



**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)
MISSION
TO
KINGDOM OF NORWAY**

Oslo, Norway

17 to 28 June 2019

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service
IRRS



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IRRS

**REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
THE KINGDOM OF NORWAY**



IRRS TEAM





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IRRS

**REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
THE KINGDOM OF NORWAY**

Mission dates: *17 to 28 June 2019*
Regulatory body visited: *Norwegian Radiation and Nuclear Safety Authority (DSA)*
Location: *Oslo, Norway*
Regulated facilities and activities in the mission scope: *Fuel Cycle facilities, Research Reactors, Radiation Sources in Industrial and Medical facilities, Waste Management facilities, Decommissioning activities, Transport of radioactive material, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Monitoring*
Organized by: *IAEA*

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

CONTENTS

| | |
|--|----|
| EXECUTIVE SUMMARY | 1 |
| I. INTRODUCTION | 4 |
| II. OBJECTIVE AND SCOPE | 5 |
| III. BASIS FOR THE REVIEW | 6 |
| 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT | 8 |
| 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY | 8 |
| 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY | 9 |
| 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE | 11 |
| 1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS .. | 13 |
| 1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK | 14 |
| 1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS | 15 |
| 1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL | 15 |
| 1.8. COMPETENCE FOR SAFETY | 17 |
| 1.9. PROVISION OF TECHNICAL SERVICES | 18 |
| 1.10. SUMMARY | 19 |
| 2. THE GLOBAL SAFETY REGIME | 20 |
| 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION | 20 |
| 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE .. | 22 |
| 2.3. SUMMARY | 23 |
| 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY | 24 |
| 3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES | 24 |
| 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS | 25 |
| 3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY | 27 |
| 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS | 28 |
| 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES | 30 |
| 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL | 30 |
| 3.7. SAFETY RELATED RECORDS | 32 |
| 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES | 32 |
| 3.9. POLICY ISSUES | 33 |
| 3.10. SUMMARY | 36 |
| 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY | 37 |
| 4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY | 37 |
| 4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM | 38 |
| 4.3. THE MANAGEMENT SYSTEM | 38 |
| 4.4. MANAGEMENT OF RESOURCES | 39 |
| 4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES | 39 |
| 4.6. CULTURE FOR SAFETY | 40 |
| 4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT | 40 |
| 4.8. SUMMARY | 40 |

| | | |
|-------|---|----|
| 5. | AUTHORIZATION..... | 42 |
| 5.1. | GENERIC ISSUES..... | 42 |
| 5.2. | AUTHORIZATION OF RESEARCH REACTORS | 43 |
| 5.3. | AUTHORIZATION OF FUEL CYCLE FACILITIES | 43 |
| 5.4. | AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES .. | 44 |
| 5.5. | AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES | 45 |
| 5.6. | AUTHORIZATION OF DECOMMISSIONING ACTIVITIES | 46 |
| 5.7. | AUTHORIZATION OF TRANSPORT | 46 |
| 5.8. | AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE | 47 |
| 5.9. | AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE | 48 |
| 5.10. | AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE | 50 |
| 5.11. | SUMMARY..... | 52 |
| 6. | REVIEW AND ASSESSMENT..... | 54 |
| 6.1. | GENERIC ISSUES..... | 54 |
| 6.2. | REVIEW AND ASSESSMENT FOR RESEARCH REACTORS..... | 55 |
| 6.3. | REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILTIES | 56 |
| 6.4. | REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES..... | 56 |
| 6.5. | REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES | 56 |
| 6.6. | REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES..... | 57 |
| 6.7. | REVIEW AND ASSESSMENT FOR TRANSPORT | 57 |
| 6.8. | REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE..... | 58 |
| 6.9. | REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE..... | 59 |
| 6.10. | REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE..... | 59 |
| 6.11. | SUMMARY | 60 |
| 7. | INSPECTION..... | 61 |
| 7.1. | GENERIC ISSUES..... | 61 |
| 7.2. | INSPECTION OF RESEARCH REACTORS..... | 63 |
| 7.3. | INSPECTION OF FUEL CYCLE FACILITIES | 63 |
| 7.4. | INSPECTION OF WASTE MANAGEMENT FACILITIES..... | 63 |
| 7.5. | INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES..... | 64 |
| 7.6. | INSPECTION OF DECOMMISSIONING ACTIVITIES..... | 64 |
| 7.7. | INSPECTION OF TRANSPORT | 64 |
| 7.8. | INSPECTION OF OCCUPATIONAL EXPOSURE..... | 65 |
| 7.9. | INSPECTION OF MEDICAL EXPOSURE | 65 |
| 7.10. | INSPECTION OF PUBLIC EXPOSURE | 65 |
| 7.11. | SUMMARY | 66 |
| 8. | ENFORCEMENT..... | 67 |
| 8.1. | ENFORCEMENT POLICY AND PROCESS..... | 67 |
| 8.2. | ENFORCEMENT IMPLEMENTATIONS | 68 |
| 8.3. | SUMMARY | 68 |
| 9. | REGULATIONS AND GUIDES | 69 |
| 9.1. | GENERIC ISSUES..... | 69 |
| 9.2. | REGULATIONS AND GUIDES FOR RESEARCH REACTORS | 70 |
| 9.3. | REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES..... | 70 |
| 9.4. | REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES | 70 |
| 9.5. | REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES | 71 |
| 9.6. | REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES | 72 |
| 9.7. | REGULATIONS AND GUIDES FOR TRANSPORT | 72 |
| 9.8. | REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE | 73 |
| 9.9. | REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE | 75 |
| 9.10. | REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE..... | 77 |
| 9.11. | SUMMARY | 78 |

| | | |
|---------------|---|-----|
| 10. | EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS | 79 |
| 10.1. | AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS | 79 |
| 10.2. | REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS..... | 80 |
| 10.3. | VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS..... | 81 |
| 10.4. | ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY..... | 82 |
| 10.5. | SUMMARY..... | 86 |
| 11. | INTERFACE WITH NUCLEAR SECURITY | 87 |
| 11.1. | LEGAL BASIS..... | 87 |
| 11.2. | REGULATORY OVERSIGHT ACTIVITIES..... | 88 |
| 11.3. | INTERFACE AMONG AUTHORITIES | 89 |
| 11.4. | SUMMARY | 89 |
| APPENDIX I | LIST OF PARTICIPANTS..... | 90 |
| APPENDIX II | LIST OF MAIN COUNTERPARTS | 92 |
| APPENDIX III | MISSION PROGRAMME | 95 |
| APPENDIX IV | SITE VISITS | 101 |
| APPENDIX V | RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | 102 |
| APPENDIX VI | REFERENCE MATERIAL USED FOR THE REVIEW | 109 |
| APPENDIX VII | IAEA REFERENCE MATERIAL USED FOR THE REVIEW | 131 |
| APPENDIX VIII | ORGANIZATION CHARTS | 134 |

EXECUTIVE SUMMARY

At the request of the Government of Norway, an international team of senior nuclear and radiation safety experts met with representatives of the Norwegian Radiation and Nuclear Safety Authority (DSA), from 17 to 28 June 2019, to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of Norway's national regulatory framework for nuclear, radiation, radioactive waste and transport safety. The review compared Norway's regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS Team members and Norwegian counterparts in areas covered by the IRRS. In addition to the regulatory body DSA, the scope of the mission included the following government ministries with regulatory responsibilities and functions: the Ministry of Health and Care Services, the Ministry of Climate and Environment and the Ministry of Foreign Affairs¹.

The IRRS Team consisted of 16 senior regulatory experts from 15 IAEA Member States, two IAEA staff members, an IAEA administrative assistant, and an observer. The review covered the IRRS core modules 1 to 10, i.e. the responsibilities and functions of the government, the global safety regime, responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, regulations and guides, and emergency preparedness and response. The review also included the optional module 11 on nuclear safety and security interface. Facilities, activities and exposure situations covered included radiation source applications, research reactors, fuel cycle facilities, waste management facilities, decommissioning, transport, occupational exposure, medical exposure, and public and existing exposure.

At the request of DSA, the IRRS mission included a discussion during which members of the IRRS Team and senior staff of DSA shared views and regulatory experiences regarding two policy issues:

- *Provision of guidance and advice.* The IRRS Team and DSA discussed strategies for maintaining regulatory independence whilst providing regulatory advice and guidance to authorized parties, without compromising the authorized parties' prime responsibility for safety.
- *Competence at DSA.* The IRRS Team and DSA shared experiences on human resources planning and competence management, the implementation of specific training programmes and on ensuring external technical support.

The review mission included a series of interviews and discussions with key personnel at the DSA. Several members of the IRRS Team informed the representatives of the three ministries on the purpose of the mission. Interviews were conducted with the Ministries and focussed mainly on responsibilities and functions of the government, on national policies and the regulatory framework for safety, the establishment of DSA as an independent regulatory body, and Norway's contribution to the global safety regime.

The IRRS Team also observed on-site inspections conducted by DSA at various facilities: research reactors and associated facilities in Halden and Kjeller, transport activities in Kjeller,

¹ The DSA is subordinate to the Ministry of Health and Care Services and has responsibilities under both the Ministry of Climate and Environment and the Ministry of Foreign Affairs.

the KLDRA repository for low and intermediate level waste in Himdalen, and radiation source applications at a medical and an industrial facility in Stavanger. The IRRS Team members reported very favourably on the professionalism of the DSA staff in the preparation and conduct of the inspections. During the site visits, open discussions took place with the management level of the authorized parties.

In preparation for the IRRS mission, DSA conducted a self-assessment and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS Team as advance reference material for the mission. The IRRS Team was positively impressed by the extensive preparation, expertise and dedication of DSA. The IRRS Team was extended full cooperation in the regulatory, technical, and policy discussions with the management and staff of DSA, in a very open and transparent manner. Throughout the mission, the administrative and logistical support was outstanding.

In 2017, DSA was re-established as a directorate under the Ministry of Health and Care Services, in order to strengthen and enhance its role as an independent regulatory body in nuclear and radiation safety. The IRRS Team found DSA staff and leadership to be highly competent and dedicated to improve the safety of facilities and activities in Norway. In the last few years, more attention and resources have been allocated by DSA for the safe operation and decommissioning of the Institute for Energy Technology (IFE) research and waste management facilities, as exemplified with the intensified inspection programme that started in 2014 and the IPPAS and INSARR missions conducted in 2015 and 2017. The IRRS Team also recognized the government's recent decision to take economic responsibility for the decommissioning and management of radioactive waste and spent fuel from the activities of the Institute for Energy Technology (IFE) and to establish the Norwegian Nuclear Decommissioning (NND). The IRRS Team considered the Nuclear Action Plan, aimed at reducing the risks from nuclear facilities and activities, in particular in Russia and Ukraine, a good practice in demonstrating a strong long lasting commitment from the government and DSA in enhancing global safety. The IRRS Team also considered the formalized cooperation group of regulatory authorities in health, safety and environmental (HSE) protection, a good practice for the harmonisation of inspections and the performance of joint inspections, integrating radiation protection with overall health and safety aspects.

The IRRS Team also identified areas of good performance, as evidenced by the policies and the regulatory framework and activities implemented in Norway. These included strengthened justification in the substitution of blood irradiators based on caesium chloride and the Nye Metoder Health Technology Assessment framework, the use of optimization in the national QA programme for radiotherapy, the National Radon Strategy and the Crisis Committee for Nuclear and Radiological Emergency Preparedness and Response.

The IRRS Team also identified challenges for the Government and DSA, specifically with regard to the regulatory framework and need for enhanced regulations and further guidance, as well as in ensuring the necessary resources and competences of DSA in all areas of its regulatory responsibility.

The IRRS Team report includes a number of recommendations and suggestions to improve the Norwegian regulatory system and the effectiveness of the regulatory functions in line with IAEA safety standards. The IRRS Team recognizes that many of its findings confirm the actions for further improvement that were identified in DSA's self-assessment. The IRRS Team concluded that the following issues are representative of those which, if addressed by the Government of Norway and DSA, should further enhance the overall performance of the regulatory system.

The government should:

- Establish a comprehensive national policy and strategy for safety;
- Update and further develop the national framework for safety and security;
- Establish a national policy and a strategy for spent fuel and radioactive waste management including decommissioning;
- Make provisions to provide DSA with the necessary resources to fulfil its obligations;
- Establish provisions regarding national competence in nuclear and radiation safety.

The regulatory body, DSA, should:

- Develop an integrated management system to ensure safety, addressing the whole organization;
- Implement a human resource plan and training programme based on an analysis of the necessary competence and skills;
- Take action for the further development of regulation and guides in order to ensure a comprehensive regulatory framework;
- Establish and implement an enforcement policy;
- Introduce and implement the concept of clearance;
- Implement an inspection programme based on a systematic graded approach.

The IRRS mission to Norway was timely with regard to present and future challenges in the decommissioning of nuclear research facilities, the implementation of a long-term strategy for the safe management and final disposal of radioactive waste and spent fuel, as well as the plans for new medical irradiation facilities (proton therapy) at public hospitals in Oslo and Bergen. The IRRS Team believes that the recommendations and suggestions, if acted upon, will contribute to meeting these challenges and enhance nuclear and radiation safety in Norway.

To conclude, in inviting the IAEA to conduct this IRRS mission and providing a transparent self-assessment, the Government of Norway and the regulatory body DSA have demonstrated their commitment to continuous improvement, a basic principle for excellence in nuclear and radiation safety. This report, in particular its recommendations and suggestions, should be viewed in that context.

The IRRS Team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of Norway, an international team of senior safety experts met representatives from the Norwegian Radiation and Nuclear Safety Authority (DSA) from 17 June to 28 June 2019 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review Norway's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Norway in March 2017. An information meeting was held 19 December 2017 at DSA Headquarters in Oslo to introduce the IRRS process and methodology. A self-assessment workshop was conducted on 6-8 March 2018 at DSA Headquarters in Oslo to introduce the IAEA Self-Assessment methodology and SARIS tool. A preparatory meeting was conducted 4 to 5 October 2018 at DSA Headquarters in Oslo to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Norway and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS Team consisted of 16 senior regulatory experts from 15 IAEA Member States, 2 IAEA staff members plus 1 IAEA administrative assistant and 1 observer. The IRRS Team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response. The scope of regulatory activities reviewed during the mission covered research reactors, nuclear fuel cycle facilities, radiation sources facilities and activities, occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning.

In addition, policy issues were discussed, including: competence at DSA and provision of guidance and advice to authorized parties.

DSA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS Team as advance reference material for the mission. During the mission the IRRS Team performed a systematic review of all topics within the agreed scope through review of Norway's advance reference material, conduct of interviews with management and staff from DSA and direct observation of regulatory activities at regulated facilities. Meetings with the Ministry of Health and Care Services (HOD), the Ministry of Climate and Environment (KLD), and the Ministry of Foreign Affairs (MFA) were also organized.

All through the mission the IRRS Team received excellent support and cooperation from DSA.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review the Norwegian radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS.

It is expected this IRRS mission will facilitate regulatory improvements in Norway and other Member State, utilising the knowledge gained and experiences shared between Norwegian counterparts and IRRS reviewers and the evaluation of the Norwegian regulatory framework for nuclear and radiation safety, including its good practices.

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

- a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- d) promoting the sharing of experience and exchange of lessons learned among senior regulators;
- e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Team members who have experience of other regulatory practices in the same field;
- f) providing the host country with recommendations and suggestions for improvement;
- g) providing other states with information regarding good practices identified in the course of the review;
- h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- i) contributing to the harmonization of regulatory approaches among states;
- j) promoting the application of IAEA Safety Requirements; and
- k) providing feedback on the use and application IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Norway, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 4 to 5 October 2018. The preparatory meeting was carried out by the appointed Team Leader Johan Anderberg, Deputy Team Leader Cantemir Ciurea and the IAEA Coordinator Mr Hilaire Mansoux, and Deputy Coordinator Mr Geza Macsuga and the DSA representatives.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of DSA represented by Ole Harbitz, General Director, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities and exposure situations would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Research reactors,
- Nuclear fuel cycle facilities;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning activities;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control; and
- Selected policy issues.

Mr Ole Harbitz made presentations on the national context, the current status of the national regulatory infrastructure and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Norway in June 2019.

The proposed composition of the IRRS Team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Liaison Officer for the IRRS mission was confirmed as Ms Kristin Elise Frogg.

Norway provided IAEA with the advance reference material (ARM) for the review in April 2019. In preparation for the mission, the IRRS Team members reviewed the Norwegian advance reference material and provided their initial impressions to the IRRS Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS Team meeting took place on Sunday, 16 June, 2019 in Oslo, directed by the IRRS Team Leader and the IAEA Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host country Liaison Officer was present at the initial IRRS Team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 17 June, 2019, with the participation of the HOD, KLD, MFA, senior management and staff of DSA. Opening remarks were made by Elin Anglevik, Department Head, HOD, Mr Ole Harbitz, Director General, DSA and Mr Johan Anderberg, IRRS Team Leader. Mr Ole Harbitz gave an overview of the Norway context, activities and the action plan prepared as a result of the pre-mission self-assessment.

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

The IRRS Team performed its review according to the mission programme given in Appendix III.

The IRRS exit meeting was held on Friday, 28 June 2019. The opening remarks at the exit meeting were presented by State Secretary Anne Grethe Erlandsen and were followed by the presentation of the results of the mission by Mr Johan Anderberg, IRRS Team Leader.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

In Norway, most of the principles and requirements for safety are stated within the existing strategy documents and the legal and regulatory framework, including:

- The Act on Radiation Protection and Use of Radiation, May 12th, 2000, No. 36
- Ot.prp. nr. 88 (1998-99) “White Papers”
- Act on Nuclear Energy Activities, May 12th, 1972, No. 28
- Ot.prp.nr. 51 (1970-71) ‘White Papers’
- Act on Pollution Control, March 13th, 1981 No. 6
- Ot.prp.nr. 51 (1979-80) ‘White Papers’
- Internal Control Regulations (IC Regulations)
- St. prp. Nr. 1 – National Budget

In order to strengthen these principles, the IRRS Team found that Norway would benefit from establishing them in a single comprehensive national policy and strategy promulgated as a statement of the Government.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| <p>Observation: While Norway has implemented most objectives of a national policy and strategy for safety within its framework for safety, said strategy is yet to be promulgated in a policy document. This has been recognized in the ARM, and is part of the action plan.</p> | |
| (1) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 1 states that <i>“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.”</i></p> |
| (2) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 1 para 2.3 states that <i>“National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government’s intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:</i></p> <ul style="list-style-type: none"> <i>(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles;</i> <i>(b) Binding international legal instruments, such as conventions and other relevant international instruments;</i> <i>(c) The specification of the scope of the governmental, legal and regulatory framework for safety;</i> <i>(d) The need and provision for human and financial resources;</i> <i>(e) The provision and framework for research and development;</i> <i>(f) Adequate mechanisms for taking account of social and economic developments;</i> <i>(g) The promotion of leadership and management for safety, including safety</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| | <i>culture.”</i> |
| R1 | Recommendation: The Government should establish a comprehensive national policy and strategy for safety promulgated as a statement of the Government’s intent, the implementation of which shall be subject to a graded approach. |

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Kingdom of Norway is a constitutional monarchy. Legislative, budgetary and supervisory power rests with the Norwegian Parliament (Storting). Executive Power is held by the King in Council, consisting of the Prime Minister and his or her cabinet of ministers. Judicial Power lies with the Supreme Court and its subsidiary courts, as well as the Court of Impeachment (Riksretten).

The overall legal basis is set forth in the Norwegian Constitution of 1814. Decisions by parliament are enacted through law or proclamations. The government may issue regulations that may further specify laws enacted by parliament and may invest agencies with executive power under their purview through government directives. All legal proceedings must be based on the Public Administration Act that defines the form and structure of administrative action, legal decisions, as well as appeal to decisions. Further specifications to the proceedings may be made within a specific act.

The legal framework for nuclear safety and radiation protection covers:

- Act on Radiation Protection and Use of Radiation, 12 of May 2000 No.36. (RP Act);
- Act on Nuclear Energy Activities, 12 of May 1972 No. 28 (NE Act);
- Act on Pollution Control, 13 of March 1981 No. 6 (PC Act);
- Radiation Protection Regulations (RP Regulations);
- Regulations on the Application of the Pollution Control Act to Radioactive Pollution and Radioactive waste (PC Regulations);
- Regulations relating to the Recycling of Waste;

Other relevant acts and regulations include:

- Air Traffic Act;
- Ship Safety Act;
- Fire and Explosion Protection Act with regulations;
- The Public Administration Act;
- Freedom of Information Act;
- Internal Control Regulations.

Regulatory functions, apart from the oversight of transport of radioactive materials, are clearly allocated within the legal framework.

The IRRS Team was informed that the legal system is set up in a way that laws may describe subject matters only in relatively general terms with some specifications within regulations, but generally the government and its agencies have much discretionary power to lay down legal provisions within each decision. This is also the case regarding the RP Act, the NE Act and the PC Act and the corresponding regulations, where regulatory decisions from DSA refer to licence conditions in many cases.

There are legal provisions that cover the siting and decommissioning stages. The Planning and Building Act, and the associated Impact Assessment Regulations, cover the siting process for nuclear installations and DSA is specifically identified as the competent authority. Furthermore, the provisions of the NE Act apply to a nuclear installation until it is released from regulatory control, and relevant permits and licences would be required throughout the decommissioning phase. The PC Act may also apply to siting and has provisions for “closure and stoppage of operations”.

However, by not including clear definitions and provisions in the legal framework with regard to several technical concepts such as siting, design and decommissioning during the licensing phase, by making provisions to this effect primarily through decisions based on licence conditions issued by the regulatory body, in the absence of more detailed guidance, the effectiveness of governmental, legal and regulatory framework for safety could be adversely impacted.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: The framework for safety does not contain clear provisions with regard to siting, design and decommissioning as licensing phases. Provisions to this effect are made through decisions by the regulatory body, yet a concrete legal basis is missing to address these topics. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 2 para 2.5 states that <i>“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Requirement 2 para 2.5 (2) states that <i>“This framework for safety shall set out the following: ... The types of facilities and activities that are included within the scope of the framework for safety.”</i> |
| (3) | BASIS: GSR Part 1 (Rev 1) Requirement 2 para 2.5 (3) states that <i>“This framework for safety shall set out the following: ... The type of authorizations that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;”</i> |
| R2 | Recommendation: The Government should update the framework for safety to include clear legal provisions and definitions for siting, design and decommissioning as licensing phases. |

The NE Act, for example, has been revised several times since it was established in 1972. Maintenance of the legal framework is done at irregular intervals on an ad hoc basis. There are no formal processes in place to ensure a periodic update of the framework, when necessary.

The IRRS Team was informed that DSA is involved and sometimes tasked by the responsible ministry in preparing and drafting changes to the Acts and Regulations concerning nuclear and radiation safety. However, there are no formal processes, apart from the general considerations of proposals for legal changes from the public, that ensure due consideration of these proposals by the Government.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: DSA is involved in preparing and drafting changes to the legal framework, however there are no processes that ensure due consideration of these proposals by the Government.

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| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 2 states that <i>“The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Requirement 2 para. 2.5 (3) states that <i>“This framework for safety shall set out the following: ... The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation;”</i> |
| S1 | Suggestion: The Government should consider formalizing the periodic review of the legal framework through DSA. |

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Government of Norway through directive issued in 2017 has appointed DSA as the regulatory body for radiation protection and nuclear safety. This function is also reflected within the RP Act, and the NE Act as well as the PC Regulations.

Oversight of DSA is shared between the Ministry of Health and Care Services (HOD), the Ministry of Climate and Environment (KDL) and the Ministry of Foreign Affairs (MFA) with the political and administrative oversight and responsibility mainly resting with HOD. Once a year the ministries issue a letter of commitment to DSA, describing the resources provided and laying down the expectations regarding regulatory tasks to perform during the year.

As a directorate DSA is generally an independent decision-making authority with competences devolved according to the legal framework. However, there are some limitations in the independence of DSA.

HOD, apart from having responsibility for DSA, also has authority over hospitals in Norway. While these hospitals are overseen by trusts who are governed by independent boards, funding is provided directly through HOD and fall under its supervision. DSA as regulatory body has oversight over hospitals as authorized parties. As both DSA and the hospitals are financed by HOD this could potentially constitute a conflict of interest if HOD is faced by the decision whether to prioritize funds for regulatory control or licensed activities. However, HOD has, under the current political regime, two health ministers, one responsible for the specialist health care services, including the hospitals, and the other health minister responsible for public health. DSA is under the responsibility of the public health minister.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Both DSA as regulatory authority and the hospitals as authorized parties are financed by HOD, this setup can potentially constitute a conflict of interest if faced by the decision whether to prioritize funds for regulatory control or licensed activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

A potential conflict of interest has been recognized in the ARM and is part of the action plan.

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| (1) | <p>BASIS: GSR Part 1 (Rev. 1) Requirement 4 states that <i>“The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on 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.”</i></p> |
| (2) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 4 para 2.8 (d) states that <i>“To be effectively independent from undue influences on its decision making, the regulatory body:</i></p> <p style="text-align: center;">...</p> <p><i>Shall be free from any pressures associated with political circumstances or economic conditions, or pressures from government departments, authorized parties or other organizations.”</i></p> |
| S2 | <p>Suggestion: The Government should consider to ensure effective independence of DSA in all its regulatory functions with respect to licensees funded by the Ministry of Health and Care Services.</p> |

The regulatory body DSA is empowered to employ the necessary staff within the respective budgetary frames and directives that are provided under the three responsible ministries. The IRRS Team was informed that in some areas of DSA’s responsibilities under HOD available financial resources have been reduced since the re-establishment of DSA as an independent regulatory body in 2017. In other areas, particularly in emergency preparedness, funding has been increased. Also, KLD has provided increased funding to DSA from 2019 for the regulation of decommissioning and radioactive waste management.

Funding provided by one ministry may not be used for activities that fall under another ministry’s competence. However, the IRRS Team was informed that DSA has latitude to prioritize the attributed budget from a given ministry within the organization in order to fulfil statutory obligations that fall within the ministry’s area of responsibility.

Although the funding of regulatory responsibilities for licensing and inspections in the nuclear sector is based on fees paid by the operators, the IRRS Team was informed that the overall funding is inadequate with respect to arising regulatory challenges in decommissioning, radioactive waste and spent fuel management. The use of these funds is currently also restrained due to resources being allocated to non-civilian sector regulatory activities in support of the Ministry of Defense control of military nuclear-powered vessels, for which there is currently no assigned DSA financing. The IRRS Team also found that HOD funding of regulatory activities regarding the use of radiation sources in the medical, industrial and research sector is restrained. For example, in 2018 inspections at hospitals were suspended for four months due to lack of funding. The establishment of two new proton therapy facilities in Oslo and in Bergen will increase the budget strain, as the oversight over these facilities will require qualified staff.

In this sector, there is no financing model ensuring funding from the authorized parties. In conclusion, there is a need for ensuring that adequate resources are provided and maintained for the fulfilment of all DSA regulatory obligations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: DSA receives funding from the ministries HOD, KLD and MFA. While the necessary resources are provided for some areas, it is not guaranteed that adequate funding is being provided in all areas of regulatory activity. For example, inspection at hospitals was halted for four months starting with August 2018 due to lack of funding. No additional provisions have been made to provide for qualified staff for new activities like the regulatory oversight of the proton therapy facilities currently under construction in Oslo and Bergen.

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| (1) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 4 para 2.8 (b) states that <i>“To be effectively independent from undue influences on its decision making, the regulatory body:</i></p> <p style="text-align: center;">...</p> <p><i>Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities.”</i></p> |
| R3 | <p>Recommendation: The Government should make provisions to provide DSA with the resources necessary to fulfil its statutory obligation for the regulatory control of all facilities and activities.</p> |

With regard to transport of radioactive material, regulatory oversight is assigned to several authorities according to the legal framework, depending on the mode of transport. While DSA in practice acts as regulatory body for all modes of transport, it is only deferred legal authority for the transport over road and rail in a Regulation by another authority (Norwegian Directorate for Civil Protection). Regulatory authority is not clearly transferred to DSA for transport at sea or in air and roles of other authorities is unclear. This has been recognized in the ARM and is part of the action plan.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The prime responsibility for safety for nuclear installations is specified in the NE Act and the PC Act for the entire lifetime of the facility. However, a provision that compliance with regulations and requirements doesn't relieve a person or organization for a facility or an activity of its prime responsibility for safety is missing for facilities and activities under the RP Act.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The prime responsibility for safety has been established in the NE Act and PC Act, however not in the RP Act.

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| (1) | <p>BASIS: SF-1 Principle 1 states that <i>“the prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give arise to radiation risks.”</i></p> |
| (2) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 6 states that <i>“The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.”</i></p> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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Suggestion: The Government should consider making legal provision that the prime responsibility for safety must rest with the person or organization responsible for facilities and activities covered by the RP Act.

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

Generally, the Government has worked to establish coordination between the various regulatory authorities and agencies. This is achieved in a variety of ways on the municipal, regional and national level.

As DSA is established as a directorate under several ministries, coordination is especially crucial. This is achieved through the government Directive for DSA. Therein, communication channels between the ministries and DSA are established through annual letters of commitment, letters concerning the delegation of authority and at least two governance meetings a year. Provision is made to expand that dialogue for technical fields to invite other relevant agencies.

In planning for or handling a nuclear or radiological emergency a Crisis Committee has been established that consists of relevant authorities, including DSA, the Norwegian Armed Forces, the Norwegian Directorate for Health, the Norwegian Coastal Administration, the Norwegian Food Safety Authority, the National Police Directorate and the Ministry of Foreign Affairs.

A formalized cooperation (TSG) has been established between organizations that have responsibilities under HSE legislation. These include DSA, the Norwegian Labour Inspection Authority, Norwegian Environment Agency, Norwegian Food Safety Authority, Norwegian Board of Health Supervision, Norwegian Industrial Safety Organization and the Norwegian Directorate for Civil Protection.

Other authorities apart from DSA have a role in the transport of radioactive material and other dangerous goods, such as Customs, Police, Norwegian Directorate for Civil Protection, Civil Aviation Authority and the Norwegian Maritime Authority. There are currently no official formalized coordination between these. The regulatory framework for biomedical research consists of a number of Acts and regulations where all research programmes must be approved by the regional committee for health and research ethics, REK. The RP Regulations require that biomedical research involving medical exposure is evaluated by REK. Therefore, a regulatory interface between REK and DSA exists, however the cooperation between the two organizations is not formalized.

