nuclear power plant sector, and the revision of the plan for the revision of SSMFS 2008:17 covers the remaining issues. The comparisons of WENRA reference levels to NPPs and other nuclear facilities and the Swedish regulatory framework showed that 74 % of WENRA reference levels for nuclear power plant

were covered in 2010. The revised version of SSMFS 2008:1 was adopted in October 2011. The parts relevant for waste management and decommissioning of the revised version of SSM 2008:1 will be in compliance with WENRA reference levels. The verification report of the fulfilment of WENRA reference levels for waste management is under preparation.

During the IRRS mission it was not possible to make a complete and thorough assessment of the SSM regulations for nuclear facilities. However the IRRS team made some observations of the gaps in the regulations. As an example, the following issues could be better covered by the regulations and general advice: licensing process and related documentation, requirements for the containment, requirements for electrical and I&C systems and components, external events, PSA, management system for the nuclear facilities, construction and design of facilities other than nuclear reactors, safety classification, fire safety, and lay-out of the nuclear power plant.

As mentioned in Section 1.2. SSM intends to completely revise its regulation and guidance to the licensees. The team suggested in Suggestion 9 to base this revision on a systematic comparison to the IAEA safety requirements.

The IRRS team made general observations of the gaps in the nuclear safety regulations and the team performed in the IRRS review process a preliminary screening of SSMs legally binding regulation (föreskrifter). Some discrepancies, which should be addressed, have been identified in the Swedish regulations as follows:

For licensees of facilities:

- Requirements for safety culture in accordance with GS-R-3, Paragraph 2.5,
- Requirements to the licensees to prepare and implement emergency plans for non-nuclear facilities in accordance with GSR Part 1 Paragraph 4.45,
- Requirements for modifications requiring SSM approval in accordance with GSR Part 1, Requirement 26, and
- Requirements for criteria for site release in accordance with WSR Part 5 Paragraph 3.6 and WSR part 5 Paragraph 9.2

The following gaps were identified by the IRRS team based on its review of SSMFS 2008:1 (revision issued 2010), which the team had in English. In the new revision of SSMFS 2008:1, issued in 2011 which is available only in Swedish, the topics were already covered. This new revision of SSMFS 2008:1 will be in force on November 1st 2012.

- Requirements for minimizing the amount of waste produced in accordance with IAEA Safety Fundamentals Paragraph 3.29 and GSR Part 5 requirement 8 (12.3),
- Requirements that LILW are to be stored in such a manner that it can be inspected, monitored and preserved in a condition suitable for its subsequent management in accordance with GSR Part 5 requirement 11,
- Criteria for decommissioning planning, including appropriate criteria for the initiation of the application process for the authorization of starting dismantling facilities, so that unnecessary long elapse of time does not occur between cease of operational activities and the initiation of the application process in accordance with WSR Part 5 Paragraph 3.6,
- Requirements for prescribing safety documentation and timeframes during dismantling and decommissioning activities in accordance with WSR Part 5 Paragraph 3.5 and WSR Part 5 Paragraph 3.6,
- Requirements for documentation content for the approval of the dismantling activities in accordance with WSR Part 5 Paragraph 3.5 and WSR part 5 Paragraph 3.6

For Transport

- Requirements for clear reporting criteria for incidents/accidents occurring during the transport of radioactive materials in accordance with TS-R-1 Paragraph 309,
- Requirements for producing the remaining procedures for the transport competent authority in accordance with GSR Part 1 Requirement 32

For occupational exposure:

- Requirements for provisions for the description of a radiation protection programme as part of the application for a license in accordance with GSR Part 1 Requirement 23,
- Requirements for provisions for responsibilities and duties of workers for the implementation of the protection and the safety measures for themselves as well as for the other workers in accordance with GSR Part 3 Requirement 22,
- Requirements for provision to ensure that employers, registrants and licensees do not offer benefits as substitutes for measures for protection and safety in accordance with GSR Part 3, Requirement 27, Paragraph 3.111

Public exposure

- Requirements for provision for an independent monitoring programme in accordance with GSR Part 3, Paragraph 3.135

For medical exposure

- Requirements for the registrants and licensees to ensure that the person subject to medical exposure has been informed as appropriate of the expected benefits and risks in accordance with GSR Part 3 Requirement 36,
- Requirements for registrants and licensees to ensure that regular and independent audits are made of the program of quality assurance for medical exposure in accordance with GSR Part 3 Paragraph 3.171,
- Requirements for registrants and licensees to place signs in appropriate places to request female patients to provide information on possible pregnancy or breast feeding in accordance with GSR Part 3 Paragraph 3.174,
- Requirements for registrants and licensees to inform the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure in accordance with GSR Part 3 Paragraph 3.180,
- Requirements for registrants and licensees to ensure that radiological reviews are performed periodically in accordance with GSR Part 3 Paragraph 3.181,
- Requirements for registrants and licensees to maintain records of the information necessary for retrospective assessment of doses in diagnostic radiology in accordance with GSR Part 3 Paragraph 3.184,
- Requirements for dose constraints for carers and comforters in accordance with GSR Part 3 paragraph 3.148,
- Requirements for the prompt investigation of accidental or intended medical exposure in accordance with GSR part 3 Paragraph 3.179

Because of the non-prescriptive character of the Swedish regulation, the team also reviewed the non-legally binding guidance to the licensees. The team identified areas were additional guidance to support the interpretation and implementation of the regulations should be considered by SSM:

For licensees of facilities:

- Guidance for the format of documents which are required to be submitted by the applicant in support of an application for an authorization in accordance with GSR Part 1 Paragraph 4.33,
- Guidance for the contents of documents, such as the radiation protection programme, to be submitted with application for an authorization in accordance with GSR Part 1 Paragraph 4.34,
- Guidance (including intervention levels) to clarify the functions and responsibilities of the operators and response organizations and the criteria for their actions in accordance with GSR Part 1, Requirement 32,
- Guidance on the key aspects of safety culture to all of the organizations in accordance with GS-R-3 Paragraph 2.5,
- Guidance for licensees regarding clearances of buildings and land in accordance with WSR Part 5 Paragraph 3.6 and WSR part 5 Paragraph 9.2

For occupational exposure control

- Guidance concerning the role and the responsibilities of the RPE and the RPO for nuclear facilities (as for non-nuclear activities) in accordance with GSR Part 3, Paragraph 2.21

Medical exposure control

- Guidance on the implementation of the requirements related to medical exposure control, in particular the requirements related to the quality assurance program as discussed in Section 12.5,
- Guidance for the protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources as result of radiological procedure or medical treatment of patients or as a consequence of an emergency in accordance GSR part 3 Paragraph 2.37,
- Guidance for criteria and guidelines for the release of patients who still retain implanted sealed sources in accordance with GSR Part 3 Paragraph 3.148(b)

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
(2)	**BASIS: GSR Part 1 Paragraph 4.62 states that** *"The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach."*
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.**

10. TRANSPORT OF RADIOACTIVE MATERIAL

10.1. REGULATORY FRAMEWORK

The transport requirements of IAEA (TS-R-1) are fully implemented in Swedish legislation, although the arrangements are complex.

The Swedish Act on the Transport of Dangerous Goods (2006:263) and its associated Ordinance (2006:311) assigns responsibility to the three main regulatory agencies. The Swedish Transport Agency are responsible for the regulations covering air and sea transport of all dangerous goods including radioactive materials, the Swedish Civil Contingencies Agency are responsible for the regulations for road and rail (they produce a Swedish translation of the European ADR and RID regulations) and the Swedish Radiation Safety Authority are the competent authority for the transport of radioactive material.

The overall structure is shown in the diagram below:

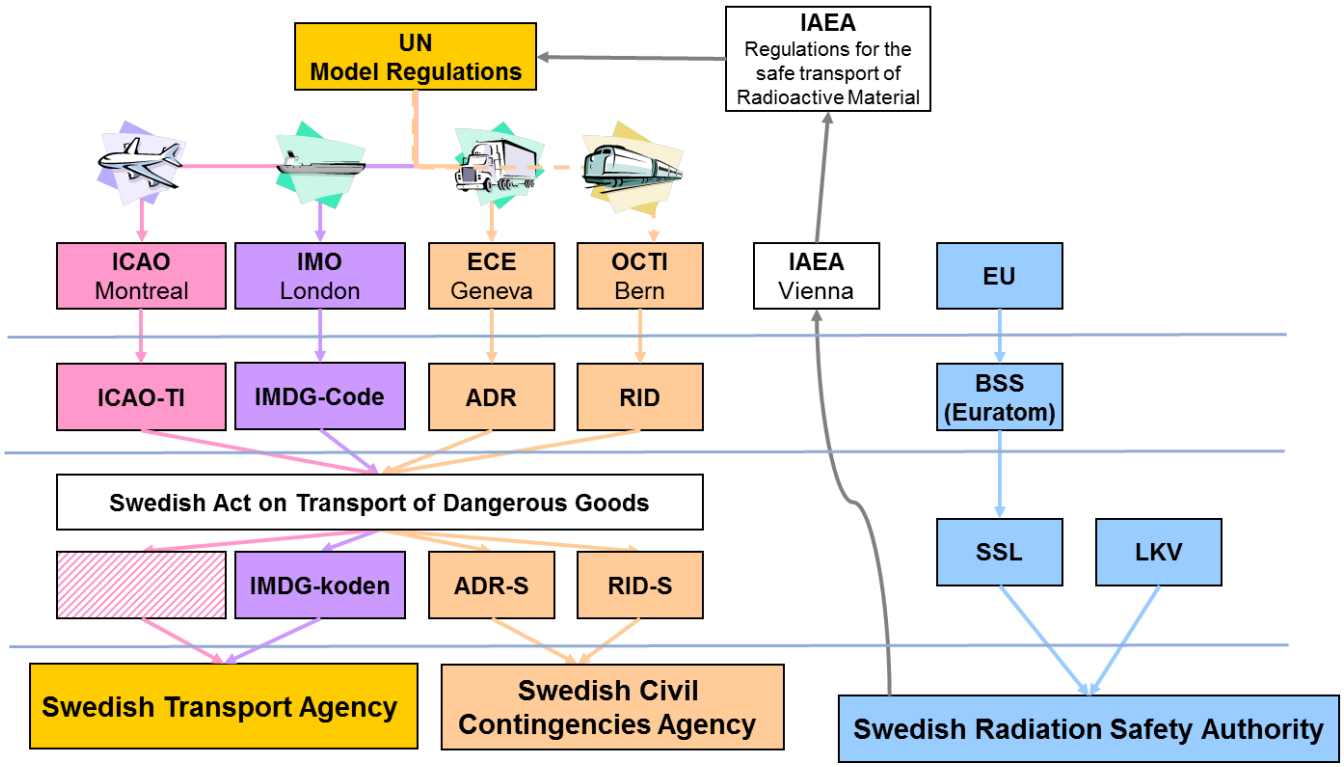

Figure 1
[SSL – Radiation Protection Act (1988:220) / LKV – Act on Nuclear Activities (1984:3)]

The complete list of regulations is:

- Act (1984:3) and Ordinance (1984:14) on Nuclear Activities
- Radiation Protection Act (1988:220) and Ordinance (1988:293)
- Transport of Dangerous Goods Act (2006:263) and Ordinance (2006:311)
- Regulations on transport of dangerous goods by road (MSBFS 2011:1ADR-S) and railway (MSBFS 2011:2 RID-S), sea (TSFS 2009:91 IMDG code) and air (Regulation EC/859/2008 ICAO-TI), i.e. the modal regulations.
- The Act on Nuclear Activities (1984:3) and the Radiation Protection Act (1988:220) require radiation protection and safety in all dealings with such material.

The Radiation Protection Act requires transporters of radioactive material to be licensed when radioactive materials are transported on Swedish territory, or when transiting Swedish territory, or when transporting radioactive materials on a Swedish flagged vessels. LKV requires transporters of nuclear materials to be licensed. Licences are required for radioactive or nuclear materials with SSM being responsible for issuing these licenses. Before a licence is issued SSM reviews the transporter's radiation protection programme and QA arrangements.

SSM are the Competent Authority for package assessments and compliance assessment, which includes inspection work and assisting in emergencies involving transport packages.

SSM are also members of the European Association of Competent Authorities.

10.2. OVERVIEW

The Swedish legislation and regulatory structure is comprehensive but complex, nonetheless there is a clear understanding regarding scope of responsibilities in each authority regarding transport.

Assessment of package designs, as required by TS-R-1, is carried out by SSM. They use a two tier system where packages that come from France, Germany and the UK are given a simplified review, unless the package contains fissile material. For fissile packages from these countries, the fissile aspects are independently verified. For packages from Sweden, or countries not part of ADR, a full review is carried out. The review process follows the IAEA TS-R-1 requirements and uses a safety report format developed with other EU countries. The SSM two tier process is novel and takes full advantage of work carried out by other Competent Authorities, without any reduction in overall safety. This graded methodology could be advantageously used by other competent authorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 14 Paragraph 3.2(e) states that** *"Multilateral and bilateral cooperation that enhances safety by means of harmonized approaches as well as increased quality and effectiveness of safety reviews and inspections."*
GP8	**Good Practice: SSM assessment of packages takes account of work done by other Competent Authorities. This approach is novel, not widely used elsewhere, helps where resources are limited and maintains safety levels.**

For a small number of packages SSM has issued Special Arrangements to allow for their continued use as the certificates of approval are out of date. The required Package Design Safety Reports were not provided to SSM in time by the applicant. Despite issuing a Special Arrangement, SSM did not ask for any compensatory safety measures as required by the IAEA transport safety regulations TS-R-1 and associated guide TS-G-1.1. In similar situations other Competent Authorities issue time limited extensions, provided no significant change has occurred to the overall safety of the package.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: TS-R-1 Paragraph 310 states that** *"Provided the competent authority is satisfied that conformity with the other provisions of these Regulations is impracticable and that the requisite standards of safety established by these Regulations have been demonstrated."*
(2)	**BASIS: TS-G-1.1 Paragraph 238.1 states that** *"The use of the 'special arrangement' should not be taken lightly. This type of shipment is intended for those situations where the normal requirements of the Regulations cannot be met."*
(3)	**BASIS: TS-G-1.1 Paragraph 312.2 states that** *"… alternative safety measures effectively equivalent to those prescribed in the Regulations."*
R16	**Recommendation: SSM should only use Special Arrangements as defined in TS-R-1.**

All the approval certificates are signed by the Head of the Control and Protections Section but there is no formal authorisation for him to carry out this function. SSM should change its management system to designate the Head of Control and Protection as being the signatory for Competent Authority functions. This suggestion is part of the Recommendation in Module 3.6

The current management system covers the required scope for the regulations but only about half of the working documents have been produced. The remaining documents that describe the processes of the Transport Competent Authority should be completed to ensure a consistent and correctly graded approach is taken. This is now part of the Recommendation in Module 9.4.

The transporters of radioactive packages are aware of the requirement to report incidents/accidents to SSM and the evidence is that this reporting is comprehensive. There are no clear reporting criteria defined by the regulator. SSM should produce clear reporting criteria for transporters of radioactive materials. This is now part of the recommendation discussion documented in Module 9.4.

Compliance inspections are carried out by SSM. The overall process is well documented and thorough using check lists that ensure the appropriate weight is given to the correct regulatory requirements. Intervention reports are produced that record the main outcomes of the inspection. The numbers of inspections completed are low (6-8 per year). SSM are aware of this issue and are trying to introduce more inspections. This is now part of the Recommendation in Module 7.2.1.

10.3. VISIT TO WESTINGHOUSE FUEL FACTORY AT VASTERAS ON 9 FEBRUARY 2012

An IRRS team member accompanied two SSM inspectors to the Westinghouse Fuel Fabrication Plant at Vasteras. This inspection was a paper based review of the Westinghouse QA procedures dealing with the requirements of Paragraph 1.7.3 of ADR on QA arrangements and some other ADR requirements relating to documentation.

The team had a pre-meeting at SSM that involved using documentation that was based on information from the EU Association of Competent Authorities. This document provided a schedule of issues that were dealt with methodically and ensured the inspection team had reviewed all issues before the inspection.

The inspection went well and by adopting a methodical approach the inspectors covered all areas. They identified two work processes where there were no procedures or the ones available were considered

inadequate. There was a de-brief meeting with Westinghouse who were made aware that the overall system was considered adequate but work processes required improvement.

This inspection will be followed up with a workplace inspection at a later date.

The inspection was well conducted and covered the relevant areas of the regulations.

11. EMERGENCY PREPAREDNESS AND RESPONSE

11.1. BASIC RESPONSIBILITIES

SSM is the competent authority in Sweden for the IAEA's Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency and the Convention on Early Notification of a Nuclear Accident. It is the responsibility of SSM to ensure that Sweden acts in accordance with the IAEA's Conventions on assistance and early warning, the European Union's early warning system under the EURATOM treaty, and to provide the Government with the expertise needed for international assistance in the field of emergency preparedness and response.

SSM's responsibility encompasses, among other things, to

- provide advice and recommendations concerning radiation protection, clean-up and decontamination following a release of radioactive substances in the event of a nuclear or radiological emergency in Sweden, or outside of Sweden with consequences for Sweden,
- maintain and lead a national organization for expert support in the event of a nuclear or radiological emergency situation,
- provide nuclear technical advice and recommendations to the authorities assigned with managing the impact of an accident if a nuclear emergency should occur in Sweden, or outside of Sweden with consequences for Sweden,
- maintain competence for providing knowledge-based decision support in radiation protection including dispersion modelling and radiation protection assessments, and
- maintain competence and capacity in radiation protection to perform relevant measurements, sampling and analysis in the field.

More specifically SSM shall provide information to the general public and cooperate and support other relevant authorities in the event of a crisis within SSM's field of responsibility. SSM shall in particular

- have the ability to immediately be able to establish a crisis management function,
- give advice to the County Administration Board in the affected county on radiation measurements and also coordinate and assist in radiation protection assessments in case of emissions of radioactive materials from a nuclear facility,
- keep the Government informed about developments, the situation, expected developments, available resources and taken as well as planned measures, and
- following a request by the Crisis Management Coordination Secretariat at the Prime Minister's Office or Swedish Civil Contingencies Agency (MSB) provide the information needed in order to get an overall picture of the situation.

SSM does not impose detailed instructions on the operators regarding the formulation of their emergency response plan, instead, the operators themselves are required to develop the details, which are documented and approved during the licensing process. The documents that in general describe the requirements of the emergency plans for the nuclear and radiological facilities are the first two regulations below. The others are relevant for SSM and, in some cases, for other authorities.

