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IRRS ARM Summary Report Norway, 2019

Norwegian Radiation and Nuclear Safety Authority

Direktoratet for strålevern og atomsikkerhet (DSA)

Østerås, 2019,
Norway

Contents

BACKGROUND

GENERAL INFORMATION

Norway forms the western and northern part of the Scandinavian Peninsula and has common land borders with Sweden, Finland and Russia. The kingdom of Norway also includes Svalbard and Jan Mayen. Norway's total area is 385 180 square kilometers. The population of Norway is approximately 5,3 million. Oslo is the capital and the largest city in Norway.

The petroleum industry is Norway's largest industry. Norway is currently the 8th largest producer of oil and the 3rd largest producer of gas in the world. The country has one of the highest per capita incomes in the world. It has the world's largest sovereign wealth fund.

Norway is a constitutional monarchy.The Norwegian Constitution was adopted on 17 May 1814. The Constitution establishes three different branches of government:

- → Legislative, budgetary and supervisory power is vested in the Storting (Norwegian Parliament);
- → Executive power is vested in the King in Council (the Government);
- → Judicial power is vested in the Supreme Courts and the subordinate courts, and in the Court of Impeachment (Riksretten).

The Executive Power is with the Government; in the Constitution and the laws, the King is referred to, for example in legislation, to mean the King in Counsel or the Government. According to article 3 of the Constitution, the Executive Power is vested in the King. However, Royal resolutions are always adopted by the King in Council (articles 27 and following). The countersignature of the Prime Minister is a prerequisite for the validity of the above, political leadership is incontestably exercised by the Cabinet (the Government), on which the constitutional and parliamentary responsibility of the Executive is bestowed.

Members of the Storting (parliament) are elected for four-year terms through general elections based on universal suffrage. The Storting has 169 members and it cannot be dissolved during its four-year term. Until the introduction of parliamentarianism in 1884, a government remained in office as long as the King wished; since then governments have been dependent on having the confidence of the Storting. It devolves upon the Storting to enact and repeal laws; to impose taxes, dues, customs and other public charges. The national budget is proposed by the Government, but adopted by the Storting on a yearly basis (article 75 of the Constitution).

Norway has both administrative and political subdivisions on two levels: counties and municipalities. The Sámi people have a certain amount of self-determination and influence over traditional territories through the Sámi Parliament and the Finnmark Act. Norway is a founding member of the United Nations, NATO, the European Free Trade Association, the Council of Europe, the Antarctic treaty, the Nordic Council and a member of the European Economic Area, the WTO and is a part of the Schengen Area.

NUCLEAR PROGRAMME

The Norwegian Radiation and Nuclear Safety Authority (DSA) regulates the safety and security of the Norwegian nuclear facilities; the two research reactors at Kjeller near Lillestrøm and in Halden, the adjacent facilities, and the waste repository in Himdalen in Akershus county. The three facilities are run by the Institute for Energy Technology (IFE). IFE is an independent research foundation with a total staff of approximately 600 employees. DSA's authority also extends to the supervision of the transport of

radioactive substances to and from these facilities, as well as the processing, storage and disposal of radioactive waste.

The Research Reactors and Adjacent Facilities

The energy production of the Norwegian reactors is respectively about 0.07 % (Kjeller) and 0.7 % (Halden) that of a typical nuclear power plant.

The reactor in Halden (HBWR) is a 25 MW research reactor and has been operated since 1959. The licence expires in December 2020. IFE must submit a new application for a licence to own and operate the reactor before September 2019. The reactor has been shut down since February 2018 and, in June 2018, IFE announced that the reactor would be permanently shut down and that preparations for the decommissioning phase would start. Activities that have been connected to HBWR are as follows:

- → OECD Halden Project for nuclear safety research;
- → Material science research;
- → High burn-up fuel performance;
- → Supply energy to one local factory.

The reactor at Kjeller, Jeep II, is a 2 MW research reactor and has been operated since 1967. In December 2018, IFE received a renewed licence to own and operate the Jeep II reactor for ten years, starting on 1 January 2019. However, the reactor has been shut down since December 2018, due to signs of corrosion found in the primary circuit. There has, so far, not been a final decision on whether the reactor will go back in operation in the future or be shut down and prepared for a decommissioning phase. DSA has withdrawn the authorization for operation pending demonstration that the reactor can be safely operated. Tasks connected to the JEEP II are as follows:

- → Production of isotopes;
- → Neutron Transmutation Doping (NTD) of silicon;
- → Neutron physics research.

