Strål
säkerhets
myndigheten
Swedish Radiation Safety Authority

2012:03

The IAEA Integrated Regulatory Review Service Mission to Sweden in February 2012

Report number: 2012:03 **ISSN:** 2000-0456
Available at www.stralsakerhetsmyndigheten.se

Foreword

The Swedish Government decided on January 22, 2009 to mandate the Swedish Radiation Safety Authority, SSM, to apply for an international review of the Author-ity and its areas of supervision, an 'IRRS' (Integrated Regulatory Review Service) carried out by the International Atomic Energy Agency (IAEA). On February 25, 2009, SSM made a formal request to the IAEA for an IRRS in Sweden. The time period for the IRRS mission was later agreed to be 6–17 February, 2012.

The reasons for requesting an IRRS were manifold:

- The latest international review of Swedish authorities in the areas of nucle-ar safety and radiation protection was performed more than fifteen years ago (Commission of inquiry for an international review of Swedish nuclear regulatory activities; SOU 1996:73-74).
- Events at Swedish nuclear power plants ('NPPs'), such as the partial loss of power at Forsmark 1 in 2006 and the preceding follow-up, resulted in a review of the operators' safety work. International reviews, IAEA OSARTs, were performed at all Swedish NPPs between 2008 and 2010. The events also resulted in a limited review of the prevailing regulatory supervision regime, but an IRRS would be the obvious option for a more comprehensive review.
- The work with a European Nuclear Safety Directive (issued on June 25, 2009 as Council Directive 2009/71 Euratom) was well underway and this legal instrument would encompass a requirement imposed on EU Member States to regularly perform international peer reviews (every 10th year) of their respective national legal systems and regulatory authorities.

In order to carry out the IRRS work at SSM, a project was set up scheduled to run between January 15, 2010 and April 30, 2012. The members of this project are Elisabeth Öhlén (project manager) Anna Norstedt, Ingemar Lund and Gustaf Löwenhielm.

This report summarises the project's progress immediately prior to the IRRS mission in February 2012. The report contains the findings from the selfassessment performed by SSM staff. It also contains a plan to implement measures to remedy deficiencies that have been identified and to improve the radiation safety work of the Authority.

ANN-LOUISE EKSBORG
Director General

Strål
säkerhets
myndigheten
Swedish Radiation Safety Authority

Authors: Swedish Radiation Safety Authority

2012:03

The IAEA Integrated Regulatory Review Service Mission to Sweden in February 2012

Date: January 2012
Report number: 2012:03 **ISSN:** 2000-0456
Available at www.stralsakerhetsmyndigheten.se

Contents

Introduction

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

The Director General Ann-Louise Eksborg is appointed by the Government and is exclusively responsible and reports the authority activities directly to the Government. The authority has an advisory council with a maximum of ten members which are appointed by the Government. SSM is organized in three operational departments, departments of administration and communication, DG-staff and a secretariat for International Co-operation and development. SSM has (end of 2010) a staff of 274 persons. The authority has a budget of approx. 400 million SEK.

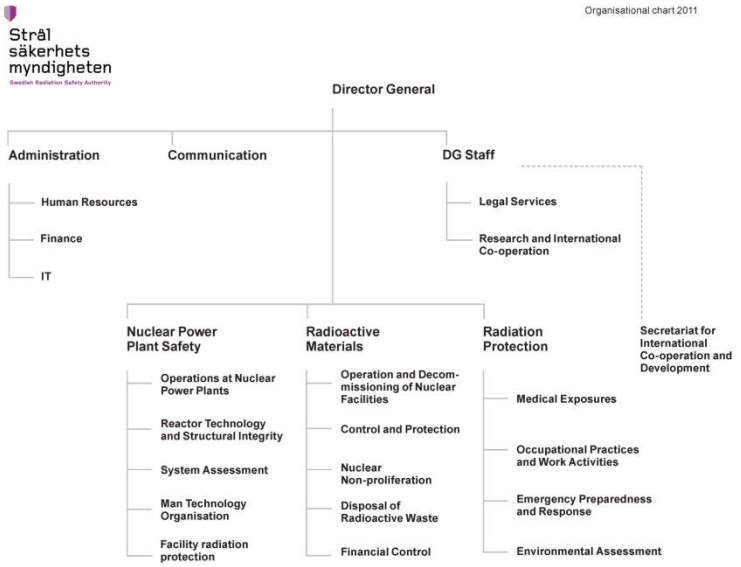

Figure 1 Organisational chart

SSM missions and tasks are defined in the Ordinance (SFS 2008:452) with instruction for the Swedish Radiation Safety Authority. The first section states that The Swedish Radiation Safety Authority is an administrative authority responsible for areas concerning the protection of human health and the environment against the harmful effects of ionising and non-ionising radiation, issues concerning safety, security and physical protection in nuclear and other activities involving radiation and also issues concerning nuclear non-proliferation.

SSM has implemented an integrated ISO-certified management system in accordance with ISO 9001 (quality) and 14001 (environment) in addition to AFS2001:1 (work environment). The management system is set up in accordance with the IAEA's guidelines GS-R-3 and fulfils the requirements.

Vision and mission statement

SSM´s vision is:

A society safe from the harmful effects of radiation

SSM´s mission statement is:

The Swedish Radiation Safety Authority works proactively and preventively to protect people and the environment from the harmful effects of radiation, now and in the future.

Operational areas

The authority works in ten areas of operation

- Safe nuclear power
- Safe health and medical care
- Safe products and services
- Safe approach to natural radiation
- Radiation safety globally
- Safe management of radioactive waste
- National preparedness and response for nuclear and radiological emergencies
- National radiation safety competence
- National Standard Laboratory for kerma, absorbed dose and dose equivalent
- Efficient and effective administration

Operational policy and fundamental organisational values

The perspective of radiation safety is to govern the operations and decision-making of the Authority.

SSM shares the fundamental values held by public administration based on the platform of democracy and human rights while continually striving to follow the rule of law, maintain efficiency and effectiveness and achieve a citizen's perspective. SSM's operations are characterised by the values of society expressed by these fundamental values. SSM shall be an attractive employer offering interesting and meaningful tasks and forms of co-operation with a special focus on involvement. This implies that SSM:

- continually improves and develops its operations and approach
- complies with legislation and other provisions
- has a high level of security in the Authority's information management
- pursues environmental work focusing on a lower level of impact on internal and external environments by conserving resources, correctly managing dangerous substances and dangerous waste and by reducing releases of greenhouse gases
- fosters a sound work environment that promotes health, equal opportunities and diversity
- works proactively to secure competence.

Key values

A key prerequisite for successful work is the legitimacy in society. The key values have the aim of guiding the actions in a way instilling confidence and strengthening the legitimacy. The three key values are: reliability, integrity and openness. These values are defined below.

Reliability means pursuing our work on the basis of facts. Reliability is achieved when employees are competent, objective and impartial. Competence means employees having the requisite professional skills, education, training and experience.

Integrity means maintaining SSM independence and not allowing staff to be influenced when it comes to decisions, standpoints, advice and recommendations. Integrity involves taking charge, both while exercising authority and on an employee level.

Openness means that the work of the Authority is transparent to the outside world and that SSM clearly and proactively provides information about the work, standpoints, advice, recommendations and decisions. Openness also involves SSM's willingness to pay attention to and consider external factors.

These fundamental values are put into effect by means of SSM's established objectives, policies and other steering documents, which are to be understood, familiar to and complied with by all members of the organisation.

Overview of regulated facilities and activities

SSM is responsible for the regulation of a number of facilities and activities. Situated at six locations there are sixteen nuclear facilities; ten operating nuclear power reactors, two shut down reactors under decommissioning, three research reactors under decommissioning, one fuel factory, one waste facility, one final storage deposit for low and intermediate waste and one central intermediate spent fuel storage. In addition to the nuclear facilities there are a number of non-nuclear licensee holders namely;

- ~250 diagnostic and/or interventional radiology facilities
    - 5 million X-ray examinations per year
    - 100 000 nuclear diagnostics per year
    - 25 000 patients radiation therapy
- About 760 licensed dentists and 8 000 on a generic license
- ~300 veterinary facilities
- 3 PET cyclotrons
- 8 irradiation facilities (industrial and/or research)
- 19 industrial radiography facilities
- 525 industrial gauge facilities
- 12 well-logging equipment
- ~390 security equipment (baggage x-ray, container inspection)

Scope of the Integrated Regulatory Review Service Mission February 2012

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 systems for the Regulatory Body
Module 5: Authorization
Module 6: Review and Assessment
Module 7: Inspection
Module 8: Enforcement
Module 9: Regulations and Guides
Module 5-9 Cross-cutting areas
- Radioactive sources
- Nuclear Power Plants
- Fuel Cycle Facilities
- Waste Facilities
- Decommissioning

Module 10: Emergency Preparedness and Response
Module 11: Thematic Areas
- Transport
- Control of Medical Exposure
- Occupational Radiation Protection
- Control of radioactive discharges and materials for clearance
- Environmental monitoring associated with authorized practices for public radiation protection purposes.
- Control of chronic exposures (Radon, NORM and past practices) and remediation

Module 12: Regulatory Implications of the Fukushima Accident

Self-Assessment using the IAEA Self-Assessment Tool (SAT)

In the autumn 2010 a SSM project-team was formed with the responsibility to make preparations for the IRRS-mission. The team was visiting IAEA in September 2010 to attend to a SAT training workshop. As a starting point an IAEA IRRS Information Meeting for all staff (half a day) and tentative counterparts (one day) was held during 21 January 2011.

A self-assessment was performed, starting in February through late August 2011 (initially May), using the IAEA's self-assessment tools, including the SAT software and question-sets for all topic areas agreed in connection to the IRRS Information Meeting. In some areas the work was delayed due to the Fukushima accident, which involved a great portion of the SSM staff. This affected the initial time frame.

For the response phase of the self-assessment, respondent teams were formed basically for each topic area, drawing on the expertise of staff ranging from relatively junior to the senior and most experienced staff in each topical area. However, since SSM has the ambition to have similar working processes regardless regulatory area the teams in the cross-cutting areas were arranged according to the modules 5-9

(Authorization, Review and Assessment, Inspection, Enforcement, Regulations and Guides). Unfortunately this was not a very effective methodology since the question-sets were arranged according to facility/activity. One member of each team was appointed team leader and one was designated as the writer responsible for entering the consensus responses of the team.

The SAT software was installed on SSM´s internal network, so it will always be accessible to SSM staff for future self-assessment cycles and as a general resource. The methodology adopted, in accordance with the draft IAEA IRRS Guidelines, was to download the relevant question-sets from the SAT software and to distribute them (as MS Word table templates) to participating SSM staff (approximately 150 of SSM staff provided input). The response phase was completed using these Word templates.

The completion of the response phase was an iterative process, by which the responses were reviewed by "analysis" teams, which were composed of more senior staff members. Main focus in this phase was to make a quality check. The finalised responses text was uploaded to the SAT software and an 'interim SAT Report' was generated.

The response phase produced a high volume of comprehensive factual information compiled in the interim SAT Report. The subsequent analysis phase was undertaken using the most current interim SAT Report. The analysis process synthesised the large volume of responses material into key issues by topic area, in terms of strengths, weaknesses, priorities for improvement and opportunities for change etc. Analysis was performed by the IRRS project team together with senior staff of SSM. From the analysis outcomes, this IRRS Advanced Reference Materials (ARM) submission was developed. It is a summary of the significant outcomes of the self-assessment. This submission includes, as an Appendix, the final SAT Report, giving the details of all responses in each topic area.

SSM Preliminary Action Plan

For more information see details in specified modules.

No	Modules	Action
1	2	**International experience** • Procedures for collecting and disseminating experiences, both nationally and internationally should be developed.
2	3, 5-7 10, 11.1, 11.2, 11.3	**Secure Competence** • Develop and implement a process including a comprehensive strategy to secure competence. Develop and enhance competence in specific areas, e.g. emergency preparedness.
3	3,4	**Management system** • Further development of routines etc. to be more detailed and work-specific. • Develop methods and criteria for follow up and performance evaluation. • Develop a strategy for capturing and compiling the expectations and stand-points of interested parties.
4	9, 11.3	**Regulations and Guides** • Develop a new structure for the radiation safety regulations to achieve a logical structure and harmonisation (New radiation safety legislation expected 2015). For example harmonisation of occupational exposure regulations are needed. • Consider and develop, as appropriate, more detailed regulations, general advice and guides. • Develop regulations for new power plants. • Consider and introduce, as appropriate, explicit requirements on safety culture in regulations. • Assessment of all radiation risks during normal operation, transients and accident conditions should be clarified in regulations and general advice and internal steering documents.
5	5	**Authorisation** • Develop licencing /regulation of disposal facilities, parts of which could be under simultaneous construction and closure. See also Review and Assessment
6	6	**Review and assessment** • Develop and improve procedures for review and assessment to be more comprehensive and complete. • Review and possible develop procedures to ensure that appropriate human resources are allocated for each review task. • Improve internal steering documents, so that the internal processes require that all relevant and available information on radiation safety are considered during reviews. • Develop process and criteria for review and assessment of long term operation of a nuclear facility within the framework of periodic safety review. • Develop process and criteria for managing situations when a licensee has seriously neglected legal/regulatory provisions so that a suspension of the licence is deemed to be necessary.
7	7	**Inspection** • Further develop supervision plans for all areas SSM supervisory areas, including an overarching SSM supervision plan presenting the overall focus and prioritisation. • Develop a structure cohesive and a database for ensuring consistent legal of relevant legislation /rules and the registration of identified factors and measures taken.

No	Modules	Action
8	5-7	**Waste management** • Develop a strategy and regulation of long-lived waste management. • Implement and update as necessarily the National Waste Plan. The management of certain types of radioactive sources needs further attention.
9	8	**Enforcement** • Develop and implement an improved enforcement strategy.
10	10, 11.3	**Emergency Exposure Situations** • Occupational exposure regulations in connection with emergency situations need revision and updating. • Develop measurable operational intervention levels and routines for application of intervention levels.
11	10	**Emergency Preparedness** • Develop the exercises and training plan to improve the crisis organisation's ability to deal with events other than nuclear power accidents. • Establish a mechanism which enables SSM to have radiation experts present on the site of an accident on short notice.
12	11.2	**Medical Exposures** • Review the requirements on, and the distribution of duties between, the prescribing doctor/dentist, the physician performing the procedures, and the radiological leadership (RALF).
13	11.2	**Co-operation between authorities** • Consolidate and further develop the co-operation with other authorities in the medical area.
14	7	**Hass- Code of Conduct** • Improve the process for management orphan sources. • Develop a new system for registration of licensed radioactive sources (including high activity sealed sources HASS). • Improve the management of HASS sources regarding confidentiality aspects in external and internal communication processes.

Table 1 Preliminary Action Plan

Advance Reference Material

The following pages comprise the self-assessment overview and summaries for each module of the agreed scope of the Swedish IRRS 2012, together with the advance reference material (ARM) and a synopsis of the elective policy issues for discussion during the mission.

Hyperlinks to the references are provided at SSM´s external web-site. (www.ssm.se/IRRS2012). Reference documents will also be available in printed form during the IRRS mission. Some documents mentioned in the text are not translated and are therefore not included in the Advance Reference Material. Most of the documents will be available for review during the IRRS mission.

Module 1: Responsibilities and functions of the government

Counterparts

Ann-Louise Eksborg
Director General
+46 8 799 42 09
Ann-Louise.Eksborg@ssm.se

Fredrik Hassel
Head of Staff
+46 8 799 41 51
Fredrik.Hassel@ssm.se

Assessment for IAEA requirements GSR Part 1– Governmental, Legal and Regulatory Framework for Safety: Requirement 1-13

Summary and Conclusions

Swedish legislation clearly states the responsibilities of parties carrying out activities involving radioactive materials and that SSM has an independent role in its regulatory work.

The proposed new Swedish legislation, combining the nuclear and radiation protection areas, will be a possible future workload for SSM. Independently of this, SSM needs to transform its regulatory framework as a consequence of the merger between the Swedish Nuclear Inspectorate and the Swedish Radiation Protection Authority.

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

National policy and strategy for safety

Requirement 1: 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.

The overall goal of the Government's environmental policy is to hand on to the next generation a society in which the major environmental problems facing Sweden have been solved. To attain the generation goal, the Swedish Government has established national Environmental Quality Objectives (EQOs) within 16 areas adopted by the Swedish Parliament. One of the objectives is formulated as "A Safe Radiation Environment". The safety objective on radiation protection states that human health and biological diversity must 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 regulatory authorities. The safety principles 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), and
- Nuclear Liability Act (1968:45).

The fundamental safety principles in the acts mentioned above are:

- The prime responsibility for safety must rest with the person or organisation responsible for facilities and activities that give rise to radiation risks.
- An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.
- Effective leadership and management for safety must be established and sustained in organisations concerned with, and facilities and activities that give rise to, radiation risks.
- Facilities and activities that give rise to radiation risks must yield an overall benefit.
- Protection must be optimized to provide the highest level of safety that can reasonably be achieved.
- Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
- People and the environment, present and future, must be protected against radiation risks.
- All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.
- Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.
- Protective actions to reduce existing or unregulated radiation risks must be justified and optimized.

The Swedish fundamental safety principles are based on the IAEA Safety Fundamentals.

Establishment of a framework for safety

Requirement 2: Establishment of a framework for safety
The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.

The safety objective stated above is established through the following acts decided by the Swedish Parliament:

- Nuclear Activities Act (1984:3)
  - maintain safety in operation, waste management and decommissioning and dismantling of nuclear facilities.
- Radiation Protection Act (1988:220)
  - protect people, animals and the environment from the harmful effects of radiation.

Together with these acts the following acts and ordinances constitute the basic nuclear safety and radiation protection legislation of Sweden:

- Environmental Code (1998:808),
- Act on Financial Measures for the Management of Waste Products from Nuclear Activities (2006:647), and
- Nuclear Liability Act (1968:45)
- Nuclear Activities Ordinance (1984:14)
- Radiation Protection Ordinance (1988:293)

In the Preamble of the Environmental Code it is stated;

> "The provisions of this Code are to promote sustainable development so that present and future generations will be assured a healthy and sound environment. Such a development is based on the recognition that nature has a protective value and that our right to change and use nature is associated with a responsibility to manage nature well."

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

The different authorities responsible for effectuating the radiation safety policy and strategy are:

The Swedish Radiation Safety Authority, SSM, is the administrative authority for protection of people and the environment against harmful effects of ionizing and non-ionizing radiation, for issues on nuclear safety including security in nuclear technology activities as well as in other activities involving radiation, and for issues regarding non-proliferation. SSM shall actively and preventively work for high levels of nuclear safety and radiation protection in the society.

The National Council for Nuclear Waste is an advisory body to the government, attached to the Ministry of the Environment, on matters related to nuclear waste management.

The Environmental Objectives Council is promoting consultation and cooperation in implementing the environmental quality objectives adopted by the Parliament. The Swedish Environmental Protection Agency, Swedish EPA, is responsible for coordinating the implementation of the environmental policy decided by the Swedish parliament, including "A Safe Radiation Environment".

The Swedish Civil Contingencies Agency, MSB, with the task to enhance and support societal capacities for preparedness for and prevention of emergencies and crisis.

The Swedish Work Environment Authority, AV, which paramount objective is to reduce the risk of ill-health and accidents in the workplace and to improve the work environment from the physical, mental and organizational viewpoints. AV is tasked with for example issuing regulations and ensuring compliance with work environment legislation.

Swedish National Board of Housing, Building and Planning, Boverket, is the central government authority for town and country planning, management of land and water resources, building and housing. Boverket provides, inter alia, building regulations, in which the maximum permissible radon level in new houses is specified.

The National Board of Health and Welfare, Socialstyrelsen, is responsible for a wide range of activities and different duties within the fields of social services, health and medical services, environmental health, communicable disease prevention and epidemiology. Socialstyrelsen is for example responsible for certain matters relating to radiation, such as radon in existing buildings.

National Food Agency, NFA, is responsible for control of radioactive substances in drinking water and other food.

The Medical Products Agency, MPA, is responsible for radiopharmaceuticals and equipment in hospitals.

The County Administrative Board has a coordinating role in the carrying out of the environmental impact assessment when a nuclear facility is to be licensed. The three County Administrative Boards where the NPPs in Sweden are situated have a dedicated role within the emergency preparedness regarding nuclear accidents. The County Administrative Boards appoints a rescue leader in a case of an emergency situation.

In 11 December 2008 the Head of the Ministry of the Environment appointed a Committee of Inquiry to examine the prospects for harmonizing the regulations concerning activities in the field of nuclear technology and radiation protection.

The Committee was to focus in particular on the feasibility of merging the provisions of the Nuclear Activities Act (1984:3) and the Radiation Protection Act (1988:220) in 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 need to simplify and streamline the rules on nuclear operations and other practices involving radiation has long been discussed. Since the Environmental Code, the Nuclear Activities Act and the Radiation Protection Act are to be applied in parallel, license conditions decided on by the Environment Court in a permit application case pursuant to the Environmental Code may encompass measures already required under the provisions of the other two laws. It is not only this double licensing procedure – the overlapping application process where two separate permits have the same legal force – that is said to be causing problems. Other issues caused by a lack of legislative coherence have also been raised.

The result of the Committee is now processed within the Government, including an extensive external referral, and the Parliament and a new legislation would be in place at the earliest in 2015.

Establishment of the regulatory body

Requirement 3: Establishment of the regulatory body
The government, through the legal system, shall establish and maintain a regulatory body, and shall confer in it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.

The Swedish Radiation Safety Authority, SSM, was established on July 1, 2008. SSM is a central administrative authority reporting to the Ministry of Environment. SSM took over the responsibility and tasks in connection of the merger of the former authorities Swedish Nuclear Power Inspectorate (SKI) and the Swedish Radiation Protection Authority (SSI). The main motive for the merger was to strengthen and reinforce the supervision of both nuclear and non-nuclear activities, relating to nuclear safety and radiation protection. There was also a general ambition by the Government to make civil service more efficient by reducing the number of administrative authorities.

According to the Ordinance (2008:452) with instruction for the authority SSM is acting as the central regulatory body under the acts on nuclear activities and radiation protection, SSM is authorized to issue regulations concerning nuclear safety and radiation protection. SSM is also responsible to conduct supervision and to control that licensees comply with applicable laws and regulations.

Moreover, SSM is fully empowered to issue, with reference to safety, prohibitions and conjunctions combined with fines, as well as to issue new conditions for the operation of a facility.

Financial resources

Swedish authorities annually submit a proposal for financing to the government (budget material) according to the responsibilities and analysed needs. The requests are processed by the government and subsequently decided by the parliament.

The government is providing SSM with resources by:

1. Granting government funds to the SSM
2. Deciding on the fees that should be paid by licensees to finance the government funds. Fees paid to the state.
3. Deciding on fees to directly finance licensing processes conducted by the

SSM. Fees paid to the SSM.
4. Granting contributions from the spent nuclear fuel management fund (KAF) to the SSM.

The SSM budget for 2011 includes general funding (wages, rents, repayments and other management costs) 230 MSEK, research funding 79 MSEK. Included in the former figures is the funding of regulatory activities regarding security and non-proliferation which is outside the scope of the IRRS-mission. SSM also receive funding to support nuclear and radiation safety in Russia, Ukraine, Moldova and Georgia (outside scope) at the amount of 55.5 MSEK.

The general funding is mainly financed by fees from licensees that either run NPP´s, are a part of the nuclear industry or perform activities involving or producing ionizing radiation, for example hospitals. A smaller part (approx. 15%) of the general funding and the research funding is tax funded and mainly finances the non-ionizing tasks of the SSM, i.e. laser, UV-radiation etc. (outside scope) and the part of SSM´s work where there is no licensees to charge (NORM).

The government also decides, based on suggestion from SSM, on fees for licensing new facilities or activities.

SSM is also allowed to use resources (70 MSEK/year) from the spent nuclear fuel management fund (KAF) in order to fulfil the regulatory responsibilities for waste management. The resources include funds for scientific research to aid the SSM´s work.

Human Competence Needs

The Director General is entitled to employ the staff needed to conduct the tasks given by government.

According to the instruction to SSM the government states that SSM shall organize and run four advisory boards. Their role is to give advice within the framework of their expertise. These advisory boards are:

- Advisory board for reactor safety
- Advisory board for research
- Advisory board for questions about radioactive waste and spent nuclear fuel
- Delegation for questions about the financing of the management of wastes from nuclear activities.

In addition to this SSM also has established a scientific advisory board for ionizing radiation within oncology as well as scientific advisory boards for UV-radiation and electromagnetic fields, respectively (outside scope).

For the first three the authority is free to appoint the expert they wish to appoint. For the last one the government appoints the members after a dialog with the authority.

In early 2011, SSM presented a report where the authority analysed the future competence needs in order to fulfil the authority´s tasks. As a consequence of this SSM argued for increased funding in the authority's budget proposal for 2012-2014 to the government. The outcome of the proposal is an increased budget from 2012 and onwards by 20 MSEK/year with an extra 5 MSEK/year from 2013 and onward.

Independence of the regulatory body

Requirement 4: Independence of the regulatory body
The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.

The regulatory body´s independence is of fundamental importance in the Swedish constitution. Although the Government has quite substantial scope for steering the operations of government agencies, it has no power to intervene in an agency's decisions in specific matters relating to the application of the law or the due exercise of its authority, i.e. authorization, supervision etc. The possibility for an individual minister to have the power to intervene directly through a decision in an agency's day-to-day operations does not exist in Sweden. Government decision making, which is made on a collective basis and the ban on instructing agencies in individual matters, are expressions of the prohibition of "ministerial rule". The Swedish Parliament is responsible for monitoring to ensure that ministerial rule does not occur.

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

In addition to this, there are provisions in the Administrative Procedure Act (1986:225), stipulating that a person that on various grounds are suspected of being biased, may not participate in the decision. It should also be mentioned that the Criminal Code provides for punishment of officials who disregard the requirements of their service. This means that anyone who breaches the high standards of impartiality and objectivity that governs the Swedish authorities may be prosecuted.

Prime responsibility for safety

Requirement 5: Prime responsibility for safety
The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organisations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.

The Nuclear Activities Act (1984:3) and the Radiation Protection Act (1988:220) state that the operator is responsible for taking all measures necessary for safety and for radiation protection.

The Radiation Protection Act (1988:220), states that a party conducting activities involving radiation, while taking into account the nature of the activity and the conditions under which it is conducted, shall;

- take the measures and precautions necessary to prevent or counteract injury to people, animals and damage to the environment,
- supervise and maintain radiation protection at the site, on the premises and in other areas where radiation occurs,

- properly maintain technical devices and monitoring and radiation protection equipment used in the activity.

A party conducting activities involving radiation shall also 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. The party shall also 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. These obligations 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.

The Radiation Protection Act also states that anyone conducting or has conducted business with radiation shall be responsible for the radioactive waste that exists in the business either is handled and, when necessary, disposed of in a radiation protection satisfactorily, or is sent to a producer who, in accordance with rules issued by virtue of the Environmental Code is required to treat the waste. Moreover, a party conducting or has conducted business with a technical device that can emit radiation is responsible for the device is destroyed when no longer in use.

The Nuclear Activities Act clearly and specifically states that the person authorized to conduct nuclear activities also have the full obligation and responsibility to take all measures necessary to maintain safety. The same rule clarifies that the obligations not only concerns the safety of the principal and intended (ordinary) operation, but they also include measures to manage and dispose of radioactive waste and nuclear material and also activities in order to safely decommission and dismantle the facilities. In addition, the party carrying out a specific nuclear activitiy should consolidate money for decommissioning measures.

The obligations remain until they are completed. It is also explicitly stated that the obligations applies even if a permit has been revoked, or if the period of validity has expired.

Compliance with regulations and responsibility for safety

Requirement 6: Compliance with regulations and responsibility for safety
The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organisation responsible for a facility or an activity of its prime responsibility for safety.

It is clearly stated in the Swedish law (section 10 of the Nuclear Activities Act, and section 6 of the Radiation Protection Act) that a person or company that holds the permit for a nuclear activity, a nuclear establishment or for any other activities involving radiation is responsible for all the measures necessary for safety and radiation protection. It is, therefore, when a permit has been issued that the various obligations will take effect. Rather than offer any kind of liberation, the permit thus means that the requirements begins to apply.

In a similar manner, the Radiation Protection Act (1988:220), states that the legal party who carries out activities involving radiation (practice) shall, given to the nature and the circumstances in which it is conducted; - take the steps and observe the precautions necessary to prevent or counteract damage to humans, animals and the

environment, - check and maintain radioprotection of the place and in the local and other areas where radiation occurs, - properly maintain the technical equipment and measuring and radiation protection equipment used in operations. A consequence of these requirements is that an licensee must conduct relevant own-control etc.

Regarding nuclear facilities the SSM regulations (SSMFS 2008:1) on safety in nuclear facilities further specify the responsibility of the licensee through a number of functional requirements on safety management, design and construction, safety analysis and review, operations, nuclear materials-/waste management and documentation/archiving. A continuous preventive safety work is legally required, including safety reassessments, analysis of events in the own and other facilities, analysis of relevant new safety standards and practices and research results. Any reasonable measure useful for safety shall be taken as a result of this proactive and continuous safety work and be documented in a safety program that shall be updated annually.

Coordination of different authorities

Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety
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.

SSM is the main regulatory body regarding nuclear safety and radiation protection in Sweden. Nevertheless there are other authorities that are responsible of different aspects of radiation protection and nuclear safety (radiation safety). According to the Authority Ordinance (2007:515) an authority is obliged to cooperate with other authorities when this is mandated.

In terms of legislation adopted by parliament and government, there are systems within the Government Offices which aims 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 concrete 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 - no matter of the level – there is a system of referrals, which reduces the risk for a legislation that ends up misplaced or inadequate.

There is also a special authority – the Regulation Council - which reviews all proposed legislation in terms of their impact on individuals and businesses.

Other authorities having regulatory, or other, responsibilities for radiation safety and adjacent matters that SSM cooperates with in different aspects are:

The Environmental Courts, which are responsible for matters in relation to the Environmental Code (1998:808), for example the application for a repository for spent fuel. The court examines the application including the content of the environmental impact statement and how it has been produced. After a public proceeding, the environmental court makes its report to the Government. In this report the environmental court supports or rejects the application. If the Government decides to grant a license, the environmental court issues detailed conditions under the Environmental Code.

Swedish Environmental Protection Agency, is responsible to coordinate the implementation of the environmental policy decided by the Swedish parliament, including "A Safe Radiation Environment". Swedish EPA is also responsible for the reporting according to the Convention on Environmental Impact Assessment in a Transboundary Context (Esbo-Convention).

Swedish Civil Contingencies Agency, MSB, is responsible for enhancing and supporting societal capacities for preparedness for and prevention of emergencies and crises, through knowledge-building, support, education, training, regulation, supervision and operational work. In a case of an emergency the Agency shall support the stakeholders involved by taking the right measures to control the situation.

The National Board of Health and Welfare, is responsible for indoor conditions and public premises regarding radon (schools, kindergarten, shopping malls etc.) and for the National medical expert group on radiation.

Swedish National Board of Housing, Building and Planning is responsible for radon in buildings (New Build).

The Swedish Work Environment Authority is responsible for protecting workers against harmful effects in the working environment including for example radon in underground work places.

The National Food Agency is responsible for safety in food including radioactive substances and radon in drinking water.

The Medical Products Agency, MPA, is responsible for radiopharmaceuticals and equipment in hospitals.

The Geological Survey of Sweden, SGU, is the central government agency responsible for issues relating to soil, bedrock and groundwater in Sweden (including radon and mining).

The Swedish National Institute of Public Health is responsible for surveys about radon and public health.

Swedish National Grid, Svenska Kraftnät, is a state-owned public utility with the task to transmit electricity from the major power stations to regional electricity networks. Svenska Kraftnät also has the task as regulatory body for the security regarding the Swedish energy supply (outside scope).

The National Police Board is a supervising central administrative authority for the Swedish Police. The main task of the National Police Board is to create the best possible conditions in a short-term and a long-term perspective for good and efficient police work.

The Swedish Security Service is responsible for countering terrorism in Sweden. This includes trying to prevent terrorist attacks from being planned in Sweden or supported from here (outside scope).

The Swedish Customs have the task of managing the flow of goods, ensuring competitive neutrality in trade and contributing to a safe and secure society. This includes radioactive materials.

The County Administrative Board has a coordinating role in environmental impact assessments in the licensing process of a nuclear facility. The three County

Administrative Boards where the NPPs in Sweden are situated also have a dedicated role within the emergency preparedness system regarding nuclear accidents. The Boards also are deciding on countermeasures in case of an accident.

The municipalities of Sweden are responsible for among other things planning and building issues, health and environmental protection, refuse collection and waste management, emergency services and emergency preparedness, as well as water and sewerage. The municipalities have the right to veto facilities that are planned inside their administrative boarders according to the Environmental Code (1998:808). The Government can, however, override such a veto in a matter of nuclear waste disposal if it is extremely important from a national point of view.

Emergency preparedness and response

Requirement 8: Emergency preparedness and response
The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.

The Government's principles for crisis management are the following:
Crucial factors for enabling quick and effective management capability include clear and practiced management principles and routines as well as a straight forward and well known organisational structure. The Swedish crisis management system is based on ordinary administrative structures and on the principle that the party in charge of an activity in normal situations also has corresponding responsibility for that activity in the event of a crisis ("the principle of responsibility"). One key principle is that a crisis is to be managed where it has occurred and by the relevant parties in charge of the crisis ("the principle of proximity"). Another principle is that organisational changes should be kept as small as possible ("the principle of parity"). However, the principle of responsibility must not be used as a pretext for non-action or avoiding necessary preparations and preventive measures based on the argument that a different stakeholder has the main responsibility.

The Government gives the provisions mainly in the Civil Protection Act (2003:778) and the Civil Protection Ordinance (2003:789). The prime responsibility to provide or finance reasonable emergency preparedness, personnel, property, and take the necessary measures to prevent or limit risks for accidents that may cause serious harm to people or the environment, is the licensee or the responsible operator. They are also required to analyse the risk of such accidents. In case of a release of toxic or harmful substances from a facility, the person engaged in the activities shall notify the county administrative board, the police and the municipality if the release calls for specific measures to protect the public. Notification shall also be provided if there is imminent danger of such emissions. The county administrative board shall in case of an emergency appoint a rescue leader.

The provisions given in the Civil Protection Act and Ordinance are not detailed and do not regulate technical infrastructural solutions nor any time requirements. In the area of nuclear safety and radiation protection, the Government therefore gives the mandate to SSM to issue further regulations for the license holders in the Nuclear Activities Ordinance (1984:14) and the Radiation Protection Ordinance (1988:293).

System for protective actions to reduce existing or unregulated radiation risks

Requirement 9: System for protective actions to reduce existing or unregulated radiation risks
The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.

The Environmental Code contains provisions for remediation of environmental damage from previous operations, which also includes certain radiation risks. The person who has pursued the activity has the prime responsibility and secondly the landowner. The State has allocated money for remediation in situations where no such responsible person is available. These funds are administered by the Swedish Environmental Protection Agency under the Ordinance (2004:100) on remediation of the contamination damage and state grants for such a remedy. Grants are given to the county administrative boards which then take the necessary measures.

For orphan sources, there is a system of disposal and funds set aside for the purpose. SSM can under the Ordinance (2007:193) on Producer Responsibility for radioactive products and orphan sources provide such sources that the Authority becomes aware to a producer of radioactive products for disposal.

The Ordinances on producer responsibility for WEEE (Waste from Electrical and Electronical Equipment 2005:2009), and Producer Responsibility for radioactive products and orphan sources (2007:193) contains provisions on producers' responsibility to collect and dispose products that contain radioactive substances.

In the Ordinance on Producer Responsibility for radioactive products and orphan sources (2007:193), such orphan sources are exempted whose activity level is so low that exception from the Radiation Protection Act (1988:220) is allowed under Section 2, first paragraph, of the Radiation Protection Ordinance (1988:293).

Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel

Requirement 10: Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel
The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.

The main principle is that the operator has the responsibility to safe disposal of waste and to provide for a safe decommissioning of facilities.

According to the Nuclear Activities Act the permit holder for nuclear activities should respond to the action needed;

- that with regard to the nature and the circumstances in which it is conducted is required to maintain the safety,
- to safely manage and dispose of nuclear waste arising in the activity or nuclear material arising therein that are not used again, and

- to safely decommission and dismantle the facilities in which activities are no longer pursued until all operations at the facilities has ceased and all nuclear materials and nuclear waste is placed in a repository that is finally sealed .

In addition to the above mentioned rules there are provisions in the Radiation Protection Act (1988:220), which clearly indicates who is responsible for the safety of activities in which radioactive material and radiation sources are produced, used, stored, transported or handled.

For the specific case of decommissioning of a nuclear power plant, there are requirements in the Environmental Code, that there must be a specific license before a decommissioning can take place.

The objective of the Act on Financial Measures for the Management of Waste Products from Nuclear Activities (2006:647) is to secure the financing of the general obligations that follow the Nuclear Activities Act (1984:3).
According to the above mentioned act, the licensees (licensees for nuclear power plants as well as other fee-liable licensees) shall allocate adequate resources for the funding of:

1. the costs for safe management and disposal of waste products,
2. the costs for safe decommissioning and dismantling of nuclear facilities,
3. the costs for research and development activities needed to enable the measures referred to in 1 and 2 to be implemented,
4. the state's costs for management of the fund assets and examination of questions pursuant to this Act,
5. the state's costs for supervision of such activities as are referred to in 2,
6. the state's costs for examination of questions concerning final disposal and monitoring and control of the final repository
7. the costs incurred by licensees, the state and municipalities for information to the public in matters relating to management and disposal of spent nuclear fuel and nuclear waste, and
8. the costs for support to non-governmental organisations for efforts in connection to questions concerning siting of facilities for management and disposal of spent nuclear fuel.

All handling of disused radiation sources is covered by the Radiation Protection Act (1988:220). The Act stipulates that anyone responsible for a practice involving radiation sources has to ensure the safe management and disposal of the disused radiation sources. The responsibility includes financial security or any other equivalent means for the safe management of the disused radiation sources. During 2005 and 2007 two ordinances were issued that establish producer's responsibility for disused radiation sources other than nuclear waste: the Ordinance on Producer's Responsibility for Electrical and Electronic Equipment (2005:209) and the Ordinance on Producer's Responsibility for Certain Radioactive Products and Orphan Sources (2007:193). Thus a licensee can fulfil his/her primary responsibility according to the Radiation Protection Act by handing over the disused radioactive source to the producer.

Competence for safety

Requirement 11: Competence for safety
The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.

According to the Environmental Code (1998:808) 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. The Nuclear Activities Act, the licensee for nuclear activities, is obliged to have an organisation with adequate human resources. 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 demands.

The Government is responsible for funding of basic university training. 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. It means that SKC will contribute to a safe, effective and thus reliable nuclear energy production. CRPR is an independent unit within the Department of Genetics, Microbiology and Toxicology of Stockholm University and engages scientists working in the fields of radiation biology, radioecology and radiation dosimetry at Stockholm University and Karolinska Institutet, a medical university.

Sweden has no Technical Support Organisation (TSO) within safety and radiation protection and very few technical training facilities. However, the research funding is partly available for use of external competence when needed in the authority´s regulatory work.

There is also a Nordic co-operation project called NKS (Nordic nuclear safety research). NKS is a platform for Nordic cooperation and competence in nuclear safety, radiation protection and emergency preparedness. It is an informal forum, serving as an umbrella for Nordic initiatives and interests. Its purpose is to carry out joint activities producing seminars, exercises, scientific articles, technical reports and other types of reference material. The work is financed and supported by Nordic authorities, companies and other organisations. The results are used by participating organisations in their decision making processes and information efforts.

In 2010 the Government appointed SSM to perform a review of the basic training in Sweden in the field of Radiation Safety. One of the conclusions is a proposal to the Government to investigate basic academic training within radiation protection further.

The Government has appointed SSM to facilitate training within the safety field:

> "The appropriation item can be used for fundamental and applied research as well as studies and investigations in order to promote national competence within the authorizations scope and to support and promote the supervision of the authority." (Budget Appropriation 2011).

According to the government´s instruction for SSM the authority may issue regulations that stipulate the necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities, including competence on the contractors working at the facilities.

Provision of technical services

Requirement 13: Provision of technical services
The government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment.

According to the Ordinance (2008:452) with instructions for SSM, the authority shall, if necessary, propose measures for environmental work, develop and coordinate monitoring, evaluation and reporting on environmental quality objective of safe radiation. The Authority shall in respect of its environmental work, report to the Environmental Protection Agency, and consult with them of the reporting required. As part of its responsibility for the environmental goals, the SSM shall continuously assess the risks of radiation for the population as a whole and for specific groups.

SSM shall maintain a national register of the radiation doses received by workers connection with activities involving radiation. SSM shall also issue personal documents and radiation passbooks for these workers.

SSM is designated by the Government to be the National Metrology Laboratory for ionizing radiation (Riksmätplats). One of the tasks of the laboratory is to calibrate measuring instruments.

Services for personal dosimetry are run by six hospitals, four nuclear facilities and one private company. The dosimetry services are authorized by the SSM.

References

SFS 1968:45 Nuclear Liability Act
SFS 1984:3 Nuclear Activities Act
SFS 1986:225 Administrative Procedure Act
SFS 1988:220 Radiation Protection Act
SFS 1998:808 Environmental Code
SFS 2003:778 Civil Protection Act
SFS 2006:647 Act on Financial Measures for the Management of Waste Products from Nuclear Activities

SFS 1984:14 Nuclear Activities Ordinance
SFS 1988:293 Radiation Protection Ordinance
SFS 2003:789 Civil Protection Ordinance

SFS 2005:2009 Ordinance on producer responsibility for WEEE (Waste from Electrical and Electronical Equipment
SFS 2007:193 Ordinance on Producer Responsibility for radioactive products and orphan sources
SFS 2007:515 Authority Ordinance
SFS 2008:452 Ordinance with instruction for the Swedish Radiation Safety Authority

SSMFS 2008:1 Regulation on safety in nuclear facilities

Module 2: Global Nuclear Safety Regime

Counterparts

Lennart Carlsson
Director
Nuclear Power Plant Safetyh
+46 8 799 42 46
Lennart.Carlsson@ssm.se

Ingemar Lund
Senior Adviser
DG Staff
+46 8 799 42 83
Ingemar.Lund@ssm.se

Assessment for IAEA requirements

GSR Part 1, Requirements 14 International Obligations and Arrangements for International Cooperation, and Requirement 15 Sharing of operating experience and regulatory experience.

International Obligations and Arrangements for International Cooperation

Requirement 14: International Obligations and Arrangements for International Cooperation
The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including peer reviews, and promote international cooperation to enhance safety globally.

International conventions

To be able to fulfill its international obligation Sweden is a contracting party to the following conventions:

- Convention on Nuclear Safety,
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management,
- Convention on Early Notification of a Nuclear Accident,
- Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency

- Convention on Physical Protection of Nuclear Material.
- OSPAR Convention
- HELCOM convention
- Convention concerning the protection of workers against ionizing radiation (C115-ILO, Geneva, 1960)
- Convention on Environmental Impact Assessment in a Transboundary Context (Espoo Convention)

IAEA standards

Since Sweden is a member of the European Union the transposition of various Euratom Directives into Swedish legislation indirectly requires consideration to application of IAEA standards. When developing SSM requirements and guides, the IAEA safety standards are one of the main bases, and there are many examples of use of IAEA standards as reference in SSM guides. However, the process for development of regulations and guides (STYR2011-51) doesn't explicitly mention the use of IAEA standards. The IAEA standards are well known at SSM, due to the fact that SSM has representatives in the IAEA safety standards committees (CSS, NUSSC, WASSC, RASSC and TRANSSC). Representatives of SSM (and before 2008 SKI and SSI) have to a large extent been involved in the development of the IAEA safety standards documents. Representatives from SSM have also participated in the development of the IAEA BSS.

Participation in international reviews

All Swedish nuclear power plants have been subject to OSART reviews during the years 2008-2010. This is in addition to international peer reviews conducted regularly at the Swedish reactors by WANO. Swedish experts are frequent participants in international peer reviews, e.g. IRRS missions in Canada, France, Spain, Russia, USA, Korea and Switzerland and in OSART missions e.g. to Japan.

Bilateral and multilateral agreements

SSM has a number of multilateral and bilateral agreements as listed below (for details, see list of agreements, SSM 2011-346):

Bilateral agreements

Australian Safeguards and Non-Proliferation Office, Australia
Administrative arrangements on conditions and controls for nuclear transfers for peaceful purposes.

Canadian Nuclear Safety Commission (CNSC), Canada
Administrative arrangements.

Bundesministerium for Umwelt, Naturschutz und Reaktorsicherheit (BMU), Germany
Agreement on division of responsibilities for regulations regarding security of transboundary shipments of nuclear fuel.

Nuclear and Industrial Safety Agency, Ministry of Economy, Trade and Industry (NISA), Japan

Memorandum of understanding for information exchange.

State Nuclear Power Safety Inspectorate (VATESI), Lithuania
Agreement on early notification of nuclear and radiological emergencies.

Ministry of Foreign Affairs, Norway
Memorandum of understanding concerning cooperation in disposal of radioisotope thermoelectric generators at the lighthouses and navigational beacons of the Baltic Fleet in the regions of Kaliningrad and Leningrad of the Russian Federation.

The State Committee for the Supervision of Nuclear and Radiation Safety, Russia
Agreement on guidelines for early exchange of information regarding nuclear facilities.

The State Committee for the Utilization of Atomic Energy, Russia
Agreement on security requirements for transboundary shipments of nuclear fuel.

Rostechnadzor, Russia
Agreement on cooperation.

National Nuclear Regulator (NNR), South Africa
Agreement for exchange of technical information and cooperation in the regulation of nuclear safety.

State Enterprise National Nuclear Energy Generation Company (Energoatom), Ukraine
International cooperation program.

Marzeev Institute of Hygiene and Medical Ecology, Ukraine
Memorandum of cooperation.

Environmental Protection Agency (EPA), USA
Memorandum of understanding on exchange of information on radiation protection, especially with regards to environmental regulations and radioactive waste.

Nuclear Regulatory Commission (US NRC), USA
Agreement for exchange of technical information and cooperation in the regulation of nuclear safety.

Department of Energy of the United States of America (DOE), USA
Statement of intent regarding emergency nuclear and radiological incident response and management capabilities.

Multilateral agreements

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

Danish Emergency Management Agency (Denmark), National Institute of Radiation Hygiene (SIS, Denmark), Radiation and Nuclear Safety Authority (Finland), Geislavarnir Rikisins (GR, Iceland), Norwegian Radiation Protection Authority (NRPA,Norway)
Memorandum of Understanding (“The Nordic manual”) on cooperation regarding exchange of information and assistance between Nordic authorities in nuclear or

radiological incidents and emergencies.

Sharing of Operating Experience and Regulatory Experience

> Requirement 15: Sharing of Operating Experience and Regulatory Experience
> The regulatory body shall make arrangements for analysis to be carried out to identify lessons learned from operating 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.

Event reporting, SSM analysis and dissemination

Nuclear facilities

According to chapter 7 of SSMFS 2008:1 the licensees have to report to SSM the events and conditions in nuclear fuel cycle facilities and nuclear power plants, which are of importance to safety. The events have to be classified by the licensee according to Appendix 1 in SSMFS 2008:1. The report shall include the safety significance of the event and a root cause analysis. SSM receives about 400 event reports from the NPPs each year. 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 the SSM.

The process used for analysis of the reported events for nuclear power plants in operation is described in a documented routine in SSM's Management System (STYR2011-151). The analysis group meets once a week and involves one person from each unit at the department of nuclear power safety. The analyses are mainly dealing with operational experience, but regulatory implications of the events are also handled. The group reviews the analysis and the conclusions of the licensee, informs the relevant parts of SSM organization and gives recommendations to the organization about actions that should be taken. There is no such process established for events at fuel cycle facilities, however, the number of events as well as the safety significance is often small at those facilities.

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

SSMFS 2008:1 (4 §, chapter 5) specifically requires licensees for nuclear facilities to take appropriate corrective actions in order to prevent the reoccurrence of safety significant events. The regulations also require licensees to report these actions to the regulatory authority, according to reporting procedures (1-3 §§ chapter 7) in the regulations.

The Forsmark 1 event year 2006 can be mentioned as an example. The information was disseminated nationally and internationally, and the Swedish licensees were

asked to report on the situation in the plants in light of the incident in Forsmark to SSM.

Non-nuclear activities

For non-nuclear facilities (i.e. activities licensed under the Radiation Protection Act) unplanned events with radiological importance have to be reported to SSM. Those that are deemed to be of general interest are published on SSM's website. The reports are analyzed by SSM and if deemed of interest for others it is published at the SSM web site. The process is not included in SSM's Management System.

Dissemination of operating and regulatory experience

Nuclear facilities

SSM disseminates lessons learned from operation of NPP's within the organization – and internationally as member of OECD/NEA IRS system. Furthermore, the licensees are themselves responsible for disseminating lessons learned and they all have access to the OECD/NEA IRS system. The licensees also have their own organizations for handling lessons learned by national and international organizations. The general regulations, SSMFS 2008:1 (9 § point 7, chapter 2) require licensees to establish processes within their management system for appropriate dissemination of lessons learned in other organizations. If the licensees don't implement lessons learned, as appropriate, SSM points out this for the licensee, or requires appropriate measures to be taken.

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

There is also a system established for regular meetings with the nuclear industry related to radiation protection issues. These meetings are important for exchange of information between involved parties and also an important channel for dissemination of feedback of experience and lessons learned.

Non-nuclear activities

SSM is represented in e.g. the European ALARA Network (EAN), the Nordic Society for Radiation Protection (NSFS), the International Radiation Protection Association (IRPA). These networks are effective forums for the dissemination of good ALARA practice and lesson learned concerning radiation protection.