- SSM's Regulations Concerning Safety in Nuclear Facilities (SSMFS 2008:1);
- SSM's Regulations Concerning Emergency Preparedness at Certain Nuclear Facilities (SSMFS 2008:15);
- the Ordinance (2008:452) with instructions for the Swedish Radiation Safety Authority;
- the Act (1984:3) on Nuclear Activities, the Ordinance (1984:14) on Nuclear Activities;
- the Radiation Protection Act (1988:220), the Radiation Protection Ordinance (1988:293);

- the Civil Protection Act (2003:778), the Civil Protection Ordinance (2003:789) and
- the Emergency Preparedness and Heightened State of Alert Ordinance (2006:942).

However, the above mentioned documents do not mention clearly in detail the content of the operator's emergency plans.

SSM has established an inspection system that controls whether emergency preparedness and response arrangements are in place for nuclear facilities; however, there are no detailed guidelines that specify what an emergency plan should contain. Moreover, the emergency preparedness and response section of SSM carries out the inspections with a staff of approximately two inspectors for the three nuclear power plants including ten nuclear reactors, plus five other nuclear facilities, which makes the inspection frequency very low to cover all the nuclear facilities. For recommendation regarding resources for regulatory responsibilities see recommendation in section 3.3.

In the case of the facilities that handle radioactive materials, there are no inspectors within the emergency preparedness and response section; this area is subject to be inspected by the inspectors in the industrial and medical sections of SSM, but it is not part of their routine inspections. SSM does not apply the concept of threat categories in the legal framework to non-nuclear practices.

PSA results have very little, if any, influence on SSM's emergency preparedness. SSM's goal is to be able to handle all scenarios regardless of their expected frequency. There are no specific rules, in terms of probabilities, in the Swedish regulations dictating what events the emergency organization should be dimensioned for. However, there are continuous discussions at SSM on dimensioning scenarios. The utilities are in charge of performing probabilistic safety analysis (PSA level 1 and 2).

SSM along with the other Nordic countries Finland, Denmark, Norway and Iceland have a long established collaboration with emergency preparedness and response, the Nordic Emergency Preparedness (NEP). This includes sharing exercises and developing common early warning capabilities. This is manifested in the Nordic Manual, also called NorMan. Among other things NorMan contains detailed descriptions of notification procedures for different scenarios and a notification time of 30 minutes. The procedures are frequently tested in exercises, five times every year.

11.2. FUNCTIONAL REQUIREMENTS

Establishing Emergency Management and Operations

The establishment of emergency operations begins with the on-site response and gives rise to the local and national response to any nuclear or radiological emergency. (A general scheme of the alarm sequence for a nuclear power plant emergency can be seen in Fig. 2).

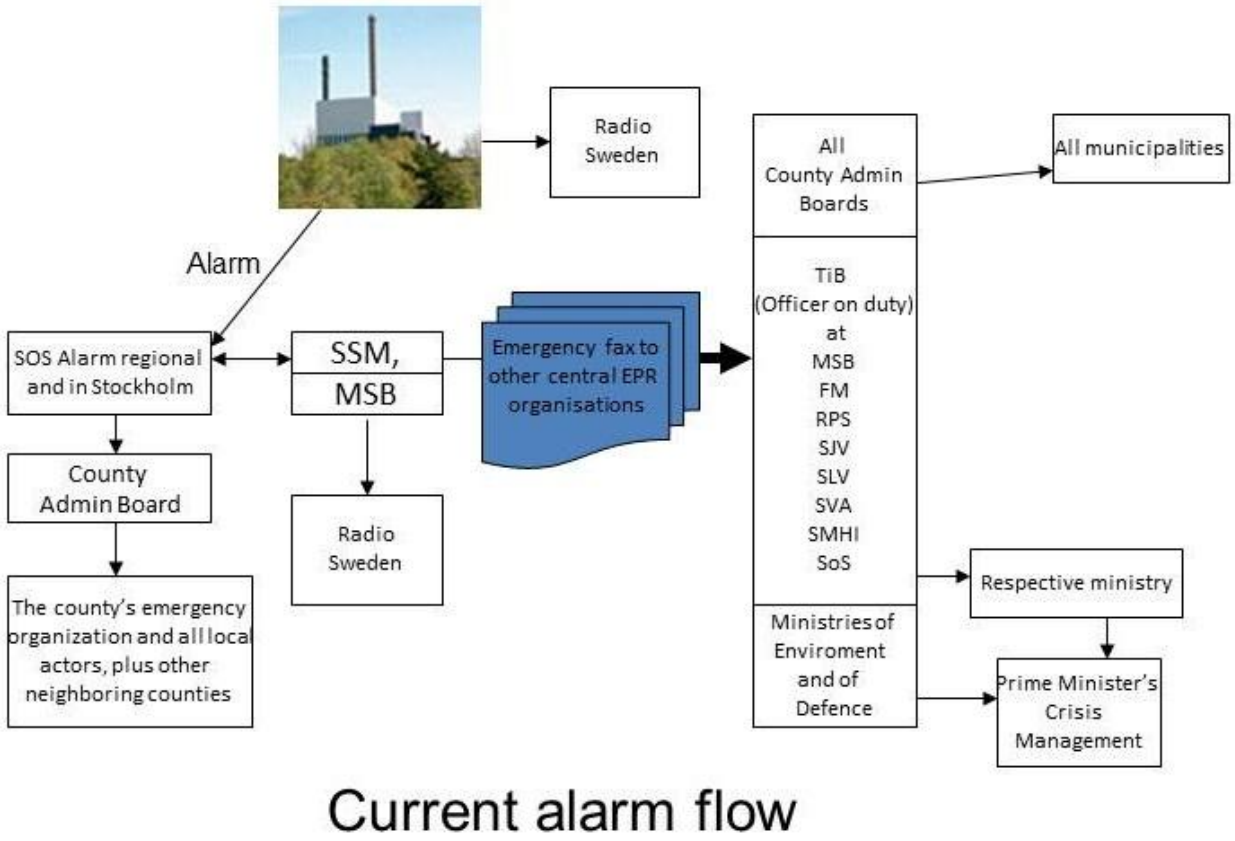

Figure 2

The responsibility for conducting the rescue operations lies with regional or local authorities. However, SSM has the responsibility for activating the national response. Among other things SSM alerts the government and central and regional authorities through a secure fax message. SSM activates and coordinates the national organization for expert support and also coordinates and assists responsible organizations with radiation protection assessments. During a crisis Swedish Civil Contingencies Agency (MSB) shall assist with resources and support the coordination between concerned authorities.

SSM's regulations specify that the operator of nuclear facilities shall deliver a source term early in an event. SSM is also responsible for assessing the source term independently to be used in SSM's analysis of the radiological consequences, however, the plant parameters that would provide the basis for the thorough assessment of the situation and the predictable accident progression and radionuclide release are not available on-line in the Emergency Response Centre of SSM.

According to the current distribution of roles and responsibilities the government has practically no role in the implementation of a response to the emergency situation. This stems from the concept of referring all response functions to the authorities (local, regional and national) and the autonomy of these authorities is traditionally well defined. However, the involvement of the national government in the coordination of handling the longer term consequences of a nuclear or radiological emergency may be necessary and a government level coordination body (committee, board etc.) may be needed to cope with the consequences of a severe emergency. In this context the establishment of a (currently non-existing) national radiation emergency response plan, which would describe the responsibilities and concepts of operation on governmental level, is highly recommended.

Identifying, Notifying and Activating

The Swedish Meteorological and Hydrological Institute (SMHI) serves as the contact point for early notification in the event of emergencies abroad (National Warning Point, NWP). However SMHI is instructed, through an agreement, to swiftly relay any incoming information of such kind to SSM which has the role of NCA (A, D). SMHI also relays the information to the national alarm central (SOS Alarm) who in turn pages the SSM Duty Officer. The Duty Officer can check the incoming notification using any internet connected device since the fax is converted to an e-mail by a fax gateway. Both SMHI and SOS Alarm are manned 24/7. SSM's Duty Officer is available 24/7.

In case of an emergency in a Swedish nuclear power plant the facility will immediately contact the national alarm center (SOS Alarm), who in turn will alert the authorities and organizations responsible for handling the situation. This includes the duty officer and the Emergency Preparedness Group at SSM (a group of approx. 30 experts with key positions in SSM's emergency organization).

In case of a radiological emergency in Sweden, the local rescue services are instructed to call the duty officer at SSM for advice. The duty officer will then decide if whole or part of the Emergency Preparedness Group should be activated to handle the situation.

Upon call, the Duty Officer will assess the information he/she receives and act in accordance. If it's deemed necessary, the Duty Officer will call in the Emergency Preparedness Group and depart to the Emergency Response Center. The Emergency Preparedness Group consists of some 30 persons holding key positions within the Emergency Response Organization. At the Emergency Response Center, the Duty Officer will together with members of the Emergency Preparedness Group follow checklists in place for the initial actions, such as initial assessment of the situation, calling in additional personnel if needed, establishing contact with collaborative actors, etc.

Most of the larger scrap metal melting facilities have radiation detectors at the entrance of their facilities. These facilities however are not subject to any radiological regulation, so the facilities perform radiation detection on their own to prevent any radioactive source melting. Monitoring at the borders to other EU countries and at international borders is not currently performed in Sweden unless there is evidence for suspected criminal acts. This can lead to the import of non-registered radioactive goods, radioactively contaminated material or smuggling of radioactive or nuclear materials.

SSM is not responsible for providing guidance to first responders. However, the responsible authorities in Sweden are expected, with the expert support of SSM, to provide such guidance to first responders.

Taking Mitigatory Actions

According to Ordinance (2008:452) with Instructions for the Swedish Radiation Safety Authority, SSM is responsible for coordinating actions needed to prevent, detect and identify events that can lead to harmful effects on humans or the environment in case of a nuclear or radiological emergency in or affecting Sweden. In particular, SSM shall give advice on radiation protection, protective measures and mitigation in case of a radiation emergency in Sweden or abroad that leads to the dispersion of radioactive material.

SSM is also responsible for organizing and maintaining a national expert response organisation that can be used for assistance in characterizing the situation in the event of nuclear or radiological emergency. The national expert response organization for nuclear and radiological emergencies consists of SSM's laboratory and nine other laboratories at other public authorities, universities and private companies. These laboratories are obliged through contract with SSM to maintain their own emergency preparedness organisation and to have equipment calibrated and ready to use. The organisation provides expert support for both field and laboratory measurements.

SSM is responsible for giving expert technical advice to the county administrative boards and other authorities who are involved in handling the consequences of an accident in a nuclear facility in Sweden or abroad. Specifically, SSM gives advice to the County Administration Board in the affected county on radiation measurements and also coordinate and assist in radiation protection assessments in case of emissions of radioactive materials from a nuclear facility.

According to Civil Protection Act (2003:778) on rescue services, SSM shall by law contribute with personnel and equipment in the event of a release of radioactive material from a nuclear facility that warrants urgent protective actions off the site unless the contribution of resources seriously endangers the possibilities for SSM to fulfil its ordinary obligations. SSM shall also, if requested by the responsible authority, give inform about available resources at SSM that can be used by the rescue services or during mitigation.

The laws and regulations specifying the above responsibilities are listed and elaborated on in the Questionnaire: Emergency Preparedness and Response which was a part of the SSM self-evaluation. SSM's responsibilities according to these laws and regulations are clarified through requirements in internal documents and instructions.

Taking Urgent Protective Action

This requirement of the GS-R-2 focuses on the priorities of radiation emergency preparedness and response. The priorities during response are life-saving, preventing the occurrence of severe deterministic effects and reasonably reducing the risk of stochastic effects. The main requirements for preparedness are associated with the facilitation of these response priorities, requiring that:

- The country adopts national intervention levels for taking urgent protective actions in accordance with the relevant international standards;
- Arrangements are in place for effectively making and implementing decisions on urgent protective actions to be taken off the site;
- Arrangements are in place to ensure the safety of all persons on the site in the event of a nuclear or radiological emergency.

SSM is responsible for developing national intervention levels. Other authorities who are directly responsible to take actions are responsible to adopt intervention levels. The county administrative boards, in the event of an emergency at a nuclear facility, are responsible for deciding and adopting the urgent protective actions that are possible considering radiological health risks, possibilities to implement the protective actions and financial cost and benefits as well as social costs and benefits. In this regard, SSM recommends the intervention levels, but these levels are not stated in any legal document. (For recommendation regarding clear guidance on intervention levels see Section 9.4.)

Providing Information and Issuing Instructions and Warnings to the Public

The arrangements to provide timely warning to the public living around a NPP are included in the emergency plans; the warning sirens are activated by the NPP, which is an outdoor warning system. The County Administration Boards are responsible for the operations of the siren network. The indoor warning system consists of a radio system (RDS) established specifically for emergencies.

Protecting Emergency Workers

SSM has adopted international recommendations on dose limitations for emergency workers in regulation SSMFS 2008:51 dealing with protection of occupational workers. The overall purpose of this regulation is protection of workers in activities with ionizing radiation and it is not fully developed for work in emergency situations. SSM has identified there is a further need for clarification regarding (This issue is partially covered in Section 12.1.3):

- the definition of emergency situations
- the classification and categorization of emergency workers
- how and in what situations incurred radiation doses should be monitored

SSM has no responsibility in managing radiation doses received by emergency workers during an intervention. This responsibility rests with the employers of the emergency workers (local rescue services and other operative authorities) through regulation SSMFS 2008:51.

It is always the employer of the emergency workers who is responsible for managing the radiation doses. In case of an accident in a nuclear power plant, the county administrative board has set up plans and preparations for dose monitoring that can be adopted by the local employers, like the rescue services. For other nuclear or radiological emergencies there is no, or very little, preparation of this kind. In case of nuclear power plants dosimeters are deployed at the entrance of the facility for the purpose of providing dosimetry service for the emergency workers arriving from outside.

Managing the medical response

The national medical expert team (N-MEG) gives medical advice to SSM and to the National Board of Health and Welfare. In Sweden N-MEG is maintained by the National Board of Health and Welfare and provides advice and information on radiation medical issues and takes part in the analysis of the situation made by SSM. The medical expert group has a workplace in the Emergency Response Centre at SSM.

At the national level, to provide initial treatment of people who have been exposed or contaminated, the regional medical centers will be activated to start giving these treatments according the County Administration Board's emergency plans. The Karolinska Institute has specially trained medical experts for difficult cases.

Keeping the public informed

The emergency organization at SSM includes a separate function for public information with the goal to make sure that the information is prompt, correct, and understandable. SSM will have close cooperation with MSB to issue information to the public. SSM also has around 15 persons with media training to be spokespersons during an emergency.

Taking agricultural countermeasures, countermeasures against ingestion and longer term protective actions

SSM will give the agricultural and food authorities advice on the values they should follow to take agricultural or food countermeasures. The Swedish agricultural and food authorities are responsible for regulating and deciding upon agricultural and food countermeasures.

11.3. REQUIREMENTS FOR INFRASTRUCTURE

SSM's Emergency Response Plan includes events at nuclear and radiological facilities (as outlined in Fig. 3). The Emergency Response Plan is subject to a QA program. The figure does not include the coordination they will have with other organizations.

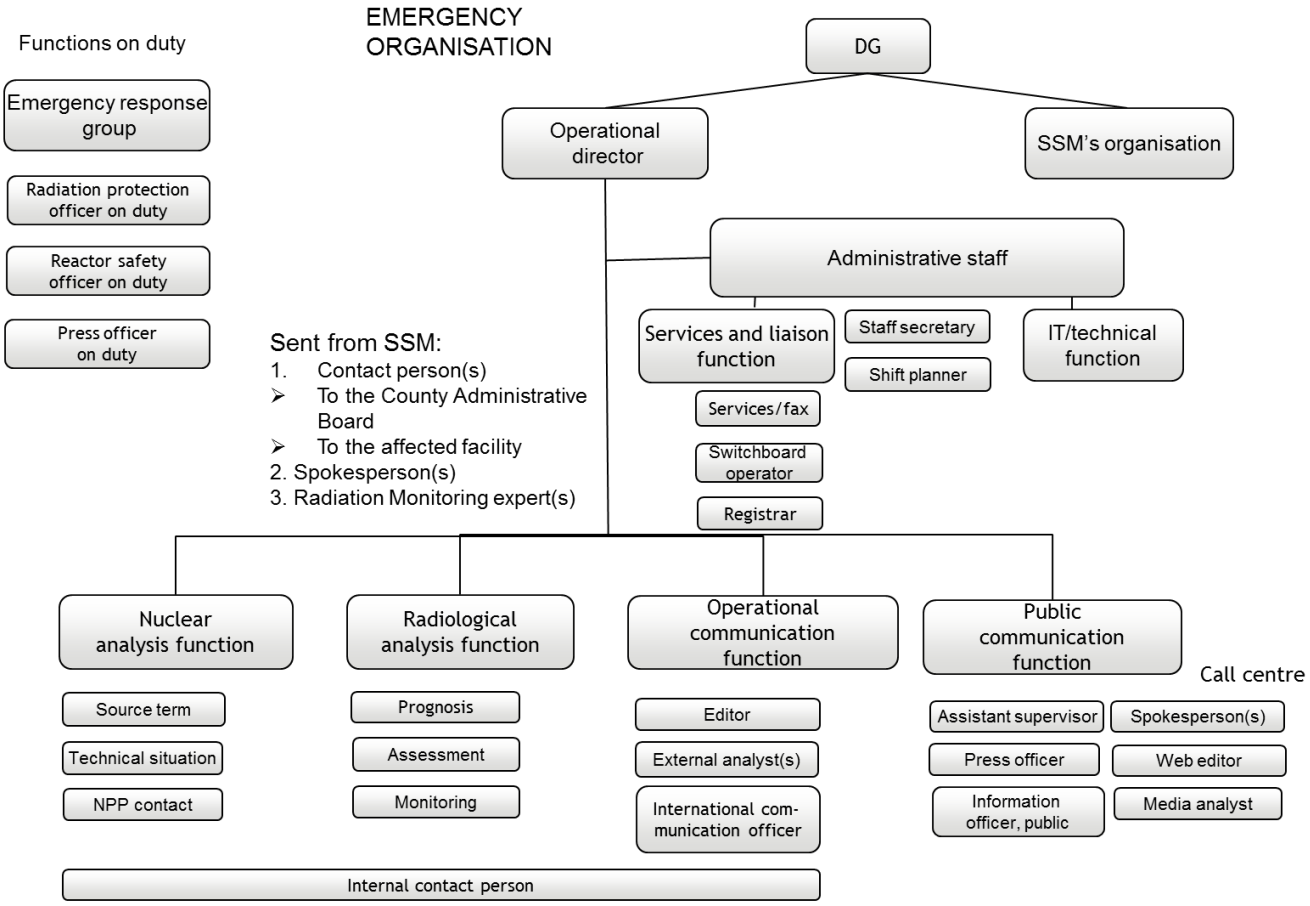

Figure 3

The authority's emergency plan describes the emergency organization appropriate for different nuclear or radiological events or accidents. Examples of possible exceptional situations are alert, site area emergency, and general emergency at Swedish nuclear power plants, situations at nuclear facilities that may cause the media to contact the authority, as well as incidents involving the handling of radioactive substances, such as transport, etc.