The coordination between these authorities should be enhanced and formalized.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: While DSA has coordination and liaison with different authorities, this does not cover all authorities that have responsibilities within the regulatory framework for safety, such as transport of radioactive material and biomedical research.

(1)

BASIS: GSR Part 1 (Rev 1) Requirement 7 para 2.18 (11) states that “Where several authorities have responsibilities for safety within the regulatory

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| | <p><i>framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:</i></p> <p><i>(3) Applications of radiation in medicine, industry and research;</i></p> <p><i>(11) Safety in the transport of dangerous goods, including nuclear material and radioactive material;</i></p> <p><i>... This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."</i></p> |
| S4 | <p>Suggestion: The Government should consider enhancing the coordination and liaison between relevant authorities with regard to transport of radioactive materials and biomedical research.</p> |

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

DSA is the competent authority under the RP act to monitor and manage radioactive sources, including unregulated and orphan sources. Systems are in place to guarantee retrieval of sources and to protect the public and the environment from unwarranted radiation exposure.

Provisions have been arranged in Norway to implement protective actions to reduce undue radiation risks, unregulated sources and contamination from past activities and events. An example that demonstrates the involvement of several authorities and interested parties is the evolution and deployment of the National Radon Plan.

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

The Norwegian Government's current waste management strategy is based on commissioned concept studies on national decommissioning and waste management solutions. The government has recently decided to take economic responsibility for the decommissioning and management of radioactive waste and spent fuel from the activities of the Institute for Energy Technology (IFE) and to establish the Norwegian Nuclear Decommissioning (NND).

However, there is no established national policy or strategy on spent fuel and radioactive waste management, with preferred options and priorities and addressing the research and development needs for safe decommissioning, waste management and disposal solutions for nuclear waste and spent fuel, nor for radioactive waste.

The IRRS Team was informed that in 2019 DSA was tasked by KLD to propose a draft national strategy for waste, building on an assessment made by DSA in 2016 on the existing and future waste-streams and the capacity needed for management of radioactive waste towards 2035.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: In 2019, the Government tasked DSA to draft a national strategy for spent fuel and radioactive waste, building on an assessment made by DSA in 2016 on the capacity for management of radioactive waste towards 2035. However, there is no national policy and strategy that includes a comprehensive inventory of current and future radioactive waste streams and that addresses decommissioning as well as predisposal spent fuel and radioactive waste management facilities and final disposal solutions, including clear provisions for funding.

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| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 10 states that <i>“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.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Para 2.28 states that <i>“Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities. The strategy shall include appropriate interim targets and end states. Radioactive waste generated in facilities and activities necessitates special consideration because of the various organizations concerned and the long timescales that may be involved. The government shall enforce continuity of responsibility between successive authorized parties.”</i> |
| (3) | BASIS: GSR Part 5 Requirement 2 states that <i>“To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste.”</i> |
| (4) | BASIS: SSR Part 5 Requirement 1 states that <i>“The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed.”</i> |
| R4 | Recommendation: The Government should develop and implement a national policy and strategy for spent fuel and radioactive waste management, that reflect national priorities and that can form the basis for long-term decision making with respect to the decommissioning of facilities, management of spent fuel, predisposal waste management and disposal of radioactive waste, including the necessary financial provisions. |

IFE has announced that both research reactors in Halden and Kjeller will enter the decommissioning phase. The Government decided to take over the costs for decommissioning both facilities with funding provided through the Norwegian Parliament. For this purpose, the Norwegian Nuclear Decommission (NND) was established that is expected to be fully operational by 2021. The IRRS Team was informed that NND will serve as a phase-out organization and will take over the responsibility of present and future waste management and disposal facilities.

Currently, there are several radioactive waste management facilities under the IFE that are operated to accept, process and temporary store and dispose of the radioactive waste produced by two research reactors and other facilities located on their sites, and to accept radioactive waste from different institutions and organizations that use radioactive sources in industry, education, medicine and scientific areas except NORM industry. Other waste repositories are in existence that accept waste from NORM industries.

1.8. COMPETENCE FOR SAFETY

While the competence of authorized parties with regard to sources and activities is established under the RP Act and the NE Act, there is no such legal provision for the PC Act. Some specifications of competences of DSA is defined within the tasks allocated by the ministries, however there is no legal requirement to build and maintain competence for the regulatory body.

There are variations between educational institutions in the context and scope of radiation protection training provided for health professionals.

While training is considered sufficient for radiographers, specialists in nuclear medicine and professionals in the dental health service, most specialist physicians receive very little radiation protection training in their medical education.

The IRRS Team noted that the RP Regulations specify designated roles for personnel with competence in medical physics in medical facilities authorized by DSA. While the educational requirements for this personnel are included in the comments to the regulations there is no national recognition and formalized educational system for medical physicists. A voluntary professional body certification system is in place by the Norwegian Association for Medical Physics (NFMF). However, in the absence of a national recognition system, evaluation of competence is challenging for DSA in issuing relevant authorizations. Aligned with the IAEA requirements it is recommended that the government should ensure requirements are established for the formal recognition of medical physicists.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: There are no national provisions regarding the building and maintaining of competences of all parties involved in radiation protection and nuclear safety. | |
| (1) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 1 para 2.36 states that “The government:</p> <ul style="list-style-type: none"> <i>(a) Shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities;</i> <i>(b) Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body’s</i> |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | <i>responsibilities in relation to safety; Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties.”</i> |
| R5 | Recommendation: The Government should establish provisions regarding the building and maintaining of competence of all parties having responsibilities in relation to the safety of facilities and activities, including the strengthening radiation protection training in health education programmes and the formal recognition of medical physicists. |

1.9. PROVISION OF TECHNICAL SERVICES

Additionally, to its regulatory tasks, DSA provides personal dosimetry service through the Department of Radiation Protection and Measurement Services and operates the national secondary standard dosimetry laboratory (SSDL). The IRRS Team was informed that DSA provides other technical services including environmental monitoring and equipment calibration not only for themselves, but also for authorized parties.

The SSDL provides traceable calibration of instruments for radiation measurements in radiotherapy, medical diagnostics and radiation protection. The personal dosimetry service is a technical service provided to authorized parties for a fee in Norway. The laboratory for environmental radioactivity analyzes radioactivity in samples from national monitoring programmes and from radioecological research and acts as support for emergency preparedness and response.

DSA has not been tasked by Government to authorize technical services.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: The Government has not made any provision for DSA to have responsibility to authorize technical services for radiation safety. A system for the authorization, approval and accreditation of dosimetry and calibration services within the regulatory framework is not established. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 13 states that <i>“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.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Requirement 13 para 2.41 states that <i>“Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate.”</i> |
| (3) | BASIS: GSR Part 3 Requirement 20 para 3.73 (c) states that <i>“The regulatory body shall be responsible, as appropriate, for: (c) Authorization or approval of</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| | <i>service providers for individual monitoring and calibration services; ...”</i> |
| (4) | BASIS: GSR Part 3 Requirement 25 para 3.99 states that “Employers, as well as self-employed persons, and registrants and licensees shall be responsible for making arrangements for assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that arrangements are made with authorized or approved dosimetry service providers that operate under a quality management system.” |
| S5 | Suggestion: The Government should consider making provision for DSA’s responsibility to authorize technical services for radiation safety. |

1.10. SUMMARY

The IRRS Team reviewed the responsibilities and functions of the government. Overall, the IRRS Team found that Norway is in good alignment with IAEA safety standards. However, observations have been made with regard to the effective independence, the framework for safety and the establishment of policies and strategies for safety and for spent fuel and waste management.

Therein the IRRS Team found some areas of improvement related to the promulgation of a national policy and strategy for safety, the update of the regulatory framework, the effective independence of the regulatory body, the full application of the prime responsibility for safety, the effective coordination of authorities regarding transport, the establishment of a policy and strategy for waste, the establishment for provisions to build and maintain competence as well as the authorization of technical services.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Norway is an active participant under the international global safety regime, both through DSA and MFA and has signed, ratified and implemented the following international conventions:

- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- Convention on Nuclear Safety;
- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- Convention on Environmental Impact Assessment in a Transboundary Context (Espoo Convention);
- The UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention);
- The Convention for the Protection of the Marine Environment of the North-East Atlantic (the OSPAR Convention);
- Convention (No.115) concerning the Protection of Workers against Ionizing Radiations.

Additionally, the IRRS Team was informed that Norway has signed a number of bilateral agreements with Ukraine, Russia, the United States of America, United Kingdom and Northern Ireland, Sweden, Germany, France, Lithuania, the Netherlands, Poland, Belarus and Australia.

Norway is also a member of several safety-related organizations:

- International Atomic Energy Agency (IAEA);
- Heads of European Radiological Protection Competent Authorities (HERCA);
- Organization for Economic Co-operation and Development/Nuclear Energy Agency (OECD/NEA);
- Arctic Council;
- International Union of Radioecology (IUR).

Norway is an observer in the following safety-related organizations:

- United Nations Scientific Committee on the effects of Atomic Radiation (UNSCEAR);
- Western European Nuclear Regulatory Association (WENRA);
- European Nuclear Safety Regulators Group (ENSREG).

Regarding international peer review missions, Norway, apart from inviting this IRRS mission, has invited the following IAEA missions:

- Waste Management Assessment and Technical Review Program in 1995;

- International Physical Protection Advisory Service (IPPAS) in 2003 and 2015. A follow-up of the 2015-mission is planned in the coming years;
- Integrated Safety Assessment of Research Reactors (INSARR) at the Institute for Energy Technology in 2007, 2010 (follow-up) and 2017. A follow-up of the 2017-mission is planned in the coming years;
- Independent Safety Culture Assessment (ISCA) at the Institute for Energy Technology in 2018.

Norway participated in the EU Topical Peer Review on aging management of nuclear power plants and research reactors in 2017/2018.

As Norway’s emergency preparedness and response system to nuclear and radiological emergencies doesn’t fully align the GSR Part 7, described in Section 10, inviting an EPREV peer review mission would be beneficial to further increase compliance with international standards.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| <p>Observation: Norway’s system for emergency preparedness and response to nuclear and radiological emergencies doesn’t fully meet the requirements regarding GSR Part 7. Therefore, it would benefit from sharing knowledge and experience and receive feedback on its existing national safety arrangements by inviting an international peer review service to further increase compliance with the international safety standards.</p> | |
| (1) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 14 states that <i>“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally.”</i></p> |
| (2) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 14 para 3.2 (d)states that <i>“The features of the global safety regime include:</i> <i>.... International peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States.”</i></p> |
| S6 | <p>Suggestion: The Government should consider inviting an Emergency Preparedness and Response Review (EPREV) Service.</p> |

Norway has established a Nuclear Action Plan (NAP) in 1995 that provides the basis for its cooperation on nuclear safety and security with Russia, Ukraine and other countries in Eurasia. This plan has been adapted and renewed in 1998, 2005, 2008, 2013 and 2018 and to this day the Government and Parliament have made available funds to initiatives of more than 2 billion NOK.

The two primary objectives under NAP are:

- To reduce the risk of serious accidents and radioactive contamination;
- To prevent nuclear and other radioactive material from falling into the wrong hands.

Projects are carefully selected and prioritized. Through the NAP, measures are implemented that have helped to secure nuclear and other radioactive material and have reduced the risk of accidents and incidents. Norway’s cooperation with Russia is the cornerstone of these efforts and for years has provided an important channel for building trust and exchanging expertise.

Norway's efforts are highly regarded internationally. International cooperation and coordination are crucial for achieving good results. Norway's cooperation with Ukraine on nuclear safety and security has been expanded in recent years.

These actions go beyond the usual scope that can be expected in a bilateral or multilateral context. By implementing the NAP Norway shows a long-term commitment to increasing nuclear safety and security aspects within Europe and worldwide.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: In 1995 Norway established a Nuclear Action Plan (NAP) that provides the basis for its cooperation on nuclear safety and security, primarily with Russia and Ukraine. Through NAP, projects are initiated and financed that have helped to secure nuclear and other radioactive material and have reduced the risk of accidents and incidents. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 14 states that <i>“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Requirement 14 para. 3.2 (d) states that <i>“The features of the global safety regime include: ... Regular multilateral and bilateral cooperation between the relevant national and international organizations to enhance safety by means of harmonized approaches as well as to increase the quality and effectiveness of safety reviews and inspections.”</i> |
| GP1 | Good Practice: The Government of Norway through establishing NAP and continuing it for more than 20 years shows a long-term commitment for international cooperation in safety and security. By strategically providing funding for projects to ensure risk reduction regarding serious accidents and radioactive contamination as well as to prevent nuclear and other radioactive material from falling into the wrong hands, Norway's NAP has substantially contributed to increasing safety and security in Russia and Ukraine. |

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

DSA participates in several IAEA international networks, to both share and receive information and international experience, such as IAEA Incident Reporting Systems for Research Reactors (IRSRR) and for Fuel Cycle Facilities (FINAS). DSA has access to IAEA databases for exchanging international regulatory experience as well as for sharing of operating experience and lessons learned from events as well as on the actions established to avoid re-occurrence of these events. However, DSA participation in the networks is not done on a regular basis.

The IRRS Team was informed that the results of information exchange are taken into account in the regulatory work and procedures of DSA. The information and international experience received by DSA is shared, in principle, with national operators, users and stakeholders as deemed necessary, although there is no specific procedure for how this should be done in a systematic manner. The IRRS Team considers that more intensive exchange of operating

experiences could further enhance the nuclear and radiological safety in Norway and could be beneficial in preparation for the decommissioning phases of the shutdown research reactors.

Consideration should be given to the creation of an event investigation group within DSA responsible for an independent analysis of events, identification of lessons learned, development of corrective action plans, and dissemination of related information. Development of supporting processes and procedures should also be considered. This will avoid taking ad-hoc decisions by DSA staff assigned to the task.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| <p>Observation: DSA did not establish processes for systematic analysis and identification of lessons to be learned from operating experience and regulatory experience, including for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities. This has been recognized in the ARM.</p> | |
| (1) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 15 para 3.4 states that <i>“The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to other lessons learned from operating experience and regulatory experience.”</i></p> |
| S7 | <p>Suggestion: DSA should consider establishing and maintaining means for systematic analysis of events, identification of lessons learned and dissemination of related information to facilitate an effective exchange and use of operating and regulatory experience with the international community.</p> |

2.3. SUMMARY

Norway through DSA and MFA is an active participant in the global safety regime through many bilateral and multilateral activities. The IRRS Team considers the establishment and continued application of NAP a good practice for international cooperation.

DSA participates in several IAEA international networks to both share and receive information and international experience. However, the participation in these networks is not done on a regular basis. The results of information exchange are taken into account in the regulatory work and procedures of DSA, although there is no specific procedure for how this should be done in a systematic manner. The IRRS Team suggests that DSA should be more active in the area of operating experiences exchange and should develop supporting processes for systematic analysis of events, identification of lessons learned and dissemination of related information to facilitate an effective exchange and use of operating and regulatory experience with the international community.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

DSA has three main departments, The Department of Radiation Protection and Measurement Services (ASM), The Department of Nuclear Safety and Environmental Protection (AOM) and the Department of planning and administration (POA). The current organization of DSA was set up in 2018 to perform the prioritized responsibilities and tasks more effectively than previously. ASM is responsible for the regulation of radiation protection and the use of radiation sources (ionizing and non-ionizing) in medical, industrial and research applications, including occupational exposures, related public health issues and international cooperation on radiation protection and radiation sources. AOM is responsible for the regulation of nuclear safety and security, transport of nuclear materials, emergency preparedness and response, nuclear safeguards and non-proliferation and protection of people and the environment from pollution (arising from discharges, radioactive wastes or radionuclides present in the environment).

The Director General (DG) is appointed by the Government. The DG reports to three ministries: HOD, KLD and MFA. The DG holds formal meetings (approximately 2 per months) with his Management Group, which consists of the DG, Heads of Departments, the Head of the Communication section and a secretary.

DSA receives funding in form of an annual budget that is allocated by parliament, based on proposals from the government, through the three ministries. DSA provide the inputs to the ministries according to risk-based priorities for its work programme over the next year. After the budget has been sanctioned by parliament, the ministries allocate the budget and assign specific tasks within their areas of responsibility to DSA through an annual letter of commitment.

In addition, resources are available from fees (licensing fees and inspection fees) in connection to regulatory oversight under the NE Act and the PC Act. Fees for inspections under the PC Act have been introduced in 2018. Fees from the nuclear operator finance the major part of DSA's work on licensing and inspection of the research reactors and associated facilities.

However, DSA also performs the tasks related to access of nuclear-powered vessels, primarily submarines, to Norwegian ports and waters, for which there is no specified financing. DSA is also responsible for operation of the secondary standard dosimetry laboratory (SSDL) and some technical services which are not connected with regulatory activities and, except for the personal dosimetry service, no fees are levied for these services at present. The IRRS Team was informed that insufficient funding is provided also for some regulatory activities like the preparations for licensing of proton therapy facilities, inspection at hospitals, industrial and research facilities and oversight of transport.

The IRRS Team found that the allocation of staff and available resources, including the fees, within each of the areas for which the ministries are responsible, only to some extent are commensurate with the radiation risk associated with facilities and activities. Even though DSA funding from the different ministries and from fees are aimed at certain tasks, DSA, within each ministerial area, have room for distributing the budget in accordance with a graded approach and the risks associated with facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: DSA is empowered to employ its staff and distribute resources within the budget provided by the Government. However, DSA’s internal procedures for the allocation of resources do not consider the radiation risks associated with facilities and activities under its regulatory control in a systematic manner.

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| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 16 states that <i>“The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Requirement 16 para 4.5 states that <i>“The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.”</i> |
| S8 | Suggestion: DSA should consider improving the management of its financial resources in a manner commensurate with the radiation risks associated with facilities and activities. |

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

DSA is an independent decision-making authority under the provisions of the RP Act, the NE Act and the PC Act. In principle, within their areas of responsibility, different ministers may make decisions and issue instructions to DSA on a general basis and also on specific cases but this is usually avoided. The NE Act specifically recognizes the primary authority of DSA on issues related to nuclear safety and security. This is to ensure that there is independence in DSA’s assessment of nuclear safety and security.

HOD has the parliamentary responsibility for the health sector (including licensed hospitals) and the regulatory body (DSA), which results in a potential conflict of interest. **Recommendation R3 in Section 1.3 addresses this issue.**

DSA is also a user of radiation sources, an employer of staff who receive occupational exposures, and in some rare cases also a producer of radioactive waste and discharges. In order to avoid possible conflicts of interest, the permits under the PC Act for relevant DSA activities, were granted by the Ministry of the Environment.

DSA has different arrangements for the use of radiation sources according to the RP Act. In these situations, DSA has issued authorizations within its own organization, but efforts have been made to keep the regulatory management as independent as possible. One section issues the licence while another section is using sources (is an authorized party).

DSA participates in research or monitoring projects in cooperation with companies or institutions that are licensed by DSA. To ensure effective independence, staff involved in regulatory activities are not involved in such projects. However, there is no formal procedure dealing with DSA’s independence in these circumstances. The IRRS Team was informed that

the new integrated management system that is currently under development, will include such procedures.

Employment and recruitment of DSA staff follows formal internal procedures and is regulated by the Act covering the employment process, which is based on the qualification principle, and how to deal with dismissal. There is no formal procedure at DSA describing how to ensure the avoidance of conflict of interests within the regulatory body when new staff members are recruited from authorized parties, but practical measures are routinely taken. The newly recruited person is not involved in administrative decision-making processes or inspections related to the authorized party in question, before a given time period has passed.

Generally, conflicts of interest of staff are handled as defined within the Public Administration Act, the Ethical Guidelines for the Public Service and in DSA’s guidelines for employees. Staff has to excuse themselves when personal or economic interests arise or seem to arise. When the Director General is disqualified due to a conflict of interest, HOD has to investigate whether or not DSA is able to perform its regulatory functions.

Training of newly recruited staff follows internal procedures where these exist, but not all newcomers have received initial training. DSA has recognized the need to formalize this process more clearly. During the internal training of staff, there is focus on the importance of ensuring the independence of the regulatory body. All DSA employees are required to sign a declaration of confidentiality at the commencement of employment.

DSA has planned improvements in developing quality assured internal procedures in the new integrated management system to ensure independence regarding situations when DSA staff participates in research, national quality assurance cooperation, or projects with undertakings or institutions that are or might become authorized parties of DSA. This might include arrangements with the ministries to delegate regulatory on delegation of authority for specific cases to other bodies to enable them to issue the necessary permits or licences.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| Observation: DSA has an established process to avoid conflicts of interest, however no procedures have been established to ensure independence in performing regulatory tasks of those DSA staff, who participates in research, national quality assurance cooperation, or projects with undertakings or institutions that are or might become authorized parties of DSA. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 17 states that <i>“The regulatory body shall perform its functions in a manner that does not compromise its effective independence.”</i> |
| (2) | BASIS: GSG 12 Para 5.65 <i>“The integrated management system of a regulatory body should be described in a set of documents that need to be applied in order for the regulatory body to achieve its goals. This set of documents typically includes the following: A description of the interfaces with interested parties and external organizations.”</i> |
| S9 | Suggestion: DSA should consider establishing procedures for ensuring effective independence in performing regulatory tasks by the staff who are involved in projects connected with authorized parties. |

In addition to its regulatory tasks, DSA provides personal dosimetry service for all types of undertakings in Norway through the Department of Radiation Protection and Measurement Services. The IRRS Team was informed that DSA provides other technical services like environmental monitoring and equipment calibration not only for themselves but also for authorized parties. However, the current organizational setup, by having the measurements unit and the SSDL under the Department of Radiation Protection and Measurement Services, could lead to a potential conflict of interest within DSA with regard to its regulatory functions.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: Providing technical services for authorized parties within the Department of Radiation Protection and Measurement Services could lead to a potential conflict of interest within DSA with regard to its regulatory functions. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 17, para. 4.7 states that “ <i>The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework.</i> ” |
| S10 | Suggestion: DSA should consider resolving any existing or potential conflict of interest within its organization with regard to the provision of technical services. |

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The DG of DSA has the power to employ the necessary staff within the budgetary framework provided by the three responsible ministries (HOD, KLD and MFA). However, at present DSA does not have a systematic human resource plan that identifies the number and the necessary qualifications and competence of staff needed to carry out its functions and discharge its responsibilities commensurate with the nature and number of facilities and activities regulated.

Past reorganization of the governmental health authorities which was initiated to reduce costs and to streamline the public sector had an impact on the staffing situation at DSA. Support functions such as the library, archive and IT were outsourced and centralized between 2016-2018. As this was considered a business transfer, the employees of DSA working in these functions were also transferred. DSA implemented further workforce reduction by natural departure of staff, mainly through retirement. In this way, the reduction in the workforce was partly random in respect to the loss of competences, vacant positions were not filled, and many sections have become understaffed.

DSA decided to close the section responsible for research and to reallocate staff from research to regulatory tasks. DSA still has a recruitment freezing strategy due to a tight budget situation.

With HOD’s plan to establish two proton therapy facilities as well as up to four hospitals planning to establish new photon beam radiotherapy facilities and the overall tight resources in the regulatory activity over the health sector, DSA needs to ensure the regulatory supervision of these new activities. DSA needs to acquire additional competence for this activity. Two research reactors have recently shut down and are entering the decommissioning phase, making further competence in both decommissioning and radioactive waste management essential.

DSA generally has highly educated and qualified staff. The employees' level of education and competence is generally commensurate with the types of tasks they fulfil. However, the recent reductions in staff were partly random and some areas with the highest risk became

understaffed. DSA also covers broad areas of competence and skills, with a relatively small number of employees. This results in a certain level of vulnerability and dependence on key individuals. This situation becomes more critical in periods where DSA is understaffed and operates under tight budgets. A formal human resource plan that identifies the number and the necessary qualifications and competence of staff would be an input to reducing DSA's vulnerability. DSA has already started the preparation of a human resource plan. It maps the competences of the employees and the needs of each department and section. DSA plans to include the new human resource within the new integrated management system, which will facilitate its frequent review and updating.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: DSA has not yet developed a systematic human resource plan that identifies the number and the necessary qualifications and competence of staff needed to carry out its functions and discharge its responsibilities that is fully commensurate with the nature and number of facilities and activities regulated. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 18 states that <i>“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.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Requirement 18 para 4.11 states that <i>“A human resource plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities.”</i> |
| (3) | BASIS: GSR Part 1 (Rev 1) Requirement 18 para 4.12 states that <i>“The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills and shall include a strategy to compensate for the departure of qualified staff.”</i> |
| R6 | Recommendation: DSA should develop a comprehensive human resource plan including a specific training programme, which is based on an analysis of the necessary competences and skills needed to fulfil its regulatory obligations. |

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

DSA does not have formal Technical Support Organization (TSO). It has established an independent expert Advisory Committee on Nuclear Safety and Radioactive Waste Management. In some cases, related to Nuclear Safety and Security and waste issues, DSA has also made arrangements with external support organizations to perform technical support functions. For emergency preparedness and for response, DSA (as the secretariat for the Crisis Committee) has cooperation with 14 advisory organizations. For the areas other than nuclear safety and security, and emergency preparedness and response, DSA does not generally use support from external organizations.

Members of the Advisory Committee on nuclear safety and radioactive waste management were requested to submit a statement regarding any potential conflicts of interest in advance of their appointment.

Use of external support is administered through a contract framework. The successful contractors have been used on a regular basis. The potential for conflicts of interest were taken into account in the evaluation of proposals from consultant companies in the establishment of framework arrangements. Consultant companies are requested to provide evidence if conflicts of interest appear during the period of the framework. The experts examine different issues, which are reflected in detailed requests for services. Experts provide updates on the status of scientific and technical developments and assessments that inform developments of policy or guidance. They may also provide an input to review and assessments, as part of the licensing process, and may attend DSA inspections. The IRRS Team observed in one example that the request for services in case of external support for review and assessment is not detailed concerning the legal requirements the licensee has to comply with. In all such cases, DSA reviews contributions from experts and the responsibility for making decisions remains with DSA. However, the IRRS Team observed that DSA does not have the necessary resources and competence to carry out a thorough examination of all aspects of application documents for nuclear installations, and to fully verify or validate the conclusions of the experts in some areas.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: DSA requests external expert support for review and assessment of application for the renewal of IFE authorizations. However, DSA does not have the necessary resources to verify and validate the conclusions of the experts in all areas. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 18 states that <i>“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.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Requirement 20 para 4.22 states that <i>“The obtaining of advice and assistance does not relieve the regulatory body of its assigned responsibilities. The regulatory body shall have adequate core competence to make informed decisions. In making decisions, the regulatory body shall have the necessary means to assess advice provided by advisory bodies and information submitted by authorized parties and applicants.”</i> |
| S11 | Suggestions: DSA should consider ensuring the necessary means to assess the advice provided by external experts. |

DSA has a comprehensive cooperation on nuclear and radiation issues with other regulatory bodies and professional organizations, who give valuable input to DSA in preparation of decision-making. DSA also has agreements on cooperation with other relevant Norwegian authorities to ensure information exchange and coordination between authorities with regulatory responsibilities for the same undertaking. In questions relating to medical exposure, DSA usually seeks advice from professional organizations for different health professionals, the Norwegian Directorate of Health, the Norwegian Board of Health Supervision and Board for Ethics for Doctors. Other professional or industry organizations are also consulted on other issues, for example oil and gas industry organizations are consulted regarding the issues related to the regulation of NORM discharges and wastes.

DSA also has considered to establish advisory bodies in relevant areas like radiation source applications, similar to the ones established for nuclear safety and waste management.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: DSA has established an advisory body for nuclear safety and waste management. However, in some other areas, like radiation source applications, DSA does not have an advisory body. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 20 states that <i>“The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions”</i> |
| S12 | Suggestion: DSA should consider expanding the use of advisory bodies in all relevant areas. |

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

DSA has developed both formal and informal ways to communicate with authorized parties. The formal decision-making process is, as a rule, performed by written communication in accordance with the Public Administration Act (PA Act). The Freedom of Information Act (FoI Act) facilitates an open and transparent public administration and communication with the authorized parties.

DSA’s Communication Strategy commits itself to take an active role in communicating its regulatory practices with licensees, registrants and other stakeholders. The Communication strategy states that DSA shall have regular contact with Ministries, agencies, institutions and organizations linked to its work, and that such contacts should be performed in a professional and service-minded manner. Formal and informal meetings, including technical meetings, workshops, seminars, etc. are arranged with authorized parties when needed and relevant information (news, reports, strategies etc.) are published on DSA’s webpages and social media.

Formal and informal communication lines are established with the main operator in the nuclear sector, IFE, and with the future licensee, NND. For example, different types of communication, meetings, have been arranged and will be conducted, as needed. DSA has also established an annual dialog meeting with radiation protection coordinators involved in medical use of radiation. Authorized parties are also consulted when establishing or updating guidelines.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

All decisions made by DSA are anchored in one or more of the acts and regulations that fall within its competence. All relevant laws and regulations are available to the public and are easily accessible through the website Lovdata.no.

The relevant acts and regulations are the basis for DSA’s regulatory practices. In addition to the provisions in the regulations, supplementary comments are provided where it is considered necessary as guidance to authorized parties. DSA has also developed a set of guidelines, which describe how to meet the regulatory requirements. Furthermore, various application forms for different user groups are available at DSA’s website. These acts, regulations and guidelines provide the basis for regulatory practice. However not all relevant regulations and guidelines

are developed, and acts should be also revised with relevant requirements. **Recommendation R14 in Section 9.1 addresses this issue.**

DSA applies international standards like the IAEA Basic Safety Standards or relevant EU directives as deemed necessary for regulatory practices.

To maintain focus on safety in the decision-making processes, particularly within the nuclear sector, DSA has developed policy statements on safety and security culture. However, these are not currently applied to the whole organization. **Recommendation R7 in Section 4.1 addresses this issue.**

At present, DSA has two parallel management systems containing some relevant procedures, templates and instructions related to DSA's regulatory activities. A new integrated management system is under development and the intention is to merge the content of the relevant documents in the two existing systems into one. This will enhance the stability and consistency of DSA's regulatory activities towards the responsible parties. **Recommendation R8 in Section 4.2 addresses this issue.**

The formal requirements for decisions made by DSA are implemented through the use of procedures and templates and quality assured by the chain of command, requiring two signatures for any decisions made by the responsible DSA staff. The procedures and templates for review and assessment and authorization are established, and will be incorporated in the integrated management system, which is under development. However, these procedures should be improved with more detail instructions. **Suggestion S15 in Section 6.1.2 addresses this issue.**

Avoiding of subjectivity in DSA decision-making processes is achieved through the implementation of the PA Act and the internal QA-procedures covering different types of regulatory decisions. The QA procedures ensure that several members of staff are involved in regulatory decision-making process; all regulatory responses are prepared, reviewed and approved in a staged process that involves staff at different levels of the organization. However, these procedures should be improved with more detail instructions. **Suggestion S15 in Section 6.1.2 addresses this issue.**

The basis for decisions made by DSA are also available to the public according to the Freedom of Information Act, unless exempted from being made publicly available under conditions within the Act.