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

Processes supporting international cooperation

There are three important documents specifically devoted to international cooperation in the SSM Management system:

- STYR2011- 66: Policy for participation in international activities
- STYR2011-142: Coordination and management of SSM:s international activities, and
- STYR2011-143: List of participation in international activities. Activities are ranked according to their formal importance and the list is used for prioritizing purposes. It gives an indication of the extent of SSM participation in international activities. The list is reviewed and up-dated on a yearly basis.

There are three Senior Advisors reporting to the research director who is also responsible for international co-operation. The advisors coordinate SSM's international work; constitute the prime contact point with some major international bodies (IAEA, EU, and OECD/NEA) and handle the contacts and coordination with the Ministry of Environment and the Foreign Department on relevant international issues. The advisors are also responsible for evaluating the overall effects of international cooperation, based on the input and data supplied by the Departments.

There is within the management system no specific process as such for improving processes, practices or requirements. Instead, there are in most processes/documents within the management system a specific element addressing feedback of experience and lessons learned from that specific process.

There is, however, a specific process (STYR2011-42) governing internal audits within the organization. The main objective with this process is to verify that the management system is appropriate, and to strive for continuous improvements.

There is also a specific process established (STYR2011-72) for the management of deviations, incidents, corrective actions and prevention or re-occurrence of events. The main objective of this process is to provide for a structured approach for learning by experience and to promote and encourage proactive thinking and strive for efficiency.

In addition, the process defined in STYR2011-66 (Policy for international activities) requires SSM staff to summarize participation in international meetings in travel reports and make them available to others. Also, the process defined in STYR2011-142 (Coordination and management of SSM´s international activities) contains guidance on feed-back of experience from SSM representatives' participation in international activities.

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.

Summary and Conclusions

Sweden has signed and ratified the Convention on Nuclear Safety, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, the OSPAR, HELCOM and Espoo Conventions and other relevant conventions in the area of nuclear safety and radiation protection. SSM has signed bilateral co-operation and information exchange agreements with several countries and participates actively at various levels in the international arena. Routines governing SSM's participation in international work have been drawn up and

the prerequisites for responsibility have been defined. However, SSM should consider strengthening its routines for the dissemination of international experience and reports in Sweden.

Internationally, experience is shared both by means of reporting to various databases as well as through various international meetings and conferences. Information to licensees is provided as necessary and usually in connection with meetings or surveillance inspections.

There is no formalized process for making information about lessons learned available to others, except as information given as feedback to licensees from inspections and reviews of licensees' activities. The quality of safety work could be improved if a more strategic and systematic approach was applied.
The conclusion of the self-assessment is that it shows good compliance overall with the requirements formulated in the IAEA's standards.

References

SFS 1988:220 Radiation Protection Act
SFS 1998:293 Radiation Protection Ordinance
SSMFS 2008:1, Regulations and guidelines of the Swedish Radiation Safety authority for nuclear facilities
STYR2011-42, Internal auditing
STYR2011-51, Development of regulations and guides (In Swedish only)
STYR2011-66, Policy for participation in international activities
STYR2011-72, Management of deviations, incidents, corrective actions and prevention of reoccurrence of events
STYR2011-142, Coordination and management of SSM´s international activities (In Swedish only)
STYR2011-143, List of participants in international activities
STYR2011-151, Reporting of deficiencies in barriers and defence in depth in Nuclear Power Plants (In Swedish only)

Module 3: Responsibilities and Functions of the Regulatory Body

Counterparts

Ann-Louise Eksborg
Director General
+46 8 799 42 09
Ann-Louise.Eksborg@ssm.se

Fredrik Hassel
Head of Staff
+46 8 799 41 51
Fredrik.Hassel@ssm.se

Assessment for IAEA requirements GSR Part 1 – Requirement 16-36

Organisation and Responsibility

Requirement 16: Organisation and responsibility
The regulatory body shall structure its organisation and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.

The SSM missions and tasks are defined in the Ordinance (SFS 2008:452) with instruction for the Swedish Radiation Safety Authority and in an annual letter of appropriation, the latter in which the Government issues directives to the authorities including the use of appropriations.

The Director General of the Swedish Radiation Safety Authority is appointed by the Government, normally for a period of six years. The Director General is exclusively responsible and reports the authority activities directly to the Government. The Director General is responsible to organize the authority also has the right to employ and lay off the staff without any restrictions other than those regulated in the Employment Protection Act (SFS 1982:80) covering all of the Swedish society. However, there are some structural restrictions that in some way influence the institutional freedom, although not to a degree that would imply insufficient institutional freedom.

The authority has an advisory council with a maximum of ten members which are appointed by the Government. Those are usually members of the parliament, agency officials or independent experts 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 kind of advisory boards is a common structure in the Swedish governmental system and is an example of the Swedish tradition of democratic transparency. The council may also alert the Government if it suspects irregularities within the authority.

In the instruction to SSM the government states that SSM shall organize and run five advisory boards. Their role is to give advice in the framework of their expertise (see also requirement 20).

Financing

The funding of different tasks is in a way controlling SSM´s prioritizing of activities. This is a two-step structure where at first SSM is given funds through an annual decision by the Parliament. In a following Governmental decision the funding is divided into separate sub-funds that are followed by directions that regulates SSM´s disposition of the funds.

The above mentioned restrictions are complemented by the restriction that the different fees that are financing 85 % of SSM´s work indicates how the funds should be used in the different areas of operation.

The authority's internal budget is decided in late December for the upcoming year. It is the result of a process involving the different departments of the authority. In the process the objectives and the performance targets for the different areas of operation are also decided.

The planning of and allocation of resources is partly based on the radiation risk of facilities and activities. However, most of the activities are indirectly financed by supervision fees. Thus, the Ordinance on fees to authorities (1992:191) governs how the authority can allocate its resources between different areas. The authority cannot freely redistribute resources between different activities since the cost of each activity over a period of time should be in balance with the incomes from fees.

There is not a complete risk-based allocation of resources, although based on the above assumptions; the authority allocates resources out of a risk assessment of the radiation safety of the various licensee holders.

According to what the government has stated in the Environmental Supervision Ordinance (2011:13) an authority with supervision functions should perform an inquest of the needs for supervision in the area of its responsibilities. In the annual plan for supervision the authority should describe how the allocation of resources is distributed between different areas and how it is adjusted to the needs of supervision. Compilation of the different supervision activities could be done in relation to the different areas of operation and/or department responsibilities. However, a plan on the strategic level is not yet in place. The work to establish such a plan is underway and will be finalized during 2012.

Organisation

The organisation of SSM is set in the "Rules of Procedure of the Swedish Radiation Authority". This document also comprises the set responsibilities of the departments, section and executives as well as the decision-making procedures.

Areas of operation

SSM has divided all different tasks into areas of operation illustrating the various public arenas where the Authority is tasked with ensuring radiation safety. 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 Annex 2 of the steering document "Management of the Swedish Radiation Authority" (STYR2011-71).

Main processes

The Authority's corporate governance management is process-oriented and encompasses the processes of corporate governance, implementation and supporting functions. SSM's processes are described in Appendix 1 in Management of the Swedish Radiation Authority (STYR2011-71).

The implementation processes are carried out within the framework of nine of the Authority's different areas of operation (excluding efficient and effective administration). The Authority's different processes serve as a foundation for how the Authority's work should be conducted and have the aim of achieving the desired performance (or fulfilling the objectives) within the framework of the Authority's areas of operation.

The implementation process encompasses several main processes which comprise an interdependent flow. This flow includes everything from building knowledge, developing rules, regulations and methods through hands-on work in the public sector to analysis and evaluation of performance. Depending on the objectives to be achieved within the framework of the respective area of operation, the Authority selects the main processes in the way that most effectively contributes to the objectives. See the Appendix 4 in the steering document The Management of the Swedish Radiation Authority (STYR2011-71) for the areas of operation respectively.

Planning and follow up

The work of the Authority is conducted by means of planned activities arranged on departmental and section level. All of these activities are linked to both an area of operation and to a main process/sub-process. The Authority will continually follow up, improve and develop its work. The annual orientations and priorities determined by the Director General set the standard for the Authority's development and improvement work over the next few years. All the planning is documented in an internal computer based system that supports both planning and evaluation of the authority's activities for the year in question.

Every four-month period an evaluation is performed to ensure that the objectives for each area are reached and that no area is lacking funds or is overfunded. If changes

are necessary to ensure effectiveness, a new budget and objective-plan is decided by the DG.

As all Swedish authorities, SSM issues an annual report to the Government summarizing major performances, results, effects, 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 summarizes major findings and conclusions on operational experience, regulatory inspections and reviews: technical safety status, radiation protection work, environmental impact, waste management, emergency preparedness as well as organisational matters, safety culture, physical protection and safeguards.

Independence of the Regulatory Body

Requirement 17: Independence of the Regulatory Body
The regulatory body shall perform its functions in a manner that does not compromise its effective independence.

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

The 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 (SFS 2009:400). The reasons for secrecy could be those of national security, international relations, commercial relations, or the individual right to privacy. No-one needs to justify a wish to see a public document or to reveal her/his identity to have access to a document. After September 11, 2001, more safety systems documentation related to nuclear power plants became classified information and the SSM has established more stringent security practices.

SSM is organized in three departments handling all inspection and application issues. These three departments have the full responsibility for activities towards licensees and other parties regarding radiation- and nuclear safety (and security).

In the Administrative Procedure Act (1986:223) applicable to all matters by the administrative authorities, provisions concerning disqualification can be found. Section 11 in the act states that a person charged with handling a matter is disqualified in four different cases, for example if the matter concerns himself or his closest family such as spouse, parents, children, brothers or sisters or someone else who is closely related to him, or if he or someone closely related to him can expect extraordinary advantage or detriment from the outcome of the matter. A person is also disqualified if there is some other special circumstance that is likely to undermine confidence in his impartiality in the matter. According to Section 12, the principal rule

is that a disqualified person may not handle the matter. SSM is one of those authorities which shall list holdings of certain members of staff.

According to Section 11 of the Notification of certain holdings of financial instruments Act (2000:1087), the Government may decide, if necessary, that an authority shall list holdings of financial instruments of Members of the Board and the employees, contractors or other officers as it determines in view of their opportunity to obtain inside information.

Referring to these acts, SSM has outlined policies regarding side-line, shareholding and disqualification, as well as external consultants´ conflicts of interest and disqualifications. The SSM policy is that the senior management team and the chief legal counsel have to report their holdings. Prior to hiring of consultants those are obliged to report on conditions which may be relevant to their objectivity and impartiality. SSM decides whether the conditions affect the authority´s possibility to behave objectively and impartially.

Two examples are: During a period of two years after employment at a site or a license holding company the inspector is not allowed to have regulatory functions towards this site or company. A site inspector is not allowed to obtain the role against the same site for more than five years in a row. The standard procedure during inspections is that the minimum numbers of inspectors are at least two in order to ensure quality and to minimize the risk for personal views intervening in the process. According to the decision-making procedures at SSM, members of the staff shall also consult other experts (internally) during decision-making.

One area where SSM always have to analyse the degree of effective independence is in the field of expensive research experiments. The policy of SSM is that researchers and companies in cooperation with SSM could not have links to or business relations with licensees. In some cases SSM needs to have access to research results which is not possible to obtain solely by SSM´s financial resources and where the only partner with interest in such results is a licensee. In these cases the need for scientific results is in conflict with the independence of SSM. SSM is of the opinion that the transparency of SSM:s research projects could in these cases be enough to ensure effective independence.

SSM also have a role as project manager regarding radiation- and nuclear safety and security matters in Russia, Ukraine, Georgia, Armenia and Moldova. The task is to support authorities and companies in these countries. In this role SSM sometime works in cooperation with companies in Sweden that also are licensees. Management of these projects is organized in a secretariat reporting directly to the head of DG Staff. To ensure effective independence staff involved in regulatory activities towards licensees is separate from the staff cooperating with the licensees in such projects.

Human resources

Requirement 18: Human resources
The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.

SSM has (end of 2010) a staff of 274 persons. The average age is 47 years. During 2010 the staff has increased with 10 %. The staff turnover rate was 3 % during 2010, and excluding retirements 4 %.

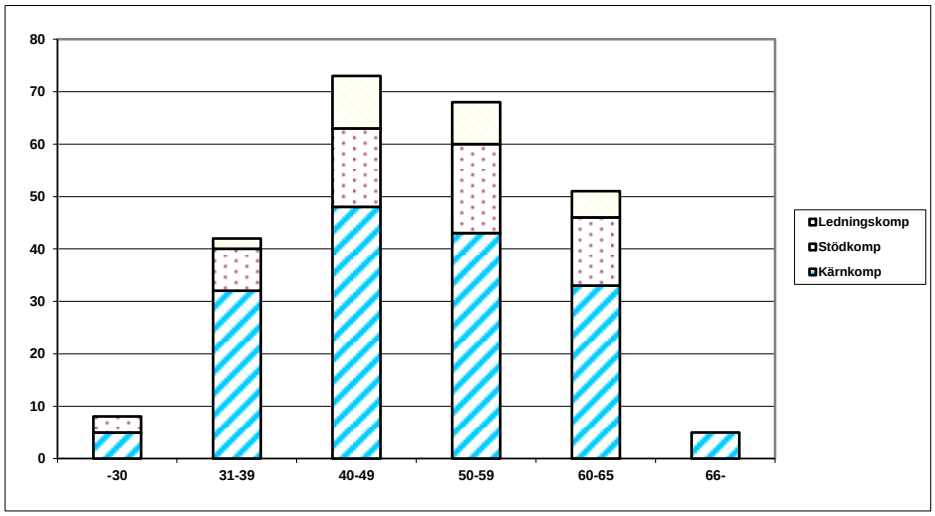

Figure 2. Staff distribution in age and competence areas in 2010

The basis of the skills needed in the regulatory operations is stated in the instruction to SSM. The merger of SSI and SKI in 2008 applied the labour law rule of transition activities so that the two authorities' existing staff was employed by the new authority, SSM. This meant that SSM took over the collective expertise who previously handled its mission in the former authorities. The final staffing in number, qualifications and competences was decided by the Organisation Committee that was set up to form the new regulatory body. This was done based on the experiences from the two former authorities.

At the end of 2010 the Department of Nuclear Power Plant Safety had a staff of 60 persons, which work with the supervision of nuclear safety and radiation protection at the 10 operating nuclear power reactors. Of their 60 staff members, 18 % have a post graduate degree, and 67 % have a bachelor or a master degree. SSM has designated one inspector for each plant as “site-coordinator”, serving as the main contact point between facility and authority.

The 47 persons belonging to the Department of Radioactive Materials use 10 - 12 person-years on issues of waste management, spent fuels, and authorized release of radioactive substances connected to the direct operation of nuclear power plants. This department mainly work with inspections of non-power producing nuclear installations (e.g. fuel factory at Västerås, waste treatment and material investigations facilities at Studsvik), decommissioning, financial issues, nuclear security, radioactive wastes and releases from non-nuclear facilities, and with planned or existing off-site spent fuel and waste management facilities - including final repositories (see Sweden’s 3rd national report under the Joint Convention). The Nuclear Non-Proliferation section uses about 6-8 person years of its resources towards the nuclear facility operations.

The 59 persons at the Department of Radiation Protection use roughly 20 person years of their work resources on the national emergency preparedness activities, environmental monitoring issues, laboratory measurements, calibrations and use of radiation sources, x-ray equipment etc. related to the operation of the Swedish nuclear facilities.

The departments responsible for SSM´s support functions totally accounted for 47 persons at the end of 2010. This included the DG staff, including units for Legal Services and Research and International Co-operation, the Communication department, and the Administrative department, including Human Resources, Finance and IT units.

The educational background of the SSM staff at the end of 2010 is shown in Table 2.

Education	Percentage
Post graduate degree	24
Bachelor/master	58
Secondary high school	15
Other	3
Total	100

Table 2 Educational background of the SSM staff in 2010

The level of education within the authority is high. More than 80 % of the employees have university degree, of these, 24 % licentiate or doctorate. Most of the new employees have a good expertise in the field they are to work with. This is a result of the many specialist areas covered by the authority, and to some extent the fact that there is no TSO in Sweden to support the regulatory body with specialist knowledge.

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

A comprehensive inventory of the authority´s needs of professional technical skills was performed in 2010. The survey has identified 59 areas of expertise, including management skills and methodology skills. The survey has given a good picture of the authority´s competence and has shown that the competence situation is good. However, some areas of expertise are subcritical and the availability of international usable excellence needs to be improved.

The experience from the nuclear accident in Japan also shows that some competence areas are critical and resource demanding from an emergency situation perspective. Overall, the authority must cover a broad and at the same time deep competence skills with a relatively small number of employees. This results in a certain vulnerability and dependence on key individuals. The competence areas that are subcritical or where competence is lacking require resources to be rectified. This has been addressed in the annual budget documents to the Government for 2012. This resulted in an increased funding from the Government from 2012 and onwards.

SSM has an established recruitment process. Recruitment is made in cooperation with the recruiting manager and the HR section. The process is activated when an employee intends to leave. When a vacancy arises an inventory of the department or section´s tasks is done and an assessment is made if a redistribution of the tasks is possible. The tasks of the position are defined and an applicant profile of demands and preferences of education, skills and other characteristics is established.

The Director General decides on recruitments. Prior to this the case is discussed in the senior management meetings. The aim is to ensure that resources are used optimally in the short and long term. After this the recruitment process proceeds. Applicants can make applications on-line. Vacancies are also advertised internally to facilitate internal rotation. After an application period of three weeks the recruiting manager evaluates the applications against the applicant profile. After at a minimum two interview rounds with qualified candidates the recruiting manager formulates a preface for the current employment with the justification for the outcome.

If the current employment involves work with ionizing radiation, a radiological medical examination must be done. If the post is security classified a security check is also made before a decision on employment can be taken. The security screening includes a personal assessment of safety and a records review by the Swedish Security Service. If the newly hired employee comes from a facility that is regulated by the authority an incubation period is applicable.

Governmental employment decisions can be appealed within a period of three weeks to the National Appeals Board. In the appeal the plaintiff explains the ground and the reason for the appeal.

When an employee with a very unique skill retires, there is a possibility to recruit in advance, i.e., to create an opportunity for the new employee to work alongside with the person leaving soon. This makes a good transfer of knowledge and gives the opportunity for the new employee to rapidly get into the work.

The potential in Sweden for a flexible retirement age, i.e., the employee can choose to retire at the age of 65, or remain up to the age of 67, creates the opportunity for the authority to maintain competence in full- or part-time during a handover period.

Knowledge management

SSM work strategically and systematically with competence issues, but further development are needed in the field of knowledge management. In practice, however, knowledge management is integrated in different ways in the activities, both formally and informally. The competence acquisition process of SSM is a systematic ongoing process to ensure that the right skills to achieve the goals and demands of both short and long term operations are available. It also ensures that skills are secured and used efficiently. The strategy for this is to:

- attract employees with the right skills
- recruit on the basis of a modern and efficient recruitment process
- retain employees with the right skills by being an attractive and stimulating workplace
- terminate employment in a professional manner.

The competence process consists of the following four steps: skills analysis, skills planning, implementation and evaluation. This is done at least once a year. The need of competence is identified within each area of activity in conjunction with the oper-

ational planning. Through annual development reviews with all employees the managers ensure that the employees have the right skills to carry out their duties and to achieve the objectives of the authority within their operating area. In the development reviews, a gap analysis of competence is made in which the employee and the manager jointly develop an educational and development plan for the employee by comparing the employee's skills today with the authority's competence needs in the short and long term.

By making an analysis of the competence profile and the demands with the help of the five competence dimensions the skills required to fulfil the task at hand can be obtained.

The five competence dimensions are:

- Personal competence - their own creative ability, ethics, respect, responsibility and values
- Social competence – the ability to work with others, to develop, to maintain and to use contacts / networks
- Vocational technical skills - the skills required to perform duties in a professional manner with close links to the tasks
- Strategic competence – the ability to ensure the integrity of the authority, to place their data in a holistic way and to look ahead
- Functional competence - the ability to apply the four other skills to solve a task or situation

The different dimensions of competence are also connected to the authority's three key values; trustworthy linked to the professional technical competence, integrity to the personal skills and openness to the competence of communication.

SSM has a relatively large volume of internal staff training, partly organised by the human resources unit. During 2010, about 1700 days – some 6 days per employee - were used for competence development. Individual training plans are documented as an agreement between the employee and the responsible manager. The employee may participate in training courses organized by SSM or get training from other training providers. For example for the technical training SSM also uses the licensee training programmes for operations staff including simulator training. Education and training covering the skills needs that are shared by the organisation are organized in one common action plan. In addition to this regular annual cycle, training programs for specific groups are being developed.

For example in 2010 a management succession program started. The objective was that participants, after completion of the program, had developed basic management skills and was prepared and motivated to seek leadership positions. The program was going on for nine months, contributing to SSM being perceived as an attractive workplace with opportunities for development.

All new employees undergo an introduction program that provides general knowledge of management of SSM, the functions and the activities for which the authority is responsible, about government and the role of civil servants, the role of the regulatory body and the values on which the activities are based. In parallel with the introduction program, new employees are trained in their new roles with the support of the manager and experienced colleagues.

Work is on-going to further develop the introduction and basic program for all employees. Documentation of this training program will be completed in 2011.

Recently requirements for employees performing regulatory activities were decided (strategy document about competence profiles STYR2011-171). This competence profile is used to create a training package for regulatory staff, primarily new inspectors, but shall, if appropriate, also apply to more experienced inspectors. The purpose of the training program is a structure ensuring right skills of the regulatory staff and that regulatory activities are performed in a consistent manner. A first training session should be possible to implement in 2012.

The research activities, financed by SSM, will contribute to developing the national skills for current and future needs, as well as SSM regulatory activities. Supporting and creating new knowledge for the regulatory work can be done through the so-called “authority support” which contributes to SSM's operations in a more direct manner and not the kind of research that meet the broader interests in society. New findings are made available through reports and seminars.

An important source of knowledge and experience is the international cooperation. Many of the employees are participating in international working groups within their expertise areas which give them the opportunity to exchange experiences and gain new knowledge. SSM does not have access to a Technical Support Organisation (TSO) in Sweden, but has the possibility to consult TSO:s in other countries, mainly in Finland and Germany. Another example of a source of knowledge is that SSM during a long time, prior to the review of the application for a permit to build a repository, has contracted some 50 international experts as an extra knowledge resource.

Management System

Requirement 19: Management system
The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.

SSM has established and implemented an integrated ISO-certified management system in accordance to ISO 9001 (quality) ISO 14001 (environment) and the Work Environment Authority´s statues AFS 2001:1 (work environment). The management system is set up in compliance with the IAEA safety standard GRS part 3 and largely fulfils the requirements. The management system is process based and focuses on the main objectives of SSM from the tasks given by the government through SSM´s vision down to different actions taken by the staff.

The purpose of the management system is to ensure effective management and governance and a systematic improvement and development of SSM´s functions and regulatory activities. No matter what kind of regular activities that are to be taken they all need to be part of some of the processes defined in the management system.

The management system of SSM is based on the management system created by the former authorities SSI and SKI. At the time of the merger the management systems were transformed into a single management system. SSI had an ISO-certified management system and the organizing committee that had the responsibility to prepare the start of SSM decided to go with the ISO-system as the model for the new authority's new management system.

One important step was to sort out different processes and to organize these into a common structure. The management system has built up a structure within which the transformation of methods and policies from the old authorities into methods and policies for SSM has been developed. This has been very successful. Two years after the merger the management system of SSM was implemented and recertified by an authorized external party.

In the development of the management system (MS) some sort of graded approach has been applied starting with the most important processes, such as supervision, authorization and strategic development. The main processes have now been described in an overall manner and main policies and routines etc. are documented through formally decided steering documents (STYR2011-XX etc.). SSM is now in a phase of further development and in some cases the processes on an activity level should be described and documented in more details. This means that although the structure of the MS is in place, the MS needs further development and improvement.

The safety goals are outlined in the steering document "Management of Swedish Radiation Authority" (STYR2011-71), including corporate values, safety objectives, description of main processes etc.

One of the key philosophies of the ISO-standard is continuous development. Main instruments for improving the management system are the senior management review, external and internal audits and the annual priorities of the DG. Also the IRRS self-assessment process is an important tool for improvements. Moreover, as a result of the Fukushima accident and an emergency preparedness exercise earlier in 2011, SSM has started a review of its crises management process.

The management system is described in all its details at the internal website accessible for all staff of SSM. All documents within the management system are open to the public and media according to Swedish law and available to all employers of SSM trough the internal website.

Technical Advice and Services

Requirement 20: Technical advice and services
The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities.

In Sweden there is no Technical Support Organisation, TSO, like in many other countries with nuclear power. However, SSM have funding for research and supporting its regulatory activities. The funds give SSM within the area of responsibility the opportunity to stimulate research and development and to finance technical and other support needed for SSM´s supervision activities.

One example are the agreements with Swedish and foreign experts, TSOs and researchers at universities that SSM has concluded to support the work of reviewing the application from SKB AB regarding the final repository for spent fuel and for the encapsulation facility that was handed over to SSM at the 16th of March 2011.

SSM´s conclusion is that the separate funding system for support gives flexibility when to choose experts. This will create an ability to increase quality and effective resource management.

SSM has several scientific or expert boards which could 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.

All three advisory boards are stipulated in the Ordinance of instructions for SSM (SFS 2008:452). These advisory boards are chaired by SSM the Research Director, the Director of the department of Nuclear Plant Safety and the Director of the department of Radioactive Materials. Advice is given to SSM to support the authority in its work. The advisory boards don't have the mandate to produce reports or to make public statements.

- The Council of radiation oncology advise on issues of radiation oncology and provides the authority with advice on questions of justification, optimization, risk assessment and risk management in medical radiotherapy. It also provides SSM with guidance on issues that require a scientific review of differing opinions or positions. The council is created by SSM but it has the freedom to publish reports and express views without consulting the SSM management.

Chairman and Members of the Boards and councils are appointed by the Director General and meetings are documented. The boards give advice within SSM´s internal organisational structure. They do not function as an independent body but members may submit dissenting opinion.

SSM has policies regarding disqualification and conflicts of interest by external consultants (STYR2011-138) and members of councils and boards (STYR2011-126), according to which they have to sign a declaration in which they describe earlier relations which may be relevant to their objectivity and impartiality. SSM decides whether the relations affect the authority´s possibility to behave objectively and impartially.

Rules concerning conflict of interest in the Administrative Procedure Act (1986:223) are applicable to such executives of the administration who manage or make decisions on matters or participate in the preparation in a way that can influence the outcome of a case. Outside experts and experts hired as consultants by SSM has normally only an advisory function and does not participate in any other way of handling a matter. They are therefore not covered in the formal sense of the rules concerning disqualification in the above mentioned act. That does not preclude that the engagement of consultants must consider the constitutional requirement of objectivity and impartiality.

Communication

Requirement 21: Communication
The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison.

M 3

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. Also meetings with branch industry organisations take place.

In order to provide a constructive liaison on safety related issues it is important to determine the different roles of SSM and the authorized parties, respectively. If the conditions for a dialogue are established, it facilitates the continued work and understanding between the authority and authorized parties.

SSM has chosen the words integrity, reliability and openness as key words to characterize how we conduct our day to day task:

- Integrity means that we uphold our independence and base our opinions on facts.
- Reliability means that our work is conducted by employees who are competent, objective and impartial.
- Openness means that we are transparent to the outside world: we clearly and actively provide information about our activities.

The three words are communicated broadly to the SSM counterparts (such as the authorized parties) with the purpose to clarify in what 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 on the part of authorized parties.

In the SSM´s decision-making process the licensee is given the opportunity to comment the factual circumstances emerging during an inspection or review. The same principle applies in major permit applications. 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.

Regulatory Control

Requirement 22: Regulatory Control
The regulatory body shall ensure that regulatory control is stable and consistent.

The management system is the basis to ensure that the regulatory control is stable and consistent. The core processes in this respect are Authorization / Review and Assessment, Supervision as well as Integrated safety assessment. These processes are described in steering documents (strategic, policies, routines) that express methods to be used by SSM staff members. In an annex to the "Rules of procedure of SSM" the decision-making process is set (Decision-making procedure).

The performance of SSM is evaluated by both internal and external audits and the results are reported to the DG. Deviations from the outlined policies and routines are handled in a systematic manner described in the management system (STYR2011-72). In one of the internal audits conducted in 2010 the quality of inspection reports

was reviewed. The result has been presented and remedial actions have been taken.

The results of the processes Authorization/Review and Assessment and Supervision are transformed into both regulatory decisions directed to increase safety and as an input to the following process Integrated safety assessment. Within these processes SSM collects the substance from performed regulatory activities and other information available, as an input to the expert assessment that is to be the result of the process.

The different decisions taken by SSM are structured in the archives of the authority and available to the SSM staff and the public. In the current DG activity plan the Department for Nuclear Power Plant Safety was assigned to develop a regulatory data base which would handle SSM´s different decisions directed to external parties and facilitate uniform application of current rules. With the database operational in the future the ability to ensure consistency in the regulatory control is fulfilled.

The principle of public access to public documents gives everyone the right to examine public documents, which can be done anonymously. All documents received or sent out from the authorities, such as letters, decisions and investigations are in principle general and public, and available for anyone to read. This fundamental principle allows anyone who is interested to take part of SSM´s assessment on various issues. Transparency is fundamental to show on what basis we make decisions. For example before SSM decides on new or revised regulations a referral takes place. A proposal and an impact assessment is submitted to external consultation of interested parties, interest groups and NGOs. When the referral period has expired and the comments are dealt with, the case is finally presented, first for SSM´s internal regulatory council and then the Director General who decides on the regulations. Finally, the printing of the finished regulations is ordered by the Chief legal officer. The regulations are published at SSM´s website. Fundamentally important questions or reviews are brought to SSM´s boards or council for consultation.

Moreover, SSM has evaluated a routine for experience feedback after inspections or other supervision activities. Our ambition is to work more systematically with experience feedback.

Cross-cutting Areas

Requirements 23 and 24: Authorization of facilities and activities and Demonstration of safety

Requirement 23: Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.

Requirement 24: The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.

Nuclear activities require a permit under the Nuclear Activities Act (1984:3) and in certain cases under the Environmental Code (1998:808). Other activities than nuclear, in which ionizing or non-ionizing radiation occurs, are governed by the Radiation protection Act (1988:220). Licensing issues according to the Nuclear Activities Act are decided by the Government or in some cases by SSM. Licensing issues according to the Radiation Protection Act are decided by SSM.

Further description of the authorization process is presented in the introduction of the cross-cutting section of modules 5-9.

Review and assessment

Requirements 25 and 26: Review and assessment and Graded approach
Requirement 25: 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.
Requirement 26: Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

Regarding complex nuclear facilities SSM – either the authority decides the case itself or prepare the case for government review - will assess the case under the Act on Nuclear Activities based on the fundamental security requirements under this Act and the basic radiation protection requirements under the Radiation Protection Act and Regulations specifying these requirements. If the application concerns a facility it must also be assessed how the general rules of consideration under Chapter 2. Environmental Code is met.

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 greater radiological risks and have more complex systems, while for less complex activities it´s the opposite. These differences are reflected in the demands made on applicants for a permit. Thus, SSM has adopted a graded approach on the issued guidance on format and content of the documents to be submitted in an application of license. If the facility or activity is less complex the authority has authored forms ready to be used by the applicant to show that they meet the requirements stipulated in our regulations.

Further description of the review and assessment process is presented in the introduction of the cross-cutting section of modules 5-9.

Inspection

Requirements 27 and 29: Inspection of facilities and activities
Requirement 27: 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.
Requirement 28: Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.
Requirement 29: Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

A general description of the inspection process is presented in the introduction of the cross-cutting section of modules 5-9.

Enforcement policy and Corrective actions

Requirements 30 and 31: Enforcement policy and Corrective actions
Requirement 30: The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.
Requirement 31: In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.

A general description of the enforcement policy is presented in the introduction of the cross-cutting section of modules 5-9.

Regulations and guides

Requirements 32 and 34: Regulations and guides
Requirement 32: 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.
Requirement 33: Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.
Requirement 34: The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.

A general description of the process of regulations and guides is presented in the introduction of the cross-cutting section of modules 5-9.

Safety Related Records

Requirement 35: Safety related records
The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.

All SSM regulatory activities are documented and registered in the authority´s case directory and document software system. The information is generally available to SSM staff and the public, unless the information is not confidential. Documents or other types of information are stored according to the Swedish National Archive´s regulations. Most of the products are stored in paper format and occasionally on other media if necessary.

Regarding activities covered by the provisions of the Radiation Act (1988:220) and the Radiation Protection Ordinance (1988:293) inspection results are documented in the inspection reports whose content and form is regulated in Annex 2 of the routine Inspect (STYR2011-106). In 2011 SSM implemented a new case directory, SSM360. In this directory there are possibilities to gather all registered cases regarding a certain nuclear facility. Moreover, in the current DG activity plan the Department for Nuclear Power Plant Safety was assigned to develop a regulatory database which would handle SSM´s different decisions directed to external parties and facilitate uniform application of current rules.

According to the regulations in SSM FS (2008:38) concerning archiving at nuclear facilities the licensee shall keep an archive of any documentation relating to the operation of radiation protection. The archive should be handled and managed so that all information can be read and to be transferred to a different medium. Documentation that can be difficult to read because of age shall be transferred to new data carriers before defects occur. The documentation should be stored in cabinets or archive facilities that meet requirements of the National Archives on archives premises.

Regarding facilities covered by the regulations in SSM FS 2008:1 concerning Safety in Nuclear Facilities, Chapter 9 Sections 1 – 3, there are requirements for the establishment of records and requirement of their inclusion into the required safety reports. On a more detailed level, regarding the waste streams that eventually arise as a result of decommissioning, the regulations in SSM SF 2010:2 establish detailed requirements for the facilities' setting up and reporting of detailed waste plans, containing records of waste components nuclide specific content, foreseen further management, storage and transfer for final disposal, and the anticipated timetables.

The regulations in SSM FS 2008:1, Chapter 7 Sections 1-3 also establish requirements for reporting circumstances described regarding accidents and non-routine releases of radioactive material to the environment. In an annex to the regulations there are detailed requirements for categorizing and for the reporting of such circumstances.

For non-nuclear applicants and licensees the requirements are related mainly to safe handling of sources and safe and secure waste management, quality assurance and the requirements of waste plans. Relevant regulations for unsealed (open) and sealed sources in hospitals are SSM 2008:27 and SSM 2008:28. Regulations for radioactive sources for non-medical use are mainly SSMFS 2008:9, SSMFS 2008:25, SSMFS 2008:28, SSMFS 2008:40.

For activities covered by the provisions of the Radiation Act (1988:220) and the Radiation Protection Ordinance (1988:293) SSM maintained a licensing database and a HASS database. These two databases are now consolidated into a common database.

License holders of the above mentioned activities are obliged to report to SSM the measured individual doses to the national dose register within 6 weeks after each measurement period ended. Provisions relating to national dose register, measurement and reporting of individual doses are found in SSM´s regulations on basic provisions for the protection of workers and the public at the business of ionizing radiation (SSMFS 2008:51) chapter 5.

For activities covered by the provisions of the Radiation Act (1988:220) and the Radiation Protection Ordinance (1988:293) SSM also maintains a mishap record and record of radiation protection experts.

Involvement of Interested Parties

Requirement 36: Communication and consultation with interested parties
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.

One of SSM´s key values is the word ‘openness'. Our communication policy is emphasizing the responsibility of communication among all employees and that communication needs to be conducted based on the prerequisites of the recipient. The web strategy states that texts on the website are to be “well written, comprehensible to our target groups as well as adapted for reading on the Internet”; in other words, being comprehensible is one way of achieving openness. Our press strategy also underlines the importance of “being transparent to the surrounding world – we must provide clear and proactive information about our work.”

One of SSM´s overall communication strategies is how the authority works with internal communication. A good internal communication is crucial for employees to be familiar with what happens in the authority's area of responsibility. The internal communication helps to bring out management's messages in the organisation, creating dialogue and disseminate information over the unit and departmental boundaries. A good internal communication is also the prerequisite for a good external communication and how SSM manage with profiling the authority. The personal contacts employees have with the stakeholders play an important role in how the authority perceived externally (STYR2011-96).

The authority´s website is an important tool for communication to the public and other interested parties. Internet news items will be published in condensed form at the website. This is also a format for descriptions of the Authority's work, such as supervision in connection with modernisation work and power uprates, the repository for spent fuel, etc.

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

All decisions towards a third party made by the Director General are published on the external website and usually communicated by means of a news item on the website. The news is accompanied with a copy of the decision or report. When required, press releases are also distributed. In addition to this SSM´s web registry will enable the publication of virtually all decisions, injunctions and reports on our public website. The Swedish legislation is based on structural separation between the government and the authority regarding decision making. The government is not allowed to intervene in a matter conducted by a Swedish authority. However, officers at the Ministry of the Environment are always informed by e-mail or phone prior to all publication of news items and press releases.

All on-site inspections generate a news item, both their being launched as well as their outcome: report plus injunctions.

The licensee is informed in a particular procedure about a decision or injunction. Before publication of a news item relating to a licensee – usually one hour in advance – the news item is forwarded to the licensee for information.

Information concerning matters reported to the prosecutor will be published on SSM´s website, provided they are not subject to the confidentiality of investigations according to the Public Access to Information and Secrecy Act.

The website can also be used to find contact details (telephone numbers and e-mail addresses) for employees at the Authority. All employees' direct telephone numbers will in the future be published on the website.

All events classified on the INES scale from Level 1 and up are listed per year starting in 2011. Events classified on the INES scale from Level 2 and up always generate a news item, whereas news items about Level 1 events need consideration in terms of news value. All Level 1 events in accordance with the Authority's own classification generate a news item on the website.

If a severe incident occurs, SSM may have access to other communication channels.

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

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

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

Summary and Conclusions

The Swedish model of public administration constitutes a solid foundation for an independent supervisory authority. Openness regulated by Swedish legislation and a strong anti-corruption legislation in combination with SSM’s work with key values gives us a strong focus on integrity in relation to licensees.

Capacity for exercising regulatory supervision has strong support in Swedish legislation. The Authority has the powers to issue regulations, interpret them and impose additional requirements and conditions. It is possible to appeal official decisions, as stated in decisions issued by SSM.

Further development of a comprehensive strategy for securing competence is needed. For example, in some areas the crisis organisation is vulnerable as only a few persons have the key expertise.

Requirements are needed concerning training of employees working with regulatory supervision. A formal training programme needs to be set up so that SSM can fulfil the IAEA’s requirements. This work has been launched by the staff of the Director General in collaboration with Human Resources and the training programme will now be implemented.

On an overall level, there is a good compliance with the requirements formulated in the IAEA’s standards.

References

SFS 1982:80 Employment Protection Act
SFS 1984:3 Nuclear Activities Act
SFS 1986:223 Administrative Procedure Act
SFS 1988:220 Radiation Protection Act
SFS 1998:808 Environmental Code
SFS 2000:1087 Notification of certain holdings of financial instruments Act
SFS 2009:400 Public Access to Information and Secrecy Act

SFS 1988:293 Radiation Protection Ordinance
SFS 1992:191 Ordinance on fees to authorities
SFS 2008:452 Ordinance with instruction for the Swedish Radiation Safety Authority
SFS 2011:13 Environmental Supervision Ordinance

AFS 2001:1 Swedish Work Environment Authority´s regulation on a systematic work environment management

SSMFS 2008:9 Regulations on the Control of High-Activity Sealed Radioactive Sources
SSMFS 2008:25 Regulations on Industrial Radiography
SSMFS 2008:27 Regulations on Practices with Accelerators and Sealed Sources
SSMFS 2008:28 Regulations concerning Work with Open Radioactive Sources at Laboratories
SSM FS 2008:38 Regulations concerning archiving at nuclear facilities
SSMFS 2008:40 Regulation on the Use of Equipment in Industry containing Sealed Sources or X-Ray Tubes
SSMFS 2008:51 Regulations concerning Basic Provisions for the Protection of Workers and the General Public in Practices involving Ionising Radiation
SSM SF 2010:2 Regulations for management of radioactive waste and releases from activities with open radioactive sources

SSM2011-99-69 Rules of Procedure of the Swedish Radiation Authority
STYR2011-71 Management of the Swedish Radiation Authority
STYR2011-72 Management of deviations, incidents, corrective actions and prevention of reoccurrence of events
STYR2011-96 Public relations (In Swedish only)
STYR2011-106 Inspection routine
STYR2011-126 Disqualification and conflicts of interest by external councils and boards
STYR2011-138 Disqualification and conflicts of interest by external consultants
STYR2011-171 Competence profiles for inspectors (In Swedish only)

Module 4: Management system of the Regulatory Body

Counterpart

Elisabeth Öhlén
Quality Manager
DG Staff
+46 8 799 42 56
Elisabeth.Ohlen@ssm.se

Assessment for IAEA requirements GSR Part 1- Requirement 19 and GS-R-3 – The Management System for Facilities and Activities

GSR Part 1- Requirement 19:
The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.

The Swedish Radiation Safety Authority, SSM, has implemented an integrated ISO-certified management system in accordance with ISO 9001 (quality) and 14001 (environment) in addition to AFS2001:1 (work environment). The management system is set up in accordance with the IAEA's guidelines GS-R-3 and fulfils the requirements. The key elements of the management system are described in the document Management of the Swedish Radiation Safety Authority (STYR2011-71).

SSM´s mandate as expressed in the Government's governance of the Authority through the Ordinance with instructions for the Swedish Radiation Safety Authority (2008:452) states the regulatory safety goals which are the basis for SSM´s overall safety objective (vision and mission statement) as presented in the introduction. A division into areas of operation illustrates the various public arenas where the Authority is tasked with ensuring radiation safety.

Safety objectives are set for each of the different major areas of operation which are documented in annex 2 to the strategy document "Management of The Swedish

Radiation Safety Authority" (STYR2011-71). The safety objectives influence several other steering documents (policy documents etc.).

The main policy documents available governing key areas are:

- Management of the Swedish Radiation Safety Authority (STYR2011-71)
- Policy on international work (STYR2011-66)
- Policy on supervision (STYR2011-97)
- Authorization and licensing of complex industrial facilities (STYR2011-131).
- Research strategy (STYR2011-119)
- Strategy for environmental monitoring (STYR2011-46)
- Public relations (STYR2011-96).

In addition to this there are several policy documents in the area of human resources.

The Authority's integrated management system is process-oriented and encompasses the processes of planning and follow-up, implementation and supporting functions.

The processes are described with a special focus on key processes (e.g. Supervision and Licensing reviews). The clickable process map is available on the internal website guiding the staff. Approved policy documents are available in connection to the relevant process but also in the authority's document management system (SSM360). The management system provides a good structure for SSM's management and document governance.

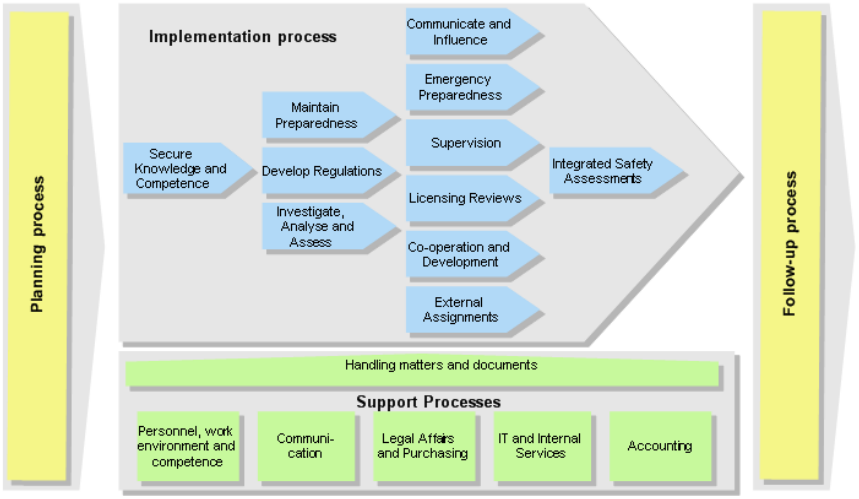

Figure 3 Process map

The basis when developing the management system appropriate for its functions and responsibilities aligned to the safety goals has been:

- defined regulatory activities and roles based on the requirements from government and laws
- developed processes for the major activities through participation from the organization on different levels
- a management system based on the regulatory safety goals.

The Authority's different processes serve as a foundation for how the Authority's work should be conducted and have the aim of achieving the desired performance

(or fulfilling the objectives) within the framework of the Authority's areas of operation.

The implementation processes are carried out within the framework of nine of the Authority's different areas of operation (excluding efficient and effective administration). The areas of operation illustrate the overall aim of the work in order to paint the full picture.

The implementation process encompasses several main processes. These main processes illustrate our modes of operation. The different main processes comprise an interdependent flow. This flow includes everything from building knowledge, developing rules, regulations and methods through hands-on work in the public sector to analysis and evaluation of performance. Depending on the objectives to be achieved within the framework of the respective area of operation, the Authority selects the main processes in the way that most effectively contributes to the objectives.

Management responsibility

The Director General and Senior management have largely been involved when developing the management system (MS). Adequate resources have been allocated for the fulfilment of the management´s commitment to the establishment, implementation, assessment and continual improvement of the MS. This is subsequently secured via the annual planning process, where adequate resources are allocated for the continuous improvement of the processes and documentation. Since the start of the authority three persons in the DG Staff have been dedicated for organisational development in a broad sense; the Quality Manager responsible for the management system development, the Senior Coordinator responsible for development of the supervision processes and internal auditing, and the Organisational Development Manager with a more general responsibility.

The commitment is expressed through SSM´s different policy documents and is outlined in the strategy document "Management of the Swedish Radiation Safety Authority" (STYR2011-71), where SSM´s cooperate vision and mission statements as well as SSM´s core values (Reliability, Integrity, Openness) are expressed.

These fundamental values are put into effect by means of SSM's established objectives, policies and other steering documents, which are to be understood, familiar to and complied with by all staff members.

Outcome objectives and performance targets

For each area of operation overall outcome objectives and performance targets have been set. The overall outcome objectives define the objectives of the Authority in terms of future development in society. The outcome objectives define the objectives of nuclear safety and radiation protection and an activity's indirect environmental impact.

The performance targets define the aims in terms of safety and radiation protection, quality and the environment (direct and indirect environmental aspects) linked to relevant activities and processes for the respective area of operation.

Management and approach

The Authority requires efficient, effective and up-to-date administration with a capacity to retain, train and recruit the professionals needed to manage the Authority's assignments. SSM's organisation and responsibilities are defined in the Authority's Rules of procedure and departmental decision-making procedures. Decisions issued by SSM are prepared in accordance with a decision-making procedure (an appendix to the Rules of procedure).

The work of the Authority is conducted by means of planned activities arranged on departmental and section level. All of these activities are linked to both an area of operation and to a process/sub-process.

Resource Management

The senior management has determined and provided the resources necessary to establish, implement, assess and continually improve the management system. This has been done by appointing a quality manager for the task. The Quality Manager is in close collaboration with the Senior Coordinator for this task as well as the group of internal auditors. These are working partial time on performing audits. Resources are available for external auditing companies and developing activities.

The amount of resources is determined in the annual planning process according to the identified needs, and the economy given by the government (see further Module 3).

According to SSM´s competence process the management annually shall analyse the need of competence to carry out the activities in the different regulatory operation areas. On the basis of this, recruitment plans are produced in each section. Also individual plans for competence development are decided on an annual basis. These plans are discussed and followed up between the employee and head of section according to a documented routine (STYR2011-33).

An internal audit in 2010 showed that the competence process is not quite implemented and some managers were using obsolete models. The HR-section has an appointment from the DG this year to further develop the competence process.

Detailed competence profiles are at the moment not fully implemented; however in the instruction of internal audit (STYR2011-42) the requirements of competence of the auditors are described. There is also a profile for managers at SSM. A newly developed competence profile and a formal training program for staff conducting regulatory supervision are now being implemented (STYR2011-171).

An inventory of competence was made by the authority in 2010; this is a platform for the long term planning of competence. In order to recruit individuals with appropriate education, skills and experience the organization analyse the requirements and needs by inventing the departments/sections activities and defining the tasks of the position. After decision of the DG an advertisement is formed and published, this includes a competence profile. The applicants are interviewed and evaluated according to the requirements. See instruction about recruitment (STYR2011-45).

There is an overall plan of education and training of staff as well as budgeted resources (time and money) for competence development. In discussion with the head of section the need for education in the different areas is identified. The individual

needs are identified in annual development reviews between manger and the employee. All new employees are presented an introduction program with different areas which are important to achieve proficiency in the approach of the regulatory body.

In order to measure the effectiveness of the actions taken to achieve and maintain the competence of the staff different kinds of evaluations exists; e.g. evaluations of exercises in the area of emergency preparedness are performed, as well as evaluations of training courses. Every measure of competence-development is followed-up by the responsible manager (head of section etc.) and involved employee. The competence activities are evaluated according to goals and documented.

The recruitment process is described in Module 3 – Responsibilities and functions of the regulatory body.

Purchasing

The Authority has decided on a process for procurement where criteria are evaluated. Swedish authorities are in general strictly ruled by common agreements between the state and different suppliers according to the Swedish Public Procurement Act (2007:1091 – LOU), which is largely based on the EU Directive 2004/18/EC concerning public procurement. Most of the purchased goods are procured according to a list of these common agreements; the authority has in this case small opportunities to make changes. In addition SSM has:

Formal requirements

- The Contractor's eligibility
- Consideration of ‘shall' requirements
- Award criteria: “The tender that is most economically advantageous” or “the lowest price” (see item 6.14 in the procurement manual).