The plan describes the general guidelines for SSM's work, the responsibilities and mandates and related information and instructions for the various functions and groups in the emergency organization (STYR2011-54; STYR2011-26;29;65;70;113).

SSM activates and coordinates the national organization for expert support and also coordinates and assists responsible organizations with radiation protection assessments. Radiation monitoring is performed both by personnel at SSM and by personnel in laboratories within the national expert response organization. The instruments, tools and programs used for monitoring cover most types of monitoring equipment, ranging from simple dose rate meters to advanced high resolution gamma spectrometers, ICPMS equipment, whole-body counters etc. The instruments, methods and programs used in most cases comply with international standards in the area. Methods for monitoring are continuously developed.

There is a secure and protected Emergency Response Centre situated at the SSM site in Solna, Stockholm. The facility is protected both physically, through strong fortification, and also by an EMP (electromagnetic pulse) shield. The facility is designed to ensure an effective and sustainable management of the authority's emergency operations both in peacetime and during times of alert.

In addition to the Emergency Response Centre described above, the authority maintains a mobile Radiological Emergency and Assessment Centre (REAC) which can enable the emergency activities and analyses to be performed anywhere off-site. The REAC support system has a server hall in preparedness.

Every year an education and training plan is developed for the emergency organization. The plan is then implemented and is a part of SSM's yearly planning at the end of every year, called the yearly activity plan.

Since 2007 SSM conducts a large yearly field exercise for the national expert support organizations for nuclear and radiological emergencies as well as for instructors from first responders. The exercise goes under the name Lärmät and the scenarios have a focus on radiological accidents or malevolent use of radiation. The exercise provides an excellent opportunity to train cooperation between radiation experts and first responders.

During the IRRS mission SSM organized a table-top exercise, with the involvement of most of the major stakeholders being involved in a nuclear emergency response. The exercise was held 9 February in the premises of SSM. During the exercise SSM activated its Emergency Response Centre (ERC) and a separate room served as simulation cells of the other offsite emergency organizations. In the morning the IRRS mission team members observed the operations at the ERC that proved the high proficiency and full commitment of the SSM staff and of the excellent cooperation between the working groups (dose prognosis, communication to the public, IAEA accident notification, NPP accident assessment, among others), as well as between the responding organizations. It was observed that dose prognosis was made taking into account a pre-established source term for the NPP in which the simulated emergency was carried out (Oskarshamn), the IRRS mission members considered for a more accurate source term direct access to the NPP parameters should be available to SSM to perform its dose prognosis. The second part of the exercise was conducted in such a way that the participant organizations stated the actions after 2 weeks of the NPP accident. The different actors were asked about the activities they would carry out to cope with the consequences regarding their areas. It was observed during the discussions, that for that late phase of the emergency more involvement of the government is needed to coordinate the efforts of the different responding organizations.

The Authority has established an electronic quality assurance programme that builds upon the management system which is built on and coupled to the Authority's organization and gives an overall description of activities within the Authority. The management system with regards to the emergency preparedness activities is built up to support the necessary functions required, which are the functions related to both the preparedness and the response components of the emergency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1, Requirement8, paragraph 2.20 states that** *"The government shall make each authorized party responsible for preparing an emergency response plan and for making arrangements for emergency preparedness and response …. Emergency response arrangements shall include a clear assignment of responsibility for immediate notification of an emergency to the competent authorities. The regulatory body shall take account of the fact that, in an emergency, routine regulatory administration such as the issue of prior authorizations may need to be suspended in favour of a timely emergency response."*
(2)	**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*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	conventional emergencies. The arrangements shall be clearly documented and this documentation shall be made available to all relevant parties."
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.**
(1)	**BASIS: GS-R-2 Paragraph 4.3 states that** *"the off-site emergency response shall be effectively managed and co-ordinated with the on-site response"*
(2)	**BASIS: GS-G-2.1, Appendix VIII (Emergency Facilities and Locations) specifies certain requirements for facilities or location. More specifically in Table 15 (Descriptions of recommended emergency facilities and locations) it states that the Technical Support Centre should have the characteristics of** *"secure and reliable communications with the control room and outside sources of technical support; access to plant data, information and tools needed to develop strategies for dealing with major emergencies…"*
S10	**Suggestion: SSM should consider developing on-line, real-time access to NPPs operational and safety parameters.**
(1)	**BASIS: GS-R-2 Paragraph 3.20 states that** *"Large scrap metal processing facilities, national border crossings and abandoned military or other facilities where large sources may have been used should be considered in the threat assessment."*
(2)	**BASIS: Code of Conduct 13 (b) states that** *"Every State should encourage bodies and persons likely to encounter orphan sources during the course of their operations (such as scrap metal recyclers and customs posts) to implement appropriate monitoring programmes to detect such sources."*
(3)	**BASIS: Code of Conduct 20 (g) states that** *"Every State should ensure that the regulatory body established by its legislation has the authority to require those supplying or transferring radioactive sources or devices incorporating radioactive sources to provide the recipient with all relevant technical information to permit their safe and secure management."*
R18	**Recommendation: SSM and other relevant authorities should control the inadvertent and illicit trafficking of radioactive material through the national borders.**
(1)	**BASIS: GS-R-2 Paragraph 5.25 states that** *"Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as procedures, checklists, telephone numbers and manuals) shall be provided for performing the functions specified in Section 4. These items and facilities shall be selected or designed to be operational under the postulated conditions (such as the radiological, working and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	environmental conditions) that may be encountered in the emergency response, and to be compatible with other procedures and equipment for the response (such as the communication frequencies of other response organizations), as appropriate. These support items shall be located or provided in a manner that allows their effective use under postulated emergency conditions."
GP9	**Good Practice: SSM has established a state-of-the-art Emergency Response Centre, equipped with all necessary tools, procedures, as well as a national network of mobile and stationary laboratories to manage the emergency response.**
(1)	**BASIS: GS-R-2 Paragraph 3.1 states that** *"Despite all the precautions that are taken in the design and operation of nuclear facilities and the conduct of nuclear activities, there remains a possibility that a failure, an intentional act or an accident may give rise to a nuclear or radiological emergency. In some cases, this may give rise to exposure or the release of radioactive materials within facilities and/or into the public domain, which may necessitate emergency response actions. Such emergencies may include transport accidents. Adequate preparations shall be established and maintained at local and national levels and, where agreed between States, at the international level to respond to nuclear or radiological emergencies."*
GP10	**Good Practice: The regional cooperation initiative of the Nordic countries NEP is a good example of regional collaboration.**

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

12.1. OCCUPATIONAL RADIATION PROTECTION

12.1.1. Introduction

The Swedish Radiation Safety Authority resulted from the unification in 2008 of the two existing regulatory bodies, SKI and SSI. Regulations on occupational exposure developed by SSI have been kept and, for some of them, adapted/amended.

"The Swedish Radiation Safety's regulations concerning basic provisions for the protection of workers and the general public in practices involving ionizing radiation" (SSFMS:2008:51) completed by the SSFMS:2008:52 on Outside Workers, and "The Swedish Radiation Safety Authority's Regulations on Radiation Protection of Individuals Exposed to Ionizing Radiation at Nuclear Facilities (SSMFS 2008:26) are three of the main documents. With "The Act on Nuclear Activities" (1984:3) and "The Radiation Protection Act" (1988:220), they provide for the regulatory framework ensuring the Protection and Safety of Occupationally Exposed Workers". Additional documents such as "The Control of High Activity Sealed Radioactive Sources (SSMFS 2008:9), "The Swedish Radiation Safety Authority's Regulations on General obligations in Medical and Dental Practices using ionizing Radiation" (SSFMS 2008:35) address specific topics or areas.

This results in the existence of a high diversity of documents providing, for some of them, very detailed requirements and guidance for the implementation of the regulations. Examples may be found, among others, in the SSMFS 2008:51 (Appendix), in SSMFS 2008:24 (Regulations on Radiation Protection Managers at Nuclear Facilities) and in SSMFS 2008:29 (General Recommendations on the Competence of Radiation Protection Experts).

During the mission, meetings with counterpart, a visit to facilities and to special services at SSM provided the opportunity for clarifying some issues addressed in the Advanced Reference Material and for collecting additional information.

In particular, contact was made with three SSM staff members in order to be informed on the status of the National Dose Register. This register is intended to collect all the dose records on occupational exposure. A new system has been quite recently developed in order to increase the efficiency and the usefulness of the previous one. Dose records from nuclear facilities will be integrated in the system and will facilitate the management and the transfer of information, in particular for outside workers.

Taking the opportunity of an SSM inspection at the Karolinska Institutet on 2012-02-09, the IRRS team conducted a visit to the cyclotron facility as well as a meeting with the Head of the Dept. of Medical Physics at the Karolinska University Hospital – acting also as Radiation Protection Manager – and with the Radiation Protection Expert. Information was made available regarding the monitoring of the occupationally exposed workers. Discussions were also held with the SSM inspectors conducting this inspection.

Meetings with the counterpart at the SSM HQ were held in a way allowing detailed discussions or provisions of additional information. While most of the documents were available in English, translation was provided by the SSM staff members which significantly increased the understanding of the present status and perspectives concerning the control of occupational exposure.

12.1.2. Structure of the regulations on Occupational Exposure

Despite the high number of documents, the existence of advisory material and general advices and the global compliance with the IAEA's Standards on Occupational Exposure, there is a need to develop a new

structure of the regulations which should be based, in a first step, on a document establishing the overarching requirements on the protection and safety of occupationally exposed workers for all activities where ionizing radiation are used and/or produced. Clear reference to - or additional requirements from - other legislation covering some aspects of the work environment and health issues could be advantageously added or referred to at this level.

Existing guidance material and general advices should be kept in the new structure and updating of them is advised.

SSM is aware of the need for improving its regulations and a proposal for "merging" the Radiation Protection Act and the Act on Nuclear Activities was planned and is still in progress. SSM should consider the need for making resources available in order to proceed to the development of the new structure for the radiation safety regulations. This should be done within a period of time to be defined taking into account that SSM is not the "acting" body as far as the development of Acts is concerned.

Moreover, the preliminary action plan established by SSM and based on the results of the Self-Assessment Tool illustrates the commitment of the Swedish Regulatory Safety Agency to proceed to the establishment of the new structure of its regulations. The actions identified by SSM in this preliminary plan should be considered in addition to the recommendations and suggestions provided in this report.

In order to assess the level of efficiency of the new structure of the regulations concerning the occupational exposure, advantage could be taken from existing assessment tools such as the Occupational Radiation Protection Appraisal Service developed by the IAEA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based."*
GP11	**Good Practice: The provision of guidance material for specific areas where ionizing radiations are used and/or produced as well as the identification of actions to be undertaken for improving the regulations on the protection and the safety of workers is acknowledged as a positive indicator of a high level of commitment from SSM in order to foster the implementation of the regulations concerning the occupational exposure.**
GP12	**Good Practice: As well for the nuclear as for the non-nuclear activities, the requirements for identifying Radiation Protection Experts and the guidance material concerning their training and competence is acknowledged and efforts for maintaining such level of supporting material are encouraged.**
(1)	**BASIS: GSR Part 1 Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and international peer reviews, and promote international cooperation to enhance safety globally".*
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.**

12.1.3. Arrangement under the Radiation Protection Programme

The implementation of a radiation protection programme for nuclear facilities and non-nuclear activities is based on the setup of several organisational and technical measures. These are provided in the regulations such as the "The Swedish Radiation Safety's regulations concerning basic provisions for the protection of workers and the general public in practices involving ionizing radiation" (SSMFS 2008:51).

There is no requirement for considering the description of the radiation protection programme as part of the licensing process. SSM should make provision in order to clearly specify that each application for a license has to be supported by a clear evidence of existing provision for such radiation protection programme (see Section 9.4).

In SSM Internal Regulations, Document Number 6, Version V3,"Description of Radiation Protection Work and Radiation Protection Organisation at Radiation Safety: Radiation Work at Radiation Safety Authority (SSM)" includes organisation's own activities with ionizing radiation. It is stated that "The Authority should lead by example in terms of radiation protection work and actively promote good internal radiation protection culture".

Moreover, guidance on SSM staff's categorization as occupationally exposed workers is provided as follows:

- Staff having access to nuclear facility must belong to Category A;
- Staff operating in facilities with high activity sources must belong to Category A;
- Staff operating in a serious radiological event should belong to Category A;
- Staff operating in non-nuclear facilities with gamma radiation would normally belong to Category B;
- Inspectors performing their tasks at licensees sites where ionizing radiation are used/produced should belong to Category B;
- Other staff are not covered by regulations on categorization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: Code of Conduct on the Safety and Security of Radioactive Sources par. 22 (d) states that** *"Every State should ensure that its regulatory body promotes the establishment of a safety culture among all individuals and in all bodies involved in the management of radioactive sources."*
(2)	**BASIS: GSR Part 3 Par 3.100 states that** *"For any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible."*
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.**
(1)	**BASIS: GSR Part 3 Requirement 24:** *"Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure".*
S13	**Suggestion: SSM should consider checking, within a defined period of time, the**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	implementation by all licensees of a radiation protection programme.

The "Swedish Radiation Safety Authority's Regulations on General Obligations in Medical and Dental Practices using Ionising Radiation" (SSFMS:2008:35) in its Section 2 defines the medical exposure as the exposure to ionising radiation of: 1) patients undergoing examinations or treatments; 2) individuals as part of occupational surveillance; 3) individuals as part of health screening programmes; 4) individuals participating in research programmes; 5) living individuals in legal investigations; or 6) individuals for insurance purposes. Requirements for protection and safety of exposed workers are dealt with by the regulations. SSM considers human imaging for purposes other than medical diagnosis, treatment or biomedical research under medical exposure control.

12.1.4. Compliance by workers

SSM requirements may only be imposed on licensees by means of regulations and licence conditions. However, the Radiation Protection Act provides many requirements regarding compliance by workers:

- Section 7: "A party conducting activities involving radiation shall ensure that those who are engaged in the operation are thoroughly aware of the circumstances, conditions and regulations under which the activity is conducted and are informed of the risks that may be associated with the activity. A party conducting such activities shall ensure that those who are engaged in the operation have the requisite training and are aware of the measures that need to be taken to ensure sound radiation protection;
- Section 7a: "The obligations under Sections 6 and 7 also encompass those who, without conducting activities involving radiation, engage a person to perform work where such activity is being conducted. These obligations apply to the extent necessary to ensure protection of persons performing such work against harmful effects of radiation".
- Section 8: "Persons engaged in activities involving radiation, or performing work where such activity is being conducted, shall use the necessary safety equipment and take other measures that are required to ensure sound radiation protection".

The responsibilities of the workers concerning the protection and safety in general is addressed in the Work Environment Act with commentary as worded on 15th February 2010, Comments on Chapter 3, "Working environment also the employees' responsibility" in the paragraph "Responsibility for the working environment is also imposed on employees". SSM should consider taking this requirement in a more explicit way in its regulations (see Section 9.4 of this report). It is also advised to update the inspection check lists in order to verify workers' awareness on this requirement.

12.1.5. Conditions of service

Existing SSM regulations on the protection and safety of occupationally exposed workers don't fully comply with the requirement 27 of GSR Part 3 which states that "*The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements, or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be used as substitutes for measures for protection and safety in accordance with the requirements of these Standards*".

As this issue is also not addressed in The Work Environment Act with commentary as worded on the 15th February 2010, it is recommended that SSM makes clear provision in its regulations (see Section 9.4.).

12.1.6. Radiation Protection Experts/Officers

SSM regulations provide for requirements regarding the need for licensees to make use of Radiation Protection Experts (RPE). Both for the Radiation Protection Expert in Nuclear Facilities and for the Competence of Radiation Protection Expert, regulations and recommendations have been issued by SSM (SSMFS 2008:24 and SSMFS 2008:29) in compliance with the GSR Part 1 and Part 3 requirements as indicated here above. In particular, for nuclear facilities and non-nuclear facilities (except for Medical Physicists), both the contents of the training and the recognition of the RPE by SSM is clearly required in the existing regulations. Additional documents such as SSMFS 2008:25 (Open Radiography), SSFMS 2008:27 (Accelerators) and SSFMS 2008:28 (Open Sources) are relevant documents for specific areas.

In the nuclear facilities, in addition to the RPE, Radiation Protection Officers belonging to the licensee's staff perform tasks related to protection and safety on the workplaces. There is no direct relation between the RPE and the RPO's. The RPE is totally independent from the production departments and advises the manager of the plant. There is some plan for changing this situation but no decision has been made up to now. The regulations don't provide requirement or guidance on such potential re-organization and on the role and responsibilities of these workers acting as RPE or RPO.

For non-nuclear activities, requirements on the need for making an RPE available are provided. For example, in the "Industrial Radiography Area", RPE are mandatory and need to be approved by SSM. They may belong or not to the company. There are, at the time of the mission, 20 licensees and five RPEs are acting for them. For other activities such as practices with open sources, veterinarian activities, accelerators and practices involving radiation sources with very high activity, specific conditions are set up in the regulations (taking into account activities of the radionuclides for example).

Concerning Medical Physicists, taking into account GSR Part 3, Requirement35, " Responsibilities of the regulatory body specific to medical exposure" which mentions that *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they meet the requirements for education, training and competence in the relevant specialty",* it has to be noted that SSM is not empowered for the definition of the contents of the training nor for the formal recognition of the Medical Physicists as these actions are done by the National Board of Health and Welfare. As the Medical Physicists "shall serve as the licence holder's qualified expert in matter related to radiation protection" (SSMFS 2008:35), provisions should be made in the legislation for empowering SSM in order to ensure compliance with the IAEA Standards (see Section 9.4.).

For the sake of consistency and efficiency, it is advised that SSM provides guidance on the responsibilities and the role of the RPE as well as of the RPO for all facilities and activities where ionizing radiations are used or produced (see Section 9.4.).

12.2. CONTROL OF RADIOACTIVE DISCARGES, MATERIALS FOR CLEARANCE AND ENVIRONMENTAL MONITORING

At the beginning of 2012 a new regulation concerning materials for clearance entered into force (SSMFS 2011:2). This regulation includes all materials, rooms, buildings and land in practices with ionizing radiation except natural occurring radioactive substances. If contaminated rooms, buildings, land and materials of more than 100 t/y by one licensee should be cleared, SSM is always included in the clearance process as an active partner, but the responsibility for clearance remains with the licensee.

Regarding the discharges of radioactive substances from nuclear facilities into the environment SSM has implemented a low dose constraint according to the requirements of IAEA BSS. Both for nuclear and non-nuclear facilities the limitation of the discharges is based on optimization of radiation protection using the best available technology. Dose calculations are carried out only by the licensee and, if a calculated effective dose is higher than a tenth of the stipulated dose constraint, more realistic calculations

have to be performed.