Before new regulatory requirements can be implemented, a risk assessment, cost-benefit and consequence analysis must be performed, according to the PA Act. In addition, a public hearing must be conducted. Relevant parties may propose their comments and changes in regulations and new provisions are made available for members of the public. Every Norwegian citizen has the opportunity to comment on proposed changes in regulatory requirements. It is common practice to inform relevant users before implementation of major changes in the regulatory practice, so they have the opportunity to give comments.

Users also have a right of appeal against decisions made by DSA as laid down in the PA Act.

DSA has planned improvements to establish policy for safety and security for all working areas and personnel within DSA in the integrated management system. Furthermore, DSA plans to propose to the government to include the NE Act to the family of Health, Environment and Safety (HES) legislation in the Internal Control regulations.

3.7. SAFETY RELATED RECORDS

Documents related to all DSA's regulatory activities are stored in DSA's archive software system called Public 360. The information contained therein is generally available to the public.

Documents related to the safety of facilities and activities, except the system of accountancy and control of nuclear material, are stored in the archive and are normally linked to the authorization/licensing process.

At present, most of the safety-related records are stored in DSA archive in a way that does not support easy statistics or analysis. DSA has therefore identified the need for developing an electronic case handling system linking all relevant records related to authorized facilities and activities and has initiated a process of procurement of such a system.

Results from inspections are documented in inspection reports, which are stored in the archive and made available to the public on DSA's web pages.

Information regarding all reported events are kept in DSA's archive. Events related to the use of radiation sources are also registered in an Excel sheet allowing for statistics and analyses. For an event that triggers the emergency organization, information on the event is stored in a separate archive for emergency events (CIM).

Inventories of radioactive waste and records of discharges are also kept in the archive. Furthermore, a national system for electronical declaration of both hazardous and radioactive waste is established with the purpose of safe handling of waste and to develop statistics as a basis for regulatory requirements and control.

Any ionizing radiation source used in Norway, with the exception of exempted sources, shall be registered in DSA's web-based electronic registration system for radiation sources (EMS). Through this system, DSA has established a complete national register of ionizing radiation sources. Each source is assigned a unique registration number, which is retained in the system even if ownership of the source is transferred from one company to another. Report functions that enable DSA to monitor relevant transactions involving the sources, such as whether a source is in use, in storage, sold, leased out, or disposed of, are implemented in EMS, facilitating efficient exchange of information between DSA and authorized users of radiation sources. EMS can only be accessed through the secure log-in portal ID-porten, which is the national system for logging into Norwegian public e-services, ensuring that the information contained in the register is appropriately protected. The IRRS Team considers establishment and use of this EMS as a good performance of DSA.

An electronic web-based national dose register for occupational doses was launched in September 2018. This register replaces the previous manual system of occupational exposure records stored in the archive.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Involvement of and consultation with interested parties is a key part of the decision-making process for DSA. Hearings are performed for licensing and are mandatory under the PC Act for permits. The application and DSA response are posted on the DSA website in advance of holding a public hearing. The details of the hearing are also announced on the website and, in some cases advertised in local press, to ensure that interested parties have an opportunity to participate.

DSA informs and consults 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.

The FoI Act is also an essential tool for ensuring the public access to information.

DSA aims to be a transparent and credible authority, by actively communicating knowledge within field of expertise to target groups in an understandable and consistent manner. DSA communicates new knowledge to all affected audiences through the strategic use of communication channels.

The authority's website is an important tool for communication to the public and other interested parties. As part of DSA's Communication Strategy, reports and information of interest to the public are published on DSA's webpages, including documents relevant to the decision-making process. In addition, DSA publishes press briefings and news, including information concerning incidents, accidents and abnormal events. Inspection reports are also published on the webpage. DSA also actively uses social media platforms such as Facebook and Twitter in its communication with the public. In addition, DSA considers the media to be an important communication channel.

DSA Communication Strategy also includes communications with relevant ministries and governmental agencies/authorities, as well as counties and municipalities.

DSA is an open and transparent and is very active on social media platforms. It has a Communication Strategy for the Crisis Committee for Nuclear Preparedness which address society's information needs in order to ensure that life, health, environment and important social interests are protected. To achieve that, DSA has a 3-year plan for population surveys, surveys amongst the media and licensees. The IRRS Team considers the communication with the public as a good performance of DSA.

DSA has planned improvements that the new integrated management system under development will include QA procedures for informing and consulting interested parties and the public about possible radiation risks associated with facilities and activities and about the processes and decisions of the regulatory body.

3.9. POLICY ISSUES

The policy issue discussions took place on 24 June 2019. DSA senior staff and IRRS Team members participated in the discussions. The host counterpart wished to collect the international experience and views of the IRRS Team regarding the topics of (1) regulatory competence and (2) provision of guidance and advice. Background information in both topics was attached to the Summary Report of the IRRS Advance Reference Material.

3.9.1. Competence at DSA

Maintaining competences and skills in the broad range of regulatory areas with a relatively small number of DSA staff is a challenge, and this results in a certain level of organizational vulnerability and dependence on key individuals. Recent developments have also resulted in the need to enhance regulatory capacity and competence in regulating decommissioning and radioactive waste management as well as new medical practices.

DSA recognized the need for developing a policy and strategy for competence management. This involves systematically identifying core regulatory competences and mapping these competences against those currently available at DSA or that may be provided by external organizations.

Topics for and outcomes of discussions are summarized below:

- Lessons learned from others which have undertaken competence mapping and if there are recommendations on approaches;
- Strategies for maintaining the necessary breadth of competence within a small organization (in country with a limited nuclear programme);
- Approaches for utilizing expertise from other countries (from TSOs, consultants or other regulatory bodies), as a complement to in-house expertise;
- How to establish a strategy for competence management for DSA including human resource plan.

In Sweden a detailed competence mapping was completed, and they identified several areas where the necessary core competences were limited both in the number of staffs having the competences and also the depth/level/range of the competence. Training programmes are developed mainly internally, building on the management system processes and supported by senior inspectors having wider range of expertise or with specific experiences in relevant areas.

In Greece an annual planning and evaluation is being completed on the basis of a well formalized internal procedure to update and sustain the regulatory staff competence.

Slovenia established a competence model following the IAEA SARCoN methodology and tool and relevant publications (Safety Report Series 79, TECDOCs 1757 and 1860). SNSA regularly completes the gap assessment of competences and updates the human resource development plan, including the training programme.

In Ireland the risk profile of regulatory competences for strategic planning is regularly updated and the training plan is harmonized with the strategic plan. Training programmes are developed internally. In some cases, inspectors attend external trainings organized by others, e.g. hospitals or other regulatory bodies of other countries.

In France inspectors are specialized according to their areas of responsibilities, like e.g. nuclear safety inspectors and inspectors for medical or industrial applications of radiation sources. Their training programmes follows systematically their areas of responsibilities.

In Canada core regulatory competences are systematically identified and the gaps are evaluated. The outcomes of the evaluation are the major inputs for the inspectors' annual training programmes. Experiences are regularly shared in the frame of internal trainings. Internal TSO services are available to extend regulatory competences in specific areas.

In summary, (1) a systematic approach to regulatory competence management is to be developed and introduced, (2) designing regulatory training programmes more attention is to be paid to internal training activities and sharing experiences and (3) establishment of cooperation programmes between the regulatory body and educational institutions, universities may contribute to the enhancement of regulatory training programmes.

3.9.2. Provision of guidance and advice

DSA is responsible for the development and promotion of guides. The development process includes, among others, gathering inputs and comments of interested parties. Once a guide is approved, information is sent to relevant parties. Regulations and guides are published on DSA's webpage and regulations, along with legislation of all types, are published on the official webpage for Norwegian legislation. Both regulations and guides are presented at meetings with relevant parties, such as annual meetings with representatives from hospitals and medical institutions or from the relevant industry groups.

DSA also provides guidance and advice directly to individual authorized parties to help ensuring compliance with regulatory requirements, through various forms of communication. Such communications may include formal letters and instructions directly related to the authorization or licence and its conditions, and communications before, during and after inspections. Communications of a more informal nature occur during meetings, telephone conversations and emails.

DSA recognizes the importance of maintaining regulatory independence in such communications and enhancing responsibility for safety of authorized parties. This often involves providing an appropriate level of guidance and advice on what needs to be achieved (the objectives of taking action) without providing details on how this should be done (means of action). Achieving this balance is challenging and DSA would like to learn more about how other regulatory bodies deal with this.

Topics for and outcomes of discussions are summarized below:

- Strategies for maintaining regulatory independence and providing regulatory advice and guidance, for example before, during and after inspections, without reducing the authorized parties' responsibility for safety;
- Approaches for dealing with potential conflicts of interest.

In Finland a new radiation protection law was recently issued. This law acts and STUK regulations include paragraph specific motivations that explain the intention of the requirement. These documents are accessible through STUK's web portal.

In Portugal the regulatory body is facing similar challenges as the community of interested parties (RB, users and licence holders, etc.) is limited. It is not easy to maintain regulatory independence when questions are received from the users on how to fulfil obligations of the regulations.

In Sweden the regulatory body (SSM) gives advice only to the public on specific behaviors, but not to the licence holders. Guidance documents are developed by the regulatory body on ways of meeting the regulations and are published on SSM's webpages.

In Australia trainings are provided regularly to the inspector staff on how to maintain independence during the daily activities.

In Ireland the inspectors never give prescriptive advice to the licensees, but instead generic regulatory guidance documents are issued on meeting the regulations. They pay specific attention to ensure that the licensees' prime responsibility for safety is not diminished.

Countries represented by the IRRS Team have different approaches in making directly accessible to the public the inspection reports. In some countries those are uploaded to the regulator's webpage. In some others, only annual summaries are uploaded or just only excerpts of the reports with highlighting that in case of interest and questions more information can be made available. Some opinions were explained that having the licensee warned in advance that the inspection report is going to be published on the regulatory body webpage, such a practice will show independence of the regulator and also a kind of transparency of the regulatory processes.

Following by the regulatory body an internal rotation policy in assigning the staff to conducting inspections to different facilities and activities may contribute to enhancing and maintaining the independence of the inspectors. Diverse practices were reported by the IRRS Team members in respect of their regulatory bodies.

3.10. SUMMARY

Overall, the responsibilities and functions of DSA are in good compliance with IAEA safety standards. However, the following areas for further improvement have been identified:

- Allocation of the resources commensurate with the risk;
- Potential conflict of interest regarding provision of technical services and establishment of procedures for ensuring independence;
- Human resource plan;
- Use of advisory bodies;
- Means to assess the advice provided by external experts.

DSA's communication with the public as well as establishment and use of electronic registration system for radiation sources were identified as areas of good performances of DSA.

The policy issue discussions took place with DSA senior staff and IRRS team members. The host counterpart collected the international experience and views of the IRRS team regarding the topics of (1) regulatory competence and (2) provision of guidance and advice.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The core regulatory functions of DSA are implemented by two departments:

- the Department of Nuclear Safety and Environmental Protection (AOM) which has since 2012 established a quality management system based on the ISO 9001 standard that includes procedures and templates for regulatory control related to the safety and security of nuclear facilities and materials and environmental protection, and
- the Department of Radiation Protection and Measurement Services (ASM) which has established a management system containing documented procedures for regulatory control related to safety and security of radiation sources and their use, for example medical and industrial use. The development of the latter system is process oriented and started in 2009.

Although different in scope, these two systems form the basis of the new integrated DSA management system under development.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

AOM has developed a Safety Culture Policy statement and a Nuclear Security Culture Policy statement. It has also formulated its mission and vision and its own values. However, these documents have not been disseminated to the whole organization. The process within which these statements have been developed is neither documented nor incorporated into the management system that is under development. The other DSA departments have no documented safety statements or decisions drafted by the top management or by the department heads in order to establish the acceptance of personal accountability in relation to safety for all the individuals in DSA.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|--|---|
| <p>Observation: Though there are two documents for safety culture policy and nuclear security culture policy in AOM, these are not developed by the whole organization. Therefore, there is no common safety policy documentation demonstrating leadership for safety by managers at all levels of DSA. This has been recognized in the ARM and is part of the action plan.</p> | |
| (1) | <p>BASIS: GSR Part 2 Requirement 2 states that <i>“Managers shall demonstrate leadership for safety and commitment to safety.”</i></p> |
| (2) | <p>BASIS: GSR Part 2 Requirement 3 para 4.2 states that <i>“Senior management shall be responsible for establishing safety policy.”</i></p> |
| R7 | <p>Recommendation: DSA should develop a safety policy document with the individual and organizational values and expectations for safety to be disseminated to the whole organization.</p> |

DSA has developed a strategic action plan for the three-year period of 2018-2020. There is no formal process for the development and revision of the strategic action plan. However, the IRRS Team was informed that the strategic plans are drafted with the involvement of all DSA personnel. During the interviews the IRRS Team noticed that not all personnel were aware of this document. Its structure is as follows: there are the main key aspects, the respective goals

per aspect and the plan for each one. However, these goals have not been linked with the personnel’s responsibilities or with measurable indicators to monitor and evaluate the system and provide suggestions for improvement.

Recommendation R8 in Section 4.2 addresses this issue.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

DSA has acknowledged that the management systems of the departments do not include all the regulatory core and supporting functions. DSA’s Director General has appointed a project manager to lead a team for the development of a new management system with the main goal of applying for a certification based on the ISO 9001 standard by the beginning of 2020. Moreover, the management team has the mandate to align the management system under development with the requirements of GSR Part 2. The management team comprises of 5 persons from all DSA’s departments to bring all the elements together into the new system. The project manager has direct access to the Director General. Training seminars on risk management have been attended by members of the management team. The IRRS Team was informed that external help could be consulted, if needed. A web-based system in DSA’s intranet has already been created where it is planned to upload all the relevant documentation.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| Observation: There are some procedures followed by the different departments of DSA but there are no formalized documented processes. No integrated management system exists in DSA to cover all core and supporting function and to integrate all elements related to safety. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 19 states that <i>“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.”</i> |
| (2) | BASIS: GSR Part 2 Requirement 3 states that <i>“Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety.”</i> |
| R8 | Recommendation: DSA should develop, establish, implement, assess and continuously improve a documented integrated management system to ensure safety, using graded approach, in line with IAEA safety standards. |

4.3. THE MANAGEMENT SYSTEM

The DSA’s management system is in the development phase. The management team has planned to integrate all the relevant elements into one system. A work plan has been drafted but, as it was noticed during the interview, there is some delay due to high workload of the staff involved. The IRRS Team noticed that the plan of integration for the system includes the harmonization of all the relevant documents, templates, reports and records that are in use by the two departments. This harmonization takes time and causes delays to the workplan.

Regarding the organizational changes in DSA these can be done based on the decision of Director General. DSA’s organization structure has been recently changed due to limited

resources for the accomplishment of the core regulatory functions that are presently more demanding than in the past. However, there is no formal documented process to describe the organizational changes in DSA (or other minor changes) that could have significant implications for safety and to ensure that they are appropriately analyzed.

The graded approach in the management system is related to the way the core functions are conducted. This is discussed in Sections 5 to 10.

The existing documentation of the management system is limited. There are templates which are not used by the whole staff due to the transition period. There are also procedures for some of the core functions, such as for the review and assessment process, but these have been recently developed within AOM. The IRRS Team was informed that more detailed guidelines will be developed within the integrated management system that will help staff to make decisions.

Recommendation R8 in Section 4.2 addresses this issue.

4.4. MANAGEMENT OF RESOURCES

DSA's responsibilities are determined in the government's directive for DSA from 2017. Moreover, there is the letter of commitment of HOD, KLD and MFA which is provided to DSA on an annual basis assigning certain tasks and the respective budget.

There are 115 persons in DSA involved in the regulatory and supporting functions. DSA has just developed a tool for managing the competence of the personnel within which the Section Head can highlight the needs of the section and verify the existing competences.

For the inspectors' training there is a 4-day course on how to perform inspections. This course is common for all the inspectors in Norway. Specific training required for DSA's personnel to accomplish its tasks is discussed within the section and the department.

However, no specific documented process for the determination of the human resource plan exists, including the training and re-training of the personnel for the core and supporting functions of the regulatory body.

Recommendation R6 in Section 3.3 addresses this issue.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The management team has defined a structure for the new system and is in the phase of identifying the processes (core and supporting ones). Currently the identified processes are: EPR (connected in a different web system called CIM); in the second group of processes there is review, assessment and authorization, inspections, handling of complaints and non-compliances. Other DSA functions are also defined in a third group like surveillance, maintenance of competence, regulations and guides and international cooperation. The last group consists of management and leadership, management of the resources, quality management, informatics and management of the technical services. It is noted by the IRRS Team that the current structure differs from the one described in IAEA guidance GSG-12.

During the interviews the IRRS Team noted that the roles of the Section Heads and the process owners are not clearly defined which causes problems in the identification and structure of the processes. Due to this, ownership of the majority of processes in the new system are currently assigned to the DG. For processes for which personnel of both departments are involved there is a question for the appointment of the process owner. Similar questions have arisen for the development of all the elements (templates, procedures, reports, external documents etc) that are designed to be included in each of the processes when addressed to different types of

facilities and activities. Moreover, the IRRS Team observed that not all of the staff has a clear understanding of the structure of the management system and the respective terminology.

Recommendation R8 in Section 4.2 addresses this issue.

4.6. CULTURE FOR SAFETY

The management team has included in the management system a tool for the analysis of problems, complaints and non-compliances with the system which is a measure to encourage DSA's staff questioning attitude. A safety and security policy statement has been created for regulation of nuclear facilities and radioactive waste management.

There is an inspection policy statement which has been disseminated to the inspectors of DSA. This is an important step towards the culture for safety that DSA would like to foster. However, the IRRS Team noticed that some of the inspectors were not aware of the inspection policy document neither of the mission, vision values and the safety culture statement that was mentioned in Section 4.1. There are currently no provisions in the management system or in the workplan on how to sustain and support the culture for safety within DSA.

The Director General meets with the department heads and the head of the communication unit every two weeks. In these meetings, decisions are made with safety as an important priority. Minutes are kept from these meetings and disseminated to all of DSA's staff. Meetings to support the collaboration between groups of the two departments (AOM and ASM) are not performed on regular basis. Though two of the DSA's departments have similar responsibilities related to different facilities or activities or exposure situations their collaboration is limited to the inspection process within which they have some common meetings for the analysis of the data from the inspection and for the drafting of the inspection plan.

Within the annual plan, tasks and responsibilities for staff are not linked with safety goals to create a motivating work environment.

Recommendation R8 in Section 4.2 addresses this issue.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The management system is still in the development phase. There are no relevant provisions for the measurement, assessment and improvement of the management system as well of the leadership for safety and safety culture.

Recommendation R8 in Section 4.2 addresses this issue.

4.8. SUMMARY

The management system of DSA has been based on some documented procedures developed by two of DSA departments and the technical services focused on quality and customer satisfaction. A management team and a project manager have been appointed with mandate to develop an integrated system in line with IAEA safety standards.

Recommendations are given to DSA for the following issues:

- Development of a policy statement to be disseminated to all DSA staff.
- Development of an integrated management system with as starting point the identification of the core functions of the regulatory body and the documentation of each individual process without focusing on the harmonization of all the documents and records for the different facilities and activities.

Within the integrated management system, it is important to establish a process to address the organizational changes of DSA in order not to jeopardize safety.

Finally, a human resource plan and specific training programme for staff based on analysis of the necessary competence and skills is also an important step for the support of the integrated management system.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The authorization process for facilities, activities and exposure situation follows the PC Act, NE Act and RP Act.

In accordance with the NE Act the following authorization documents can be issued: licences to construct, own and operate a nuclear installation and permits to manufacture, own, store, handle, transport, sell or otherwise hold or dispose of nuclear substances.

The government, through HOD, grants, revokes or modifies licences. DSA makes recommendations on all licence applications under the NE Act. These recommendations include the outcome of DSA's review and assessment of the application and proposals for licence conditions. Although a facility cannot operate without a permit from DSA, the IRRS Team noted that the ministry has the power to grant a licence in the absence of a positive recommendation from DSA. However, DSA have legal powers to stop the operation of a facility for safety reasons even if it has a licence.

The frequency of regulatory review of application and submitted documents depends on the type of authorization to be issued. Licences issued under the NE-Act should have a duration limited to a specific period. In practice licences issued to IFE are revised at least every 10 years. In this regard, the licensee (IFE) submits an application and supporting documents up to two years before the licence expiration date. The outputs of DSA's authorization process are the recommendations that are to be submitted to the Ministry to support the decision-making process regarding the licence application.

However, the NE Act does not cover early stages of development of nuclear installations: siting and design. In addition, the decommissioning stage is not specified as a stage requiring authorization. **Recommendation R2 in Section 1.2 addresses this issue.**

The PC Act establishes provisions for management of different types of pollution and waste. Pollution is defined as the following:

1. The introduction of solids, liquids or gases to air, water or ground;
2. Noise and vibrations;
3. Light and other radiation to the extent decided by the pollution control authority;
4. Effects of temperature, which cause or may cause damage or nuisance to the environment and anything that may aggravate the damage or nuisance caused by earlier pollution..."

In accordance with PC Act the 'pollution control authority' may issue a permit for any activity that may lead to pollution and waste management. DSA issues permits under the PC Act for activities and facilities giving rise to radioactive discharges and management of radioactive waste (including disposal of radioactive waste). DSA has the authority to amend, renew, suspend or revoke permits. DSA does not authorize siting, design and construction stages of facilities under the PC Act, these are covered by Planning and Building Act (PB Act) with a clear role for DSA. The decommissioning stage is included according to the PC Act in the list of activities that require a permit issued by DSA. **Recommendation R2 in Section 1.2 addresses this issue.**

Through the NE-Act DSA developed and recommended General Licence Conditions that have legal force through the Kjeller licence. The IRRS Team was informed that in the future they will be incorporated into the Halden and Himdalen licences.

In addition, the draft of “Guidance on the Application of the General Licence Conditions to Research Reactors, Nuclear Fuel Cycle Facilities, and Radioactive Waste Handling, Storage and Disposal” have been developed by the DSA to clarify the expectations of the regulatory body for the authorization process of different stages of lifetime of facilities under the NE Act.

The IRRS Team has identified that the current authorization process is giving rise to interpretation issues for licensees (research reactors and fuel cycle facilities). This is resulting from lack of provisions in the NE Act and the need to further develop detailed guidance. DSA’s authorization procedure describes the administrative steps of an authorization. The authorization procedure needs strengthening to reflect the different technical requirements relating to different types of authorization e.g. modifications, new licences.

The NE Act (changes in installation and operating conditions) does not give sufficient precision on the type of modification that are subject to an authorization. DSA should clarify the type of modifications subject to authorization and issue guidance on the authorization process.

Recommendation R 14 in Section 9.1 addresses this issue

In accordance with the RP Act, any activity involving ionizing radiation sources is subject to a requirement of authorization. The Regulations on Radiation Protection and Use of Radiation (RP Regulations) distinguish between activities requiring authorization by *licensing* and activities requiring authorization by *registration*, in accordance with the principle of a graded approach.

5.2. AUTHORIZATION OF RESEARCH REACTORS

The operation of research reactors is authorized by a licence that is limited to a specific period. The licence of the reactor JEEP II in Kjeller was granted from January 2019 to 2028. The GLCs were issued for the renewal of the authorization and include a series of 25 additional requirements. The reactor was shut down in December 2018.

The licence of the HBWR reactor in Halden was granted from 2015 to 2020 and the renewal process is ongoing. The GLCs are not yet been implemented into the Halden and Himdalen licences. IFE have been notified however that the GLCs will be used as a basis for the forthcoming assessment for a new licence at Halden. The reactor was put into a cold shutdown state with no intention from the licence holder to restart the reactor in June 2018 following a failure of an isolation valve in the primary circuit identified during maintenance. The aspect of the operating authorization allowing the reactor to be operated at power has been temporarily withdrawn as a consequence-of this incident.

The General Licence Conditions, for Kjeller only, require safety analysis to be updated and maintained, and periodic safety reviews to be conducted. However, regulations do not exist detailing how the safety analysis report of the research reactor must be periodically updated over the research reactor’s operating lifetime to reflect modifications made to the facility according to the authorization process. **Recommendation R14 in Section 9.1 addresses this issue.**

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

The localization of the facilities operated by IFE on the sites of Halden, Kjeller and Himdalen is not clearly described in the ARM.

One licence is granted for each site although one of the facilities located in Halden is included in the Kjeller licence: the Halden Fuel Instrumentation Workshop.

The nuclear FCF are quite different and they have different life time expectancy.

The IRRS Team was informed that in the future DSA could be asked to assess and modify the authorizations of FCF at different stages in their lifetime. At Kjeller and Halden sites it is expected that there would be FCF with different status: operation or decommissioning and potentially different-operators and thus different licensees.

The IRRS Team considers that it would be beneficial for DSA to analyse granting separate licences for the different FCF, especially if the decommissioning would be performed by the NND.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Facilities for predisposal waste management and for disposal of radioactive waste are subject to authorization process in accordance to the PC Act and, where appropriate, the NE Act.

At the IFE Kjeller site there are several radioactive waste management facilities that are operated to accept, process and temporary store the radioactive waste produced by two research reactors and other facilities located on their sites, and to accept radioactive waste from different institutions and organizations that use radioactive sources (industry, education, medicine and scientific areas except NORM industry). KLDRA Himdalen is the combined Disposal and Storage facility for low and intermediate level waste.

In Norway, NORM waste is managed as ‘radioactive waste’ if its activity levels are above of the levels established in the Regulation on the Application of the Pollution Control Act to Radioactive Pollution and Radioactive Waste (such waste is ‘subject to disposal requirement’). NORM waste is produced for example by oil and gas industries as well as acid forming rocks containing radionuclides. NORM waste constitutes the largest part (volume) of radioactive wastes arising in Norway. There are four repositories in Norway for radioactive waste with NORM.

For some radioactive waste facilities for example for radioactive waste disposal facility in KLDRA Himdalen there are two separate authorization documents issued: a licence in accordance with NE Act (to 28 April 2028) and a permit issued for management of discharges and radioactive waste in accordance to the PC Act.

The following licensing procedures are developed and approved by the DSA to clarify authorization process:

- “Guidelines for applying for a permit under the PC Act for radioactive discharges and for the management of radioactive waste”;
- “Authorization procedure” to clarify decision-making process regarding the application for authorization in accordance with legal and regulatory requirements for all types of facilities and;
- Review and assessment procedure;
- “General Licence Conditions” (under the NE Act).

There are no requirements established for the period of time needed for duration of authorization process for issuing of a permit under the PC Act. Time for regulatory review depends on complexity of facilities and activities to be authorized, however the PC Act states that regulatory reviews should be performed if the damage caused by the pollution is greater than anticipated, if damage may be reduced without unreasonably cost, new technology makes substantial reduction in pollution and in any case a review shall be performed every 10 years, if it has not been done earlier.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Under the Norwegian Regulatory system, any activity involving ionizing radiation sources is subject to a requirement of authorization. The RP Regulations distinguish between activities requiring authorization by licensing and activities requiring authorization by *registration*, in accordance with the principle of a graded approach. This system includes a mechanism for the exemption of radiation sources from some of the requirements of regulatory control but the IRRS Team could not find evidence of a mechanism for the clearance of sealed radiation sources from regulatory control. **Recommendation R9 in section 5.10 addresses this issue.**

Licensing is required for conducting any type of work or activity involving or potentially involving high-activity radioactive sources or high radiation doses, or that requires a high level of competence (i.e., for any type of activity that may engender a non-negligible risk). The specific types of work or activities subject to the requirement of licensing are listed in the RP regulation. Registration is required for any activity involving ionizing radiation sources that is not subject to licensing.

All authorized parties subject to a requirement for authorization must appoint a Radiation Protection (RP) coordinator, in order to comply with the competence requirements in the RP Regulations. The RP Coordinator is the undertaking's contact person with DSA.

Applicant intending to be licensed shall apply in writing to DSA, in accordance with section 8 of the RP Regulations. For most activities subject to licensing, specific application forms are available from DSA's web pages. The application forms are designed such that the information provided, together with the mandatory attachments, demonstrate whether the most important and relevant aspects related to safety are properly considered and managed by the applicant.

Applicants planning to use or handle radiation sources shall, regardless of whether their planned activity is subject to licensing, prepare a written risk assessment related to the use of radiation according to the RP Regulations. The IRRS Team was informed that risk assessments are only submitted as part of licence applications for irradiation facilities.

Registration is performed using DSA's web-based electronic registration system, which is called EMS. All radiation sources and their return arrangements are registered, along with relevant information about the registrant's organization, the type of activities they perform, and name and contact information of the RP Coordinator. Radiation sources shall not be used until the registrant has received confirmation from DSA regarding the registration.

An activity subject to a requirement of authorization shall not be started until a licence is given or registration dealt with according to the RP Act, section 6. There is no separate requirement for notifying DSA of an intention to carry out an activity involving radiation sources, since authorization by licensing or registration is required before the activity can be started.

Licences are always granted for limited validity periods, typically varying from three to ten years depending on the type of activity. The validity period associated with each type of activity is set using a graded approach based on practical experience and an evaluation of relevant risk factors.

A key difference between authorization by licensing and authorization by registration, is DSA's opportunity to set specific conditions or limits in licences that the licensees must comply with. The conditions are used by DSA as a tool to limit the risks that are identified to be the most important for the activity, consistent with the principle of a graded approach.

The justification principle is implemented in both the RP Act and Regulations. All uses of radiation shall be justified, i.e. all production, import, export, transport, transfer, possession,

installation, use, handling and waste management of radiation sources shall be justifiable to ensure that risks do not arise to those performing any such activity, to other persons or to the environment.

Consistent with the justification principle, the authorized party assesses alternatives to the use of ionizing radiation. This principle of substitution has proven to be an effective measure for enhancing both safety and security in the use of ionizing radiation. According to this principle, alternatives to the use of ionizing radiation shall always be assessed, and methods not involving ionizing radiation shall be chosen if feasible without unreasonable disadvantage.