SSM has enquiry documents including the following parts:

- Preconditions for tenders: The preconditions for the procurement process per se should be described in a section entitled ‘Preconditions for tenders' (see item 6.4 in the procurement manual) and under the procurement tab of SSM's process map.
- Specification of requirements: The requirements imposed on the product or service are described in a specification of requirements. (See items 6.3 and 6.10 in the procurement manual and under the procurement tab of SSM's management system.)
- The contract: (The contract normally states how the product/service is to be supplied, developed and approved.) How deviations are to be dealt with as well as the conditions and documentation to be encompassed by the product (good or service). Ownership and right of use of the results.

Working environment

SSM considers the work environment as an important prerequisite for the human resource management and the quality of work. The Swedish legislation is clear on how the working environment should be at workplaces. The purpose is that ill-health and accidents are prevented and that the employees have a satisfactory working

environment. The structure of the development of working environment is described in the management system in the working-environment process. This process also shows what should be done within the areas risk assessment, planning, implementation and evaluation. Risk assessments are carried out regularly according to a documented procedure - Annual Risk Assessment of the working environment (STYR2011-41). The risk assessments comprise all physical, psychological and social conditions of importance for the work environment.

A risk assessment is done by every section and the identified risks are documented in an action plan (in the SSM planning system SINUS). The risks, which are common to the organization, will be added into a joint action plan. Implementation is carried out according to plan and follow-up and evaluation of the actions are carried out regularly and annually. Safety inspections in the laboratories as well as fire escape exercises are conducted annually.

Process Implementation

Developing processes

Prior to the establishment of the Swedish Radiation Safety Authority a preparatory work was conducted in order to have a management system in place 1July 2008. During the following time to date SSM has focused on the establishment and implementation of the management system. In addition to the international ISO-standards that are a requisite for a certified management system, the IAEA standards GS-R-3 were applied.

The starting point was the identified processes at the former authorities SKI and SSI, which both had originated from the assignment from the Government. The processes were then adjusted according to the new authority´s assignment. On several occasions the staff was invited to discuss and to come with suggestions.

The strategy used was to make a description of the main processes at an aggregated level and, if applicable, the underlying parts (sub processes). This was the starting point for an extensive work performed from October 2008, which involved a great number of the staff for several months. The work focused mainly on two of the processes, namely “Supervision” (Compliance inspections, surveillance inspections etc.) and “Assess applications / Authorization” were the work was performed as projects. The work was aiming to find a consensus about these matters regardless areas of operation.

The main processes are divided into different categories; implementation (operational) processes, planning and follow-up processes and supporting processes. The sequence and interactions of the processes have been determined in trying to get a logistic flow – from the starting point “Ensure knowledge and competence” which is the basis for assessments and analyses as well as development of new regulations. These two processes are subsequently a base for different operational actions. These actions are then the ground for the assessments done in the process “Integrated Safety assessment”. See process map.

Process management

The overall responsibility for development/improvement of the processes lies with the DG Staff and the quality manager. The head of the Staff (deputy DG) has a specific responsibility in relation to the Senior Management. Certain key persons have

been appointed to manage the development and implementation of some of the processes. However, the managers at different levels are responsible for the implementation, evaluation and control of the processes in their respective area of responsibility (Rules of procedure). In the near future there will be a decision about appointed individuals ("process managers") with the responsibility to follow-up, evaluate and develop the processes.

Control of documents, products and records

All official documents are registered in the authority's case and document software system. The registered documents in the case directory are stored in PDF-format and stamped with the deciding manager or, if delegated, the responsible individual. The matter of electronic archiving has not yet been decided on; thus the main part of registered documents is so far preserved on paper.

All registered documents should have metadata with the following details:

- Document number and version (auto generated)
- The external party (if relevant)
- Regulatory activity area (mandatory)
- Main Process (mandatory)
- Sub process (mandatory for internal steering documents)

The decision making process is decided through the "Rules of procedure" where responsibilities are assigned to managers and individuals.

According to the "Rules of Procedure" all decisions made for an item of business shall be accompanied by the above details mentioned as well as:

- matter number,
- date of decision,
- content of decision,
- decision-maker,
- rapporteur, if the matter was formally presented,
- those who participated in the final administration but without participating in the decision-making, and
- existence of any dissenting opinions.

The software system makes retrieval of documents and cases possible by using these registered metadata.

Major processes and other important work activities should follow specific procedures as decided in the internal steering documents. The above mentioned "Rules of procedure" is the top document in this hierarchy. The "Rules of procedure" (including annexes) regulates how the authority is organized and governed as well as the decision-making procedures.

The process "Control of documents" (STYR2011-32) describe how internal steering documents and documents verifying performed activities and the results of the authority are produced, up-dated, approved and published, filed and eliminated.

The managers (department and/or section) have the main responsibility to ensure that the documentation that they are responsible for is consistent with other relevant

documentation. Thus, managers have to check that the correct document format has been used and that all the necessary steps have been followed according to the procedures. In the case of involvement of more than one department/section there is a procedure of internal consultation. If necessary, the lawyers are also involved in decision making. On a metadata level the register office should make a quality check before completion of matters.

The internal auditors are assigned to do controls of documentations consistency towards relevant steering documents, but this is done as "random samples". One example of this is a recent audit activity how the inspection reports is consistent with the routine for inspection (STYR2011-106).

In order to ensure the identification of the products for their proper use and ensure their traceability the products are marked with a unique register number and archived systematically according to operational area and main process. Products are stored according to the Swedish National Archive´s regulations. Most of the products are stored in paper format and occasionally on other media if necessary. The paper quality meets the set national quality standards. Products are stored in flame secure filing cabinets (short term) or in the authority´s central archive with stipulated environmental conditions (middle long term). Long term storage is done at the National Archive. Registered documents from external parties are not possible to alter or to remove permanently.

Communication

All relevant information (mainly steering documents) should be published on our internal web-site. The managers are responsible for communicating important decisions and questions that are of common interest to all personnel.

Information is communicated at the internal web-site and at the departments and sections internal meetings. Section-meetings are held every week and department-meetings are held approximately once a month. Especially the heads of sections normally have daily contact with the staff on an individual level. Once a month all personnel are gathered and the Director General and others will tell about prioritized issues and important changes influencing the staff.

Data on all registered matters in SSM´s case directory, unless confidential, are published on our external web-site; this includes decisions towards a third party. On different levels there are meetings with external parties both on regular and ad hoc basis.

All internal decisions made by the Director General are registered in the authority's case directory and easily available to all staff.

Organisational change

SSM has recently developed a process for the management of its organisational changes (STYR2011-165).

According to Swedish regulations employers are obliged to negotiate and inform the staff about important organisational changes and perform a risk- and consequence analysis. Employees and union should have opportunities to participate in the pro-

cess. The Director General takes decisions on organisational changes. Prior to this the co-operation with the union and staff should be conducted in two steps:

1. A proposal and the risk- and consequence analyses of the proposal are presented to the union and the proposal will be discussed and further adjustments will be made
2. Discussions on the proposal at section level in the organisation to collect comments. The senior management takes a stand and the proposal is negotiated with the representatives of the union.

Measurement, assessment and improvement

The Authority will continually follow up, improve and develop its work. The annual orientations and prioritisations determined by the Director General set the standards for the Authority's development and improvement work over the next few years. The performance of the work carried out in the different areas of operation and processes is to be traceable and documented.

Follow-up is carried out periodically in the context of the ordinary activities in what extent the Authority and departmental activities are proceeding according to plan. This is documented in the planning tool SINUS in accordance with the routine for Planning and Follow-up (STYR2011-98).

Self-assessment

All managers are responsible to evaluate the effectiveness of the performance in the area of their responsibilities (Rules of procedure and STYR2011-98). This is done on an annual basis, when the results of last year´s activities are followed up, but also once every fourth month. However, the specific method for the evaluation is not formalised so far. The result of the assessment is done in a dialog with the Director General. Any proposals for improvements should subsequently be added to the responsible departments' operation plan.

Independent assessment

Independent assessments are regularly performed by internal and external audits. During these audits the internal auditors and the auditing company take part in different documentation, have meetings with the senior management as well as performing different interviews with responsible managers and staff.

All national authorities are annually reviewed by the Swedish National Audit Office, Riksrevisionen. The Office reviews SSM at least once a year when last year´s results are audited. They review financial matters but also the effectiveness of the processes. They could also perform ad hoc reviews in certain areas.

An external auditing company visits the authority twice a year according to an agreement made at a total of five days. The reviews are conducted according to the requirements in ISO 9001, ISO14001 and the regulation in the Working Environment Authority´s regulations (AFS 2001:1) on a systematic working environment management. The reviews should over time cover the entire management system.

Approximately every second year the National Standards Laboratory (Riksmätplatsen) are reviewed by SWEDAC, Swedish Board for Accreditation and Conformity Assessment, according to the international laboratory standard ISO 17025.

There are ten to twelve internal auditors appointed by the DG (STYR2011-42). They should meet certain competence criteria and the auditor may not audit an operation or process in which he or she is normally involved or dependent on. The senior co-ordinator at the DG Staff has the task of coordinating the internal auditors' work as directed by the head of staff.

The internal auditors are conducting internal audits according to a three year program and an annual plan. Audits are performed for the purpose of monitoring the operation at all levels, checking the Authority's fulfilment of external and internal requirements, checking how the key values are realised in practice and to investigate whether application of the management system is fit for purpose and effective.

Management system review

Each year, SSM's senior management reviews the performance of the management system in terms of its suitability for the organisation and in order to identify needed improvements and to take subsequent actions. These reviews are conducted at least twice per year during the senior management's ordinary meetings. The reviews are documented in the form of minutes from meetings of the senior management and its 'ML' decision documents (i.e. the decisions issued by it).

Audits are to provide significant decision-making input to the Authority's senior management and other parties in charge of particular areas or processes while also providing impetus to development work. Audit work is thus a key part of improving and developing work activities. The senior management decides on the operations' and SSM processes' development and improvement, for example based on the audit results. Analyses of operations and external factors are conducted annually and serve as the platform of the Director General's orientation, which is the most important tool for continuant improvement.

The Senior Coordinator conducts follow-ups and checks overall development of the operation and the management system on the basis of work performance and audit results.

Non-conformances and corrective and preventive actions

Non-conformances can be defined in internal and external audits, also by employees and managers in daily activities. Non-conformances of importance are documented with a description of the problem, possible cause of the problem and suggestions for action which may be either corrective or preventive according to routine "Manage improvements, non-conformances and corrective actions" (STYR2011-72). The manager responsible for the deviation decides what measure to be done and that the outcome of the measure is examined. Major non-conformances can result in a formal DG assignment.

On the overall authority level there is a cumulative reporting during Senior management review (STYR2011-98).

Corrective actions for eliminating non-conformances in regulatory activities or processes are determined according to the Authority´s Rules of procedure at appropriate level. Any corrective actions due to serious non-conformities are decided by the Director General.

In order to eliminate the causes of potential non-conformances in regulatory activities or processes a model for risk management is decided which will be implemented/established starting with the planning activities for 2012.

Information about corrective actions will take place in meeting of the senior management team. All managers then share the information within their departments. If appropriate, information about improvements and actions taken is also available on the internal web-site.

Improvement

The need for improvements is identified through internal and external audits, as well as any investigations made in a certain area. The investigation could be performed as an action due to non-conformity or other findings as for example the annual horizon scanning.

All staff is encouraged to make suggestions for improvements and should report to the responsible manager if any non-conformity occurs according to the routine "Manage improvements, non-conformances and corrective actions" (STYR2011-72). In the planning tool "SINUS" anybody could report any potential non-conformity; however this is not fully implemented yet.

A continuous dialog with the Director General on further improvements is performed, and annually the senior management reviews the Management System (MS) to assure that it is functional and suits the organization. The aim of this annual revision is to identify improvements of the MS and decide on actions to be taken for their implementation. The approach follows requirements in the ISO 9001 standard and is described in document STYR2011-98 under "Ledningens genomgång" (Management review).

The Director General's prioritizations are annually used to set resources for coming years. The basis for this is the annually performed horizon scanning as well as analysis of the last years work activities and results.

Summary and conclusions

The integrated management system implemented has been setup in accordance with the IAEA's guidelines GS-R-3 and fulfills the requirements. The key elements of the management system, including main processes, are described in the document "Management of the Swedish Radiation Safety Authority".

Although the main components of the management system are set, some work remains to be done; for instance, several processes have only been described in a general way. Thus, there is a need in certain areas to develop routines that are more detailed and work-specific.

A great deal of work remains to be done on developing and implementing the process to secure competence, including a comprehensive strategy for securing competence. Competence requirements for employees exercising regulatory supervision have recently been developed; the application of these requirements now needs to be implemented in addition to training programmes linked to these requirements. This work should be developed further, as well as other competence-related areas.

Also, methods and criteria for how to follow up and evaluate the performance of the processes and the management system should be developed as well as how to assess the efficiency of operations.

The Authority needs to develop a strategy for systematically capturing and compiling the expectations and standpoints of interested parties.

References

SFS 2007:1091 Swedish Public Procurement Act (LOU)
SFS 2008:452 Ordinance with instructions for the Swedish Radiation Safety Authority

AFS 2001:1, Systematic Work Environment Management

Swedish Radiation Safety Authority´s Rules of Procedure (Reg no SSM2011-99-69)
STYR2011-32 Management of documents (In Swedish only)
STYR2011-33 Routine for individual competence planning (In Swedish only)
STYR2011-41 Annual Risk Assessment of the working environment (In Swedish only)
STYR2011-42 Internal auditing
STYR2011-45 Recruitment instruction (In Swedish only)
STYR2011-46 Strategy for environmental monitoring
STYR2011-66 Policy on international work
STYR2011-71 Management of the Swedish Radiation Safety Authority
STYR2011-72 Manage improvements, non-conformances and corrective actions
STYR2011-96 Public relations (In Swedish only)
STYR2011-97 Policy on supervision
STYR2011-98 Planning and follow-up (In Swedish only)
STYR2011-106 Routine for compliance inspections
STYR2011-119 Research strategy
STYR2011-131 Authorization and licensing of complex industrial facilities
STYR2011-137 Routine on safety controls in laboratories (In Swedish only)
STYR2011-165 Manage organisational changes (In Swedish only)
STYR2011-171 Competence profile for inspectors

Modules 5-9:
Cross-cutting areas

Counterparts

Cross-cutting

Anna Norstedt
Senior Coordinator
DG Staff
+46 8 799 42 59
Anna.Norstedt@ssm.se

Regulations & Guides

Ulf Yngvesson
Head of Section
Legal Services
+46 8 799 43 41
Ulf Yngvesson@ssm.se

Radioactive sources

Carl-Göran Stålnacke
Inspector
Radiation Protection
+46 8 799 43 76
Carl-Goran.Stalnacke@ssm.se

Erik Welleman
Head of Section
Radioactive Materials
+46 8 799 43 11
Erik.Welleman@ssm.se

Helene Jönsson
Head of Section
Radiation Protection
+46 8 799 43 74
Helene.Jonsson@ssm.se

Nuclear Power Plants

Lennart Carlsson
Director
Nuclear Power Plant Safety
+46 8 799 42 46
Lennart.Carlsson@ssm.se

Leif Karlsson
Head of Section
Nuclear Power Plant Safety
+46 8 799 41 02
Leif.Karlsson@ssm.se

Lars Skånberg
Head of Section
Nuclear Power Plant Safety
+46 8 799 42 72
Lars.Skanberg@ssm.se

Fuel Cycle Facilities

Svante Ernberg
Inspector
Radioactive Materials
+46 8 799 43 05
Svante.Ernberg@ssm.se

Eric Häggblom
Inspector
Radioactive Materials
+46 8 799 41 69
Eric.Haggblom@ssm.se

Stig Wingefors
Analyst
Radioactive Materials
+46 8 799 41 25
Stig.Wingefors@ssm.se

Waste Facilities

Johan Anderberg
Director
Radioactive Materials
+46 8 799 44 77
Johan.Anderberg@ssm.se

Bengt Hedberg
Analyst
Radioactive Materials
+46 8 799 41 87
Bengt.Hedberg@ssm.se

Stig Wingefors
Analyst
Radioactive Materials
+46 8 799 41 25
Stig.Wingefors@ssm.se

Waste Facilities

Johanna Sandwall
Head of Section
Radioactive Materials
+46 8 799 42 84
Johanna.Sandwall@ssm.se

Anders Wiebert
Inspector
Radioactive Materials
+46 8 799 41 82
Anders.Wiebert@ssm.se

Bo Strömberg
Analyst
Radioactive Materials
+46 8 799 41 63
Bo.Stromberg@ssm.se

Decommissioning

Björn Dverstorp
Government Specialist
Radioactive Materials
+46 8 799 42 15
Bjorn.Dverstorp@ssm.se

Mathias Leisvik
Inspector
Radioactive Materials
+46 8 799 41 72
Mathias.Leisvikt@ssm.se

Henrik Efraimsson
Inspector
Radioactive Materials
+46 8 799 42 88
Henrik.Efraimsson@ssm.se

Summary and Conclusions

The modules cover the following areas: authorisation, review and assessment, inspection, enforcement, regulations and guides for the operations Radioactive Sources, Nuclear Power Plants, Fuel Cycle Facilities, Waste Facilities, Decommissioning, Emergency Preparedness and Response.

Current regulations for a licensee to construct and operate a nuclear facility under the Act on Nuclear Activities and the Environmental Code can be difficult to grasp, but SSM's management system contains a clear description of different phases of licensing reviews at an overall level. This process complies with the view of the IAEA on the licensing process and on a graded approach. SSM's methods of working with licensing reviews and regulatory supervision are governed clearly on an overall level.
The capacity for exercising supervision has strong support in Swedish legislation. Through the regulatory supervision methods of compliance inspection, surveillance inspection, rapid investigation and review, SSM has the capability to identify circumstances requiring action by the licensees.

According to the IAEA's standards, reviews and assessments must at different phases be conducted as stipulated by clear procedures and well-defined methods. De-

tailed procedures have been drawn up in some areas, such as authorisation for power up-rates and reviews of complex sites. However, limited quantities of steering documents have these kinds of procedures.

SSM does not completely fulfil the requirements imposed by the IAEA's standards regarding radioactive sources. It is mainly the security aspects that are not fully complied with in terms of enactments. The management of powerful orphan sources could also be improved and a formal system of management be introduced. The frequency and scope of inspections in this area and the related SSM database should be improved.

Sweden has advanced systems for waste management. However, there is room for improvement as regards acceptance criteria for disposal of some historical waste currently stored. As far as concerns decommissioning, the legislative and regulatory framework does not prescribe specific timeframes.

In general, there is a good compliance with the requirements formulated in the IAEA standards. SSM has authorisation in Swedish legislation to issue regulations, interpret them and impose additional requirements and conditions. SSM's decisions and statements shall be justified in accordance with the Administrative Procedure Act. The decisions also provide information about the possibility to appeal

Module 9: Regulations and Guides

Assessments for IAEA requirements: GSR Part 1 – Requirement 32-34

Regulations and guides

Requirement 32: Regulations and guides
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.

Legal framework

Basic rules on nuclear safety are regulated in the Act on Nuclear Activities (1984:3). Section three in this Act require that Nuclear activities shall be conducted in a way so that the requirements imposed on safety are met and the obligations are fulfilled as prescribed by Sweden's agreements aimed at preventing the proliferation of nuclear weapons and unauthorised dealings with nuclear material. Section four of the Act states that the Safety of nuclear activities shall be maintained by implementing the measures necessary in order to prevent defects in or the malfunction of equipment, improper handling, sabotage or other circumstance that could result in a radiological accident, and prevent unlawful dealings with nuclear material and nuclear waste.

The general obligations in section 10 of the Act states that a party that holds a licence for nuclear activities shall be responsible for ensuring that all the necessary measures are taken for:

1. maintaining safety, taking into account the nature of the operation and the circumstances in which it is conducted,
2. safe management and disposal of nuclear waste generated by the operation or nuclear material derived from the operation that is not reused, and
3. safe decommissioning and dismantling of facilities in which the operation shall be discontinued until all operations at the facilities have ceased and all nuclear material and nuclear waste have been placed in a repository that has been sealed permanently.

In section 10 it is also stated that a party that holds a licence for nuclear activities shall, as soon as possible in connection with incidents, threats or other similar circumstances, provide information that is relevant to an assessment of safety to the regulatory authority.

Section 13 of the Act states that a party that holds a licence to conduct nuclear activities is obliged to:

1. bear the costs for the measures referred to in Section 10 as well as the necessary research and development to fulfil the requirements, and
2. have an organisation for the activity with sufficient financial, administrative and human resources in order to implement:
    a. the measures referred to in 1,
    b. measures ensuing from conditions or regulations issued under the Act, and
    c. protective measures in the event of disruptions in the operations or accidents in the facility.

The Act on Financing of Management of Residual Products from Nuclear Activities (2006:647) contains provisions regarding the obligation of licensees to ensure financing of such costs and to certain costs incurred by the State. To this end the licensees pay annual fees that are collected in funds administered by the Nuclear Waste Fund (a governmental authority).

The primary purpose of the Swedish financing system is to secure the financing of the licensees' costs to manage and dispose of the spent nuclear fuel and nuclear waste, decommission and dismantle the nuclear facilities and to carry out the needed research and development activities, but also to minimise the State's risk of being forced to bear the costs which is considered to be the licensee's liability.

The authority reviews the nuclear power utilities' cost estimates as well as the size of the guarantees that nuclear power utilities must make available. After its review, the authority submits a proposal for the size of the fees, and of the size of the guarantees required, to the Government. Based on this proposal, the Government sets the fees and guarantees. The fees are set for a three year period and are individual for each utility.

The Radiation Protection Act (1988:220) requires that anyone conducting activities with radiation shall take into account the nature of and the circumstances under which this activity is conducted, and take the steps and the precautions necessary to prevent or counteract damage to humans, animals and the environment and control and maintain radiation protection of places and areas where radiation occurs.

Regulatory framework

Acting as the central regulatory body under the Act on Nuclear Activities and the Radiation Protection, SSM is authorised to issue regulations concerning safety and radiation protection. Based on this authorisation and the requirements in the legislation, the SSM has issued regulations which include the use of graded approaches. The graded approaches used in regulations and regulatory work are based either on safety importance or on risks of a facility, part of a facility, a system or an activity.

Nuclear power plants and fuel cycle facilities

It is mandatory for the licensees of nuclear facilities to apply the requirements of the regulatory body according to section 3 of the Act on Nuclear Activities. Such requirements are to be found in SSMFS 2008:1, SSMFS 2008:13 and SSMFS 2008:17. SSM also has the authorisation to decide on such additional conditions to a license that are necessary from the standpoint of safety.

Waste management

Chapter 6 of SSMFS 2008:1 and SSMFS 2008:22 contain specific requirements for waste management. In addition, SSM 2008:21 and SSM 2008:37 contain specific requirements for disposal of spent nuclear fuel and nuclear waste.

Decommissioning

Requirements on decommissioning of nuclear facilities are provided in Chapter 9 of SSMFS 2008:1 and in SSMFS 2008:19. Decommissioning of nuclear facilities does not require a specific licence as decommissioning is seen as an integral part of the lifecycle of the facility. Decommissioning is however not allowed to start until authorized by the regulatory authority.

Radioactive Sources

A set of regulations exists dealing with radioactive sources and specifically High activity sealed radioactive sources (HASS) (SSMFS 2008:9, SSMFS 2008:10, SSMFS 2008:27, SSMFS 2008:40). The IAEA Code of Conduct has not been literally implemented in all parts, however by implementing the EU HASS-directive all major safety and radiation protection requirements are taken care of. It is national regulations that are communicated to users since those are legally binding.

Security issues is a part of a separate SSM activity initiated with the aim to implement fundamental security issues as identified in international documents and these are not further elaborated here.

Review of regulations and guides

Requirement 33: Review of regulations and guides
Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained.

The SSM management system includes a specific process for development of new or revised regulations (STYR2011-51) as well as for development of general advice to the regulations. After a decision at management level, a project group is established involving both technical and legal expertise to develop a draft proposal for new/revised regulations. A standing advisory council on regulations provides for advice to the project group as well as for quality assurance of the work performed.

When a proposal for new or modified regulations is prepared and has been submitted to the council, an internal referral to the proposal is made. When this is done, the proposal and an impact assessment is submitted to external consultation of interested parties, interest groups and NGOs. When the referral period has expired and the comments are dealt with, the case is finally presented, first for the council and then the Director General who decides on the regulations and general advice.

Remittance of proposed new or revised regulations is an essential element in the Swedish legislative process. The Instrument of Government stipulates that the government must obtain the appropriate information and an opinion before a case is decided. This also applies to authorities that are subordinate to the government. As described a mandatory part of the authority's regulatory and advisory process is to provide feedback through an external referral. A proposal for a regulation or general advice and an impact assessment is to be sent to interested parties, interest groups and NGOs, which may have up to three months to submit comments. The proposal is also posted on the authority's website to allow comments from members of the public. Submitted commitments are considered by the authority and additional contacts may take place to address any uncertainties. Licensees and other stakeholders may also be invited to meetings for information and clarification when deemed necessary.

Feedback on compliance and suitability of requirements are collected during inspections and reviews, as well as at regular contacts with industry representatives. This information together with feedback of experience from international networks is also considered in the development process. A key element is also SSM*s monitoring of the development of IAEA Safety Standards as well as other internationally accepted standards, rules and regulations.

Involvement of interested parties

Requirement 34: Promotion of regulations and guides to interested parties
The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.

The regulations and general advice of the Authority are published on its website. The principle of public access to public documents gives everyone access to public documents for examination, without having to say why or who you are. All documents received or sent out from the authorities, such as letters, decisions, inspection reports, review reports and investigations are in principle for anyone to read. The authority also performs education and conduct specific information for companies.

Areas of improvement

- The implication of future legislation expected to enter into force in 2015 is that SSM will need to adapt its regulatory framework to the changes. In addition we have to continue to improve the regulatory frame work so that the regulations get more uniform in their structure and better harmonise between themselves.
- SSM regulations are often general in character. SSM should analyse whether it would be justified to develop more detailed regulations, general advice or guidelines where relevant.
- There is a need for development of regulations for building nuclear power plants. Existing focus on operation of nuclear facilities.

- SSM's regulations do not impose explicit requirements on safety culture. SSM should analyse whether aspects of safety culture are encompassed by current regulations and thereafter review the need to introduce related requirements in the regulations.
- It is not clear in the regulations and internal steering documents that all radiation risks during normal operation, transients and accident condition should be assessed regularly during a nuclear plants lifetime to determine whether these risks are as low as reasonably achievable. Some of these aspects are currently included in the assessment of the periodic safety review that the licensees must report according to the Act on Nuclear Activities, but clarification is needed.

Module 5: Authorization

Assessment for IAEA requirements: GSR Part 1 – Requirement 23 and 24

Authorization and Demonstrations of safety

Requirement 23: Authorization of facilities and activities by the regulatory body
Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.
Requirement 24: Demonstrations of safety for the authorization of facilities and activities
The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.

General

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). Issue of licensing according to the Act on Nuclear Activities is decided by the Government or in some cases by SSM. In those cases when the decision is made by the Government. SSM acts as drafting authority and when the decision is made by the court SSM acts as a referral body. Licensing issues according to the Radiation Protection Act are decided by SSM.

SSM handles licensing issues in several areas. The licensing process is there for described on a general level in the management system. The process is divided in to two categories depending on whether SSM is a decision making or drafting authority.

Review in connection with an authorisation of a facility SSM seeks to determine whether the requested operation or activity can be expected to be conducted so that the relevant requirements are meet. The review process is described within the supervision process in the management system.

Nuclear power plants and fuel cycle 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. Nuclear power plants require a special permit under the Environmental Code for decommissioning.

No facilities are exempted from regulatory authorization but 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).

For applications that are notified to the authority, there are clearly defined procedures for review and assessments. The procedures are described in the "Licensing" process in the Management System and also in the process "Review" (STYR2011-124) under the processes "Supervision". The regulations formulates the requirements on which the assessments are based

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 greater radiological risks and have more complex systems, while for less complex activities it´s 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 the 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 shall – along with the particular documents concerning construction and nuclear safety – contain an Environmental Impact Assessment (EIA).

The case will be evaluated by SSM under the Act on Nuclear Activities on the basis of the basic safety requirements under this Act and the basic radiation protection requirements under the Radiation Protection Act and regulations specifying those requirements. An assessment should also be made of how the general rules under Chapter 2, the Environmental Code are met. Documents to be assessed are the submitted EIA and an initial preliminary safety analysis report (PSAR) along with technical and other statements of the proposed plant and its operation which shall be included in the application. SSM shall in its preparation assess 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 safe guards are met.

The court prepares the case in accordance with the provisions of Chapter 22 in the Environmental Code. The basis is, just as in the case under the Act on Nuclear Activities, 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 Land and Environment Court give then their opinions to the Government, who decides on permissibility according to Chapter 17 of the Environmental Code, and for a permit under the Act on Nuclear Activities.

If SSM in its preparation of the case find it likely that the plant will be located, designed and operated in such a way that the safety and radiation protection requirements and the requirements for security are met SSM suggests that the government grants a permits under the Nuclear Activities Act. In these cases SSM also suggest that the government decides on 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 the SSM.
- the nuclear power plant may not be taken into routine operation without being approved by the SSM.

The same procedure applies to applications of power up-rates of the operated plants, which need a new permit/license and stepwise examinations and approvals.

Based on licensing conditions and SSM's regulations further reviews and assessments of new nuclear power plants, other major nuclear facilities, complex plants where radiations is used as well as power up-rates of operating plants follow a stepwise procedure:

1. Review and decision on approval of a more developed preliminary safety report (PSAR), than the initial PSAR attached permit application, as the basis for detailed design and construction of a new plant or modification of an operating plant for power up-rate. This review shall verify that the SSM's regulations on safety, radiation protection and security that have a bearing on the design and the construction will be met.
2. Review and examination of organizational, human and administrative capacity to procure equipment and carry out works to the extent and the quality needed according to the PSAR that it has been approved. This step also includes the examination of security measures during construction phase. Furthermore, this step includes the review of preliminary plans for the future decommissioning of the plant. These reviews and examinations form the basis for the SSM's decision on approval to begin construction of a new plant or power up-rate modification of an operating plant. Thereafter, SSM will follow and monitor the construction works or power up-rate modification work as part of the basis for the positions in the next step.
3. Review and decision on approval of a renewed safety analysis report (SAR) that reflect the plant as it has been built or modified and that shows how the requirements have been met. This step also includes the review and assessment of the operational conditions in technical specifications and instructions which will provide guidance for operational staff, and reviewing test operation program and review of programs for training of operating personnel. In addition, this step includes review and assessment of security measures, emergency preparedness plans and plans for the test operation of the plant. These reviews, examinations and assessments form the basis for the SSM's decision on approval of commissioning and taking the plant in test operation. Thereafter, SSM will follow and monitor the test operation as part of the basis for the positions in the next step.
4. Review and decision on approval of a SAR that have been supplemented with experience from the commissioning phase including test operation, and inspections at the first outage in the event this becomes necessary. This step also includes the review and assessment of the operational conditions in technical specifications and instructions which have been complemented with experience from the test operation. These reviews and assessments

form the basis for the SSM's decision on approval of taking the plant in routine operation.

Waste management

Waste management activities at nuclear power plants constitute an integrated part of the operation of the plant and thus addressed as part of the authorization of the plant.

Authorization for other waste management and waste disposal facilities and activities follows the same general procedure as is described for fuel cycle facilities but with due consideration to the character of the facility/activity in question.

Decommissioning

Chapter 9 of SSMFS 2008:1 contains specific requirements for decommissioning. Before a facility may be constructed, a preliminary plan shall be drawn up for the future decommissioning of the facility. The preliminary plan shall be supplemented and kept up to date for the duration of the facility´s operation and shall be reported to the Swedish Radiation Safety Authority every ten years.

Radioactive sources

There are requirements in section 6 to 8 of the Swedish Radiation Protection Act which state that persons engaged in activities with radiation, or work where such activity is performed, shall use the safety equipment and take any other measures that are required for ensuring sound radiation protection conditions. High activity sealed sources (HASS) are specifically regulated through SSMFS 2008:9. The use of other radiation sources in general requires licensing and is regulated by provisions in SSMFS 2008:40, SSMFS 2008:45, SSMFS 2008:28 and SSM 2008:27.

A license application shall contain a requested data and information related to the radiation source technical parameters as well as conformity with norms and standards, but also the applicants' personnel qualification, procedures and practices for the source management. Information about equipment for the source handling and related emergency procedures and reporting are also part of the application presented by the licensee.

The licensees are registered at the authority as well as the sealed sources they possess if individual activity exceeds certain level (500 MBq), but without individual source ID. The licensee should however always keep registers of their own.

All licensees have the full responsibility for their activities including the sources they hold and use (SSMFS 2008:40 Section 3). The task of SSM is to regulate and supervise to ensure that the party responsible conducts the activity in a safe manner. For example SSMFS 2008:9 is requiring the applicant to demonstrate among others how it does meet the safety requirements. The application shall contain information about measures taken and planned for safe management of a source in case of discard, release to an another licensee or deposit to an approved radioactive waste storage.

Areas for improvement

- Co-operation between SSM and various public authorities needs to be reviewed, reconfirmed and possibly strengthened.
- The current licensing process is mainly developed for facilities established, operated and decommissioned in a staged sequence. SSM may want to review whether there is a need to develop regulations to make them more eas-

ily applicable also for disposal facilities where activities (i.e. construction, disposal, and back filling/closure) occur in parallel.

- Control of high-activity sealed sources (Hass) as well as the handling of disused sources needs reviewing. Funding needs to be assured and clearer allocation of responsibility needs to be conducted in terms of management of orphan HASS sources.
- The authority must regulate to ensure proper waste management of disused sources, for example final storage/treatment of some specific sealed/open radioactive sources is not in place. The national waste plan addresses these and other issues.

Module 6: Review and Assessment

Assessments for IAEA requirements: GSR Part1 – Requirements 25and 26

Review and assessment

Requirement 25: Review and assessment of information relevant to safety
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.

General

Reviews are performed in connection with supervision, licensing work and examination of licensing conditions for the purpose of analysing and considering the underlying documentation presented. Results from reviews are to be documented in a review report. The review work is governed by acts, ordinances and the Authority's regulations and general advice and/or international agreements and other regulatory schemes. The reviews may also be subject to particular requirements imposed by the Government or the Authority in connection with licences issued for a certain activity or other supervisory decisions. The Authority may also initiate its own review. This for example applies to categories of matters that must be notified to the Authority as stipulated by the Authority's regulations.

The aim of reviewing a supervisory matter is to check whether the requirements imposed are fulfilled. Licensing reviews aim at determining whether the activity or practice applied for is likely to be conducted in compliance with the relevant regulations. Reviews when examining licensing conditions aims at checking whether the requirements associated with the conditions are fulfilled.

SSM's reviews must, according to the management system, be documented in written 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.
SSM's decisions are documented in accordance to procedures in the management system. The decision must give clear information on what have been decided, the

case or subject, the relevant requirements and the motive for SSM's decision as well as who has taken the decision and who has been involved in the final preparation of the decision.

Nuclear power plant and Fuel cycle facilities

The major areas of review and assessment during licensing can be described in four successive stages.

In stage 1 the focus is on review and evaluation of basic design criteria for the facility according to the PSAR, and that all applicable SSM requirements has identified, interpreted and translated into design requirements in a proper manner. At this stage the focus is also on the control that the more detailed design and construction standards referred to in the PSAR and its planned application meets SSM's requirements. Moreover, the focus is on safety analysis that justify that the proposed design of the facility will meet the requirements.

In stage 2 the focus is on review and evaluation the licensee's organizational, human and administrative capacity to

- assess and control main vendors and suppliers for design and manufacture systems, structures and components,
- to procure components and equipment
- ensure that manufacturing, installation and construction works is done to the extent and the quality needed according to the PSAR that it has been approved.

This stage also includes the examination of documents describing security measures during construction phase. Furthermore, this stage includes the review and assessment of preliminary plans for the future decommissioning of the plant. Stage 2 also includes inspection and oversight of construction work after the construction permit has been decided.

In stage 3 the focus is on renewed safety analysis report (SAR) and control that this report reflects the plant as it has been built or modified and that shows how the requirements have been met. This means that SSM also in this stage reviews updated safety analysis. SSM also reviews and assess proposed operational conditions in technical specifications and those instructions which will provide guidance for operational staff. In this stage SSM's reviews also focus on the test operation the program and reviews of performed programs for training of operating personnel. In addition, this step includes review and assessment security measures and plans for the test operation of the plant. Stage 3 includes inspection and oversight of the test operation period after the test operation permit has been decided.

In stage 4 the focus is on the SAR that has been supplemented with experience from the test operation. This stage also includes the review and assessment of the operational conditions in technical specifications and instructions which have been complemented with experience from the test operation.

When the plant/facility has been taken into routine operation SSM apply an inspection and oversight program which areas related to nuclear safety, radiation protection and security. Some areas are inspected or reviewed more frequently while other areas when changes or modifications are done. In total 17 areas are defined for which the corresponding requirements are found in regulations, licensing conditions and to some extent in regulatory decisions.

1. Design and construction of the facility (including modifications)
2. Management, control and organization of the nuclear activity

3. Competence and staffing of the nuclear activity
4. Operations, including the handling of deficiencies in barriers and defence-in-depth
5. Core and fuel issues as well as criticality issues
6. Emergency preparedness
7. Maintenance, materials and in-service inspection issues, particularly taking into account degradation due to ageing
8. Primary and independent safety review
9. Investigation of events, experience feedback and external reporting
10. Physical protection
11. Safety analyses and safety reporting
12. Safety programme
13. Retention of facility documentation
14. Handling of nuclear material and nuclear waste
15. Non-proliferation control, export control and transport safety
16. Radiation protection
17. Environmental control

The ambition is to successively cover these areas in a basic inspection programme and to document the inspection findings. Moreover, the same 17 areas are used in the annual assessments of the licensees (SSM integrated safety assessments, see below) as well as in the periodic, 10-year periodic safety reviews (PSR). Like this, the SSM is able to maintain a systematic picture of the safety situation and to monitor the development. When new assessments start, already performed and documented assessments of the areas can be consulted and any emerging picture be consolidated. The idea is to use the regulatory information and knowledge in a more efficient way. In order to further guide inspections and safety assessments there is also a sub-structure in each of the 17 areas.

When a decision has been made on final shutdown of a nuclear power plant within a certain time, SSM increase its inspection activities in order to ensure that the license takes necessary actions for maintaining safety during the time remaining until the closure shall be made without delay. These increased inspection activities focus on management, working conditions and staffing.

Periodic Safety Review
The Nuclear activity act (1984:3) requires that anyone who has a permit to own or operate a nuclear plant shall at least every ten years perform a period safety review (PSR). The PSR should take account of developments in science and technology. It should include an analysis and reports of

- how the plant's construction, operation, organization and activities meet the requirements of the Nuclear activity Act, the Environmental Code and the Radiation Act (1988:220) and the regulations and conditions imposed under those laws, and
- conditions for these rules and conditions to be met until the next global assessment.

In SSMFS 2008:1 general advice is given on PSR. The periodic safety review should cover, to applicable extent safety within the 17 areas mentioned above as well as provide an overall evaluation

Analyses should be conducted of how devices and activities in each area comply with regulatory requirements as well as internal requirements at the time of analysis, and if the applied solutions have a continued capacity to prevent such possible deficiencies in barriers and defence-in-depth that can lead to a nuclear accident. Furthermore, a systematic analysis should be conducted in each area of how devices and

activities meet new safety standards and practices that are relevant for the facility. The need for measures that follow from these analyses should be listed, and the importance for safety should be assessed using deterministic, and where appropriate, probabilistic methods, or where this is not possible or reasonable, through expert assessment with specified criteria.

Where the facility does not fulfil relevant, new safety standards, measures should be implemented if this is considered to be reasonable with respect to the benefit to safety and suitable, taking into account the existing design assumptions of the facility. An action plan should be prepared for such measures and other measures that are not of an acute character, but which are judged to need to be conducted so that the facility can continue to be operated with a high level of safety up to the time of the next safety review. The action plan should state priorities, types of measures and time of implementation. After it is decided, the plan should be incorporated into the facility's safety programme.

The PSR should be documented in a systematic and comprehensive manner in an integrated report. The report should contain an overview of the analyses and evaluations conducted in the different areas as well as an overall evaluation. References to underlying documents should be explicitly stated

The PSR is reported to SSM, which reviews and assess the results.

Review Programme
The main area of the regulatory review and assessment programme for nuclear power plants is the same as for the PSR. The 17 main areas are then further broken down and explained in a comprehensive graded oversight program with subareas. For each subarea in this program responsible organizational units (sections) are identified, as well as information indicating the nature of supervision that will be implemented and how often. The program also indicates the type of skills required for various regulatory activities within each of the subareas.

Principal modifications
In SSMFS 2008:1 SSM 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 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 in accordance with the first paragraph may be implemented, the SSM shall be notified of the modifications.

A standing group of experts (Notification Processing Group, ABG, (STYR2011-111) has been established by SSM in order to make a first assessment and screening of all notifications. The group makes a proposal to the department management meeting (Dep. of Nuclear Power Plant Safety and Radioactive Materials) regarding each notification:

- No further action
- To be postponed until the notification meets the expected quality
- The notification should be further reviewed 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.

SSM has over ten year's experiences from this process. The pre-review of notifications is today a well-functioning routine which works well and meets the expectations of SSM. It is also clear that SSM has the necessary regulatory control of the modifications, without having to review everything in detail and issue approvals. This has enabled SSM to allocate resources to more important safety tasks. The ABG criteria in use sort about 20-25% of all notifications into the recommendation "review to be performed".

Waste management

Waste management activities at nuclear power plants constitute an integrated part of the operation of the plant and are thus addressed as part of the reviews and assessments related to the plants.

Review and assessments for other waste management and waste disposal facilities and activities follows the same general procedure as is described for fuel cycle facilities but with due consideration to the character of the facility/activity in question.

For disposal facilities, special attention is paid to analyses of post-closure operations and any need for post-closure monitoring.

Decommissioning

Chapter 9 of SSMFS 2008:1 contains specific requirements for decommissioning.

Before dismantling of the facility may be initiated, the preliminary decommissioning plan shall be supplemented and incorporated into the facility´s safety analysis report. The report shall be reviewed and approved by the Swedish Radiation Safety Authority.

When a decision has been made on final shutdown of a facility within a certain period of time, an integrated analysis and assessment of how safety is to be maintained during the time remaining until the facility's closure shall be conducted without delay. The analyses, assessments and measures emanating from these shall be documented and reported to the Swedish Radiation Safety Authority.

Radioactive sources

In conjunction with the issue of a license or during the period of validity of the license, the licensing authority may issue such conditions relating to the license as required with respect to radiation protection.

There exist regulatory requirements of annual reporting over status of, and compliance with conditions concerning the use of, radiation sources. However, there is work in progress on further national requirements relating to the verification of the safety and security of such sources.

Graded approach

Requirement 26: Graded approach to review and assessment of a facility or activity
Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

SSM's reviews both in connection with licensing and in different operational stages aims to control that the requirements in regulations are or will be fulfilled. SSM's regulations include the use of a graded approach. The graded approach is based on safety importance, hazards or on type of a facility, system, or activity. This is illustrated for example in Chapter 2 Section 1 of the regulations (SSMFS 2008:1) on safety in nuclear facilities where it is required that nuclear accidents shall be prevented through a facility-specific design of multiple barriers as well as a facility-specific defence in-depth system. In Chapter 3 Section 4 of SSMFS 2008:1 it is required that structures, systems, components and devices shall be designed, manufactured, installed, controlled and tested in accordance with requirements which are adapted to their function and importance for facility safety. Safety classification systems are used to fulfil this requirement. Other examples of graded approaches in the regulatory framework are:

- The SSM's general advice to the requirements of Chapter 4 Section 2 of the Regulations (SSMFS 2008:1) on safety analysis reports. In these general advices it is stated that the extent and level of details of such safety analysis reports, including design basis information, should reflect both the complexity and risk profile of the facility.
- The regulations (SSMFS 2008:13) of mechanical components and structures, which require that the determination of design requirements and quality assurance measures shall be based on a safety and quality classifications reflecting the safety importance.

This also means that the SSM does more extensive and thorough reviews and assessments of facilities and activities with greater safety importance, hazards or on risks than those with lower.

Areas of improvement

- Of the IAEA standards follows that review and assessments at different stages must follow clear and well defined procedures. The procedures need therefore also describe how the review and assessments in various areas is done to ensure that all relevant radiation safety aspects are properly considered. Procedures with such information exist now in a very limited extent. This means that we now rely on the knowledge and experience that each employee has.
- It needs to be investigated further if procedures are required that shows how we ensure that the right skills are used and sufficient resources are allocated to various review tasks. Work, tasks and resource allocation is today based on the Rules of Procedure's Annex about the organisation and concerned directors or section heads.
- It is not clear from internal steering documents that all information relevant to nuclear safety and radiation protection at a facility, including the compliance with requirements, should be reviewed and assessed. This should be done regardless whether the information is provided by the licensee or from other sources, such as manufactures or suppliers. A procedure for the consistent use of such information should be established.

- IAEA standards highlight the importance of review and assessment for long term operation (beyond the originally analysed/designed lifetime) of a nuclear facility. This will be developed and addressed within the framework of the periodic safety review. The authority will establish rules for which specific aspects should be reviewed and assessed.
- Another area for improvement concerns the need of establishing a process and criteria for managing situations when a licensee has seriously neglected legal/regulatory provisions so that a suspension of the licence is deemed to be necessary. This process should include guidance on how the contacts with the licensing body, i.e. the Government, should be handled.

Module 7: Inspection

Assessment for IAEA requirements: GSR Part 1 – Requirement 27-29

Inspection

Requirement 27: Inspection of facilities and activities
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.

Supervision

Supervision must be done in a uniform manner and therefore the authority has a supervisory policy (STYR2011-97).The policy states how inspectors and other experts are to work with supervision and has the Authority's fundamental values as its platform.

The definition of supervision is to verify that nuclear safety and radiation protection are being maintained and improved. This is done by:

- checking compliance with acts, ordinances, regulations, conditions and other requirements, and
- monitoring the parties' activities as a basis for proactive and preventive work.

The supervisory policy states a number of basic objectives of supervision. One principle is that supervision assesses the capability of licensees to lead and manage their activities from the perspective of nuclear safety and radiation protection. Another is that supervisory action must be conducted so that substantiated assessments and conclusions can be drawn. Assessments and conclusions are to be formulated so that it is clear whether the requirements imposed are fulfilled.

SSM's key values are also stated in the policy from a supervisory perspective.
The Supervision process contains of six different processes:

Compliance inspection – see section on types inspection

Surveillance inspection – see section on types inspection

Rapid investigation – see section on types inspection

Review – see section on review and assessment above

Managing and evaluating reports – the process describes how reports from the licensees and operators are handled. Reporting is in accordance with requirements of laws, ordinances, and regulations and in accordance with permit conditions or individual decisions. The process gives information on which reports to be submitted to the authority, how the reporting will be done and how often and the further handling of the reports.

The reports from the licenses constitute one of the bases for deciding further supervision activities. One example is the routine for handling management and evaluation of nuclear power plants reported deficiencies (STYR2011-151).

Supervisory guidance – the process describes how we guide municipalities other agencies within our supervisory area in accordance with the Environmental Code.

Inspection

Inspections are carried out by the SSM as authorized by the Nuclear Activities Ordinance, the Radiation Protection Ordinance, and as instructed by the Government. SSM issues requirements regarding nuclear safety and radiation protection for licensees through its regulations. SSM verifies that licensees follow laws and regulation by performing inspections. The license holder is responsible for undertake measures needed to comply with the regulations.

Types of inspection

Requirement 28: Types of inspection
Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.

SSM carry out three types of inspections: Compliance inspection, Surveillance inspection and Rapid investigation. SSM has mandate to perform unannounced inspections in all its supervisory areas but in practice it is only done in the field of non-proliferation.

Compliance inspection

Compliance inspection means that in a planned and systematic way to analyse and assess whether the licensee in charge of the activity complies with applicable legislation, regulations and conditions relating to the operation and the licence.

An inspection always involves steps carried out on site when inspecting the subject/object. Inspections may vary in terms of their scope and extent. However, each inspection must have a specific aim and meaningful delimitations on the basis of the requirement parameters of the inspection and the parts of the operation being focused on (STYR2011-106).

Surveillance inspection

Surveillance inspection is a procedure in which supervision is exercised in order to give impetus to nuclear safety and radiation protection safety work. A surveillance

inspection takes place through continuous monitoring of a licensees activity and by providing and gathering information. The results are used to disseminate information within SSM and to plan additional supervisory measures; also, to give the party carrying out an activity response on SSM's observations (STYR2011-107).

Rapid investigation

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

The aim of a rapid investigation is for the Authority to gain a quick and independent interpretation of the event or circumstance that has been discovered. Rapid investigations are performed in close connection with SSM's receipt of the information initiating action (STYR2011-108).

Nuclear power plants and Fuel cycle facilities

The methods used are mainly based on reviewing relevant documents in the licensee's management system, interviews with personal at various hierarchical levels in the organisation (top down) and walk downs. To some extent also control measurements and sample-taking is a part of the inspection.

Focus for inspections are the licensees activities for self-assessment like safety reviews, internal audits etc.

A number of inspections are planned on a yearly basis following the inspection programme. The planning does not include reactive inspection because of their nature. It is not possible to foresee on what site they will be needed. If there is a need of reactive inspections it will result in changes in the plan for the year.

The inspection programmes and the frequency of inspections are based on the regulations. The frequency is also based on previous experience and the authority's organisation and resources.

SSM has not yet established a systematic inspection programme for fuel cycle facilities stretching beyond the annual planning. Such a programme is under development.