Monitoring and measurements for discharges of radioactive substances from nuclear facilities are performed by the licensee; however, in case of non-nuclear facilities monitoring is not mandatory. The results of the measurements are submitted to SSM for review and reported to EU, the Oslo-Paris Convention (OSPAR), and the Helsinki Convention (HELCOM). SSM regularly carries out control measurements of the radioactive discharges and inspects the nuclear and non-nuclear facilities. In addition the licensees of the nuclear facilities and SSM meet twice a year to discuss issues of interest.

A specific environmental monitoring program is established for each nuclear facility in normal operation and will be adapted by SSM if the facility is in shutdown or in decommissioning. The program is carried out by the licensee according to a basic and an intensive program and encompasses the terrestrial and the marine environment. Intensive program in this case means an extension of the basic program in the marine environment and is performed every four years. The results of the measurements are reviewed by SSM and reported to OSPAR and HELCOM. Control measurements are carried out by independent laboratories designated by SSM. Non-nuclear facilities are exempted from environmental monitoring program due to the magnitude of their sources.

SSM describes the performance of control measurements mentioned above in its internal regulations (STYR-documents), but with the exception of liquid discharges the control measurements are not clearly stipulated in the regulation SSMFS 2008:23 (see Section 9.4.).

Monitoring of gamma radiation in the vicinity of the nuclear facilities is performed by the operators and reported twice a year to SSM. This monitoring is not a part of the Swedish automatic gamma-monitoring system operated by SSM. In addition the Swedish communities are also able to carry out measurements of gamma radiation with hand-held systems.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Paragraph 3.137 states that** *"registrants and licensees shall, as appropriate, verify the adequacy of the assumptions made for the assessment of public exposure and radiological environmental impacts."*
S14	**Suggestion: SSM should consider ensuring that the registrants and licensees verify the adequacy of assumptions used in site specific dose assessment models.**
(2)	**BASIS: RS-G-1.8 Paragraph 5.25 states that** *"The design of an environmental monitoring programme should be consistent with the objectives of monitoring. ... Measurements should be made and sampling carried out at appropriate locations accessible to the public outside the operations boundary of the facility. "*
S15	**Suggestion: SSM should consider extending the national gamma monitoring system for gamma monitoring stations near nuclear facilities.**

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

The responsibilities related to radon exposures are divided among several authorities: SSM, the Swedish National Board of Housing, Building and Planning, The National Board of Health and Welfare, the Swedish Work Environment Authority, the Geological Survey of Sweden, the National Food Administration, the county council and the municipalities. A working group with representatives from the

responsible authorities meet at least twice a year to discuss issues of interest related to radon.

SSM is the expert authority concerning radon exposure. The main responsibilities of the authority are risk estimation and measuring technology. SSM is the operator of the national calibration laboratory for radon instrumentation and finances research projects as a way to follow development in health risk analysis. Other roles of SSM include information and education. In addition SSM designs and provides training programs to different target groups.

Concerning natural occurring radioactive materials (NORM) SSM carried out a survey in identifying NORM industries. During this survey measurements a few inspections were made to sites working with NORM that had not been investigated earlier, for the purpose of performing measurements and looking into the management of NORM. A new regulation exempts natural occurring radioactive materials in specified cases from the Radiation Protection Act (SSMFS 2011:4); furthermore NORM should be disposed on landfills or can be reused for backfilling of roads and land in certain cases.

The legal framework concerning remediation of contaminated areas is the Radiation Protection Act, the Act on Nuclear Activities and the Environmental Code. Potentially contaminated areas are identified, investigated and classified regarding mainly non-radiological impacts, but no area have been identified for remediation in respect of radioactive substances by the responsible County Administrative Boards. However the identification of potentially contaminated areas is still an on-going process. Generic remediation strategies and remediation plans in cases of nuclear incidents are already described in a handbook developed by experts from the former Swedish Rescue Services Agency, the former Swedish Radiation Protection Institute and the Swedish Board of Agriculture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3, Requirement 47 states that** *"the government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."*
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.**

12.4. WASTE MANAGEMENT

With a national plan for waste management, an overall policy and strategy for the disposal of all types of waste is achieved. This creates a foundation and a direction for continued work and facilitates the management of specific waste streams.

Requirements for the management of waste coming from nuclear power plants are regulated through the Act on Nuclear Activities and the radiation Protection Act. The Act on Nuclear Activities states that the nuclear industry must present a programme every three years which describes the waste management plan and provides details of research, development and demonstration (the RD&D programme) relating to waste management. SKB every three years submits a RD&D programme to SSM for their evaluation. SSM comments on it and eventually submits its statement to the government. There is also a system to provide sufficient financial resources for waste management through the Financing Act and the Studsvik Act. The Swedish nuclear power companies established SKB with the assignment to dispose radioactive waste from NPP.

Independently from that programme, the Swedish Government gave the former Swedish Radiation

Protection Authority (SSI) the assignment of establishing a national plan for all radioactive waste (2008). The first plan was elaborated in 2009 and SSM proposed a revision of it every three years. The first version of the plan focuses on the management of the radioactive waste generated outside the nuclear fuel cycle. A revision of this national plan will be elaborated for 2013.

The scope of this waste management plan for non-nuclear waste includes the management of disused radioactive sources. In general, disused radioactive sources which are not returned to the manufacturer are transferred to Studsvik, a private waste management facility. Also orphan sources found are usually delivered to Studsvik. However, there are some radioactive sources and waste in licensees' premises which cannot be returned back to the manufacturer, nor transferred to Studsvik because they do not comply with Studsvik acceptance criteria for storage and disposal. Same applies also to some orphan sources. This issue has been identified in the waste management plan, but as of today there is no plan in place for the final management of the sources or the waste.

The main driver for the merger of the former regulatory authorities, SKI and SSI, was to strengthen the supervision of nuclear and non-nuclear activities. The elaboration of the first version of the national waste management plan met in time with the process of merging, during the establishment of the new authority. The next revision, to be elaborated during 2013, will be performed by a stronger and more consolidated and established regulatory body, which means that there will be better conditions for an integration of the strategies for nuclear and non-nuclear wastes. The authority will also be in a better position to elaborate and put forward the key aspects of the regulatory safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1. Requirement 1 states that** *"National policy and strategy for safety. The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals"*
S17	**Suggestion: The government should consider assigning SSM to review and integrate the national waste management policy and strategy plan.**

12.4.1 Low and Intermediate Level Waste

The regulatory framework is well developed. Under the Act on Nuclear Activities and the Radiation Protection Act, SSM is authorised to issue regulations concerning safety and radiation protection. Based either on safety importance or on risk of a facility, part of the facility, a system or an activity, SSM applies a graded approach for the authorisations and licensing.

For the control of waste generation, SSM has issued the regulation SSM FS 2008:1, which establishes the requirement for the elaboration of an inventory of waste and the confinement of the waste that is handled, processed, stored or disposed of at the facility in a safe manner.

The necessary preparatory measures shall be taken at the facility for a safe confinement of the waste in connection with transport for storage or disposal in another facility. Measures required are specified in the safety analysis report, in accordance with SSM FS 2008:1 Chapter 4.2.

The aim defined for the regulation SSM FS 2008:22 on the "Handling of radioactive waste and nuclear waste at nuclear facilities" is to ensure that radioactive waste and nuclear waste are handled in a satisfactory way and to establish conditions for limiting the amount of waste. However, the requirements

in the regulation do not complete the defined scope, as it does not establish the conditions for the limitation of the amount of waste. The recently decided revision of chapter 6 in the regulation SSMFS 2008:1, accounts for limitation of waste amounts and will enter into force at the first of November 2012 for LILW arising from nuclear facilities.

In relation with the storage facilities, the existing regulations do not explicitly require that monitoring, inspections and maintenance to be performed specifically for stored waste. However, there are general requirements on such measures, and they are relevant also for stored waste (SSM FS 2008:1, Ch. 5, 3 § together with Ch. 3.1 §). SSM has amended these deficiencies in the regulations by the revision of SSM FS 2008:1 that will enter into force in November 2012.

For non-nuclear activities there are requirements in several regulations on how radioactive waste should be stored on site. Although the purpose is not explicitly to make sure that the waste can be inspected and monitored, the requirements facilitate inspections, monitoring and maintenance. These requirements can be found in: SSMFS2008:28, 30-34§§; SSM 2008:27, 17-19 §§; SSM 2008:33, 28 §; SSMFS 2008:40, 20-22 §§; SSM 2008:47, 12 §; SSMFS 2010:2, 12-16 §§. Recommendation in this respect is included in section 9.

Most of the LILW are conditioned at the point of origin, in the reactor sites. Some wastes from NPP are sent to Studsvik for treatment being incinerated or melted. Studsvik does the treatment and conditioning of its own waste and some of the waste generated in hospitals, research institutions and industry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: SF Paragraph 3.29 states that** *"Radioactive waste must be managed in such a way as to avoid imposing an undue burden on future generations; that is, the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long term management. The generation of radioactive waste must be kept to the minimum practicable level by means of appropriate design measures and procedures, such as the recycling and reuse of material"*
(2)	**BASIS: GSR Part 5 Requirement 8 states that** *"All radioactive waste shall be identified and controlled. Radioactive waste arising shall be kept to the minimum practicable. (...) 4.6. Measures to control the generation of radioactive waste, in terms of both volume and radioactivity content, have to be considered before the construction of a facility, beginning with the design phase, and throughout the lifetime of the facility, in the selection of the materials used for its construction, and in the control of the materials and the selection of the processes, equipment and procedures used throughout its operation and decommissioning. The control measures are generally applied in the following order: reduce waste generation, reuse items as originally intended, recycle materials and, finally, consider disposal as waste".*
R19	**Recommendation: SSM should make explicit in the regulations the principle for minimizing the amount of waste produced in non-nuclear practice.**

Three different licenses are required for a nuclear facility: a permit under the Environmental Code, a licence under the Act on Nuclear Activities and a building permit under the Planning and Building Act. Licensing under the Environmental Code and the Act on Nuclear Activities run in parallel.

The general regulation for safety SSM FS 2008:1 applies to the operation of all types of nuclear installations, including facilities for waste treatment, storage and disposal except shallow land disposal

facilities. The regulation requires the elaboration of a safety analysis before a facility is constructed. A preliminary safety report before the facility is constructed shall be updated after trial operation and subsequently kept up-to-date. In the updating the safety report shall reflect the plant as built. A periodic safety review shall be performed by the operator of the disposal facility every ten years, and submitted to SSM.

The regulations SSMFS 2008:21 and SSM FS 2008: 37 concern long term safety of disposal facilities. According to them, the safety assessment for a disposal facility shall cover also features, events and processes that can lead to the dispersion of radionuclides disposed in the facility after closure.

All types of wastes must be approved by SSM before disposal. Compliance with regulations and with the approved Waste Type Description (WTD) of the waste generated in done by inspections both to the waste producer and the operator of the Swedish repository for low and intermediate level waste at Forsmark (SFR) and the shallow land burial facilities. Historical waste are varying with regards to categorization, measurements accuracy and conditioning. Most of these wastes are managed at the Studsvik facilities. The waste acceptance process for these historical wastes is being done on a case by case basis as the final packages must fit the disposal options.

The existing facilities and practices for final waste disposal for each waste category are:

- Cleared waste can be deposited on municipal disposal sites.
- Four shallow land burial facilities are licenced for disposal of short-lived low-level waste. Licensing of these facilities follows the Nuclear Activities Act, and the conditions of the licence give the scope for operations, including the requirement for the licensee to establish access control and control of releases for these facilities for a period of up to 30 years after closure. After this period of 30 years, control on the site will be only under the legislation for conventional waste disposal.
- SFR is the licensed disposal facility for LILW resulting from the operation of NPPs. In addition, wastes from Studsvik, hospitals, research institutions and industry can also be disposed of by means of a civil law agreement between SKB and Studsvik.

There are planned activities to allow for the disposal of other waste categories. The application by SKB for extension of the capacity of SFR for both operational and decommissioning waste is planned for 2013.

Another facility is planned for disposal of long-lived low and intermediate level waste (SFL). The first step is expected to be the development and evaluation of conceptual designs and foreseeable geological environments. According to a recent Government decision, the NPP owners and SKB will start regular consultations with SSM with regards to this process. The goal is for SKB according to the RD&D programme is to present their conceptual designs and preliminary safety assessments for the different options in 2016.

The review and assessment of the applications by SSM for these facilities will require similar skills of expertise and they may coincide in time as well as further regulatory activities such as inspections. SSM should consider the planning to ensure staff competences and enough number of staff available for the forthcoming activities. Recommendation with this respect is included in section 3.

12.4.2 High Level Waste Disposal

The legislation and regulatory framework for high level waste disposal is well established in Sweden. The framework provides the formal basis for the review of a high level waste disposal facility in a stepwise approach with consideration of stakeholder input and independent outside reviews at appropriate and key steps. The major steps to occur over a 60 year period are (1) license to construct, possess and operate (SKB's license application is currently under review by SSM); (2)permit to start the actual

construction; (3) permit to test operations; (4) permit for routine operations; and (5) license for closure, which represents the final licensing decision for the repository and provides for the termination of the operator obligations with respect to the Act on Nuclear Activities (General recommendations on Section 1 in SKI FS 2002:1 [SSM FS 2008:21, which is only available in Swedish, replaced SKI FS 2002:1 in 2008 with identical technical requirements and advice]). The licensing review is carried out in two parallel processes according to the Act on Nuclear Activities (e.g., SSM review of application for repository) and the Environmental Code (SSM acts as a review body to the Environmental Court on the safety and radiological protection aspects of the Environmental Impacts Assessment). The Radiation Protection Acts provides the basic requirements and principles for radiation protection.

Every three years, SKB prepares an updated Research, Development and Demonstration (RD&D) Report (the demonstration portion of the report was added beginning in 1992) that describes the programme for management of nuclear waste and the research needed to support the development of the repository. The RD&D Reports are submitted to SSM for review, evaluation and public consultation. Based on SSM's recommendations, the Government approves or disapproves the general direction of the RD&D program. Public consultation is an important consideration for SSM and the Government decisions. Additionally, a Cost Calculation Report is submitted every three years that presents estimates for the financial resources necessary to complete the development of the repository up till the time of closure. SSM and the government review SKB's reports and provide comments to SKB to ensure regulator and government concerns are appropriately reflected in SKB plans and the government can ensure that fees to the waste fund are consistent with anticipated costs and adjust the fees accordingly.

According to the Environmental Code a prospective licensee is required to submit an Environmental Impact Statement. This statement must contain a plan for the formal process on consultation with stakeholders. SKB's formal consultation for a final high level waste repository started in 2002 and ended in 2010. Consultations provided an opportunity for a number of stakeholders to participate in the decision-making process on local, regional, and the state level, including politicians and interest groups. Local municipalities and environmental non-government organizations (NGOs) receive special funding from the waste fund to be able to effectively participate in the consultations and licensing process. Many of the stakeholders have been involved in the public consultations on the RD&D program since the 1980s.

The Swedish approach for public participation and stakeholder consultations represents an excellent approach for building trust in the Swedish high level waste management system, as well as the integrity of the regulator.

Observations and Conclusions on Assuring Resources over Repository Operational Lifecycle

SSM, SKB and the government understand that the time period to operate and close a repository is long and attention is needed to ensure the appropriate resources are available over the operational lifetime of the repository (e.g. on the order of 50 years). The reconsideration of the resources every three years by SKB, SSM, and the government provides an excellent approach for ensuring resources are appropriate for the identified research needs and for the lifetime of the project, including regulatory reviews and maintenance of competencies. SSM's proposal for future contributions to the waste fund is based both on the SKB cost calculation and SKB's Research, Development and Demonstration Programme that presents a basis and direction for future research needs. Contributions to the waste fund were recently increased as a result of this process. SSM and government reviews can provide further direction and comment on the needed research.

The five key steps in Sweden's stepwise approach enumerated above will occur over approximately 60 years, however, there is no indication of the approximate duration expected for regulatory reviews. Development of precise timelines for the regulatory review would not be justified because the actual time for reviews will be driven by the complexity of the technical issues and uncertainties, however, the lack of

any discussion in legislation or internal guidance documents regarding time expectations for regulatory reviews could lead to differing expectations between SSM, SKB, the government, and other stakeholders. To ensure that all parties have a common understanding and expectations for the completion of the licensing review currently underway, SSM could initiate discussions with representatives from the government and SKB. These discussions would also provide a means of informing other stakeholders, including the local municipalities at Forsmark and Oskarshamn, of expectations for the review.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: SSR-5 Requirement 1 states that** *"The government responsibilities include securing of financial and other resources."*
GP13	**Good Practice: Financial resources are evaluated periodically (e.g., every three years) by SKB, SSM and the government to ensure financial resources are sufficient and consistent with the technical work needed to develop the repository and demonstrate its safety, including resources for regulatory review. The Swedish approach for public participation and stakeholder consultations regarding the RD&D programs and environmental impact assessments represents an excellent approach for building trust in the Swedish high level waste management system, as well as the integrity of the regulator.**

Preparations for Safety Reviews

Over the past 30 years the Swedish Radiation Safety Authority (SSM) and its predecessors have spent significant time developing its competencies for reviewing repository especially the evaluation of post closure safety for this first of a kind facility that is evaluated for potentially hundreds of thousands of years. In particular, SSM and its predecessors have reviewed all of SKB's preliminary safety assessments (SKI, 1984 and 1992, SKI and SSI, 2001 and 2008) for the geological repository. Additionally, the former authority (the Swedish Nuclear Power Inspectorate – SKI) also completed two safety assessment projects in the 1990s, Project-90 (SKI, 1991) and Site-94 (SKI 1996). Over this time period SSM has used the experience gained with safety assessments to enhance and clarify the regulations and guidance for the long term safety assessments.

SSI FS 2005:5 (SSM FS 2008:37, which is only available in Swedish, replaced SSI FS 2005:5 in 2008 with identical technical requirements and advice) provides a number of specifications to assist the development of the safety assessment for the post-closure safety such as: (1) future biosphere conditions, (2) handling of future climate evolution, and (3) inadvertent human intrusion. Other portions of SSI-FS 2005:5 provide guidance on the how the safety assessment is to be used at different time periods and the use of the safety assessment to improve understanding of repository performance:

- the first thousand years is the approximate time for which risk analyses can be carried out with high credibility with respect to factors such as climatic and biosphere conditions
- up to one hundred thousand years supplementary indicators of the repository performance should be used to provide further confidence in the calculated risks,
- in addition to risk calculations, after one hundred thousand years the safety assessment should be used to illustrate the long term behaviour of the repository's barriers functions and the importance of major external disturbances (e.g., earthquakes and glaciations), and
- separate analyses that evaluate the loss of one or more barrier functions after closure with the intention to demonstrate how the different barriers contribute to repository safety.