In particular, X-ray apparatus shall be utilized rather than radioactive sources when practically achievable. The latter requirement has successfully been applied as a legal basis for the substitution of blood irradiators based on caesium chloride with X-ray irradiators, thereby reducing the number of Category-1 radioactive sources in Norway by about 75% and removing all high-activity caesium-chloride sources. The IRRS Team considers this to be an area of good performance in strengthening justification and reducing the use of high activity sealed sources.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

General provisions regarding the authorization process for decommissioning are established in the PC Act. In the NE Act decommissioning' is not mentioned as a stage of the life time of nuclear facilities to be authorized. However, the set of licensing procedures that are mentioned in the Section 5.4 above is applicable for decommissioning activities also. **Recommendation R2 in Section 1.2 addresses this issue.**

In addition, the draft of "Regulatory requirements for decommissioning of facilities" is under development by DSA. The provisions of these requirements and expected guidance will clarify the authorization process and expectations of DSA regarding the decommissioning stage.

Currently, there are no nuclear decommissioning projects under implementation. The upcoming decommissioning of the research reactors will require the development of clear licensing procedures and regulatory requirements for the structure and content of documents to be submitted by the operator.

Recommendation R14 in Section 9.1 addresses this issue.

5.7. AUTHORIZATION OF TRANSPORT

The transport of radioactive material is recognized as a practice but authorization is not specifically required in the RP Act and transport is not in the scope of RP Regulation. The transport of nuclear material requires an authorization per the NE Act.

The authority to issue approvals based on the SSR-6 for all modes is not clearly transferred to DSA for all modes of transport. Package design certificates and validation certificates issued in past years by DSA make varying references to ADR/RID Regulations, IMDG Code and RP Act.

Authorizations based on SSR-6 are generally done by different departments of the DSA depending on whether the authorization includes nuclear material or not. Nuclear material is defined in the NE Act and may differ from the definition of fissile material in SSR-6 (para 222).

There is no internal guidance on the contents of the approval certificates. These are, though, regulated in in detail in the Modal Requirements.

There is a procedure in AOM management system that describes the basic steps and responsibilities in all kinds on authorizations including transport. The guide includes for

example a list of required content of the application to be filled in. The actual list is created based on the template by the case handler on a case by case basis. The procedure has not yet been included in an integrated management system. The procedure does not include notifications (SSR-6 paras 557 – 560) or packaging serial numbers (SSR-6 para 824) **Recommendations R8 in Section 4.2 addresses these issues.**

The NE Act has no transport-specific requirements for authorization and the licence conditions do not include any transport-specific requirements based on SSR-6. While there is no active manufacture or design of packages or material requiring competent authority approval, there is no external guidance for applicants on how to apply for such an approval. SSR-6 para 306 states that where competent authority approval is required, such approval shall take into account, and be contingent upon, the adequacy of the management system. There are no general criteria for an acceptable management system. **Recommendation R14 in section 9.1 addresses these issues.**

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

Legislated requirements for authorization issues of occupational exposures and for the protection of workers are established in the RP Act, the RP Regulations, and the IC Regulations. DSA administrates the RP Act, RP Regulations, and IC Regulations. The Working Environment Act (WE Act) and associated regulations also include additional requirements for authorized parties for the protection of workers, including worker health surveillance. These are administrated by the Norwegian Labour Inspection Authority.

The RP Act requires justification and optimization of occupational exposures. Exposures to ionizing radiation must be as low as practically achievable, taking into account technological knowledge, social and economic factors. The RP Act requires radiation doses to not exceed established effective and equivalent limits, which are set in the RP Regulations. Dose limits are set occupationally exposed workers and apprentices and students between the age of 16 and 18 years. The Regulations concerning action and limit values for physical and chemical agents in the working environment and classified biological agents (Regulations Concerning Action and Limit Values), established by the WE Act, also adopt these dose limits which must not be exceeded by authorized parties whose employees may be exposed to ionizing radiation. The dose limits prescribed in both these regulations comply with IAEA GSR Part 3 requirements.

The Regulations Concerning Organization, Management and Employee Participation (established by the WE Act), sets dose limits for young people aged between 16 and 18 years who are not required to go to school and who are permitted to perform work that entails exposure to ionizing radiation. The IRRS Team identified that the lens of the eye dose limit of 50 mSv/year is not in alignment with Schedule III.2 (b) of IAEA GSR Part 3, which stipulates a dose limit of 20 mSv/year. **Recommendation R15 in Section 9.8 addresses this issue.**

Authorized parties must classify areas as controlled or supervised in accordance with the requirements of the RP Regulations. Authorized parties are also required to prepare instructions and work procedures in writing that ensures proper radiation protection. The IC Regulations require authorized parties to establish rules and procedures for the protection and safety for workers and other persons, and workers shall contribute to both following and making of internal control regarding radiation protection.

Requirements for the monitoring and recording of occupational exposures in planned exposure situations are legislated in the RP Regulations. Authorized parties are responsible for maintaining occupational exposure records for workers, and the regulated retention period for the records aligns with IAEA GSR Part 3 requirements.

In 2018, DSA established a national dose register for occupational exposed workers, and the RP Regulations requires authorized parties that have determined workers' individual radiation exposure to report dose data to the register, at an annual frequency. The report must include information regarding the dose, including the name of the worker, worker's personal identity number, type of work, employer (organization number) and place of work. The IRRS review determined that work continues by DSA to populate the register and create supporting procedures.

DSA operates a dosimetry service offering thermoluminescent dosimeters for individual monitoring with Hp(10) and Hp(0.07) capabilities. DSA is a national personal dosimetry service provider for a majority of authorized parties, making DSA both a technical service provider and a regulatory body. Presently, there are no formal regulatory requirements regarding authorization, approval, and accreditation of personal dosimetry services in Norway. Quality assurance procedures are implemented for technical services offered by DSA based on the ISO 17025 standard, and parts of the laboratory services are accredited by Norsk Akkreditering. In the ARM, DSA has identified that accreditation should be obtained for the technical services it provides as a planned improvement for its organization. **Suggestion S5 in Section 1.9 addresses this issue.**

The RP Act requires employees and other associated persons of authorized parties to have instruction or training as necessary to ensure that they have sufficient qualifications or knowledge in respect of radiation protection and safe use of radiation. The RP Act also establishes requirements for a radiation protection organization, including the designation of a responsible radiation protection officer. The RP Regulations require authorized parties to ensure that employees and other associated persons who install or work with radiation sources, or who may become exposed to radiation, have sufficient competence in the field of radiation protection. When issuing authorizations for uses of radiation, DSA may also set specific requirements regarding training and competence. DSA guidance documents regarding different uses of radiation provide specific information on the expectations on competence and training.

The RP Act requires authorized parties to ensure that persons who, because of young age, pregnancy or other reasons, are particularly sensitive to radiation be assigned tasks that do not involve exposure to radiation, or to be protected by other appropriate measures. The WE Act also establishes supplementary regulations, including a minimum age for workers exposed to radiation, as well as medical examination of persons who are exposed to radiation. The Performance of Work (established under the WE Act) requires employers to ensure that pregnant and breastfeeding employees are relocated to other work if exposures in the working environment (for example ionizing radiation) entails a risk of reproductive harm to the child. DSA guidance documents for medical uses of radiation, nuclear medicine, and use of open radioactive sources also include these recommendations.

Dose limits are set for the foetus of pregnant workers and for apprentices and students under the age of 18. Pregnant and breastfeeding workers must not perform work activities that might imply a significant risk for intakes of radionuclides or contamination. Pregnant women are also not allowed to participate in emergency response operations.

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

The RP Regulations specify the activities involving ionizing radiation and medical exposure that require an authorization from DSA. The authorization function for these activities is performed by the Medical Applications Section within the Department of Radiation Protection and Measurement Services. DSA implements a graded approach with two levels of authorization: licensing and registration.

The authorization process reflects a graded approach with different application forms developed depending upon the medical exposure and risk which require different levels of documentation to be submitted by the applicant. The forms include a self-declaration that the undertaking will comply with the regulations and requirements. For the higher risk activities, the submitted documentation, for example risk assessment is reviewed by DSA prior to issuing of the licence. It is noted, however, while there is a document trail reflecting the various stages of the process a documented procedure does not exist for recording the authorization process and decision. It is recommended that the authorization procedure is formally documented in conjunction with review and assessment. **Suggestion S15 in Section 6.1.2 addresses this issue.**

In addition to the licenses that are issued for nuclear medicine facilities, the Department of Nuclear Safety and Environmental Protection also issue a permit for discharge to the environment. The licence to nuclear medicine facilities is valid for 10 years while the permit for discharge has no time-limitation. Recognizing there are interdependencies between the licence and permit, both issued by DSA, it is important there is effective co-ordination in the regulation of these facilities. This issue is also discussed in Section 4.2.

The IRRS Team noted that the RP Regulations specify designated roles for personnel with competence in medical physics in medical facilities authorized by DSA. While the educational requirements for these personnel are included in the comments to the regulation there is no national recognition and formalized educational system for medical physicists. A voluntary professional body certification system is in place by the Norwegian Association for Medical Physics (NFMF). However, in the absence of a national recognition system, evaluation of competence is challenging for DSA in issuing relevant authorizations. Aligned with the IAEA requirements it is recommended that the government should ensure requirements are established for the formal recognition of medical physicists. **Recommendation R5 in Section 1.8 addresses this issue.**

The IRRS Team was informed of the developments with respect to the plans to introduce two new proton therapy centers within Norway. The IRRS Team were advised work has commenced within DSA on planning for the authorization of these facilities where a multi-stage licensing process will be implemented to include commissioning, building design and shielding, testing and clinical operation. Noting the introduction of new technological applications to Norway it is recommended that DSA build its technical competence and ensure sufficient resources are in place for the authorization of proton therapy. **Recommendation R3 in Section 1.3 addresses this issue.**

The IRRS Team noted that Norway established a National System for the managed introduction of new health technologies within the Specialist Health Service in 2013 (referred to as Nye Metoder). This system ensures the systematic use of health technology assessment (HTA) as a tool for decision-making of new methods. HTA is performed on a national and local level at the hospital. HTA-assessments always address the benefits and risks associated with the method, but can also address ethical, organizational, economic and social aspects. The system ensures that there is a broad cooperation among all relevant responsible parties including DSA. The role of DSA is to ensure that the principle of generic justification and radiation protection issues for patient and staff are fully addressed in the HTA-assessment and taken into account in the final decision-making process. The advantage of this approach is that generic justification and relevant radiation protection issues are evaluated as part of the overall risk-benefit evaluation of the HTA. HTA-reports demonstrating compliance with the Nye Metoder criteria is considered as sufficient documentation to demonstrate generic justification for the purposes of authorization. The IRRS Team considers ‘Nye Metoder’ as an area of good performance for its achievement in strengthening the generic justification process.

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The main responsibilities of authorized users for the control of public exposure are specified in the three main regulations covering nuclear and radiological applications. Dose limits for public exposure are defined in line with the IAEA safety standards. The application of a dose optimization approach is required in the regulation, in the same manner, a generic effective dose constraint of 0.25 mSv/year has been established for the public exposure.

According to section 4 of the regulation on the application of the PC Act to Radioactive Pollution and radioactive Waste, any activity that leads to or may lead to the discharge of radioactive substances whose total or specific activity exceeds or are equal to the values stated in Annex II, requires the authorization of DSA (discharge permit). The reference values in the regulation are set at sufficiently conservative levels. Nevertheless, when appropriate, the discharge limits are based on the application of BAT (Best Available Technique).

Operators are required to monitor discharges of radionuclides into the environment. The requirements for monitoring are graded in proportion with the potential radiation-associated risks.

According to Section 20 of the Act on Radiation Protection and Use of Radiation, the DSA may refuse the import or sale of any consumer product or substance and any item that may involve a risk to health or environment due to radiation. Nevertheless, specific responsibilities and safety requirements to be followed by suppliers are not defined in the regulatory framework.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| <p>Observation: DSA may refuse the import or sale of any consumer product or substance and any item that may involve a risk to health or environment due to radiation. Nevertheless, specific responsibilities and safety requirements to be followed by suppliers are not defined in the regulatory framework. This has been recognized in the ARM.</p> | |
| (1) | <p>BASIS: GSR Part 3 requirement 33 para 3.139 states that <i>“Upon receipt of a request for authorization to provide consumer products to the public, the regulatory body:</i></p> <p><i>(a) Shall require the provider of the consumer product to provide documents to demonstrate compliance with the requirements in paras 3.138–3.144;”</i></p> |
| S13 | <p>Suggestion: DSA should consider establishing dedicated regulatory guidance that should address, in line with the GSR Part 3, all relevant responsibilities of the providers of consumer products.</p> |

National organizations have made an important effort for the identification of the existing exposure situations in the country that are of concern from the point of view of radiation protection. In this respect, projects for the detailed characterization of the scenarios associated with the radon and radon reach areas, NORM industries, legacy sites and areas contaminated by radioactive materials from the Chernobyl nuclear accident have been successfully implemented. Once concerns related to the public exposure have been identified, the DSA has been taking a leading role in promoting and regulating the remediation actions.

There are legislative provisions allowing the regulatory body to assign responsibilities for conducting remediation actions after the organization responsible has been identified.

Since elevated indoor radon concentrations can be found almost anywhere in Norway, an extensive programme to address this issue have been developed over the last three decades. This includes a national radon strategy that encompasses key areas of interest such as radon in existing, new buildings and workplaces, population exposed to especially serious radon problems. The IRRS Team considers the implementation of this strategy as a good performance of DSA.

Several authorities are participating in this programme enacting dedicated regulations and, when possible, enforcing its implementation. Radon concentration limits (200 Bq/m³) and action levels (100 Bq/m³) in diverse scenarios as well as measurements and inspection protocols are established. Regulations with legally binding limits for radon have been introduced for new buildings and for schools, kindergartens and rental accommodations. It is especially remarkable the very comprehensive system to inform the public on Radon matters which is led by the DSA. Despite the important results achieved through the implementation of the strategy, there are identified areas of work, especially activities related to the mitigation in private homes and the protection strategy in areas with extreme radon levels which require further efforts on the part not only of DSA, but also of all relevant organizations and decision-makers. In this regard, the DSA needs to ensure continuing the operational implementation and permanent updating of the national strategy.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: Important results have been achieved through the implementation of the Radon strategy, nevertheless, there are identified areas of work, especially activities related to the mitigation in private homes and areas with extreme radon levels which require further efforts. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 3 requirements 50 para 5.20 states that <i>“Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered as required in para. 5.19(a), the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings....”</i> |
| S14 | Suggestion: DSA should consider continuing the implementation of the Radon strategic programme prioritizing those activities that are addressing the mitigation actions in private homes and the protection strategy in areas with extreme radon levels. |

Clearance is not established as a term in legal and regulatory documents such as there are no provisions related to establishing of radiological clearance criteria. However, in the PC regulations there are activity concentration levels and total activity levels that are used to segregate ‘non-radioactive waste’ from ‘radioactive waste’ that means unconditional clearance. Moreover, the situation is not clear with application of this levels for all types of radioactive materials generated at different facilities (for example during the decommissioning of nuclear facilities).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The concept of clearance from regulatory control does not exist in the legal and regulatory framework.

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| (1) | BASIS: GSR Part 3 Requirement 8 states that <i>“The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control.”</i> |
| (2) | BASIS: GSR Part 3 para 3.12 states that <i>“The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies.”</i> |
| (3) | BASIS: GSR Part 5 para 3.8 states that <i>“To facilitate compliance with regulatory requirements, the regulatory body has to do the following:</i> <ul style="list-style-type: none"> - ... Establish criteria for the clearance of material from regulatory control, in accordance with national policy.” |
| R9 | Recommendation: DSA should introduce and implement the concept of clearance. |

5.11. SUMMARY

DSA operates an authorization system covering all facilities, activities and exposure situations, in accordance with the principle of a graded approach.

However, the IRRS Team identified the following areas for improvement:

- DSA should clarify the type of modifications subject to authorization and issue guidance on the authorization process under the NE Act.
- DSA should complete the authorization process with the requirements the applicant for an authorization has to comply with.
- DSA should include in the regulation the frequency and conditions for updating the safety analysis report over the research reactor’s operating lifetime so that successive modifications are taken into account.
- DSA should consider developing guidance to manage notifications based on SSR-6.
- DSA should consider arrangements to be informed of the serial number of each packaging manufactured to an approved design.
- DSA should consider establishing dedicated regulatory guidance that should address, in line with the BSS, all relevant responsibilities of the providers of consumer products.

- DSA should consider continuing the implementation of the Radon strategic programme prioritizing those activities that are addressing the mitigation actions in private homes and the protection strategy in areas with extreme radon levels.
- DSA should introduce and implement the concept of clearance.

The IRRS Team identified the following areas as good performances:

- The successful utilization of the principle of justification contributing to the substitution of blood irradiators based on cesium chloride with X-ray irradiators, thereby reducing the number of Category-1 radioactive sources in Norway by about 75% and removing all high-activity cesium-chloride sources is recognized as a good performance in strengthening justification and reducing the use of high activity sealed sources.
- The Nye Metoder Health Technology Assessment framework, coordinating the assessment and evaluation process of new methods into a single decision-making process ensuring radiation protection issues are an integral part of the process, is recognized as a good performance in strengthening generic justification.
- The implementation of the National Radon Strategy.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The PA Act requires DSA, through specific provisions, to ensure that all aspects of authorization are investigated as thoroughly as possible before a decision is made. The level of detail and the resources allocated to review and assessment are determined in line with a graded approach.

The information to be submitted for an authorization under the PC and RP Acts, is specified within PC and RP regulations and guidance available on DSA's website. Applications under the NE Act include details of the site, purpose, nature and size of facility including an evaluation of the safety features of the installation.

DSA has prepared guidelines for applicants for authorization that are specific for particular facilities and activities and related to the requirements associated with the Acts and their associated regulations.

For nuclear facilities, the guidance on the application of the GLC's indicates the requirements to be fulfilled for an application and makes the link with international safety standards to be considered in the review and assessment process.

The review and assessment of applications under the PC Act and the RP Act is undertaken by case handlers, in consultation with a suitably qualified colleague and the relevant Section Head.

A recruitment process has commenced to acquire further competence in the area of nuclear safety, security and waste management, to undertake, among other things, review and assessment. DSA uses advice from the Nuclear Safety and Radioactive Waste Advisory Committee as well as technical support from independent external consultants as necessary, as mentioned in Section 3.4.

Reporting frequency is established in licences/permits. The licensee of a nuclear installation is required to submit an annual report. All facilities and activities with a licence according to the PC Act are required to submit an annual report. Under RP regulations DSA require each authorized medical facility to submit an annual report which is designed for each of the three applications of nuclear medicine, radiotherapy and general radiology.

6.1.2. BASES FOR REVIEW AND ASSESSMENT

DSA has prepared guidelines, some of which are in draft, for applicants for authorization that are specific for particular facilities and activities which relate to the requirements associated with the Acts and their associated regulations. They provide one of the bases for reviewing the completeness and adequacy of submitted materials.

Permit and licence conditions require that the authorized party informs DSA in the event of significant changes that could affect the applicability of the information presented in the authorization application.

Recently a review and assessment procedure for the nuclear sector was developed and approved. That procedure covers organization of regulatory review during the authorization process.

Application forms and guidance documents exist but the DSA internal procedures in relation to the process of review and assessment of authorizations, amendments, renewal, suspension or revocation of authorizations are general and not specifically documented.

The GLCs include, a licence condition that the licensee shall carry out a periodic safety review (PSR), at intervals to be specified by the DSA. However, specific provisions on the periodicity of such PSRs have not been provided. Until now, no PSR has been undertaken for any facility in Norway since the GLC on PSR was first issued for the Kjeller site in January 2019.

DSA would benefit from the establishment of regulations and guidance regarding review and assessment process.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: Application forms and guidance documents exist but the DSA internal procedures in relation to the process of review and assessment of authorizations, amendments, renewal, suspension or revocation of authorizations are general and not specifically documented. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Para 4.37 states that <i>“Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure and shall make provision for the timely submission of applications for the renewal or amendment of the authorization.”</i> |
| S15 | Suggestion: DSA should consider strengthening its review and assessment procedure to clarify the aspects that must be considered for different types of authorization, and subsequent amendments, renewal, suspension or revocation of the authorization for all facilities and activities. |

6.2. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The operation of research reactors is authorized in a licence that is limited to a specific period. The research reactors are situated on the same site where other facilities are operated. A licence addresses all the facilities of a site.

When a licence has to be renewed, IFE submits an application for authorization, which is to be reviewed and assessed by DSA according to the internal procedure for review and assessment. It is noted that the requirements the licensee has to fulfil are not defined in the regulations furthermore the DSA’s criteria for the acceptance of the application are not defined.

DSA carries out the assessment with the participation of external experts.

Provisions do not exist in current regulations for the following:

- the periodic safety review and assessment of the research reactors required by the international standards. **Recommendation R14 in Section 9.1 addresses this issue.**
- the assessment of modifications for the lifetime of research reactors.

Suggestion S15 in Section 6.1.2 addresses this issue.

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

FCF are licensed under the NE Act provisions. Currently, the operator is in the process of acquiring information to support the development of processes to comply with DSA General Licence Conditions, in accordance with the special condition placed on them in the Kjeller licence.

Provisions do not exist in current regulations for the following:

- the periodic safety review and assessment of FCF required by the international standards. **Recommendation R14 in Section 9.1 addresses this issue.**
- the assessment of modifications for the lifetime of FCF. **Suggestion S15 in Section 6.1.2 addresses this issue.**

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

For licensing RWM facilities under the PC Act (referred to as Permits), PC Regulations are applied. For licensing RWM facilities under the NE Act, an authorization procedure has been recently approved.

Applications for licensing under the NE Act and PC Act are handled in accordance with the recently developed review and assessment procedure. Safety important installation modifications, operating organization or management changes are also authorized by DSA under these Acts.

Provisions do not exist in current regulations for the following:

- the periodic safety review and assessment of RWM facilities required by the international standards. **Recommendation R14 in Section 9.1 addresses this issue.**
- the assessment of modifications for the lifetime of RWM facilities. **Suggestion S15 in Section 6.1.2 addresses this issue.**

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Review and assessment of information relevant to safety for radiation sources facilities and activities are performed in connection with licence applications, annual reports and dose reports, and through inspections. In addition, the status of every registered ionizing radiation source is recorded and reviewed through DSA's electronic source registry EMS.

For most categories of radiation sources, facilities and activities, there are specific application forms. Application forms are designed such that questions cover the requirements in the RP Regulations relevant for the particular facility/activity. The information provided through the completed application forms (and submitted attachments) aim to demonstrate whether the most important and relevant aspects related to safety are properly considered and managed by the applicant. During its review, DSA verifies that the applicant has submitted all the information requested in the application form, including mandatory attachments.

For practices where application forms are not available, the application needs to contain sufficient information to allow DSA to verify that relevant requirements of the RP Regulations are fulfilled. All previously issued licences are recorded in DSA's archive along with all the information supplied by the applicants. This allows DSA to base its review and assessment of associated radiation risks on experience from review of similar applications in the past, as well as on expertise and judgment. When reviewing licence applications for new types of practices

or equipment, where there are no precedent regulatory decisions to consider in the review process, DSA puts emphasis on reviewing the applicant’s demonstration of justification.

For high-risk facilities, such as radiotherapy centers, the application and licensing process are more comprehensive, and DSA reviews parts of the project, for example the design and shielding of laboratories and radiotherapy treatment rooms, already in the planning stage. Construction cannot be started before the licensee has issued a Declaration of Conformity with the RP Regulations, and DSA has issued a Statement of Consent. For type A isotope laboratories, radiotherapy facilities and irradiation facilities involving high-activity radioactive sources, it is part of DSA’s regulatory practice to inspect the location or site at the planning stage.

DSA also conducts review and assessment through a requirement in the licence conditions for some licence categories to submit annual reports, and inspections are used as a method to verify that the information provided by licensees through applications and annual reports is correct and that the licensee is complying with the regulatory requirements. The EMS system is also used to monitor the status of radiation sources in Norway.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: Safety assessments for practices involving radiation sources are not always reviewed prior to issuing a licence. Safety assessments are reviewed as part of the inspection programme. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Para 4.33 states that <i>“Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [9], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.”</i> |
| R10 | Recommendation: DSA should review and assess safety assessments submitted by the applicant in accordance with clearly specified procedures in advance of the issuing of any licence in accordance with a graded approach. |

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

In Norway, no nuclear decommissioning activities are under implementation, but the decommissioning of both research reactors is foreseen in the near future. The review and assessment process for authorization of decommissioning activities would be performed under current situations for facilities according to the NE Act and PC Act.

A formal procedure does not exist detailing the information of the technical aspects to be reviewed and assessed in the process of issuing a decommissioning licence. **Suggestion S15 in section 6.1.2 addresses this issue.**

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

When applying for a licence based on NE Act, one of the documents supplied is the management system. There is, however, no guidance on what to be considered an acceptable

management system (SSR-6 para 306). **Recommendation R14 in Section 9.1 addresses this issue.**

In review and assessment of for example industrial radiography applications, only some elements of transport operations are completed in the application form by the applicant, mainly a statement that there is a transport system. However, it should be noted that the transport of these sources does not require a licence based on RP Act or approval based on SSR-6.

The authorized operator IFE sends DSA annual reports which includes information on transport operations and internal inspections of their approved packages. An inspection by an independent body is required for each renewal of the certificate. This requirement is in the package approval certificate. DSA had been doing a review of past approval certificates based on SSR-6. This review work has ceased due to lack of staff resources. **Suggestion S8 in Section 3.1 addresses this issue.**

According to para 308 of SSR-6 it is required that the competent authority shall arrange periodic assessments of the radiation doses to person due to the transport of radioactive material. This includes transport workers and members of the public as well. Doses for radiation workers are communicated to the national dose registry maintained by DSA. However, no dose assessment for transport workers or general public have been made so far.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: No comprehensive dose assessment for transport workers or general public have been made so far. | |
| (1) | BASIS: SSR-6 para 308 states that <i>“The relevant competent authority shall arrange for periodic assessments of the radiation dose to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with GSR Part 3.”</i> |
| (2) | BASIS: GSR Part 3 Requirement 3 (2.31) states that <i>“The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation.”</i> |
| R11 | Recommendation: DSA should arrange, in accordance with a graded approach, for periodic assessments of the radiation doses to transport workers and members of the public associated with the transport of radioactive material. |

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

Applicants are required to demonstrate compliance with the RP Act, RP Regulations, and IC Regulations as part of the review and assessment process, including the preparation of instructions and work procedures for the internal control for radiation protection. This includes the risk assessment, classification of areas, categorization of occupationally exposed workers, protective measures, and individual dose monitoring and recording.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

The review and assessment for authorized medical exposure activities is performed by the Medical Applications Section within the Department of Radiation Protection and Measurement Services.

The RP Regulations provide for an authorized party, when requested by DSA, to provide necessary information to monitor the medical use of radiation. These annual reports include information about the governance of radiation protection within the facility, data on activities, radiological incidents and results from internal revisions taken as result of the previous year's report. The annual reporting requirements for radiology is currently being revised due to the requirements to establish a system for automatic reporting of patient exposure data by 2020.

For radiotherapy, annual reporting was established through the national quality assurance programme, KVIST, details of which are provided in section 9.9. KVIST has also established a strong system for clinical audits in collaboration with the radiotherapy specialist community.

To assess optimization of patient doses in diagnostic radiology, DSA collects information on diagnostic reference levels (DRL) for each relevant facility. DSA perform a review of this information and those facilities that significantly exceed the national DRL are identified as requiring an inspection.

While there are multiple documents providing evidence of the review and assessment performed by DSA there is no procedure for recording the results and decisions deriving from reviews and assessments. It is therefore recommended that the review and assessment procedure is formally documented. **Suggestion S15 in Section 6.1.2 addresses this issue.**

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

When applying for a discharge permit, the applicant is required to submit documentation of the possible impact on humans and the environment for the relevant discharge. This is required according to PC Regulation and further described in the DSA guideline for applications for discharge permits. Discharge limits for all relevant nuclides are specified in the permit.

When applying for an authorization for the use of ionizing radiation, the applicant is required to demonstrate compliance with RP Act and RP Regulations regarding public exposure. This includes risk assessment, classification of areas, protective measures and shielding.

A source and environmental monitoring programme, if required in accordance with a graded approach, is submitted by the licensees to DSA for approval. The DSA assesses the proposed programme based on the monitoring requirements, environmental scenarios and the radiation source inventory as per the discharge permit. Provisions for delivering reports on monitoring results are also evaluated by the DSA. It was observed that there are no provisions covering all operator's responsibilities such as those related to the verification of the adequacy of the assumptions made for the assessment of public exposure and the establishment of a capability to conduct monitoring in emergency events.

The radiological characterization of existing situations is followed by a comprehensive assessment of the potential impact to the public and occupational exposure as well as to the environment. In the assessment and evaluation processes the DSA apply recognized international approaches and for several practices, guidance documents have been developed which included licensing procedures for NORM industry which are regulated as planned exposure situation using a graded approach.

There are two areas contaminated by residual radioactive material deriving from the past activities. These are legacy site Søve, former Nb mining site, and legacy site Taraldrud, former disposal site for alum shale. In both cases, DSA has recognized the issue with the hazards properly identified and a process of putting the sites under regulatory control has been initialized. PC Act regulates all pollution, including NORM, independent of its cause and have a risk based approach, which helps to review and assess exposure from the site case by case taking into account the specific situation of the site. Many existing exposure situations have to be managed case by case taking into account the specific situations and arrangements.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: DSA is requiring applicants, when relevant, to develop an environmental monitoring programme and it is evaluated before approval by DSA. However, there are no provisions addressing the operator’s responsibilities, in terms of the management and technical requirements applicable for the source and environmental monitoring. | |
| (1) | <p>BASIS: GSR Part 3 Requirement 32 para 3.137 states that <i>“Registrants and licensees shall, as appropriate:</i></p> <p><i>(e) Report promptly to the regulatory body any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorized practice, in accordance with reporting criteria established by the regulatory body.</i></p> <p><i>(g) Verify the adequacy of the assumptions made for the assessment of public exposure and the assessment for radiological environmental impacts.”</i></p> |
| S16 | <p>Suggestion: DSA should consider specifying the responsibilities of the licensees in the establishment and implementation of the environmental monitoring programme.</p> |

6.11. SUMMARY

Prior to authorization, DSA performs review and assessment of relevant information submitted as part of the application process in accordance with a graded approach, to determine whether facilities or activities comply with regulatory requirements in accordance with legal documents. In some cases, verification of documentation is reviewed during inspection.