Inspections are performs in all areas that are covered in our regulations.

1. Design and construction of the facility (including modifications)
2. Management, control and organization of the nuclear activity
3. Competence and staffing of the nuclear activity
4. Operations, including the handling of deficiencies in barriers and defence-in-depth
5. Core and fuel issues as well as criticality issues
6. Emergency preparedness
7. Maintenance, materials and in-service inspection issues, particularly taking into account degradation due to ageing
8. Primary and independent safety review
9. Investigation of events, experience feedback and external reporting

10. Physical protection
11. Safety analyses and safety reporting
12. Safety programme
13. Retention of facility documentation
14. Handling of nuclear material and nuclear waste
15. Non-proliferation control, export control and transport safety
16. Occupational Radiation Protection
17. Release and environmental monitoring

Inspection activities do not cover the off-site activities of suppliers of services and products to the operator. SSM does not yet have the legal instruments available. SSM's focus is instead on supervision of licensee's procedures, competence and resources for their own manufacturers and suppliers assessments and that they carry out audits with good quality.

Unannounced inspections are not normally performed and the reason for this is to avoid unnecessary interference with the licensee's on going safety work. Unannounced "visits" occur in order to gather information. However, during surveillance inspection inspectors have unlimited entrance to the facilities without any preannouncement. They can also without further notification demand to have access e.g. certain documents or data logs. Of course all safety procedures shall be followed also by inspector (STYR 2011-86).

Waste management

Inspections of waste management and waste disposal facilities and activities follows the same general procedure as is described for fuel cycle facilities but with due consideration to the character of the facility/activity in question. Special attention is paid to interdependencies between waste arising, waste conditioning, transports and disposal of waste packages.

For disposal facilities, special attention is also paid to inspection of features and elements that may affect post-closure safety.

Decommissioning

The scope of inspections during decommissioning will depend on the actual decommissioning arrangements and activities. It can be foreseen that it will include the following:

- Organisation, planning and management of decommissioning, including internal review of safety and radiation protection
- Staff competence
- Documentation and verification of the facility
- Methods for radiological characterisation of the facility
- ALARA precautions (monitoring, training, planning etc.)
- Decontamination
- Precautions against non-radiological hazards that might indirectly have impact on radiological safety

- Radioactive waste characterisation, conditioning, storage and transport
- Waste disposal at site (if applicable)
- Methods for clearance of materials
- Methods for control and limitation of releases to the environment
- Physical protection
- Emergency preparedness
- Use of financial funds

Radioactive Sources

In accordance with the Swedish Radiation Protection Act (1988:220) supervision of compliance with the Act and with regulations or conditions issued pursuant to this Act is exercised by the authority appointed by the Government. Beside the existing regulatory requirements of documentation and periodic control as well as annual self-assessment and reporting (SSMFS 2008:9 Section 5, SSMFS 2008:10 Section 11and SSMFS 2008:33 Section 22), inspections are done to verify compliance with legal requirements. But inspection frequency is relatively low and there are no complete national requirements covering all specific aspects available yet.

Graded approach

Requirement 29: Graded approach to inspections and activities
Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

SSM has issued regulations which include the use of a graded approach. Inspections are commensurate with the radiation risks associated with the facility or activity, within the inspection plans. The inspection plans have taken account for a graded approach.

Areas of improvement

- The IAEA imposes requirements on systematic planning of regulatory supervision, as also stipulated in the Environmental Inspection Ordinance. SSM needs to improve present planning practises and develop an overall strategy for producing these plans and their content.
- In order to create a more cohesive structure for ensuring consistent legal application in accordance with the IAEA's standard, all supervisory action should be integrated in a kind of system in which all factors identified and measures taken are registered. The Director General has assigned to the department of Nuclear Power Plant Safety to develop such a system.
- SSM currently has no right to inspect suppliers to licensees for nuclear power plants, but an amendment enabling the SSM to carry out such inspections is proposed in a draft of new radiation safety legislation.
- The requirements imposed on security measures in connection with management and protection of HASS need to be reviewed. Development work relating to regulations in this area has commenced.
- Awareness confidentiality concerns related to information about HASS sources should be improved at the Authority. This also includes information exchange between SSM and external stakeholders. This is partly in

progress within the framework of the risk analysis project, where the occurrence of valuable information worth protection will be identified and have requirements imposed on it.

- SSM keeps a registry of high activity sealed sources (the HASS database) which forms one part of the licence and authorisation database (Kardex). Work remains to be done in conjunction with the introduction of a new licence and authorisation database to quality assure this information and decide how the information should be protected.
- Co-operation between SSM and various public authorities needs to be reviewed, reconfirmed and possibly strengthened.
- The method and extent to which regulatory supervision should be exercised in the area of radioactive sources must be reviewed when developing plans for regulatory supervision. Here, a graded approach should be applied.

Module 8: Enforcement

Assessment for IAEA requirements: GSR Part 1 – Requirement 30-31

Enforcement policy

Requirement 30: Establishment of an enforcement policy
The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.

It is the task of the regulatory authority to enforce the constitutional rules, judgments, conditions and other decisions governing the activities of a licensee. The authority shall provide advice and information to create the conditions for regulatory purposes to be met, and take the necessary steps to remedy the situation if necessary. Under the Act on Nuclear Activities, the Radiation Protection Act and the Environmental Code, the regulatory authority has extensive legal powers to enforce the regulations and its decisions.

Enforcement actions can be described as a penalty-stair. Depending on the severity 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 (STYR2011-87). Injunctions and prohibitions can be combined with conditional fines. The legislation also gives SSM the legal right to require actions beyond the written regulations. If there is a non-compliance with the regulations, SSM is obliged to notify the prosecutor for further actions. It is a criminal offense to infringe conditions or regulations issued under the legal framework.

Corrective actions

Requirement 31: Requiring of corrective actions by authorized parties
In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.

The regulatory authority has access to a variety of measures that can be used to remedy a non-compliance situation. An overarching principle for these, as expressed in chapter 26 section 9 second paragraph of the Environmental Code, is that a measure is not to be more restrictive than necessary in the case. Also the SSM management system provides guidance on how different measures should be taken that is in line with this principle. It is not regulated in statutory text as acts or regulations on what basis SSM will make an assessment of which corrective action to choose. Instead SSM makes an assessment on a case by case basis. Whoever becomes the subject of a regulatory decision always has the option to appeal the decision.

Remarks are normally given in an inspection report and no separate documents are produced. Injunctions with conditions are handled separately. Depending on the severity of the non-compliance the decision is taken at different hierarchal levels in the SSM organisation. Decisions with requirements may include a fine if actions are not taken within the specified time period.

Areas of improvements

SSM needs to further develop procedures judging appropriate enforcement actions in relation to non-compliance and its importance to radiation safety.

References modules 5-9

Act on Nuclear Activities (1984:3)
Act on Financing of Management of Residual Products from Nuclear Activities (2006:647)
The Radiation Protection Act (1988:220)
Environmental Code (1998:808)

Swedish Radiation Safety Authority´s Rules of Procedure (Reg no SSM2011-99-69)
STYR 2011-51 Development and revision of regulations (not translated)
STYR 2011-97 Supervisory policy
STYR 2011-106 Compliance Inspection
STYR 2011-107 Surveillance Inspection
STYR 2011-108 Rapid Investigation
STYR 2011-124 Review
STYR 2011-111 Notification processing (not translated)
STYR 2011-87 Sanctions as part of the Swedish Radiation Safety Authority's regulatory supervision
STYR 2011-131 Licensing work and examination of licence conditions as regards nuclear facilities and other complex installations where radiation is used

SSMFS 2008:1 The Swedish Radiation Safety Authority's Regulations concerning Safety in Nuclear Facilities
SSMFS 2008:9 The Swedish Radiation Safety Authority's Regulations on the Control of High-Activity Sealed Radioactive Sources
SSMFS 2008:10 Regulations on the Import and Export as well as Reporting of Radioactive Substances (SSIFS 2006:1)

SSMFS 2008:13 Strålsäkerhetsmyndighetens föreskrifter om mekaniska anordningar i vissa kärntekniska anläggningar
SSMFS 2008:17 The Swedish Nuclear Power Inspectorate's Regulations concerning the Design and Construction of Nuclear Power Reactors (SKIFS 2004:2)
SSMFS 2008:19 The Swedish Radiation Safety Authority's Regulations on Planning before and during Decommissioning of Nuclear Facilities
SSMFS 2008: The Swedish Nuclear Power Inspectorate's Regulations concerning Safety in connection with the Disposal of Nuclear Material and Nuclear Waste (SKIFS 2002:1)
SSMFS 2008:22 Regulations on Handling of Radioactive Waste and Nuclear Waste at Nuclear Facilities (SSIFS 2001:1)
SSMFS 2008:27 Regulations on Accelerators and Sealed Sources (SSIFS 2000:9)
SSMFS 2008:28 Regulations on Laboratory Work with Unsealed Radioactive Substances (SSIFS 2000:7)
SSMFS 2008:33 Regulations on Radiation Therapy
SSMFS 2008:37 Regulations on the Protection of Human Health and the Environment in connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste (SSIFS 1198:1)
SSMFS 2008:40 Regulations on the Use of Equipment in Industry containing Sealed Sources or X-Ray Tubes (SSIFS1995:2)
SSMFS 2008:45 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 (SSIFS 1992:3)

Module 10: Emergency Preparedness and Response

Assessment for IAEA requirements –GS-R-2 Preparedness and Response for a Nuclear or Radiological Emergency and GSR Part 1- Requirement 8

Counterparts

Johan Friberg
Director
Radiation Protection
+46 8 799 41 01
Johan.Friberg@ssm.se

Lynn Hubbard
Head of section
Radiation Protection
+46 8 799 42 62
Lynn.Hubbard@ssm.se

Summary

Sweden's national nuclear and radiological emergency management builds on the principles of responsibility, proximity and parity. Cooperation and coordination are the means for achieving a well organised emergency response. The central government and its ministries maintain a large number of central authorities with responsibilities during non-crisis times that shall be the same as their responsibilities during a crisis. These responsibilities are officially designated in governmental acts and ordinances.

SSM has the collective responsibility in Sweden for radiation protection and nuclear safety. SSM is the expert authority responsible for advising within their area of responsibility the county administrative boards, as well as both local and other central authorities and the Government. SSM makes recommendations for radiation protection based on intervention levels that are in accordance with international standards.

The county administrative boards in Sweden are responsible for the protection of people and the environment in the event of a release of radioactive material from a nuclear facility that warrants urgent protective actions off the site, and for the response and rescue operations within their respective counties.

SSM has the responsibility for activation of national response, including alerting the Government and central and regional authorities through robust and secure communication channels. SSM shall coordinate the necessary emergency preparedness measures for preventing, identifying and detecting nuclear and radiological events that can lead to damage to human health or the environment. SSM also provides information on the event to the general public.

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.

SSM shall cooperate with and support other relevant authorities in the event of a crisis within SSM's area of responsibility. SSM shall in particular:

- have the ability to immediately establish a crisis management and response function,
- keep the Government informed about developments, expected developments, the current situation including adopted as well as planned measures and available resources, and
- provide the Swedish Civil Contingencies Agency (MSB) with the information needed in order to obtain an overarching picture of the crisis situation.

The Authority maintains the emergency organisation using staff members who are employees of SSM. As part of the emergency organisation, SSM has officers on duty 24/7 and an emergency preparedness group of around 30 persons, established with the purpose of responding to a crisis on short notice. The emergency organisation works from SSM's Emergency Response Centre.

In conclusion, Swedish legislation clearly stipulates the allocation of responsibility in the emergency preparedness and response system for nuclear and radiological accidents.

SSM does not completely meet the requirements imposed by the IAEA's standards in the area of conducting its own probabilistic safety analyses. However, this choice is intentional as its orientation is for the crisis organisation to be capable of dealing with all kinds of events regardless of their frequency.

There are some deficiencies in the regulation of dose limitation and protection of emergency response workers. It is, for example, unclear how emergency situations are defined and how response personnel are to be categorized.

GSR Part 1- Requirement 8

Requirement 8: Emergency preparedness and response
The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.

The Swedish crisis management system is based on ordinary administrative structures and on the principle that the party in charge of an activity in normal situations also has a corresponding responsibility for activities in the event of a crisis ("the principle of responsibility"). One key principle is that a crisis is to be managed where it has occurred and by the relevant parties in charge of the crisis ("the princi-

ple of proximity"). Another principle is that changes to an organisation should be kept as small as possible ("the principle of parity"). However, the principle of responsibility must not be used as a pretext for non-action or avoiding necessary preparations and preventive measures based on the argument that a different stakeholder has the main responsibility.

The Government gives the provisions mainly in the Civil Protection Act (2003:778) and the Civil Protection Ordinance (2003:789). The prime responsibility to provide or finance reasonable emergency preparedness, personnel, property, and take the necessary measures to prevent or limit risks for accidents that may cause serious harm to people or the environment, is the licensee or the responsible operator. They are also required to analyze the risk of such accidents. In case of a release of toxic or harmful substances from a facility, the person engaged in the activities shall notify the county administration board, the police and the municipality if the release calls for specific measures to protect the public. Notification shall also be provided if there is imminent danger of such emissions.

The provisions given in the Civil Protection Act and Ordinance are not detailed and do not regulate technical infrastructural solutions nor any time requirements. In the area of nuclear safety and radiation protection, the Government therefore gives the mandate to SSM to issue further regulations for the license holders in the Nuclear Power Ordinance (1984:14) and the Radiation Protection Ordinance (1988:293).

GS-R-2 Preparedness and Response for a Nuclear or Radiological Emergency

Basic Responsibilities

According to the Ordinance (2008:452) with Instructions for the Swedish Radiation Safety Authority, SSM has a general responsibility to build up and disseminate knowledge and to take initiatives for research and development projects within the field of radiation safety. Furthermore, SSM shall coordinate the necessary emergency preparedness measures for preventing, identifying and detecting nuclear and radiological events that can lead to damage to human health or the environment. This responsibility encompasses, among other things, to

- provide advice and recommendations concerning radiation protection, cleanup 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 organisation for expert support in the event of a nuclear or radiological emergency situation, and
- provide technical advice and recommendations to the public authorities assigned with managing the impact of an accident if a nuclear emergency should it occur in Sweden, or outside of Sweden with consequences for Sweden.

In the international context, it is the responsibility of SSM that Sweden acts in accordance with IAEA's conventions on assistance and early warning, and SSM is Sweden's Competent Authority for these conventions. SSM shall pursue international work in the field of radiation protection emergency preparedness by monitoring the production of international recommendations and standards, and provide the

government with underlying documentation and the expertise needed for international work in the field of radiation protection emergency preparedness.

According to the Civil Protection Ordinance (2003:789) SSM shall give advice on radiation measurements and also coordinate and assist in radiation protection assessments in case of emissions of radioactive materials from a nuclear facility. The responsibility for directing the rescue services lies with the County Administrative Board in the affected county unless the Government decides otherwise. In this context, the demands on SSM only encompass support to the leader of the rescue operation at the County Administrative Board in the affected county.

According to the Ordinance (2006:942) on Emergency Preparedness and Heightened State of Alert, SSM shall take the measures needed in order to be able to deal with the consequences of a crisis situation within SSM's field of responsibility. SSM shall among other things

- have an Officer on Duty,
- educate and train its staff to enable it to solve its tasks during crisis,
- participate in training activities,
- be able to receive and send encrypted messages,
- take into account the need for security and compliance of technical systems,
- take into account the need for implementing Rakel technology (Terrestrial Trunked Radio),
- annually conduct a risk and vulnerability analysis and report it to the government,
- cooperate with the county administrative boards, other State authorities, municipalities, county councils, associations and manufacturers,
- participate actively in the national working group on dangerous materials,
- take into account the cooperation that takes place within the European Union and international forum in matters relating to emergency preparedness, and
- take into account the need for research and development work and other learning such as experience and feed-back from past events.

Moreover SSM shall 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,
- 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.

European Union’s (EU) EURATOM 96/29 lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. According to EURATOM 96/29 Sweden has a responsibility to make preparations in order to be able to handle radiological emergency situations and, inter alia, ensure that there is technical and medical expert support available for such situations. In Sweden this ability is maintained by SSM and the National Board of Health and Welfare. Furthermore, SSM is the Competent Authority in

Sweden for the EU regarding RN events. This means that special demands are made on SSM. SSM shall

- ensure that measures to be taken in different radiological emergency situations are in place,
- be able to receive alerts 24/7 all days of the year in case of a radiological emergency situation inside of or affecting Sweden or Swedish citizens abroad, and
- have the ability to assess if a radiological emergency situation in Sweden may affect other countries.

EURATOM 87/600 regards the community arrangement on early exchange of information in the event of a radiological emergency. If Sweden decides to take extensive measures to protect the public in case of a radiological emergency situation it is up to SSM to promptly inform the European Commission and the member countries that might be affected. The information shall be of such a nature that it can be used by the member countries to minimize radiological consequences. Furthermore, SSM shall continuously inform on what measures Sweden intends to take due to the emergency situation.

EURATOM 2000/473 regards the application of article 36 of the Euratom Treaty concerning the monitoring of levels of radioactivity in the environment for the purpose of assessing the exposure of the population as a whole. According to Euratom 2000/473 Sweden is obliged to have an environmental monitoring programme for ionizing radiation. SSM shall continuously send measurement results to EU. The same mechanism shall be used in an emergency response situation.

Assessment of threats

SSM does not perform probabilistic safety analyses (PSA) for facilities belonging to threat category I. 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. However, some of the resources allocated by society for taking actions (e.g. implementing the emergency preparedness zones for evacuation and monitoring) have been based on a station black-out event with core meltdown and emission through the filtered venting system (scrubber) equivalent to 100 % noble gases and organic iodine, and 0.1 % of cesium and non-organic iodine.

SSM's opinion is that the utilities' emergency preparedness should also be flexible enough to be able to handle complex and unforeseen events. There are no specific rules, in terms of probabilities, in our regulations dictating what events the emergency organisation should be dimensioned for. However, there are ongoing studies at SSM on dimensioning scenarios and corresponding application of those studies to dimensioning of the emergency organisation.

The utilities are in charge of performing probabilistic safety analyses (PSA level 1 and 2) and they also have the responsibility to keep the PSA models and results up-to-date (regulated in 4 kap 1§ SSMFS 2008:1). The results and conclusions of the PSA are part of the safety analysis report (SAR) for each plant, and the utilities must report updates to SSM. The models are not part of the SAR, but are delivered to SSM on CD. Hence, SSM has access to the latest models and results.

When the PSA documentation is delivered to SSM, all necessary parts are checked to ensure they are included and that the results are reasonable. This is not intended to

be a full review of the PSA. Instead, and in accordance with SSM's reviewing philosophy, focus is on assessing the utilities' processes, resources and competence through reviews, inspections and audits.

Establishing Emergency Management and Operations

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 organisation for expert support and also coordinates and assists responsible organisations with radiation protection assessments.

The importance of coordination during emergency response is widely recognized in the Swedish emergency planning community. Coordination is the basis for the Swedish emergency system and is regulated on the national level in the Ordinance (2006:942) on Emergency Preparedness and Heightened State of Alert. During preparation activities coordination of different authority's responsibilities is constantly developed and improved. Coordination is a challenge and an issue that needs to be addressed continuously as a vital part of the planning process and tested regularly during exercises.

Identifying, Notifying and Activating

SSM is appointed by the Swedish Government as the National Competent Authority (NCA) to fulfil Sweden's obligations regarding early notification of the international community should an emergency occur in Sweden with consequences beyond the threshold for such notification.

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 to carry out its role as NCA (AD). SMHI also relays the information to the national alarm central (SOS Alarm) **who in turn pages the SSM Duty Officer, providing a redundant, back-up alarm.** 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 organisations 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 organisation).

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.

In case of a radiological or nuclear emergency abroad (with a possible request for assistance), the alarm will go to the national warning point in Sweden, SMHI. They will in turn contact the officer on duty at SSM, through fax and pager, who will assess the situation and call additional personnel if needed.

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 Organisation. 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.

Taking Mitigatory Action

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 organisation 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.

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 in and elaborated on in the accompanying QUESTIONNAIRE: EMERGENCY PREPAREDNESS AND RESPONSE. SSM's responsibilities according to these laws and regulations are clarified through requirements in internal documents and instruction.

Taking Urgent Protective Action

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 are responsible for the protection of people and the environment in the event of a release of radioactive material from a nuclear facility that warrants urgent protective actions off the site. The county administrative

boards are responsible for adopting the recommended urgent protective actions considering radiological health risks, logistics for implementing the protective actions and financial as well as social costs and benefits. In order to make these decisions the county administration boards are dependent on advice from expert authorities.

SSM is the expert authority responsible for advising the county administrative boards on radiation protection. SSM makes recommendations on urgent protective actions based on intervention levels that are in accordance with international standards for radiation protection. SSM is also responsible for advising local, regional and central authorities on radiation protection in the event of a radiological emergency that is not caused by the release of radioactive material from a nuclear facility but still warrants urgent protective actions.

Local authorities are responsible for adopting intervention levels for taking urgent protective actions in the event of a radiological emergency that is not caused by the release of radioactive material from a nuclear facility but still warrants urgent protective actions. SSM has a general responsibility to give advice on radiation protection and mitigation to local, regional and central authorities in such events.

The government has decided upon emergency planning zones for facilities in threat category I. However, SSM has provided the government with qualified advice on how to designate the planning zones. The government has furthermore decided that the county administrative board in Södermanlands län is responsible for the development of an emergency plan for the nuclear facility at Studsvik (threat category II) that could, if appropriate, involve emergency planning zones. SSM is responsible for giving advice to Södermanlands län in this matter. The responsibility for adopting emergency planning zones for the two remaining facilities in Sweden that are in threat category II (CLAB at Simpevarp and Westinghouse in Västerås) is not regulated.

SSM gives qualified advice on safe distances for radiological emergencies to the adopting local or regional authorities. The county administrative boards are responsible for adopting safe distances in the event of a release of radioactive material from a nuclear facility that warrants urgent protective actions off the site. Local authorities are responsible for adopting safe distances in the event of a radiological emergency that is not caused by the release of radioactive material from a nuclear facility but still warrants urgent protective actions.

It is always possible (24/7) for local, regional and central authorities as well as members of the public to get in contact with the officer on duty at SSM. In minor events, the officer on duty at SSM, who is an expert in radiation protection, can give the advice on urgent protective actions. In major events when the crisis organisation at SSM is established, it is the responsibility of the head of the crisis organisation to give the advice on urgent protective actions to the county administrative board or any other local, regional or central authority that is in charge of adopting the urgent protective actions.

SSM has a crisis organisation that can be activated in two different ways:

- immediately when one of the two predefined alarm criteria have been established at a nuclear facility in threat category I, or
- after a decision from the officer on duty or the Director of the Department of Radiation Protection at SSM.

The officer on duty shall be able to give advice on urgent protective actions within 10 minutes after an alarm. SSM has no time limit for establishing the crisis organisation. However, regular tests (about 10 per year) that are not advertised in advance show that out of a group of 30 people who carry pagers at least 10 (usually more) are able to commence the work in the crisis organisation in less than an hour.

Protecting Emergency Workers

SSM has adopted international recommendations on dose limitation 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. There is a further need for clarification regarding:

- 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 in 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.

Assessing the Initial Phase

According to the Ordinance (2008:452) with Instructions for the Swedish Radiation Safety Authority, Section 15, SSM shall advise on radiation protection and decontamination after release of radioactive material, in case a nuclear or radiological emergency occurs in Sweden or abroad with consequences for Sweden. Measurable quantities of deposition and dose rates will aid in giving such advice and it will also make it easier for responsible organisations with non-radiation experts to take actions according to given recommendations. Adopting OILs is therefore an important part of the responsibility of the authority even though there is no explicit demand for this in SSM's Instruction (2008:452). However, it is up to the local or regional authorities responsible for handling the emergency to decide to use the OILs.

SSM is the expert authority responsible for advising the county administrative boards (or other authorities) on radiation protection. In an event that may require urgent protective actions SSM will use operational intervention levels (OILs) as one part in its assessment to be able to decide when an intervention level (in accordance with international standards) has been reached. SSM will have access to emergency radiation monitoring results through the national database RadGIS. Through this database SSM has the possibility to process monitoring results and, through OILs, decide on recommendations for urgent protective actions. However, it is important to note that in the early and critical phase of a large nuclear accident there may be need for urgent protective action before measurement results are available. In that case SSM uses predefined actions. These can be based on dispersion and source term estimates, or based on the alarm status at a nuclear facility. Finally, it is up to the authorities responsible for handling the emergency to decide if the recommendations from SSM shall be implemented.

Monitoring within the precautionary action zone and the urgent protective action planning zone in the initial phase of a NPP accident is the responsibility of the county administrative boards (both environmental monitoring and monitoring of contaminated people). Arrangements for this have been made with specially trained local first responders. SSM has the responsibility to assess the monitoring results with the aim to advise on radiation protection, monitoring strategies and urgent protective

actions. Recommendations on urgent protective actions and monitoring strategies can also be made based on dispersion calculations and plume modeling performed by SSM. A project is currently ongoing to install automatic monitoring stations within the precautionary action zone, which will also give information needed in determining protective actions and monitoring strategies.

SSM is not responsible to dispatch an emergency team of radiation specialists to the scene. The national expert response organisation (with laboratories that can identify gamma, beta and alpha emitters) will be activated in a nuclear or radiological emergency. The organisation is led by SSM and will support the Authority in assessing the situation and making recommendations to the county administrative board. However, the laboratories are not obliged to respond and the strategy on how the organisation will be used will depend on the situation and the teams and resources available at the time.

Keeping the Public Informed

According to the Ordinance with Instructions for the Swedish Radiation Safety Authority (2008:452), SSM shall, by means of communication and transparency, contribute toward public insight into all operations encompassed by SSM's mandate. The aim of this work shall be to:

- promote health,
- prevent acute radiation injuries and reduce the risk of delayed injuries due to radiation, and
- provide advice and information about radiation, its properties and areas of application as well as about radiation protection.

This has been developed into a SSM internal communication policy.

The emergency organisation at SSM includes a separate function for public information with the goal to make sure that the information is prompt, correct, and understandable. The main tasks for the function include the following.

- The authority publishes adequate information on the website, including news, situation report, FAQs and fact sheets.
- Information will also be published on a website common for all responsible authorities (krisinformation.se).
- The authority actively informs and serves the media and is accessible 24/7 on the phone. Spokespersons are trained and available for direct participation in TV and radio programs.
- On demand, the authority's spokespersons take part in chats on media websites.
- News is also sent out on Twitter.
- If decision is taken, SSM also goes to its own site on Facebook to be able to answer the public's questions there.

Taking long term Protective Actions

SSM’s basic role in determining long term protective actions is regulated and is the same as SSM’s role in any phase of an emergency. SSM´s role in providing advice on radiation protection, and specifically protective measures, does not change with time after an emergency.

Making decisions for long term protective actions requires a sound cooperation

between organisations with competences and capabilities in different fields. In case of nuclear or radiological emergencies, the county administrative board has the lead and is responsible for decisions on protective measures during all phases of the emergency. In order to make balanced decisions they need input from other expert organisations such as SSM. Consequently they will immediately establish contact and begin cooperation with SSM and other authorities according to procedures and arrangements in place at the county administrative board and other authorities such as SSM.

SSM shall provide advice on radiation measurements and coordinate, assist with and provide advice on radiation protection assessments. In order to fulfil this obligation and before delivering any recommendation on long term protective actions, SSM will consult other relevant authorities, for instance the Swedish Food Administration, the Swedish Board of Agriculture or the Swedish Board of Health and Welfare, depending on the situation.

The Civil Protection Act, Chapter 3 Section 7, Chapter 4 Sections 1-6 along with the Civil Protection Ordinance, Chapter 4 Section 15 dictates that the responsibility of the rescue operations and decontamination lies with different authorities depending on the situation. In case of an emergency at a nuclear installation, in or outside Sweden, the county administrative boards are responsible for the response within their counties. In cases of radiological emergencies other than those at nuclear facilities the responsibility lies with the municipality in which the emergency occurs.
The responsibilities mentioned above include management of radioactive waste following emergencies, which by the Swedish legislation, Nuclear Power Act (1984:3), Article 2, is defined as nuclear waste. Handling of nuclear waste requires permission from the regulatory body SSM. But pursuant to the same Act, article 2a, SSM can decide on exemptions from that requirement.

Specifically for decontamination and waste management SSM has a special expert group, consisting of experts from SSM and other authorities, which could be called in to work as an expert advisory group in the emergency response organisation. The experts in question have been specially picked based on their competence and the role of the group is to formulate tactical and strategic advice to the organisations responsible for dealing with the waste.

Conducting Recovery Operations

SSM is by legislation required to support the local and/or national officials in the recovery phase. Responsibilities are stated in the Civil Protection Act 2003:778 on rescue services and Ordinance 2008:452 with Instructions for the Swedish Radiation Safety Authority.

When the emergency organisation at SSM is activated, the support will be provided directly from this organisation. Furthermore, SSM has two organisations with participants within and outside the authority that are intended to perform specified support activities when required in a recovery phase. The first group is the national expert response organisation. This group will support the need for measurements and analyses before and during the recovery phase.

The second group is the national expert group for decontamination, NESA. This group has the purpose to support the actions with expert advice regarding decontamination in the recovery phase after a radiation emergency.

The Civil Protection Act (2003:778) Chapter 4 and 6, and the Civil Protection Ordinance (2003:779), chapter 6, states responsibilities and requirements regarding

long term actions such as decontamination. SSM shall take part in such activities upon request.

Organisation

SSM maintains an emergency organisation with staff members from the regular staff at the authority that are activated when a crisis occurs and a decision is taken that the emergency organisation is needed. A staffing list for the emergency organisation is prepared and kept up to date. The staff is regularly educated and trained in their assigned duties in the emergency organisation. The main components of the emergency organisation are a radiological analysis function, a nuclear site analysis function, an operational communications function, a public communications function, and an administrative staff which includes a service and communications function and an IT / technical function. The emergency organisation has its principal place of work in the Emergency Response Centre at SSM.

The Director General is the head of SSM, and also the head of the authority's emergency organisation. SSM's work in the emergency organisation is headed by an operational director.

The decision to activate the emergency organisation can be made by the radiation protection officer on duty (TiB) or by the reactor safety officer on duty (RB). These officers are on call around the clock. The emergency organisation may also be activated by a decision from the Head of the Department of Radiation Protection or the Director General (DG).

SSM has an emergency preparedness group of around 30 persons, established with the purpose to respond to a crisis on short notice. The managers in the emergency organisation, the radiation protection officer on duty and the reactor safety officer on duty are a part of the emergency preparedness group. SSM has no time limit for establishing the emergency preparedness group. However, regular tests (about 10 per year) that are not advertised in advance show that at least 10 (usually more) are able to commence the work in the crisis organisation in less than an hour. The emergency preparedness group is contacted via pager, cell phone, work phone or home phone, in that order.

The emergency organisation has its principal place of work in the Emergency Response Center at SSM. The emergency organisation consists of

- An operational director
- A radiological analysis function,
- A nuclear analysis function,
- An operational communications function,
- A public communications function, and
- An administrative staff which includes a service and communication function and an IT / technical function.

In accidents at nuclear facilities SSM sends liaison officers to the county administrative board and to the affected nuclear facility. The main task of the liaison officer is to transfer information and advice to and from SSM.

The operational director can also decide to activate the emergency organisation's specific advisory functions, which are designed to support the emergency organisation. These specific advisory functions are the national medical expert team (N-MEG), the national expert group on decontamination and remediation (NESA) and an expert advisory group on radiation protection.

Plans and Procedures

The authority's emergency plan describes the emergency organisation appropriate for different nuclear or radiological events or accidents. Examples of possible exceptional situations are increased preparedness 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 organisation (STYR2011-54; STYR2011-26;29;65;70;113).

The nuclear analysis function is used in nuclear facility related events. The function's main task is to develop a source term from the affected facility and present it to the radiological analysis function, to document and pass on details of the affected nuclear facility and to provide technical information on the status of the facility to inform the public, government agencies and other organisations involved. This includes collecting and analyzing technical data on the event and formulating a source term from the affected nuclear installation(s), provide an assessment of the situation at the installation and a forecast of how the situation may evolve and contribute to the advice and information which SSM provides to external actors.
The main task of the radiological analysis function is to produce a prognosis and assessment in a timely manner in order to identify recommendations for protective actions that are justified from a radiation protection perspective. The function also assesses the radiological situation and consequences in order to inform the public, authorities and other organisations involved. The radiological analysis function coordinates the national expert response group.

The nuclear analysis function is divided into three groups, the source term group, the technical situation group and the NPP contact group. The radiological analysis function is divided into four groups, the monitoring group, the prognosis group, the assessment group and the internal information group, where each group has its own action plan with different procedures which are easily accessible in the emergency center and also from SSM's management system on the internal network. The procedures are tested regularly during emergency exercises, and evaluated and developed afterwards.

Logistical Support and Facilities

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.

The facility is equipped with a high level of physical protection and equipment to ensure safety and health even during a CBRN impact on the environment. Furthermore, the facility can be operated by autonomous systems of power and communications. Next to the Emergency Response Centre is another protected room which serves as an information center in the case of an event.

The Emergency Response Centre is fed by an independent power supply and can operate even under extended losses in the external power supply. Two types of power outlets exist in the emergency response center, an outlet that is supplied through the central UPS (Uninterruptable Power Supply), and outlets that are connected directly via a diesel unit.

Inside the Emergency Response Centre is a server room which houses the authority's central IT resources. SSM also maintains a duplicate server room in preparedness, geographically well separated from the authority's Emergency Response Centre in Solna. The purpose of this establishment is to ensure access to critical information systems and databases even if SSM in Solna is be put out of working order.

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.

Radiation monitoring is performed both by personnel at SSM and by personnel in laboratories within the national expert response organisation. 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, ICP-MS 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.

SSM has made every possible effort to ensure that the need for adequate and sustainable communication is met even under situations where publicly available communications systems are compromised/degraded/overloaded. The resulting communication and transmission systems are adapted to prevailing conditions among the counterparts with whom there exists a need for interaction.

The Emergency Response Centre has both fixed and cell telephony. Since the Centre is equipped with electromagnetic protection, radio signals are by default absent within the premises. In order to ensure the ability to maintain communication over GSM/GPRS/3G/CDMA networks, relay transmitters have been installed throughout the Centre, thereby enabling the use of such systems with the exception of some minor 3G providers. The corresponding frequency bands are being fed in to the Centre through controlled EMP filters.

SSM has installed within its premises fax gateways for the efficient sending, receiving and rerouting of fax communication. Fax gateways are present both within the Emergency Response Centre and at the backup location described further below.

The emergency response functions at SSM have access to multiple radio communication systems. All emergency field units at SSM are also equipped with Rakel terminals. By linking in the terrestrial part of the Rakel network into SSM's PABX, the authority's Rakel terminals may also be used as traditional cellular phones. Rakel is also available in the Emergency Response Centre, both in terms of air coverage and in the form of a dispatcher station physically connected to the terrestrial Rakel network through dedicated lines within the Armed Forces infrastructure.

SSM is connected to the Internet via a redundant high-capacity link, terminating at geographically separated points in the ISP backbone. Furthermore, SSM is redundantly connected to the nation-wide county administration network LstNet, which enables digital information exchange with the counties should Internet connectivity be interrupted. SSM is also linked to the closed Armed Forces Network.

To enable the distributed management of complex emergency events, SSM has invested in a high-performing infrastructure for video telecommunication. Video terminals in various sizes are available within the Centre. A number of VTC systems for field use are readily available for deployment. SSM has also provided VTC equipment to critical counterparts such as the Met Office and the Emergency Response Centra in counties with nuclear power plants. Systems connected to the SSM VTC infrastructure are able to communicate over both public and closed telecommunication networks as well as over public and closed IP networks. Core VTC infrastructural components are installed both within the Emergency Response Centre and at the backup location described below.

SSM maintains an unmanned installation in the form of a server hall in hot standby, geographically well-separated from the authority's main location, and being able to take over the support of emergency functions should SSMs main premises be compromised. In such an event, mission-critical parts of the emergency response can be relocated to a safe location and operations maintained with the help of this resource. The site may also be used to route communication to and from the Emergency Response Centre if parts of the transmission pathways from Stockholm fails.

In order to be able to fulfil the tasks that are upon the Authority even under emergency conditions, SSM conducts a yearly risk and vulnerability analyses. During the analysis, events are identified which could impact SSM's ability to perform as planned. Such events include, but are not limited to, disturbances in societal infrastructure (power supply, telecommunications, public transportation etc.) either per se or as a consequence of a nuclear or radiological event, and events with direct impact on SSM's premises or the premises of contracted organisations. Mitigation action is thereafter taken in order to meet the sustainability requirements issued either by SSM itself or by the Government.

Training, Drills and Exercises

Every year an education and training plan is developed for the emergency organisation. 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. In general all personnel in the emergency organisation has to reserve seven - ten days each for their own education and training during the year.

The education and training sessions during the year are developed for every function or group in the emergency organisation. The plan includes both individual education and training for each function or group and also common sessions for whole or parts of the emergency organisation. Currently the education and training plan includes both initial training and ongoing refresher training. Education and training plans for 3 to 5 years is under development and is expected to be fully implemented during 2012.

Besides the training that's conducted within the authority, there is also an extensive exercise plan for the national expert response organisation for nuclear and radiological emergencies, and for the voluntary organisations that are involved in the national arrangements for emergency preparedness and response. These exercises mainly focus on radiation monitoring and can consist of field exercises, inter-comparison exercises etc. SSM often trains internal personnel in parallel in these exercises.

Since 2007 SSM conducts a large yearly field exercise for the national expert support organisation 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.

A country-wide exercise focused on a nuclear power plant accident, SAMÖ/KKÖ 2011, was conducted in Sweden during February to April 2011. Many external organisations, including both national and international organisations/authorities, participated in the exercise. The Swedish Civil Contingencies Agency (MSB) was responsible for the whole exercise. The aim of SAMÖ-KKÖ 2011 was to test society's capacity for dealing with the consequences of a nuclear power emergency. The exercise involved all levels of society for the management of both the short-term and long-term consequences.

Normally the authority participates in exercises like, INEX (OECD/NEA), ConvEx

(IAEA), NEPEX (Nordic Regulatory Bodies) and ECURIE (EU). Furthermore the authority participates in IAEA's comparison measurements and to various extents in exercises conducted by neighboring countries. SSM has on several occasions invited neighboring countries (both Nordic and European countries) to field exercises conducted in Sweden. The main exercises of this kind have been Resume-99 in 1999, Barents Rescue in 2001 and DemoEx in 2006. A new exercise of this kind is planned for September 2012.

Quality Assurance Programme

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 organisation 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 organisation. The quality assurance programme contains components related to the preparedness mode including the education programme and exercise plan for the current year or planning period. Also, the operational emergency plan is available through this system, providing procedures and routines for operational work in the response mode easily accessible to the emergency organisation. (See Rules of Procedure for SSM´s Emergency Organisation and the steering documents STYR2011-54; STYR2011-26;29;65;70;113)

The quality assurance programme also has to ensure a correct dimensioning of the emergency organisation, both with regards to staffing (competence, start-up time, amount of personnel) and to equipment and facilities. SSM (along with many other central and regional authorities) performs a risk and vulnerability assessment analysis on a yearly basis which is delivered to the government. The analysis is based on available facts regarding foreseen risks and threats and recent experiences from exercises and real events (both in Sweden and in other countries). It highlights shortages with respect to competences, personnel, equipment, facilities and legislation. In the analysis there is also a set of dimensioning scenarios for which the authority shall evaluate its capacity. The analysis forms the basis for obtaining a correct dimensioning of the emergency organisation at SSM. There is only limited guidance for dimensioning in legislation, but the Ordinance (2006:942) on Emergency Preparedness and Heightened State of Alert gives some help with regards to demands on start-up times, availability and endurance. Ultimately, the dimension of the emergency organisation comes down to the amount of resources the authority is granted for these activities.

Conclusions

Swedish legislation clearly stipulates the allocation of responsibility in the emergency preparedness and response system for nuclear and radiological accidents. However, regulations and procedures need to be developed in certain areas.

SSM's crisis organisation has advanced support for technical management. The Emergency Response Centre with its associated equipment for analyses and communication, in addition to equipment enabling technical management support at other locations, significantly enhances the potential for the emergency organisation to work efficiently and effectively.

SSM has an established and efficient system for activation of the crisis organisation. Staffing of the officers on duty for emergency preparedness consists of radiation

protection experts, which is an essential aspect of expedient and qualified consultation. With the fast response time required for the officer on duty along with the emergency preparedness group – around 30 persons carrying pagers – work to analyse an event can be launched quickly.

Sweden (SSM) does not completely meet the requirements imposed by the IAEA's standards in the area of conducting its own probabilistic safety analyses. However, this choice is intentional as its orientation is for the crisis organisation to be capable of dealing with all kinds of events regardless of their frequency.

SSM cannot guarantee that radiation safety experts can be sent out at short notice for monitoring and analysis at the site of an accident as personnel are not available on a 24-hour call basis.

There are deficiencies in terms of dose limitation and protection of emergency response workers (SSMFS 2008:51). It is, for example, unclear how emergency situations are defined and how response personnel are to be categorized. There is also a need for better preparations for monitoring individual doses.

Some of the functions in the crisis organisation are manned by too few persons having the necessary expertise. A long-term plan to rectify this vulnerability needs to be drawn up.

SSM has intervention levels for civil protection in connection with events at nuclear facilities. There are, however, some deficiencies in the routines for application of possible intervention levels. There is also a certain lack of operational intervention levels that are measurable for these events.

References

SFS 2003:778 Civil Protection Act

SFS 1984:14 Nuclear Power Ordinance
SFS 1988:293 Radiation Protection Ordinance
SFS 2003:789 Civil Protection Ordinance
SFS 2006:942 Ordinance on Emergency Preparedness and Heightened State of Alert
SFS 2008:452 Ordinance with Instructions for the Swedish Radiation Safety Authority

SSMFS 2008:51 Regulations concerning Basic Provisions for the Protection of Workers and the General Public in Practices involving Ionising Radiation

Rules of Procedure for SSM´s Emergency Organisation (In Swedish only)
STYR2011-26 Instruction for Emergency Response Centre (ERC) (In Swedish)
STYR2011-29 Instruction for Officer on Duty for Nuclear Reactors (In Swedish)
STYR2011-54 Emergency Plan (In Swedish)
STYR2011-65 Instruction for the emergency preparedness group (In Swedish)
STYR2011-70 Signal security (In Swedish)
STYR2011-113 Instructions for technical management support systems (In Swedish)
STYR2011-175 Instructions for first in place in the ERC (In Swedish)

Module 11: Thematic Areas

11.1 Transport

Assessment for IAEA requirements – TSR-1 2009

Counterpart

Erik Welleman
Head of Section
Radioactive Materials
+46 8 799 43 11
Erik.Welleman@ssm.se

Introduction

SSM is the competent authority regarding transport of radioactive materials, responsible for issuing approval certificates for transport (package designs, special form radioactive material, low dispersible radioactive material, special arrangements and shipments) and compliance assurance. Parts of the compliance assurance are performed in cooperation with other authorities and is coordinated by the Swedish Civil Contingencies Agency. The transport group at SSM consists of six staff members including Head of unit, and two senior consultants.

Transportation of spent nuclear fuel and nuclear waste is largely done by sea, since most of the nuclear facilities are situated on the coast. This transportation system has been in operation since 1982 and consists of the ship M/S Sigyn, transport casks and containers, and terminal vehicles for loading and unloading. Fresh nuclear fuel is usually transported by road to and from the fuel fabrication plant in Västerås. Radioactive materials such as radiopharmaceuticals are transported by air and road. There are no transports of express parcels by railway anymore (since 1999), but some LLW are transported by railway in containers, destined for Studsvik´s waste treatment plant.

Legislation

The Government has promulgated the following legislation on the regulatory control of the transport of radioactive material:

- 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 2011:1 ADR-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 (1984:3) on Nuclear Activities and the Radiation Protection Act (1988:220) require radiation protection and safety in all dealings with such material.

The modal regulations are implemented into Swedish legislation by the Swedish Civil Contingencies Agency (land transport) and the Swedish Transport Agency (sea and air transport) in cooperation with SSM.

Responsibilities

The Swedish Civil Contingencies Agency and the Swedish Transport Agency have together with SSM a joint responsibility for the transport regulations (7§ Transport of Dangerous Goods Ordinance (2006:311)). According to the Ordinance (1984:14) on Nuclear Activities, the Radiation Protection Ordinance (1988:293) and Transport of Dangerous Goods Ordinance (2006:311) SSM is the competent authority regarding the authorization of transport of nuclear and radioactive materials and radioactive waste.

According to the Radiation Protection Ordinance (1988:293) SSM may issue regulations on all obligations required to protect against or control of radiation at e.g. transportation. Similarly SSM may, according to the Ordinance (1984:14) on Nuclear Activities, issue all necessary safety requirements.

SSM is responsible for compliance assurance of transport of radioactive materials. Compliance is assured in respect of the design of packaging in the review process of the Safety Analysis Report. The compliance assurance program is decided annually based on previous experiences, reported incidents, etc. However, there is no formal process for choosing licensees to inspect.

Approvals and permits

The Safety Analysis Report shall include data that the heat transfer is less than required. Calculations in the SAR are controlled and assessed. (The actual packaging may be inspected if relevant). The Safety Analysis Report is part of the application for package approvals and the information is often referred to in the certificate. The Safety Analysis Report shall include data that the criticality safety is adequate. External consultants may be contracted for assistance in reviewing safety analysis reports, such as criticality safety aspects, brittle fracture analysis, testing, etc.

A radiation protection program is a necessity for a permit to transport radioactive materials in accordance with the Radiation Safety Act (SFS 1988:220) or the Nuclear Activity Act (SFS 1984:3). Dose registration is compulsory and is registered in a central dose registry, monitored by SSM (SSMFS 2008:51). The radiation protection program and personalized dosimeters are required if the assessed effective dose from occupational exposures arising from transport activities is likely to exceed 6 mSv in a year.

There are required emergency procedures according to the modal regulations. In all transport permits issued by SSM there are also instructions to contact the duty officer (TiB) of the Swedish Radiation Safety Authority.

Summary and Conclusions

Transport of radioactive materials is well-regulated and implemented in Swedish legislation. The IAEA's safety standards series TS-R-1 2009 has in principle been fully implemented in the Swedish regulatory framework.

The modal regulatory framework regulates in detail all aspects related to physical transports. Transport of radioactive materials is also regulated under either the Radiation Protection Act or the Act on Nuclear Activities (nuclear materials and nuclear waste), implying that such transports and/or stakeholders are subject to licensing reviews by SSM.

Due to the level of complexity and the involvement of many authorities, SSM needs internal documented routines specifically for licensing reviews and regulatory supervision relating to transport of radioactive substances. This area currently needs improvement.

A review is needed as to the kind of technical expertise (internal and mainly external) available in connection with licensing reviews.

References

SFS 1984:3 Nuclear Activities Act
SFS 1988:220 Radiation Protection Act
SFS 2006:263 Transport of Dangerous Goods Act

SFS 1984:14 Nuclear Activities Ordinance
SFS 1988:293 Radiation Protection Ordinance
SFS 2006:311Transport of Dangerous Goods Ordinance

MSBFS 2011:1 ADR-S Regulations on transport of dangerous goods by road
MSBFS 2011:2 RID-S Regulations on transport of dangerous goods by railway
SSMFS 2008:51 Regulations concerning Basic Provisions for the Protection of Workers and the General Public in Practices involving Ionising Radiation
TSFS 2009:91 IMDG-code Regulations on transport of dangerous goods by sea
Regulation EC/859/2008 ICAO-TI on transport of dangerous goods by air

STYR2011-167 Transport of radioactive substances (In Swedish only)

11.2 Control of Medical Exposure

Counterparts

Torsten Cederlund
Head of Section
Radiation Protection
+46 8 799 41 23
Torsten.Cederlund@ssm.se

Catarina Danestig Sjögren
Inspector
Radioactive Protection
+46 8 799 42 69
Catarina.Danestig.Sjogren@ssm.se

Assessment for IAEA requirements

The regulatory framework is well developed and covers all relevant areas. No exemption from authorization is allowed in Swedish legislation, and in the medical sector, inspection and verification activities are never outsourced to a contractor. However, more documents providing guidance need to be developed.

The requirements of the IAEA standards are in some areas not fulfilled in a strict sense, for example due to the Swedish model for allocation of responsibility (radiological leadership, medical physicist), the use of projected dose (rather than activity) for the release of patients who have undergone a therapeutic procedure, etc.

Regarding investigation of incidents and accidents, the regulations are less prescriptive but there are well-developed procedures which fulfil the requirements' objectives (such as root-cause identification, measures to avoid reoccurrence and information sharing).

The regulatory framework is straightforward and clear. Any legal party involved in a practice in the medical sector has a defined responsibility to identify suitable and radiation-safe solutions for the work involving radiation.

SSM imposes strict requirements in terms of sufficient competence (on site) where the practice is carried out (diagnostic or therapeutic procedures). Sweden has a large number of certified medical physicists linked to the medical facilities who also are given specific responsibilities.

The system, and use, of diagnostic reference levels are advanced and have proven to be very effective for reducing patient doses.

Strengths

The regulatory framework is straightforward and clear. Any legal party involved in a practice in the medical sector has a defined responsibility to identify suitable and radiation safe solutions for the work involving radiation.

The SSM imposes strict requirements in terms of sufficient competence (on-site) where the practice is carried out (diagnostic or therapeutic procedures). Sweden has a large number of certified medical physicists attached to the medical facilities which also are given specific responsibilities.

The system, and use, of diagnostic reference levels is well developed and has proven very effective to reduce patient doses.