Regulations and guidance for the pre-closure safety assessment at SSMFS 2008:1, while not containing as much detail as is provided for the post-closure assessment, provide the same general approach. In particular, Chapter 4, Section 1 of SSMFS 2008:1 states:

"The safety analyses shall be based on a systematic inventory of events, event sequences and conditions which can lead to a radiological accident. Such events, sequences and conditions that have been identified are to be broken down into event classes. For each event class, quantitative analyses are to demonstrate that limits applying to barriers are maintained and that a radiological impact on the environment is acceptable in relation to the limits stated under the Radiation Protection Act (1988:220)."

Section 10a of the Act on Nuclear Activities requires safety assessments needs to be updated every 10 year to account for developments in science and technology. Additionally, the safety assessments for the long term safety are expected to be submitted before construction, operations, and closure.

SSM has set up four sub-projects to cover the safety review of the repository and the encapsulation plant, namely sub-projects for: post-closure repository safety, operational or pre-closure repository safety, encapsulation plant, and repository system. SSM's Post-Closure Safety Review Program Plan describes a Safety Integration Review Team to manage the information flow with respect to cross-boundary issues that need to be covered by the different sub-projects. Such an approach was set-up to ensure that the safety review appropriately considered the "connections" between different activities (e.g., operational activities, encapsulation activities) and post-closure safety.

Observations and Conclusions for SSM Preparations for Safety Reviews

SSM has devoted significant time and resources over the past 30 years to develop staff competencies for the review of the long term safety case. As described above, the SSM effort has resulted in appropriate detail in regulations and guidance with respect key areas of the safety assessment. SSM has also developed safety assessment models, which are independent from those used by SKB, that provide review tools for SSM staff to independently audit the calculations in SKB's license application. SSM focus, consistent with the IAEA's safety requirements for geological disposal at SSR-5, is on assuring the long term safety. SSM's Safety Integration Review Team serves a very useful function of ensuring key aspects of long term safety are not adversely impacted by other activities (e.g., operational safety, closure of repository).

SSM has not spent as much time developing independent review methods for the operational period, in part, due to the similarity of certain aspects of activities at other nuclear facilities and the repository (e.g., heavy lifting by cranes). However, the repository is a first-of-a-kind facility and despite similarities in operations there will be a number of considerations that are unique to the repository (e.g., heavy lifting deep underground versus heavy lifting in a surface facility). SSM should consider how best to increase staff competencies in the operational activities of the review as was done for the long term safety assessment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: SSR-5 Requirement 4 states that** *"Throughout the process of development and operation of a disposal facility for radioactive waste, an understanding of the relevance and the implications for safety of the available options for the facility shall be developed by the operator. This is for the purpose of providing an optimized level of safety in the operational stage and after closure."*
GP14	**Good Practice: SSM established a review team to ensure potential impacts to post-closure safety are considered across all operational activities (e.g., monitoring activities,**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	closure activities) and other relevant facilities (e.g., encapsulation facility) during the review of the license application.

Monitoring during the Operational Period

As described above, the operational period of a repository is expected to last 60 years in Sweden. The operational period provides a long time to conduct monitoring and testing (e.g., corrosion tests on waste package materials) to provide further confidence in safety and to evaluate the effects of construction on the repository (e.g., fracturing of rock near the repository drifts and tunnels). General Recommendations from SKI FS 2002:1 state:

"it is the responsibility of the licensee, as long as the repository is in operation, to continuously keep informed of the conditions of importance to the assessment of repository safety, also after closure (General Recommendations for Section 4), and Measures can be adopted during construction and operation for the possible monitoring of a repository's integrity and its barrier performance after closure. (General Recommendations for Section 8)"

In discussions with SSM, it was explained that there is no responsible party identified at this time for monitoring after closure (see discussion below on Institutional Controls after Permanent Closure).

Observations and Conclusions Monitoring during the Operational Period

The regulator has identified the need for monitoring that is consistent with the IAEA Safety Requirement 21 (SSR-5), which states:

"A programme of monitoring shall be carried out prior to, and during, the construction and operation of a disposal facility and after its closure, if this is part of the safety case."

However, there is limited guidance (general advice) to assist the development of monitoring and testing plans for the 60 year operational period. A primary goal of the monitoring and testing programs is to obtain confirmatory information related to the key safety functions, to the extent practical. The monitoring and testing program is expected to be site and facility specific (e.g., safety functions specific to the KBS-3 design and the Forsmark site), therefore, SSM direction (e.g., general advice, license conditions) for monitoring and testing will have a design and site specific nature (e.g., appropriate safety functions are monitored, monitoring plans do not have an adverse impact on the post-closure safety functions). It may be reasonable to impose a license condition that SKB submit monitoring and testing plans on a regular basis (e.g., every 3 years) or the updates of the safety assessments, required to occur every 10 years, could also require an update of the monitoring plans.

Institutional Controls after Permanent Closure

Geologic repositories are designed to provide for passive safety during the post-closure period and, as such, any active measures (e.g., institutional controls to prevent human intrusion and to monitor environmental pathways) to ensure safety in this period are not given any credit in safety assessments of the post-closure period. Although safety assessments assume that institutional controls are <u>not</u> effective in either reducing the likelihood or consequences of a potential release in the future after the repository is permanently sealed, it is generally acknowledged that implementation of institutional controls (e.g., presentation of information regarding the design and inventory of the repository, controls to preclude human activities that might potential degrade certain passive safety functions of the repository, monitoring of environmental pathways) would be expected to potentially enhance safety and increase public confidence while the controls were present (IAEA SSR-5, Requirement 22). The Swedish repository program acknowledges that preservation of knowledge as an activity to be taken as means to

reduce the risk of human intrusion after the repository is closed (SSI FS 2005:5) and monitoring could occur after closure (see references to SKI FS 2002:1 above under Monitoring). Additionally, the regulator has indicated that SKB's obligations with respect to the Act on Nuclear Activities will end with the license for closure:

"With respect to a repository, this can be achieved after SSM has approved the closure of the repository. As soon as SSM can establish that a licensee has fulfilled its obligations with respect to a repository, the obligations to comply with the provisions in these regulations for the repository also cease." [SSM 2008:21;]

Based on discussions with SSM, the government is clear that it will take responsibility for institutional controls after closure and discussions are currently underway in Sweden for the need to make clear that this responsibility lies with the Swedish government and not the municipality associated with the repository.

Observations and Conclusions for Institutional Controls after Permanent Closure

Institutional controls can be both independent of the site and facility design (e.g., preservation of records) and dependent on the site and facility design (e.g., monitoring), however, detailed plans may not be warranted at this time due to the long time period before they will be implemented (at least 50 years in the future assuming the present application is approved in the near future). As was discussed above for monitoring, SSM could consider the appropriate approaches (e.g., general advice, license conditions) to ensure that SKB provides sufficient information for SSM's regulatory review, which would be appropriate as this point of the stepwise process. For example, it may be reasonable to impose a license condition with the permit to construct the repository that SKB submit information on the types of monitoring to be considered, identification of any concerns for how the monitoring might impact current repository design and potential adverse impacts on the post-closure safety functions, and potential integration of institutional controls and construction and monitoring plans during the operational period of the repository. Detailed plans for institutional controls should be developed at a time closer to when the plans are needed. SSM could consider a license condition or other appropriate approaches to require SKB to submit final recommendations for the institutional controls in connection with the license for closure.

12.4.3 Dismantling and Decommissioning

The Environmental Code and the Act on Nuclear Activities make possible the gradual replacement of the ten operating nuclear power reactors with new ones at an existing site, when the old reactor has permanently being shut down.

Decommissioning is contemplated as an integral part of the lifecycle of the facilities, i.e. decommissioning is considered to be included in the license according to the Act on Nuclear Activities. On the other hand, a specific licence for decommissioning of nuclear reactors is required according to the Environmental Code. The principle assessing body for applications under the Environmental Code is the Environmental Court, that liaison with SSM takes place in the review process.

In the review of the RD&D programme, SSM and the Government have supported the immediate dismantling strategy for the NPP facilities.

The licensee has an obligation according to the Nuclear Activities Act to ensure a safe decommissioning of the facility. According to SSMFS 2008:1 and 2008:19 regulation, the licensee for the operation of a nuclear facility shall produce a preliminary decommissioning plan before construction of the facility which shall be kept updated during the operation of the facility and must be submitted to SSM every ten years during operation. One year after final shut down, the licensee shall present to SSM a more detailed plan. Before starting the dismantling activities, the licensee shall provide a new decommissioning plan and a safety analysis report that shall be approved by SSM. No requirement on the elapse of time between

the final shut down and the resubmission of the final decommissioning plan and application for starting dismantling is set in regulation by SSM. However, according to the regulations, the licensee shall describe and motivate a schedule for the decommissioning activities.

In the amended regulation SSMFS 2008:1, chapter 9, that will be in force in November 2012, SSM has modified the requirements on the documentation needed before starting dismantling activities and during the decommissioning. Further documentation shall be presented during decommissioning phase for its review which reflects specific safety issues concerning major milestones identified in the planning for decommissioning. Guidance should be developed to facilitate the elaboration of the required documentation.

According to the Nuclear Activities Act, the licensee is obliged to safely decommission and dismantle until all operations have been finished and all nuclear materials and waste have been placed in a disposal site that has been permanently sealed. The obligations may be transferred to another party by Government decision. It is however not stated in the legislation how it shall be concluded that the licensee has fulfilled all, or parts of the obligations. Nor do the regulations address the termination of the licence or the procedures for concluding that the obligations have been fulfilled and that the waste has been disposed of and this disposal facility is sealed. It is only stated that when dismantling activities are finalised, a decommissioning report shall be submitted to SSM (SSM FS 2008:1) for information. The decommissioning report could be used to support a statement from SSM that the licensee has no further obligations concerning the site and that a transfer of the remaining obligations to another party could be approved by the Government. The procedures for this should be clarified in the legislation and the regulations.

New regulations have recently entered into force (SSMFS 2011:2, described in SSM 2008/549, January 2012) for establishing developed requirements concerning clearance of materials, rooms, buildings and land. No clearance levels are given for land in the regulation, as this will be decided on a case by case basis. After completed decommissioning, a decision on clearance will be taken by SSM based on an application by the licensee, including the results of a final survey of the site. Guidance needs to be developed by SSM with respect to the documentation and methodologies to demonstrate that the release criteria have been met. A final evaluation of the end state of the site by performing a thorough inspection after decommissioning activities have been completed should be performed by SSM.

The decommissioning regulatory staff needs to be trained and qualified to ensure personnel have appropriate training and experience in decommissioning safety. SSM should evaluate the training programmes and ensure lessons learned from research and power reactors decommissioning projects are incorporated into SSM regulatory program and disseminated to the licensees.

Recommendations concerning dismantling and decommissioning are included in Sections 5 and 9.

12.5. MEDICAL EXPOSURE

The legal basis for medical exposure control in Sweden is primarily based on the Radiation Protection Act (SFS 1988:220). In addition to SSM, the National Board for Health and Welfare (SoS) is involved in different aspects of medical exposure control such as patient safety, education and staff diplomas and management systems. The Medical Products Agency (LV) plays a role with respects to medical devices and radiopharmaceuticals.

The Radiation Protection Ordinance (SFS 1988:293) empowers SSM to issue detailed regulations regarding radiation protection for licensed practices. In implementing this provision, SSM has issued a number of regulations and guides (which are called ‘general advise’ in the Swedish system) covering various applications of ionizing radiation in medicine. These include:

- SSMFS 2008:35 General obligations and requirements for practices involving medical and dental exposure
- SSMFS 2008:31 Specific regulations for medical and dental x-ray diagnostics
- SSMFS 2008:33 Specific regulations for radiation therapy
- SSMFS 2008:34 Specific regulations for nuclear medicine
- SSMFS 2008:4 Diagnostic reference levels for use in nuclear medicine
- SSMFS 2008:20 Diagnostic reference levels for use in x-ray diagnostics
- SSMFS 2008:5 Regulations and general advise for dental x-ray diagnostic using intra-oral image receptor

SoS and LV have also a set of regulations and guides in their respective areas.

In the public sector, SSM consider a county council a licensee and issues one license for each practice (diagnostic and interventional X-ray, nuclear medicine, and radiotherapy) to all of its hospitals and radiological departments. In total there are about 31 such 'big' licensees and around 70 'small' licensees, encompassing 250 X-rays departments, 33 nuclear medicine departments and 17 radiotherapy departments. There are also about 7000 dentists.

In reviewing these regulations and their implementation, the IRRS team concluded that the Swedish system for medical exposure control is detailed and provides for clear assignment of responsibilities, high level of competence of key personnel, high equipment design and performance standards, and quality assurance in the medical facilities. There are well established arrangements for the optimization of protection in medical exposure. Provisions for reporting of medical exposure incidents are in place. The Swedish system provides also for justification, optimization and quality assurance in other areas of medical exposure such as screening programs and biomedical research. The interaction and coordination among the involved authorities, i.e. SSM, SoS and LV, is well established and provides for continuous and consistent control.

The team identified, however, a number of areas where improvements can be made to ensure compliance with the IAEA safety standards. The following paragraphs describe these areas and provide recommendations and suggestions. It is worth mentioning that SSM has identified some of these areas in the thorough self-assessment which was conducted in preparation to this mission.

The Radiation Protection Act (SFS 1988:220) stipulates that all practices involving medical and dental exposure are subject to regulation and require a license from SSM. There are no provisions in this act for exemption from a license. For dental X-ray it was observed that SSM only licenses dentists having panoramic X-ray equipment and does not license dentists having only intraoral X-ray equipment. This approach is based on the regulations SSMFS 2008:5 which include a generic license for all registered dentists allowing them to use intraoral X-ray equipment. These regulations were first issued in 1978 and latest revised in 2008. In the view of the IRRS team this approach is not fully in line with the provisions of the Radiation Protection Act. SSM has informed the IRRS team that it is considering changing this approach

SSM regulations SSMFS 2008:35 implies that the referral is to be done by a medical physician or dentist. The team was informed that the National Board of Health and Welfare gives other medical professionals (e.g. chiropractors, nurses) the right to prescribe medical exposure.

In the Site visit to the Akademiska University Hospital in Uppsala, the IRRS team noticed that the licensee's top management, which is the county council, is not aware of the conflicting requirements. The team was informed that, although patients are in practice only referred by medical doctors, the referring procedure for simple radiological examinations can be done by specialised nurses.

The team was informed that SSM does not review the referral for medical exposure during inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 36 states that** *"Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral"*
(2)	**BASIS: GSR Part 1 Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
R20	**Recommendation: SSM should cooperate with the National Board of Health and Welfare to ensure that the requirements regarding referring medical practitioners are consistent.**

SSM has pointed out in the preliminary action plan the need to consolidate and further develop the co-operation with other authorities in the medical area.

SSM regulations assign the responsibility for the justification of new methods for medical exposure to the licensee. Paragraph 3.155 of GSR Part 3 however requires "*Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies*". Indeed, the IRRS team was informed in the site visit to Akademiska University Hospital that the justification of new methods is carried out at the departmental level, and it's then reported to the radiation protection committee of the hospital. Radiation protection aspects are not systematically considered in the justification process. The licensee's top management is not involved in the justification process. Neither SSM nor the health authorities review or assess the justification of new methods. Only the existence of a system for justification is checked in SSM inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 37 states that** *"Relevant parties shall ensure that medical exposures are justified."*
(2)	**BASIS: GSR Part 3 Paragraph 3.155 states that** *"Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies."*
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.**

Requirements on optimization of protection in medical exposure are in place. There is a well-established and systematic approach to the optimization of protection. In particular, provisions for issuing Diagnostic Reference Levels (DRL) exist in the regulations (SSMFS 2008:35, SSMFS 2008:4, SSMFS 2008:20). DRLs for a number of procedures in diagnostic radiology and nuclear medicine are established.

SSM has well established arrangements requiring all licensees to measures and analyse patient standard dose (DSD). For diagnostic radiology, SSM regulations SSMFS 2008:20 requires that the diagnostic

standard dose shall be determined for all specified examination at least each third year, and in connection with planned or unplanned changes in the equipment or the examination methodology. The regulations SSMFS 2008:4 set similar provisions for nuclear medicine. SSM requires that the results of the DSD be reported to SSM upon request. SSM analyses this information periodically and can demonstrate continuous decreasing trend in DSD. It also uses this information to inform its regulatory supervision.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Paragraph 3.167 states that** *"Registrants and licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:* *a) For diagnostic medical exposures, typical doses to patients for common radiological procedures;* *b) For image guided interventional procedures, typical doses to patients;"*
(2)	**BASIS: GSR Part 3 Paragraph 3.168 states that** *"Registrants and licensees shall ensure that: (a) Local assessments, on the basis of the measurements required in Paragraph 3.167, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established"*
GP15	**Good Practice: SSM requires all licensees to determine the diagnostic standard dose for all specified examinations at least each third year, and to provide this information upon request. Using these data SSM demonstrates continuous decreasing trend in DSD.**

SSM imposes requirements on the radiation protection organization in medical facilities. A medical facility shall have a radiation protection expert. Facilities having more than one department using ionizing radiation are requested to have a radiation protection committee. Additionally, SSM regulations recognize two key positions within the organization of medical facilities. These are the RALF, a medical doctor specialized in radio-diagnosis, nuclear medicine or radiotherapy, and the medical physicist. There are well established criteria for the qualification of the RALF, medical physicists and the radiation protection expert but there are no requirements on the minimum education and training levels for other personnel engaged in medical exposure such as medical radiation technologists and nurses.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 3 Requirement 35 states that** *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they meet the requirements for education, training and competence in the relevant specialty."*
(2)	**BASIS: GSR Part 3 Paragraph 2.21 states that** *"The government shall ensure that requirements are established for: (a) education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety"*
(3)	**BASIS: GSR Part 1 Paragraph 2.36(a) states that** *"The government: (a) Shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
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.**

The IRRS team examined how the other GSR Part 3 requirements related to medical exposure are considered within the Swedish regulatory system. The team concluded that, although the Swedish regulations related to medical exposure control are generally in line with GSR Part 3, a number of GSR Part 3 requirements are not fully covered by the existing regulations and guides. In particular, the team pointed out the following:

1. SSM has guidelines for cremation of deceased persons containing unsealed radioactive sources as a result of medical treatment (SSMFS2008:34). These guidelines do not fully cover the requirements of paragraph 2.37 in GSR Part 3 which require the regulatory body, in consultation with the health authority, to ensure that provisions are in place for ensuring protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources either as a result of radiological procedures for medical treatment of patients or as a consequence of an emergency.
2. SSM requires licensees to apply the ALARA principle to the protection of carers and comforters Dose constraints for carers and comforters, as required by paragraph 3.148 of GSR Part 3, are specified in paragraph 16 of SSM regulations SSMFS2008:34 for nuclear medicine, but there are no such dose constraints for diagnostic radiology .
3. SSM has issued guidelines on the release of patients who have undergone therapeutic procedures using unsealed sources. However no similar guidelines exists for the release of patients who still retain implanted sealed sources as requested in paragraph 3.148(b) of GSR Part 3.
4. SSM does not require informing patients about radiation risk. The existing requirements only apply to volunteers, occupationally exposed workers, and comforters. Requirement 36 of GSR Part 3 requires, however, that persons subject to exposure be informed of the expected benefits and risks.
5. SSM does not require placing signs to request female patients to provide information on possible pregnancy or breast feeding as requested in paragraph 3.174 of GSR Part 3.
6. Apart from fluoroscopy, SSM has no requirements on keeping records of information necessary for the retrospective assessment of doses in diagnostic radiology GSR Part 3 Paragraph 3.184
7. SSM regulations do not explicitly require that licensees promptly investigate unintended or accidental medical exposures in all cases mentioned in paragraph 3.179 of GSR Part 3. The Patient Safety Law (SFS 2010:659) however requires in section 3 of chapter 3 the investigation of events that has lead o could lead to an injury.
8. SSM has no requirements on the radiological medical practitioner to inform the referring medical practitioner and the patient (or the patient's legal authorized representative) of the unintended or accidental medical exposure, as requested in paragraph 3.180 of GSR Part 3. The regulation SoSFS 2005:28 requires patient notification in case of injury or potential injury.
9. Although SSMFS 2008:35 include specific requirements for the licensee to ensure that a quality assurance program of medical exposure is established, there are no specific requirements on independent or regular audits of the quality assurance programme, as requested by paragraph 3.171 of GSR Part 3
10. SSM has no requirements on radiological review in medical facilities as requested by paragraph 3.181 of GSR Part 3

Related recommendations and suggestions are in section 9.4. SSM has identified the need to review its requirements and included this in the preliminary action plan.