The IRRS Team identified areas for improvement regarding review and assessment of activities performed by DSA:

- Specific regulations and internal procedures for systematic safety reviews and periodic safety assessments;
- Specific regulation and guidance related on preparation and maintenance of safety case during construction and operation of RWM facilities;
- Provisions for assessment of doses for transport workers and public;
- Provisions addressing the operator’s responsibilities, in terms of the management and technical requirements applicable for the source and environmental monitoring.

7. INSPECTION

7.1. GENERIC ISSUES

Norwegian legislation provides the necessary legal basis for inspection activities covering all areas that DSA regulates. The internal control principle ensures that regulatory inspections do not diminish the authorized party's prime responsibility. To ensure coordination and harmonized regulation among the Norwegian Health, Safety and Environment authorities, a formalized cooperation group has been established.

DSA has established an inspection group, which coordinates DSA's inspection work and manages the inspection process. This inspection group has assisted in the development of a DSA inspection strategy for the period 2016 to 2020 which is focused on a graded and a risk-based approach. The strategy document addresses, inter alia, the possibility of enforcement actions. This strategy is to be used as the guideline to develop both yearly and long-term inspection programmes. The IRRS Team noted that there were no provisions to ensure that every facility, and activity is regularly inspected.

Both departments in DSA, develop separate annual inspection plans but the numbers of targets for on-site inspections is not consistent with the strategy for each area. The annual list is approved by the management of DSA and can be adapted during the year as circumstances change.

DSA has also recently issued an updated inspection procedure describing the responsibilities and the administrative steps for an inspection. The possible types of inspections are described as programmed, reactive, announced or unannounced. The basis for decision making for reactive inspections is not described. The procedure mentions report templates and checklists for inspections, but they are not detailed, and checklists are only issued for some areas. For example, a checklist for industrial radiography includes "procedures for transport for gamma sources". All safety inspection reports are accessible to public.

Inspections are carried out by DSA inspectors, but external experts may support inspections when needed. The ARM mentions that the actual frequency of inspections is lower than DSA's target frequencies for several areas due to lack of resources.

The inspection strategy is not systematically used to establish the inspection programme. The list of inspections for the current year is not consistent with the strategy, and there is no long-term comprehensive programme.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: DSA has an inspection strategy. However, it is not used to establish overall long-term inspection programme for DSA. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 29 § 4.50 states that <i>"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections) and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Paragraph 4.52 states that <i>"Regulatory</i> |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | <i>inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach.”</i> |
| (3) | <p>BASIS: GSR Part 1 (Rev 1) Paragraph 4.53 states that <i>“In conducting inspections, the regulatory body shall consider a number of aspects, including:</i></p> <ul style="list-style-type: none"> <i>– Structures, systems and components and materials important to safety;</i> <i>– Management systems;</i> <i>– Operational activities and procedures;</i> <i>– Records of operational activities and results of monitoring;</i> <i>– Liaison with contractors and other service providers;</i> <i>– Competence of staff;</i> <i>– Safety culture;</i> <i>– Liaison with the relevant organization for joint inspections, where necessary.”</i> |
| R12 | <p>Recommendation: DSA should develop, implement, review and continuously improve the inspection process including establishing a long term programme of inspection according to criteria for selection of facilities and activities to be inspected consistent with a graded approach.</p> |

The IRRS reviewers have attended inspections at the Halden research reactor, Kjeller facilities, the Radioactive Waste Management facility and KLDRA in Himdalen, transport at Kjeller site, Stavanger University hospital (interventional radiology) and Aker Solutions (industrial radiography).

The IRRS Team noted that that all inspections were prepared well and performed in a professional manner by DSA inspectors who demonstrated a high level of competency and understanding of all issues discussed during the inspections.

The IRRS Team noted that DSA is a member of a formalized cooperation group with six other regulatory authorities that have responsibilities for health, safety and environmental (HSE) protection under the Internal Control Regulations. One of the main goals of this cooperation is to ensure that that inspections are carried out as uniformly and in as coordinated a manner as possible. The authorities cooperate to coordinate strategic plans for inspection and have established joint guidelines for inspections, a database for coordinating inspections and joint training of inspectors. The HSE authorities have also established courses, for example in communication related to inspection and on performing risk-based inspections. All DSA inspectors receive the HSE training in addition to in house training in DSA processes for inspection. This cooperation is recognized as a good practice for its holistic approach to integrating radiation protection with overall health and safety aspects, devising joint guidelines and training to harmonize inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: DSA is a member of a formalized cooperation group with six other regulatory authorities and a non-governmental organization that have responsibilities for health, safety and environmental (HSE) protection under the Internal Control Regulations. The authorities cooperate to coordinate strategic plans for inspection and have established joint guidelines for inspections, a database for coordinating inspections and joint training of inspectors.

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| (1) | <p>BASIS: GSR Part 1 (Rev 1) Requirement 29 para 4.53 states that <i>“In conducting inspections, the regulatory body shall consider a number of aspects, including:</i></p> <p><i>- Liaison with the relevant organization for joint inspections, where necessary.”</i></p> |
| GP2 | <p>Good Practice: The formalized cooperation group of regulatory authorities, proactively devising joint guidelines and training for harmonising inspections and the performance of joint inspections, integrating radiation protection with overall health and safety aspects is identified as a good practice.</p> |

7.2. INSPECTION OF RESEARCH REACTORS

The intention for the inspection of research reactors is to have each point of the GLCs inspected at least once a year. The basis for the inspections are the NE Act, IC Act, SAR and the GLC. The GLCs are only issued for the Kjeller site facilities with a list of 25 points. The GLCs of Halden site are not yet binding.

In the absence of a long-term systematic inspection programme, there is no provision to assure that every topic is inspected with the relevant frequency.

Recommendation R12 in Section 7.1 addresses this issue.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

DSA has not established a comprehensive inspection programme particular to each FCF. However, several inspections are conducted each year on FCFs, sometimes supported by external consultants. **Recommendation R12 in Section 7.1 addresses this issue.**

The IRRS Team noted that the report of an inspection carried out in August 2018, was sent to the licensee in March 2019. However, the issues identified during the inspection were discussed regularly in meetings between DSA and IFE following the inspection.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

DSA has not established a comprehensive inspection programme particular to RWM facilities as described in Section 7.1. However, several inspections are conducted each year on RWM facilities.

Recommendation R12 in Section 7.1 addresses this issue.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

DSA has performed a risk – based assessment to identify priorities in the inspections to be put in the annual programme. This process lead to a categorization of the activities and their level of risk. These two elements are merged in a matrix to elaborate the inspection plan. Eleven activities have been identified as being both high risk and high priority, including industrial radiography, well logging, irradiators, type A laboratories, nuclear medicine, interventional radiology and brachytherapy. DSA concentrates its inspection resources within its Department of Radiation Protection and Measurement Services.

A graded approach is being implemented across the industrial and medical uses of radiation. Annual inspection plans are developed which identify the licensees that DSA plans to inspect. The annual plans utilize inspector judgement, experience and available resources and are working documents that are amended throughout the course of the year.

Data from the inspection programme for the 2016, 2017 and 2018 years was examined by the IRRS Team. There is typically a close alignment between the number of inspections that DSA planned to conduct and the number of inspections that are actually performed. However, the connection between the annual plan and the strategy and prioritization process is not evident. For instance, there are approximately 80 licensed companies performing industrial radiography work. The DSA intends to inspect these licensees every 3 years. In the years 2016, 2017 and 2018 there were twelve, one and six inspections, respectively, conducted on industrial radiography licensees. However, in order to achieve the inspection frequency target for industrial radiography as set down in the inspection strategy, approximately 27 licensees would need to be inspected every year. This is not achievable due to the lack of resources available to carry out DSA’s inspections of radiation sources facilities and activities. **Recommendation R3 in Section 1.3 addresses this matter.**

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

Currently there are no activities related to nuclear decommissioning under implementation. Approaches for organization and implementation of inspections related to nuclear decommissioning will be similar to those for inspecting of other facilities.

7.7. INSPECTION OF TRANSPORT

The basis and the application of a graded approach or the use of findings from transport inspections in planning are not included in the integrated management system.

There has been a number of events in the nuclear sector that have triggered reactive inspections. This, along with limited human resources and new applications in the nuclear sector have caused the DSA to not being able to do the planned transport inspections. **Recommendation R3 in Section 1.3 addresses this issue.**

Transport specific inspections, which are limited to authorized road transports, are not automatically included in the inspection programme of DSA. Air and sea operators are not inspected by DSA. Packages or their maintenance are not inspected systematically whereas they contribute largely to safety.

Recommendation R12 in Section 7.1 addresses this issue.

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

During inspections, DSA reviews and verifies the authorized party's compliance with radiation protection requirements legislated by the RP Act, the RP Regulations, the IC Regulations, and conditions in the authorization. Compliance checks include, for example, the authorized party's risk assessment; classification of workers; controlled and supervised areas; proper use, calibration, testing and maintenance of equipment; competence and training programmes; and, records of occupational dose and compliance with dose limits and action levels.

Inspections consist of interviews of management and employees involved in radiation use and radiation protection, and include a review of the authorized party's documentation and records regarding radiation protection, and observations of work techniques and work practices.

7.9. INSPECTION OF MEDICAL EXPOSURE

Inspections of medical facilities are performed by the Medical Applications Section within the Department of Radiation Protection and Measurement Services. In the medical field, there are seven inspectors that cover nuclear medicine, radiotherapy and diagnostic radiology. Inspection planning is performed annually for the upcoming year taking account of available resources and may be revised depending upon budget and availability of personnel.

From a review of records, it was determined five inspections of medical facilities were performed in 2018 from the 14 planned. The IRRS Team was informed that due to budgetary constraints inspections of medical facilities were suspended for four months in 2018. 12 inspections are planned for 2019 with four performed to date. The IRRS Team noted the lack of resources available to carry out DSA's inspections of medical exposure. **Recommendation R3 in Section 1.3 addresses this matter.**

Furthermore, no unannounced inspections are performed in medical applications, it is recommended in devising the inspection programme that a proportion of unannounced medical inspections are performed in accordance with the IAEA standards. **Recommendation R12 in Section 7.1 addresses this issue.**

7.10. INSPECTION OF PUBLIC EXPOSURE

DSA performs inspections of all activities and facilities with an authorization to use ionizing radiation or a permit to discharge radioactive pollution or to handle radioactive waste as stated in the RP Act or the PC Act. DSA can also carry out joint inspections with other competent authorities on areas which are especially relevant for the control of public exposure, such as NORM waste facility and offshore installations. Inspections focus on the on-site evaluation of the level of compliance with the licence conditions.

Discharge permits issued by DSA include an obligation to submit an annual report to DSA, according to requirements defined in the permit and/or according to guidelines issued by DSA, which includes, inter alia, data from source monitoring and other requirements in the permit. DSA uses the reports to verify compliance with the discharges limits and requirements in the permit.

Independent monitoring of the Norwegian marine, freshwater and terrestrial environments, including seafood and other select food product is carried out by DSA. In addition, nation-wide networks continuously monitor radionuclide levels in air and ambient gamma radiation. There are specific stations placed near the two research reactors to identify any unusual releases

7.11. SUMMARY

Whereas DSA conducts inspections professionally and competently, the inspection process should be improved to have a comprehensive programme of inspection and operational procedures.

DSA encounters difficulties to fulfil the inspection programme due to lack of resources.

The inspection programme does not give sufficient importance to transport of radioactive material activities.

DSA has the possibility to carry out joint inspections with other competent authorities on areas which are especially relevant for the control of public exposure, such as NORM waste facility and offshore installations.

The participation of DSA in a formalized cooperation group is considered as a good practice.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The RP, NE and PC Acts provide enforcement powers to DSA. Through different sections of the legislation, these Acts empower DSA to amend or revoke an operating permit, shutdown a facility or stop an activity, require further information to be provided, or require a modification of a facility to be performed. If, and when, these enforcement powers are used, DSA must do so in a manner that is consistent with the Public Administration Act (PA Act) as this regulates how administrative agencies, including DSA, may secure compliance through enforcement. An example of this, is that the PA Act requires pre-notification of the intent to apply an enforcement action prior to making the administrative decision to do it. However, in serious circumstances, DSA may also notify police of non-compliances with requirements from all Acts enabling further action, and if relevant, prosecution to occur.

DSA has recently published procedures for determining regulatory reaction when there is non-compliance. This document briefly describes how DSA staff should pursue non-compliance. This has been issued by the Director General of DSA and is applicable to all activities and facilities. This procedure is supplemented by the inspection procedure which describes the elements that should be considered when determining how the regulatory body responds to non-compliances in accordance with a graded approach. The elements that are specified for consideration included whether the violation was serious, due to wilful conduct and repeated behaviour. This is typically contained within an enforcement policy which DSA have not developed.

DSA has not established criteria for when corrective actions, including enforcing the cessation of activities or the shutting down of a facility, are necessary. Furthermore, the procedure also does not establish criteria for DSA staff taking corrective actions if they are present when there is imminent likelihood of a safety significant event.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| Observation: DSA has a procedure for responding to non-compliance. However, this does not establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility. The procedure also does not establish criteria for DSA to take corrective actions if there is imminent likelihood of safety significant events. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 1 (Rev 1) Para 4.58 states that <i>“The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take corrective action if there is an imminent likelihood of safety significant events.”</i> |
| R13 | Recommendation: DSA should develop and implement an enforcement policy that fulfils all requirements associated with enforcement mentioned in IAEA GSR Part 1 (Rev 1). |

8.2. ENFORCEMENT IMPLEMENTATIONS

DSA staff assess compliance with the various Acts and their associated regulations. This can lead to the identification of non-compliances. The basis for the non-compliance is normally identifiable from the provision that has been breached. However, when non-compliances with transport regulations are identified, DSA has referred to both ADR Regulations and RP Act.

When non-compliance is identified, written correspondence identifying the legal basis for the non-compliance, and a time for rectification, is transmitted to the licensee. A variety of enforcement options are available to DSA. These are daily coercive fines, a direction to stop conducting an activity, and the capacity to confiscate equipment. A number of letter templates are available depending on the chosen enforcement option. These templates are listed in the enforcement procedure. Whenever an enforcement action is taken, the order is signed by both the relevant Head of Section and Director of Department of DSA.

Staff can consult with DSA lawyers on the selection of the appropriate enforcement action. The enforcement is known as an individual decision within the Norwegian regulatory framework. The option selected is determined on a case-by-case basis. However, there is no documented basis for what factors should be considered, and how they should be weighted, when selecting the enforcement option. An example of this would be the identification of a licensee repeatedly failing to comply with the regulatory provisions. This has occurred with IFE repeatedly failing to transmit information relating to its full fuel inventory. This information is required for adequate oversight for spent fuel, radioactive waste management and disposal. For example, the full range of fissile materials are needed for demonstrating adequate criticality safety. When IFE does not satisfy the request, it is renewed without any escalation of enforcement measures. There is, however, a new section that entered into force in November 2018 in the NE Act which gives DSA the mandate to issue coercive fines. There is also a new section about coercive fines in RP Act, although it has not entered into force yet.

Parties subject to an individual decision by DSA may appeal against the decision, under the provisions of either the RP Act, the NE Act or the PC Act. The appeal must be sent to DSA for comments. If DSA maintains its decision, the appeal is forwarded to the relevant ministry for final decision.

All of the non-compliances that have been identified are visible to the inspection group. The DSA will close each matter when the authorized party has transmitted documentation demonstrating that the non-compliance has been corrected. The correspondence is saved in DSA's archive along with all information supplied by the authorized party. DSA staff can see the non-compliances that have not been closed.

8.3. SUMMARY

DSA has developed a procedure for determining regulatory reaction when there is non-compliance. This is part of the integrated management system under development. However, several aspects of enforcement have not been developed and implemented.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

As described in section 1.2, the legal framework for nuclear safety and radiation protection includes the RP Act, the NE Act and the PC Act. There are a number of regulations established by these Acts, which DSA administrates.

The Internal Control (IC) Regulations, under the Norwegian health, safety and environment legislation, is also a key part of safety regulation. The IC Regulations are based on requirements of several Acts, including the RP Act and the PC Act. DSA has identified in their Action Plan to further strengthen their regulatory framework by considering whether the NE Act should be included as a legislative basis for the IC Regulations.

General and Specific Guidance for the General Licence Conditions has been developed. The Specific Guidance entitled “Guidance on the Application of the General Licence Conditions to Research Reactors, Nuclear Fuel Cycle Facilities, and Radioactive Waste Handling, Storage and Disposal” have been developed by DSA with the support of external experts, and shared with the relevant current and prospective licence holders. These guidance documents clarify how the requirements from the International Safety Standards are linked, and thus may be applied through the General Licence Conditions. This provides a mechanism for the applicable International Safety Standards to be regulated against for nuclear installations in Norway. For transport, Norway has also adopted relevant international modal requirements, in the national legislation. DSA has responsibilities for developing and publishing supporting guidance on the requirements of the Acts and regulations. DSA has published guides on the use of radiation authorized by the RP Act and RP Regulations. In addition, there are published guidelines which include: annual reporting by authorized parties with permits for radioactive waste management and discharges; reporting discharges from the oil and gas industry; application for permits for radioactive waste management and discharges; and, use of ionizing radiation in biomedical research.

DSA and the IRRS Team have identified opportunities for improving the regulatory framework on many topics that are discussed throughout this report.

A procedure for the review, revision and development of regulation and guides, which includes a five year programme and an annual plan has been issued within DSA. However, the procedure has yet to be implemented across the whole organization.

As described throughout the report DSA and the IRRS Team have identified improvements needed to regulations and guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: DSA’s procedure for the development of regulation and guides specifies a five-year programme and an annual plan. However, this programme and plan have yet to be implemented across the whole organization. Improvements of the regulatory framework are identified in several sections of this report.

(1)

BASIS: GSR Part 1 (Rev 1) Requirement 32 states that “*The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory*

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | <i>judgements, decisions and actions are based.”</i> |
| (2) | BASIS: GSR Part 1 (Rev 1) Requirement 33 states that <i>“Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained.”</i> |
| R14 | Recommendation: DSA should take actions for the further development, review and revision of regulations and guides to ensure that the regulatory framework is comprehensive. |

9.2. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

As discussed in section 5.2, the requirements for the safety of research reactors are not clearly specified within the regulatory framework, although they appear in licence conditions.

The licence for the JEEP II reactor in Kjeller was granted from January 2019 to 2028. The GLCs were issued for the renewal of the authorization and include a series of 25 additional requirements. The reactor was shut down in December 2018.

The licence for the HBWR reactor in Halden was granted from 2015 to 2020, and the renewal process is underway. The draft Specific Guidance on the Application of the GLCs to RR, FCF and RW Handling, Storage and Disposal will be used as a basis for the forthcoming assessment for a new licence at Halden and have been provided to the licence holder to aid preparation. The reactor was put into a cold shutdown state with no intention from the licence holder to restart the reactor in June 2018. DSA has not specified the requirements for the extended shutdown period, and for the stages of the decommissioning of research reactors. In addition; although licensees must provide a decommissioning plan in support of the licence application, DSA has not defined the acceptance criteria for the plan. **Recommendation R14 in Section 9.1 addresses these issues.**

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

DSA has guidance for the licensee on the form of GLCs and the “Specific Guidance to the General Licence Condition”, and the “Guidance on the Application of the GLCs to RR, FCF and RW Handling, Storage and Disposal”. The GLCs were recently approved for the Kjeller licence valid from January 2019, and the Specific Guidance is in draft version.

Occasionally, DSA drafts guides in English, using IAEA recommendations related to the corresponding topic, and then translation is made to Norwegian. Guides cover all regulatory activities; however, there are no specific regulations and guides for the separate regulatory activities, such as authorizations, review and assessment, inspections and enforcement. DSA does not indicate a timeframe for developing and implementing these guides.

Recommendation R14 in Section 9.1 addresses these issues.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

In Norway there is set of regulations developed under the three main acts that are applicable to the regulation of safety relevant aspects for predisposal radioactive waste management and disposal of radioactive waste:

- Regulations on the Physical Protection of Nuclear Material, Regulations on Exemption from the Act on Atomic Energy Activity for Small Amounts of Nuclear Material, Regulations on Possession, Transfer and Transportation of Nuclear Material and Dual-use Equipment, Regulations on Economical Compensation after Nuclear Accidents (*developed under the NE Act*).
- RP Regulations, and the Regulations on the Applicability of the Act on Radiation Protection and Use of Radiation on Svalbard and Jan Mayen (*developed under the RP Act*).
- Regulation on the application of the PC Act on Radioactive Pollution and Radioactive Waste, Regulation on the Recycling of Waste (chapter 16), Regulation on Pollution control (*developed under the PC Act*).

To support practical implementation of legal and regulatory requirements, the following procedures were developed and approved by DSA to clarify provisions established in the regulations and authorization and review and assessment processes:

- Guidelines for applying for a permit under the PC Act for radioactive discharges and for the management of radioactive waste;
- Authorization procedure;
- Review and assessment procedure;
- GLCs under the NE Act.

The existing legal Acts and regulations are very generic to regulate all safety aspects related to predisposal management of and disposal of radioactive waste. Practically all details that should be regulated through the requirements are established in licences and permits conditions, with this being handled on a case by case basis. The IRRS Team was informed that licences and permits conditions depend on the complexity of facilities or activities being authorized and are usually based on the IAEA Safety Requirements. However, there are a very limited number of regulations establishing specific requirements for safety of predisposal radioactive waste management and disposal of radioactive waste. In particular; in the area of predisposal management of radioactive waste, there are no provisions for radioactive waste classification established based on final points of destination identified for different of waste streams. There are also no detailed provisions addressing the application of principles of minimization of radioactive waste and interdependences among the different stages in management of radioactive waste including disposal. There are no specific requirements for establishing of waste acceptance criteria and requirements for safe storage of radioactive waste. Most requirements that are relevant to safe disposal of radioactive waste and development of disposal facilities are also not stated in the existing regulations. Moreover, guidance exists but no regulatory requirements are established for safety case and safety assessments to be performed for different types of radioactive waste facilities and activities in the context of authorization process. **Recommendation R14 in Section 9.1 addresses these issues.**

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

DSA publishes guidance on how licensees may meet the requirements stipulated in the RP Act and RP regulation. These guides do not prescribe additional requirements that are included in the Acts or regulations. The guides are published on the DSA webpage. Nine guides have been published on a variety of subjects related to activities using radiation sources emitting ionizing radiation. Further guidance is published in the form of short leaflets.

When DSA prepares new guidance, or makes major changes to existing guides, it usually sends a draft version to the largest licensees for their views. There is an internal system within DSA for the review of guides. This includes the department head, communication section, and DSA's lawyers. Reviewers sign-off on the document and any changes are referred back to the original author. The author typically is involved in conducting inspections. These inspections can inform further amendments to the guides based on the issues that are identified.

DSA staff and management indicated that guides have broadly covered the areas where further guidance is needed due to the potential for substantial radiological risks and where guidance might result in lower doses. For instance, further improvements could result from guides on transport and veterinary medicine. Conversely, guides have not been published on closed X-ray cabinets as specific requirements are provided by the regulations. Likewise, a guide for well logging has not been prepared as there is only a small number of operators in the country. **Recommendation R14 in Section 9.1 addresses these issues.**

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The decommissioning of both research reactors is foreseen in the near future. Currently, the regulatory requirements do not cover all safety relevant aspects related to planning, conducting and completion on decommissioning activities, such as requirements for content and structure of a decommissioning plan and related safety assessment to be performed for decommissioning. However, a draft regulation, "Regulatory Requirement for Decommissioning" has been developed by DSA. In addition, in the draft "Guidance for the Application of the General Licence Conditions" which are applicable to fuel cycle facilities and radioactive waste handling, storage and disposal, there are provisions for decommissioning of nuclear facilities. The IRRS Team confirmed the need for DSA to develop regulatory requirements covering all aspects relevant to decommissioning. **Recommendation R14 in Section 9.1 addresses these issues.**

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The NE Act states that the transport of nuclear material requires a permit from the Ministry of Health. The RP Act also includes transport in its scope. However, the RP Regulations exclude transport outside a closed area. There are no detailed requirements for transport in either NE or RP legislation.

More elements from SSR-6 could be included in GLCs based on the NE Act, such as the radiation protection programme and the management system, to further enhance compliance with SSR-6 provisions.

There is no detailed guidance on applying for or issuing approvals based on the SSR-6, such as package design approvals, transports under special arrangements, or licence or permit applications for transport based on NE Act. It should be noted that such approvals are rare.

There is a process guide used for approval, and review and assessment of all kinds of matters for nuclear material. These guides have not been used for transport yet. The guides are more of a process description assigning responsibilities and do not include guidance on, for example, documents that the application should be cross-checked with. **Recommendation R14 in Section 9.1 address these issues.**

DSA has published a guide on the transport of excepted packages. The government could benefit from publishing more guidance material based on SSR-6 and its supplementary guides, such as on radiation protection programmes, management systems and transport of NORM-material to further enhance the compliance with SSR-6 provisions.

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The government has enforced requirements for authorized parties' responsibilities for occupational exposures through the RP Act, and the RP Regulations established under this Act. The RP Regulations also require authorized parties to implement internal controls, including for radiation protection, pursuant to the IC Regulations.

The WE Act, and associated regulations, include additional requirements for authorized parties for the protection of workers from ionizing radiation, including worker health surveillance. These are administrated by the Norwegian Labour Inspection Authority. As discussed in section 5.8, section 12-7 of the Regulations Concerning Organization, Management and Employee Participation (established by the WE Act), sets dose limits for young people aged between 16 and 18 years who are not required to go to school and who are permitted to perform work that entails exposure to ionizing radiation. The IRRS Team identified that the lens of the eye dose limit of 50 mSv/year is not in alignment with Schedule III.2 (b) of IAEA GSR Part 3, which stipulates a dose limit of 20 mSv/year.

The Acts and regulations legislate various responsibilities of employers, registrants and licensees concerning occupational exposure in planned exposure situations. The RP Act requires justification, optimization, and dose limits with respect to uses of ionizing radiation. The RP Regulations set requirements for assessing, monitoring and recording of occupational exposures; compliance by workers; cooperation between employers and authorized persons; and, special arrangements for protection and safety of female workers and for persons under the age of 18.

In the ARM, DSA identified that the regulatory framework does not require the authorized party responsible for the source or for the exposure to obtain from the employers, including self-employed individuals, previous occupational exposure history of workers.

In the ARM, DSA also identified that the RP Regulations set requirements regarding engineered controls, administrative controls and personal protective equipment, but is not explicitly stipulated in the hierarchy of these preventive measures. In the ARM, DSA identified that the requirement for authorized parties to not offer benefits as substitutes for measures for protection and safety is also not explicitly stated within the regulatory framework.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observations: The dose limit for the lens of the eye for young people within the Regulations Concerning Organization, Management and Employee Participation is currently 50 mSv/year.

The regulatory framework does not require workers to provide employers information regarding their past or current work with radiation with other employers. There is no requirement for the authorized party to obtain previous occupational exposure histories of workers. There are also no explicit requirements within the regulatory framework which stipulate the hierarchy of preventive measures to minimize the reliance on administrative controls and personal protective equipment, and to not offer benefits as substitutes for measures for protection and safety. This has been recognized in the ARM.

(1)

BASIS: GSR Part 3 Requirement 12 para 3.26 states that *“The government or the regulatory body shall establish and the regulatory body shall enforce compliance with the dose limits specified in Schedule III for occupational exposures and public exposures in planned exposure situations.”*

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| (2) | BASIS: GSR Part 3 Schedule III.2 (b) states that <i>“For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are: (b) An equivalent dose to the lens of the eye of 20 mSv in a year; ...”</i> |
| (3) | BASIS: GSR Part 3 Requirement 22 para 3.83 (d) states that <i>“Workers shall provide to the employer, registrant or licensee such information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others.”</i> |
| (4) | BASIS: GSR Part 3 Requirement 23 paras 3.87(a) and (c) state that <i>“As part of the cooperation between parties, the registrant or licensee responsible for the source or for the exposure as appropriate: (a) Shall obtain from the employers, including self-employed persons, the previous occupational exposure history of workers as specified in para. 3.103, and any other necessary information; ... (c) Shall provide both the worker and the employer with the relevant exposure records.”</i> |
| (5) | BASIS: GSR Part 3 Requirement 24 para 3.93 states that <i>“Employers, registrants and licensees shall minimize the need to rely on administrative controls and personal protective equipment for protection and safety by providing well engineered controls and satisfactory working conditions, in accordance with the following hierarchy of preventive measures: (1) Engineered controls; (2) Administrative controls; (3) Personal protective equipment.”</i> |
| (6) | BASIS: GSR Part 3 Requirement 27 para 3.111 states that <i>“The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements, or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be used as substitutes for measures for protection and safety in accordance with the requirements of these Standards.”</i> |
| R15 | Recommendation: DSA, in coordination with other authorities, should harmonize its regulatory framework with all requirements of IAEA GSR Part 3 for the protection and safety of workers in planned exposure situations. |

The provisions for occupational exposure to ionizing radiation within the RP Regulations applies to the occupational exposure of aircrew. Requirements include dose limits for workers, personal dosimetry and reporting of doses to the national dose register. Regulatory requirements also require individual doses above 1 mSv per year to be reported to the national dose register. In the ARM, DSA identified that aviation companies will need to be informed and guidance provided on how to report occupational doses of aircrew to the register. DSA identified this issue in the ARM and raised a recommendation to assess the need for further regulatory control and surveillance of doses to aircrew.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The provisions for occupational exposure to ionizing radiation, within the Radiation Protection Regulations apply to aircrew. However, the estimated doses are not being reported to DSA. This has been recognized in the ARM.

(1)

BASIS: GSR Part 3 Requirement 52 para 5.31 states that “*Where such assessment is deemed to be warranted, the regulatory body or other relevant authority shall establish a framework which shall include a reference level of dose and a methodology for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation.*”

S17

Suggestion: DSA should consider implementing provisions to ensure the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation.

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

DSA informs licensees about their responsibilities by a letter accompanying the licence. DSA also provide information and guidance on radiation protection matters, including changes in regulations and new requirements, through a number of platforms to the health services.