Areas of improvement

The Swedish regulatory framework for medical exposure requires the appointment of a person with the radiological leadership. This person has a key role and his/her duties match many of the IAEA Standards requirements to, directly or indirectly, ensure the issues of justification and optimisation on procedures of the practice.

There is a need to review these circumstances and assess the present balance of responsibilities between the prescribing medical doctor/dentist, the physician performing the procedures and the radiological leadership (RALF).

SSM has to further develop its management system and include documented requirements on competence, education and training for inspectors.

There is a need to further develop guidance (both external and internal) and general advice on the application of the present regulatory framework.

Several authorities have responsibilities in the medical area and SSM should consolidate and further develop its cooperation with these authorities.

Regulations

GS-R-1 5.26
The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations.

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. The Act addresses the overall framework for the legal aspects regarding radiation protection (RP). The Act states that the Government or the Authority the Government points out may issue further regulations. The Radiation Protection Ordinance SFS 1988:293 empowers the SSM to issue more detailed regulations regarding RP for licensed practices.

The Swedish Radiation Safety Authority (SSM) has issued regulations with general obligations and requirements for practices involving medical and dental exposures

(SSMFS 2008:35). More specific regulation of various practices exists in the SSM regulations, for example:

- SSMFS 2008:31 for medical and dental x-ray diagnostics
- SSMFS 2008:33 for radiation therapy
- SSMFS 2008:34 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

For dental x-ray diagnostic using intra-oral image receptor, regulations and general advice are found in SSMFS 2008:5. General advices for performance specification in connection with purchasing x-ray diagnostic equipment are found in SSMFS 2008:42. Together with the licences issued by SSM, specific obligations can be given as licence conditions.

Other regulatory bodies regulating practices involving medical exposure are the National Board for Health and Welfare (patient safety, requirements for education and staff diplomas, management systems etc.) and the Medical Products Agency (medical devices, radiopharmaceuticals).

Responsibilities for Medical Exposure

International BSS 115 2.14
The legal person responsible for a source to be used for medical exposure shall include in the application:

(a) The qualifications in radiation protection of the medical practitioners who are to be designed by name in the registration or licence; or

(b) A statement that only medical practitioners with the qualifications in radiation protection specified in the relevant regulations or to be specified in the registration or licence will be permitted to prescribe medical exposure by means of authorized source

International BSS 115 II.1 Registrants and licensees shall ensure that:

a) No patient be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;

b) Medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of medical exposure;

c) Medical and paramedical personnel be available as needed, and either be health professionals or have appropriate training adequately to discharge assigned tasks in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes;

d) For therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of the Standards be conducted by or under the supervision of a qualified expert in radiotherapy physics

f) Training criteria be specified or be subject to approval, as appropriate, by the Regulatory Authority in consultation with relevant professional bodies

International BSS 115 II.2
Registrants and licensees should ensure that for diagnostic uses of radiation the imaging and quality assurance requirements of the Standards be fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate

International BSS 115 II.3
Medical practitioners shall promptly inform the registrant or licensee of any deficiencies or needs regarding compliance with the Standards with respect

M11

In the Swedish regulations (SSMFS 2008:35, 6§) it is mentioned that the referring medical physician or dentist, and the doctor or dentist who decides on the medical exposure shall, if possible, access earlier diagnostic information or journals in order to avoid unnecessary exposure. It is pointed out that referral criteria are given in the publication Radiation Protection 118 from the European Commission "*Referral Criteria for Imaging*". The medical practitioner according to the definition of the IAEA has its correspondence in the Swedish RALF who shall see to that all medical exposures to be performed are justified and hence indirectly is prescribing them.

The provisions of SSMFS 2008:35, 1§ and 5§ require assessment of justification for every medical exposure. For all practices a person shall be appointed to hold the radiological leadership (RAdiologisk LedningsFunktion – RALF (SSMFS 2008:35, 11§). This person has the responsibility to ensure that the evaluations of justification

are conducted (SSMFS 2008:35 11 §, it. 2). This implies that RALF shall be involved in the establishment of routines regarding justification. These can be based on either individual or general assessments depending on the type of clinical question. In practice, these assessments for the individual patient will be made by the physician with the clinical responsibility for this patient or other medical staff according to established and documented routines. During the licensing process, the qualification of the RALF is compared with the requirements of the SSM regulations. At inspections the routines are reviewed. It is also checked that the appointment of the RALF involves the responsibility to provide routines for the assessment of justification for every patient. Thus, direct or indirect – every medical exposure is executed under the supervision of RALF, ensuring patient protection and safety in the prescription, and during its delivery.

The regulations require registrants and licensees to ensure that a medical practitioner is responsible for patient protection and safety in the prescription of, and during the delivery of, each medical exposure. The issues of justification and optimisation are covered in SSMFS 2008:35, 3§ and 8§.

The RALF has the duty to have an overriding influence on the practice within her or his area, ensure that the evaluations of justification are conducted, have knowledge of and, in co-operation with the medical physicist, actively influence and optimize the working methods, in consultation with the medical physicist and superiors of the personnel concerned, ensure that the personnel has the required competence and receives continuing education, and in consultation with the medical physicist, ensure that suitable equipment is used in the practice (SSMFS 2008:35, 11§). In the process of granting a licence and during inspections, SSM checks whether RALF is appointed for all practices (involving ionising radiation) and whether formal competence of RALF is in compliance with the regulations.

The regulations, in addition to the RALF function, require a medical physicist for most practices. There are however no requirements on the numbers of medical personnel. During inspections, the requirements on staff, RALF and medical physicist are checked by examining organisation plans and/or through interviews.

The regulations require registrants and licensees to ensure that any person directly involved in the conduct of medical exposures has appropriate training to discharge assigned tasks. The person holding the radiological leadership shall see to, together with the medical physicist and the head of the clinic that all personnel has the competence needed and receive further education (SSM FS 2008:35, 10 §, 11 § it. 4, 13 §). For different types of practices additional requirements are given (x-ray diagnostic SSMFS 2008:31, 8 §, nuclear medicine SSMFS 2008:34, 6 §; and radiation therapy SSMFS 2008:33, 6 §). Routines for staff education shall be documented (in writing), including those elements that are mandatory for performing certain work. The personnel shall sign a statement that safety routines and other education elements has been covered. The check of education and training is a vital part of SSM's inspections. The lists of mandatory education and training are examined and also that individual training is signed.

Regulations require registrants and licensees to ensure that therapeutic uses of radiation (incl. teletherapy and brachytherapy), calibration, dosimetry and quality assurance (QA) requirements of the BSS are conducted by or under the supervision of a certified medical physicist (SSMFS 2008:35, 12§). She/he shall be the leader of those parts which concern the physical and measurement related stages. The medical physicist shall actively participate in the process of optimisation of the dose for each

patient and ensure that the absorbed dose is correctly checked and administered. The medical physicist shall be the licence-holders' expert on issues related to RP and shall co-ordinate the RP work by

- Having a clear insight into the radiological practice of the licence-holder,
- In cooperation with the person who holds the radiological leadership (RALF), formulate procedures for treatments where radioactive sources are retained in the body,
- Participate in the establishment and implementation of QA programmes for equipment and procedures,
- Ensure that new treatment methods are evaluated from RP point-of-view,
- Participate in investigations of unplanned events that are of importance from RP point-of-view,
- Participate in the equipment purchasing process,
- Plan for and check the RP issues (physical) when premises are built or are being rebuilt,
- In consultation with the superiors of the personnel and RALF, participate in RP education,
- Have a leading role in the design and establishment of routines for individual dose monitoring of the staff/personnel,
- Participate in developing procedures for the transport of radioactive substances and the management of radioactive wastes.

During inspections, these issues are checked, for example, by the SSM by examination of the quality manual and of the organisational chart. In addition, e.g. calibration certificates, the results of absolute dosimetry and periodic checks of equipment are examined (See template for inspection of radiation therapy department).

The regulations require that registrants and licensees should ensure, for diagnostic uses of radiation, that the imaging and QA requirements of the BSS are fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate. The medical physicist and the person who holds the radiological leadership shall together ensure that the radiation is used in an optimised way taking into account the medical objectives and the radiation dose to the patient (SSMFS 2008:31, 7§ and SSMFS 2008:34, 5§). At inspections compliance/non-compliance is checked by examination of the quality manual and of the organisational chart and by interviews with the personnel in question.

The Swedish regulations do not require that the legal person submits in the application for an authorisation named medical practitioners and their qualifications in RP. Neither a statement is made that only medical practitioners with the qualifications in RP specified in the relevant regulations or to be specified in the registration or licence will be permitted to prescribe medical exposure by means of the authorised source. Conditions for authorisation of practices involving medical exposures are that a practitioner (RALF) with specified qualifications has to be within the organisation [SSMFS 2008:35, 11, 13 §§; SSMFS 2008:34, 4 § (nuclear medicine); SSMFS 2008:33, 4 § (medical radiation therapy); and SSMFS 2008:31, 4-6 §§ (medical and dental x-ray diagnostics)]. The duty of RALF is to, among other things, have the overriding influence over the practice within her or his area and to ensure that evaluations of justification are conducted. Thus RALF is having control over on which grounds patients do undergo medical exposures.

Furthermore, the regulatory body has not specified (or approved) training criteria in RP for persons who have responsibilities or assigned tasks in the conduct of medical exposures, and neither consulted relevant professional bodies in this matter. In SSM's regulations the responsibility to define criteria for education and training for all personnel involved in medical exposures is appointed to the licensee (SSMFS 2008:35, 10 §). These criteria shall be developed by RALF with the medical physicist (SSMFS 2008:35, 11 §, it.4). In the organisational chart it shall be documented how the education and training relating to RP, methods and handling of equipment are organised for the personnel concerned (SSMFS 2008:35, 13 §). For the RALF qualification requirements are given in SSMFS 2008:34, 4 § (nuclear medicine); SSMFS 2008:33, 4 § (medical radiation therapy); SSMFS 2008:31, 4-6 §§ (medical and dental x-ray diagnostics).

The qualified expert for radiotherapy, radiodiagnostic and nuclear medicine physics shall be a certified medical physicist. The medical physicist shall be certified by the National Board of Health and Welfare (SoS) according to the regulations SSMFS 2008:35, 12§. The competence requirements for medical physicists are described in "*Kompetensbeskrivningar för sjukhusfysiker, Artikel nr. 2001-105-1, ISBN 91-7201-519-5, Ale Tryckteam, Bohus, april 2001".* The certification is granted for the basic education of the medical physicist and it is stressed that certain tasks in clinical practice would need continuing and deeper studies for the newly graduated medical physicist. Note that the professional title "sjukhusfysiker" is protected by SoS and reserved for certified medical physicists.

The SSM regulations do not require formally that medical practitioners shall promptly inform the licensee of any deficiencies or needs regarding compliance with the Standards (BSS) with respect to protection and safety of patients. However, the Radiation Protection Ordinance (SFS 1988:293, 5§) stipulates that

> "If there are reasons to believe that someone, due to a practice involving ionizing radiation, may have been harmed through the exposure to radiation or if a mishap or incident has occurred which could be of importance for radiation protection, the registrant or licensee shall immediately report this to the Swedish Radiation Safety Authority."

SSM's regulations require that unplanned events and accidents shall be reported to SSM through the contact person (medical physicist) as soon as possible, but at the latest within one week (SSMFS 2008:35, 29§). Implicitly the RALF has an overriding influence over the activities and if deficiencies are detected it is his/her tasks to see to that remedial actions are performed, a part of which is to inform concerned persons (SSMFS 2008:35, 11 §). At inspections, SSM checks that unplanned events have been reported to SSM and that the medical physicist is involved in their investigation and disseminating of findings, by comparing the licensee's register on unplanned events with those reported to SSM.

Justification of Medical Exposures

International BSS 115, II.4 – II.9
Medical exposures should be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of alternative techniques that do not involve medical exposure.
In justifying each type of diagnostic examination by radiography, fluoroscopy or nuclear medicine, relevant guidelines will be taken into account, such as those established by the WHO

The Swedish regulations require the justification of medical exposures (SSMFS 2008:35, 3§). The regulations state that at any practice there shall assigned a person who holds the radiological leadership (RALF) who shall ensure that evaluations of justification are conducted. All exposures shall be judged to be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved. An exposure may be justified in an individual case even if it is not generally justified. All new methods or applications shall have been judged to be justified prior to their general use (SSMFS 2008:35, 5§). The referring physician or dentist and the physician or dentist who decides on the exposure shall seek, whenever possible, previous diagnostic information or journals in order to avoid unnecessary exposures (SSMFS 2008:35, 6 §). The licence holder is encouraged to make use of the EU publication RP 118 on referral criteria for imaging (SSMFS 2008.35, 6 § foot-note).

The referring physician and the physician who decides on exposures (diagnostic or therapeutic) shall, when relevant, ask women of child bearing age if they are pregnant. The referring physician and the physician who decides on nuclear medicine procedures shall likewise ask women of child bearing age if they are pregnant. If so, or pregnancy cannot be excluded, particular attention shall be paid in order to protect the unborn child. When judging whether exposure is justified, the projected dose to the foetus, the degree of urgency and the existence of alternative methods for diagnostic or treatment without ionizing radiation shall be taken into account (SSMFS 2008:35, 24§).

The person who holds the radiological leadership shall ensure that women of child bearing age are asked whether they are pregnant or not before examinations where the lower abdomen is in the primary beam are performed. If the woman is pregnant, or if pregnancy cannot be excluded, the justification of the examination and the urgency shall be scrutinised particularly. Pregnant women shall be examined with such equipment and methods that give a radiation dose to the foetus as low as reasonably achievable. The selection shall, however, be made such that the necessary diagnostic information is obtained or other medical purposes are achieved (SSMFS 2008:31, 11§).

When planning a nuclear medicine examination or treatment of a woman of childbearing age, special care shall be taken when she is pregnant or breastfeeding. If pregnancy is confirmed or cannot be excluded, the justification and the degree of urgency shall be scrutinised. Breastfeeding women shall, before the examination or treatment starts, be provided with information concerning recommended breaks in breastfeeding, in accordance with the general advice (SSMFS 2008:34, 15§).

At inspections, SSM checks the existence and content of routines regarding fertile and/or breastfeeding women are compared with how these issues have been treated

by examining patient records. Furthermore, routines and guidelines on how justification is performed, e.g. who is receiving and checking incoming referrals and who is deciding on whether to carry out the examination, are also controlled by the SSM. A more complete picture is also provided by interviews with the staff and personnel on how the different procedures are carried out. Through inspections, the existence of alternative procedures and methods for pregnant women in diagnostic radiology is verified.

The regulations have the effect that any radiological examination for occupational, legal or health insurance purposes is unjustified unless undertaken with reference to clinical indications or expected to provide useful information on the health of the individual examined or is a specific type of examination justified by those requiring it in consultation with relevant professional bodies. When examining persons who are not regarded to gain any medical benefit from the exposure, the method giving the smallest possible radiation dose, sufficient to answer the question at issue, shall be selected (SSMFS 2008:35, 25§).

Examinations for occupational purposes are regarded as medical exposures. The outcome of such examinations is a medical diagnosis and justification is assessed as for examinations of patients, i.e. the value of the diagnostic information shall outweigh the detriment the exposure will cause (SSMFS 2008:35 2§).

An x-ray examination with the purpose of finding foreign objects within the body may be performed if there are reasons to suspect a crime and if a body examination is allowed according to Chapter 28 of the Swedish Code of Juridicial Procedure *("Rättegångsbalken"*) and if the general radiation principles in the regulations SSMFS 2008:35 are met (SSMFS 2008:35, 26§)

Radiological examinations with the purpose of verifying injuries after a suspected assault may be performed if a physician is judging that the examination may be of benefit for the person and if moreover general RP principles are met. Examinations on insurance grounds may likewise be performed if the person involved participates on a voluntary basis and the general radiation principles in SSMFS 2008:35 are met (SSMFS 2008:35 27-28 §§).

All new screening projects shall be reported to SSM for assessment before they are started (SSMFS 2008:35, 9§). SSM reviews the project in order to determine whether it is justified or not. When a licensee is reporting the intent to start a new screening project the established standard is that SSM is consulting the National Board of Health and Welfare (SoS) to get their opinion. SSM's decision on the proposed screening project will then be based on the judgement given by SoS and on basic RP principles. The only existing screening programme in Sweden is mammography which was regarded justified on a general level by SoS based on the outcome of large studies in Sweden which provided the evidence that screening is reducing breast cancer mortality. SSM (at the time SSI) and SoS issued general advice on how to perform screening with mammography. The latest was issued in 1998: *Screening with mammography – basis for recommendations on screening for breast cancer, National Board of Health and Welfare (SoS) Report No. 1998-03-017.* The current standpoint is that mammography is justified on a general level and the issue of justification is not dealt with at inspections. However, through the system with diagnostic reference levels (DRL) compliance with the dose recommendation is checked and the licensee is obliged to take actions if the DRL is exceeded (SSMFS 2008:20, 4 and 6 §§).

The Swedish regulations (SSMFS 2008:35, 22 and 23§§) state that the exposure of humans for medical research is only justified if it fulfills certain basic provisions. A part of these requirements are from the Helsinki Declaration. For ethics committees, a special law/act has been in force since January 1 2004 (SFS 2003:460 *Act Concerning the Ethical Review of Research Involving Humans)* which deals with the vetting the ethics of research that involves humans, thus implementing the Helsinki declaration into national law. One important change compared to previous regulations is the establishment of one central ethical vetting board (ethical committee) and six local ones as independent authorities. SSM requires that research projects, in which test subjects are exposed to radiation, are approved by the local ethics committee and the local RP committee. A license holder running a smaller practice, without a RP committee, shall for the judging of research programmes consult the nearest local RP committee or the competent authority (SSMFS 2008:35 22-23§§). Unless SSM is notified on the issue of non-compliance for such medical research, compliance is not routinely verified by the SSM.

Optimisation of Protection for Medical Exposures

International BSS 115 - II.16 (a, b, f), II.17 (a, b), II.18 (a, d)
Regulatory requirements regarding optimisation of protection for diagnostic and therapeutic exposure

International BSS 115 - II.13, II.14, II.15
Design and performance requirements to be met by equipment

International BSS 115 - II.12
Preventive steps to minimize the probability and magnitude of incidents (unintended and accidental medical exposures)

International BSS 115 - II.16(b), II.17(e)
Particular attention to the optimisation of protection for medical exposures of children

International BSS 115 - II.16(e), II.18(d)
Particular attention to the optimisation of protection for medical exposures of women who are pregnant or likely to be pregnant

International BSS 115 – II.19
Calibration of sources used for medical exposure

International BSS 115 – II.20
Specific requirements for clinical dosimetry

International BSS 115 – II.22
Comprehensive quality assurance programme for medical exposures

International BSS 115 – 2.27, II.24-25, and ICRP 103 (335-336)
The use of guidance levels (diagnostic reference levels (DRLs) in medical exposures

International BSS 115 – II.8
The establishment by Ethical Review Committee, or other institutional body assigned similar functions by the national authority, of dose constraints for the use in the optimisation of the protection

International BSS 115 – II.27
Constraining dose to individuals incurred while voluntarily helping in the care, support or comfort of patients to a level unlikely to exceed 5 mSv during the period of the patient's diagnostic examination or treatment

M11

Regulations require the optimisation of protection for medical exposures. The use of any method or application shall be reconsidered if there are new findings on their effect or risks (SSMFS 2008:35, 7§). The optimisation procedures shall include the ensuring of diagnostic information or treatment results, the practical aspects of the performance and the evaluation of the methods with respect to the radiation doses given to patients (SSMFS 2008:35, 8§). It is required that the holder of the radiological leadership (RALF) shall have knowledge of and, in cooperation with the medical physicist, actively influence and optimize the working methods (SSMFS 2008:35, 11§). It is required that activities (diagnostic radiology) shall be carried out considering the diagnostic reference dose levels regulated through SSMFS 2008:31, 12§ and SSMFS 2008:20.

For diagnostic radiology, according to SSMFS 2008:31, 9§, all equipment shall be provided with written method descriptions covering the examinations that are conducted there. The descriptions shall comprise *inter alia* exposure tables and information about adequate dose reduction methods like compression and use of devices for the protection of gonads or the thyroid. It is further required that (15§) the equipment shall be well adapted to the intended use. Equipment that is intended to be used mainly for screening, examination of children and for high dose procedures such as computed tomography or interventional radiography should be specially designed for the respective application.

For diagnostic radiology, SSMFS 2008:35, 8§, stipulates that the optimisation procedures shall include the selection of equipment. RALF shall in consultation with the medical physicist ensure that suitable equipment is used in the practice (11§).

For diagnostic nuclear medicine, it is required that procedures shall be conducted considering the reference activity levels regulated through SSMFS 2008:34, 14 § and SSMFS 2008:4. It is furthermore required that the license-holder shall have an established QA programme including a quality manual containing a description of procedures which ensure that the right patient receives the correct radiopharmaceutical and the correct amount of activity, and descriptions of special procedures for reducing the amount of activity for administration to children according to body weight, body surface area or other appropriate criteria (SSMFS 2008:34 7§).

The regulations on radiation therapy (SSMFS 2008.33) require through 7§ that the license-holder shall have an established quality manual as part of the QA programme describing procedures that make sure that the absorbed dose in the target volume corresponds to the planned dose for each patient. The quality manual shall contain descriptions of procedures preventing foreseeable faults which would result in unintentional or incorrect exposure (10§). Each treatment shall be preceded by an optimised individual dose planning which shall be conducted in close cooperation between the physician and the medical physicist (13§).

SSM inspectors, with basic theoretical knowledge in the corresponding subject as well as practical experience from clinical work carry out inspections. Availability of documented RP plan, quality manual, routines, policies, instructions, protocols etc. and how they are implemented and used is reviewed and assessed during inspections. Specific for the current issue, it is investigated whether the licensee actively and systematically conducts optimisation projects and implements the findings in the daily practices. The cooperation form between the key function holders (medical physicist, radiological leadership, chief of staff and others) is reviewed and the fulfillment of their stipulated tasks is examined. The compliance of the licensee's education program with the regulations is closely assessed. It is investigated whether all

personnel have received adequate education and training and signed certificates are checked. In diagnostic radiology for a number of specified types of examinations, practices that might not be optimised are identified by the use of a system of diagnostic reference levels (SSMFS 2008:20). Similarly, in nuclear medicine examinations diagnostic reference levels (SSMFS 2008:4) are applied. For interventional radiology and radiotherapy there are no such quantitative checks.

Regulations specify design and performance criteria to be met by equipment used for medical exposure. The Act on medical devices (SFS 1993:584) require that all medical devices must be suitable for intended use (5§). Furthermore, the Medical Product Agency (*Läkemedelsverket*) prescribe that all medical devices must comply with the essential requirements for their intended purpose (LVFS 2003:11, 3§ 1). These requirements are regarded to be fulfilled if the devices comply with relevant standards (LVFS 2003:11, 5§). The devices shall be marked with the CE-mark when introducing them into the market (LVFS 2003:11, 11§).
According to the IEC 60601-1, which is binding for Sweden and all EU countries, medical equipment must comply with requirements concerning single fault conditions. Single fault condition for medical electrical (ME) equipment shall be so designed and manufactured that it remains single fault safe, or the risks remains acceptable as determined through the application of 4.2 in the same standards.

M11

SSM stipulates additional requirements: X-ray equipment using fluoroscopy must have two dose levels and computed tomography, equipment for interventional radiography, angiography, gastro-intestinal examinations and equipment designated for paediatric examinations shall have a device indicating the amount of radiation delivered (SSMFS 2008:31, 14 §). Fluoroscopy without imaging intensifier or similar technique is not permitted (SSMFS 2008:31, 13§).

As a condition for a general license for dentists regarding equipment with intraoral image receptor a number of requirements are given that are more strict than in the applicable IEC standards (SSMFS 2008:5, 7§).

For x-ray generators IEC 60601-2-7, 2nd Ed. applies (according to LVFS 2003:11). Clause 29.1.103 refers to limitation of radiation output with a number of specific requirements in order to reduce the probability and consequence of unintended exposures. There is furthermore a general requirement by the SSM for all medical equipment to minimize unintended exposures (SSMFS 2008:35, 20§): Potential exposures shall be taken into account. The likelihood of, and the consequence of unintentional or incorrect exposures shall, as far as possible, be minimised by adequate selection of equipment.

Generally the IEC 60601-1, 3rd Ed. 2006 Clause 7.9.2.1 applies: The instructions for use shall be in a language that is acceptable to the intended user. However, the Medical Product Agency requires (LVFS 2003:11 4 § 3) that markings and instruction for use of a medical device (annex 1, item 13 in the regulations) shall be in Swedish when the device is reaching the final user, regardless whether the device is intended for professional or other use. For dental x-ray equipment intended for intra-oral image receptor SSMFS 2008:5, 7§ requires that the equipment is CE-marked and that it fulfills the requirements in a specific appendix of the regulations. Instructions in Swedish are mandatory. At inspections carried out by SSM compliance are checked with SSM requirements. The presence and content (including language) of instructions for use of equipment is checked. Availability of multiple dose levels and the presence of indicating devices are checked by randomly selecting some equipment at the inspected site.

The Swedish regulations require that registrants and licensees take preventive steps to minimize the probability and magnitude of incidents (unintended and accidental medical exposures). The likelihood of, and the consequence of unintentional or incorrect exposure shall, as far as possible, be minimised by adequate selection of equipment and design of quality controls, working methods and education (SSMFS 2008:35, 20§). Possible equipment failures must hence be identified. SSMFS 2008:35, 19§ stipulates that the quality manual shall contain information on which characteristics of the equipment that are acceptable and also contain an action plan on measures to be taken when deviations are identified. If a check shows that the equipment deviates in such a way that it is no longer deemed acceptable from a radiation point-of-view, the defect(s) shall be corrected before any further use.

When an unplanned event has taken place, the medical physicist shall participate in the investigation of events that are of importance for RP (SSMFS 2008:31, 7§; SSMFS 2008:33, 5§; SSMFS 2008:34, 5§). The event is expected to be investigated in all its aspects, whether the cause may be equipment failure, human error or due to some other root cause, including a combination of different factors. Unplanned events shall be reported to SSM through the contact person as soon as possible but latest within one week. Such a report shall include a description of the event and the measures that have been taken to prevent recurrence of the event (SSMFS 2008:35, 29§). It is further required through SSMFS 2008:33, 16 § that for radiation therapy, procedures shall exist for recording and correcting deviations. Identified and/or detected deviations shall be documented in the "treatment protocols/records". A system for compiling and analyzing deviations is compulsory according to the same paragraph (16§).

The SSM regulations on general obligations in medical and dental practices using ionizing radiation (SSMFS 2008:35) stipulate that the licensees shall ensure that all personnel that is taking part in the practice with medical exposures has the theoretical and practical skill that is needed to ensure the practice to be performed under good RP conditions. All personnel taking part in the practice shall have good knowledge of the RP regulations that apply to their work. All personnel shall furthermore receive education whenever new equipment or new methods are introduced (10§). The person(s) holding the radiological leadership (RALF) shall in consultation with the medical physicist and the superiors of the personnel concerned, work towards that the personnel has required competence and receives continued training and education as needed (11§).

Regulations on nuclear medicine (SSMFS 2008:34, 7§) require that the quality manual contains a contingency plan, which includes measures aiming at mitigating the harmful effects if an incorrect dose should be administered, in spite of everything. A plan should also exist on how to act if a patient with administered radioactivity deceases.

Regarding the work to minimize the probability and magnitude of incidents, during inspections the radiation organisation plan, the quality system, the documented routines, written procedures etc. are examined in terms of adequateness, sufficiency and implementation. The appointment of key function holders (RALF, members of RP committee, medical physicist) are assessed where applicable. The awareness of the staff regarding the existence and role, and practical functions of the key function holders are examined. The cooperation between different parties is reviewed and their fulfillment of stipulated tasks is controlled. The protocols from meetings of the RP committee are studied and compared to factual situations, for instance, if un-

planned events have been discussed and investigated. The measurement protocols from calibration and quality controls are reviewed with special attention to control after service and remedy measures. Registered unplanned events of the licensee's accident management programme are compared to the reports sent to SSM and the measures taken are pursued. The compliance of the licensee's educational programme with regulations is closely assessed. It is investigated whether all personnel have received adequate training and education, and signed certificates are checked. Many other issues, such as how new equipment is purchased, installed, tested and introduced into the practice, how new methods are implemented, how and how often revisions of the activities are carried out etc. are also examined.

The regulations require that particular attention is given to the optimisation and medical exposure of children. The SSM regulations on x-ray diagnostics (SSMFS 2008:31, 14§) require that new purchased x-ray equipment shall be provided with means showing the amount of radiation that the equipment emits during the examination if the equipment is to be used especially for the examination of children. In the subsequent paragraph (15§) requires that equipment to be used mainly for examination of children should be specially designed for the respective application. The (9§) requires that all equipment, including the one used for children, shall be provided with written method descriptions covering the performed examinations. These descriptions should comprise inter alia exposure tables and information about adequate dose reduction methods. The 8§ stipulates that all personnel in the practice shall have adequate training but for personnel working routinely with x-ray examinations of children particular high demands shall be required regarding education.

M11

Furthermore, the regulations on nuclear medicine (SSMFS 2008:34, 7§) require that the established quality management programme should control, through descriptions of established procedures, how to adapt administered activity to children. The 6th paragraph addresses requirements on theoretical and practical education and particularly high demand are requested for personnel working routinely with children examinations.

During inspections, quality manual, routines, policies etc. are checked, in particular the availability, adequateness and implementation of routines concerning treatment of children and the connected training and examination activities. Amid physical inspections of examination rooms and equipment, adapted examination protocols and exposure tables for children are controlled. The awareness, knowledge and education records, including signed certificates, are checked through direct control and through interviews.

The regulations require that particular attention is given to the optimisation and medical exposure of women who are pregnant or might be pregnant. Regulations on general obligations in medical and dental practices using ionizing radiation (SSMFS 2008:35) stipulate through 24 § that the referring physician and the physician who decides on the exposure shall ask women of child bearing age if they are pregnant. If the woman is pregnant, or if pregnancy cannot be excluded, particular attention shall be paid in order to protect the unborn child. As already stated above, when judging whether exposure is justified, the expected dose to foetus, the degree of urgency and the existence of alternative diagnostic or treatment methods shall be taken into account. Likewise, the regulations on x-ray diagnostic (SSMFS 2008:31, 9§) requires alternative procedures or methods for examination of pregnant women to be described in the QA programme. The 11§ stipulates that RALF shall ensure that women of child bearing age are asked whether they are pregnant or not before examinations where the lower abdomen is in the primary beam are performed. The justifica-

tion of the examination and the urgency shall be particularly scrutinised if pregnancy cannot be excluded. Pregnant women shall be examined with such equipment and methods that give a radiation dose to the foetus as low as reasonably achievable but so that the necessary diagnostic information is obtained or other medical purposes are achieved. Likewise SSMFS 2008:33, 15§ requires that therapeutic procedures for pregnant women, or in cases where pregnancy cannot be excluded, the justification of the exposure, including evaluation of alternative treatments, are scrutinised.

For x-ray diagnostics, nuclear medicine, and radiation therapy it is inherently deducted that in judging the justification of the treatment/examination, the determination of a potential foetal dose is necessary. During inspections, SSM assesses the implementation of the QA programme and the availability, adequateness and implementation of routines concerning examination of pregnant women and women of reproductive capacity are in in focus.

The radiation therapy regulations (SSMFS 2008:33, 21§) require that suitable reference instruments shall be available for dose monitoring and checks. These instruments shall be calibrated at the National Standards Laboratory (metrology), or at an equivalent laboratory, at least once every second year as well as when considered to be necessary. The function and stability of the instruments shall be regularly checked. Furthermore (7§) it is required that the licensee's quality manual includes procedures for controls of equipment and working methods and in (8§) requirements on descriptions concerning procedures for checking correct performance, verification, calibration and control of equipment used for exposure, as well as procedures for determining and checking the dose in the radiation field. Sealed sources used for brachytherapy are calibrated in terms of activity, reference air kerma rate in air or absorbed dose rate in a specified medium, although this is only implicitly required through SSMFS 2008:33 5,7,11 and 13 §§.

In the regulations LVFS 1999:4 and LVFS 2005:10, the Medical Product Agency regulates the preparation and control of radiopharmaceuticals (competence, localities, manufacturing, recording, administration). All locally produced radiopharmaceuticals should be checked according to instructions from the pharmaceutical company; all pharmaceuticals should be prepared and controlled according to *Good Manufacturing Practice* (GMP) as regulated by the European Directives 2003/94/EC and 91/412/EEC. SSMFS 2008:34, 5§, requires that the medical physicist shall have a leading position in developing measurement methodology in connection with measurements of the amount of radioactivity administered to patients as well as management and control of the used instruments. In 13§ of the same regulations it is stipulated that the medical physicist shall ensure that the activity given to the patient is checked by measurements prior to each treatment and that these performed checks are signed.

During inspections, relevant part of the management and quality systems are checked. The implementation of the QA programme (e.g. written procedures) is assessed through interviews with the staff. Measurement protocols of physical parameters of equipment are checked concerning frequency and results. The calibration of dosimetry and monitoring equipment is checked. The check of distributed amounts of activity prior to each treatment by the medical physicist and that performed verifications are signed are checked. The fulfillment of the requirements regarding procedures for ensuring that absorbed dose in the target volume agrees with the planned dose for each patient is verified.

The Swedish regulations do specify requirements for clinical dosimetry. During inspections, the clinical dosimetry requirements are checked. In radiological examinations representative values for typical sized adult patients of entrance surface doses, dose-area product, dose rates and exposure times, or organ doses are to be determined and documented. For x-ray diagnostics (SSMFS 2008:31, 12§) stipulates that the diagnostic standard dose (defined patient dose indicator, 3§) shall be determined for those examinations for which SSM has established diagnostic reference levels (DRLs). The results from the dose measurements shall be documented and, on request, be sent to SSM. There are no DRLs established for dental x-ray diagnostics. The regulations SSMFS 2008:20 regulates and provide information and more detailed guidance on the established DRLs, how to determine the corresponding diagnostic standard doses, documentation and reporting of results, measurement frequency and required corrective measures.

For nuclear medicine SSMFS 2008:34, 14§, stipulates that for the different types of examinations for which SSM has established DRLs, the average values of radioactivity administered to a group of patients of "normal size" shall be determined. The results of the average values shall be documented and, on request, be sent to SSM. SSMFS 2008:4 regulates and provides information and more detailed guidance on the established DRLs, how to determine corresponding average values, documentation and reporting of results, measurement frequency and required corrective measures.

SSMFS 2008:33, 13§ requires that each radiotherapy treatment shall be preceded by an optimised individual dose planning which shall be conducted in close cooperation between the physician and the medical physicist. The established dose plan shall be signed by the physician and the medical physicist in individual, patient-specific, medical treatment records. All other parameters of importance for the treatment shall be entered in these medical treatment records. A quality manual within the QA programme shall describe the procedures that make sure that the absorbed dose in the target volume corresponds to the planned dose for each patient (7§). 14§ stipulates that parameters of importance for the treatment shall be checked, if possible by two mutually independent methods, and be signed by two persons. In any circumstances the parameters shall be checked independently by two persons. The reasonableness of the selected parameter values shall always be controlled. Specifically, for intracavitary and interstitial treatments, the patient dose shall be measured to the extent that is possible.

Regarding nuclear medicine, SSMFS 2008:34, 7§, requires that a quality manual shall include a description of implemented procedures which ensures that the right patient receives the correct radiopharmaceutical and the correct amount of activity. Each treatment shall be preceded by individual dose planning conducted in close cooperation between the physician and the medical physicist (12§). Activity amounts shall be checked prior to each administration and performed checks shall be signed (13§). As inherently deducted from 18§ of the regulations SSMFS 2008:34, it is required that the number of examinations and treatments as well as the pharmaceuticals used and the amount of activity distributed for each examination and treatment are recorded.

The Swedish regulations SSMFS 2008:35 require through (17§) that registrants and licensees shall ensure that a RP manual is established in both medical and dental practices. In this work the medical expertise should be involved. According to SSMFS 2008:35, 11§, RALF shall have an overriding influence on the work/practice within his/her area. The radiological leadership may be shared by sev-

eral persons working at different medical units. In all practices (excluding dental practices not conducting specialist examinations) a medical physicist should be a member of the staff. The medical physicist should serve as the licensee's qualified expert in matters related to RP (SSMFS 2008:35, 12§). The level of education and complementary training needed for the position as RALF are specified in the regulations SSMFS 2008:31, 4-6§§ (x-ray diagnostics), SSMFS 2008:33, 4§ (radiation therapy), SSMFS 2008:34, 4§ (nuclear medicine). The responsibilities for the medical physicist are specified in 2008:35, 12§; 2008:31, 7§; 2008:33, 5§ and 2008:34, 5§.

Concerning the QA programme, SSMFS 2008:35 (all medical exposures) refers to the European Commission's report: RP 91: *Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations. Office for Official Publications of the European Communities, L-2985 Luxembourg, ISBN 92-828-1140-9.* All the SSM regulations mentioned above (i.e. SSMFS 2008:35, SSMFS 2008:31, SSMFS 2008:33 and SSMFS 2008:34) refer to general regulations for quality systems provided by the National Board of Health and Welfare in SOSFS 2005:12.

Registrants and licensees are required to ensure that the QA programme for medical exposures include measurements of the physical parameters of radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter. The regulations (SSMFS 2008:35, 19§) on general obligations in medical and dental practices using ionizing radiation require an acceptance test of new equipment before the first clinical use. Checks shall thereafter be periodically performed and especially after services that may influence the characteristics. The quality manual shall describe the acceptable characteristics of the equipment and action plans when deviations are detected / found.

For x-ray diagnostics (SSMFS 2008:31) it is required that the licence-holder shall have a QA programme which comprises checks of equipment as well of the working methods (9§). In the regulations, requirements for acceptance test (17§), and periodic and non-periodic measurements and controls should be described, including extent and frequency (18-19 §§). A technical measuring protocol shall be drawn up and signed for each equipment check and such protocols shall be kept so that long term trends of deviations may be detected (20§). Confirmed faults shall be corrected (21§). The required measurements and checks are specified per modality of equipment (conventional, panoramic, computed tomography, mammography) for medical and dental x-ray diagnostics. Most of the periodic measurements and controls are annually but a few are weekly or daily. Examples of annual measurements are checking the agreement between indicated and real tube voltage, relationship between dose (mGy) and indicated tube loading (mAs), weighted CTDI values and reference dose for mammography with standard phantom. The 7§ requires that the medical physicist should have a leading position in how mandatory checks of equipment are carried out/performed.

In nuclear medicine, SSMFS 2008:34, 7§, requires the licensee to have a quality manual (as part of the QA programme) which includes a description of procedures for checking the performance of gamma cameras, uptake monitors and other equipment used in the practice; a description of procedures for acquisition, calibration., administration and maintenance of RP instruments, instruments for the identification of radionuclides as well as for activity measurements. Furthermore 8§ requires that instrument for activity measurements shall be checked, and the results documented, with respect to function and stability at least once a month. The 5§ states that the

medical physicist shall participate in establishing and implementing the QA programme for equipment and procedures and have a leading position in developing methodology in connection with measurements of activity amounts delivered to patients as well as for the management and control of measurement instruments.

In radiation therapy, SSMFS 2008:33, 7-9§§, stipulate that the licensee shall have an established QA programme covering equipment control and checks of working methods. The quality manual shall include descriptions of the procedures for controlling the correct performance of equipment used for exposure, verifications, calibration and control and procedures for determining and verifying the doses in the radiation field. In addition to regular controls, the equipment shall be inspected after technical repair, maintenance or other work which may have affected the functionality, after recharging as well as whenever it is otherwise considered necessary. The outcome of inspections and service measures shall be documented and faults shall be corrected. SSMFS 2008:33, 11§ requires external that the quality manual shall contain a plan for external, independent, monitoring of the dose in the radiation field. Such monitoring shall always be done before new equipment is taken into clinical operation as well as when it otherwise is considered to be necessary. The medical physicist shall participate in the establishment and conduct of QA programme for equipment and procedures (SSMFS 2008:33, 5§).

M11

The Swedish Radiation Protection Act (SFS 1988:220) stipulates through 11 § that those installing or performing maintenance work on equipment capable to emit ionising radiation, shall ensure that RP devices are put into place and that other necessary RP measures are undertaken after installation or maintenance work.

Registrants and licensees are required to ensure that QA programmes for medical exposures include verification of the appropriate physical and clinical factors used in patient diagnosis or treatment. Regularly performed audits of the practice are required in the regulations regarding general obligations in medical and dental practices using ionizing radiation (SSMFS 2008:35, 21§). The use of any method or application regarding medical exposures shall be reconsidered if there are new findings on their effects or risks (SSMFS 2008:35, 7§).

As mentioned earlier, registrants and licensees are required to ensure that QA programmes for medical exposures include written records of relevant procedures and results. The regulations SSMFS 2008:35 require the inclusion into the QA programme of written manuals to be available at each equipment for all examinations or treatments that are routinely carried out. For x-ray diagnostics (SSMFS 2008:31) it is required that all equipment is provided with written method descriptions covering the examinations conducted. These descriptions shall contain *inter alia* exposure tables and information about dose reduction methods like compression and use of devices for protection of gonads or the thyroid. When applicable, the method descriptions shall contain alternative procedures or methods for examination of pregnant women (9§). It is also required (10§) that fluoroscopy times for interventional procedures and for x-ray equipment used outside the x-ray department shall be recorded in a logbook.

As already mentioned before, for nuclear medicine (SSMFS 2008:34) a quality manual that is part of the QA programme is required which shall include a description of the used procedures that ensure that the right patient will receive the correct radiopharmaceutical and the correct amount of activity; descriptions of the used procedures for adapting the amount of activity to be administered to children; a preparedness plan with measures aiming at mitigating the harmful effects if an in-

correct dose should be administered; and measures to be taken if a patient with radioactive substances remaining in the body should decease (7§).

Finally, for radiation therapy (SSMFS 2008:33) a quality manual that is part of the QA programme is required which shall include a description of the used procedures that make sure that the absorbed dose in the target volume corresponds to the planned dose for each patient (7§). The manual shall also include descriptions of used procedures for determining and verifying the doses in the radiation field (8§). The manual shall furthermore include descriptions of procedures preventing foreseeable faults which would result in unintentional or incorrect exposures (10§) and a plan for external, independent, monitoring of the dose in the radiation field (11§). Written method descriptions shall exist for all treatment methods. The descriptions shall specify each employee performing/assisting in the various steps of the treatment.

The licensees are required to ensure that QA programmes for medical exposures include verification of the appropriate calibration and conditions for operation of dosimetry and monitoring equipment in connection with nuclear medicine and radiation therapy practices. For nuclear medicine this has been described above, for radiation therapy (SSMFS 2008:33, 8-9§§) it is stipulated that the quality manual shall include descriptions of the procedures for checking the correct performance of equipment used for verification, calibration and control. SSMFS 2008:33, 21§, requires that suitable reference instruments shall be available for dose monitoring and checks. These instruments shall be calibrated at the National Standards Laboratory (or at equivalent laboratory) at least once every second year as well as when considered to be necessary. The functionality and the stability of the reference instruments shall be regularly checked.

SSM regulations do not explicitly require that QA programmes of registrants and licensees include, as far as possible, regular and independent quality audit reviews of the QA programme for radiotherapy procedures. SSMFS 2008:35, 21§, requires that audit of the practice shall be performed regularly.

The availability of documented RP plan, quality manual, routines, policies, instructions, protocols etc. and how they are implemented are reviewed and assesses during inspections, investigations in connection with unplanned events/accidents and to some extent during the authorisation process. During inspections it is controlled that the practice is conducted under good RP conditions, that the documentation regarding RP aspects is adequate, and that there is compliance between the documentation and how the actual activities are carried out in practice. Furthermore the presence of the required competence and fulfillments of responsibilities are checked. The implementation of the QA programme is assessed through interviews with personnel and visual inspection of the practice activities. Measurement protocols of the physical parameters of the radiological equipment are checked concerning measuring frequency and results. The calibration status of dosimetry and monitoring equipment is verified and compared with regulatory and QA programme requirements. During the authorisation process, the availability of an adequate RP plan and the competence of the recruited staff are examined prior to authorisation.

Regulations require the use of diagnostic reference levels (DRLs). The current DRLs are the outcome of a cooperation project among the Nordic countries and are based on national and international surveys and publications. The Nordic DRLs were first established in 1996 and were subsequently applied during a pilot study in 1999. Regulations on DRL formalism entered into force in 2002, in close cooperation with

the professions. The first assessment of patient doses with regulated DRLs was carried out in 2005.

DRL formalism for x-ray diagnostics is regulated through the regulations SSMFS 2008:31, 12§ and SSMFS 2008:20, as already mentioned above. DRLs are established for 12 examinations. Six are conventional x-ray examinations with DRL given as DAP-values: 1) heart and chest, chest health check-up, 2) coronary angiography (one or several vessels), 3) Barium enema with double contrast, 4) urography with urethra compression, 5) lumbar spine and SI-joints and 6) pelvis, hip joints (only PA/AP view). Four computed tomography examinations with DRL as CTDI and DLP-values for brain, lumbar spine, thorax/lungs, and abdomen examinations and two mammography examinations (screening and clinical) with DRL:s as average glandular dose both per exposure and per complete examination. For mammography DRL-values are also established for exposures with a standard phantom.

For x-ray examinations, SSMFS 2008:20, 6§, requires that the diagnostic standard dose (patient dose indicator) shall be determined for all specified examinations at least each third year. When changes of equipment or examination methodology are planned the expected effect on the diagnostic standard dose shall be analysed. Measurements of the diagnostic standard dose shall be performed in connection with changes and for unplanned changes, at least within three months. For equipment used for screening with mammography the diagnostic standard dose shall be determined annually.

M11

For nuclear medicine examinations the DRLs are established as average administered activities through the regulations in SSMFS 2008:34, 14§, and SSMFS 2008:4. Levels are stated for cerebral blood flow (2 levels, SPECT), lung perfusion (1 level, planar), myocardial perfusion (4 levels, SPECT), tumour localisation in abdomen/thorax (1 level, PET), Reno graph (2 levels, planar), skeletal (1 level, planar), thyroid (1 level, planar), thyroid uptake (1 level).

For examinations in nuclear medicine SSMFS 2008:4, 4§, requires that the average values of activity administered to a group of adult patients of normal size are determined for all specified examinations at least each third year. If the examination method or the equipment is altered such that the average values of activity administered could have been affected, a new corresponding average value of activity shall be determined.

Diagnostic standard dose is defined as the radiation dose for a certain type of examination, confirmed by the licensee and determined in the same way as applicable for the corresponding DRL (SSMFS 2008:20, 2§). Diagnostic standard doses shall be determined for all x-ray examination rooms where the corresponding examination is performed at least each three years and after changes that could influence the patient doses (SSMFS 2008;20, 6§). The results have to be reported to the SSM on request (SSMFS 2008:31, 12§). The same principle applies for nuclear medicine (SSMFS 2008:4, 4§, and SSMFS 2008:34, 14§).

SSM is responsible for establishing DRLs and does so through regulations. This is performed in close cooperation with the health care professions. SSM is responsible for revisions as can be deducted from SSMFS 2008:31, 12§ (x-ray examinations) and SSMFS 2008:34, 14§ (nuclear medicine). There are no DRLs established below which the licensees are required to take action, however, optimisation is a funda-

mental requirement as stipulated throughout the regulations and more specifically through SSMFS 2008:35, 3§.

For x-ray examinations, if the diagnostic standard dose exceeds the DRL, the reason for that shall be investigated and measures shall be taken as to reduce the dose (SSMFS 2008:31, 12§). The requirements are further accentuated in SSMFS 2008:20, 2 and 4 §§. A measuring protocol for the determination of diagnostic standard doses shall be established and be kept for at least three years (5§). The same applies for results from investigations on exceeding DRLs and information about measures taken (SSMFS 2008:35, 30§; SSMFS 2008:31, 12 and 25§§).

For nuclear medicine examinations, if the average values of activity administered to a group of adult patients of normal size exceed the DRLs, the reason for that shall be investigated and measures should be taken to optimise the examination (SSMFS 2008:34, 14§). The requirements are further accentuated in SSMFS 2008:4, 2 and 3§§. Measurement protocols from the determination of the average values of administered amounts of activity shall be kept for at least three years. (SSMFS 2008:4, 5§). The same applies for results from investigations on exceeding DRLs and corrective measures taken (SSMFS 2008:35, 30§, SSMFS 2008:34, 14 and 18 §§).

The verification is performed through regulated and established reporting systems, amid inspections, and in conjunction with investigating unplanned events. The requirements for determination and reporting of patient dose indicators allow for a continuous supervision on how regulated DRLs are respected.

Anyone who conducts a medical, dental or biomedical research project where test subjects are exposed shall ensure that the project is approved by the RP committee and the ethic committee (SSMFS 2008:35, 22§). It is required that dose constraints are established and used for persons not having a direct medical benefit from the exposure. If a licensee's practice comprises more than one clinic, a RP committee shall be established as part of the RP organisation. The committee shall consist of the medical physicist, the person or persons holding the radiological leadership (RALF(s)) and representatives for further practices as decided by the licensee. One of the responsibilities of the RP committee is to judge on research programmes in which volunteers are exposed to radiation and to assist the ethics committee in its judgments (SSMFS 2008:35 14-16§§). A licensee operating a minor practice, without a RP committee shall, for judging research programmes, consult the nearest local RP committee or the competent authority (SSMFS 2008:35, 23§). For research with radiopharmaceuticals and in accordance with the Medical Products Act (SFS 1992:859) and Ordinance (SFS 1992:1752), the Medical Products Agency is the competent authority. For other such research the SSM is assigned as the competent authority. The founding of, and the work of, a RP committee is checked during licensing and inspections. The RP plan and organisation must address the RP committee (SSMFS 2008:35 13-14§§) and the records from its meetings shall be kept (SSMFS 2008:35 16§). These protocols are reviewed and the data is compared with the information from e.g. interviewing personnel.