Since SSM regulatory system is performance oriented, challenges are put on the licensees as well as on SSM staff in relation to the consistent interpretation and implementation of the regulatory requirements. In areas where appropriate guides are missing, the IRRS team observed that certain regulatory requirements related to medical exposure control are not easily understood and may be subject to different interpretations. SSM requirements related to quality assurance programs in medical facilities are such an example. The need for more guidance on the quality assurance program was also confirmed in the site visit to Akademiska University Hospital in Uppsala, where the licensee expressed his wish for a clear guidance that would allow him to better know SSM expectations prior to licensing or inspection. Except for complex facilities, SSM does not assess the quality assurance program in the licensing process but only during inspection, which may be at a much later stage. This contributes to possible divergence between licensees' implementations and SSM expectations and emphasizes the need for relevant guides.

The chief medical physicist of the Akademiska University Hospital presented his view on the relationship of the hospital with SSM. In his view, SSM inspections have changed drastically over the last years, and are getting more complicated. The level of inspection changes from inspection to inspection. He interpreted this as due to a learning process in SSM. However, he believes also that SSM is changing or tightening its interpretation of the requirements. In SSM views, no changes have been made to the interpretation of regulations since 2005 but inspections have become more comprehensive.

The IRRS team observed cases where SSM compensates for the absence of certain requirements in the regulations by imposing generic license conditions. An example is the requirement for periodic radiological review for medical facilities. In the view of the IRRS team, license conditions should be established within existing regulations and guides while the introduction of new requirements should follow a formal process involving consultation and communication with interested parties.

The IRRS teams concluded that there is room in SSM regulatory system for improving guidance, communication with licensees and consistency in the application of regulatory requirements. The need to develop further guides and general advise on the application of the present regulatory framework has been identified by SSM in its self-assessment. Related recommendations and suggestions are in Section 3.6.

13. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

This module brings together the information accumulated by the Team on Fukushima implications during the course of the mission and contains the views and conclusions of the team for each of the standard modules of the IRRS.

In particular, this module includes the policy issue discussion dedicated to the implications of the Fukushima accident.

13.1. ACTIONS TAKEN BY THE REGULATORY BODY IN THE AFTERMATH OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

A. IMMEDIATE ACTIONS TAKEN BY THE REG**U**LATORY BODY

The crisis management organization of SSM was brought together right after the first news arrived from Fukushima already on March 11, 2011. The organization was expanded as the situation became more severe at the power plant and about 130 persons had some role in its functioning. The organization was active 24/7 with three shifts until March 25. From that time on only the day shifts served until March 31, when the crisis organization was deactivated.

The main duties of the SSM crisis team included technical discussions and information exchange with partner organizations and governmental agencies and authorities on technical issues related to radiation protection and nuclear safety; informing and advising governmental entities (e.g. Ministry of Foreign Affairs, Ministry of Environment, Government Office, Prime Minister's Office); information of the media and the general public; and last, but not least collecting the information available on the actual situation in Fukushima.

For the information dissemination purposes SSM utilized various channels. The most effective among them were the media appearance of SSM experts as a daily routine and the website of SSM which was regularly updated and very frequently accessed. A FAQ page was also administered, but inquiries from the general public were also rather frequent. The open and active information policy of SSM is to be commended.

SSM had an important role in certain governmental decisions on Fukushima related actions such as advising Swedish citizens in Japan to evacuate as well as to avoid the 80 km surroundings of Fukushima; sending iodine tablets to Japan and recommending iodine prophylaxis within a radius of 250 km around the site; and on the possible monitoring of passengers and goods arriving from Japan.

No immediate action was deemed necessary in the Swedish nuclear power plants since the existing safety analyses, as well as the safety increasing modifications performed earlier, excluded the possibility of such devastating earthquakes, tsunamis or external hazards that were experienced in Japan. SSM judged the plants to be robust and there was no risk for the same event as in Fukushima. The external events have to be analysed even more, but the schedule of the stress tests was sufficiently prompt. Thus no activity by the licensees, or inspection, was initiated by SSM, although SSM requested the licensees on March 22 to take actions as necessary in the light of the lessons learned from the event progression. In this respect it is worth mentioning that while no requirements arrived from the regulator, the licensees obtained guidance and suggestions from WANO in the form of a SOER. On the other hand, in line with the request by the European Commission SSM has ordered the performing of the European targeted safety reassessment (stress test) at all three sites with operating NPP units in Sweden.

B. TECHNICAL ISSUES CONSIDERED IN THE LIGHT OF THE FUKUSHIMA ACCIDENT

The Swedish NPPS have submitted their stress test related safety reassessment in the scope as required by the EC. The assessment results were summarized in a report by SSM. The report describes the status and defines actions deemed necessary in the light of the Fukushima accident in the following subjects: earthquakes; floods; extreme weather conditions; loss of electrical power and loss of ultimate heat sink; severe accident management and emergency preparedness. The report includes the assessments and conclusions regarding these subjects by both the licensees and the regulatory body. In general terms it was established that the Swedish NPPs are sufficiently robust, nonetheless the lessons learned from Fukushima call forth a number of further investigations, analyses and modifications.

For the case of earthquakes SSM has concluded that the assumption of the largest event with a 10^{-5}/year frequency is suitable as the design base and the plants are expected to withstand DB earthquakes, although SSM has identified deficiencies in the demonstration of the ability for safe shutdown in case of some of the units. On the other hand earthquakes with a frequency of 10^{-7}/year possibly result in consequences that may need further analysis and/or modifications for certain units (The reason why earthquakes of a frequency of 10^{-7} are interesting is that such an earthquake is DB for some of the systems like those used in a severe accident in the plant). Earthquake induced internal flooding is also an issue to further investigate for the Ringhals and Forsmark NPPs.

For flooding the only event to investigate is the rise of the seawater level, any other water induced extremity can be excluded in case of the Swedish plants. The licensees reported that the design basis seawater level-raise is between 2 and 3 meters and its frequency of occurrence is between 10^{-6}/year and 10^{-5}/year. SSM concluded that further analysis is needed especially on the effects of the sea waves in case of high water level and in the issue of high groundwater level.

The report includes results on a variety of extreme weather conditions including rain, snow, wind, seawater level and temperature, sea waves, air temperature, lightning, tornados, and seaweed growth. In these cases SSM concluded that some of the issues are treated in connection with other extreme events in the report (flood, loss of ultimate heat sink), while others are slow events that can be handled with the existing protective tools, and some issues (like access of the plant in extreme conditions, consequences of ice storm) need further considerations beside those (e.g. revision of procedures, taking certain measures and performing investigations) identified by the licensee.

For loss of electrical power the licensees' assessment concluded that the number of mobile power sources may not be sufficient. In addition SSM requires further evaluations on a number of subjects including pipes and equipment needed for the refuelling of emergency diesel generators; need for additional I&C equipment as well as for standardized mobile DG's; and accessibility of important site areas.

In case of loss of ultimate heat sink the licensees identified a number of issues related to the blockage of the water intake and outlet; the necessity of investigating the water volume stored in tanks; and the potential necessity of manual intervention for spent fuel pool cooling. SSM identified the need for re-evaluating the emergency procedures related to alternative cooling capabilities and to manual hydrogen venting.

Components of severe accident management and of emergency preparedness and response are discussed in details in the report and a number of actions are foreseen by the licensees (e.g. plans for managing several affected units; improvements in spent fuel pool cooling; enhancing hydrogen management; off-site emergency centre, etc.). SSM concluded that beside the actions foreseen by the licensees the long term availability of filtered venting should also be analysed. Furthermore, SSM considers it necessary to increase the robustness of the severe accident management for long lasting (more than 24 h) emergencies by elaborating emergency guidance, handling chemistry problems, and solving filtered venting issues. An extensive list of necessary actions is given by SSM for the emergency preparedness and response area,

including planning and resourcing for multiunit accidents; accessibility of the emergency control centre; ensuring personal safety; and resourcing issues.

In summary SSM concluded that although a considerable number of tasks and needs have been identified, there is no immediate need of any urgent intervention by the regulatory body.

The IRRS team finds it necessary to note that according to both parties the cooperation and information exchange between the licensees and the regulatory body were very effective and efficient during the elaboration of the stress test report.

C. OTHER ISSUES CONSIDERED IN THE LIGHT OF THE FUKUSHIMA ACCIDENT

The self-assessment report as well as the discussions between the IRRS Team and the SSM counterparts revealed certain specificities of the SSM approach to the management of the Fukushima implications which fully or partially differed from the approach followed by many other countries.

A large number of experts of SSM (more than 10) were able and entitled to answer questions and requests by the media and the general public. This shows a good cooperation among the members of the emergency team and also with the possible spokespersons. The frequent and competent public appearances of the SSM experts as well as the advising activity to other governmental organizations give credit to the professionalism of the regulatory body and contributed to the acceptance of SSM by the public. This was corroborated by a representative 1000 sample public enquiry demonstrating that the recognition of SSM that was 56% prior to the event rose to 84% during these times. It was also shown that SSM became the most trusted information source related to the accident.

SSM`s crisis organization through their nuclear and radiological analysis functions performed assessments on the consequences resulting from different possible developments at the Fukushima reactors and cooling ponds. The US advice to evacuate the 80 km surroundings of Fukushima verified SSM`s assessments. Based on the recommendation by SSM, Sweden advised their citizens to evacuate the 80 km surroundings of Fukushima. It would be expedient to perform a thorough post-event analysis of the consequences, benefits and drawbacks of this action.

Similarly, the SSM recommendation that the Swedish citizens within an area of radius 250 km around the site should take iodine tablets one week after the beginning of the accident was unique in the international community. Lessons learned and consequences analysed may be quite enlightening.

SSM is to be commended for their professionally sound recommendation that in spite of certain contradictory opinions no monitoring devices were necessary to install at the Swedish airports as there was no radiological justification for such an action.

SSM has started to summarize the experience gained from the domestic handling of the accident consequence. Analysis of these experiences my essentially influence the strategy, policy and activity of the emergency preparedness organization of SSM.

CONCLUSION [1]
The Team concluded that SSM reacted promptly and efficiently to the challenges posed by the TEPCO Fukushima Dai-ichi accident in compliance with its duties related to providing information to the Government, other agencies and the public. The SSM emergency team served for an extended period of time with an effort sometimes above what is expected. Public information activity of SSM was exemplary. The safety of the Swedish nuclear installations did not necessarily require immediate actions from the part of the regulatory body, although providing more instructions as to the precautionary actions to be taken by the licensees might

CONCLUSION [1]
have been beneficial. **Activity of the emergency team and of the SSM management during the early stages of the accident is worth analysing in comparison to the various international protective actions that were taken. Conclusions may be drawn for the benefit of increasing the harmonization of the international response.**

13.2. PLANS FOR UP-COMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

The Government of Sweden assigned SSM to make investigations and take steps in order to increase nuclear safety in Sweden and specifically in order to provide background for the long term operation of the NPPs in April 8, 2010. As a consequence of the TEPCO Fukushima Dai-ichi accident and following the decision of the European Union on performing the stress test investigations at all NPPs within the EU, the Swedish Government extended its assignment to cover also the findings and task stemming from the Swedish stress test report. The main areas required to be investigated are:

- Compliance of the NPPs with the safety regulations and requirements with emphasis on the recent modernisations
- Conditions of and requirements for long term operation of the units
- Analysis of the Swedish nuclear safety supervisory system
- Safety requirements of long term operation in the international nuclear community
- Results and requirements by the stress test and their regulatory evaluation

To comply with the orders by the Government, SSM initiated a project including three subprojects and several stages therein. The subprojects are aimed at the following subjects:

1. Investigation of safety improvements in the Swedish NPPs
2. Investigation of issues related to long term operation of the units
3. Analysis of the Swedish nuclear safety regulatory supervision

The first subproject extends over a large number of areas and stages including the revision of the current Swedish safety requirements in the light of the international practice for Generation III reactors; overview of the safety related modification made in other countries for long term operation; overview of the status of the modernization in the Swedish NPPs as against the requirements posed earlier on the design and construction of nuclear reactors; summary of the actions taken as results of the stress test. Part of these tasks have been performed by external expert contractors and are under evaluation by SSM.

In the second subprogram the main emphasis is put on ageing management issues and in-depth analysis of a number of processes is foreseen, including radiation damage of reactor vessel material; ageing of I&C components; ageing management programs and mechanisms; investigation and control of the containment. This part of the project is put into an international context by making use of the results of the similar international cooperation projects performed in the framework of the CSNI and CNRA standing committees of OECD NEA.

The third subprogram aims at making use of the results of the present IRRS mission. This is intended to be done by analysing the answers in the Self-Assessment document; by collecting the experience of other countries and by analysing the results of the mission.

The task related to the stress test includes not only the evaluation of the task following from the targeted safety re-evaluation of the Swedish NPPs, but also the summary of the experience of all leading nuclear

countries in Europe as well as of US and the inclusion of the results of the extraordinary meeting of the Convention on Nuclear Safety to be held in August 2012.

The timeframe of the project extends over most of the year 2012; SSM is due to submit its report to the Government by October 31, 2012 (by December 15, 2011for the stress test issues).

CONCLUSION [2]
The Team concluded that SSM performed an extended investigation on the utilization of international experience in long term operation and safety improvement actions related to the Fukushima event. **The IRRS Team suggests that the post mission Action Plan of SSM, which is to be compiled after the analysis of the IRRS mission findings should also include the tasks identified by the project above.**

13.3. SIGNIFICANCE OF REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA ACCIDENT ACROSS REVIEWED AREAS

Note: ***The significance of Fukushima implications was considered as part of the review of each IRRS module. The review conclusions below and the plans presented by Sweden to further address Fukushima issues in the coming years should be included in the scope of the follow-up IRRS mission to be invited by Sweden.***

Module 1: Responsibilities and Functions of the Government

In Japan insufficient independence of the regulatory body and interface problems between different authorities have been identified as the primary area of improvement for governmental responsibilities and functions after the TEPCO Fukushima Dai-ichi accident. The Team observed a good situation for both areas in Sweden.

SSM is an Authority established under Swedish law that is legally and functionally independent in the sense as defined by the IAEA safety requirements. It is the main regulatory body regarding nuclear safety and radiation protection in Sweden. The duties and responsibilities of the various authorities having role in nuclear and radiation safety are clearly defined in the legislation and assure their cooperation in routine and emergency situations.

The emergency preparedness aspects of governmental functions and responsibilities are discussed in the part related to Module 10 below.

CONCLUSION [3]
The Team did not identify any element regarding the responsibilities and function of the government which would raise particular concern in light of the TEPCO Fukushima Dai-ichi accident. It was also noted that the Government required, and SSM is committed, to address the relevant implications and lessons learned from the accident within the framework of the EU stress test.

Module 2: Global Nuclear Safety Regime

Sweden is a contracting party to the Convention on Nuclear Safety (CNS), one of the major international conventions currently focused on evaluating and sharing lessons learned from the TEPCO Fukushima

Dai-ichi accident. Sweden also plans to participate in an Extraordinary Meeting of the CNS in 2012 with the topic being the Dai-ichi accident. SSM is active internationally, participating on commissions and working groups in the OECD, IAEA, and WENRA. SSM maintains an awareness of current activities internationally with regard to safety improvements that should be considered in relation to the TEPCO Fukushima Dai-ichi accident. SSM participated, via review and comment, with the development of the IAEA Nuclear Safety Action Plan, which includes actions and expectations for IAEA and Member States to address nuclear safety concerns following the Dai-ichi accident.

With regard to operating experience feedback, SSM promptly, following the accident required that its licensees initiate actions to evaluate and address the initial lessons learned from the event.

CONCLUSION [4]
The Team concluded that SSM is appropriately engaged in international activities with regard to the TEPCO Fukushima Dai-ichi accident, including the EU Stress Test, and has already taken initial actions to improve the safety of Swedish NPPs.

Module 3: Responsibilities and Functions of the Regulatory Body

The Team found that SSM has taken its actions with regard to the TEPCO Fukushima Dai-ichi accident within its responsibilities in the Swedish government and without interference. It became clear that SSM is able to exercise its authority and to take timely decisions in order to prevent any radiation or nuclear risk or in handling a nuclear emergency situation.

Since SSM did not identify anything in the Fukushima accident that would require immediate action in the Swedish NPPs, SSM decided to carry out its improvement programme within the framework of the EU stress test.

SSM took highly effective actions to inform interested parties and the public in a transparent manner.

CONCLUSION [5]
The Team did not identify elements regarding the responsibilities and functions of the regulatory body which would raise particular concern in light of the TEPCO Fukushima Dai-ichi accident. The Team also recognized that SSM is committed to fostering improvement of the safety of the Swedish NPPs as well as its regulatory processes as a result of lessons learned from the TEPCO Fukushima Dai-ichi event. **The Team considers that the communication to the public and interested parties was carried out in an exemplary manner.**

Module 4: Management System

Following the TEPCO Fukushima Dai-ichi accident SSM identified a number of opportunities for continuously improving its management system, many which are being directly applied to the management of the crisis organization. Action has been taken to: improve its approach to self-assessment, management review and independent assessment; clarify and document roles and responsibilities; identify and address gaps in required competencies including focused training on procedures, equipment and services; close gaps in the management of documentation to assure access at point and time of use; and improve the SSM working environment.