DSA also invites all radiation protection coordinators working in the field of medical exposure to an annual dialogue meeting referred to as the *November Meeting*. The objective of this meeting is to discuss the RP Regulations, how to meet the requirements, changes in the administration of the regulations and other radiation protection issues. The meeting has been held since 2005 after the IC Regulations were made applicable to the RP Regulations. The IRRS Team noted this engagement as an area of good performance.

The IRRS Team noted that the government has not provided for the establishment of dose constraints for exposures of comforters and carers, and for volunteers participating in biomedical research. The government has also not provided for the establishment criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures. Some guidance is available from DSA and the Directorate of Health (DoH), which can be referred to by licensees; however, it does not cover all relevant radiological procedures and in some cases, the guidance is not consistent. Licensees cannot therefore implement the IAEA requirements in a consistent manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The government has not provided for the establishment of:

- (a) dose constraints for exposures of comforters and carers and for volunteers participating in biomedical research;
- (b) criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures.

This has been recognized in the ARM and is part of the action plan.

(1)

BASIS: GSR Part 3 Requirement 34 para 3.149 (a) states that “*The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following*

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | <p><i>are established:</i> <i>Dose constraints, to enable the requirements of paras 3.173 and 3.174, respectively, to be fulfilled for:</i> <i>(i) Exposures of carers and comforters;</i> <i>(ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research.”</i></p> |
| (2) | <p>BASIS: GSR Part 3 Requirement 34 para 3.149 (b) states that “<i>The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:</i> <i>Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources.”</i></p> |
| R16 | <p>Recommendation: The Government should ensure that, as a result of consultation between the HOD, relevant professional bodies and DSA, the following are established:</p> <p>a) Dose constraints for exposures of carers and comforters and volunteers participating in a programme of biomedical research.</p> <p>b) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures.</p> |

With respect to the individual justification of medical exposures a single set of national referral criteria covering all radiological procedures is not available in Norway. DoH has published national guidelines that may be used across the patient pathway. However, these guidelines do not cover all radiological procedures and do not include reference to radiation dose and the associated risks. DSA also provides information in the guides to licensees on the sets of referral criteria available internationally. HOD requested DoH to undertake a review of the efficient use of medical imaging which resulted in the publication of the document entitled ‘Strategy for the Rational Use of Diagnostic Imaging – Proposal from DoH – February 2019’. DSA participated in this work and the proposed strategy is currently being evaluated by HOD. The document also includes an action for the implementation of interactive referral and decision support for individual justification of medical exposures.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | <p>Observation: While DoH has published some guidelines to assist with the individual justification of medical exposures, a single set of national referral criteria covering all medical imaging procedures including the provision of information on radiation dose and associated risks is not available in Norway. This has been recognized in the ARM and is part of the action plan.</p> |
| (1) | <p>BASIS: GSR Part 3 Requirement 37 para 3.158 states that “<i>Relevant national or international referral guidelines shall be taken into account for the</i></p> |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | <i>justification of the medical exposure of an individual patient in a radiological procedure.”</i> |
| (2) | BASIS: SSG 46 Requirement 37 para 2.59 states that “ <i>National or international referral guidelines should be used as an important tool in the application of the process of justification of medical exposure for an individual patient. The health authority should support the relevant professional bodies in developing and implementing evidence-based referral guidelines (see also para. 2.65).”</i> |
| R17 | Recommendation: The Government should ensure that the relevant authorities, in cooperation with relevant professional bodies, adopt a national set of referral guidelines for the justification of medical exposure for an individual patient in a radiological procedure. |

DSA established a national quality assurance (QA) programme in radiotherapy (KVIST) in 2000. The programme was initiated by HOD to help undertakings through a planned, extensive increase in radiotherapy capacity in Norway. This QA programme facilitates implementation of QA at a hospital level. The KVIST initiative, which consists of a multidisciplinary team employed by DSA, has resulted in several national consensus and guideline documents covering areas including incident reporting and clinical audit strengthening optimisation in radiotherapy. The IRRS Team considers the KVIST national QA programme strengthening optimisation in radiotherapy and improving communication between radiotherapy centres and the relevant professions as a good performance.

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The RP Act, RP Regulations, and the PC Act provide the basis for the development of specific regulatory provisions aiming to ensure the proper control over public exposures to ionizing radiation. Major aspects that are relevant in the matter of public exposure, such as dose limits and constraint approach, requirements for the control of discharges, limits for indoor radon and relevant measures have been included in dedicated guides.

There are no regulatory reference values for radionuclides in building materials: there are, however, regulatory requirements for radon indoor that limit the radioactive content in such materials. Reference levels for Cs-134 and Cs-137 in foodstuffs are established. When necessary, further limits could be defined by the Crisis Committee based on Guidelines and Recommendations 2014, “Protective Measures in Early and Intermediate Phases of a Nuclear or Radiological Emergency”. Maximum permitted levels of both radon and tritium in drinking water have been laid down by the Ministry of Health and Care Services.

The IRRS Team acknowledged the importance for DSA to complete the regulatory framework to address the particularities of the remediation process, considering that the remediation of legacy sites Søve, a former Niobium mining site, and legacy site Taraldrud, are about to begin. PC Act is a useful tool for management of public exposure due to different forms of pollution including NORM and legacy sites of different origin. Although DSA has initiated actions aiming to regulate these remediation processes, based on international experiences and standards used for similar situations, the regulatory framework is not addressing specific requirements and responsibilities for remediation of areas with residual radioactive material.

There is no dedicated regulatory guidance to address all steps, responsibilities and particularities of the remediation process. This has been recognized DSA in the ARM. **Recommendation R14 in section 9.1 addresses these issues.**

9.11. SUMMARY

DSA has regulations and guides to support the legal framework for nuclear safety and radiation protection. The IRRS Team has identified the need to ensure that regulation and guides are reviewed, revised and developed as necessary for facilities and activities covered by current regulations.

The IRRS Team considers the KVIST national QA programme strengthening optimisation in radiotherapy and improving communication between radiotherapy centres and the relevant professions as a good performance.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The main acts, legal codes and statutes for the regulation of the emergency preparedness and response in Norway are the RP Act; the NE Act and the PC Act supported by the RP Regulations and the Internal Control Regulation. In addition, general guides that encompass emergency management planning have been developed on regulation on the application of the PC Act to authorized discharges and management of radioactive waste.

The RP Act assigns to the authorized party the responsibility for the on-site Emergency Preparedness and Response (EPR). The RP Act also explicitly assign the responsibilities of the DSA to regulate on-site and off-site EPR. Facilities and activities under the NE Act and the PC Act also fall under the RP Act on EPR arrangements. Nevertheless, the provisions for DSA to approve the emergency response plan of the authorized parties differ depending on the type of the facility or activity involved.

For the nuclear facilities, under the NE Act, the licence application requires that the emergency response plan be submitted with the licence request. The same applies for the permits granted under the PC Act, which are mainly for non-nuclear industrial applications associated with the petroleum industry, for the waste management and for authorized discharges. DSA then evaluates the EPR arrangements of the authorized party before issuing the licence or permit.

One of the main acts of the regulatory body when regulating on-site EPR arrangements is the review and assessment of the on-site emergency arrangements of the authorized party before the commencement of the activity.

For the facilities and activities under the RP Act, DSA does not evaluate the EPR arrangements of the authorized party during the authorization process because the applicant does not have to submit with the application for authorization an emergency response plan, only to acknowledge that that plan exists. This implies that for these facilities and activities DSA doesn't have arrangements in place for the approval of the emergency response plan of the authorized parties.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| <p>Observation: It was observed that for the industrial, medical or research activities under the RP Act, DSA does not evaluate the EPR arrangements of the applicant during the authorization process, because the applicant does not have to submit with the application for authorization an emergency response plan, only to acknowledge that the plan exists. This implies that for these facilities and activities DSA doesn't have arrangements in place for the approval of the emergency response plan of the authorized parties.</p> | |
| (1) | <p>BASIS: GSR Part 7 Requirement 23 para 6.19 states that <i>“The operating organization of a facility or for an activity in category I, II, III or IV shall prepare an emergency plan. This emergency plan shall be coordinated with those of all other bodies that have responsibilities in a nuclear or radiological emergency, including public authorities, and shall be submitted to the regulatory body for approval.”</i></p> |
| R18 | <p>Recommendation: DSA should ensure that arrangements are in place so that applicants under the RP Act submit the emergency response plans to the</p> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

regulatory body for the approval or renewal of a licence.

In all cases it is required that the authorized party notifies the regulatory body immediately about any emergency and has in place a system for response to an on-site emergency.

Afterwards, during the lifetime of the facility or of the activity, the regulatory control in EPR is ensured by the approval of the authorized party revisions and updates of the on-site emergency response plan resulting from revisions of renewals of the licences and permits and by conducting inspections on EPR arrangements and, in the case of the Institute of Energy Technology (IFE), also by observing and evaluating exercises.

The IRRS Team was informed that DSA applies a graded approach to the assignment of resources for EPR regulatory control. The main efforts go to the EPR regulation of the two research reactors of IFE.

The licences under the NE Act have a validity up to 10 years. Under the RP Act, the authorizations have different expiration periods, ranging for 3 to 10 years. Under the PC Act, permits may have no expiration period. The IRRS Team was informed that in these cases, there is a verification of the conditions of the permit every 10 years. For licences and for permits it's inferred that the emergency response plan is revised at least every 10 years.

The regulations do not specifically require that the on-site emergency response plans from the authorized parties should be coordinated with the relevant off-site emergency arrangement of the response organizations. Nevertheless, for IFE, the EPR plan includes actions to be coordinated with the competent off-site emergency response organizations, if necessary. The IRRS Team was informed that DSA has been encouraging a better articulation between on-site and off-site responders for other facilities and activities which use radioactive sources.

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

In Norway there are only facilities or activities classified in Emergency Preparedness Categories (EPC) II, III, IV and V, as per IAEA categorization, no facilities of EPC I exists in the country.

According to the RP Act and the Internal Control Regulation, the authorized party, in the event of changes to the facility or activity, should have arrangements in place for reviewing and updating the emergency response plan.

The RP Act defines a legal basis for the protection of emergency workers for all facilities and activities, but no definition for "Emergency Worker" exists. The RP Regulations establishes dose limits for emergency workers. No clear criteria exist for the designation of on-site emergency workers. No formal "just in time" training for non-designated in advance emergency workers exists. Also, no definition was found for "Helpers" and no arrangements are in place for the protection of helpers in a nuclear or radiological emergency. **Recommendation R20 in Section 10.4 addresses these issues.**

In case of an emergency, the dose assessment is done by the DSA, but in need, DSA may require biodosimetry services from other institutions.

The reference levels and dose criteria used for undertaking urgent protective actions are the ones stated on the Nordic Flag Book, nevertheless no reference level in accordance with the

GSR Part 7 is established in the legal framework. **Recommendation R20 in Section 10.4** addresses this issue.

Whatever the facility or activity, in case of loss, theft or unauthorized use of a radiation source and in any other emergency related to radiation practices, DSA should be notified immediately by the authorized party, and a written report should follow in the next 3 days.

No criteria is established for transition from an emergency exposure situation to an existing exposure situation and also no criteria exists for the termination of an on-site or off-site emergency, this has been recognized in the ARM. **Recommendation R20 in Section 10.4** addresses these issues.

No specific EPR guidance has been issued for nuclear operators, since IFE is the only operator of nuclear facilities, the guidance is included in the licences.

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

The IRRS Team was informed that annual inspections to facilities and activities often include the EPR matters, regardless of the fact that inspection of EPR arrangements are not specifically required in the legislation. The DSA conducts inspections as described in section 7 of this report.

Verification of compliance of the on-site emergency response plans is based on a graded approach which also serve for defining the frequency of the assessment of EPR matters during inspections.

Requirements on the contents of emergency response plans for facilities and activities are stated in the Internal Control Regulation, including the need to state the available equipment and human resources for dealing with an emergency, and criteria for initial assessment of the situation. The emergency response plans have to be updated and/or reviewed if major changes are implemented or during the renewal of the licences or permits.

Under IFE licences there are several permits, which apply general EPR conditions. The emergency response system of IFE consists of overarching plans for how the response should be handled by: strategic level (level 1), operational level (level 2) and by the responders for each part of the facility (level 3). Level 2 and 3 are catered to the specific campus and then to each individual area of IFE.

The authorized party should provide for training to their employees for emergency situations and also conduct periodic exercises. DSA participates in the notification exercises performed by the operators for all the facilities and activities. Nevertheless, except for IFE, DSA does not observe or evaluates exercises performed by other industrial or medical operators.

Presently the result of exercises conducted by the authorized parties other than the nuclear facilities are only assessed during inspections. Furthermore, with the exception of nuclear facilities DSA does not have in place an established comprehensive process for sharing the lessons learned by the on-site training drills and exercises conducted by the authorized parties, for facilities and activities. **Recommendation R20 in Section 10.4 addresses this issue.**

The fulfilment of the requirements for the emergency response plan, notification of emergencies and training of the staff is verified by inspectors of DSA.

Neither the Acts or the Regulations states that DSA has the specific obligation to perform inspections of the facilities or activities after an emergency has occurred, nevertheless the IRRS

Team was informed that depending on the severity of the emergency, an inspection will take place.

From the observations made by the IRRS Team and to facilitate the compliance of the Norwegian EPR system with the GSR Part 7, the Norwegian emergency preparedness and response system for nuclear and radiological emergencies could benefit from an Emergency Preparedness and Response Review (EPREV) Service. **Suggestion S6 in Section 2.1 addresses this issue.**

10.4. ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

The nuclear preparedness organization for Norway is specified upon the Royal Decree of 23 August 2013 “Norwegian Nuclear and Radiological Emergency Organization – Central and regional organization” and on the RP Act. The Royal Decree is the main legal document for regulating off-site emergency preparedness and response. The Plan for the Crisis Committee for Nuclear and Radiological Preparedness (Crisis Committee) is the main operational document describing the emergency preparedness and response for all members of the Crisis Committee.

The Norwegian preparedness organization as a whole consists of the Crisis Committee, its Advisors (14 organizations from universities, research institutes and public directorates), and the secretariat (DSA), with the County Governors acting as the Committee’s regional representatives. According to the Royal Decree on Nuclear Preparedness, the role of chair of the Crisis Committee is assigned to the Director of the DSA.

If a nuclear or radiological accident or incident has either occurred or may occur, and such an event can affect either Norwegian territory or Norwegian interests, the Crisis Committee shall ensure that the emergency is addressed with coordinated measures and coordinated information to the public. Also, the Crisis Committee has the responsibility for deciding on mitigation of non-radiological consequences of a radiological or nuclear emergency.

The Crisis Committee consists of representatives from: DSA, Norwegian Armed Forces, Directorate of Health, Food Safety Authority, National Police Directorate, Ministry of Foreign Affairs, Coastal Administration, and the Directorate for Civil Protection. During the acute and intermediate phase of a nuclear or radiological event, the Crisis Committee is mandated to decide, by consensus, on implementation of early mitigating measures to protect life, health, environment and important societal interests. The IRRS Team considers the fact that the Crisis Committee consists of decision makers that take the decisions by consensus and in a timely manner as good performance of Norway on complying with the standards.

One of the Crisis Committee’s aims is to provide information quickly and to disseminate information to target groups. The Crisis Committee’s communication units of the institutions represented in the Crisis Committee have jointly developed a communication plan for each postulated scenario, with an explanation of roles and responsibilities between the communication actors within the Crisis Committee, these communication plans are aimed at specific target groups, the media and the general public. The IRRS Team considers the communication plans developed as good performance in complying with the IAEA Safety Standards.

Based on the hazard assessment for radiological and nuclear vulnerabilities, the Government has postulated six defined nuclear and radiological emergency scenarios. DSA takes the leading role in supporting the national emergency response to these scenarios. DSA is also responsible for defining the criteria for agricultural countermeasures, ingestion, longer-term protective measures and the procedure to guide the coordination of these activities.

DSA has an annual programme for EPR training, drills and exercises, and each year DSA staff also participate in exercises organized by the IAEA and the European Commission. DSA staff also provide training to regional and local authorities and organize an annual exercise for the Crisis Committee.

DSA maintains a dedicated emergency support centre. During routine situations, the centre is manned only during office hour. Nevertheless, several staff members ensure that duty officer functions can be performed 24 hours a day and 7 days a week (24/7), with means of communication and defined procedures. DSA also maintains a Crisis Information Management System (CIM) that is compatible with the Information Management System of the other authorities belonging to the Crisis Committee.

The IRRS Team was informed that the outsourcing of information and communication technologies and services to Norsk Helsenett (NHN) has entailed periods of non-conformity to the requirements related to DSA’s role as National Warning Point as stated in the Convention on Early Warning. No service level agreement or other arrangements are in place to ensure NHN assistance in an emergency response situation, in particular in complex situations where vital decision support systems may fail, this has been recognized in the ARM. The IRRS Team was informed that DSA and NHN have been given an assignment by HOD to analyse the risks concerning the system connected to National Warning Point and to come up with a suggestion that can provide DSA with an optimal solution in this context.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| <p>Observation: The IRRS Team was informed that the outsourcing of information and communication technologies and services has entailed periods of non-conformity to the requirements related to DSA role as National Warning Point with 24/7 availability as required by the Convention on Early Warning. No arrangements are in place to ensure assistance in an emergency response situation, in particular in complex situations where vital decision support systems may fail. This has been recognized in the ARM.</p> | |
| (1) | <p>BASIS: GSR Part 7 Requirement 2 para 4.8 states that <i>“The government shall ensure that response organizations, operating organizations and the regulatory body have the necessary human, financial and other resources, in view of their expected roles and responsibilities and the assessed hazards, to prepare for and to deal with both radiological and non-radiological consequences of a nuclear or radiological emergency, whether the emergency occurs within or beyond national borders.”</i></p> |
| R19 | <p>Recommendation: The Government should put in place arrangements to ensure that assistance and support for the information and communication technologies are available to respond to an emergency situation.</p> |

During confirmed events, medical response actions are put in place. Nevertheless, no formal procedures and systematic arrangements are in place for general practitioners and medical emergency staff to be made aware of the symptoms of radiation exposure in patients and notification procedures in routine situations.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| <p>Observation: No formal procedures or systematic arrangements are in place for general practitioners and medical emergency staff to be made aware of the symptoms of radiation</p> | |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

exposure in patients and notification procedures, in routine situations.

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| (1) | BASIS: GSR Part 7 Requirement 12 para 5.63 states that <i>“Arrangements shall be made for medical personnel, both general practitioners and emergency medical staff, to be made aware of the clinical symptoms of radiation exposure, and of the appropriate notification procedures and other emergency response actions to be taken if a nuclear or radiological emergency arises or is suspected.”</i> |
| S18 | Suggestion: DSA should consider ensuring that arrangements are in place so that medical personnel, both general practitioners and medical emergency staff, are made aware of the clinical symptoms of radiation exposure and notification procedures to be taken. |

For protective actions arrangements Norway relies on the “Nordic Flag Book Recommendations for Protective Measures in Early and Intermediate Phases of a Nuclear or Radiological Emergency”, dated from 2014. Nevertheless, the arrangements for EPR in Norway lack a full compliance with the GSR Part 7. For example, there is no protection strategy with a definition of reference levels, general criteria and emergency phases aligned with GSR Part 7. The EPR arrangements also do not encompass criteria for the termination of an emergency and, for EPC II and V, there is no formal outline of the emergency planning distances.

The IRRS Team was informed that a revision of the Nordic Flag Book is being prepared and will address these subjects for off-site emergencies.

Norway is a Party to the IAEA “Convention on Early Notification of a Nuclear Accident”, and “Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency”. DSA has the competency of being the National Warning Point, National Competent Authority for Emergencies Abroad and National Competent Authority for Domestic Emergencies for these conventions and also assumes the role of INES National Officer. DSA also represents Norway on the Emergency Preparedness and Response Standards Committee of the IAEA. Norway have registered capabilities in the RANET.

Norway has established comprehensive and efficient bilateral agreements with several countries, namely: Finland, Sweden, UK, France, Germany, Netherlands, Poland, Russia, Belarus, Ukraine and Lithuania. As an example, the exchange on EPR arrangements with Russia allows DSA to gain a better insight on Russian decisions support systems, forecasting tools and emergency response organizations. This bilateral collaboration also provides the Norwegian authorities with good information about Russian facilities, and new bilateral notification procedures were signed in 2015 and are tested annually in joint exercises.

Norway has established comprehensive multilateral agreements, namely: the Nordic Mutual Assistance Agreement in Connection with Radiation Accidents between Denmark, Finland, Sweden and Norway; the Nordic Mutual Assistance Agreement in the event of a disaster or major accident; the Agreement (for the Nordic and Baltic region) on the Exchange of Radiation Monitoring Data; the Nordic Manual.

DSA also has in place arrangements for emergencies at sea, aiming mainly to accidents with floating nuclear power plants transported along the Norwegian coast, nuclear powered vessels and high-level radioactive waste transport. The IRRS Team notes the ARCSAFE initiative: “The cross countries cooperation network to improve emergency prevention, response and the

safety of emergency workers in a case of a maritime accident involving the potential release of radioactive substances in the Arctic”.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| <p>Observation: Some of the existing requirements for emergency preparedness and response are not fully in compliance with the requirements of IAEA safety standards GSR Part 7; for example: no protection strategy aligned with the standard; no criteria for the termination of an emergency; no designation of “Helpers”; no clear criteria for the designation and just-in-time training of “Emergency Workers”; no established process for sharing the lessons taken by the on-site training drills and exercises for facilities and activities (other than the nuclear facilities) with DSA; no emergency planning zones aligned with the standard. This has been partially recognized in the ARM.</p> | |
| (1) | <p>BASIS: GSR Part 7 Requirement 5 states that <i>“The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.”</i></p> |
| (2) | <p>BASIS: GSR Part 7 Requirement 18 states that <i>“The government shall ensure that arrangements are in place and are implemented for the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of social and economic activity.”</i></p> |
| (3) | <p>BASIS: GSR Part 7 Requirement 11 states that <i>“The government shall ensure that arrangements are in place to protect emergency workers and to protect helpers in a nuclear or radiological emergency.”</i></p> |
| (4) | <p>BASIS: GSR Part 7 Requirement 11 para 5.52 (b) states that <i>“Providing emergency workers not designated in advance and helpers in an emergency immediately before the conduct of their specified duties with instructions on how to perform the duties under emergency conditions, (‘just in time’ training);”</i></p> |
| (5) | <p>BASIS: GSR Part 7 Requirement 25 para 6.30 states that <i>“The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained.”</i></p> |
| (6) | <p>BASIS: GSR Part 7 Requirement 9 para 5.38 (a) states that <i>“The specification of off-site emergency planning zones and emergency planning distances for which arrangements shall be made at the preparedness stage for taking protective actions and other response actions effectively.”</i></p> |
| R20 | <p>Recommendation: The Government should revise the legislation and regulations on emergency preparedness and response to ensure consistency with the IAEA Safety Standards GSR Part 7.</p> |

10.5. SUMMARY

Norway is a country with facilities and activities classified to Emergency Preparedness Categories II, III, IV and V, as per IAEA categorization. The existing regulatory framework and hazard assessment provide a basis for implementing the IAEA requirements in order to achieve a harmonized graded approach in establishing arrangements for preparedness and response to radiological emergencies. Nevertheless, some aspects of the on-site and off-site emergency preparedness and response requires further development to ensure compliance with the IAEA Safety Standards GSR Part 7.

The IRRS Team considers the establishment of the Crisis Committee and the communication plan developed as good performance on the implementation of the EPR standard.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

DSA is the regulatory body and the highest specialist body as far as safety and security are concerned, and responsible for supervision in Norway.

The current legal framework for all nuclear activities, including interfaces of nuclear safety with arrangements for nuclear security are regulated by the NE Act, Regulations on the Physical Protection of Nuclear Materials and Nuclear Facilities, Regulations on Possession, Transfer and Transportation of Nuclear Material and Dual-use Equipment, Act on Radiation Protection and Use of Radiation (RP Act), and the Security Act.

However, none of these Acts and regulations contains specific provisions for interface between safety and security and with the system of accounting for, and control of, nuclear material.

The IRRS Team understood that the word for safety and security in the Norwegian language is one word: “sikkerhet”. This can promote the interface on safety and security but it can also create ambiguities in the implementation of the legal requirements, since it might not always be clear if all necessary measures related to safety and security interface are included in the requirements of the licences, permits and physical protection measures.

When revising the legal framework, the government should consider to clearly differentiate between safety and security. The regulatory framework should be clear when legal requirements apply to safety, security or both.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The legal and regulatory framework does not include specific provisions regarding interfaces between nuclear security and safety, including a system of accounting for and control of nuclear materials.

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| (1) | BASIS: GSR Part 1 (Rev 1) Requirement 12 that <i>“The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material.”</i> |
| (2) | BASIS: SSR-5 Requirement 23 states that <i>“Consideration of the State system of accounting for, and control of, nuclear material In the design and operation of disposal facilities subject to agreements on accounting for, and control of, nuclear material, consideration shall be given to ensuring that safety is not compromised by the measures required under the system of accounting for, and control of, nuclear material.”</i> |
| (3) | BASIS: SSR-5 Requirement 24 states that <i>“Measures shall be implemented to ensure an integrated approach to safety measures and nuclear security measures in the disposal of radioactive waste.”</i> |
| (4) | BASIS: GSR Part 5 Requirement 5 states that <i>“Requirements in respect of security measures shall be implemented to ensure an integrated approach to safety and security in the predisposal management of radioactive waste.”</i> |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| (5) | BASIS: GSR Part 5 Requirement 21 states “System of accounting for and control of nuclear material for facilities subject to agreements on nuclear material accounting, in the design and operation of predisposal radioactive waste management facilities the system of accounting for and control of nuclear material shall be implemented in such a way as not to compromise the safety of the facility.” |
| R21 | Recommendation: The Government should revise the legal framework to ensure that the interface between safety and security is addressed for all facilities and activities and to establish a clear distinction between safety and security. |

11.2. REGULATORY OVERSIGHT ACTIVITIES

As the highest specialist agency in terms of nuclear safety and nuclear security issues, DSA is entitled to provide recommendation and advice to the government and is responsible for preparation and for issuing opinions on all applications for licences and permits. It is the responsibility of DSA to provide oversight and implement enforcement of arrangements to ensure that safety and security measures are designed and implemented in an integrated manner. DSA, on its own initiative, takes measures it considers necessary for safety and security reasons.

Both radiation safety and security aspects are subject to investigations during DSA inspections on facilities involved with radioactive sources. The evaluation of security and safety arrangements, for radioactive sources, are performed by the same DSA staff, in an integrated manner, making sure that the measures for security and safety are not compromising each other. The IRRS Team was informed that any corrective action provided to the licensee, following an inspection activity on facilities involved with radioactive sources, is assessed both from safety and security point of view.

Nuclear safety and security measures for nuclear installations in Norway are assessed by two separate groups in DSA. The IRRS Team was informed that in order to coordinate the work, these two groups meet informally 2 times per month, on average. Various work assignments and certain challenges, related to the work on safety and security are discussed at these meetings. The individual measures related to safety and security are also addressed.

There are no statutory, nor internal procedures available in DSA to formalize how the safety and security measures are designed implemented, reviewed and assessed in an integrated manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

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| Observation: There is no documented process available in DSA’s management system to formalize how the safety and security measures are reviewed and assessed in an integrated manner. This has been recognized in the ARM and is part of the action plan. | |
| (1) | BASIS: GSR Part 1 Requirement 22 para 4.26 states that “The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system.” |

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S19

Suggestion: DSA should consider developing a formal process to establish how the safety and security measures are reviewed and assessed in an integrated manner.

11.3. INTERFACE AMONG AUTHORITIES

DSA has established good interface with Police Security Service (PST), the Norwegian National Security Authority (NSM), the Police Directorate (POD), Local Police force, and Directorate of Norwegian Customs. Following the recommendation given by IAEA's IPPAS (International Physical Protection Advisory Service) in Norway 2015 and by decision of the Government, a Government Forum for the Protection of nuclear installations and nuclear fuel in Norway was established in 2016. The aim of the Government Forum is to secure cooperation between national authorities and agencies and to produce, summarize and disseminate knowledge about how best to secure nuclear installations and materials in Norway. The members of the forum share knowledge concerning preventive security work relevant to the protection of nuclear installations and materials. The forum is also required to identify security challenges and issues for further investigation and possible interaction.

The emergency response plan covers both safety and security related incidents. Since nuclear materials and nuclear installations that fall under the Regulations on the Physical Protection of Nuclear Materials and Nuclear Facilities are by default a national asset, the emergency response arrangements are integrated, to apply to both safety related and nuclear security related situations.

11.4. SUMMARY

DSA is the regulatory body as far as safety and security are concerned, and responsible for supervision. Infrastructural arrangements have been established within the governmental framework to enable effective interfaces between safety and nuclear security and the State system of accounting for, and control of nuclear material. However, none of the current Acts and regulations contains specific provisions for interface between safety and security and with the system of accounting for, and control of, nuclear material.

DSA is responsible with the oversight and enforcement of arrangements for safety, security and the system of accounting for, and control of nuclear materials. However, there are no statutory, nor internal procedures available in DSA to formalize how the safety and security measures are designed implemented, reviewed and assessed in an integrated manner. Therefore, the IRRS Team recommended DSA to revise the legal framework regarding the interface between nuclear security and safety, including system of accounting for and control of nuclear materials to ensure that requirements for nuclear security and for system of accounting for and control of nuclear materials are not compromising the safety of nuclear and radiological facilities, as well as to consider developing a formal process to document how safety and security measures are reviewed and assessed in an integrated manner.