Regulations on general obligations in medical and dental practices using ionising radiation (SSMFS 2008:35, 4§) require that written instructions on suitable measures to minimise exposures of relatives or other persons supporting and comforting patients undergoing medical exposures shall be available. The instructions shall be adjusted to the circumstances of the patients exposures and include foreseeable situations where the supporting persons might be exposed. No specific dose constraints are given in these regulations, it is however required that the radiation

doses shall be as small as reasonably achievable with respect to the circumstances. Regulations concerning nuclear medicine (SSMFS 2008:34 16§) require an assessment of the radiation doses which relatives and members of the general public can be exposed to as guidance for when a patient can be discharged from hospital after treatment. It shall be unlikely that the effective dose will exceed: 0.3 mSv to any member of the general public; 1 mSv to children related to the patient; 3 mSv to adults related to the patient; 15 mSv for relatives aged 60 or more. Some values indicating when a patient can be discharged from hospital are provided in the general advice, clause 2. It is stated in SSMFS 2008:34 17§ that before a patient is discharged from hospital, the physician who has conducted the treatment shall ensure that the patient or the person accompanying the patient receives the information stipulated in the general advice, clause 2 and 3 as appropriate. The information shall be provided in writing and formulated so that it can be understood by a layman. For brachytherapy there are no numerical values for dose constraints given in the regulations. During inspection, documented routines for assessment of the radiation doses which relatives and members of the general public can incur when a patient is discharged from hospital after treatment are checked. During interviews with the staff it is controlled how routines are implemented, e.g. how patients and their relatives acquire the necessary information.

Maximum Activity for Patients in Therapy on Discharge from Hospital

International BSS 115, II.28
In order to restrict the exposure of any members of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and members of the public, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in Schedule III, Table III-VI. Written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

The Swedish regulations do not require that a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in the International BSS (1100 MBq for Iodine-131). Instead, the regulations concerning nuclear medicine (SSMFS 2008:34 16§) require an assessment of the radiation doses which relatives and members of the general public can be exposed to as guidance for when a patient can be discharged from hospital after treatment. It shall be unlikely that the effective dose will exceed: 0.3 mSv to any member of the general public; 1 mSv to children related to the patient; 3 mSv to adults related to the patient; 15 mSv for relatives aged 60 or more. SSM states in the general advice section of the regulations SSMFS 2008:34 examples of activity levels that fulfills the dose constraints given in SSMFS 2008:34, 16-17 §§ (regarding ^{131}I: 600 MBq). The Swedish regulations also require that a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides (or the person accompanying the patient) shall, on discharge, be provided with written instructions concerning contact with other persons and relevant precautions for radiation protection. In SSMFS 2008:34, clause 3, examples on how such information should be formulated are given [Material based on the report: *European Commission: Radiation Protection following Iodine-131 Therapy, Radiation Protection 97, Office for Official Publications of the European Communities, 1998, L-2985, Luxemburg, ISBN*

92-828-4194-4]. During inspections, written instructions and their use and implementation are verified.

Investigation of Accidental Medical Exposures

International BSS 115, II.29
Registrants or licensees shall promptly investigate any of the following incidents:

(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fraction differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;
(b) any diagnostic exposure substantially greater than intended or resulting in dose repeatedly and substantially exceeding the established guidance levels; and
(c) any equipment failure, accident, error, mishap, or other unusual occurrence with the potential for causing a patient exposure different from that intended.

International BSS 115, II.30
Registrants or licensees shall, with respect to any investigation required under paragraph II.29:

(a) calculate or estimate the doses received and their distribution within the patient;
(b) indicate the corrective measures required to prevent reoccurrence of such an incident;
(c) implement all the corrective that are under their own responsibility;
(d) submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Regulatory Authority; and
(e) inform the patient and his or her doctor about the incident.

The regulations do not explicitly require that registrants and licensees promptly investigate accidental medical exposures.

The Radiation Protection Ordinance stipulates that if there are reasons to believe that someone, due to a practice involving ionizing radiation, can have been damaged due to the radiation or if there has occurred mishap or incident which could be of importance from RP point-of-view, the legal person who is responsible for the practice (the licensee), shall immediately report this to the Swedish Radiation Safety Authority (Radiation Protection Ordinance SFS 1988:293, 5§). Furthermore, the Radiation Protection Act (SFS 1988:220, 6§) stipulates that the licensee must *take the measures and precautions necessary to prevent or counteract injury to people and animals and damage to the environment.*

The SSM regulations SSMFS 2008:35 (29§), and SSMFS 2008:51 (4§) require that an accidental medical exposure shall be reported to SSM as soon as possible, at least within a week. The report shall describe the accident and what kind of actions the licensee has taken to prevent similar accidents to happen again. When SSM re-

sponds to the initial report it is required that the licensee investigate the accident and report back to SSM about measured and calculated doses, the equipment/radiation source used, taken or planned actions etc. The regulations SSMFS 2008:34, 5§ item 6 (nuclear medicine) and SSMFS 2008:33, 5§, item 5 (radiation therapy) require both that a medical physicist shall participate in the investigation of any incident (including accident).

SSM's internal routine "*Investigation of unplanned events",* states that the licensee has the responsibility to investigate the incident and take necessary actions to prevent that a similar accident/incident reoccurs.

The regulations do not specify the actions that registrants and licensees must perform following an accidental medical exposure. SSMFS 2008:35, 29-30 §§, states that the licensee shall report the accidental exposure to the SSM (as described above). After that SSM receives the first report of an accident, the registrant or licensee is asked to send in a full description of the investigation and the results, including measured and/or calculated doses. At any point the licensee must provide the statistical data requested by the SSM. The actions are followed up by SSM during the next inspection or, alternatively, if a major accident occurred, SSM carry out a prompt site inspection, sometimes including an independent investigation of the event. It is not explicitly specified in regulations that the licensee must disseminate information from investigated accidents, but this is one of the issues that are included in SSM's inspections (and follow-up). SSM publishes some of the reported incidents on the home page for others to learn from the occurring events at other sites. SSM will inform other users of equipment involved in an accident if it is considered that the equipment caused or negatively influenced the event. According to the Act on Patient Safety, the National Board for Health and Welfare is responsible for issues on information to the patient and his or her doctor about accidental medical exposures. When accidents with substantial effects occur, SSM carries out special inspections. The purpose is to check on the result of the accident analysis, the measures taken to prevent reoccurrence, measures for mitigating effects etc., and to verify how they have been implemented. During some inspection, SSM investigates how the licensee follows its own routines, as described in quality manuals and management systems, regarding accidental medical exposure and if these routines satisfy the requirements.

Records

International BSS 115, II.31-32
Registrants and licensees shall keep for a period specified by the Regulatory Authority and make available, as required, the following records:

(a) in diagnostic radiology, necessary information to allow retrospective dose assessment, including the number of exposures and the duration of fluoroscopic examinations;
(b) in nuclear medicine, types of radiopharmaceuticals administered and their activities;
(c) in radiation therapy, a description of the planning target volume, the dose to the centre of the planning target volume and the maximum and minimum doses delivered to the planning target volume, the doses to other relevant organs, the dose fraction, and the overall treatment time; and
(d) the exposure of volunteers in medical research.

Registrants and licensees shall keep and make available, as required, the results of the calibration and periodic checks of the relevant physical and clinical parameters selected during treatment.

The Swedish regulations require that registrants and licensees keep records relating to patient doses. (a) For 12 specified x-ray examinations the licensees are requested to assess patient doses as an average for some 20 patients each third year and keep the records at least for three years. The records should comprise the number of exposures and the duration of fluoroscopy. However, the records comprise representative patient data and not data for individual identified patients (SSMFS 2008:20, 3§, 5-6 §§, and Appendix 1, General Advice SSMFS 2008:20, Item 2). The licensees are required to report the results on request to SSM and also data on number type of x-ray examinations including patient doses (SSMFS 2008:31, 12 and 25 §§). (b) The licensees are requested to assess the average administered activity for 11 specified nuclear medicine examinations for some 20 patients each third year and keep the records at least for three years (SSMFS 2008:4, 3-5 §§, and Appendix 1). In addition, the licensees have to report to SSM annually the mean activity and number of examinations for all types of nuclear medicine examinations and treatments (SSMFS 2008:34, 18§). However, the records comprise representative patient data and not data for individual identified patients. (c) In radiation therapy, there are requirements for the licensee to report the number and type of radiation treatments including the dose delivered to the target volume to SSM (SSMFS 2008:33, 29§). These data were asked for and reported the last time in year 2008. (d) SSM is normally not involved directly in the process of approving clinical research projects but occasionally this might happen (SSMFS 2008:35, 23§). The licensee is required to establish dose restrictions to be used in the research project.

It should be noted that other authorities than SSM require, in conjunction with therapy, that official records are kept, including document of relevance to radiation protection.

SSM requests the reports on patient dose assessments (x-ray diagnostics) and average administered activity (nuclear medicine) each third year. Licensees not responding are alerted and if necessary compliance is enforced. Three-year record keeping is checked by requesting both the current and the previous data. However, SSM does not have a documented routine for these activities. For the 11 specified examinations in nuclear medicine, the same procedures as above apply. SSM registers and stores

the annually reported data on average activities from all nuclear medicine departments. There is no obligation for the licensees to store their own data for a specified period. For radiation therapy, SSM is entitled (SSMFS 2008:33, 29§) to request data on number, type of treatments, and target doses but have so far only once made use of this option.

In radiation therapy, the licensee shall establish procedures and routines for function checks of equipment, assessment of the dose, and for calibration and check of measuring devices. The results of periodic checks and control after service shall be documented (SSMFS 2008:33, 8§ Items 1-4, 9§). There is however no specification for how long time the documents shall be kept. Reference instruments hall be calibrated at an accredited laboratory every second year (SSMFS 2008:33, 21§), there is however no requirements that the results of the calibration shall be kept and stored. At inspections the documentation of routines for calibrations and periodic control are scrutinised. Some measuring protocols and calibration certificates are requested, selected and checked.

For therapy with radiopharmaceuticals it is required that the device for measuring the activity has to be checked with respect to function and stability at least once a month. The results shall be documented (SSMFS 2008:34, 8 §). The medical physicist shall be responsible for that a measurement of the administered activity is performed before each treatment of a patient. These checks shall be signed (SSMFS 2008:34, 13§). For nuclear medicine therapy, during inspections the quality manuals are checked with respect to calibration routines.

M11

Authorisation

GS-R-1 requirement 5.2-5.6
For all facilities and activities, a prior authorization, a notification or an exemption shall be in force. Alternatively, activities of a particular type may be authorized in general to be performed in strict accordance with detailed technical regulations (such as the routine shipment of radioactive materials in packages approved under detailed transport safety regulations).

Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures. The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented. Thus, for example, a dental X ray machine may require only registration with the regulatory body, whereas for a radioactive waste repository a multistage authorization process may be required.
The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization. The operator shall be required to submit or make available to the regulatory body, in accordance with agreed time-scales, all information that is specified or requested. For complex facilities (such as a nuclear power plant) authorization may be carried out in several stages, each requiring hold points, separate permits or licences. In such cases, each stage of the process shall be subject to review and assessment, with account taken of feedback from the previous stages.
The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either:
(1) the granting of an authorization which, if appropriate, imposes conditions or limitations on the operator's subsequent activities; or
(2) the refusal of such an authorization.
The regulatory body shall formally record the basis for these decisions.

Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure. The procedure shall include requirements for the timely submission of applications for renewal or amendment of authorizations. For amendment and renewal, the associated regulatory review and assessment shall be consistent with the requirements of para. 5.3.

The Swedish legislation does not allow for exemption of practices undertaking medical exposures. All practices involving medical exposure require authorisation, either from the Government or the competent authority (the Swedish Radiation Protection Authority) empowered by the Government according to the Radiation Protection Act (SFS 1988:220) and the Radiation Protection Ordinance (SFS 1988:293). This includes dental radiology, x-ray, nuclear medicine and radiotherapy. All licensed dentists in Sweden are granted a general authorisation for using conventional x-ray equipment, with a nominal high voltage not exceeding 75 kV, intended for intra oral image receptors. SSM has no individual authorisation process for such practices. All other use of radiation sources and branches of activities, diagnostic or therapeutic, is subject to an individual authorisation process. As a consequence, notification is not an option since all medical practices need authorisation. Before granting a license, SSM evaluates to what extent the applicant has resources and routines to fulfill all regulations.

Applicants are required to submit information about the practice involving medical exposure they plan to carry out. Information on the RP organisation, shielding arrangements, used equipment, available competence and programme for education and training concerning radiation safety of patients, personnel, and the general public is required. Applicants must fulfill all requirements of the SSM regulations.

The initially available information is outlined and appended to the application forms, available through the SSM public web site. The RP organisation has to be adapted to the extent and type of practice to be carried out and shall be documented in an organisation plan. It is required that the responsibilities and co-operation forms for those involved in the work with ionizing radiation is detailed.

For all medical exposures it is required that for all radiological activities there is a radiological leadership available to the organisation (SSMFS 2008:35). Depending on the conducted activity this radiological leadership (RALF) must be assigned to a physician or dentist having specified specialist competence or a certain level of complementary education (SSMFS 2008:31, SSMFS 2008:33, and SSMFS 2008:34). For medical and dental radiology within the defined framework of specialist examinations, it is required that a medical physicist is available to the organisation (SSMFS 2008:35). For dental tomography examinations with panoramic radiograph, it is required that the RALF is assigned to a dentist with specialised competence in dental radiology but no medical physicist is required in such practices.

SSM follows the general process "*Tillståndspröva*" for review and assessment of applications prior to authorisation. The process includes detailed instructions (routines 89 and 90) for review and assessment of the applications. The routine 89 deals with all types of medical exposures as defined in SSMFS 2008:35 except dental practices which are covered by the routine 90.

SSM issues guidance to the operator on the format and content of documents to be submitted in support of an application. For medical and dental practices, wishing to use x-ray equipment there are written instructions and application forms available to be downloaded from the SSM web site. There is a specific set of instructions for dental practices and one for medical (x-ray, nuclear medicine and radiotherapy) ones. For nuclear medicine and radiotherapy there is no general guidance readily available – applications of these kinds are extremely rare and instructions are made available for each specific case when necessary. For the license application of high activity sealed sources (HASS), application forms, including detailed instructions, are also made available on the SSM web site.

Authorisation (Licences) can be limited to a specific site or for specific equipment. It can also be conditioned to be valid only under certain circumstances. For new types of instrumentation or applications which are not covered by existing regulation, limitations are usually set up considering national/international legislation and practice, international standards and in cooperation with professional organisations. Other types of conditions and limitations are described below.

For dental exposure, the use of x-ray equipment can be limited to certain procedures, based on the competence of the user. If panoramic x-ray equipment has a 3D optional module, it is required that the module is only used under the radiological leadership of a dentist with special competence in dental radiography. For portable x-ray equipment there is a range of limitations, such as normally using the equipment with a foot stand. For small medical x-ray practices all changes in equipment possession must be reported to SSM one month in advance for review and reassessment of the

authorisation. Larger x-ray diagnostic entities such as e.g. a county shall report the actual list of x-ray equipment once a year to SSM. In nuclear medicine, limitations are given on the maximum activity. In radiation therapy the use of high activity sealed sources require a contact for the back-end management of the source (de-commissioning) and financial guarantees for this. Regarding conventional dental x-ray equipment (not exceeding 75 kV) intended for intra-oral image receptors there exist a specific set of requirements listed in the regulations SSMFS 2008:5.

In general the use of medical equipment is regulated by the Board of Health and Welfare whereas the production of medical equipment is regulated by the Medical Products Agency. All types of equipment must have CE labeling.

Amendments to licences are not required in general, if a licensee has an authorisation for instance for medical x-ray procedures, it covers all activities within this discipline. Major changes in all practices, relative to the existing licence, however call for a new application and authorisation process. In the licence it is stated when, where and in which application fields and under what conditions the licence is valid, any divergence from these conditions calls for an assessment of the needs for a revised licence. If the authorisation is equipment specific, site specific, or requires another specific competence, a new application is required for additional equipment, change of site etc. All projects including screening must be reported to SSM prior to start (SSMFS 2008:35, 9§). The licensee can contact SSM via e-mail, telephone, fax or mail.

Inspection and Enforcement

GS-R-1 5.12 and 5.15
Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or regulations. In addition, the regulatory body shall take into account, as necessary, the activities of suppliers of services and products to the operator. Enforcement actions shall be applied as necessary by the regulatory body in the event of deviations from, or non-compliance with, conditions and requirements.

Inspection by the regulatory body, both announced and unannounced, shall be a continuing activity. If the regulatory body uses the services of consultants for the inspections, then it shall have the responsibility for taking any actions on the basis of these inspections.

The regulatory body carries out inspections of practices that perform medical exposures. No consultants are used in inspection work. An inspection programme for a period of 5 years exists. The programme is established by the SSM and is regularly updated (ref: "*Tillsynsplan sjukvård"*). According to the programme, each county council which is responsible for providing a significant proportion of the health care to the public should be inspected with a period of five (5) years. Private hospitals and clinics are not inspected that frequently but are also included in the inspection programme. Small private clinics and dental practices are seldom inspected. In the annual activities planning, a detailed inspection plan for the coming year is established. This yearly planning depends on workload and other prioritised tasks, as given in the Director Generals: "*GD:s inriktning för verksamhetsplanering*". In order to keep up with the inspection programme and the planned inspections from

year 2013 and onwards, four (4) new inspectors were planned to be employed during a 4-year period (2008-2012). So far three of these are employed.

SSM can, according to the routine no 106 undertake both announced and unannounced inspections of facilities carrying out practices involving medical exposures. However, SSM does not on a regular basis carry out unannounced inspections in this area.

There are yet no formal, documented requirements for qualifications, training and experience of inspectors (to be developed!) but only medical physicists perform inspections and they all have good RP qualifications. The medical physicist education includes knowledge in relevant areas such as dosimetry etc. In the responsible SSM unit there are for each area (x-ray, nuclear medicine and radiation oncology) at least 1-2 inspectors being specialists in the respective area. SSM provides courses for new inspectors which cover interview training, public administrative legislation and procedures etc. The level of competence of each inspector is annually evaluated during individual performance interviews. The inspectors maintain competence through international and national conferences and courses within the medical exposure field (ESTRO, RSNA; ICRP and Swedish continuous physics development programme).

An inspection team consists of two or more inspectors of which one is the inspection leader. The team shall have sufficient knowledge in the area to be reviewed. The inspection leader should well know the process "*Inspect*" and have experience in carrying out inspections. Also the other inspectors should have good knowledge and proven competence in inspection work. To reach this level, newly employed personnel participate in "on the job training". In practice, an individual assessment of each inspector's competence is performed by the unit manager. In order to be available to work independently, it is required that inspectors for medical exposures have participated "under supervision" in a number of inspections.

After an accident, the normal procedure is that the licensee performs an investigation and reports to the regulatory body on investigation results such as root causes, doses, measures taken etc., however, in more severe cases SSM performs a rapid on-site inspection and draws its own, independent conclusions.

SSM does not usually follow the actual staff work; however, during inspections routines and methods are reviewed and the staff is interviewed on their day to day work procedures.

The National Board of Health and Welfare (*Socialstyrelsen* – health standards, patient safety, supervises operations and licensed health care professionals), the Swedish Work Environment Authority (*Arbetsmiljöverket* – general issues about working environment), and the Medical Products Agency (*Läkemedelsverket* – drugs and medical devices) also perform inspections in the medical sector.

Development of Regulations and Guides

GS-R-1 5.25 – 5.28
The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated. Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate time-scales.

The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations.

Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary. These guides may also provide information on data and methods to be used in assessing the adequacy of the design and on analyses and documentation to be submitted to the regulatory body by the operator.

In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards.

SSM develops regulations to cover practices and facilities performing medical exposures and issues these regulations in its Code of Statutes (SSMFS). The Radiation Protection Act (SFS 1998:220, 12§) constitutes the legal basis for these regulations and the Radiation Protection Ordinance (SFS 1988:293, 7-12§§) empowers the Swedish Radiation Safety Authority to issue such regulations. When developing regulations, internationally recognised safety standards and recommendations are taken into account (EU directives, EU guidelines concerning implementation of the medical exposure directive, IAEA standards and recommendations, standardisation documents from the IEC). SSM has, as already earlier mentioned, issued regulations covering all practices and facilities performing medical exposures:

- SSMFS 2008:35 *Regulations and General Obligations in Medical and Dental Practices using Ionising Radiation*,
- SSMFS 2008:31 *Regulations on X-ray Diagnostics,*
- SSMFS 2008:33 *Regulations on Medical Radiotherapy, and*
- SSMFS 2008:34 *Regulations and General Advice on Nuclear Medicine*.

The regulations establish requirements which all operators of practices and facilities performing medical exposures must comply with. They also give the framework for more detailed requirements given as conditions for individual licences, however these are not very many. One example is that the tomographic function of dental panorama equipment is not allowed to be used unless a specialist in dental radiology is involved. Another example is that the summed activity which may be handled in a nuclear medicine practice is limited.

Proposed regulations are always submitted for comments to other authorities, licensees, registrants, professional organisations, and other concerned bodies (including the European Commission). Before approval of regulations due consideration shall be taken to the received comments. The regulations were developed, as appropriate, in close cooperation with the National Board of Health and Welfare. The regulations concerning diagnostic reference levels:

- SSMFS 2008:4 *Regulations and General Advice on Diagnostic Reference Levels within Nuclear Medicine, and*
- SSMFS 2008:20 *Regulations and General Advice on Diagnostic Standard Doses and Reference Levels within Medical X-ray,*

were developed in close cooperation with the appropriate professional societies. SSM does not systematically develop guides to cover practices and facilities performing medical exposures. However, apart from those already listed together with the regulations above, SSM has issued:

- SSMFS 2008:29 *General Advice on the Competence of Radiation Protection Experts, and*
- SSMFS 2008:42 *General Advice on Performance Specifications for Purchasing Equipment for X-ray Diagnostics.*

SSM has issued non-mandatory guides concerning for example the RP organisation and educational matters.

References

SFS 1942:740 Swedish Code of Juridicial Procedure *("Rättegångsbalken")* (Ds. 1998:6)
SFS 1988:220 Radiation Protection Act
SFS 1988:293 Radiation Protection Ordinance
SFS 1992:859 Medical Products Act
SFS 1992:1752 Medical Products Ordinance
SFS 1993:584 Act on medical devices
SFS 1993:876 Ordinance on Medical Devices
SFS 2003:460 Act Concerning the Ethical Review of Research Involving Humans

91/412/EEC European Commission Directive laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products, July 23, 1991, L 228/70, 17.8.91

2003/94/EC European Commission Directive laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, October 8, 2003, L262/22, 14.10.2003

LVFS 1999:4 (as amended by LVFS 2005:10) Medical Products Agency's Regulations and General Advice on Control of Radiopharmaceuticals
LVFS 2003:11 Medical Product Agency's Regulations on Medical Devices

SOSFS 2005:12 Management Systems for Quality and Patient Safety in Health Care and Medical Sector

SSMFS 2008:4 Regulations and General Advice on Diagnostic Reference Levels within Nuclear Medicine
SSMFS 2008:5 Regulations and general advice for Dental X-ray Diagnostic using Intra-oral Image Receptor
SSMFS 2008:20 Regulations and General Advice on Diagnostic Standard Doses and Reference Levels within Medical X-ray
SSMFS 2008:29 General Advice on the Competence of Radiation Protection Experts

SSMFS 2008:31 Regulations on X-ray Diagnostics
SSMFS 2008:33 Regulations on Medical Radiotherapy
SSMFS 2008:34 Regulations and General Advice on Nuclear Medicine
SSMFS 2008:35 Regulations and General Obligations in Medical and Dental Practices using Ionising Radiation
SSMFS 2008:42 General Advice on Performance Specifications for Purchasing Equipment for X-ray Diagnostics

IEC 60601-1 (International Electrotechnical Commission) Medical equipment|medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-2-7 (International Electrotechnical Commission) Medical electrical equipment – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators

Kompetensbeskrivningar för sjukhusfysiker, (In Swedish) Artikel nr. 2001-105-1, ISBN 91-7201-519-5, Ale Tryckteam, Bohus, april 2001

Screening with mammography – basis for recommendations on screening for breast cancer, National Board of Health and Welfare (SoS) (In Swedish) Report No. 1998-03-017.

Radiation Protection 91, European Commission, Directorate-General Environment, Nuclear Safety and Civil Protection, 1997, *Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations*, Office for Official Publications of the European Communities, L-2985 Luxembourg, ISBN 92-828-1140-9.

Radiation Protection 97, European Commission, Directorate-General Environment, Nuclear Safety and Civil Protection, 1998, *Radiation Protection following Iodine-131 Therapy*, Office for Official Publications of the European Communities, L-2985, Luxemburg, ISBN 92-828-4194-4.

Radiation Protection 118, European Commission, Directorate-General for the Environment, 2000, "*Referral Criteria for Imaging*", ISBN 92-828-9454-1 (electronic update posted in 2008 by Directorate-General for Energy and Transport Directorate H — Nuclear Energy Unit H.4 — Radiation Protection on their website).

STYR2011-89 (In Swedish) Hantering av tillståndsärenden för medicinsk verksamhet
STYR2011-90 (In Swedish) Hantering av tillståndsärenden för odontologisk verksamhet

*"Tillsynsplan hälso- och sjukvården 200-2013" (In Swedish), (*Inspection plan – Health Care and Medical Sector), ML-Protokoll 59/2009, 2009-04-06

11.3 Occupational Radiation Protection

Counterparts

Jan Lillhök
Head of Section
Nuclear Power Plant Safety
+46 8 799 42 67
Jan.Lillhok@ssm.se

Helene Jönsson
Head of Section
Radiation Protection
+46 8 799 43 74
Helene.Jonsson@ssm.se

Peter Hofvander
Analyst
Radioactive Materials
+46 8 799 41 25
Peter.Hofvander@ssm.se

M11

Assessment for IAEA requirements

Swedish workplace legislation is mainly based on the Work Environment Act and the supervisory work of the Swedish Work Environment Authority. This framework sets up the main structures for cooperation and strategic and systematic work environment activities between employers, employees and their representatives.

Hence, the Radiation Protection Act does not cover some of the general worker liabilities but does impose the responsibility of workplace radiation protection arrangements on the licensee of the practice. Some of the applicable IAEA requirements in this area are not addressed by the radiation protection legislation but are covered by other acts or regulations.

The Swedish system is based on the responsibility of the parties carrying out the activities. For example, in contrast to the wording of the IAEA's standards, the Swedish system offers no training companies approved by a government authority; parties carrying out activities/practices are in charge of employee training and defining the kind of training the personnel need. In addition, there are neither approved companies for carrying out workplace monitoring nor external undertakings that register individual doses as mentioned in the IAEA's standards. The National Dose Register is kept by SSM.

The IAEA Safety Standards place more emphasis on the shared responsibility for licensees, registered parties carrying out the activities, contractors and employees. This is only partly the case in the radiation protection legislation (e.g. sharing of dose information), while this is more evident and developed in the overall work environment legislation as described above.

This area shows close compliance with the IAEA's standards.

Strengths

The legislation is well developed with clear allocations of responsibilities. The licensee or party carrying out the practice involving ionising radiation is responsible for its work and the connected RP arrangements.

The Swedish legislation has sometimes more details related to medical examinations, special work activities and the content of quality manuals but in general the system is not descriptive.

The requirements on optimisation for nuclear facilities are well developed and implemented since many years. The use of dose constraints and ALARA-programs has a long tradition.

Areas of improvement

The regulations of the SSM do not impose requirements on (good) safety culture at work places, only indirectly so. SSM should review the need to introduce such requirements in the regulations.

Basic regulations are issued for provisions on the protection of workers and the general public in SSMFS 2008:51. The same requirements are presently imposed by other regulations specific for certain practices but they use different wordings and there is room for harmonization without negatively affecting the use of a graded approach. Requirements already stated in SSMFS 2008:51 could be removed from the more detailed regulations.

The regulations on dose and dose commitments will need to be reviewed, e.g. SSMFS 2008:51. Such a review should include the assessment of the need to further develop the regulations for certain areas (airline crews, emergency preparedness personnel, underground workers etc.)

In a strict sense the SSM regulations do not meet the requirements imposed on the employee responsibility regarding RP. These are mostly covered by the general work environment legislation and the RP legislation puts the main responsibility on the licensees. The RPA nevertheless clearly states that the employee should use PPEs and take the measures necessary to contribute to good RP work conditions. It could be worth reviewing whether the present balance is correct, without compromising the main responsibility of the licensee.

The ability and appropriateness of Swedish RP education should be reviewed. This has been stated by SSM as a conclusion in an investigation ordered by (and reported to) the Ministry of Environment in 2011.

Legal / Regulatory Framework

GS-R-1, 2.2
There are certain prerequisites for the safety of facilities and activities. These give rise to the following requirements for the legislative and governmental mechanisms of States:
(1) A legislative and statutory framework shall be established to regulate the safety of facilities and activities.

(2) A regulatory body shall be established and maintained which shall be effective-

ly independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety.

(3) Responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides.

…

(7) Adequate infrastructural arrangements shall be made for the safe transport of radioactive material.

…

International BSS 115 II-5 and II-6

The occupational exposure of any worker shall be so controlled that the following limits be not exceeded:

(a) an effective dose of 20 mSv per year averaged over five consecutive years;
(b) an effective dose of 50 mSv in any single year;
(c) an equivalent dose to the lense of the eye of 150 mSv in a year; and
(d) an equivalent dose to the extremities (hand and feet) or the skin of 500 mSv in a year.

For apprentices of 16 to 18 years of age who are training for employment involving exposure to radiation and for students of age 16 to 18 who are required to use sources in the course of their studies, the occupational exposure shall be so controlled that the following limits be not exceeded:

(a) an effective dose of 6 mSv in a year;
(b) an equivalent dose to the lense of the eye of 50 mSv in a year; and
(c) an equivalent dose to the extremities or the skin of 150 mSv in a year.

M11

International BSS 115 2.28

A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency, which shall ensure that….

International BSS 115 1.9

The general responsibilities of principal parties, within the requirements specified by the Regulatory Authority, are:

(a) to establish protection and safety objectives in conformity with the relevant requirements of the Standards; and
(b) to develop, implement and document a protection and safety program commensurate with the nature and extent of the risks associated with practices and interventions under their responsibility and sufficient to ensure compliance with the Standards, and….
…
(c) to establish arrangements , through representatives if appropriate, for facilitating consultation and co-operation between all relevant parties with respect to protection and safety; and
(d) to keep appropriate records regarding the discharge of their responsibilities.

International BSS 115 3.9

Each registrant or licensee responsible for sources for which prompt intervention may be required shall ensure that an emergency plan exists that defines on-site responsibilities and takes account of off-site responsibilities appropriate for the source and provides for implementation of each relevant form of protective action, as set out in Appendix V.

International BSS 115 2.31
Qualified experts shall be identified and made available for providing advice on the observance of the Standards.

The regulatory framework established in Sweden regarding safety of facilities and activities and Occupational Radiation Protection (ORP) in particular consists of the following legislation:

- **The Radiation Protection Act (RPA)** (SFS 1988:220) has the objective to protect people, animals and the environment from the harmful effects of radiation. The Act describes overall general responsibilities, general responsibilities for licensees, workers, and obligations and rights of the Government and authorities.
- **The Radiation Protection Ordinance** (SFS 1988:293) gives further instruction from the Government, assigns the *Swedish Radiation Safety Authority* (SSM) as the main competent authority in this area (licensing, supervision, etc.) with the right to issue binding radiation protection regulations in its Code of Statutes SSMFS.
- **The Instructions for the Swedish Radiation Safety Authority** (SFS 2008:452) states that SSM is the central administrative authority for the protection of peoples health and the environment against harmful effects of ionising and non-ionising radiation and defines the missions and tasks of the Authority. The Ordinance covers all of the Authority's fields of expertise and addresses issues connected to duties of international agreements and conventions.
- **The Act of Transport of Dangerous Goods** (SFS 2006:623) and Sections 1.7.2 of part I in *ADR-S* and *RID-S*, respectively, require the use of radiation protection programmes in connection with transports.
- **The Ordinance of Transport of Dangerous Goods** (SFS 2006:311) assigns SSM as the responsible supervision authority in matters of radiation protection.

Of importance is also the general legislation in the Work Environment Act (SFS 1977:1160) and the regulations of the Work Environment Authority.

Most regulations issued by SSM contain paragraphs that address ORP issues. However, there are two general ORP regulations: SSMFS 2008:51 Regulations on basic requirements for protection of workers and the public in connection with work involving ionising radiation and SSMFS 2008:52 Regulations on outside (itinerant) workers at work with ionizing radiation (as amended by SSMFS 2010:1, 30 March 2010).

The Swedish regulations specify dose limits for the occupational exposure of any worker. The regulations SSMFS 2008:51, 3rd chapter, 2§ stipulates the dose limits, more or less exactly as stated in the International BSS, paragraphs II-5 and II-6. Persons less than 18 years of age may not be assigned to any work which would result in their being exposed workers (RPA, 16§). For students and apprentices between 16 and 18 years, special dose limits apply (SSMFS 2008:51, 3rd chapter, 2§) which are the same as those of International BSS, II-6. Furthermore, additional requirements regarding pregnant and breast-feeding women (protection of foetus and small children) are given in the 3rd chapter, 5-7§§.

The Swedish regulations allow for temporary changes of the dose limits under special circumstances as specified in SSMFS 2008:51, 10-13§§. As far as can be controlled (is known) from records, these provisions have never been utilised in Sweden. The regulations do provide guidance for limitation of exposures of workers undertaking work (interventions) in emergency situations (SSMFS 2008:51, 14§).

The Swedish regulations do not explicitly require the fostering and maintaining of a good safety culture to encourage a questioning and learning attitude to protection and safety (PAS) and to discourage complacency. However, in connection with requirements on optimisation of PAS at nuclear facilities (SSMFS 2008:26, 5 §) and barriers & the defence-in-depth concept (General Advice to SSMFS 2008:1, 2nd chapter, 1§) the necessity of a good safety culture is addressed.

There are no immediate plans to implement requirements on safety culture but there are ongoing discussions in all areas on how to implement safety culture requirements in the SSM regulations. SSM also actively participated in the European research project TRASNUSAFE, WP2-*Relationship between "radiation protection and ALARA" and "safety culture"*. Furthermore, the ongoing review of the Swedish safety and RP legislation will address this topic.

The SSM has several regulations in place which require reporting and recording of incidents (the prompt reporting is also required in the RP Ordinance, SFS1988:293, 5§), which subsequently leads to SSM requirements (case-by-case decisions) on analysis of the event, corrective actions, measures to prevent reoccurrence etc.). General organizational and competence requirements on RP are found already in the RPA (SFS 1988:220, 26-27§§) and further provisions on organizational arrangements, training and qualifications are given in several SSM regulations and in the General Advice (SSMFS 2008:29) on competence of radiation protection experts.

The SSM does not regulate the allowed radon concentration at work places (including mines) or allowed radiation dose to air crew. The Swedish Work Environment Authority and the Air Navigation Services of Sweden are the competent authorities in these areas. Limits for allowed radon concentration are issued by the Swedish Work Environment Authority (currently 400 Bq/m^3, except for mines and areas where ore is handled, where it is 2.5 $MBqh/m^3$ per year, AFS 2005:17).

The Swedish regulations do require the development and implementation of a radiation protection program to reflect the application of management responsibility for radiation PAS. For nuclear facilities this is formulated in SSMFS 2008:26 4-5 §§, and 10§. For medical and dental practices, similar requirements can, for example, be found in the regulations SSMFS 2008:35 13-17§§, for industrial radiography in SSMFS 2008:25 3§, 5§, and 8§, and for non-nuclear industry practices in SSMFS 2008:40 3§. For trading practices, such requirements are found in the generic license conditions S-137, #1, #7 and for transport in the Swedish ADR-S and RID-S, part I, 1.7.2. It should be emphasized that the requirements are formulated using a "graded approach".

The regulations SSMFS 2008:9, 9§ (for practices involving high activity sealed sources, HASS[1]) and SSMFS 2008:15, 5§ (nuclear facilities) requires that an emergency plan exists which defines on-site responsibilities. It should be noted that other legislation, such as the Civil Protection Act (SFS 2003:778) and Ordinance (SFS 2003:789) regarding protection against accidents with serious potential consequences for human health and the environment, requires preventive measures and emergency preparedness to be arranged by the owner or operator of a facility with dan-

[1] See also the European Council Directive 2003/122/Euratom **on the control of high-activity sealed radioactive sources and orphan sources** from December 22, 2003, EGT L346, 31.12.2003

gerous activities. The Act further defines the responsibilities for the individual, the local communities, and the state in cases of serious accidents, including radiological accidents. The County Administrative Board is obliged to make a radiological emergency response plan. The Swedish Civil Contingencies Agency is responsible, at the national level, for the coordination and supervision of the preparedness for the rescue service response to release of radioactive substances.

The Swedish regulations require that Qualified Experts are identified and made available for providing advice on the observance and implementation of PAS. A general advice on the competence of RP experts is issued in SMSFS 2008:29. In some cases SSM issues license conditions on a RPE, for instance in connection with veterinarians using unsealed radioactive sources. Identification of a qualified expert is required in the regulations concerning the following practices:

- SSMFS 2008:24 3-4§§ nuclear facilities
- SSMFS 2008:25 8§ industrial radiography
- SSMFS 2008:27 5§ accelerators and use of sealed radiation sources
- SSMFS 2008:28 5§ laboratory work with unsealed radiation sources
- SSMFS 2008:35 12§ medical and dental exposures

General Responsibilities of Registrants, Licensees and Employers

International BSS 115, I.1-I.2
Registrants and licensees and employers of workers who are engaged in activities involving normal exposures or potential exposures shall be responsible for:

(a) the protection of workers from occupational exposure; and
(b) compliance with any other relevant requirements of the Standards.

Employers who are also registrants or licensees shall have the responsibilities of both employers and registrants or licensees.

International BSS 115, I.4 (a) – (k)
Employers, registrants and licensees shall ensure, for all workers engaged in activities that involve or could involve occupational exposure, that:

(a) occupational exposures be limited as specified in Schedule II,
(b) occupational protection and safety be optimised in accordance with the relevant principal requirements of the Standards;
(c) decisions regarding for occupational protection and safety be recorded and made available to the relevant parties, through their representatives where appropriate, as specified by the Regulatory Authority;
(d) policies, procedures and organizational arrangements for protection and safety be established for implementing the relevant requirements of the Standards, with priority given to design and technical measures for controlling occupational exposures;
(e) suitable and adequate facilities, equipment and services for protection and safety be provided, the nature and extent of which are commensurate with the expected magnitude and likelihood of the occupational exposure;
(f) necessary health surveillance and health services be provided;
(g) appropriate protective devices and monitoring equipment be provided and arrangements made for its proper use;
(h) suitable and adequate human resources and appropriate training in protection and safety be provided, as well as periodic retraining and updating as required in order to ensure the necessary level of competence;
(i) adequate records be maintained as required by the Standards;

(j) arrangements be made to facilitate consultation and co-operation with workers with respect to protection and safety, through their representatives where appropriate, about all measures necessary to achieve the effective implementation of the Standards; and
(k) necessary conditions to promote a safety culture be provided.

International BSS 115, I.6-7, I.13, and I.30
Registrants or licensees shall, as a precondition for engagement of workers who are not their employees, obtain from the employers, including self-employed individuals, the previous occupational exposure history of such workers and other information as may be necessary to provide protection and safety in compliance with the Standards.

If workers are to be engaged in work that involves or could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source shall provide:
(a) Appropriate information to the employer for the purpose of demonstrating that the workers are provided with protection in accordance with the Standards; and
(b) such additional available information about compliance with the Standards as the employer may request prior to, during and after the engagement of such workers by the registrant or licensee.

M11

Registrants and licensees shall, as a precondition for engagement of workers in activities that involve or could involve exposure from a source not under the registrant's or licensee's control, provide the employer with any information about worker protection under the Standards which the employer requests in order for the employer to demonstrate compliance with other applicable laws or regulations governing workplace hazards.
If workers are engaged in work that involves or could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall co-operate by the exchange of information and otherwise as necessary to facilitate proper protective measures and safety provisions.

International BSS 115 I.8-9, I.12, I.16-17, I.29
Employers, registrants and licensees shall take such administrative actions as are necessary to ensure that workers are informed that protection and safety are integral parts of a general occupational safety and health programme in which they have certain obligations and responsibilities for their own protection and the protection of others against radiation and for the safety of sources.

Employers, registrants and licensees shall facilitate compliance by workers with the requirements of the Standards.

Employers, registrants and licensees shall record any report received from a worker that identifies circumstances which could affect compliance with the Standards, and shall take appropriate action.

A female worker should, on becoming aware that she is pregnant, notify the employer in order that her working conditions may be modified if necessary.

The notification of pregnancy shall not be considered a reason to exclude a female worker from work; however, the employer of a female worker who has notified pregnancy shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public.

Registrants and licensees shall minimize the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate protective measures and safety provisions, including well engineered controls and satisfactory working conditions.

The Swedish legislation (RPA SFS 1988:220, 6-7§§) requires that anyone performing a practice involving ionising radiation is responsible for the protection of workers. In the SSM regulations SSMFS 2008:51, 2nd chapter, 1§, general responsibilities are stipulated (justification, optimisation, application of dose limits).

The regulations SSMFS 2008:52 (amended by SSMFS 2010:1) require cooperation between the licensee (performing the practice) and the contractor. The new amendments (SSMFS 2010:1) require that both the licensee (principal) and the contractor have a legal responsibility in accordance with SSMFS 2008:52 4-5, 7§§. The licensee shall cooperate with the contractors and they shall apply the same legislation/regulations for all personnel (certify medical condition; verify dose data and ensure that limits/constraints are upheld; ensure adequate education, training; supply suitable protective equipment; ensure the use of suitable dosimeter(s) etc.; ensure proper monitoring, registration and report of required dose data to national dose register).

The responsibilities of registrants, licensees and employers of workers for the protection of workers in activities involving normal and potential exposures, and for the compliance with the regulations are clear from legislation and regulations. RPA (SFS 1988:220, 6-7§§) stipulates that anyone performing a practice involving radiation shall,

- according to the nature and the conditions of the practice, prevent or counteract injury to people and animals and to the environment; supervise and maintain RP at the site, on the premises and in other areas where radiation occurs; and properly maintain technical devices and equipment for measuring and radiation protection used in the practice.
- be responsible for ensuring that those who are employed are familiar with the circumstances, conditions and regulations relating to the practice, and are informed of the associated risks.
- ensure that the employed personnel have the requisite training and know what measures must be taken to ensure that radiation protection work functions in a satisfactory manner.

Furthermore, the Act also states (7a§) that this responsibility encompasses, to the extent needed to protect the workers, employers who engage workers at a site where a practice involving radiation is carried out. Section 8 of RPA (SFS 1988:220, 8§) requires that persons engaged in activities with radiation, or work where a practice involving radiation is carries out, shall use the necessary safety equipment and take other measures that are required to ensure sound radiation protection.

The limitation of occupational exposures is regulated by SSMFS 2008:51, 2nd chapter, 1§, #3 (general responsibilities); 3rd chapter, 2§ (dose limits); and 5th chapter, 1§ (monitoring), 9-10, 12§§ (monitoring). The dose limits are the same as recommended by the ICRP and in the International BSS (effective dose 50 mSv/year and 20 mSv/year as average over 5 consecutive years) both for workers, stu-

dents/apprentices, the general public, and for pregnant women. Changes (lower limits) are expected with the introduction of the new EU BSS.

Optimisation of occupational protection and safety is stipulated in SSMFS 2008:51, 2nd chapter, 1§ *Anyone performing a practice involving ionising radiation shall ensure that;* #2: *the radiation protection is optimised, which means that each exposure of persons shall be limited to the extent reasonably achievable taking economic and social factors into account…*Further requirements and specifications on optimisation are found e.g. in SSMFS 2008:35, 3§ (medical and dental exposures), SSMFS 2008:26 4-5 §§ (nuclear facilities).

There are no specific requirements in the Swedish regulations formulated such that "*decisions taken regarding measures for occupational radiation protection and safety are recorded*". The requirements of the regulations address documented quality assurance programs (including routines for RP activities and/or RP programmes). For nuclear facilities, it is required that very many documents must be archived (applications, licences, construction requirements, SAR, ASAR, instructions on operation and deviations with connection to RP, event and incident reporting, RP instructions, dose records, emergency plans, annual reports, results from environmental monitoring, records on waste management etc.) for varying time periods (10-50 years up to indefinite) according to the regulations SSMFS 2008:38 on archiving at nuclear facilities. In connection with other regulations concerning nuclear facilities there are explicit requirements for documentation in SSMFS 2008:1, 8§ (documentation of management system including routines and instruction) and SSMFS 2008:26, 5§ (goals and needed actions of ALARA programme). There are of course, requirements on documentation of dose, dose rate and release monitoring data, in connection with RP activities.

M11

The regulations require employers, registrants and licensees to ensure that policies, procedures and organisational arrangements for protection and safety are established:

- SSMFS 2008:11, 2-6 §§ shielding and design of premises for therapy and diagnostics
- SSMFS 2008:35, 11-13 §§ management systems for medical and dental practices
- SSMFS 2008:30, 3§ management systems in veterinary medicine
- SSMFS 2008:25, 3§, 28-31 §§ management system and requirements on design and technical measures in connection with industrial radiography
- SSMFS 2008:27, 3§ management system requirements for practices with accelerators and sealed sources
- SSMFS 2008:28, 3§ , 10-18§§ management systems and requirements on design and technical measures for practices with open radioactive sources
- SSMFS 2008:1 7-9 §§, SSMFS 2008:26, 4§ management system requirements for nuclear installations

RP requirements for shielding, construction etc. of nuclear facilities were not issued in regulations but rather, at the time, in decisions and licence conditions.

The regulations do require that suitable and adequate facilities, equipment and services for protection and safety are provided, the nature and extent of which are commensurate with the expected magnitude and likelihood of the occupational exposure. First of all this is generally addressed in RPA, 6§ as an obligation of anyone

conducting a practice involving radiation, but is also more specifically addressed in several of the SSM regulations: SSMFS 2008:25 (industrial radiography), SSMFS 2008:27 (practices with accelerators and sealed sources), SSMFS 2008:26 (radiation protection at nuclear facilities), SSMFS 2008:28 (laboratory work with open radiation sources), SSMFS 2008:11 (shielding of premises for therapy and diagnostics). Requirements on the necessary health surveillance (medical examinations) and health services are described in the RPA (SFS 1988:220, 18§) and in SSMFS 2008:51, 6th chapter, 1§. Sweden does not support generic screening (x-ray) of lungs.

The Swedish regulation requires that appropriate protective devices and monitoring equipment are provided and that arrangements are made for their proper use. The mandatory use of protective equipment is derived from overall requirements in the RPA and the regulatory requirements on optimisation. The RPA, 8§ require that persons engaged in practices involving radiation shall use the necessary safety equipment and SSMFS 2008:51, 4th chapter 11-12 §§ (basic requirements), 5th chapter, 1§, 6-8§§ (measurement and reporting of doses) addresses monitoring of radiation and doses. Furthermore, explicit requirements regarding protective equipment, protective gloves, contamination control etc. are found in some SSM regulations, e.g. SSMFS 2008:28, 21§, 23-28§ (practices with open radiation sources).

The regulations require employers, registrants and licensees to ensure that adequate human resources and appropriate training in protection and safety are provided, as well as periodic training and updating. Specific and general requirements of adequate human resources are found in SSMFS 2008:26, 4§ (nuclear facilities), SSMFS 2008:1 7-9§§ (management system at nuclear facilities). Requirements for human resources/information/education/training and retraining are found in RPA, 7§, in several of the SSM regulations, SSM licence conditions regarding trading practices, and in transport regulations ADR-S, section 1.7.2.5 (regarding transport personnel). Radiation protection experts are also required: SSMFS 2008:24, 3§ (RPE/RP manager at nuclear facilities); SSMFS 2008:25, 8§ (industrial radiography); SSMFS 2008:27, 5§ (accelerators and sealed sources); SSMFS 2008:28, 5-6§§ (laboratory work with open sources); 2008:35, 12§ (medical and dental practices).

According to the regulations in SSM FS (2008:38) concerning archiving at nuclear facilities the licensee shall keep an archive of any documentation relating to the operation of radiation protection. The archive should be handled and managed so that all information can be read and to be transferred to a different medium. Documentation that can be difficult to read because of age shall be transferred to new data carriers before defects occur. The documentation should be stored in cabinets or archive facilities that meet requirements of the National Archives on archives premises. Several of the SSM regulations require recording and record keeping: e.g. SSMFS 2008:51, 5th chapter 9-10§§ (radiation dose and monitoring data); SSMFS 2008:9 (data on HASS[2], high activity sealed sources); SSMFS 2008:28, 29§, 36§ (journals during laboratory work, records of radioactive substances, and results); SSMFS 2008:51, 6th chapter, 9-10§§ (health surveillances); SSMFS 2008:30 11§ and 26§ (x-ray equipment in veterinary work); SSMFS 2008:27, 21§ (instrument calibration data at accelerators or sealed sources practices); SSMFS 2008:40, 18§ (sources of industrial use) and several other regulations on medical and dental exposures, and more specifically for x-ray diagnostics, medical radiation treatments, non-nuclear industrial practices etc.