Several other facilities are also included in the licence for the research reactors, including storage facilities for fresh and spent fuel, a pellet production plant, a welding workshop, and an instrumentation workshop for experimental fuel. IFE produces all the fuel placed in the research reactors and the spent fuel is stored on site.

Most of the nuclear waste in Norway is located at IFE at Kjeller and in Halden. Low and intermediate waste is treated at the radioactive waste treatment facility at Kjeller and transported to the radioactive waste repository at Himdalen.

Repository for Low and Intermediate Level Radioactive Waste

A combined disposal and storage facility for low and intermediate level waste (KLDRA) is in operation in Himdalen in Aurskog-Høland municipality. The KLDRA facility in Himdalen was taken into service in 1999, and consists of four rock caverns with two concrete sarcophaguses in each cavern. The facility contains a storage part and a disposal part. The current policy is to dispose of all the Low and Intermediate Level Waste (LILW) in Norway (except NORM, high activity disused sealed sources and long-lived intermediate level waste) at the KLDRA facility in Himdalen. Estimates show that this facility has sufficient capacity to accommodate disposal needs until 2030. Other facilities exist for the disposal of radioactive wastes containing NORM.

OTHER REGULATED FACILITIES AND ACTIVITIES

Radiation Sources

The Regulations on Radiation Protection and Use of Radiation distinguish between activities requiring authorization by licensing and activities requiring authorization by registration, in accordance with the principle of a graded approach. DSA has issued in total 755 authorizations related to the use of ionizing radiation, and 120 authorizations related to the use of non-ionizing radiation. Some of these are expired and not renewed. The highest number of authorizations are issued within the area of industrial radiography (187), X-ray in diagnostics (191) and to distributors of radiation sources (122).

At present 9640 ionizing radiation sources and 6658 non-ionizing radiation sources are registered “in use” in Norway. The number of registered sources includes 6 376 X-ray sources and 3 781 sealed radiation sources.

All cancer related radiotherapy is carried out in public hospitals in Norway. Two hospitals are in the process of establishing proton therapy capabilities. The facilities will be ready for use in 2023 and 2025. In addition, four public hospitals will establish new radiotherapy facilities in the period 2023-2030.

Due to the petroleum industry in Norway, a large number of radiation sources are spread over a wide geographic area, both land based and off shore, on the western coast of Norway.

Pollution Control (Radioactive Waste and Discharges)

Radioactive discharges and the disposal of radioactive waste are regulated under the Pollution Control Act and the associated regulations. There are currently 274 permits under this Act; 33 are for facilities for treatment and disposal of radioactive waste; 127 are for offshore petroleum installations; 78 for hospitals; 22 for research institutes and 14 for other facilities.

REGULATORY BODY

As of 1 January 2019, Norway’s regulatory body, formerly known as the Norwegian Radiation Protection Authority (NRPA), changed its name to the Norwegian Radiation and Nuclear Safety Authority (DSA).

DSA is the national authority and expert body in matters concerning nuclear safety and security, radiation use, natural radiation and radioactive contamination in the environment and radioactive waste. DSA carries out assignments on behalf of the Ministry of Health and Care Services, the Ministry of Foreign Affairs and the Ministry of Climate and Environment.

In addition to the national mandate for safety, security, and safeguards, DSA undertakes international tasks related to promoting radiation protection, nuclear security, nuclear safety, disarmament and non-proliferation. DSA is the responsible agency and expert body for nuclear security, for all uses of radiation, for natural radiation and for radioactive contamination of the environment.

DSA chair and serve as the secretariat for Crisis Committee, which coordinates nuclear and radiological emergency preparedness and response in Norway, and is the point of contact for reporting national and international nuclear or radiological events.

DSA is the national reference laboratory for units of measurement related to radiation and radioactivity. DSA is a partner in the Centre for Environmental Radioactivity (CERAD), which has been designated a Centre of Excellence by the Research Council of Norway.

DSA's main office is situated in Østerås just outside the capital, Oslo. In addition, section High North is situated in Tromsø and outside Kirkenes, in northern Norway.