APPENDIX I LIST OF PARTICIPANTS

| INTERNATIONAL EXPERTS | | | |
|-----------------------|-----------------------------|--|--|
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| INTERNATIONAL EXPERTS | | | |
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| 3. | SWOBODA Zumi | Division of Radiation, Transport and Waste Safety | Z.Swoboda@iaea.org |
| LIAISON OFFICER | | | |
| 1. | FROGG KRISTIN ELISE | Norway Liaison Officer Director Legal Affairs Department of Nuclear Safety and Environmental Protection | Kristin.Elise.Frogg@dsa.no |

APPENDIX II LIST OF MAIN COUNTERPARTS

| IRRS EXPERTS | DSA COUNTERPARTS |
|---|---|
| RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT | |
| Dominik Reisner Cantemir Cinrea | Ole Harbitz , Per Strand, Hanne Kofstadmoen, Kristin Frogg |
| GLOBAL SAFETY REGIME | |
| Dominik Reisner Cantemir Cinrea | Ingar Amundsen, Håkan Mattsson |
| RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY | |
| Matjaz Podjavorsek | Per Strand , Hanne Kofstadmoen , Eva Godske Friberg, Mette Nilsen, Carol Robinson |
| MANAGEMENT SYSTEM | |
| Eleftheria Carinou | Unn Hilde Refseth , Solveig Dysvik, Elisabeth Lindbo Hansen, Annette Andersen |
| AUTHORIZATION | |
| Helene Vacelet Jose Manuel Martin Calvarro Marcela Medici Tetiana Kilochytska Andrew McCormick Jack Madden Santtu Hellsten Christina Dodkin Tanya Kenny Miguel Prendes | Håkan Mattsson , Edward Bray , Giedrius Paskevicius Ronny Lystad , Marte Holmstrand Sindre Øvergaard , Håvar Sollund, Tone-Mette Sjømoen, Ingeborg Hovde Grimstad Solveig Dysvik , Sindre Øvergaard, Nina Bratteteig, Håvar Sollund, Giedrius Paskevicius Tone-Mette Sjømoen , Kristine Wikan Ingrid Espe Heikkilä , Eva Godske Friberg, Anders Widmark, Annette Andersen, Ida Wendelbo Ormberg Anne Liv Rudjord , Bård Olsen, Merete Hannevik, Trude Dahl Jør- gensen, Mette Nilsen, Ingvild Finne |
| REVIEW AND ASSESSMENT | |
| Helene Vacelet Jose Manuel Martin Calvarro Marcela Medici | Håkan Mattsson , Edward Bray , Giedrius Paskevicius |

| IRRS EXPERTS | DSA COUNTERPARTS |
|---|--|
| <p>Tetiana Kilochytska Andrew McCormick Jack Madden Santtu Hellsten Christina Dodkin Tanya Kenny Miguel Prendes</p> | <p>Ronny Lystad, Marte Holmstrand Sindre Øvergaard, Håvar Sollund, Tone-Mette Sjømoen, Ingeborg Hovde Grimstad Solveig Dysvik, Sindre Øvergaard, Nina Bratteteig, Håvar Sollund, Giedrius Paskevicius Tone-Mette Sjømoen, Kristine Wikan Ingrid Espe Heikkilä, Eva Godske Friberg, Anders Widmark, Annette Andersen, Ida Wendelbo Ormberg Anne Liv Rudjord, Bård Olsen, Merete Hannevik, Trude Dahl Jør- gensen, Mette Nilsen, Ingvild Finne</p> |
| INSPECTION | |
| <p>Helene Vacelet Jose Manuel Martin Calvarro Marcela Medici Tetiana Kilochytska Andrew McCormick Jack Madden Santtu Hellsten Christina Dodkin Tanya Kenny Miguel Prendes</p> | <p>Håkan Mattsson, Edward Bray, Giedrius Paskevicius Ronny Lystad, Marte Holmstrand Sindre Øvergaard, Håvar Sollund, Tone-Mette Sjømoen, Ingeborg Hovde Grimstad Solveig Dysvik, Sindre Øvergaard, Nina Bratteteig, Håvar Sollund, Giedrius Paskevicius Tone-Mette Sjømoen, Kristine Wikan Ingrid Espe Heikkilä, Eva Godske Friberg, Anders Widmark, Annette Andersen, Ida Wendelbo Ormberg Anne Liv Rudjord, Bård Olsen, Merete Hannevik, Trude Dahl Jør- gensen, Mette Nilsen, Ingvild Finne</p> |
| ENFORCEMENT | |
| <p>Helene Vacelet Jose Manuel Martin Calvarro Marcela Medici Tetiana Kilochytska Andrew McCormick</p> | <p>Håkan Mattsson, Edward Bray, Giedrius Paskevicius Ronny Lystad, Marte Holmstrand Sindre Øvergaard, Håvar Sollund, Tone-Mette Sjømoen, Ingeborg Hovde Grimstad</p> |

| IRRS EXPERTS | DSA COUNTERPARTS |
|--|--|
| <p>Jack Madden Santtu Hellsten</p> <p>Christina Dodkin Tanya Kenny</p> <p>Miguel Prendes</p> | <p>Solveig Dysvik, Sindre Øvergaard, Nina Bratteteig, Håvar Sollund, Giedrius Paskevicius</p> <p>Tone-Mette Sjømoen, Kristine Wikan</p> <p>Ingrid Espe Heikkilä, Eva Godske Friberg, Anders Widmark, Annette Andersen, Ida Wendelbo Ormberg</p> <p>Anne Liv Rudjord, Bård Olsen, Merete Hannevik, Trude Dahl Jør- gensen, Mette Nilsen, Ingvild Finne</p> |
| REGULATION AND GUIDES | |
| <p>Helene Vacelet Jose Manuel Martin Calvarro</p> <p>Marcela Medici Tetiana Kilochytska</p> <p>Andrew McCormick Jack Madden</p> <p>Santtu Hellsten</p> <p>Christina Dodkin Tanya Kenny</p> <p>Miguel Prendes</p> | <p>Håkan Mattsson, Edward Bray, Giedrius Paskevicius</p> <p>Ronny Lystad, Marte Holmstrand</p> <p>Sindre Øvergaard, Håvar Sollund, Tone-Mette Sjømoen, Ingeborg Hovde Grimstad</p> <p>Solveig Dysvik, Sindre Øvergaard, Nina Bratteteig, Håvar Sollund, Giedrius Paskevicius</p> <p>Tone-Mette Sjømoen, Kristine Wikan</p> <p>Ingrid Espe Heikkilä, Eva Godske Friberg, Anders Widmark, Annette Andersen, Ida Wendelbo Ormberg</p> <p>Anne Liv Rudjord, Bård Olsen, Merete Hannevik, Trude Dahl Jør- gensen, Mette Nilsen, Ingvild Finne</p> |
| EMERGENCY PREPAREDNESS AND RESPONSE | |
| <p>Joao Oliviera Martins</p> | <p>Astrid Liland, Monica Dobbartin, Anne Marit Skjold, Øyvind Selnæs, Jonas Collett Knudtzon, Synne Egset</p> |
| INTERFACES WITH NUCLEAR SECURITY | |
| <p>Cantemir Ciurea Dominik Reisner</p> | <p>Tronn Berge, Per Strand, Trude Dahl Jørgensen</p> |

APPENDIX III MISSION PROGRAMME

| Sunday June 16, 2019 | | | | | | | | | | | | | | |
|---------------------------|---|---|-----------------------|-------|---|-------|---|-------|--|-------|---|-------|-------------|--|
| IRRS Initial Team Meeting | | | | | | | | | | | | | | |
| 13:30–18:00 | <ul style="list-style-type: none"> → Opening remarks by the IRRS Team Leader → Introduction by IAEA Coordinator → Self-introduction of all attendees → IRRS Process (IAEA) → Report writing (IAEA) → Schedule (TL, IAEA) → Administrative arrangements (host country Liaison Officer, IAEA): Detailed Mission Programme → First impression from IRRS Team members arising from the Advance Reference Material (all team members): Presentations | Venue: Hotel Participants: IRRS Team + Liaison Officer | | | | | | | | | | | | |
| Monday June 17, 2019 | | | | | | | | | | | | | | |
| IRRS Entrance Meeting | | | | | | | | | | | | | | |
| 09:30–12:00 | <table border="0" style="width: 100%;"> <tr> <td style="width: 10%; vertical-align: top;">09:30</td> <td>Arrival, registration</td> </tr> <tr> <td style="vertical-align: top;">10:00</td> <td>Welcoming Address – (officials from the host country)</td> </tr> <tr> <td style="vertical-align: top;">10:30</td> <td>IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team</td> </tr> <tr> <td style="vertical-align: top;">10:45</td> <td>IRRS Team members’ and Counterparts’ self-presentation</td> </tr> <tr> <td style="vertical-align: top;">11:00</td> <td>Host Institution presentation – Regulatory Overview, SARIS results (strengths, challenges, action plan)</td> </tr> <tr> <td style="vertical-align: top;">11:45</td> <td>Group Photo</td> </tr> </table> | 09:30 | Arrival, registration | 10:00 | Welcoming Address – (officials from the host country) | 10:30 | IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team | 10:45 | IRRS Team members’ and Counterparts’ self-presentation | 11:00 | Host Institution presentation – Regulatory Overview, SARIS results (strengths, challenges, action plan) | 11:45 | Group Photo | Venue: R6 Auditorium A-64, Oslo Center Participants: HOD, MFA, KLD, DSA Management and staff, Official from relevant organizations, IRRS Team + Liaison Officer |
| 09:30 | Arrival, registration | | | | | | | | | | | | | |
| 10:00 | Welcoming Address – (officials from the host country) | | | | | | | | | | | | | |
| 10:30 | IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team | | | | | | | | | | | | | |
| 10:45 | IRRS Team members’ and Counterparts’ self-presentation | | | | | | | | | | | | | |
| 11:00 | Host Institution presentation – Regulatory Overview, SARIS results (strengths, challenges, action plan) | | | | | | | | | | | | | |
| 11:45 | Group Photo | | | | | | | | | | | | | |
| 12:00–13:00 | Lunch | Hosted by HOD | | | | | | | | | | | | |
| 13:00–13:30 | Travel from Oslo to DSA Headquarters | | | | | | | | | | | | | |
| 13:30–17:00 | Interviews and discussions with counterparts (parallel discussions, see detailed programme) | Venue: DSA HQ Participants: IRRS Team + Counterparts | | | | | | | | | | | | |
| 17:00–18:00 | Daily IRRS Team meeting | Venue: DSA Mega Room Participants: IRRS Team + Liaison Officer | | | | | | | | | | | | |

Tuesday June 18, 2019

Daily Discussions / Interviews

| | | |
|-------------|--|---|
| 09:00–17:00 | Interviews and discussions with counterparts (parallel discussions) | Venue: DSA HQ Participants: IRRS Team +Counterparts |
| 12:00–13:00 | Lunch | |
| 13:00–17:00 | Interviews with the Ministries (HOD, MFA, KLD) for modules 1, 2 and 3. 13.00 – 13.30 Transport DSA - HOD 13.45- 14.30 Interview with HOD 14.30 – 15.15 Interview with KLD 15.15 – 15.30 Coffee Break 15.30 – 16.15 Interview with MFA 16.15 – 17.00 Meeting with HOD/KLD/UD | Venue: HOD, city center Participants: TL, TC Reviewer Modules 1, 2 and 3. |
| 17:30–18:30 | Daily IRRS Team meeting | Venue: DSA Mega Room Participants: IRRS Team + Liaison Officer |

Wednesday June 19, 2019

Daily Discussions / Interviews

| | | |
|-------------|---|--|
| 09:00–17:00 | Interviews and discussions with counterparts for all modules (except those going on sites visits) | Venue: DSA HQ Participants: IRRS Team +Counterparts |
| | Site-visits | Medical and Industrial facilities in Stavanger: A. McCormick, J.Madden, C. Dodkin, T.Kenny RR in Halden: H. Vacelet, G. Macsuga Fuel Pellet production facility in Kjeller: J.M. Martin Calvarro Waste management facilities in Kjeller and Himdalen: M. Medici, T. Kilochytska Transport activity in Kjeller: S. Hellsten |

| | | |
|---------------------------------------|--|--|
| 12:00–13:00 | Lunch | |
| 17:00–18:00 | Daily IRRS Team meeting, including quick briefing on site visits | Venue: Hotel Participants: IRRS Team + the LO |
| 18:30 - | Writing the report | |
| Thursday June 20, 2019 | | |
| Daily Discussions / Interviews | | |
| 09:00–12:00 | Follow-up Interviews and discussions with counterparts, if necessary (parallel discussions) | Venue: DSA HQ Participants: IRRS Team +Counterparts |
| 12:00–13:00 | Lunch | |
| 13:00–16:00 | Report preparation preliminary findings (recommendations, suggestions, good | IRRS Team |
| 16:00–17:00 | Preliminary findings delivery and compilation | Venue: DSA Mega Room Participants: IRRS Team |
| 17:00–18:30 | Daily IRRS Team Meeting: recommendations, suggestions and good practices | Venue: DSA Mega Room Participants: IRRS Team + the LO |
| 20:00–22:00 | Recommendations, suggestions and good practices | Venue: Hotel Participants: IRRS Team + the LO |
| Friday June 21, 2019 | | |
| Daily Discussions / Interviews | | |
| 09:00–17:00 | Follow-up Interviews as needed Preparation of the report | Venue: DSA HQ Participants: IRRS Team +Counterparts |
| 12:00–13:00 | Lunch | |
| 14:00–18:00 | Daily IRRS Team Meeting: report preparation: finalize observations, basis, recommendations, suggestions and good practices | Venue: DSA Mega Room Participants: IRRS Team + the LO |
| 20:00–22:00 | Finalize observations, basis, recommendations, suggestions and good practices | Venue: Hotel Participants: IRRS Team + the LO |

| Saturday June 22, 2019 | | |
|--------------------------------------|--|--|
| 09:00–18:00 | →IRRS Team members draft the report and finalize recommendations, suggestions and good practices →Draft report cross reading →Finalization of the report by the entire IRRS Team | Venue: hotel Participants: IRRS Team |
| 20:00–22:00 | IRRS Team Lead and IAEA Coordinators edit draft report | Venue: hotel Participants: IRRS Team |
| Sunday June 23, 2019 | | |
| IRRS Team rest day + cultural events | | 12:00 – |
| Monday June 24, 2019 | | |
| | | |
| 09:00–12:00 | Parallel individual review and discussions of the report sections with the counterparts. Report writing | Venue: DSA HQ Participants: IRRS Team, Counterparts |
| 12:00–13:00 | Lunch | |
| 13.00–15:00 | | |
| | Policy issue discussions (topics: Competence at DSA; Provision of Guidance and Advice to Licensees) | Venue: DSA HQ Participants: IRRS Reviewers and Counterparts |
| 13:00–17:00 | Report finalizing by the IRRS Team | Participants: IRRS Team |
| 17:00–18:00 | IRRS Team Lead and IAEA Coordinators finalize draft report editing | Venue: DSA HQ Participants: IRRS Team |
| Tuesday June 25, 2019 | | |
| | | |
| 10:00–18:00 | DSA organizes the review of the draft by all national counterparts and start review | |

| | | |
|--------------------------------|---|---|
| 10:00–18:00 | IRRS Team Lead and IAEA Coordinators draft: executive summary and prepare exit presentation | Venue: DSA HQ Participants: IRRS TL, DTL, TC, DTC |
| Wednesday June 26, 2019 | | |
| | | |
| 09:00–12:00 | DSA finalizes the review of the draft report and submit written comments to the IRRS Team | |
| 12:00–13:00 | Lunch | |
| 13:00–18:00 | IRRS Team reviews Host’s comments and finalizes draft report. | Venue: DSA Mega room Participants: IRRS Team |
| Thursday June 27, 2019 | | |
| | | |
| 09:00–12:00 | Discussions with Hosts on findings | Venue: DSA, ALFA 3 meeting room Participants: IRRS Team and Host counterparts |
| 12:00–13:00 | Lunch | |
| 13:00–17:00 | Team meeting for report finalization based on discussions with the Hosts Submission of the Final Draft Report to the Hosts | Venue: DSA Mega Room Participants: IRRS Team |
| 17:00–18:00 | Press release finalization | Venue: DSA Mega Room IRRS Team Lead and IAEA Coordinators, |
| 19:00–21:00 | Farewell dinner | Venue : «Ekeberg Restauranten» Participants: IRRS Team and Counterparts |
| Friday June 28, 2019 | | |
| | | |
| 10:00–11:00 | IRRS Exit meeting | Venue: HOD, City Center |

| | | |
|--|--|---|
| | Main findings of the IRRS mission (Team Leader) | Participants: Government Officials, DSA Management and staff, the IRRS Team + the Liaison Officer |
| | Remarks by the Host Institution in response to the mission findings. | |
| | IAEA Official: Closing | |

APPENDIX IV SITE VISITS

1. Institute for Energy Technology (IFE) Kjeller – Research Reactor
2. Institute for Energy Technology (IFE) Kjeller – Fuel Cycle facility
3. Institute for Energy Technology (IFE) Kjeller//Himdalen - Waste
4. Institute for Energy Technology (IFE) Kjeller - Transport
5. Aker Solution Stavanger
6. Stavanger University Hospital

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

| Area | R: Recommendations | Recommendations, Suggestions or Good Practices |
|--|-------------------------------------|---|
| | S: Suggestions G: Good Practices | |
| 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT | R1 | The Government should establish a comprehensive national policy and strategy for safety promulgated as a statement of the Government’s intent, the implementation of which shall be subject to a graded approach. |
| | R2 | The Government should update the framework for safety to include clear legal provisions and definitions for siting, design and decommissioning as licensing phases. |
| | S1 | The Government should consider formalizing the periodic review of the legal framework through DSA. |
| | S2 | The Government should consider to ensure effective independence of DSA in all its regulatory functions with respect to licensees funded by the Ministry of Health and Care Services. |
| | R3 | The Government should make provisions to provide DSA with the resources necessary to fulfil its statutory obligation for the regulatory control of all facilities and activities |
| | S3 | The Government should consider making legal provision that the prime responsibility for safety must rest with the person or organization responsible for facilities and activities covered by the RP Act. |

| Area | R: Recommendations | Recommendations, Suggestions or Good Practices |
|--------------------------------|--------------------|---|
| | S: Suggestions | |
| | G: Good Practices | |
| | S4 | The Government should consider enhancing the coordination and liaison between relevant authorities with regard to transport of radioactive materials and biomedical research. |
| | R4 | The Government should develop and implement a national policy and strategy for spent fuel and radioactive waste management, that reflect national priorities and that can form the basis for long-term decision making with respect to the decommissioning of facilities, management of spent fuel, predisposal waste management and disposal of radioactive waste, including the necessary financial provisions. |
| | R5 | The Government should establish provisions regarding the building and maintaining of competence of all parties having responsibilities in relation to the safety of facilities and activities, including the strengthening radiation protection training in health education programmes and the formal recognition of medical physicists. |
| | S5 | The Government should consider making provision for DSA's responsibility to authorize technical services for radiation safety |
| 2. GLOBAL SAFETY REGIME | S6 | The Government should consider inviting an Emergency Preparedness and Response Review (EPREV) Service. |
| | GP1 | The Government of Norway through establishing NAP and continuing it for more than 20 years shows a long-term commitment for international cooperation in safety and security. By strategically providing funding for |

| Area | R: Recommendations S: Suggestions G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|
| | | projects to ensure risk reduction regarding serious accidents and radioactive contamination as well as to prevent nuclear and other radioactive material from falling into the wrong hands, Norway's NAP has substantially contributed to increasing safety and security in Russia and Ukraine. |
| | S7 | DSA should consider establishing and maintaining means for systematic analysis of events, identification of lessons learned and dissemination of related information to facilitate an effective exchange and use of operating and regulatory experience with the international community. |
| 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY | S8 | DSA should consider improving the management of its financial resources in a manner commensurate with the radiation risks associated with facilities and activities. |
| | S9 | DSA should consider establishing procedures for ensuring effective independence in performing regulatory tasks by the staff who are involved in projects connected with authorized parties. |
| | S10 | DSA should consider resolving any existing or potential conflict of interest within its organization with regard to the provision of technical services. |
| | R6 | DSA should develop a comprehensive human resource plan including a specific training programme, which is based on an analysis of the necessary competences and skills needed to fulfil its regulatory obligations. |
| | S11 | DSA should consider ensuring the necessary means to assess the advice provided by external experts. |

| Area | R: Recommendations | Recommendations, Suggestions or Good Practices |
|--|--------------------|---|
| | S: Suggestions | |
| | G: Good Practices | |
| | S12 | DSA should consider expanding the use of advisory bodies in all relevant areas. |
| 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY | R7 | DSA should develop a safety policy document with the individual and organizational values and expectations for safety to be disseminated to the whole organization. |
| | R8 | DSA should develop, establish, implement, assess and continuously improve a documented integrated management system to ensure safety, using graded approach, in line with IAEA safety standards. |
| 5. AUTHORIZATION | S13 | DSA should consider establishing dedicated regulatory guidance that should address, in line with the GSR Part 3, all relevant responsibilities of the providers of consumer products. |
| | S14 | DSA should consider continuing the implementation of the Radon strategic programme prioritizing those activities that are addressing the mitigation actions in private homes and the protection strategy in areas with extreme radon levels. |
| | R9 | DSA should introduce and implement the concept of clearance. |
| 6. REVIEW AND ASSESSMENT | S15 | DSA should consider strengthening its review and assessment procedure to clarify the aspects that must be considered for different types of authorization, and subsequent amendments, renewal, suspension or revocation of the authorisation for all facilities and activities. |

| Area | R: Recommendations | Recommendations, Suggestions or Good Practices |
|-----------------------|--------------------|--|
| | S: Suggestions | |
| | G: Good Practices | |
| | R10 | DSA should review and assess safety assessments submitted by the applicant in accordance with clearly specified procedures in advance of the issuing of any licence in accordance with a graded approach. |
| | R11 | DSA should arrange, in accordance with a graded approach, for periodic assessments of the radiation doses to transport workers and members of the public associated with the transport of radioactive material. |
| | S16 | DSA should consider specifying the responsibilities of the licensees in the establishment and implementation of the environmental monitoring programme. |
| 7. INSPECTION | R12 | DSA should develop, implement, review and continuously improve the inspection process including establishing a long term programme of inspection according to criteria for selection of facilities and activities to be inspected consistent with a graded approach. |
| | GP2 | The formalized cooperation group of regulatory authorities, proactively devising joint guidelines and training for harmonising inspections and the performance of joint inspections, integrating radiation protection with overall health and safety aspects is identified as a good practice. |
| 8. ENFORCEMENT | R13 | DSA should develop and implement an enforcement policy that fulfils all requirements associated with enforcement mentioned in IAEA GSR Part 1 (Rev 1). |

| Area | R: Recommendations S: Suggestions G: Good Practices | Recommendations, Suggestions or Good Practices |
|---------------------------------|---|--|
| 9. REGULATION AND GUIDES | R14 | DSA should take actions for the further development, review and revision of regulations and guides to ensure that the regulatory framework is comprehensive. |
| | R15 | DSA, in coordination with other authorities, should harmonize its regulatory framework with all requirements of IAEA GSR Part 3 for the protection and safety of workers in planned exposure situations. |
| | S17 | DSA should consider implementing provisions to ensure the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation. |
| | R16 | The government should ensure that, as a result of consultation between the HOD, relevant professional bodies and DSA, the following are established: c) Dose constraints for exposures of carers and comforters and volunteers participating in a programme of biomedical research. d) Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures. |
| | R17 | The Government should ensure that the relevant authorities, in cooperation with relevant professional bodies, adopt a national set of referral guidelines for the justification of medical exposure for an individual patient in a radiological procedure. |

| Area | R: Recommendations | Recommendations, Suggestions or Good Practices |
|---|--------------------|---|
| | S: Suggestions | |
| | G: Good Practices | |
| 10.EMERGENCY PREPAREDNESS AND RESPONSE | R18 | DSA should ensure that arrangements are in place so that applicants under the RP Act submit the emergency response plans to the regulatory body for the approval or renewal of a license. |
| | R19 | The Government should put in place arrangements to ensure that assistance and support for the information and communication technologies are available to respond to an emergency situation. |
| | S18 | DSA should consider ensuring that arrangements are in place so that medical personnel, both general practitioners and medical emergency staff, are made aware of the clinical symptoms of radiation exposure and notification procedures to be taken. |
| | R20 | The Government should revise the legislation and regulations on emergency preparedness and response to ensure consistency with the IAEA Safety Standards GSR Part 7. |
| 11.INTERFACE WITH NUCLEAR SECURITY | R21 | The Government should revise the legal framework to ensure that the interface between safety and security is addressed for all facilities and activities and to establish a clear distinction between safety and security. |
| | S19 | DSA should consider developing a formal process to establish how the safety and security measures are reviewed and assessed in an integrated manner. |

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

REFERENCE MATERIAL PROVIDED BY DSA

| Nr | Name | Comment | English/ Norwegian |
|-------------|---|--|-------------------------------|
| 0001 | Act on radiation protection and use of radiation | Strålevernloven No. 36 of 12 May 2000 | English |
| 0002 | Nuclear Energy Act | Atomenergiloven No. 28, 12 May 1972 | English |
| 0003 | Regulation on Radiation Protection | Strålevernforskriften | English |
| 0004 | Security Act | Act of 20 March 1998 No. 10 relating to Protective Security Services (the Security Act) Sikkerhetsloven | English |
| 0005 | Regulations on Possession etc of Nuclear Material and Dual Use Equipment | Forskrift om besittelse, omsetning og transport av nukleært materiale og flerbruksvarer 12 May 2000 | English |
| 0006 | Regulations on the Physical Protection of Nuclear Material and Nuclear Facilities | Forskrift om fysisk beskyttelse av nukleære materialer 2 November 1984 | English |
| 0007 | Regulations on Protection of Norwegian National Assets | Forskrift om objektsikkerhet 22 October 2010 | English |
| 0008 | ADR/RID 2019 | ADR/RID Forskrift 1. april 2009 nr. 384 om landtransport av farlig gods, 2019 | Norwegian |
| 0009 | Intermediate storage solution for spent reactorfuel and long-lived intermediate level waste | Mellomlagerløsning for brukt reaktorbrensel og langlivet mellomaktivt avfall, NOU 2011:2 | Norwegian |
| 0010 | Alun shale – source to radioactive waste and radioactive pollution, NRPA Bulletin 7:2012 | Alunskifter – kilde til radioaktivt avfall og radioaktiv forurensning, Stråleverninfo 7:2012 | Norwegian |
| 0011 | IAEA INSARR Report Halden 2010 | IAEA INSARR Report Halden 2010 | English |

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| 0013 | Uranium in alun shale, sampling and measurement methods, NRPA Technical document 10:2016 | Uran i alunskifer, Prøvetaking og målemetoder, NRPA Teknisk dokument 10:2016 | Norwegian |
| 0014 | Regulation on the application of the Pollution Control Act to pollution and radioactive waste | Forskrift om forurensningslovens anvendelse på radioaktiv forurensning og radioaktivt avfall | English |
| 0015 | Act relating to procedure in cases concerning the public administration (Public Administration Act) | Forvaltningsloven | English |
| 0016 | Pollution Control Act | Pollution Control Act, 13 March 1981, No.6 Forurensningsloven, | English |
| 0017 | Norway's Topical Peer Review report 2017 | | English |
| 0018 | Norway Report for JC 2018 | Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. National Report from Norway to the sixth review meeting, 21 May – 1 June 2018. | English |
| 0019 | 7th National Report for Norway CNS2017 | Implementation of the obligations of the Convention on Nuclear Safety in Norway. The seventh Norwegian Report in Accordance with Article 5 of the Convention | English |
| 0020 | Nuclear Preparedness - Central and Regional Organisation - Royal Decree of 23 august 2013 | Atomberedskap – sentral og regional organisering, Kgl. Res. av 23. august 2013, StrålevernHefte 31 | English |
| 0021 | Strategic Action Plan 2018-2020 | Strategisk plan for Strålevernet 2018-2020 | English |
| 0022 | Protocol for Radon measurements in schools and kindergartens | Måleprosedyre for radon i skoler og barnehager | English |
| 0023 | Act on a national register for land information | Matrikkelloven | English |

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| 0024 | Regulations relating to pollution control [Pollution regulations] | Forurensningsforskriften Para. 2-9 | English |
| 0025 | Organisational chart NRPA | January 2018 | English |
| 0026 | Overview of Acting Management | Fungeringsoversikt ledere | Norwegian |
| 0027 | Cooperation between Norway, Slovakia and Ukraine to prevent smuggling of hazardous materials | Cooperation between Norway, Slovakia and Ukraine to prevent smuggling of hazardous materials NRPA Bulletin/Strålevernrapport 10:2017 | English |
| 0028 | Nuclear Safety Cooperation between Norway and Romania under Norway Grants | NRPA Bulletin/StrålevernRapport 7:2015 | English |
| 0029 | Internal control regulations | Internkontrollforskriften | English |
| 0030 | Regulations on impact assessments | Forskrift om konsekvensvurderinger | English |
| 0031 | Directive for the Norwegian Radiation Protection Authority 2018 | Instruks Statens Strålevern 2018 | English |
| 0032 | Letter of Commitment, Norwegian Radiation Protection Authority 2018 | Tildelingsbrev Statens Strålevern 2018 | English |
| 0033 | Communication Strategy for the Crisis Committee for Nuclear Preparedness | Kommunikasjonsstrategi for Kriseutvalget ved atomulykker | English |
| 0034 | The Crisis Committee's Communication Plans | Kriseutvalgets kommunikasjonsplaner | English |
| 0035 | Directive concerning the work of the ministries relating to public security (the Public Security Directive) | Instruks for departementenes arbeid med samfunnssikkerhet (samfunnssikkerhetsinstruksen) | English |
| 0036 | The Norwegian Radiation Protection Authority's new recommendations concerning radon in Norway | Strålevernets nye anbefalinger for radon i Norge, Stråleverninfo 25:2009 | English |

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| 0038 | Kompetansekartlegging - prosess | Mapping of competence | Norwegian |
| 0039 | Underskriftsfullmakter | Signature Decision Document | Norwegian |
| 0040 | Årshjulet | Year Decision Wheel | Norwegian |
| 0041 | Bnotat: Felles kvalitetssystem | Quality Management System | Norwegian |
| 0042 | Omorganiseringsbeslutning 2012 | Organisation Decision Document 2012 | Norwegian |
| 0043 | Organisation Decision Document 2018 | Organisasjonsjusteringer fom 2018 | Norwegian |
| 0044 | Fungeringsoversikt ledere | Acting Management Document | Norwegian |
| 0045 | Nuclear Safety Romania 13-2013 | Nuclear safety cooperation between Norway and Romania under EEA and Norway Grants NRPA Bulletin 13:2013 | English |
| 0046 | Repository for Norwegian low- and mediumlevel nuclear waste | Deponi for norsk lav- og middelaktivt atomavfall | Norwegian |
| 0047 | Evaluation of strategies for final storage of high-active reactor fuel | Vurdering av strategier for sluttlagring av høyaktivt reaktorbrensel, NOU 2001:30 | Norwegian |
| 0048 | Measurement Procedure for Radon in Homes | Måleprosedyre for radon i boliger | English |
| 0049 | Concerning supervision of health-related circumstances linked to the letting of residential properties and concerning action and limit values for radon in rental properties, preschools and schools | Om tilsyn med helsemessige forhold ved utleie av boliger og om tiltaks- og grenseverdier for radon i utleieboliger, barnehager og skoler, IS-8/2013 | English |
| 0050 | Plan for the Crisis Committee for Nuclear Preparedness | Plan for Kriseutvalget for atomberedskap | English |