CONCLUSION [6]
The Team concluded that SSM has taken appropriate actions with regard to the TEPCO Fukushima Dai-ichi accident in accordance with its roles and responsibilities as an independent regulator.

Module 5: Authorization

In the preceding paragraphs it is described how SSM reacted on the developments in Fukushima. No authorization specific issue arose.

CONCLUSION [7]
The IRRS-team concluded that measures to be imposed by SSM through authorisation were not needed.

Module 6: Review and Assessment

There hasn't been a Significant Operating Event Report (SOER) evaluation at CLAB, although this nuclear installation was later subjected to a stress test. SSM did not ask the nuclear facilities explicitly whether the WANO SOER findings justified continuation of operation nor did SSM assess the findings of the SOER. Following the requirement by the European Commission, SSM ordered that all three sites with operating NPP units in Sweden perform a stress test. Moreover SSM did also request a stress test by CLAB. Other nuclear installations were not requested to do a stress test.

CONCLUSION [8]
The Team concluded that SSM has complied with EU stress program. In addition to the EU-program CLAB has also been subjected to a stress test. The IRRS team concluded that the course of actions by SSM and by the Swedish NPPs after the TEPCO-Fukushima Dai-ichi accident were commensurate with the risk posed.

Module 7: Inspection

In response to the TEPCO Fukushima Dai-ichi accident, SSM had discussions with the licensees and noted the actions they undertook as a result of the WANO SOER 2011-2 request. SSM did not formally identify anything in the TEOCO Fukushima Dai-ichi accident that might have direct implication on the Swedish nuclear power plants in a way that would require further immediate action. SSM did not require any physical measures to be done at the plants or require any restrictions in plant operation. SSM's opinion was that the time table for stress test implicated an intensified analyses process. With regard to the fact that analysis and the quality of their results requires resources and time, SSM thought that there were no reasons for a national analysis activity with a schedule that was even more forced than the stress test schedule.

The background for the SSM judgment that there was no need for immediate action in the Swedish plants was that Sweden is neither exposed to tsunamis nor earthquakes of the kind found in Japan. Another reason is that the Swedish nuclear power plants are relatively robust in case of an event similar to those that occurred in the Fukushima, due to the filtered venting systems installed after the Three Mile Island accident as well as the severe accident management procedures implemented and other mitigation measures taken. An example is the introduction of passive hydrogen re-combiners (PAR) in the Swedish PWRs. New regulations came into force in 2005 concerning design and construction of NPPs.

So SSM carried out no specific inspection on the Swedish NPPs, and the annual inspection programme was not modified. But of course, during planned surveillance inspections occurring after March 2011, SSM checked several items related to the TEPCO Fukushima Dai-ichi accident (electrical supplies for example).

CONCLUSION [9]
The Team concluded that specific inspections could have been carried out more formally and more in depth in order to confirm the compliance of the NPPs after the TEPCO Fukushima Dai-ichi accident.

Module 8: Enforcement

The content and the time table of the Swedish stress tests are in accordance with the European stress test decision. The national report was finalized in December 2011and the European peer review will be finished in April 2012.

One SSM activity which will handle the results from the stress tests is an assignment from the government. This assignment is focused on the long term safety development in the Swedish NPP´s and on the additional actions to be taken. The task was given in 2010 and shall be reported in October 2012 as described in more details in Section 13.2 above.

The findings from the stress tests include severe accident scenarios for several days, all units affected at one site, measures against earthquakes (electrical components, pipe anchorage), procedures and instructions in many aspects, extreme natural phenomena (e.g. ice storms are not covered by the safety analysis).

SSM will, as far as possible, handle the findings from the stress tests by incorporating them in the ordinary processes for supervision, review, inspection, decisions on licensee actions, investigation, research and issuing regulations. SSM will put together a list containing all identified issues and potential measures for improvements, and demand all licensees to perform further evaluations and analysis; the issues will be prioritized as short term and long term..

CONCLUSION [10]
The Team considers that the implementation of the governmental assignment in response to the TEPCO Fukushima Dai-ichi accident is on-going. The actions taken by SSM are in accordance with the European stress tests and seem to be commensurate with the safety importance of the issues raised by the accident. The SSM enforcement process is capable of dealing with the enforcement activity needs created by the TEPCO Fukushima Dai-ichi accident without any change.

Module 9: Regulations and Guides

In the SSM report on Fukushima Lessons it was recognized that the possible impact of the TEPCO Fukushima Dai-ichi accident on regulations and guidelines needs further analysis. This is addressed in the framework of the SSM project described in Section 13.2, which is related to the long term operation of the Swedish nuclear reactors and to the Swedish governments' order to cover also the findings and task stemming from the Swedish stress test report.

Review of SSM guidelines in the light of the events in TEPCO Fukushima Dai-ichi is in progress. SSM stated that it intends to wait for the outcome of the various projects that deal with the implications of the

lessons learned from TEPCO Fukushima Dai-ichi in Sweden.

Furthermore, in 2011 the Swedish government and parliament decided on the possible construction of new reactor units, and the preparation of the regulations for construction and design has been started.

CONCLUSION [11]
The Team noted the commitment of SSM to include lessons learned from TEPCO Fukushima Dai-ichi accident in revision of SSM nuclear safety regulations. The team considered this response adequate in the area of regulation and guides.

Module 10: Transport of Radioactive Material

There was only one issue on transport from the Fukushima event. This was the potential contamination levels on goods coming from Japan. Sweden as a member of the European Association of Competent Authorities (EUCA) discussed this issue with other members of the EUCA. The EUCA agreed that the levels of contamination defined in the IAEA transport standard TS-R-1 should be used as a control level. SSM sent this advice to their port authorities. Sweden had no reported incidents of contamination above these levels.

CONCLUSION [12]
The Team considered that there were no significant issues on transport from Fukushima and welcomes the harmonized approach of the European Association of Competent Authorities.

Module 11: Emergency Preparedness and Response

SSM activated its emergency response system immediately after getting the first news of the earthquake and tsunami in Japan on 11 March 2011. The system was in full activation mode (with the involvement of about 130 people) for about 3 weeks. SSM's main role throughout the event in Japan was to formulate advice and recommendations for the Ministry of Foreign Affairs (UD) to support the Swedish citizens in Japan, the Swedish Embassy in Japan and any Swedish citizens that had plans to travel to Japan, and to inform the general public about the situation at the Fukushima nuclear power plant and how it affected Sweden. Another task involved providing recommendations to other authorities, such as the National Board of Health and Welfare, National Food Agency, Swedish Customs, MSB and other Government Offices.

SSM played an important role during the emergency in the provision of public information through the media. SSM had a pre-existing media strategy for work in the crisis organization. This strategy involved allowing specialists to respond to questions from the mass media instead of communication officers and supervisors, for example. The strategy also involved their being available when the mass media wanted an expert for a talk show or news broadcast, radio interview and the like. These spokespersons were from SSM's regular organization and have expertise in the issues at hand (in this case, know-how from the fields of nuclear energy and radiation protection). The spokespersons are updated regularly by the crisis organization. This information included updates on and analyses of the situation at hand and key messages that SSM wanted to communicate.

An issue thoroughly discussed during the IRRS mission was the administration of iodine tablets to Swedish citizens staying in Japan. A few days after the initial events SSM began to consider a possible need to recommend that Swedish citizens in Japan take iodine tablets. A strategy was drawn up during the first week and information about these tablets and a recommendation related to them was produced. On 16 March, SSM sent 4,000 boxes of iodine tablets that were available from stocks in Sweden, to Japan

with the aim of distributing one box per Swedish citizen in Japan. After the iodine tablets had been sent, it was discussed how the message about taking iodine tablets should be worded. SSM also drew up criteria for recommending that iodine tablets be taken on the basis of feasible discharge scenarios. On Saturday, 19 March, the Ministry of Foreign Affairs, based on a recommendation by SSM issued a recommendation stating that Swedish citizens within a radius of 250 kilometres from Fukushima should take iodine tablets as a precaution. This zone included Tokyo.

CONCLUSION [13]
The Team concluded that SSM responded promptly and properly to the urgent EPR-related challenges in Sweden and to Swedish citizens staying in Japan. The proposal for the Swedes in Japan to take iodine tablets should be further discussed along with examples from other countries of actions that were independents from those taken by the Japanese authorities and the embassies of other countries, such as the evacuation zones, evacuation of citizens from Tokyo, changes of the INES level etc. with the goal of increasing the harmonization of international actions in the event of a serious nuclear accident in another country.

IRRS-TEAM

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
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SSM LIAISON OFFICERS		
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APPENDIX II – MISSION PROGRAMME

Date and Time	Activity	Team Members
Sunday, 2012-02-05		
14:00-18:00	Opening Team Meeting (SSM Liaison Officers)	All
Monday, 2012-02-06		
09:00-12:30	Entrance Meeting : - Welcome and Opening Remarks (A.-L. Eksborg, F. Hassel) - Introduction (A.-L. Eksborg) - Management system (F. Hassel) - IRRS –Nuclear Power Plant Safety (L. Carlsson) - Main processes-Rule making (A. Norstedt) - The Swedish Radioactive Waste Management System and regulatory challenges (J. Anderberg) - Radiation Protection (J. Friberg) - Sweden's administrative structure (B. Dufa)	All
13:30-17:00	Module Discussion/Interviews (SSM Counterparts)	All
17:00-	Team Meeting (SSM Liaison Officers)	All
Tuesday, 2012-02-07		
08:30-09:00	IRRS meeting with SSM management	TL, DTL, D. Graves, H. Suman
09:00-17:00	Module Discussion/Interviews (SSM Counterparts)	All
17:00 -	Team Meeting (SSM Liaison Officers)	All
Wednesday, 2012-02-08		
08:30-09:00	IRRS meeting with SSM management	TL, DTL, D. Graves, H. Suman
09:00-17:00	Module Discussion/Interviews (SSM Counterparts)	All
15:00-17:00	Discussion Ministry of Environment (B. Dufa)	TL, DTL, D. Graves, H. Suman, D. Senior

17:00 -	Team Meeting (SSM Liaison Officers), Report Drafting	All
Thursday, 2012-02-09		
08:30-09:00	IRRS meeting with SSM management	TL, DTL, D. Graves, H. Suman
09:00-17:00	Module Discussion/Interviews (SSM Counterparts)	All
09:00-17:00	Emergency Exercise at SSM (SSM Counterparts)	A. Cortes, P. Zombori, TL, DTL, David Graves, Hazem Suman
17:00 -	Team Meeting (SSM Liaison Officers), Report Drafting	All
Friday, 2012-02-10		
08:30-09:00	IRRS meeting with SSM management	TL, DTL, D. Graves, H. Suman
09:00-11:00	Fukushima Discussion/National Metrology Laboratory	All
09:30-11:00	Advisory Board on Radioactive Waste and Spent Fuel (SSM Counterparts)	I. Simon Cirujano, T. McCartin
14:10-16:00	Meeting with SKB	I. Simon Cirujano, T. McCartin, DTL
17:00	Team Meeting (SSM Liaison Officers), Report Drafting	All
Saturday, 2012-02-11		
09:00 – 16:00	Team Meeting, Report Drafting	All
Sunday, 2012-02-12		
09:00-12:00	Team Meeting, Report Drafting	All
13:00-	Social Event	All
Monday, 2012-02-13		
07:45-12:30	Interview at Medical Products Agency Uppsala	TL/DTL, D. Senior
08:30-09:00	IRRS meeting with SSM management	TL, DTL, D. Graves, H. Suman

09:00-12:30	Module Discussion/Interviews (SSM Counterparts)	All
13:30-15:00	Policy Discussion 1 – Supervisory Strategies (SSM Counterparts)	All
15:30-17:00	Policy Discussion 2 – Competence at SSM (SSM Counterparts)	All
17:00-	Team Meeting (SSM Liaison Officers), Report Drafting	All
Tuesday, 2012-02-14		
08:30-09:00	IRRS meeting with SSM management	TL, DTL, D. Graves, H. Suman
09:00-12:30	IRRS team review of report and its findings (SSM Liaison Officers)	All
13:00-17:00	IRRS team review of report and its findings (SSM Liaison Officers)	All
17:00-18:00	Team Meeting (SSM Liaison Officers), Report Drafting	All
21:00	Initial Draft Report forwarded to SSM	M. Ubani
Wednesday, 2012-02-15		
08:30-09:00	IRRS meeting with SSM management	TL, DTL, D. Graves, H. Suman
09:00-12:30	SSM review of draft IRRS Draft Report (SSM Counterparts)	All
13:30-18:00	SSM review of draft IRRS Draft Report (SSM Counterparts)	All
17:00-18:00	Team Meeting	All
Thursday, 2011-12-01		
09:00-10:30	Discussion of SSM Report Review	All
10:30-17:00	Plenary review of Draft Report (SSM Management/Project Teams)	All

19:00	Submission of final IRRS Mission Report to SSM	M. Ubani
Friday, 2011-12-02		
10:00-12:00	Exit Meeting (SSM Management + Counterparts)	All
12:00-13:00	Press Conference (SSM Management + Counterparts)	All

APPENDIX III – SITE VISITS

SITE VISITS	
1.	Forsmark NPP
2.	Westinghouse Fuel fabrication facility
3.	Clab Intermediate Storage Facility for Spent Fuel
4.	Studsvik Nuclear AB
5.	SVAFO/Studsvik
6.	Karolinska Institutet – PET cyclotron
7.	Akademiska hospital in Uppsala

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	SSM Lead Counterpart	SSM Counterpart
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Georg Schwarz Lawrence Kokajko David Senior	Ann-Louise Eksborg	Fredrik Hassel
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Georg Schwarz Lawrence Kokajko David Senior David Graves	Lennart Carlsson	Ingemar Lund
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Georg Schwarz Lawrence Kokajko David Senior	Ann-Louise Eksborg	Fredrik Hassel
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Roy Edwards	Elisabeth Öhlén	-
5.	**AUTHORIZATION**		
	Teodros Hailu Faizan Mansoor Piet Müskens Mika Markannen	Anna Norstedt Carl-Göran Stålnacke Lennart Carlsson Svante Ernberg	Erik Welleman Helene Jönsson Leif Karlsson Lars Skånberg Eric Häggblom

	IRRS EXPERTS	SSM Lead Counterpart	SSM Counterpart
			Stig Wingefors
6.	**REVIEW AND ASSESSMENT**		
	Teodros Hailu Faizan Mansoor Piet Muskens Mika Markannen	Anna Norstedt Carl-Göran Stålnacke Lennart Carlsson Svante Ernberg	Erik Welleman Helene Jönsson Leif Karlsson Lars Skånberg Eric Häggblom Stig Wingefors
7.	**INSPECTION**		
	Sweng-Woong Woo Hubert Mennesiez Teodros Hailu Mika Markannen	Anna Norstedt Carl-Göran Stålnacke Lennart Carlsson Svante Ernberg	Erik Welleman Helene Jönsson Leif Karlsson Lars Skånberg Eric Häggblom Stig Wingefors
8.	**ENFORCEMENT**		
	Sweng-Woong Woo Hubert Mennesiez Teodros Hailu Mika Markannen	Anna Norstedt Carl-Göran Stålnacke Lennart Carlsson Svante Ernberg	Erik Welleman Helene Jönsson Leif Karlsson Lars Skånberg Eric Häggblom Stig Wingefors
9.	**REGULATIONS AND GUIDES**		
	Marja-Leena Järvinen Rustem Paci	Anna Norstedt Ulf Yngvesson Carl-Göran Stålnacke Lennart Carlsson	Erik Welleman Helene Jönsson Leif Karlsson Lars Skånberg

	IRRS EXPERTS	SSM Lead Counterpart	SSM Counterpart
		Svante Ernberg	Eric Häggblom Stig Wingefors
10.	**TRANSPORT OF RADIOACTIVE MATERIAL**		
	George Sallit	Erik Welleman Charlotte Ahlberg	-
11.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Alejandro Cortes Peter Zombori	Johan Friberg	Lynn Hubbard
12.	**RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING, OCCUPATIONAL, PUBLIC AND ENVIRONMENTAL EXPOSURE CONTROL**		
	Hazem Suman Vasiliki Kamenopoulou Pascal DeBoodt Timothy McCartin Inmaculada Simon Cirujano Andrea Heckel	Johan Anderberg Carl-Göran Stålnacke Johanna Sandwall Bo Strömberg Björn Dverstorp Henrik Efraimsson Ann-Christine Hägg Jan Lillhök Kirlna Skeppström Peter Hofvander Helene Jönsson	Bengt Hedberg Stig Wingefors Anders Wiebert Ansi Gerhardsson Erik Welleman Mathias Leisvik Erica Brewitz Maria Lüning Ann-Louis Söderman
13.	**REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT**		
	Ivan Lux	Lynn Hubbard Jan Hanberg Anders Hallman	

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	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.
	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.
2. GLOBAL NUCLEAR SAFETY REGIME	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.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	GP1	**Good Practice:** The transition of two regulatory bodies into the Swedish Radiation Safety Authority (SSM) organisation represented a considerable achievement. The organisational change management process adopted by the SSM leadership and management team brought about an integration of regulatory functions.
	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.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		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.
	GP2	Good Practice: SSM has developed a strong Man-Technology-Organisation (MTO) specialist regulatory competence and provided training in this area to a wide range of its inspectors. The training equips inspection teams to assess MTO matters in their routine compliance and supervision inspections at licensee sites in order to capture important MTO safety performance information.
	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.
	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.
	GP3	Good Practice: The Communications function in SSM was working well with evidence of some good practices and plans to further improve the area. In particular the training and briefing of specialists/experts to communicate complex regulatory and technical arguments on Television