[2] [2] See also the European Council Directive 2003/122/Euratom **on the control of high-activity sealed radioactive sources and orphan sources** from December 22, 2003, EGT L346, 31.12.2003

The SSM regulations do not comprehensively require the employers, licensees, registrants to ensure that arrangements are made to facilitate consultation and co-operation with workers with respect to protection and safety with regard to all measures necessary to achieve the effective implementation of the regulations and no plans exists to implement such general requirements. However, the Work Environment Act (SFS 1977:1160) and the regulations of the Swedish Work Environment Authority (AFS 2001:1, 3-5§§) require this:

> *Natural part of the activity, participation, work environment policy and routines*
>
> **Section 3**
> Systematic work environment management shall be included as a natural part of day-to-day activities. It shall comprise all physical, psychological and social conditions of importance for the work environment.
>
> **Section 4**
> The employer shall give the employees, safety delegates and pupil safety delegates the possibility of participating in systematic work environment management.
>
> **Section 5**
> There shall be a work environment policy describing how working conditions in the employer's activity shall be in order for ill-health and accidents at work to be prevented and a satisfactory working environment achieved.
> There shall be routines describing how systematic work environment management shall proceed. The work environment policy and the routines shall be documented in writing if there are at least ten persons employed in the activity.

M11

Some SSM specific regulations e.g. SSMFS 2008:35 about medical and dental exposures (13§, #1-2) and SSMFS 2008:52 on regulations of external (itinerant) workers (8§), do address the issue and require cooperation between employers, employees etc. Some other SSM regulations address suitable RP organisations which facilitate consultation and cooperation.

As already stated earlier, the Swedish Radiation Safety Authority regulations do not require the employers, registrants and licensees to "*ensure the necessary conditions to promote a (good!?) safety culture*". In connection with requirements on optimisation of PAS at nuclear power plants (SSMFS 2008:26, 5 §) and barriers & the defence-in-depth concept (General Advice to SSMFS 2008:1, 2nd chapter, 1§) the necessity of a good safety culture is addressed. SSM actively participated in the European research projects on the issue and the ongoing review of the Swedish safety and RP legislation addresses this topic. There are ongoing discussions in all areas on how to implement safety culture requirements in the SSM regulations.

Likewise, the SSM regulations do not explicitly, in regulating nuclear safety and RP issues, require employers, registrants and licensees to co-operate by the exchange of information and otherwise as necessary. Some regulations (e.g. SSMFS 2008:52 on regulations of external (itinerant) workers) require exchange of information after and before engagements. However, in relation with optimisation of RP/PAS, SSM (or rather the preceding authority Swedish Radiation Protection Authority) advocated on the use of pre-job and post-job briefings (including feed.-back and documentation) and this is frequently used, especially in connection with outage work at nuclear facilities. The regulations on occupational RP at nuclear facilities (SSMFS 2008:26, 6§, 3rd passage) addresses the need for extra information/education before carrying out certain tasks and that this shall be tailored to the particular type of work and the relevant work environment. SSMFS 2008:26, 35§, addresses the recording and reporting of RP experience (lessons learned) in connection with carrying out larger work (with projected collective doses exceeding 100 mmanSv). The Swedish

Work Environment Authority has issued complementary relations on systematic planning and follow-up of the work environment.

The Radiation Protection Act, 7§ and 7a §, requires that a legal party conducting activities involving radiation, or engage a person to perform work where such activity is being conducted, shall ensure that those who are engaged 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. It shall also be ensured 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. In several of the SSM regulations (SSMFS 2008:25, SSMFS 2008:26, SSMFS 2008:27, SSMFS 2008:28, SSMFS 2008:30 and SSMFS 2008:35) this is explicitly addressed. In the regulations SSMFS 2008:40 (3§) *on the Use of Equipment in Industry containing Sealed Sources or X-Ray Tubes*, it is required that the RP work shall be a part of the internal audit of the working environment.

The SSM regulations on occupational RP do not in a generic way require employers, registrants and licensees to facilitate compliance by workers with the requirements of the regulations compliance and there are no immediate plans to address this issue. However, there are general responsibilities stated in the RPA (6-8 §§) and there exist requirements on information, tr5aining, expertise and RP instructions in SSMFS 2008:24, 3§ (radiation protection expert at nuclear facilities) and the already above listed regulations (SSMFS 2008:25-28, SSMFS 2008:30, SSMFS 2008:35 and SSMFS 2008:40). Also the Swedish transport regulations ADR-S and RID-S, in part 1, 1.7.2, require such information to be given. Note also that the general work environment legislations address this issue, for example:

> *Work Environment Act (SFS 1977:1160), chapter 3, Section 3:*
> The employer shall ensure that the employee acquires a sound knowledge of the conditions in which work is conducted and that he is informed of the hazards that the work may entail. … The employer shall ensure that the employee has the training necessary and knows what he must observe to avoid risks with the work. The employer shall ensure that only employees who have received sufficient instructions gain access to areas where there is a manifest risk of illness or accidents. (SFS 2002:585)
> The employer shall make allowance for the specific characteristics of employees for the work by adopting work conditions or taking other appropriate measures. In the planning and arrangement of work, due regard shall be made for the fact that individual persons have differing capabilities for the duties involved.

The radiation protection legislation does not require employers, registrants and licensees to record any report received from a worker that identifies circumstances which could affect compliance with the regulations and to take appropriate actions, however indirectly this is so since SSM requires that SSM should be informed about incidents in accordance with paragraph 5 (5§) of the RPA. This is also addressed in several SSM regulations. As an incident is reported to the SSM, further oral or written requirements concerning analysis of the incident, corrective actions, measures to prevent reoccurrence etc. are given. The Work Environment Act (SFS 1977:1160), Chapter 3, Section 4 states:

> The employee shall participate in work relating to the work environment and shall take part in the implementation of the measures needed in order to achieve a sound work environment…
> An employee who discovers that work involves an immediate and serious danger to life or health shall immediately notify the employer or a safety officer. The employee shall not be

held liable to pay compensation for any loss or damage resulting from his non-performance of work pending instructions regarding its resumption. (SFS 1991:677).

And furthermore in WEA (SFS 1977:1160), Chapter 6, Section 4 and 6a:

> The safety delegate represents the employees on work environment matters and shall work for a satisfactory working environment. To this end the delegate shall, within his safety area, supervise the safeguards against ill-health and accidents and compliance by the employer with the requirements of Chap. 3, Section 2 a….
>
> The delegate shall participate in the planning of new premises, devices, work processes, working methods and work organisation or alterations to existing ones, and in planning the use of substances liable to cause ill-health or accidents. Furthermore, the safety delegate shall take part in the preparation of action plans as referred to in Chap. 3, Section 2 a…
>
> The employer shall notify the safety delegate of any changes having a significant bearing on work environment conditions within his safety area.
>
> ---
>
> Where there is a safety committee in place, a safety representative may directly demand the committee to consider a question concerning the working environment.
>
> A safety representative's request in accordance with the first paragraph may also refer to safety measures needed for the employer on the worksite where the safety representative is active to fulfil his obligations towards external labour in accordance with Chapter 3, Section 12.

M11

The Swedish regulations do require employers to encourage female workers, on becoming aware that she is pregnant, to notify her employer in order that her working conditions may be modified if necessary. Furthermore, a pregnant woman has the right to be relocated to an occupation not involving ionising radiation as described in SSMFS 2008:51 (basic requirements for protection of workers and the public), 3rd chapter, 5§. The Act SFS 1995:584 (Parental Leave Act) requires (18-19§§) in addition that (some time and other limitations are given in 20-21 §§):

> A female employee, who is expecting a child, has recently given birth to a child or is breast feeding is entitled to be transferred to other work while retaining her employment benefits, provided that she has been prohibited from continuing her regular work under a regulation issued under Chapter 4, Section 6 of the Work Environment Act (1977:1160). (SFS 2003:373)
>
> A female employee, who is expecting a child and, as a result, cannot carry out physically demanding work duties, is entitled to be transferred to other work while retaining her employment benefits.

The RP legislations do not explicitly require registrants and licensees to minimize the need for relying on administrative controls and personal protective equipment (PPE). However, the Work Environment Act (SFS 1977:1160), chapter 2, section 7 states:

> Personal protective equipment shall be used when adequate security from ill-health or accidents cannot be achieved by other means. This equipment shall be provided by the employer.

In the SSM regulations for workers at nuclear facilities SSMFS 2008:26, 5§, first sentence, it is pointed out that: "*The goals and actions of controls*

shall be adjusted with respect to the prerequisite of the plant and be drawn up to take care of the daily as well as long term radiation protection". With long term RP the SSM means actions taken to improve for example working conditions, source term reduction, to include RP issues during rebuild and refurbishment etc...Other specific requirements can be found in 2008:51 (categorisation of workplaces); SSMFS 2008:28 (work with unsealed sources), SSMFS 2008:35 (quality assurance of new equipment); and several on storage of radioactive sources (SSMFS 2008:27 17§, SSMFS 2008:28 30§; SSMFS 2008:40 20§) and in licence conditions.

General Responsibilities of Workers

International BSS 115, I.10 – I.10
Workers shall:

(a) Follow any applicable rules and procedures for protection and safety specified by employer, registrant or licensee;
(b) Use properly the monitoring devices and the protective equipment and clothing provided;
(c) Co-operate with the employer, registrant or licensee with respect to protection and safety and the operation of radiological health surveillance and dose assessment programs;
(d) Provide to their employer, registrant or licensee such information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others;
(e) Abstain from any willful action that could put themselves or others in situations that contravene the requirements of the Standards; and
(f) Accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the Standards.

If for any reason a worker is able to identify circumstances that could adversely affect compliance with the Standards, the worker shall as soon as feasible report such circumstances to the employer, registrant, or licensee.

The Radiation Protection Act, SFS 1988:220, 8§, states that:

> 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 Work Environment Act (SFS 1977:1160), Chapter 3, Section 4 states:

> The employee shall assist in work relating to the working environment and shall take part in the implementation of the measures needed in order to achieve a good working environment. He/She shall comply with provisions issued and use the safety devices and exercise such other precautions as are needed for the prevention of ill-health and accidents…

In the SSM regulations, workers responsibilities are not explicitly addressed, instead it is required that the licensee shall ensure that the applicable rules and procedures are followed.

The SSM regulations require workers to properly use the monitoring devices and the PPE and clothing provided by the employer, registrant or licensee. Apart from the

general statement in the RPA, 8§, it is addressed in several regulations (SSMFS 2008:25, 14§ (industrial radiography); SSMFS 2008:26, 17§, 19§, 21§ (for workers at nuclear facilities); SSMFS 2008:27 13-14§§ (practices with accelerators and sealed sources); SSMFS 2008:28, 23§, 26-27§§ (laboratory work with unsealed sources); SSMFS 2008:30, 9§ (use of x-rays in veterinary medicine). In the general regulations SSMFS 2008:51 there are implicit requirements to this end in the 5th chapter describing monitoring and reporting of individual doses for workers in 1§. In other SSM regulations (or in licence conditions) workers responsibilities are not explicitly addressed, instead the licensee is required to ensure that the workers use monitoring devices, and the PPE provided (SSMFS 2008:35, 11§, 5# (medical and dental practices using ionising radiation); SSMFS 2010:1, 5§ (addendum to SSMFS 2008:52 on external workers); licence conditions S-137, #9 (on using monitoring instruments for workers performing installations or maintenance); ADR-s 1.7..2.5 (transport sector; measures of caution for protecting the worker).

The RP regulations do not explicitly require workers to cooperate with the employer, registrant or licensee with respect to PAS and the operation of radiological health surveillance and dose assessment programmes. The Radiation Protection Act SFS 1988:220, 8§ can however not be said to be observed without the worker cooperation (Persons engaged in activities involving radiation, or performing work where such activity is being conducted…and take other measures that are required to ensure sound radiation protection…). The Work Environment Act (SFS 1977:1160), Chapter 3, Section 4, 6, 8, state, for example:

M11

> The employee shall assist in work relating to the working environment and shall take part in the implementation of the measures needed in order to achieve a good working environment. He shall comply with provisions issued and use the safety devices and exercise such other precautions as are needed for the prevention of ill-health and accidents.
> …
> The employer and the employees shall conduct suitably organised safety activities.
> …
> Safety representatives shall be appointed by a local trade union organization which currently or customarily has a collective agreement with the employer. In the absence of such an organization, safety representatives shall be appointed by the employees.
> …
> A safety committee consisting of representatives of the employer and of the employees shall be appointed at every worksite where fifty or more persons are regularly employed. A safety committee shall also be appointed at worksites with fewer employees, if requested by the employees.
> …
> The safety committee shall consider questions concerning
> 1. occupational health services,
> 2. action plans as referred to in Chap. 3, Section 2 a,
> 3. the planning of new or altered facilities, devices, work processes and working methods and of work organisation,
> 4. planning of the use of substances liable to cause ill-health or accidents,
> 5. information and education concerning the working environment,
> 6. job adaptation and rehabilitation activities at the worksite.

In the SSM regulations concerning outside (itinerary workers) SSMFS 2008:52 (as amended by SSMFS 2010:1) it is required (4§) about cooperation between the licence holder and the contractor regarding RP. In the 5th paragraph of the same regulations there are requirements on dose assessments and medical examinations. In SSMFS 2008:51 (requirements for protection of workers and public) the 5th chapter, 1§ requires that the licence holder ensures that individual dose assessment is performed as appropriate and in the 6th chapter, 1§, that medical examinations are car-

ried out before commencement of work at controlled areas (category A worker). The SSM regulations nearly always (due to the construction of the legislation) hold the licensee (the one carrying out the practice involving ionising radiation) as responsible for ensuring that these requirements are fulfilled and the licensee is also responsible for keeping records on these issues (health examinations and when health examinations are in line for renewal, dose records, etc.). This does not mean that the cooperation and responsibility of the employee is not accounted for. ADR-S 1.7.2.5 (transport sector) requires a RP programme that includes responsibility of worker as described in report SSI 2004:10 part 6.2 (roles an responsibility distribution).
The SSM regulations do not explicitly require workers to provide to the employer, registrant or licensee such information on their past and current work as is relevant to ensure effective and comprehensive PAS for themselves and others. The SSM RP regulations require that the party carrying out the practice, the licensee ensures that medical examinations, dose records etc. are available and that the legal and regulatory requirements are met before work can start. The Radiation protection Act, 18§, requires that

> …Only persons who have undergone medical examinations under the first paragraph may be engaged in work involving ionising radiation. Those who are found upon medical examination to run a particular risk of injury from exposure to ionising radiation may not, without the permission of the Government or the public authority appointed by the Government, be engaged in work involving ionising radiation.

As stated above, in SSMFS 2008:51 (requirements for protection of workers and public) the 5th chapter, 1§ requires that the licensee ensures that individual dose assessment is performed as appropriate and in the 6th chapter, 1§, that medical examinations are carried out before commencement of work at controlled areas (category A worker). The regulations SSMFS 2008:52 (on external workers) contain provisions for licensees and contractors (indirectly workers) in order to ensure that information on received doses (e.g. dose passports), suitable educations, PPE, dosimetry, and health examinations are met.

The SSM regulations do not explicitly require workers to refrain from willful action that could put themselves or others in situations that contravene the requirements of the regulations. As stated repeatedly above, the RPA, 8§, requires the worker to shall use the necessary safety equipment and take other measures that are required to ensure sound radiation protection. The RPA however does not open for legal actions against anyone breaching or neglecting this paragraph. According to the Work Environment Act (SFS 1977:1160), 8th chapter, it is a punishable offence to

- furnish untruthful particulars when the Work Environment Authority has requested information, documents or specimens, and to
- remove a safety device or render it inoperative without valid cause.

One precondition of penal liability in all these cases is that the offence must have been committed deliberately or negligently. The penalty is fines. There are also stipulations of the Penal Code which may come into play when an accident or a work-related disease has resulted from irregularities in the working environment. Abuses of this kind can therefore result in one or more representatives of the employer being convicted of work environment offences. Incidents can also lead to punishment if they were due to gross negligence.

The RP regulations do also not specifically require that workers accept such information, instruction and training concerning PAS as will enable them to conduct their work in accordance with the requirements of the regulations. The RPA, 7-7a§§, require that the licensee shall assure that all workers are well informed about the risks and conditions and regulations concerning the RP at the workplace. Several other SSM regulations specify that the licensee is responsible for the competence of workers regarding RP: SSMFS 2008:25, 4§ (industrial radiography); SSMFS 2008:26, 6-7§§ (workers at nuclear facilities); SSMFS 2008:27, 4§ (practices with accelerators and sealed sources); SSMFS 2008:28, 4§ (laboratory work with unsealed sources); SSMFS2008:30, 5§ (x-rays in veterinary medicine); SSMFS 2008:35, 10§ (medical and dental practices using ionising radiation); SSMFS 2008:40, 17§ (non-nuclear industry practices); and Licence Conditions S-137 #9 (for trading practices). It is common that knowledge tests or other means of assurance are applied to verify the education and training.

The RP regulations do not explicitly require state that the workers should report to the employer, registrant or licensee if for any reason they are able to identify circumstance that could adversely affect compliance with regulations. Apart from RPA, 8§ , referred to above, the Work Environment Act (SFS 1977:1160), Chapter 3, Section 4, states that "*the employee shall assist in work relating to the working environment and shall take part in the implementation of the measures needed in order to achieve a good working environment. … An employee finding that work entails an immediate and serious danger to life or health shall immediately notify the employer or a safety delegate".* In fact, the whole work environment legislation is built on the cooperation of employer and employees (or through delegates as appropriate) cooperates on work environment issues. The Swedish system is well developed in this area. No plans exist to amend the RP legislation on these issues.

M11

Requirements for Radiation Protection Programmes

International BSS 115 I.21-I.23
Registrants and licensees shall designate as controlled area any area in which specific protective measures or safety provisions are or could be required for:

(a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and
(b) preventing or limiting the extent of potential exposures.

In determining the boundaries of any controlled area, registrants and licensees shall take account of the magnitudes of the expected normal exposures, the likelihood and magnitude of potential exposures, and the nature and extent of the required protection and safety procedures.
Registrants and licensees shall:

(a) delineate controlled areas by physical means or, where this is not reasonably practicable, by other suitable means;
(b) …..(c)…..(d)…(e)….(f)….(g)….; and

(h) periodically review conditions to determine the possible needs to revise the protection measures or safety provisions, or boundaries of controlled areas.

International BSS 115 I.24- I.25
Registrants and licensees shall designate as a supervised area any area not already designated as a controlled area but where occupational exposure conditions need to be kept under review even through specific protection measures and safety provisions are not normally needed.
Registrants and licensees shall, taking into account the nature and extent of radia-

tion hazards in the supervised areas:

(a) Delineate the supervised areas by appropriate means;
(b) Display approved signs at appropriate access points to supervised areas; and
(c) Periodically review the conditions to determine any need for protective measures and safety provisions or changes to boundaries of supervised areas.

International BSS 115 I.28
Employers, registrants and licensees shall ensure that:
(a)….(f)[AVAILABILITY, USE, TRAINING, MAINTENANCE etc OF PERSONAL PROTECTIVE EQUIPMENT]

International BSS 115 I.32
The employer of any worker, as well as self-employed individuals, and the registrants and licensees shall be responsible for arranging the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that adequate arrangements be made with appropriate dosimetry services under an adequate quality assurance programme.

International BSS 115 I.37
Registrants and licensees, in co-operation with employers if appropriate, shall establish, maintain and keep under review a programme for the monitoring of the workplace under supervision, if so required by a Regulatory Authority, of a qualified expert and a radiation protection officer.

International BSS 115 I.41
Employers, registrants and licensees shall make arrangements for appropriate health surveillance in accordance with the rules established by the Regulatory Authority.

International BSS 115 I.18
Employers shall make every reasonable effort to provide workers with suitable alternative employment in circumstances where it has been determined, either by the Regulatory Authority or in the framework of health surveillance programme required by the Standards, that the worker, for health reasons, may no longer continue in employment involving occupational exposure.

International BSS 115 I.26
Employers, registrants and licensees shall, in consultation with workers, through their representatives if appropriate:

(a)….(f) [REQUIREMENTS ON LOCAL RP RULES AND PROCEDURES, RPO etc.]

International BSS 115 I.27
Employers, in co-operation with registrants and licensees, shall:

(a) – (d) [REQUIREMENTS ON INFORMATION ON HEALTH RISKS; EMERGENCY INFORMATION & TRAINING AND RECORDS OF TRAINING]

International BSS 115 I.44
Employers, registrants and licensees shall maintain exposure records for each worker for whom assessment of occupational exposure is required in paragraphs I.32 – I.36 of this Appendix.

The SSM regulations SSMFS 2008:51 (basic provisions for protection of workers and require that controlled areas are, taking into account the magnitude of expected normal exposures as well as likelihood and magnitude of potential exposures, designated in which specific protective measures or safety provisions are, or could be required for controlling normal exposures or preventing the spread of contamination,

or preventing or limiting potential exposures. The regulations also specify means of delineation of the areas, display signs, access control, local rules and procedures, protective equipment etc. as appropriate. The regulations do not specify periodic reviews but it is assumed that they should be kept up to date and the actuality and relevance has been discussed and changed, for example in connection with temporary refurbishment work and in connection with power up rates at NPPs. The requirements are found in SSMFS2008:51, 4th chapter, 1§ and 3§ and the provisions on managing and supervising the controlled area are given in SSMFS 2008:51, 4th chapter, 4-7§§ and 11-12§§. Requirements for specific practices are given in several SSM regulations: SSMFS 2008:25, 9§, 14-27§§ (industrial radiography); SSMFS 2008:26, 10-21§§ (work at nuclear facilities); SSMFS 2008:27, 9-19§§ (accelerators and sealed sources); SSMFS 2008:28, 9§ and 10-35§§ (laboratory work with unsealed sources); SSMFS 2008:30, 7-11§§ (x-rays in veterinary medicine); SSMFS 2008:35, 17-21§§ (medical and dental practices).

The regulations SSMFS 2008:51 also specify the means by which supervised areas shall be managed. In the 4th chapter, 1§ and 8§, describe the requirements for assignment of supervised areas whereas in the same chapter (4th) paragraphs 9-12 give provisions for management and supervision of the supervised area. Furthermore there are requirements for specific practices in SSMFS 2008:25, 28-31§ (industrial radiography); SSMFS 2008:26, 10§ (work at nuclear facilities); SSMFS 2008:27, 9§, 13§, 15-19§§ (practices with accelerators and sealed sources); SSMFS 2008:28, 9-11§§, 30-35§§ (laboratory work with unsealed sources); SSMFS 2008:30 7-11§§ (x-rays in veterinary medicine); SSMFS 2008:35, 17-21§§ (medical and dental practices).

M11

SSM has issued requirements about protective equipment but doesn't require standards or specifications. Regulations about medical exposures have specific requirements regarding education of workers on how to operate equipment (including equipment for protection). The regulations SSMFS 2008:31, 8§ (diagnostic radiology); SSMFS 2008:33, 6§ (radiation therapy); and SSMFS 2008:34, 6§ (nuclear medicine) require that workers must have the theoretical and practical training needed for the work to be performed in a way that is satisfying regarding the RP. There are requirements regarding testing the protective equipment for good fit. There are also general requirements on competence and education of workers in RPA 6-7a §§ and in: SSMFS 2008:25, 4§, 7§, 10§, and 15§ (industrial radiography); SSMFS 2008:26, 6-7§§ (work at nuclear facilities); SSMFS 2008:27, 4§ and 6§ (practices with accelerators and sealed sources); SSMFS 2008:28, 4§, 7§, and 24§ (laboratory work with unsealed sources); SSMFS 2008:30, 5§ (use of x-rays in veterinary medicine); SSMFS 2008:35, 10§ (medical and dental practices using ionising radiation); SSMFS 2008:40, 17§ (non-nuclear industry practices); Licence Conditions S-137, #9 (trading practices); ADR-S and RID-S part 1, 1.7.2 (transport sector).

The Radiation Protection Act 6§, 3# states that the employers, registrants and licensees must maintain all technical equipment, including protective equipment. This is more specifically required in some of SSM's regulations for medical exposure: SSMFS 2008:31 (diagnostic radiology) where it is required in 19§, table 1, that PPE is tested once a year; SSMFS 2008:33 (radiation therapy) where it is required in 7§ that the licensee must have a quality programme including testing of equipment; SSMFS 2008:34 (nuclear medicine) where it is required in 7§, #5 that the licensee must have procedures for testing instruments and in #6 that the licensee has a description of routines for calibration and maintenance of RP instruments. Other SSM regulations do not have specific requirements but there are requirements on performing self-monitoring in: SSMFS 2008:1, 2nd chapter, 8§, part 2 (nuclear safety re-

quirements); SSMFS 2008:25, 9§ #13 (industrial radiography); SSMFS 2008.27, 9§, #16 (practices with accelerators and sealed sources); SSMFS 2008:28, 9§, #15(laboratory work with unsealed sources).

The regulations SSMFS 2008:15 (emergency preparedness at nuclear facilities) require that iodine tablets (including instructions for distribution and use) and personal protective equipment shall be available for all persons in the emergency preparedness and response organisation, including persons that could be foreseen to arrive to the facility.

There are no specific requirements that the use of protective equipment shall be taken into consideration in the planning of work but this is implicit in the regulations SSMFS 2008:51, 2nd chapter, 1§ about optimisation of RP. There are few direct references to PPE in the SSM regulations but is mentioned occasionally, e.g. in SSMFS 2008:52 (amended in SSMFS 2010:1), 5§, #4 on that both the licensee and the contractor shall ensure that the needed PPE shall be available to the workers.

The regulations SSMFS 2008:51 (basic provisions for protection of workers and the public), 5th chapter, 1§, require that anyone conducting a practice involving ionising radiation shall ensure that monitoring of individual doses are performed for all persons of category A (whom may receive significant doses and work in controlled areas). In the same chapter (5th) it is required in 8§ that where there is risk for intake of radioactive substances or for skin contamination, the assessment of exposures shall be tailored to the type of work and occurring radionuclide(s). The committed effective dose due to intakes shall be determined using the dose coefficients as listed in Table III of 96/29/Euratom , EGT, L159, 29 June 1996 . Further requirements are found in specific regulations, e.g. SSMFS 2008:25, 14§ (industrial radiography); SSMFS 2008:26, 17-19§§ (work at nuclear facilities) about the use of electronic dosimeters that shows the accumulated dose, alarm function on accumulated dose , and on monitoring of visitors; SSMFS 2008:27, 13-14§§ (practices with accelerators and sealed sources) about dose monitoring (alarm functions) in areas with high risk of exposure and contamination; and SSMFS 2008:28, 26§ (laboratory work with unsealed sources) about monitoring in areas with risk for internal or external contamination.

In general, the SSMFS2008:51, 4th chapter, 11-12§§, give provisions about monitoring workplaces (controlled and supervised) ant that, in case needed, it should be possible to use the results from the monitoring to calculate the individual doses to people in the workplace. SSMFS2008:51, 4th chapter, 2§, states that the category-B workers surveillance of doses shall be performed in such an extent that it is possible to demonstrate that this classification is correct.

There is no direct provisions in the SSM regulations addressing the case where individual monitoring for any worker who is normally employed in a controlled area, or who occasionally work in a controlled area and may receive significant occupational exposure, is inappropriate, inadequate or not feasible, the occupational exposure of the worker is assessed on the basis of results of monitoring the workplace and on information on the locations and duration of exposure of the worker. However, in SSMFS 2008:51, 4th chapter, 12§ there are requirements about monitoring workplaces and that, in case needed, it should be possible to use the results from this monitoring to estimate/calculate the individually incurred doses in the workplace. SSM has occasionally allowed for such calculated doses to be registered in the national dose register in connection with loss of dosimeters, malfunctioning of dosimeters etc. In certain work places (reactor hall at BWR NPPs) it has furthermore been

traditionally allowed to position personal dosimeters in the breast pocket of the protective overall in order to minimise the risk of dropping objects into the pools but thereby covering the beta window with cloth and subsequently reducing the beta sensitivity.

In the regulations about basic requirements for protection of workers (and public) SSMFS 2008:51 there are requirements in the 5th chapter, 8§ about monitoring at workplaces where there is a risk of intake or a risk for skin contamination. In specific regulations and in SSM general advice on screening for intakes, a three step procedure for monitoring is used: continuously monitoring a control group, regularly measuring staff exposed to an increased risk of intakes, monitoring individuals involved in incidents with intakes/contaminations (or when such are suspected). This is, at the nuclear facilities, complemented with exit screening/monitoring equipment sensitive to both external and internal contamination.

The SSMFS 2008:51 11-12§§ require that work place monitoring is performed at workplaces. The ambient dose rates and the air activity concentrations shall be monitored as appropriate, taking into account the geometry and homogeneity of the radiation fields and the likelihood of airborne radioactive substances. The surveillance shall be performed, taking into account the occurring types of radiation fields, energies and the chemical and physical composition of the radioactive substances. The results of the surveillance/monitoring program shall be documented and be available for calculation of/estimating radiation exposures, projected or incurred radiation doses or committed radiation doses as appropriate. Furthermore there are more specific requirements for practices such as SSMFS 2008:27, 13§ (work at accelerators and with sealed sources) , SSMFS 2008:25, 16§ (industrial radiography); SSMFS 2008:26, 29§ (work at nuclear facilities).

The Swedish Radiation Safety Authority's regulations SSMFS 2008:51, 9-10§, require that for any employee there should be records regarding type of work carried out, health examinations and periodic controls, and incurred doses. The data on incurred effective doses (including intakes and estimated committed effective doses) shall be kept as long an individual is involved with work involving ionising radiation and must thereafter be archived until the person has reached the age of 75 years, but at least 30 years after the work in a controlled area (as category A) stopped. If the practice of the employer ceases to exist at an earlier time, the Swedish Radiation Safety Authority should be contacted/informed.. In practice, however, the registered dose data is also saved in the central Swedish dose register.

There are no specific requirements in the SSM regulations on that the results of the workplace monitoring shall be made available to workers, where appropriate through their representatives. It is common practice that the results of the monitoring programme is posted and that results of contamination levels or radiation levels are clearly marked at exit/entrances to controlled areas. A system of colour coding (blue, yellow, red) is used to further delineate the controlled areas at nuclear facilities into sub-levels depending on the radiation and contamination (air and surfaces) levels of the premises. These values are also used in the day-to-day ALARA work and for planning both the use of PPE and the dose budgets for different work procedures. The absence of such regulation could perhaps be due to the fact that this is taken for granted, anyhow, the annual reports to the SSM containing at least summaries of such information are public documents.

General requirements for health surveillance are stipulated in RPA, 18§. Furthermore, in the regulations on basic requirements for protection of workers and the

public SSMFS 2008:51 there are general requirements in the 6th chapter, 1-8§§ about health surveillance. The regulations SSMFS 2008:51, 6th chapter, require that health examinations are performed as appropriate and in accordance with the EC Directive 96/29/Euratom from May 13, 1996. The health surveillance program is to be based on the general principles of occupational health and is designed to assess the initial and continuing fitness for workers for their intended tasks. The specific requirements are given in SSMFS 2008:51, 6th chapter, 4§ and Appendix 4. These regulations do not require the employer to find alternative employment for the employee if the Regulatory Authority or in the framework of the health surveillance program, the worker may no longer continue in employment involving occupational exposure. However, the Discrimination Act (2008:567), 2nd chapter, 1§ and the Work Environment Act (SFS 1977:1160), 3rd chapter, 3§, together give the same protection for the worker. In the regulations SSMFS 2008:51, 3rd chapter, 5§ (pregnant women) and 6th chapter, 6§ (workers fit for service under certain conditions) situations with temporary alternative employment or fitness for duty under certain restrictions are addressed.

The Swedish RP regulations require anyone carrying out a practice involving ionising radiation to establish local rules and procedures adequate for the type of practice and the work environment. The SSM regulations stipulate both investigation levels and authorized levels and procedures to be followed when these are exceeded. It is however not required that these should be written down in the local procedures, even if it is most likely and to the knowledge of the authority this is the case. The requirements on the local procedures are more general but SSM expects that the requirements of the authority are incorporated in local procedures. For sure this is for example the case at all Swedish nuclear facilities where the local rules and procedures concerning RP both cover the specific requirements of the authority as well as a list of the relevant regulations. It is required that the radiation protection expert at such facilities (SSMFS 2008:24, 4§, #2, #4, #8) apart from functioning as the radiation protection expert, oversees and work towards that the requirements of the RPA, valid regulations and licence conditions are implemented and followed, supervise the establishment of local rules and procedures to the effect that persons are not subject to unacceptable or unnecessary exposure, supervise that requirements on reporting are observed etc.

The RPA, 7§, stipulates that a party conducting activities involving radiation (a practice) 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. There are further requirements of disseminating the content of the local rules and the contents of ALARA programmes to workers in several SSM regulations: SSMFS 2008:25, 9§ (industrial radiography); SSMFS 2008:26, 5-6§ (workers at nuclear facilities); SSMFS 2008:27, 9§ (practices with accelerators and sealed sources); SSMFS 2008:28, 7§ (laboratory work with unsealed sources); SSMFS 2008:30, 8§ (use of x-rays in veterinary medicine); SSMFS 2008:35, 13§, #3 (medical and dental practices); Licence Conditions S-137 (trading practices).

In the RP regulations of the SSM workers responsibility in observing and following rules, procedures, using protective measures etc. are not expressed. Instead the SSM regulations require the licensee (registrant, employer) to ensure that applicable rules and procedures are followed.

Adequate information and training with regards to radiation PAS must be provided and this is required both in the RPA and in the SSM regulations: SSMFS 2008:25, 4§, 7§, and 15§ (industrial radiography); SSMFS 2008:26, 6-7 §§ (work at nuclear facilities); SSMFS 2008:27, 4§ and 6§ (practices with accelerators and sealed sources); SSMFS 2008: 28, 4§, 7§ (laboratory work with unsealed sources); SSMFS 2008: 30, 4-5§§, 9§ (x-rays in veterinary medicine); SSMFS 2008:35 10§, 11§ #4 (medical and dental exposures); SSMFS 2008:40, 17§ (non-nuclear industry practices); Licence Conditions S-137 #7-9 (trading practices).

The regulations SSMFS 2008:51, 3rd chapter, 5§ require that information is given to women about radiation related risks connected to pregnancy. The issue of breast feeding women is addressed in 7§.

The Swedish RP regulations require employers, in co-operation with registrants and licensees to provide those workers which could be affected by an emergency plan appropriate information, instruction and training. SSM does in general regulate who should be affected by an emergency plan but that anybody should have education regarding measures in case of an emergency alarm. This is however not the case for major organisations (i.e. nuclear facilities) for which requirements on competence and plans for education and training should exist for all staff of the emergency organisation: SSMFS 2008:15, 18-20§§ (emergency preparedness at certain nuclear facilities); SSMFS 2008:25, 9§, #11 (industrial radiography); SSMFS 2008:27, 6§ (practices with accelerators and sealed sources); SSMFS 2008:28, 9§, #12 (laboratory work with unsealed sources); SSMFS 2008:30, 8§, #7 (practices with x-rays in veterinary medicine); SSMFS 2008:34, 7§, #3 (medical and dental practices using ionising radiation).

There are also provisions which require licensees to keep records of the training provided to individual workers: SSMFS 2008:25, 9§ (industrial radiography); SSMFS 2008:26, 8§ (workers at nuclear facilities); SSMFS 2008:27, 9§ (practices with accelerators and sealed sources); SSMFS 2008; 28, 9§ (laboratory work with unsealed sources); SSMFS 2008:30, 8§ (practices with x-rays in veterinary medicine); SSMFS 2008:31, 8§ (diagnostic radiology); SSMFS 2008:33, 6§ (radiation therapy); SSMFS 2008:34, 6§ (nuclear medicine).

The Swedish regulations require employers, registrants and licensees to maintain exposure records for each worker for whom assessment of occupational exposure is required under the regulations (SSMFS 2008:51, 5th chapter, 12§). Furthermore, in SSMFS 2008:52 (as amended by 2010:1; for external workers) it is required that the licensee and the employer of the worker (including self-employed) are both responsible for monitoring and registration of the workers individual dose.

The SSM has not postulated the content of exposure records at the licensee, they are however requirements in SSMFS 2008:51, 5th chapter, 12§ (archiving of exposure records); SSMFS 2008:26, 38§ (work at nuclear facilities) which require how the external and internal doses should be evaluated. In the regulations on basic requirements for protection of workers and public SSMFS 2008:51 there are requirements in the 5th chapter, 9§ to the effect that all the measured dose equivalents measured at a practice with ionising radiation should be reported within six weeks after the measurement period. Many larger practices (nuclear installations, hospitals) have their own authorized dosimetry laboratories which are able to report the doses to the central national dose register. In appendix 3 of the same regulations, relevant performance requirements on dosimeters are given (these were taken from EUR 14852

EN, *Radiation Protection 73*, 1994 *Technical recommendations for monitoring individuals occupationally exposed to external radiation*). Furthermore SSMFS 2008:51, 10§ stipulate that any intake resulting in an estimated committed effective dose above 1 mSv and any equivalent dose to skin exceeding 20 mSv must be reported - in practice, lower values are reported. For workers at nuclear facilities the paragraphs 9-10§§ are not valid, instead the following requirements are applied according to SSMFS 2008:26 (work at nuclear facilities):

- 39§ external doses equal to or above 0.1 mSv during any recording period (usually monthly but alternatively a 4-week period) should be registered. All recorded intakes should be recorded (in practice those which are larger than > 0.3 mSv, but the estimated amount of activity is also registered).
- 36§ a commit effective dose equal to or above 5 mSv from one single internal contamination shall be especially reported to the Swedish Radiation Safety Authority.
- 33§ requires that a detailed annual report regarding the incurred doses during the preceding year to the personnel (including contractors) should be reported to the SSM.

According to the Personal Data Act SFS 1998:204, 23-26§§, regulates that all registered persons are entitled to get information about their records. Also the SSM, on request, must deliver dose information from the national dose registers to concerned individuals.

SSMFS 2008:51, 5th chapter, 12§ require that exposure records of workers must be kept for at least 30 years after the person ended his/her occupation as a category A worker and until the person has reached the age of 75 years. There are general requirements in the regulations from the National Archives about maintenance of records. For nuclear facilities the SSM has issued the regulations SSMFS 2008:38 which address the issues of maintaining records, which record should be kept, suitable record keeping media and transfer of media, and for how long periods documentation should be kept.

Monitoring programmes and technical services

RS-G-1.3 *Assessment of Occupational Exposure Due to External Sources of Radiation***;**
Chapter 9 [*Quality Assurance***]**

All individual dosimetry services shall be approved by the competent authority, Swedish Radiation Safety Authority. SSMFS 2008:51, 5th chapter, 6§ requires that all personal doses shall be measured with dosimeters from an approved laboratory. Furthermore, there are requirements regarding procedures for measuring internal contamination in SSMFS 2008:26, 22§ (work at nuclear facilities); SSMFS 2008:28, 28§ (laboratory work with unsealed sources).

The competent authority is the Swedish Radiation Safety Authority and the technical requirements for approval are described in the regulations SSMFS 2008:51, 5th chapter, 13-16§§. The record keeping services are not specially approved. The Swedish Radiation Safety Authority is also responsible for the National Dose Data Register as required in the instructi**o**n (SFS 2008:452) for SSM. Furthermore, the licensees are required to keep dose records according to SSMFS 2008:51, 5th chapter, 12§.

The Swedish work place monitoring services are not approved. Requirements for calibration of the measuring instruments for specific practices are given in SSMFS 2008:25, 9§, #8 (industrial radiography); SSMFS 2008:26, 10§, #6 and 23-26§§ (nuclear facilities); SSMFS 2008:27, 9§ #9-11, 15§ (practices with accelerators and sealed sources); SSMFS 2008:28, 9§, #9 (laboratory work with unsealed sources); SSMFS 2008:33, 21§ (radiation therapy); SSMFS 2008:34, 6-7§§ (nuclear medicine).

There are no Swedish regulations which require that personnel training services in radiation PAS shall be approved by a competent authority. For Swedish health physicists Sweden has a certification procedure by the National Board of Health and Welfare. Otherwise, in the SSM regulations, all responsibility for education and training is put on the licensee. There have been discussions on approval of educations but there are no such plans for the moment.

References

SFS 1977:1160 (as amended up to, and including SFS 2002:585) Work Environment Act
SFS 1988:220 Radiation Protection Act
SFS 1988:293 Radiation Protection Ordinance
SFS 1995:584 Parental Leave Act
SFS 1998:204 Personal Data Act
SFS 2003:778 Civil Protection Act regarding protection against accidents with serious potential consequences for human health and the environment
SFS 2003:789 Civil Protection Ordinance regarding protection against accidents with serious potential consequences for human health and the environment
SFS 2006:311 Ordinance of Transport of Dangerous Goods
SFS 2006:623 Act of Transport of Dangerous Goods
SFS 2008:452 Instructions for the Swedish Radiation Safety Authority
SFS 2008:567 Discrimination Act
Swedish Penal Code - Ds 1999:36 http://www.regeringen.se/sb/d/108/a/1536

ADR-S (MSBFS 2011:1) *Accord Européen Relatif au Transport International des Marchandises Dangereuses par Route* (ADR) – Swedish version as issued in the Code of Statutes of the Swedish Civil Contingencies Agency

RID-S (MSB 2011:2) *Règlement concernant le transport international ferroviaire de marchandises Dangereuses* – Swedish version as issued in the Code of Statutes of the Swedish Civil Contingencies Agency

AFS 2001:1 Provisions of the Swedish Work Environment Authority on Systematic Work Environment Management, together with General Advice on the implementation of the Provisions
AFS 2005:17 Occupational Exposure Limit Values and Measures against Air Contaminants

SSMFS 2008:1 (as amended by SSMFS 2011:3) Regulations and General Advice concerning Safety in Nuclear Facilities
SSMFS 2008:9 Regulations on the Control of High-Activity Sealed Radioactive Sources
SSMFS 2008:11 Regulations and General Advice on Shielding and Design of Premises used for Therapy and Diagnostics

SSMFS 2008:15 Regulations concerning Emergency Preparedness at Certain Nuclear Facilities
SSMFS 2008:24 Regulations on Radiation Protection Managers at Nuclear Facilities
SSMFS 2008:25 Regulations on Industrial Radiography
SSMFS 2008:26 Regulations on Radiation Protection of Workers Exposed to Ionising Radiation at Nuclear Plants
SSMFS 2008:27 Regulations on Practices with Accelerators and Sealed Sources
SSMFS 2008:28 Regulations concerning Work with Open Radioactive Sources at Laboratories
SSMFS 2008:29 General Advice on Competence of Radiation Protection Experts
SSMFS 2008:30 Regulations and General Advice on the Use of X-rays in Veterinary Medicine
SSMFS 2008:31 Regulations on Diagnostic Radiology
SSMFS 2008:33 Regulations on Radiation Therapy
SSMFS 2008:34 Regulations and General Advice on Nuclear Medicine
SSMFS 2008:35 Regulations on General Obligations in Medical and Dental Practices using Ionising Radiation
SSMFS 2008:38 Regulations on Archiving at Nuclear Facilities
SSMFS 2008:40 Regulation on the Use of Equipment in Industry containing Sealed Sources or X-Ray Tubes
SSMFS 2008:51 Regulations concerning Basic Provisions for the Protection of Workers and the General Public in Practices involving Ionising Radiation
SSMFS 2008:52 (as amended by SSMFS 2010:1) Regulations on Outside Workers in Practices involving Ionising Radiation

European Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, May 13, 1996, EGT L159,29.6.1996

European Council Directive 2003/122/Euratom on the Control of High-Activity Sealed Radioactive Sources and Orphan Sources, December 22, 2003, EGT L346, 31.12.2003

EUR 14852 EN, Radiation Protection 73, 1994 Technical recommendations for monitoring individuals occupationally exposed to external radiation,

IAEA Safety Series No.115, International BSS for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA, Vienna, 1996

SSI Report 2004:10 (In Swedish) *Riktlinjer för utformning av strålskyddsprogram för transportörer av radioaktiva ämnen* (Guidelines for the development of Radiation Protection Programmes for Transport of Radioactive Materials)

SSM General Licence Conditions for Trading Purposes, S-137

11.4 Control of radioactive discharges and materials for clearance

Counterpart

Ann-Christine Hägg
Analyst
Nuclear Power Plant Safety
+46 8 799 41 26
Ann-Christine@ssm.se

M11

Assessment for IAEA requirements – Safety Series no 115: Basic Safety Standards

General

According to the Radiation Protection Act (1988:220) section 32, SSM has the mandate to enforce that the licensee takes actions to fulfill regulations or license conditions. SSM also has the mandate to take actions on the expense of the licensee.

SSM does not have the mandate to review releases of non-radiological substances. However, SSM has an obligation to inform other Swedish authorities if such issues are identified. In the licensing process according to the Environmental Code, all environmental impacts are considered. Thereby, there exists a process to ensure that this issue is taken into account, although it is not the responsibility of SSM.

Nuclear facilities

The control of discharges from nuclear facilities including nuclear power plants and nuclear fuel facilities during normal operation is regulated in SSMFS 2008:23.

The systems for limitation and monitoring of discharges shall be described in the Safety Analysis Report of the facility (SSMFS 2011:3). Before new facilities are taken into operation investigations shall be conducted to determine the size and composition of the release, the environmental and dispersion conditions as well as expected doses. The investigation shall be submitted to the SSM for review. If necessary, SSM can specify additional license conditions. Whenever the operational conditions are changed so that new release pathways or new release sources arise or

an existing release pathway is modified the licensee is obliged to send in a new investigation for review.

A dose constraint of 0,1 mSv/year to the most exposed individual in the defined critical group is set. The regulation does not give nuclide specific limits but require that the concepts of applying Best Available Technique and optimization of protection and safety, (BAT and ALARA), shall be used for the limitation of discharges.

In principle, all discharges must be monitored. However, in the case of unavoidable diffuse leakages, it is sufficient to estimate the releases. SSMFS 2008:23 states that the function of monitoring equipment and release-limiting systems shall be regularly controlled. To verify compliance SSM is controlling that the licensee fulfills these requirements by performing inspections. The licensee shall also send samples of the water released to the environment for independent control. Furthermore, the licensee shall submit the results from environmental monitoring conducted according to a monitoring program decided by the authority. As a complement SSM takes samples of the filters in the aerosol monitoring systems in the main stack at the nuclear power plants. These samples are measured at the SSM laboratory to ensure compliance with the measurements conducted by the licensee (SSM routine STYR2011-159).

Events leading to increased emissions of radioactive substances from nuclear facilities must immediately be reported to the Radiation Safety Authority. The report shall include a description of measures for reducing the releases. According to SSMFS 2008:23 SSM may require that additional environmental monitoring is performed and that consequences are analysed.

For accidental releases, there are also requirements on corrective actions in SSMFS 2008:1 concerning Safety in Nuclear Facilities and 2008:15 regarding emergency planning at certain nuclear facilities. The latter also regulates control of discharges in emergency situations. Among other things the regulations states that emergency filters should be in place at the facilities in threat category I.

Contamination of off-site areas could (independently of the license-holder) be detected by the community measurement system and/or the national system of air- and gamma monitoring stations.

It is not at present required in the regulations that licensees should recurrently verify the adequacy of the assumptions made for the prior assessment of radiological consequences of the discharges. However, this will be included in the revision of SSMFS 2008:23, which is currently being performed.

Criteria for clearance of materials from regulatory control are given in SSMFS 2008:39 concerning discharging of goods and oil from controlled areas at nuclear facilities. The clearance values for free reuse are based on IAEA TECDOC 855. Activity values for disposal on municipal dumps and for incineration of oil are based on Swedish studies.

Regarding larger decommissioning activities SSM has used the activity values recommended by the European Union for buildings. These have however been applied on a case-by-case basis.

Non-nuclear facilities

For non-nuclear facilities control of discharges are regulated in SSMFS 2010:2 concerning radioactive waste and releases from practices using open sources. According to these regulations the legal person who will carry out the practice shall during planning apply the concept of BAT to the limitation of releases. If the estimated dose from the practice exceeds 10 microsievert (µSv)/year, more detailed dose assessments should be performed. For these practices discharges should be assessed according to methodologies described in internal quality handbooks (SSMFS 2010:2).

For non-nuclear facilities monitoring of discharges are not mandatory. Activity limits concerning the maximum allowed discharge to the sewer system is given in SSMFS 2010:2 Appendix 1.

To verify compliance at non-nuclear facilities SSM conducts inspections, review documents and reports. However the inspection frequency is less than for nuclear facilities due to the potential lower risk.

SSM also requires that data is submitted annually according to SSMFS 2010:2.

According to SSMFS 2010:2 concerning non-nuclear facilities, the licensee shall take corrective actions in order to ensure that BAT is applied. Also SSMFS 2008:28 concerning work with open sources at laboratories states that the facilities are obliged to have a plan for corrective actions due to unplanned situations and those incidents should be reported to SSM. Similar requirements are given in SSMFS 2008:27 concerning accelerators.

Criteria for clearance of waste from non-nuclear activities involving unsealed radioactive sources are given in SSMFS 2010:2. In this regulation maximum allowed amount of activity in waste packages sent for incineration during one calendar month is specified. The surface dose rate of waste parcels leaving the site should however always be measured and shall not exceed 5 µSv/h.

Summary and conclusions

SSM's regulations cover most aspects of discharges, clearance and site release. A new clearance and release regulation will be in force as of 1 January 2012; also, the regulations concerning discharges from nuclear facilities are currently under revision.

One strength of SSM's present and forthcoming regulations on clearance and release is that they allow for flexibility and a graded approach. This is achieved by stipulating several alternative clearance levels depending on how the cleared material is to be managed after clearance. Another strength of the regulations is that they encourage continuous improvement. Optimisation and use of Best Available Technique (BAT) shall reduce discharges; it is insufficient to merely fulfil the dose constraint of the regulations.