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| 0051 | Radon from extraneous material under buildings – recommended limit value | Radon fra tilkjørte masser under bygg – anbefalt grenseverdi, Stråleverninfo 6: 2015 | English |
| 0052 | Regulations on technical requirements for building works (TEKI7) | TEKI7 - Veiledning om tekniske krav til byggverk Veiledning om tekniske krav til byggverk, kapittel 13, § 13-5 Radon | English |
| 0053 | Guide to the monitoring of radon in schools, preschools and rental properties | Veileder i tilsyn med radon i skoler, barnehager og utleieboliger, 2016 | English |
| 0054 | Operating Plan for Department of Nuclear Safety and Environmental Radioactivity 2018 | Virksomhetsplan for Avdeling Sikkerhet, Beredskap og Miljø 2018 | Norwegian |
| 0055 | Operating Plan for Department of Radiation Applications 2018 | Virksomhetsplan for Avdeling Strålebruk 2018 | Norwegian |
| 0056 | Ethical guidelines for the public service 2005 | Etiske retningslinjer for statstjenesten | English |
| 0057 | Strategy for the reduction of Radon exposure in Norway | | English |
| 0058 | Kartlegging av radon i 114 kommuner, Strålevernrapport 2001:6 | Mapping of radon in 114 communities, NRPA Bulletin 2001:6 | Norwegian |
| 0059 | Radon i nye boliger, StrålevernRapport 2017:3 | Radon in new houses, NRPA Bulletin 2017:3 | Norwegian |
| 0060 | Årstidsvariasjoner i skoler og barnehager med balansert ventilasjon | Yearly variations in schools and kindergartens, NRPA Report | Norwegian |
| 0061 | Forskrift om visse forurensende stoffer i næringsmidler | Regulation on contaminated materials in food | Norwegian |
| 0062 | Forskrift om særlige regler for gjennomføringen av offentlig kontroll av produkter av animalsk opprinnelse beregnet på konsum (animaliekontrollforskriften) | Regulation on certain rules for regulatory control of animal products intended for food | Norwegian |
| 0063 | Forskrift om soneinndeling i forbindelse med nedføring pga. radioaktivitet, 2005 | Regulation on the zone division related to changed feeding pattern due to radioactivity, 2005 | Norwegian |

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| 0064 | Protective Measures in Early and Intermediate Phases of a Nuclear or Radiological Emergency | | English |
| 0065 | Risk Assessment of radioactivity in food | Risk assessment of radioactivity in food, Opinion of the Scientific Committee of the Norwegian Scientific Committee for Food Safety, VKM Report 2017:25 | English |
| 0066 | Permission TU16-07 | Tillatelse TU16-07 etter forurensningsloven til mottak og deponering av radioaktivt avfall og utslipp av radioaktive stoffer | Norwegian |
| 0067 | Working Environment Act | Arbeidsmiljøloven | English |
| 0068 | Yrkeseksponering i Norge, Ioniserende stråling, Ikke-ioniserende stråling | Radiation exposure of workers in Norway. StrålevernRapport 2005:15 | Norwegian |
| 0069 | Tiltak mot radon i eksisterende boliger | Measures against radon in existing houses, NRPA Report 7, 2018 | Norwegian |
| 0070 | Tilsyn med radon i skoler | Inspection with radon at schools, NRPA Bulletin 4, 2017 | Norwegian |
| 0071 | Mandate for the Coordination Group responsible for following up the government's National Radon Strategy 2015-2020 | Mandat for Koordineringsgruppen for oppfølging av regjeringens radonstrategi 2015-2020 | English |
| 0072 | Risk in a Safe and Secure Society Norwegian Ministry of Justice and Public Security On Public Security, Report to the Storting, White Paper 2016-2017 | | English |
| 0073 | NGU report 2007: Radioactivity from old mines | NGU rapport 2007: Radioaktivitet fra gamle gruver | Norwegian |
| 0074 | NRPA 2015:13. Radiation doses to the Norwegian Population | StrålevernRapport 13/2015 NRPA Bulletin 13/2015 | English |

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| 0075 | NRPA 2017:10. Radioactivity in Norwegian Food | Radioaktivitet i norsk mat, StrålevernRapport 10/2017 NRPA Bulletin 10/2017 | Norwegian |
| 0076 | Guidelines for application for permit for radioactive pollution and handling of radioactive waste | Retningslinjer for søknad om tillatelse til radioaktiv forurensning og håndtering av radioaktivt avfall | Norwegian |
| 0077 | The ERICA Tool_2008 | | English |
| 0078 | NIVI Survey 2017 on the population's knowledge and opinions on radiation protection and preparedness | Nasjonalt Strålevernbarometer | Norwegian |
| 0079 | KS-1: future decommissioning of nuclear facilities in Norway | Only Table of Contents | English |
| 0080 | Guidelines biomedical research | Guideline from NRPA on Radiation Protection in Biomedical Research | English |
| 0081 | Veileder om strålebruk innen odontologi, Veileder nr. 14 | NRPA Guidelines no 14 Use of radiation in Odontology | Norwegian |
| 0082 | Veileder om nukleærmedisin, Veileder nr. 10 | NRPA Guidelines no 10 Nuclear Medicine | Norwegian |
| 0083 | Veileder om stråleterapi, Veileder nr. 6 | NRPA Guidelines no 6 Radiation therapy | Norwegian |
| 0084 | Veileder om medisinsk bruk av røntgen og MR apparatur, Veileder 5 | NRPA Guidelines no 5 Medical use of x-ray- and MRapparatuses. | Norwegian |
| 0085 | Strålevern i utdanningen for helsepersonell, Strålevernrapport 2014:5 | NRPA Report 2014:5, Radiation Protection education for selected medical professions involved with ionising radiation | Norwegian |
| 0086 | Representative doser i Norge 2017, Strålevernrapport 2018:3 | NRPA Report 2018:3, Representative doses in Norway | Norwegian |

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| 0087 | Kliniske revisjoner av stråleterapi ved brystkreft ved norske stråleterapientheter i perioden 2009-2011, Strålevernrapport 2014:8 | NRPA Report 2014:8, Clinical audit for breast cancer radiotherapy in Norway | Norwegian |
| 0088 | Om kvalitetskontroll-av linac, Strålevernrapport-2010:3 | NRPA Report 2010:3, Quality assurance of linear accelerators | Norwegian |
| 0089 | Pilotprosjekt for kliniske revisjoner i stråleterapi, Strålevernrapport 2004:9 | NRPA Report 2014:9, Pilot project for clinical audits in radiotherapy | Norwegian |
| 0090 | Virksomhetsrapportering i stråleterapi - definisjoner og beskrivelser 2001-2002, Strålevernrapport 2003:10 | NRPA Report 2003:10, On activity reporting for radiotherapy | Norwegian |
| 0091 | Reviderte og nye nasjonale referanseverdier for røntgendiagnostikk og intervensjon per 2018, Stråleverninfo 2018:3 | NRPA Pamphlet 2018:3, National reference levels for radiological and interventional procedures. | Norwegian |
| 0092 | Diagnostiske referansenivå for nukleaermedisinske undersøkingar, Stråleverninfo 2010:3 | NRPA Pamphlet 2010:3, On diagnostic reference levels in Nuclear Medicine | Norwegian |
| 0093 | Radiation Protection 100 | Radiation Protection 100 Guidance for protection of unborn children and infants irradiated due to parental medical exposures | English |
| 0094 | Radiation Protection 99 | Radiation Protection 99 Guidance on medical exposures in medical and biomedical research | English |
| 0095 | Radiation Protection 97 | Radiation Protection 97 following I-131 therapy | English |
| 0096 | Henvisningsveileder - Helsedirektoratet | National referral guidelines - Directorate of health | Norwegian |
| 0097 | Curriculum for medical specialist in Radiology | Curriculum DNLF Radiologi | Norwegian |

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| 0098 | Curriculum for medical specialist in Oncology | Curriculum DNLF onkologi | Norwegian |
| 0099 | Curriculum for medical specialist in Nuclear Medicine | Curriculum DNLF Nukleærmedisin | Norwegian |
| 0100 | Council Directive Concerning Medical Devices | Council Directive 93-42-EEC | English |
| 0101 | HERCA statement on I-131 Treatment Release Criteria | | English |
| 0102 | Handlingsprogram thyroideakreft | National guideline for diagnostics and treatment of thyroidal cancer | Norwegian |
| 0103 | KVU: future decommissioning of nuclear facilities in Norway | Table of Contents | English |
| 0104 | NRPA Guideline no. 1: industrial radiography | Veileder 1: industriell radiografi | Norwegian |
| 0105 | NRPA Guideline no. 2: use of unsealed radioactive material in laboratories | Veileder 2: bruk av åpne radioaktive kilder i laboratorium | Norwegian |
| 0106 | NRPA Guideline no. 9: use of nuclear gauges | Veileder 9: industrielle kontrollkilder | Norwegian |
| 0107 | Permission for radioactive waste | Tillatelse etter forurensningsloven for mottak og deponering av radioaktivt avfall Wergeland-Halsvik AS | Norwegian |
| 0108 | Regulations concerning the design and layout of workplaces and work premises (the Workplace Regulations) | Forskrift om utforming og innretning av arbeidsplasser og arbeidslokaler (arbeidsplassforskriften) | English |
| 0109 | Letter to undertakings performing industrial radiography – new requirements concerning security of radioactive sources | Brev til virksomheter som utfører industriell radiografi – skjerpede krav til sikring | Norwegian |
| 0110 | Investigation of need for capacity for treatment and handling of radioactive waste until 2035 | Utredning av behov for kapasitet til behandling og håndtering av radioaktivt avfall fram mot 2035 | Norwegian |

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| 0111 | Strand T., SCS rapport 2007. Radon in household water from ground water sources in Norway, summary of measurements by NRPA 1996-1998 | Radon i husholdningsvann fra grunnvannskilder i Norge - Kort oppsummering av målinger utført av Statens strålevern i perioden 1996-98 | Norwegian |
| 0112 | The Regulations concerning the performance of work, use of work equipment and related technical requirements | Forskrift om utførelse av arbeid, bruk av arbeidsutstyr og tilhørende tekniske krav (forskrift om utførelse av arbeid) | English |
| 0113 | Regulations concerning Action and Limit values | Forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier) | English |
| 0114 | Regulations concerning Organisation, Management and Employee Participation | Forskrift om organisering, ledelse og medvirkning | English |
| 0115 | Act relating to the right of access to documents held by public authorities and public undertakings (Freedom of Information Act) | Lov om rett til innsyn i dokument i offentlig verksemd (offentleglova) | English |
| 0116 | NRPA's communication strategy | Strålevernets kommunikasjonsstrategi | English |
| 0117 | Proposition 1 S for 2018, Chapter 747 and 3747 | Proposisjon 1 S for budsjettåret 2018, kapittel 747 and 3747 | English |
| 0118 | The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway (powerpoint) | Presentation "The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway" | English |
| 0119 | Process map | | English |
| 0120 | Advisory Committee on Nuclear Safety and Radioactive Waste Management (AC NS & RWM) - Terms of Reference | | English |

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| 0121 | Nuclear Safety and Security – The Norwegian Government’s Action Plan 2018-2022 | Atomsikkerhet og Miljø - Regjeringens handlingsplan 2018–2022 | English |
| 0122 | Skuterud and Thørring, 2012: Averted doses to Norwegian Sami Reindeer Herders after the Chernobyl accident | | English |
| 0123 | Liland and Skuterud, 2013: How long is longterm? Reflections based on 20 years of postChernobyl management in Norway | | English |
| 0124 | Regulation on waste, Chapter 16 | Avfallsforskriften kapittel 16 | English |
| 0125 | The Planning and Building Act - planning part | Plan- og bygningsloven planlegging | English |
| 0126 | The planning and building act - building part | Plan og bygningsloven – bygging | English |
| 0127 | Permission TU15-03 | Tillatelse TU15-03 etter forurensningsloven for mottak og håndtering av radioaktivt avfall | Norwegian |
| 0128 | Quality assurance in radiotherapy on a national level: experience from Norway - the kvist initiative | Hellebust et al, Journal of Radiotherapy in Practice (2014) 13, 35–44 | English |
| 0129 | Assessment of dose from discharges to air to the environment from St. Olavs Hospital | | English |
| 0130 | Initial radiological assessment methodology part 1- user report | | English |
| 0131 | Initial radiological assessment methodology part 2 - methods and input data | | English |

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| 0132 | Regulatory requirements for decommissioning of facilities | | English |
| 0133 | The Norwegian Radiation Protection Authority's recommendation regarding a licence pursuant to Section 10 of the Nuclear Energy Activities Act, December 2018 | The Norwegian Radiation Protection Authority's recommendation pursuant to Section 10 of the Nuclear Energy Activities Act regarding the Institute for Energy Technology's application for renewal of its licence to own and operate nuclear facilities at Kjeller and the fuel instrument workshop on Os allé, Halden from 1 January 2019 Statens stråleverns innstilling til konsesjon etter atomenergiloven §10, Kjeller og brenselinstrumentverkstedet i Halden, fra 1. januar 2019 | English |
| 0134 | Forskrift om farlig last på norske skip | Regulations on Dangerous Goods on Norwegian Ships, No. 944, of 1 July 2014 | Norwegian |
| 0135 | Forskrift om landtransport av farlig gods | Regulations on Transportation of Dangerous Goods by Land, No. 384, of 1 April 2009 | Norwegian |
| 0136 | Forskrift om transport av gods i luftfartøy | Regulations on the Transport of Goods in Aircraft (BSL D 1-7), No. 41, 11 January 2003 | Norwegian |
| 0137 | Lov om skipssikkerhet | Act Relating to Ship Safety and Security, No. 9, 16 February 2007 | Norwegian |
| 0138 | DSA Specific Guidance for the General Licence Conditions (Draft) | | English |

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| 0139 | Generelle vilkår for vurdering av søknader om konsesjon etter atomenergiloven | General Conditions for evaluating applications for licence under the Nuclear Energy Act The conditions in this document is the same as the general licence conditions for IFE/Kjeller for 20192028. | Norwegian |
| 0140 | Nuclear Installation Authorization Procedure (Draft) | | English |
| 0141 | Review and Assessment Procedure (draft) | | English |
| 0142 | Forskrift om forurensningslovens anvendelse på radioaktiv forurensning og radioaktivt avfall – delegering av myndighet etter forurensningsloven til Statens Strålevern | Regulation on the use of the Pollution Control Act on radioactive pollution and radioactive waste | Norwegian |
| 0143 | The management regulations | Regulations relating to management and the duty to provide information in the petroleum activities and at certain onshore facilities (the management regulations) | English |
| 0144 | Risikoklassifisering tilsynsområder, avdeling strålebruk | Classification of risk in inspection areas | Norwegian |
| 0145 | Act on use of X-ray and radium etc. | Lov om bruk av røntgenstråler og radium m.v. | Norwegian |
| 0146 | Veileder for bruk av tvangsmulkt | Procedure for imposing coercive fine | Norwegian |
| 0147 | Prosedyre for vedtak om pålegg | Procedure for issuing order of rectification | Norwegian |
| 0148 | Prosedyre for pålegg om opplysninger | Procedure for issuing order to supply information | Norwegian |
| 0149 | Prosedyre for forhåndsvarsel | Procedure for issuing advance notification | Norwegian |

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| 0150 | Forberedelse til behandling av godkjenningssøknad | Preparations for review of licence application | Norwegian |
| 0151 | Prosedyre for gjennomgang av godkjenningssøknad | Preparations for review of licence application | Norwegian |
| 0152 | Utstede godkjenning – gi svar på søknad | Issue licence – reply to application | Norwegian |
| 0153 | Beslutningsnotat: Etablering av et integrert styringssystem | Bnotat Integrated Management System | Norwegian |
| 0154 | Meeting minutes: Radiation protection coordination meeting, Helse Sør-Øst | Møtereferat: Koordineringsmøte strålevern | English |
| 0155 | Guidelines for annual reporting to the Norwegian Radiation Protection Authority by enterprises which handle radioactive waste | Retningslinjer for årlig rapportering til Statens strålevern for virksomheter som håndterer radioaktivt avfall | English |
| 0156 | Recommendation concerning licence for continued operation of combined storage facility and landfill site for radioactive waste, KLDRA Himdalen | Innstilling om konsesjon for videre drift av kombinert lager og deponi for radioaktivt avfall, KLDRA Himdalen | English |
| 0157 | DSA General Guidance for the General Licence Conditions (Draft) | | English |
| 0158 | Prosedyre for planlegging av tilsynsvirksomhet | Procedure for planning of inspections by NRPA | Norwegian |
| 0159 | Prosedyre for gjennomføring av stedlig tilsyn | Procedure for inspections | Norwegian |
| 0160 | Prosedyre for forberedelse av tilsyn | Procedure for preparing an inspection | Norwegian |
| 0161 | Mal intervju skjema tilsyn Straaleterapi | Template for interviews radiotherapy facilities | Norwegian |
| 0162 | Mal intervju skjema tilsyn Rtg Diagnostikk | Template for interviews general x-ray facilities | Norwegian |

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| 0163 | Mal intervju skjema tilsyn NM | Template for interviews nuclear medicine facilities | Norwegian |
| 0164 | Mal for tilsynsrapport | Template for inspection report | Norwegian |
| 0165 | Mal Avslutningsmøte etter tilsyn | Template closing meeting after inspection | Norwegian |
| 0166 | Mal Avslutning av tilsynet | Template closing of the inspection | Norwegian |
| 0167 | Mal Åpningsmøte ved tilsyn | Template opening meeting at inspection | Norwegian |
| 0168 | Mal Agenda for tilsyn | Template agenda for inspection | Norwegian |
| 0169 | Radiation Protection 175 | Guidelines on radiation protection education and training of medical professionals in the European Union | English |
| 0170 | Prosedyre for oppfølging av tilsyn | Procedure for the follow up after the inspection | Norwegian |
| 0171 | Varsel om Tilsyn_mal_DSA | Template for letter of notice | Norwegian |
| 0172 | Tilsynsmyndighetenes retningslinje for samordnet tilsyn og felles tilsynsprofil, 6. mars 2014 | The regulator bodies guidelines for coordinated inspection and mutual inspection profile, 6 March 2014 | Norwegian |
| 0173 | Brudd på myndighetskrav | DSA Procedure | Norwegian |
| 0174 | Tilsynsstrategi | Inspection strategy | Norwegian |
| 0175 | Søknader etter forurensningsloven | DSA Procedure | Norwegian |
| 0176 | Environmental investigation by NRPA in Tromsø Harbour | | Norwegian |

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| 0177 | Royal decree on licence for Institute for Energy Technology nuclear facilities in Kjeller and the fuel instrumentation workshop in Halden | Kongelig resolusjon for Institutt for energiteknikk atomanlegg på Kjeller og brenselsinstrumentverksted i Os allé i Halden | Norwegian |
| 0178 | Royal decree on renewed licence for Institute of Energy Technology nuclear facilities in Halden | Fornytt konsesjon for Institutt for energiteknikk atomanlegg i Halden | Norwegian |
| 0179 | Application for amendment to Permit TU12-272 granted to Sørlandet sykehus HF, Kristiansand | Søknad om endring av Tillatelse TU12-27-2 gitt til Sørlandet sykehus HF, Kristiansand | English |
| 0180 | Permit TU13-38 pursuant to the Norwegian Pollution Control Act for the disposal and storage of radioactive waste at a combined storage and landfill facility for low- and medium-level radioactive waste (KLDRA) | Tillatelse TU13-38 etter forurensningsloven for deponering og lagring av radioaktivt avfall i kombinert lager og deponi for lav- og middelsaktivt radioaktivt avfall (KLDRA) | English |
| 0181 | Guidelines for the reporting of radioactive substances from the petroleum industry | Retningslinjer for rapportering av radioaktive stoffer fra petroleumsvirksomheten | English |
| 0182 | Sørlandet Sykehus – Sub-plan for Nuclear and radiation accidents | Sørlandet Sykehus – Delplan atom- og stråleulykker | English |
| 0183 | Permit TU13-32-2 in accordance with the Norwegian Pollution Control Act to discharge radioactive substances and handle radioactive waste St. Olavs hospital HF | Tillatelse TU13-32-2 etter forurensningsloven for utslipp av radioaktive stoffer og håndtering av radioaktivt avfall, St. Olavs hospital HF | English |
| 0184 | Iodine tablets to municipalities and the public | | English |
| 0185 | Strålevernrapport 2018:10: Endringer i trusselbildet. Trusselvurdering for Kriseutvalget for atomberedskap, 2018 | NRPA Report 2018:10 | Norwegian |

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| 0186 | DSA prosedyre IAEAs stående komiteer | DSA Procedure IAEA standing committees | Norwegian |
| 0187 | DSA prosedyre: Deltakelse på internasjonale møter og konferanser | DSA procedure: Participation in international meetings and conferences | Norwegian |
| 0188 | Application for change in permit from NOAH Langøya | Disposal of alum shale via landfill for ordinary waste. Application for amendment to permit no. TU13-56 for activity pursuant to the Norwegian Pollution Control Act for NOAH's facility on Langøya, June 2016 Deponering av alunskifer i deponi for ordinært avfall. Søknad om endring av tillatelse nr. TU13-56 til virksomhet etter Forurensningsloven for NOAH's anlegg på Langøya, juni 2016 | Norwegian |
| 0189 | Closure and post-closure plan current, NOAH Langøya | Avslutnings – og etterdriftsplan, Nordbruddet, 30.12.2014 | Norwegian |
| 0190 | DSA Internasjonal strategi for 2019-2023 | DSA International Strategy 2019-2023 | Norwegian |
| 0191 | NRPA Licence Recommendation IFE/Halden 2014 | The Norwegian Radiation Protection Authority's Recommendation Regarding the Institute for Energy Technology's Application for Renewal of the Permit to Own and Operate the Halden Reactor and Associated Fuel Storage Facilities after 31 December 2014 Konsesjonsinnstilling Halden 2014 | English |

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| 0192 | NOAH Langøya permit TU17-10 | Permit TU17-10 pursuant to the Norwegian Pollution Control Act to receive and dispose of radioactive waste and discharge radioactive substances from NOAH AS, Langøya Tillatelse TU17-10 etter forurensningsloven til mottak og deponering av radioaktivt avfall og utslipp av radioaktive stoffer fra NOAH AS, Langøya | English |
| 0193 | Service statement NRPA | Serviceerklæring NRPA | Norwegian |
| 0194 | Regulations relating to health, safety and the environment in the petroleum activities and at certain onshore facilities (the framework regulations) | Forskrift om helse, miljø og sikkerhet i petroleumsvirksomheten og på enkelte landanlegg (rammeforskriften) | English |
| 0195 | The supervisory authorities' guidelines regarding coordinated supervision and a joint supervision profile | Tilsynsmyndighetenes retningslinje for samordnet tilsyn og felles tilsynsprofil | English |
| 0196 | Application form for industrial radiography | Søknad om godkjenning | Norwegian |
| 0197 | Guidelines for applying for a permit under the Pollution Control Act for radioactive discharges and for the management of radioactive waste | | English |
| 0198 | Agreement between MD-HOD on the use of NRPA, 25 October 2005 | Avtale mellom MD-HOD om bruk av Strålevernet, 25. oktober 2005 | Norwegian |
| 0199 | Agreement between NRPA and the Norwegian Metrology Service, 12 March 2010 | Avtale mellom Strålevernet og Justervesenet, 12. mars 2010 | Norwegian |
| 0200 | Agreement between MFA-HOD on the use of NRPA, 25 October 2005 | Avtale mellom MD-HOD om bruk av Strålevernet, 25. oktober 2005 | Norwegian |
| 0201 | Codicils to Regulations on Radiation Protection and Use of Radiation | Merknader til de enkelte bestemmelsene i forskrift om strålevern og bruk av stråling (strålevernforskriften) | Norwegian |

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| 0202 | Basic agreement for the civil service purpose of the agreement and intentions of the parties, 2017-2019 | Hovedavtalen i staten, 2017-2019 | English |
| 0203 | Agreement NRPA-NHN, November 2017 | Avtale for levering av tjenester innenfor områdene IKT, anskaffelser og arkiv, 27. November 2017 | Norwegian |
| 0204 | The constitution of the Kingdom of Norway | Norges grunnlov | English |
| 0205 | Public Procurement Regulation | Forskrift om offentlige anskaffelser (anskaffelsesforskriften) | Norwegian |
| 0206 | Public Procurement Act | Lov om offentlige anskaffelser (anskaffelsesloven) | Norwegian |
| 0207 | Auditor General Act | Lov om Riksrevisjonen | Norwegian |
| 0208 | Archive Depot Act | Lov om arkiv [arkivlova] | Norwegian |
| 0209 | The Act on duty of information, quarantine and prohibition of politicians, officials and government employees (Quarantine Act) | Lov om informasjonsplikt, karantene og saksforbud for politikere, embetsmenn og statsansatte (karantene-loven) | Norwegian |
| 0210 | Government Employee Act | Lov om statens ansatte mv. (statsansatteloven) | Norwegian |
| 0211 | Act on units of measurement, measurements and standard time | Lov om målenheter, måling og normaltid | English |
| 0212 | Allocation Letter of Commitment (118.21/118.70) | Belastningsfullmakt 118.21 / 118.70 | Norwegian |
| 0213 | Allocation Letter of Commitment (118.01/118.71) | Belastningsfullmakt NorNed 118.01 / 118.71 | Norwegian |

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| 0214 | The Air Traffic Act | Table of contents. Whole document here: Norwegian https://lovdata.no/dokument/NL/lov/1993-06-11 https://lovdata.no/dokument/NL/lov/1993-06-11-101?q=lov%20om%20luftfart101?q=lov om luftfart Lov om luftfart | Norwegian |
| 0215 | Short guidelines about the Public Administration Acts chapter about disqualification | Regler om habilitet | Norwegian |
| 0216 | The Fire and Explosion Protection Act | Lov om vern mot brann, eksplosjon og ulykker med farlig stoff og om brannvesenets redningsoppgaver (brann- og eksplosjonsvernloven) | Norwegian |
| 0217 | Export Licence Act | Lov om kontroll med eksport av strategiske varer, tjenester og teknologi m.v. [eksportkontrollloven] | Norwegian |
| 0218 | Act on State Supervision of Health and Care Services | Lov om statlig tilsyn med helse- og omsorgstjenesten m.m. (helsetilsynsloven) | Norwegian |
| 0219 | Specialized Health Services Act | Lov om spesialisthelsetjenesten m.m. (spesialisthelsetjenesteloven) | Norwegian |
| 0220 | The Health Personnel Act | Lov om helsepersonell m.v. (helsepersonelloven) | Norwegian |
| 0221 | Patient- and User Rights Act | Lov om pasient- og brukerrettigheter (pasient- og brukerrettighetsloven) | Norwegian |
| 0222 | Regulations relating to the Recycling of Waste | Table of contents. Whole document here: Norwegian https://lovdata.no/dokument/SF/forskrift/2004-06-01 https://lovdata.no/dokument/SF/forskrift/2004-06-01-930930 Forskrift om gjenvinning og behandling av avfall (avfallsforskriften) | Norwegian |

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| 0223 | Prioritisation regulation | Regulations on the prioritization of health services, the right to necessary health care from the specialist health service, the right to treatment abroad and the complaints board Forskrift om prioritering av helsetjenester, rett til nødvendig helsehjelp fra spesialisthelsetjenesten, rett til behandling i utlandet og om klagenemnd (prioriteringsforskriften) | Norwegian |
| 0224 | Regulations no. 1373 of 29 November 2013 Relating to Handling of Medical Equipment and Devices | Forskrift om håndtering av medisinsk utstyr | Norwegian |
| 0225 | Regulations no. 1690 of 15 December 2005 Relating to Medical Equipment | Forskrift om medisinsk utstyr | Norwegian |
| 0226 | Act no. 4 of 24 May 1929 Relating to Inspection of Electrical Installations and Electrical Equipment | Lov om tilsyn med elektriske anlegg og elektrisk utstyr (el-tilsynsloven) | Norwegian |
| 0227 | Application form for licence for well logging | Søknadsskjema godkjenning for brønnlogging | Norwegian |
| 0228 | Application form for licence for comprehensive non-medical use of radiation in research | Søknadsskjema godkjenning for omfattende ikkemedisinsk strålebruk | Norwegian |
| 0229 | Inspection check list for industrial gauges | Tilsynsskjema industrielle kontrollkilder | Norwegian |
| 0230 | Inspection check list for industrial radiography | Tilsynsskjema industriell radiografi | Norwegian |
| 0231 | National Governmental Personnel Manual - Table of contents | Statens personallhåndbok 2019 (innholdsfortegnelse) The whole document: https://lovdata.no/dokument/SPH/sph-2019 | Norwegian |

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| 0232 | DSA Safety Culture Policy Statement | Draft version | English |
| 0233 | DSA Nuclear security culture policy statement | Draft version | English |
| 0234 | DSA Procedure for signing letters | DSA Prosedyre: Underskrive brev | Norwegian |
| 0235 | Guidelines on radioactive pollution and radioactive waste from the petroleum industry, NRPA Guideline nr. 13 | Veiledning om radioaktiv forurensning og radioaktivt avfall fra petroleumsvirksomheten, NRPA Veileder no. 13 | Norwegian |
| 0236 | Invitation to all the country's health authorities | | English |
| 0237 | Application for change of authorisation TU1332-1 | | English |
| 0238 | Ot.prp.nr.88 (1998-1999) Regarding the Radiation Protection Act | Ot.prp.nr.88 (1998–1999) Om lov om strålevern og bruk av stråling | English / Norwegian |
| 0239 | Ot.prp.nr.51 (1970-1971) Regarding the Nuclear Energy Act. | Ot.prp.nr.51 (1970–1971) Om lov om atomenergivirksomhet | English / Norwegian |
| 0240 | Ot.prp.nr.11 (1979-1980) Regarding the Norwegian Pollution Control Act | Ot.prp.nr.11 (1979–1980) Om lov om vern mot Forurensninger og om avfal (Forurensningsloven) | English/Norwegian |

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

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- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).
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- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).
- [8] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).
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- [12] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).
- [13] INTERNATIONAL ATOMIC ENERGY AGENCY, Site Evaluation for Nuclear Installations, IAEA Safety Standards Series No. SSR-1, IAEA, Vienna (2019).
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APPENDIX VIII ORGANIZATION CHARTS