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		and Radio proved to be very effective. The use of social media to target specific groups in society and inform the public on some key health and safety information is working well and should be considered for deployment across a wider range of SSM's regulatory business.
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**GP4**	**Good Practice: SSM's decision to lead by example and demonstrate that it too is open to review and certification in choosing to certify against recognized international and national standards, including ISO 9001 (quality), ISO 14001 (environment), ISO 17025 (laboratory) and AFS 2001:1 (Systematic Work Environment Management).**
	GP5	**Good Practice: SSM has taken a creative approach in how it chose to increase awareness of its key processes, reinforce their relative placement and interconnectedness, and provide a direct and simple means to access required guidance documents – SSM has developed, validated and posted an interactive process model to its intranet. This interactive tool represents one of many ways for staff to quickly gain access to the appropriate guidance documents and information for key processes.**
	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.**
	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.**
	S4	**Suggestion: SSM should consider addressing safety culture in its management system in a more comprehensive and integrated manner.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
5. AUTHORIZATION	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.
	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.
6. REVIEW AND ASSESSMENT	GP6	**Good Practice:** The NPPs refurbishment program as required by SSM is a good practice.
	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.
7. INSPECTION	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.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	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.**
	GP7	**Good Practice: SSM prepares and publishes (and makes publicly available on website) summary reports on inspection findings and incidences in different uses of radioactive sources including suggestions on how to improve level of safety and compliance, with regulatory requirements and license conditions. In case of medical practices in public hospitals, the summary report is discussed with the representatives of the county.**
8. ENFORCEMENT	**S7**	**Suggestion: SSM should consider monitoring the implementation status of corrective actions of licensees.**
9. REGULATIONS AND GUIDES	**S8**	**Suggestion: SSM should consider ensuring that the "General advice" for radiation protection is kept up to date.**
	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.**
10. TRANSPORT OF RADIOACTIVE MATERIAL	**GP8**	**Good Practice: SSM assessment of packages takes account of work done by other Competent Authorities. This approach is novel, not widely used elsewhere, helps where resources are limited and maintains safety levels.**
	R16	**Recommendation: SSM should only use Special Arrangements as**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		defined in TS-R-1.
11. EMERGENCY PREPAREDNESS AND RESPONSE	**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.**
	GP9	**Good Practice: SSM has established a state-of-the-art Emergency Response Centre, equipped with all necessary tools, procedures, as well as a national network of mobile and stationary laboratories to manage the emergency response.**
	GP10	**Good Practice: The regional cooperation initiative of the Nordic countries NEP is a good example of regional collaboration.**
12. RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING, OCCUPATIONAL, PUBLIC AND ENVIRONMENTAL EXPOSURE CONTROL	**GP11**	**Good Practice: The provision of guidance material for specific areas where ionizing radiations are used and/or produced as well as the identification of actions to be undertaken for improving the regulations on the protection and the safety of workers is acknowledged as a positive indicator of a high level of commitment from SSM in order to foster the implementation of the regulations concerning the occupational exposure.**
	GP12	**Good Practice: As well for the nuclear as for the non-nuclear activities, the requirements for identifying Radiation Protection Experts and the**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		guidance material concerning their training and competence is acknowledged and efforts for maintaining such level of supporting material are encouraged.
	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 dosemeters 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.
	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.
	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.
	S17	Suggestion: The government should consider assigning SSM to review and integrate the national waste management policy and strategy plan.
	R19	Recommendation: SSM should make explicit in the regulations the

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		principle for minimizing the amount of waste produced in non-nuclear practice.
	GP13	**Good Practice: Financial resources are evaluated periodically (e.g., every three years) by SKB, SSM and the government to ensure financial resources are sufficient and consistent with the technical work needed to develop the repository and demonstrate its safety, including resources for regulatory review. The Swedish approach for public participation and stakeholder consultations regarding the RD&D programs and environmental impact assessments represents an excellent approach for building trust in the Swedish high level waste management system, as well as the integrity of the regulator.**
	GP14	**Good Practice: SSM established a review team to ensure potential impacts to post-closure safety are considered across all operational activities (e.g., monitoring activities, closure activities) and other relevant facilities (e.g., encapsulation facility) during the review of the license application.**
	R20	**Recommendation: SSM should cooperate with the National Board of Health and Welfare to ensure that the requirements regarding referring medical practitioners are consistent.**
	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.**
	GP15	**Good Practice: SSM requires all licensees to determine the diagnostic standard dose for all specified examinations at least each third year, and to provide this information upon request. Using these data SSM demonstrates continuous decreasing trend in DSD.**
	R22	**Recommendation: The government should ensure that requirements are in place for education, training, qualification and competence in**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		protection and safety of all health professionals with responsibilities for medical exposure.
13. REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICI ACCIDENT	**-**	**-**

APPENDIX VI – CONCLUSIONS ON THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT

AREA	NO.	CONCLUSION
ACTIONS TAKEN BY THE REGLATORY BODY IN THE AFTERMATH OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT	C 1	The Team concluded that SSM reacted promptly and efficiently to the challenges posed by the TEPCO Fukushima Dai-ichi accident in compliance with its duties related to providing information to the Government, other agencies and the public. The SSM emergency team served for an extended period of time with an effort sometimes above what is expected. Public information activity of SSM was exemplary. The safety of the Swedish nuclear installations did not necessarily require immediate actions from the part of the regulatory body, although providing more instructions as to the precautionary actions to be taken by the licensees might have been beneficial. Activity of the emergency team and of the SSM management during the early stages of the accident is worth analysing in comparison to the various international protective actions that were taken. Conclusions may be drawn for the benefit of increasing the harmonization of the international response.
PLANS FOR UP-COMING ACTIONS TO FURTHER ADDRESS THE REGULATORY IMPLICATIONS OF THE TEPCO FUKUSHIMA DAI-ICHI ACCIDENT	C 2	The Team concluded that SSM performed an extended investigation on the utilization of international experience in long term operation and safety improvement actions related to the Fukushima event. The IRRS Team suggests that the post mission Action Plan of SSM, which is to be compiled after the analysis of the IRRS mission findings should also include the tasks identified by the project above.
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	C 3	The Team did not identify any element regarding the responsibilities and function of the government which would raise particular concern in light of the TEPCO Fukushima Dai-ichi accident. It was also noted that the Government required, and SSM is committed, to address the relevant implications and lessons learned from the accident within the framework of the EU stress test.

AREA	NO.	CONCLUSION
2. GLOBAL NUCLEAR SAFETY REGIME	**C 4**	**The Team concluded that SSM is appropriately engaged in international activities with regard to the TEPCO Fukushima Dai-ichi accident, including the EU Stress Test, and has already taken initial actions to improve the safety of Swedish NPPs.**
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**C 5**	**The Team did not identify elements regarding the responsibilities and functions of the regulatory body which would raise particular concern in light of the TEPCO Fukushima Dai-ichi accident. The Team also recognized that SSM is committed to fostering improvement of the safety of the Swedish NPPs as well as its regulatory processes as a result of lessons learned from the TEPCO Fukushima Dai-ichi event.** **The Team considers that the communication to the public and interested parties was carried out in an exemplary manner.**
4. MANAGMENT SYSTEM OF THE REGULATRY BODY	**C 6**	**The Team concluded that SSM has taken appropriate actions with regard to the TEPCO Fukushima Dai-ichi accident in accordance with its roles and responsibilities as an independent regulator.**
8. AUTHORIZATION	**C 7**	**The IRRS-team concluded that measures to be imposed by SSM through authorisation were not needed.**
9. REVIEW AND ASSESSMENT	**C 8**	**The Team concluded that SSM has complied with EU stress program. In addition to the EU- program CLAB has also been subjected to a stress test. The IRRS team concluded that the course of actions by SSM and by the Swedish NPPs after the TEPCO-Fukushima Dai-ichi accident were commensurate with the risk posed.**

AREA	NO.	CONCLUSION
10. INSPECTION	**C 9**	**The Team concluded that specific inspections could have been carried out more formally and more in depth in order to confirm the compliance of the NPPs after the TEPCO Fukushima Dai-ichi accident.**
11. ENFORCEMENT	**C 10**	**The Team considers that the implementation of the governmental assignment in response to the TEPCO Fukushima Dai-ichi accident is on-going. The actions taken by SSM are in accordance with the European stress tests and seem to be commensurate with the safety importance of the issues raised by the accident. The SSM enforcement process is capable of dealing with the enforcement activity needs created by the TEPCO Fukushima Dai-ichi accident without any change.**
12. REGULATIONS AND GUIDES	**C 11**	**The Team noted the commitment of SSM to include lessons learned from TEPCO Fukushima Dai-ichi accident in revision of SSM nuclear safety regulations. The team considered this response adequate in the area of regulation and guides.**
13. TRANSPORT OF RADIOACTIVE MATERIAL	**C 12**	**The Team considered that there were no significant issues on transport from Fukushima and welcomes the harmonized approach of the European Association of Competent Authorities.**

AREA	NO.	CONCLUSION
14. EMERGENCY PREPAREDNESS AND RESPONSE	**C 13**	**The Team concluded that SSM responded promptly and properly to the urgent EPR-related challenges in Sweden and to Swedish citizens staying in Japan. The proposal for the Swedes in Japan to take iodine tablets should be further discussed along with examples from other countries of actions that were independents from those taken by the Japanese authorities and the embassies of other countries, such as the evacuation zones, evacuation of citizens from Tokyo, changes of the INES level etc. with the goal of increasing the harmonization of international actions in the event of a serious nuclear accident in another country.**

APPENDIX VII – SSM REFERENCE MATERIAL USED FOR THE REVIEW

[1] IRRS Questions and Answers:

- *Module 1: Responsibilities and Functions of the Government*
- *Module 2: Global Nuclear Safety Regime*
- *Module 3: Responsibilities and functions of the Regulatory Body*
- *Module 4: Management System of the Regulatory Body*
- *Module 5: Authorization*
- *Module 6: Review and Assessment*
- *Module 7: Inspection*
- *Module 8: Enforcement*
- *Module 9: Regulations and Guides*
- *Module 10: Emergency Preparedness and Response*
- *Module 11a: Occupational Radiation Protection*
- *Module 11b: Control of Radioactive Discharges and Materials for Clearance*
- *Module 11c: Environmental Monitoring*
- *Module 11d: Control of control of chronic exposures (radon, NORM and past activities) and remediation*
- *Module 11e: Waste Management (policy and strategy, predisposal and disposal)*
- *Module 11f: Transport Safety*

[2] Regulations

1. *SSMFS 2008:51*
2. *SSMFS 2008:39*
3. *SSMFS 2008:37*
4. *SSMFS 2008:35*
5. *SSMFS 2008:32*
6. *SSMFS 2008:29*
7. *SSMFS 2008:26*
8. *SSMFS 2008:24*
9. *SSMFS 2008:23*
10. *SSMFS 2008:22*
11. *SSMFS 2008:19*
12. *SSMFS 2008:17*
13. *SSMFS 2008:15*
14. *SSMFS 2008:9*
15. *SSMFS 2008:7*
16. *SSMFS 2008:6*
17. *SSMFS 2008:1*

Nuclear Technology[1]

1. *SKIFS 2005:1 The Swedish Nuclear Power Inspectorate's Regulations concerning Physical Protection of Nuclear Facilities*
2. *SKIFS 2004:2 The Swedish Nuclear Power Inspectorate's Regulations concerning the Design and Construction of Nuclear Power Reactors*
3. *SKIFS 2002:1 The Swedish Nuclear Power Inspectorate's Regulations concerning Safety in connection*

[1] The listed regulations (SKIFS and SSIFS), which are translated into English, is transferred to SSMFS.

with the Disposal of Nuclear Material and Nuclear Waste

4. *SKIFS 2002:1 The Swedish Nuclear Power Inspectorate's Regulations concerning Safety in connection with the Disposal of Nuclear Material and Nuclear Waste*

Radiation Protection[2]

1. *Ordinance (SFS 2007:193) on Producer's Responsibility for Certain Radioactive Products and Orphan Sources*
2. *SSI FS 2006:1 Regulations on the Import and Export as well as Reporting of Radioactive Substances*
3. *SSI FS 2005:5 Guidelines on the application of the regulations (SSI FS 1998:1) concerning protection of human health and the environment in connection with the final management of spent nuclear fuel and nuclear waste*
4. *SSI FS 2005:4 Regulations on Lasers*
5. *SSI FS 2005:3 Regulations on Amendments to the Regulations (SSI FS 1995:3) on Drying with Microwaves*
6. *SSI FS 2005:1 Regulations and General Advice on the handling of Ashes Contaminated by Caesium-137*
7. *SSI FS 2004:1 Regulations on amendments to the regulations (SSI FS 1995:4) on Control of Shipments of Radioactive Waste into or out of Sweden*
8. *SSI FS 2003:2 Regulations on Amendments to the Regulations (SSI FS 1998:5) on Monitoring and Reporting of Individual Radiation Doses*
9. *SSI FS 2002:4 Regulations on Planning for and during Decommissioning of Nuclear Facilities*
10. *SSI FS 2002:3 General Advice on the Limitation of Exposure of the General Public to Electromagnetic Fields*
11. *SSI FS 2002:2 Regulations and General Advice on Diagnostic Standard Doses and Reference Levels within Medical X-ray Diagnostics*
12. *SSI FS 2001:1 Regulationson Handling of Radioactive Waste and Nuclear Waste at Nuclear Facilities.*
13. *SSI FS 2002:3 General Advice on the Limitation of Exposure of the General Public to Electromagnetic Fields*
14. *SSI FS 2002:2 Regulations and General Advice on Diagnostic Standard Doses and Reference Levels within Medical X-ray Diagnostics*
15. *SSI FS 2001:1 Regulationson Handling of Radioactive Waste and Nuclear Waste at Nuclear Facilities.*
16. *SSI FS 2000:9 Regulations on Accelerators and Sealed Sources*
17. *SSI FS 2000:8 Regulations and General Advice on Radiography*
18. *SSI FS 2000:7 Regulations on Laboratory Work with Unsealed Radioactive Substances*
19. *SSI FS 2000:5 Regulations and General Advice on Practice with X-rays in Veterinary Medicine.*
20. *SSI FS 2000:4 Regulations on Radiation Therapy*
21. *SSI FS 2000:3 Regulations and General Advice on Nuclear Medicine*
22. *SSI FS 2000:2 Regulations on X-ray Diagnostics*
23. *SSI FS 1998:2 Regulations on Sun Beds.*
24. *SSI FS 1998:1 Regulations on the Protection of Human Health and the Environment in connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste*
25. *SSI FS 1997:1 Regulations on Filing at Nuclear Plants.*
26. *SSI FS 1996:3 Regulations on Outside Workers at Work with Ionising Radiation.*
27. *SSI FS 1995:4 Regulations on Control of Shipments of Radioactive Waste into or out of Sweden*
28. *SSI FS 1995:3 The Swedish Radiation Protection Institute´s Regulations on Drying with Microwaves*
29. *SSI FS 1995:2 Regulations on the Use of Equipment in Industry containing Sealed Sources or X-Ray Tubes.*
30. *SSI FS 1995:1 General Advice on Performance Specifications for Purchasing Equipment for X-ray*

[2] The listed regulations (SKIFS and SSIFS), which are translated into English, is transferred to SSMFS.

Diagnostics

31. *SSI FS 1994:4 Regulations on Technical Devices Unintentionally Emitting X-ray radiation*
32. *SSI FS 1994:3 Regulations on Smoke Detectors containing Radioactive Sources*
33. *SSI FS 1992:4 Regulations on Smoke Detectors for Domestic Use containing Radioactive Sources*
34. *SSI FS 1992:3 Regulations on Licence to Schools for the Possession and Use of certain X-ray Equipment and Sealed Sources for Educational purposes as well as Import, Manufacturing and Transfer of such Sources*
35. *SSI FS 1992:1 Regulations on Captain's Bearing Instruments and Bearing Compasses provided with a Tritium Light Source.*
36. *SSI FS 1990:1 The Swedish Radiation Protection Institute´s General Advice on Exposure Limits to Ultraviolet Radiation.*
37. *SSI FS 1989:2 Regulations on Equipment for Industrial Radiography*
38. *SSI FS 1983:7 Regulations on Radioactive Waste Not Associated with Nuclear Energy*

Acts and Ordinances

1. *The Act on Nuclear Activities*
2. *Radiation Protection Act*
3. *Ordinance with instructions for the Swedish Radiation Safety Authority*

[3] Regulatory Framework

1. *The Swedish system of government*
2. *The Swedish Law-Making Process*
3. *Public Access to Informationand Secrecy Act*
4. *The Act on Nuclear Activities*
5. *Radiation Protection Act*
6. *Ordinance with Instructions for the Swedish Radiation Safety Authority*
7. *The Environmental Code*
8. *Sweden's Environmental Objectives*

[4] Internal documentation

1. *Decision-making procedure for the Swedish Radiation Safety Authority*
2. *Rules of procedure for the Swedish Radiation Safety Authority*
3. *STYR2011-42 Internal auditing*
4. *STYR2011-71 Management of the Swedish Radiation Safety Authority*
5. *STYR2011-87 Sanctions as part of SSM's regulatory supervision*
6. *STYR2011-97. Supervisory policy*
7. *STYR2011-98 The processes of planning and follow-up*
8. *Time schedule_Planning and follow-up*
9. *STYR2011-102 Policy for international agreements*
10. *STYR2011-106 Compliance inspection*
11. *STYR2011-107Surveillance inspection*
12. *STYR2011-108 Rapid investigations*
13. *STYR2011-124 Reviews*
14. *STYR2011-134 Situational and scenario analysis*
15. *STYR2011-138 Dealing with disqualification and conflicts of interest*
16. *STYR2001-171 Strategy document Competence profile supervision*

[5] Policy Issues

1. *Supervisory strategy*
2. *Competence at Swedish Radiation Safety Authority*

[6] Report

1. *Report 2012:03: The IAEA Integrated Regulatory Review Service Mission to Sweden in February 2012*

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**IAEA SAFETY STANDARDS SERIES No. SF-1** - Fundamental Safety Principles
2.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 1** - Governmental, Legal and Regulatory Framework for Safety
3.	**IAEA SAFETY STANDARDS SERIES No. GS-R-2 -** Preparedness and Response for a Nuclear or Radiological Emergency
4.	**IAEA SAFETY STANDARDS SERIES No. GS-R-3 -** The Management System for Facilities and Activities
5.	**IAEA SAFETY STANDARDS SERIES No. NS-R-1 –** Safety of Nuclear Power Plants: Design
6.	**IAEA SAFETY STANDARDS SERIES No. NS-R-2 –** Safety of Nuclear Power Plants: Operation
7.	**IAEA SAFETY STANDARDS SERIES No. NS-R-4 -** Safety of Research Reactors
8.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.1 -** Organization and Staffing of the Regulatory Body for Nuclear Facilities
9.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.2 -** Review and Assessment of Nuclear Facilities by the Regulatory Body
10.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.3 -** Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body
11.	**IAEA SAFETY STANDARDS SERIES No. GS-G-1.4 -** Documentation for Use in Regulatory Nuclear Facilities
12.	**IAEA SAFETY STANDARDS SERIES No. GS-G-2.1 -** Arrangements for Preparedness for a Nuclear or Radiological Emergency
13.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.1 -** Application of the Management System for Facilities and Activities
14.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.2 -** The Management System for Technical Services in Radiation Safety
15.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.3 -** Assessment of Occupational Exposure Due to External Sources of Radiation
16.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.4 -** Building Competence in Radiation Protection and the Safe Use of Radiation Sources
17.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.8** – Environmental and Source Monitoring for purposes of Radiation Protection
18.	**IAEA SAFETY STANDARDS SERIES No. NS-G-2.10 -** Periodic Safety Review of Nuclear Power Plants Safety Guide

19. **IAEA SAFETY STANDARDS SERIES No. NS-G-211 -** A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide

20. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

21. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Generic Assessment Procedures for Determining Protective Actions during a Reactor Accident, IAEA-TECDOC-955, IAEA, Vienna (1997).

APPENDIX IX – ORGANIZATIONAL CHART