The discharge regulations should be revised and requirements be introduced on e.g. regular reviews of the dose models being used for calculating individual doses in the critical groups. A review of requirements concerning targets and reference values is planned. Discharges during dismantling of nuclear facilities are currently not controlled by general regulations. In order to avoid dual regulation, a review has begun

of the discharge regulations. Currently, no explicit requirements have been imposed on waste minimisation nor on using clearance of waste to limit the resulting quantities of radioactive waste. SSM should provide guidelines related to the implications of optimised waste management.

The conclusion of the self-assessment is that there is good compliance with the IAEA's standards.

11.5 Environmental monitoring associated with authorized practices for public radiation protection purposes

Counterparts

Jan Lillhök
Head of Section
Nuclear Power Plant Safety
+46 8 799 42 67
Jan.Lillhok@ssm.se

Maria Lüning
Analyst
Nuclear Power Plant Safety
+46 8 799 41 28
Maria.Luning@ssm.se

Safety Series no 115: Basic Safety Standards RS-G-1.8 - Environmental and Source Monitoring for Purposes of Radiation Protection

Assessment for IAEA requirements

The Swedish regulations require the registrants and licensees to have appropriate monitoring equipment and carry out monitoring programs in cases where there is a potential for unexpected/unknown discharges leading to non-negligible public exposures, e.g. nuclear facilities. These provisions are found in the regulations SSMFS 2008:23 regarding protection of human health and the environment from the releases of radioactive substances from certain nuclear facilities and SSMFS 2008:16 regarding handling of ashes containing Cs-137 produced in incinerators. The magnitude of expected doses to members of the public is an important parameter when considering whether environmental monitoring should be required or not. Monitoring is required at nuclear facilities but not at small laboratories using radioactive substances. For nuclear facilities a specific environmental monitoring program for each facility is designed and reviewed as appropriate by SSM (SSI report 2004:15).

Pre-operational studies would first be designed and carried out by a license applicant as a necessary step in producing an environmental impact assessment that should be included in the application to the Environmental Court and to the Swedish Radiation Safety Authority if so demanded by the Authority. Monitoring programs during the operational stages are reviewed regularly to reflect, for example, changes in the operation of facilities.

During decommissioning, monitoring programs are reviewed as the decommissioning proceeds (SSMFS 2008:19).The monitoring program at the shut-down Barsebäck site

is thus currently less intensive compared to corresponding programs at operational NPPs as spent fuel, other fissile materials and highly radioactive components have been removed (see SSM decision SSM2008-858). The program will once more be reviewed when the next steps of decommissioning proceeds with dismantling and decontamination activities.

In the monitoring programs the requirements take into account the source characteristics as they are designed individually for each nuclear facility. This means for example that less aquatic samples are taken around the fuel factory (Westinghouse AB in Västerås) compared to the nuclear power plants. However, nuclide specific uranium analyses are instead required for all samples at this site.

Monitoring programs for nuclear facilities encompass biota and environmental media in both aquatic and terrestrial ecosystems in order to cover a wide range of actual and possible exposure pathways due to controlled and potential uncontrolled discharges.

Nuclear facilities should report monitoring results twice every year. Discharges should be reported as discharged activity as well as resulting dose to a representative individual. If discharges of radioactive substances to air and/or water results in monthly doses to a representative person exceeding 10 µSv, or if the results from the environmental monitoring program display higher than normal activity levels, the authority should immediately be notified.

Monitoring around deposits of wood ashes is limited to Cs-137 in leaching water, surface water and ground water, as the source of concern in this case is soluble Cs-137.

As mentioned above, for most other practices with ionising radiation, e.g. hospitals and laboratories, it is judged that no regular environmental monitoring is needed. In practices, where gaseous radionuclides are produced or are generated from systems with substances labelled with radionuclides, SSMFS 2010:2 require the responsible party to estimate and report the yearly amount of activity discharged to the air (section 5).

Record holding requirements varies between 5 years (estimated discharges from laboratories, SSMFS 2010:2), 10 years (results from ash deposit monitoring, SSMFS 2008:16), 25 years (yearly report of discharges from nuclear facilities, SSMFS 2008:38), and long term (results of environmental monitoring at nuclear facilities, SSMFS 2008:38).

Summary and Conclusions

Environmental monitoring activities and discharge surveillance around Swedish nuclear facilities are systematic and work well. The degree of compliance with the regulations issued by SSM is judged to be high.

SSM has concluded that a general monitoring programme is not usually needed for other types of facilities, i.e. laboratories and hospitals. However, there is a requirement stipulating that doses due to releases should be estimated.

SSM's resources and the need for competence in terms of environmental monitoring as well as control activities and database management should be reviewed.

There is good compliance with the requirements formulated in the IAEA's standards.

11.6 Control of chronic exposures (Radon, NORM and past practices) and remediation

Counterparts

Kirlna Skeppström
Analyst
Radiation Protection
+46 8 799 41 17
Kirlna.Skeppstrlom@ssm.se

Ann-Louis Söderman
Analyst
Radioactive Materials
+46 8 799 43 71
Ann-Louis.Soderstrom@ssm.se

M11

Safety Series no 115: Basic Safety Standards
WS-R-3 - Remediation of Areas Contaminated by Past Activities and Accidents

Radon in air

Responsibility for issues related to radon exposure and subsequent actions taken to decrease the harmful effects are shared by several authorities.

The Swedish National Board of Housing, Building and Planning (Boverket) is responsible for establishing radon and gamma action levels in new dwellings (currently 200 Bq/m3, BFS 2006:12, BBR12). The Swedish National Board of Housing, Building and Planning are also administrating a state grant for remediation.

The Swedish Radiation Safety Authority (SSM) is responsible for making risk assessment and follows the development in measurement technology.

The National Board of Health and Welfare (Socialstyrelsen) is responsible for supporting the municipalities regarding radon and indoor environment supervision. Socialstyrelsen also establishes recommended action levels for dwellings, schools, kindergartens and public venues (currently 200 Bq/m^3, SOSFS 2004:6 and SOSFS 1999:22).

Swedish Working Environment Authority (Arbetsmiljöverket) is responsible for radon levels in work places and establish the action level for these (currently 400 Bq/m^3, except for mines and areas where ore is handled, where it is 2,5 $MBqh/m^3$ per year, AFS 2005:17).

Geological Survey of Sweden (Sveriges geologiska undersökning) is responsible for geological aspects of radon.

The municipalities are responsible for the health and environment of the inhabitants. And to make sure that dwellings with high radon levels are traced, measured and remediated.

Radon and other radionuclides in drinking water

The allowed amounts of radionuclides in drinking water are regulated in SLVFS 2001:30 issued by the National Food Administration, which regulates drinking water from bigger facilities serving more than 50 persons or has a daily production exceeding 10 m^3 and also all public or commercial water plants.. The total indicative dose (TID) should not exceed 0.1 mSv per year. However radon-222 potassium-40 and tritium is not included in the TID. For radon and tritium the limit is 100 Bq/l.

Regarding private water facilities, e.g. drilled wells, the National Board of Health and Welfare regulations SOSFS 2003:17 and 2005:20 apply. These regulations recommend that drinking water should not be used if radon concentrations exceed 1000 Bq/l.

NORM

A survey was initiated by the SSI/SSM as a response to a requirement from the EU-BSS to estimate the impact of NORM work activities. This survey included the following NORM occurrences; ashes from incineration of wood fuel and peat, water filters, scales inside water pipes, slag from the iron and steel industry, thoriated welding electrodes, zircon sand, historical waste as burned alum shale, mining residues and phosphor gypsum, discharges from factories producing cement, bricks or roofing tiles, and the exposure of aircrew.

The survey indicated that besides from ashes from tree fuel and peat burning the dose consequences are negligible. Protective measures, as regulations, are in place for the handling of ashes from tree fuel, and are under development regarding peat burning, with the aim to limit doses to the general public and to avoid transfer of radionuclides to land with originally lower content of radionuclides. SSM is responsible for this. So far, the local authorities have not been involved. A preliminary statement is that the work activity for NORM is not required to be authorized or licensed.

Regulations on exemption and clearance of NORM up to certain activity concentrations entered into force in January 2012 (SSMFS 2011:4). These regulations are aiming at simplifying the management of NORM that is enforced according to the Environmental regulations. SSM follows the radiological situation for different activities continuously to see if any legal actions are needed. The situations are thus handled in an ad hoc manner. The guidelines for deciding if any action is needed for an ongoing work activity are the suggested constraints for exemption in the planned new EU-BSS (only draft) i.e. more than 300 µSv/year for NORM and for artificially occurring radio nuclides more than 10 µSv/year or more than 1 manSv/ year.

Legal framework concerning remediation of contaminated areas

The Polluter Pays Principle (PPP) is included in the Radiation Protection Act (section 6 and 13), the Act on Nuclear Activities (section 5 b and 10) and the Environmental Code (chapter 2, section 3 and chapter 10). Under that principle the operator is responsible for emissions during normal operation of an enterprise or for accidents that may cause harm to humans and the environment. If the land is contaminated by emissions from the activity, the operator is required to take remedial actions.

If the enterprise has ceased and the operator does not longer exist, responsibility for remedial actions could, under certain circumstances, be placed on the legal person who owns the land that is contaminated (chapter 10 in the Environmental Code). If responsibility cannot be placed on the operator or the later land owner, government subsidies may be disbursed for the remedial actions needed (Regulation 2004:100 on remediation of contamination and state subsidies for such remedial).

Remedial actions are covered by the Radiation Protection Act, the Act on Nuclear Activities or the Environmental Code and must consequently comply with all relevant provisions in these acts. This means, for example, that the remediation work has to be justified, optimised (ALARA) and implemented under specified dose limitations. Furthermore, all relevant requirements on radiation protection, nuclear safety and environmental protection must be complied with, e.g. regulations on outside workers in practices involving ionising radiation (SSMFS 2008:52), regulations on fundamental provisions for protecting workers and the public in connection with practices with ionising radiation (SSMFS 2008:51), regulations on personal radiation protection in activities with ionising radiation in nuclear installations (SSMFS 2008:26), regulations on the protection of human health and the environment of discharges of radioactive substances from nuclear facilities (SSMFS 2008:23).

Additionally, under the above mentioned acts SSM may issue additional conditions and prohibitions concerning remediation of contaminated areas.
There are additional legal provisions regarding remediation in case of future accidental releases of radioactivity (Civil Protection Act (2003:778) and Civil Protection Ordinance (2003:789)) where the County Administrative Board is appointed the responsibility for remediation work after releases of radioactivity from nuclear facilities (Chapter 4, section 15).

Waste from remedial actions falls under the same legal control as other wastes or materials containing radionuclides.

Identification and prioritization of existing contaminated areas

A national survey of contaminated areas has identified approximately 80 000 potentially contaminated sites in Sweden. These are classified and prioritized by the county administrative boards coordinated by the environmental protection agency. All sorts of contaminants from industries and other sources of contamination are included in the survey. No areas have been identified as needing active remediation because of contamination with radioactive substances.

The draft version of the next Euratom Basic Safety Standards, BSS, lists NORM practices with possible radiation protection concern. In connection with the work

with the new BSS, a review of such practices in Sweden, including past activities potentially involving contaminated areas, was carried out between 2006 and 2007 (SSI ref no. 2006/880-40). Although there are large quantities of NORM from activities in the past, including the gypsum production industry and residues from alum shale exploitation, no need for remediation was identified.

Strategies and plans for remediation

As no areas in need of remediation regarding radioactivity have been identified, there are no strategy or specific plans in place to deal with existing contaminated areas.

Generic plans regarding remediation after accidents are required by the Civil Protection Act (2003:778) and are produced by the county administrative boards. Such plans for civil protection and remediation shall consider: 1) organization and leading, 2) operational communication, 3) radiation measurements, 4) information to members of the public, 5) human and material resources, remediation methods, 6) other aspects of importance to emergency preparedness.

To help to produce such generic plans there are guiding materials on different levels available such as guidance and comments to the civil protection act from the Swedish Civil Contingencies Agency (SRVFS 2007:4), Handbook on planning for remediation regarding radioactivity (*Handbok, Sanering av radioativa ämnen, Räddningsverket December 2007*) and Guidance on remedial actions regarding plant production (*Jordbruksverket , rapport 2008:27*).

Summary and Conclusions

SSM/Sweden does not strictly fulfil the requirements formulated in the IAEA's standards regarding contaminated areas. The IAEA's safety standards require a very systematic review of potentially contaminated areas and their being classified as being contaminated or not based on established criteria. Sweden has not employed this kind of systematic inventory/classification. Based on less formal input such as conclusions from a previous national project ('UPPÅT', i.e. 'Upwards'), SSM nevertheless holds the view that there are no areas needing decontamination from radioactive substances.

Responsibility, including financial liability for decontamination of areas, is clearly described in the legislation.

For radon, the responsibility is divided between different central authorities with different areas of responsibility. The areas are well defined and the authorities have a joint working group for discussion of radon issues. The role of SSM is to be the expert authority with a special mission to follow the development of risk estimation and measurement techniques.

References

SFS 1988:220 Radiation Protection Act
SFS 1998:808 Environmental Code
SFS 2003:778 Civil Protection Act
SFS 2003:789 Civil Protection Ordinance

SFS 2004:100 (In Swedish) *Förordning om avhjälpande av föroreningsskador och statsbidrag för sådant avhjälpande*

AFS 2005:17 Occupational Exposure Limit Values and Measures against Air Contaminants

BFS 2006:12, BBR12 (In Swedish) *Boverkets föreskrifter om ändring i verkets byggregler (1993:57) – föreskrifter och allmänna råd*

SLVFS 2001:30 (In Swedish) *Gränsvärden för dricksvatten*

SOSFS1999:22 (as amended by SOSFS 2004:6) (In Swedish) *Socialstyrelsens allmänna råd om tillsyn enligt miljöbalken – radon i inomhusluft*
SOSFS 2003:17 (as amended by SOSFS 2005:20) (In Swedish) *Socialstyrelsens allmänna råd om försiktighetsmått för dricksvatten.*

SSMFS 2008:1 (as amended by SSMFS 2011:3) regulations and general advice concerning Safety in Nuclear Facilities
SSMFS 2008:15 concerning Emergency Preparedness at Certain Nuclear Facilities
SSMFS 2008:16 regulations and general advice on the handling of Ashes Contaminated by Cs-137
SSMFS 2008:19 on Planning before and during Decommissioning of Nuclear Facilities
SSMFS 2008:23 on Protection of Human Health and the Environment in connection with Discharges of Radioactive Substances from certain Nuclear Facilities
SSMFS 2008:27 on Practices with Accelerators and Sealed Sources
SSMFS 2008:28 concerning Work with Open Sources at Laboratories
SSMFS 2008:38 regulations on Archiving at Nuclear Facilities
SSMFS 2008:39 on the Discharging of Goods and Oil from Controlled Areas at Nuclear Facilities
SSMFS 2008:51 regulations concerning basic provisions for the protection of workers and the general public in practices involving ionising radiation
SSMFS 2008:52 Regulations on outside workers in practices involving ionising radiation
SSMFS 2010:2 concerning Radioactive Waste and Releases from Practices using Open Sources
SSMFS 2011:4 concerning naturally occurring radioactive material

Guidance on remedial actions regarding plant production, *Jordbruksverket* (Swedish Board of Agriculture), Report 2008:27
Handbok, Sanering av radioaktiva ämnen (In Swedish), Räddningsverket (Former authority now part of Swedish Civil Contingencies Agency), December, 2007

SSI 2006/880-40 (SSI-Report 2007:02, m.fl.) Investigation of NORM activities in Sweden. Söderman, A-L, Brewitz, E. and Möre, H.

SSI-Report 2004:15: *Omgivningskontrollprogram* (In Swedish)

SSM decision SSM2008-858 (In Swedish) *Radiologiska omgivningskontrollprogrammet för Barsebäck Kraft AB (BKAB)*

IAEA TECDOC 855 Clearance levels for radionuclides in solid materials

STYR2011-159 *Control of aerosol filters in the main stack* (In Swedish)

Module 12: Documentation from the event in Japan

Counterparts

Lynn Hubbard
Head of Section
Radiation Protection
+46 8 799 42 62
Lynn.Hubbard@ssm.se

Jan Hanberg
Head of Section
I Nuclear Power Plant Safety
+46 8 799 42 21
Jan.Hanborg@ssm.se

Anders Hallman
Analyst
Nuclear Power Plant Safety
+46 8 799 42 42
Anders.Hallman@ssm.se

Introduction

During the period 11-31 March 2011, the Swedish Radiation Safety Authority (SSM) had its crisis organisation activated around the clock in the Emergency Response Centre (‘LedC’) located in the premises of the Authority. The cause was a severe earthquake and ensuing tsunami that caused enormous difficulties at several reactors at the Fukushima nuclear power plant located in northeast Japan.
During the period when the crisis organisation was activated, a total of around 130 persons worked with a variety of duties at the LedC. Several other authorities and organisations were affected by the situation in Japan, for example the Swedish Civil Contingencies Agency (MSB), the National Board of Health and Welfare, Swedish Customs, the Swedish National Food Agency, the Ministry for Foreign Affairs (UD), the Ministry of the Environment and the Swedish Defence Research Agency (FOI).

Information about the earthquake

During the morning of 11 March, information began to reach Sweden about a severe earthquake having hit eastern Japan. Employees of the Nuclear Safety Department (Dept. K) began to consider the possible impact on the nuclear power reactors located along the east coast of Japan.

Around 10 am, the officer on duty (TiB) received information that the reactors in Fukushima had experienced an emergency shut down as a result of the earthquake. The TiB then contacted the Emergency Preparedness and Response Section (SB) and the press officer on call. At this time, the mass media had begun posing questions to SSM about the emergency shutdown at the Fukushima reactors. TiB also

discussed the event with the officer on duty for reactor emergencies (RB) and it was speculated that the reactors had problems with their cooling.

Around 1 pm, SSM's senior management was informed about the impact of the earthquake on the nuclear power reactors in Fukushima. SSM's Director General (DG) then issued instructions that SB was to monitor the situation. At 14.00, SB held a discussion with MSB and described the situation. In the afternoon, MSB also held a telephone conference for information gathering including participants from SSM, UD and the National Board of Health and Welfare. During this conference, SSM was informed about the fact that some 1,500 Swedish citizens were in Japan. Between 300 and 400 of them were permanent residents. UD (the Ministry for Foreign Affairs) also informed SSM about lists that had been compiled on Swedes who were in Japan. The information available to SSM at the time was that several reactors in Fukushima had problems with emergency cooling of their reactor cores. The information received by SSM that afternoon mainly came from news sites on the Internet and television broadcasts. It took several hours until information came from official sources, such as the International Atomic Energy Agency (IAEA) and the Nuclear and Industrial Safety Agency in Japan (NISA).

Activation of the crisis organisation

At 16.00 on 11 March, the head of the Emergency Preparedness and Response Section (cSB) convened a meeting at SSM's LedC. At this time, the decision had been made by the director of the Radiation Protection Department (cS) to activate a small-scale crisis organisation for monitoring the event. The cSB was assigned to appoint staff for the crisis organisation. The initial crisis organisation was staffed by these functions: TiB, RB, press officer on call, cSB as well as a few staff members with expertise in radiation protection from SB. Four of these staff members also worked in the LedC to monitor the event and seek out information during the evening and night; other personnel were on call from home for emergency preparedness duty. It became clear during the evening that the event was developing and becoming more serious.

Around 8 o'clock on Saturday morning, more persons were called in and cSB took the decision at the first staff meeting at 09.00 to activate the crisis organisation. More persons began to be called in according to the staffing plan.
That Monday, the decision was made to instruct SSM's Administration Director to maintain and manage the responsibilities of the authority which were unrelated to crisis management.

Expanding the organisation

In the early hours of 15 March, the event in Fukushima took a far more serious turn. The operational chief (OC) on duty took the decision to expand staffing of the crisis organisation throughout all three shifts for the coming week. The crisis organisation never reached the full staffing level that would be needed for an accident in Sweden or near Sweden with consequences for Sweden. Nevertheless, problems in staffing the crisis organisation arose, illuminating the greater need for personnel in the event of an accident that directly affects Sweden.

As of the afternoon of 15 March, a representative from the nuclear medicine team of experts (N-MEG) from the National Board of Health and Welfare was available at

the LedC for assistance to SSM in areas relating to medicine. This was the result of a discussion between the National Board of Health and Welfare and SSM concerning assistance needed regarding questions and matters related to (among other things) radiation injuries and iodine tablets.

On 25 March, a discussion with Swedish Defense Research Agency (FOI) commenced on possibly bringing in personnel from FOI to the function of radiological and nuclear analysis because SSM's staff had begun to show signs of exhaustion, indicating the need to supply the shift teams with replacement personnel. Several FOI employees also began to undergo training to prepare them for the work at SSM's LedC. During the final week of the crisis organisation's work, FOI employees staffed the function of both radiological and nuclear analysis from time to time.

SSM's role

SSM's main mission 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.

Mass media

SSM had a pre-existing media strategy for work in the crisis organisation. This strategy involves allowing specialists to respond to questions from the mass media instead of communication officers and supervisors, for example. The strategy also involves their being available when the mass media wants an expert for a talk show or news broadcast, radio interview and the like. These spokespersons are from SSM's regular organisation 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 organisation. This information includes updates on and analyses of the situation at hand and key messages that SSM wants to communicate.

Three persons were initially appointed as spokespersons, but in pace with the event's growing scope and mass media demand, and also because it became clear that the situation would continue to unfold over several days, additional spokespersons were appointed.

Already during the first weekend, the word 'meltdown' was quoted in the mass media from a spokesperson. Comparisons with Chernobyl were also made early on. This sparked discussions in the crisis organisation, but it turned out that using commonly understood terms was a good approach, even if they have strong connotations. The spokespersons were conscientious when explaining the meaning of the concepts; also, information and explanations about the concepts were published on SSM's website.

During the period when the crisis organisation was activated, ten or so persons worked as spokespersons and SSM was mentioned daily in news broadcasts during

the entire three weeks. From time to time, the spokespersons were also accessible in various chat forums.

Information for the general public

For the purpose of communicating information to the general public, SSM utilised the mass media for conveying key messages concerning the situation in Japan (as described above) as well as information officers for responding to questions from the general public by telephone, e-mail and (after some time) on Facebook. Questions from the general public varied over the period in terms of both the quantity and kind of questions posed. Some of the most common questions had to do with the travel advisories issued by the Ministry for Foreign Affairs as well as iodine tablets. The public information officers had a difficult role. A majority of the telephone queries were from people very concerned for their own part, relatives or family members. It was not uncommon for the public information officers to have to deal with anger and criticism.

SSM also published information regularly on its website and an FAQ ('Frequently Asked Questions') was drawn up using updated responses to the most common questions posed by the general public. The website received a gradually more prominent role in pace with the information published there. It also became an important source of information for other government authorities.

The rising frequency of questions related to the travel advisories and their duration led to a decision being taken on 24 March to retain the recommendations issued by SSM to the Swedish UD as a permanent item for the staff meetings. The intention here was to regularly reassess whether the recommendations were still relevant and should remain in effect.

SSM's message over the first few days was for Swedish citizens in Japan to follow the recommendations issued by Japanese authorities. After five days had passed, however, SSM issued its own advice and recommendations to the Swedish UD based on the monitoring data available, as well as analyses conducted by SSM's crisis organisation. This work was also backed up by analyses conducted by other countries. This was largely a result of the 'silence' from the Japanese authorities when the flow of information from Japan suddenly stopped. This was apparently because the pressure on the Japanese authorities became so severe that international communication was not prioritised.

Information and the recommendations for the Swedish Government and Government Offices

Throughout the sequence of events, the Government Offices were kept informed based on the information available to SSM. The main information requested by the Government Offices was what the worst potential scenario could be.

At 15.00 on Saturday, 12 March, a state secretary meeting was convened at the Rosenbad location of the Government Offices. SSM attended and on this occasion reported a relatively upbeat interpretation of the situation. The information available then indicated that correct action was being taken at the nuclear power plants. This observation was delivered with reservations because of the uncertainty and lack of information available. Prior to the state secretary meeting, representatives from SSM

had attended meetings at the Ministry of the Environment and Ministry for Foreign Affairs. Representatives of the Government Offices were also informed that Sunday. The information provided by SSM became increasingly pessimistic as the situation in Japan became clearer.

On Monday, 14 March, a meeting was held at the Government Offices where representatives of SSM met with representatives of the Prime Minister's Office, the Crisis Management Coordination Secretariat, the Ministry for Foreign Affairs and Ministry of the Environment. It was during this meeting that regular debriefing meetings in the form of video conferences between SSM and the Government Offices were mentioned and agreed upon. A second state secretary meeting was held on 18 March. This time around, the perception of the situation was much gloomier. A third state secretary meeting was held on 22 March where SSM reported on the situation in Japan.

As of Tuesday, 15 March, regular videoconference meetings were held between the Government Offices (the Prime Minister's Office and the Crisis Management Coordination Secretariat) and SSM.

Direct contact was established with the Swedish embassy in Tokyo in addition to the contacts established between SSM and the Government Offices. The Swedish embassy was also sent minutes from staff meetings of SSM crisis organisation.

Information and recommendations for other authorities

During SSM's handling of the accident in Fukushima, there was a considerable need to provide other relevant authorities in Sweden with information. Various forums for this communication evolved during the sequence of events. Three main channels were set up at an early phase for regular reporting: e-mail lists, SSM's website and WIS (a protected web-based information system), where SSM published information frequently.

WIS enabled other central government authorities as well as other stake-holders to gain access to the information. Initially, SSM limited the access to published information to central government authorities. Already that first weekend, other stakeholders requested access to the information (that they then lacked access to), whereupon the OC on duty verbally announced the decision to expand the scope of dissemination to several other stakeholders, such as municipal authorities and county administrative boards. The frequency and content of the information published on WIS varied over time. At first, the minutes from staff orientation meetings and the recommendations issued by SSM were published. On 14 March, the decision was made to replace the minutes with updated reports on the situation.

SSM also maintained regular contact with several other authorities, mainly the National Board of Health and Welfare and the Swedish Civil Contingencies Board. SSM predominantly submitted recommendations to the National Board of Health and Welfare, Swedish Customs and the National Food Agency (see below for more information about them).

The recommendations and information from SSM were also published on SSM's website. This was usually done before the information was published on WIS, thus making the website the fastest source of information for other authorities. To some extent, this undermined the aim of WIS.

Retrieving information

The information disseminated by Japanese authorities and the IAEA was delayed by several hours. The Internet and international mass media were the main sources of information, but the personal networks of employees also provided important information sources.

During the first few days, SSM had an opportunity to receive help with translations of press conferences and the like from Japan. This facilitated and made information retrieval more expedient. However, SSM did not use information until it had been confirmed through official sources (Japanese authorities, the IAEA, etc.). This is partly why confirmation of information took a long time.

The time aspects of the flow of information resulted in SSM not receiving any new information directly from the official sources in Japan. Instead, it was necessary to confirm the accuracy of information and recommendations from Japanese authorities with (for example) websites and television news broadcasts.

Should a team of experts be sent to Japan?

On 12 March, the IAEA asked if SSM could send a measurement team to Japan. On 15 March, the Ministry of the Environment posed the same question. The DG function on duty and OC discussed this question and established relatively quickly that this was impossible due to a lack of resources. A preliminary cost estimate for this action was nevertheless made and presented to the Government Offices, which also had the opportunity to make the final decision on whether or not to send a team from SSM. At this time, the attitude at SSM was: "if the Government wants us to, then we will go". After this, SSM heard nothing more about this question from the Government Offices. MSB also asked SSM if it could provide a radiation protection expert for assignment to a team of experts whose destination was Japan. SSM also turned down this request owing to a lack of resources.

UD wanted expertise available to the embassy in Tokyo. SSM suggested that UD contact FOI. Two persons from FOI (the Swedish Defence Research Agency) in Umeå travelled to Tokyo and SSM maintained regular contact with them. Finland, Norway and Denmark also sent experts from their corresponding government authorities.

Decisions and recommendations issued by SSM

As mentioned above, one of SSM's tasks during a serious incident abroad is to provide recommendations to the Government Offices and other authorities while also providing information to the general public for the purpose of maintaining nuclear safety and radiation protection. During the event in Japan, a number of key decisions were made with the aim of, among other things, helping UD to interpret the degree of severity of the event, hypothetical scenarios and possible risks of measured or potential radiation levels.

Decisions concerning recommendations for UD

Early in the morning of 15 March, SSM submitted a recommendation to the Ministry for Foreign Affairs (UD) that Swedish citizens should avoid unnecessary travel

to the area around Fukushima (a 80 km radius). SSM announced this recommendation together with UD. The background here was that the situation at Fukushima remained grave and unsafe; also, the weather conditions were unpredictable.

Late in the evening of 16 March, this recommendation was updated to apply to all of Japan based on the information available to SSM about a significantly lower level of water than was safe in reactor 4's pond containing spent nuclear fuel. There was a risk that the fuel would ignite and cause a large release of radioactive material.

That same evening, on 16 March, SSM also issued a recommendation stating that Swedish citizens within a radius of 80 kilometres from Fukushima should evacuate. This recommendation had been issued earlier that same day by the United States. The U.S. Department of Energy (DOE) had its own personnel and monitoring equipment on site. SSM's own radiological analyses showed that this recommendation was reasonable, for which reason the decision was made to issue the same recommendation for Swedish citizens in Japan.

The recommendations provided by SSM to UD were partly based on SSM's own analyses from weather forecasts, information about raised radiation levels measured around the nuclear power plant as well as information about the technical situation plus the recommendations issued by other countries.

Decisions concerning iodine tablets

Already after a few days in the LedC, 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.

When the iodine tablets first arrived in Japan on 18 March, they got stuck in customs with the explanation that there was no way of knowing what the tablets contained. SSM was asked to send a letter with a list of ingredients along with an explanation for the shipment. After this, the tablets were cleared by Japanese customs and arrived at the Swedish embassy in Tokyo. Instructions regarding iodine tablets were sent to UD during the early hours of 17 March. Norway, Denmark and Finland also sent iodine tablets to their respective embassies.

On Saturday, 19 March, 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 includes Tokyo. When this recommendation was issued, SSM staffed the LedC with additional information officers for the general public. However, an increase in the frequency of telephone calls from the general public did not materialise.

The decision to recommend taking iodine tablets was based on discussions involving experts from many fields. For instance, it was considered which recommendations would have been issued if the event had occurred in Sweden and it was established that the recommendations would nevertheless have been the same for the Swedish

citizens in Japan. Another key aspect was the delay before information about the situation in Fukushima reached SSM. When analyses implied potential scenarios that would necessitate taking iodine tablets, SSM began to consider whether crucial information could reach SSM in time. SSM made the assessment that this information risked taking too long to arrive, which is why SSM decided to recommend taking iodine as a precaution before it had been fully established that a discharge would take place. Discussions with the National Board of Health and Welfare contributed to the perception that it was better to take iodine in time, but perhaps unnecessarily, than to take them too late.

Other countries reacted quite strongly to this recommendation and Sweden was the only country to recommend its citizens located in Japan to take iodine tablets. Other countries assessed that taking iodine tablets unnecessarily could imply a risk. The general public also reacted after a day or two. This was noticed in the LedC, as many questions from the general public had to do with where to obtain iodine tablets and the dose that should be taken. In a nutshell, many people in Sweden became concerned and wanted to take iodine tablets to be on the safe side. Many pharmacies also ran out of iodine tablets. However, this should probably not be viewed as an effect of SSM's decision about taking iodine tablets in Japan as there were indications that stocks of iodine tablets had already run out earlier. SSM communicated (for instance on its website) that there was no reason for concern, or to take iodine tablets, in Sweden. Following the recommendation about taking iodine tablets, the number of visits from Japan on SSM's website rose. SSM also observed an increase of postings on Twitter about this recommendation.

Monitoring passengers arriving from Japan

On Monday 14 March, the crisis organisation discussed the need for monitoring passengers arriving in Sweden from Japan. During a staff meeting on Monday evening, the decision was made to draw up a strategy for this work. This topic would also involve reviewing the collaboration with the National Board of Health and Welfare and the nuclear medicine experts, N-MEG.

A meeting with the National Board of Health and Welfare was held on 15 March, in which the possibility of performing monitoring at airports was discussed. What was discussed was the possibility of setting up scanning arches at Swedish airports in order to perform monitoring. This kind of action would require the involvement of several different stakeholders. SSM would provide the equipment, Swedish Customs would perform the monitoring and Swedavia, who run the airport, would need to make premises available. On 15 March, the OC on duty also contacted the Ministry of the Environment for approval for activation of the emergency preparedness laboratories so that monitoring could be performed at Stockholm Arlanda Airport.

Already at an early stage, Swedavia expressed its reservations about the idea of performing monitoring at airports. Swedavia proposed using airport premises belonging to the police or Swedish Customs instead.

At the LedC, the opinions of the staff differed as to whether or not to perform monitoring. The members of the crisis organisation agreed that, from a radiological perspective, there was no justification for performing monitoring. There was only a slight risk that people arriving in Sweden from Japan would be contaminated. On the other hand, however, it was argued that from a psychological perspective, it would

be meaningful to offer people the possibility of body scans at the airport if they were concerned. It was also argued that this could risk alarming people unnecessarily.

During the first week, SSM published information on its website stating that there was no reason for people who had been in Japan to undergo monitoring or medical examinations. SSM also published information about the on-going work to identify solutions to calm people who were nevertheless concerned.

Early in the morning of 17 March, radiological analysts and public communication officers worked together to develop procedures and draw up instructions for scanning arches at airports. It was pointed out that the decision to launch preparations for this work was based on the willingness to respond to and ease people's concern and not because SSM was of the opinion that it was necessary in terms of radiation safety. This work continued that day and scanners were on standby at nuclear power plants, which in this case would lend them out for monitoring at airports. Staff at the emergency preparedness laboratories throughout Sweden was also ready to provide assistance with monitoring. In addition, SSM had established contact with Swedavia and the Swedish Customs, which were ready to begin monitoring work if this decision was made.

Later in the evening of 17 March, SSM produced information together with the National Board of Health and Welfare stating that Swedish citizens arriving home should contact their county council for a medical examination if they were concerned. After this point, discussions and preparations related to monitoring at airports tapered off.

The other Nordic countries had varying strategies for monitoring of citizens returning home. As Sweden, Norway also considered setting up monitoring equipment, whereas Finland and Denmark had no plans to do so.

Monitoring incoming shipments from Japan

On 18 March, discussions were launched with the National Food Agency and Swedish Customs about inspections of foodstuffs and other goods coming from Japan. SSM also informed the National Food Agency about new limits for nuclides in foodstuffs produced by the European Commission. On 19 March, it was established that raised levels of radioactive substances had been measured in certain foodstuffs (e.g. spinach and milk) in the near vicinity of Fukushima. That same day, SSM produced a decision concerning instructions for Swedish Customs about inspections for determining whether shipments from Japan were contaminated with radioactive substances. The next day, Swedish Customs received instructions about contacting SSM if the measured radiation levels for goods exceeded a certain recommended value; then SSM would deal with these matters on a case by case basis. Following a request, the National Food Agency received recommendations from SSM to monitor Cs-137, Cs-134 and I-131 as well as conduct random sampling of alpha and beta radiation. SSM was of the view that this monitoring should suffice.

Over the next few days, several questions were received from both private individuals and enterprises about how to deal with imported goods from Japan. SSM subsequently produced a document describing the recommended procedure for shipments from Japan, which was published on SSM's website on 21 March.

Monitoring radiation levels in Sweden

During the crisis organisation's second week, SSM tasked FOI with monitoring the air filter stations placed throughout Sweden more often than under normal conditions. Monitoring was to be conducted once every 24 hours and the monitoring results reported to SSM. SSM's intention was to show through actual measurements to what extent the levels would be elevated. It was anticipated that they would be elevated but not to any dangerous degree. In the evening of 23 March, the first monitoring results arrived, showing raised radiation levels measured in Umeå and Kista. This information was published as a news item on SSM's website, resulting in questions from the mass media about the implications. Throughout 24 March, many questions were posed by the general public about the radiation levels that had been measured. People were concerned about the radiation having reached Sweden and wanted to know how to protect themselves. In response, the function of radiological analysis drew up an example comparing the monitored levels with a conventional dental X-ray examination. This example helped to illustrate that the radiation measured in Sweden corresponded to one-thousandth of the dose received when X-rayed by a dentist. This example was conveyed to the information officers for the general public, who in turn could explain it to concerned callers. SSM also published similar information on its website with a more detailed explanation about the measured values being very low and entirely as anticipated.

Downsizing and closure of the crisis organisation

Already during the night of 14/15 March, an attempt was made to reduce staffing during night shifts in order to relieve the burden on personnel. This attempt was called off when the situation in Fukushima deteriorated.

On 25 March, the decision was made to reduce staffing of the crisis organisation; this mainly affected staffing of night shifts. This decision was mainly based on the stabilising situation in Japan. The assignments for the LedC had become more clearly defined and the staff had a number of specific tasks to focus on. There was also less pressure from the mass media and the need for spokespersons had reduced. Schedules were drawn up in which certain emergency preparedness functions could be managed from home and the staff could be called in when necessary. This for instance applied to spokespersons.

During the third week, a certain level of discontent began to spread among members of the crisis organisation and SSM. Many people were exhausted and affected in other ways after having worked irregular hours. The regular SSM organisation also began to question the situation as many employees and managers/supervisors had been away from the regular SSM organisation for an extended period of time, which began to have an impact on day-to-day work.

At 15.00 on 31 March, the decision was made to disband the crisis organisation. After this point, SSM continued to monitor the situation in Japan, but this work was managed by the regular organisation. This work was mainly managed by SB with particular tasks for TiB and a number of employees from department K. On-going analyses were conducted regularly by the Radiation Protection Department (radiological analysis) and the Nuclear Power Plant Safety Department (nuclear technical analysis). Questions from the general public and mass media have continued to be dealt with by the regular organisation. This was initially done as directed by the Communication Department and gradually taken over by SB.

Internal information

During the first weekend, the crisis organisation discussed how to disseminate information to the entire Authority. It was initially decided that managers should inform their staff. However, one problem here was that many managers were themselves involved in the crisis organisation, so they had little contact with co-workers still engaged in day-to-day work.

During the first few days, more and more information became available to employees via the intranet. On Sunday, 12 March, information was prepared for all of the Authority's employees. This preparatory work was twofold: to provide information on the intranet and to inform all employees of the Authority about the situation in Japan and the work of the crisis organisation over the weekend. On 14 March, all the employees gathered for an Authority-wide meeting. These large-scale meetings were then held every day at first and gradually every couple of days. These meetings generally appeared to be appreciated by employees. Information about the situation in Japan and the work of the crisis organisation were retained as main items presented at these large meetings. Presentations were also made about mass media coverage at a few of the meetings. The interpretation conveyed was the high visibility of SSM in the mass media and that this was beneficial for SSM's image while also being a good opportunity to increase awareness of SSM. Details on the number of television and radio broadcasts and publications that had mentioned SSM or interviewed SSM employees were also presented.

Actions taken by SSM due to the experiences from the Fukushima accident

During the three weeks following the start of the Fukushima accident SSM had a 24/7 activity to inform and support the Swedish government, other Swedish authorities and to inform media and the public.

Handling a nuclear power accident in a country far from Sweden but still with implications for Sweden and Swedes living in Japan has led to several lessons learned regarding the functioning of SSM's crisis organisation, including combining its work with SSM's regular organisation. Since April of 2011, SSM's work with crisis planning has concentrated on improving

1. the internal instructions for regulating the roles and responsibilities of the different functions in SSM's crisis organisation,
2. routines for registering and recording various types of internal documentation,
3. revising procedure-lists for the different functions in the crisis organisation,
4. conducting education of different managing positions in the staff of the crisis organisation,
5. developing the role of the operative communication function,
6. educating the staff in basic operation of the various technical devices and services available in the emergency crisis centre,
7. developing routines for shift planning, and
8. improving the work environment and work requirements in the emergency crisis centre.

Work is planned during 2012 for continued improvements on SSM's crisis organisation based on identified problems.

Regarding the licensees, actions are also being taken. During the spring 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 Fukushima accident that had an implication on the Swedish nuclear power plants in a way that would require further immediate action. Accordingly SSM did not require any physical measures be done at the plants or any restrictions in the operation. SSM's opinion was that the stress test time table 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 not 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 with consequences similar to those that occurred in the Fukushima accident, 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.

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

SSM expect the findings from the stress tests to include the need for some plant modifications, new or revised safety analyses, changes and completion of emergency procedures, organization and staffing. Most of the expected improvements and needed plant modifications have probably to be proceeded by more detailed analyses to give guidance on how to implement them.

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.

One SSM activity which will handle the results from the stress tests is an assignment from the government. This assignment focuses on the long term safety development in the Swedish NPP´s and additional actions to be taken. The task was given 2010 and shall be reported in October 2012. The report shall include:

- An overall evaluation of the licensees compliance with the SSM requirements on modernization of existing NPP`s and how SSM judges the influence of the modernization on the safety. These so called back-fitting regulations were decided in 2004 with a transition period for each individual reactor depending the type and extent of safety improvement needed.
- An analysis of the conditions for long term operation, including the need for additional safety improvements and safety improvements as a consequence of development in technic and science.
- A judgment of the conditions being critical for the possibility for long term operation of the reactors.
- International experience from safety improvements.

The government's assignment was expanded in May 2011, by including the following:

- Reporting on the stress test results.

- Measures implemented by the licensees, in response to the stress tests, and the SSM assessment of them.
- Assessment of the issues identified by the stress tests, which need a more in depth analyses and other lessons learned from accidents in Fukushima and conclusions on the possible further actions needed at the Swedish NPP `s

The results of the stress tests as well as results from analysis and other investigations within the government assignment to SSM will be handled in different ways, depending of the safety importance of the identified safety improvements and the importance of the needed safety analyses. Decisions on actions by the licensees will be taken, but there is also a possibility for changes in the SSM regulation due to results of on-going activities.

M12

Policy issues

Supervisory strategy

Background

The Swedish Radiation Safety Authority (SSM) was established on the 1st of July 2008 by merger of the former authorities Swedish Nuclear Power Inspectorate (SKI) and the Swedish Radiation Protection Authority (SSI). Due to different backgrounds and tasks, the supervision strategy and methods had developed in different ways for the two authorities and, therefore, the approaches to supervision varied. The merger of the two authorities provides a motivation and an opportunity for increasing harmonisation, unification, and general overview of the supervision methods within the new authority.

Basic general steering documents for supervision and process descriptions for exercising supervision have been developed. These documents recognize that the supervision of radiation safety is complex and that the many licensees differ significantly, ranging from nuclear power plants to hospitals and small businesses that use radiation sources in their operations. Conditions for conducting supervision vary considerably across the following areas of operation.

- Safe nuclear power and other nuclear facilities
- Safe health and medical care
- Safe products and services
- Safe management of radioactive waste
- National preparedness and response for nuclear and radiological emergencies

Topics for discussion

SSM would like to discuss the international experience and collect the views of the IRRS-team regarding efficient and effective supervision across different areas of operation. For example, SSM is interested in the effects of the size of the country, available human resources and the scope and extent of the activities to be supervised on the methods available for supervision and the effectiveness of those methods. The following issues are key:

- How regulatory strategies for supervision of licensees differ depending on regulatory regime, type of licensee and area for supervision.
- What basic regulatory approaches are preferred (e.g. prescriptive, case-based, outcome-based, risk-informed, process-based, and self-assessment strategies)
- Lessons learned of different supervisory strategies – pros and cons
- Supervisory effectiveness and efficiency
    - The measures and indicators are available to evaluate supervisory strategies

- How evaluations are best accomplished

Discussion Goal: To identify issues and ideas for the SSM to further develop its regulatory supervisory strategy.

Proposed agenda for discussion:

- Introduction and presentation of SSMs earlier and on-going study on regulatory strategies
- Input by the different participating IRRS-experts
- General discussion.

Competence at SSM

Topics for discussion

SSM would like to discuss the international experience and collect the views of the IRRS-team regarding competence out of the following issues.

- SSM is a fairly small authority in a country with many activities in radiation safety, e.g. a large nuclear program
- A comprehensive survey shows that there are competence gaps at SSM
- Technical Support and expert professional advice in Sweden

Comparing internationally, the number of regulatory employees in Sweden is small for the size of the nuclear program. When comparing the number of employees between different countries, it is however important also to consider the types of legal obligations put on the licensees and the different supervision strategies.
Overall, the authority must cover a broad and at the same time deep competence with a relatively small number of employees, this gives a certain vulnerability and dependence on key individuals. Many of our employees are involved in several different tasks, such as inspections, regulatory reviews and approval tasks, revision of regulations etc. each activity requiring his or her expertise. Most employees have a good expertise within the field they are to work in. This is a result of the many specialist areas covered by the authority, and to some extent the fact that there is no Technical Support Organization (TSO) in Sweden to support the regulatory body with specialist knowledge.

The large number of different competences needed is a challenge when it comes to securing competence. An optimal situation would be to have good expertise as well as broad competence rolled into one person.

The comprehensive survey of the skills situation that has been made in February 2011 has shown that the competence situation is rather good. However, some areas of expertise are subcritical and the availability of international usable excellence needs to be improved. The experience from the nuclear accident in Japan also shows that some competencies are resource demanding from an emergency organization perspective. The survey has identified 59 areas of expertise, including management skills and methodology skills. The competence areas that are subcritical and have lack of skills require resources to be rectified and have therefore been addressed in the budget documents to the Government for 2012. The outcome of the proposal is

an increased budget from 2012 and onwards by 20 MSEK/year with an extra 5 MSEK/year from 2013 and onwards. Subcritical areas within the field of **nuclear safety** are; operations of PWR:s, the construction of electrical systems within nuclear reactors etc. There is also a lack of competence to carry out transient analysis and probabilistic safety analysis. Up to today these competences have been provided through external experts but our opinion is that in the future we will need these competences in-house. Within the field of **radiation protection** some competence areas are close to subcritical, these areas are; effects of radiation on human beings and internal dosimetry.

In Sweden there is not the type of TSO that exists in many other countries with nuclear power programs. SSM has decided not to establish a dedicated support organisation. Technical and other expert advice and services is provided in several other ways by experts external to SSM. For instance, SSM has the opportunity to use TSOs located in other countries, mainly in Finland and in Germany.

SSM have to its disposal funds for research support for activities. The funds give SSM the power to develop new knowledge and to finance technical and other support needed to enforce SSM´s supervision activities and to stimulate research and development within the area of responsibility of SSM. Other sources of advice are the scientific councils and expert boards that are linked to SSM.

A good example in using the funds for research activities are the agreements with Swedish and foreign experts (TSO) and researchers at universities that SSM has concluded to support the work of reviewing the application from SKB regarding the final repository for spent fuel and for the encapsulation facility that was handed over at the 16th of March 2011.

SSM´s conclusion is that the separate funding system for support gives the authority freedom to pick and choose experts when needed and without restrictions and that this creates ability to increase quality and effective resource management. However this model might cause problems. For integrity reasons it is not advisable for SSM to use the same consultants used by the license holders that SSM are to inspect. This reduces the selection of experts and might jeopardize the possibility for the authority to contract the very best within certain competences. The situation is manageable today but if an operator should apply for to build a new power plant – the situation might change and cause a troublesome concurrence situation. SSM is not arguing for a TSO to be established but must be aware of and handle the consequences.

Discussion Goal: To identify issues and ideas for SSM to secure competence out of the issues above.

Proposed agenda for discussion:

- Introduction and presentation of SSM:s programme for securing competence
- Input by the different participating IRRS-experts

- General discussion.

Project Management

Elisabeth Öhlén
Quality Manager
DG Staff
+46 8 799 42 56
Elisabeth.Ohlen@ssm.se

Ingemar Lund
Senior Adviser
DG Staff
+46 8 799 42 83
Ingemar.Lund@ssm.se

Anders Hallman
Analyst
Nuclear Power Plant Safety
+46 8 799 42 42
Anders.Hallman@ssm.se

Gustaf Löwenhielm
Senior Adviser
DG Staff
+46 8 799 41 21
Gustaf.Löwenhielm@ssm.se

Anna Norstedt
Senior Coordinator
DG Staff
+46 8 799 42 49
Anna Norstedt@ssm.se

Senior Management team

Ann-Louise Eksborg
Director General

Fredrik Hassel
DG Staff

Lennart Carlsson
Nuclear Power Plant Safety

Johan Anderberg
Radioactive Materials

Johan Friberg
Radiation Protection

Anneli Hällgren
Communication

Per-Olov Nützmann
Administration

Ylva Snell
Human Resources

2012:03

The Swedish Radiation Safety Authority has a comprehensive responsibility to ensure that society is safe from the effects of radiation. The Authority works to achieve radiation safety in a number of areas: nuclear power, medical care as well as commercial products and services. The Authority also works to achieve protection from natural radiation and to increase the level of radiation safety internationally.

The Swedish Radiation Safety Authority works proactively and preventively to protect people and the environment from the harmful effects of radiation, now and in the future. The Authority issues regulations and supervises compliance, while also supporting research, providing training and information, and issuing advice. Often, activities involving radiation require licences issued by the Authority. The Swedish Radiation Safety Authority maintains emergency preparedness around the clock with the aim of limiting the aftermath of radiation accidents and the unintentional spreading of radioactive substances. The Authority participates in international co-operation in order to promote radiation safety and finances projects aiming to raise the level of radiation safety in certain Eastern European countries.

The Authority reports to the Ministry of the Environment and has around 270 employees with competencies in the fields of engineering, natural and behavioural sciences, law, economics and communications. We have received quality, environmental and working environment certification.

Strålsäkerhetsmyndigheten
Swedish Radiation Safety Authority

SE-171 16 Stockholm
Solna strandväg 96

Tel: +46 8 799 40 00
Fax: +46 8 799 40 10

E-mail: registrator@ssm.se
Web: stralsakerhetsmyndigheten.se