Regulatory Framework

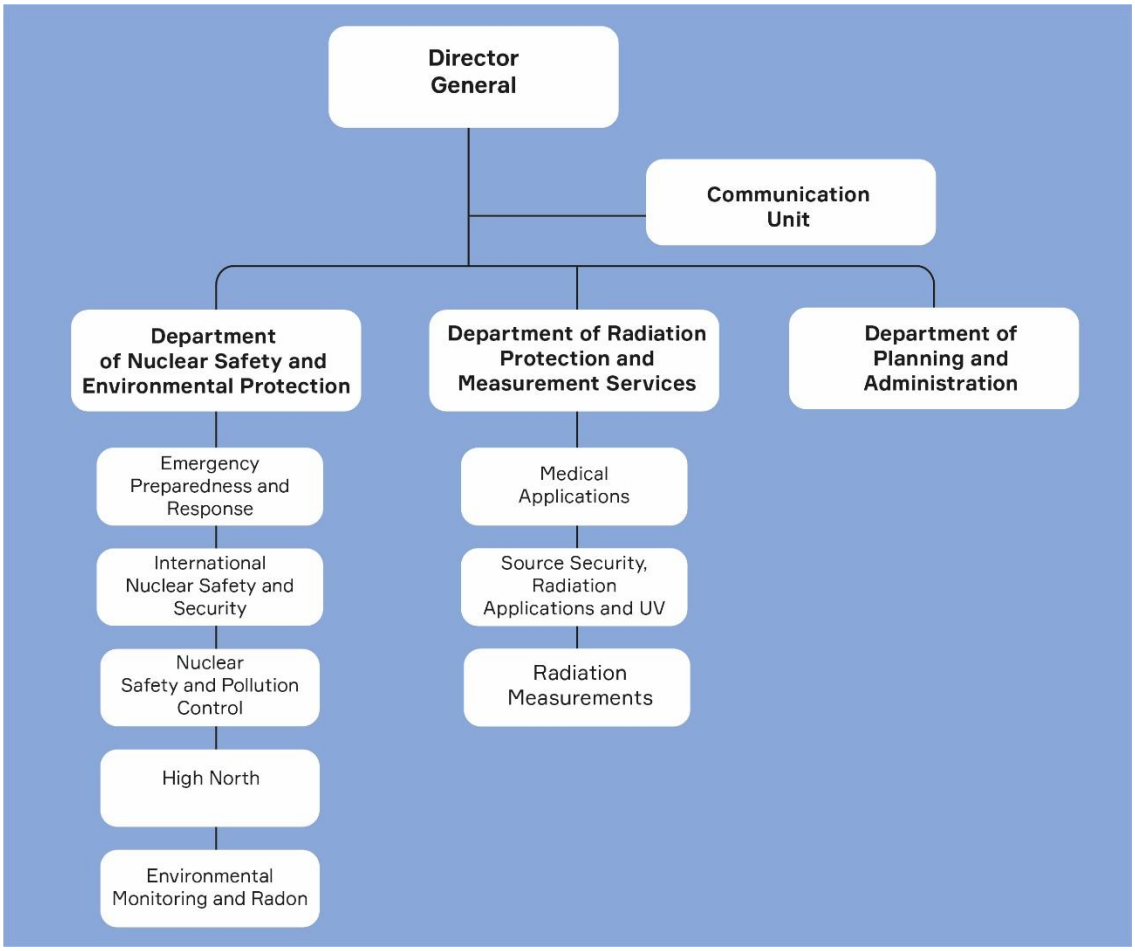
The Norwegian Radiation and Nuclear Safety Authority (DSA) administers three acts along with associated regulations:

- → Act on Radiation Protection and Use of Radiation (2000) (RP Act); Regulates the use of ionizing and non-ionizing radiation, radiation protection requirements, medical use of radiation and contingency planning.
- → Act relating to Protection against Pollution and concerning Waste (1981), (PC Act) and associated Regulations (2010) regulate nuclear waste, radioactive waste and discharges (on radioactive pollution and radioactive waste only).
- → Act on Nuclear Energy Activities (1972), (NE Act).

This legislation and associated regulations provide the basis for the licensing regime, general requirements for licences, inspection regime and the legal basis for the regulatory body.

DSA's mandate for nuclear and radiological emergency preparedness and response is specified in the Royal Decree of 23rd August 2013, based on the RP Act section 16. This includes EPR-responsibilities and mandates for early phase, late phase and DSA's daily work in this area.

Structure, Organization and Staffing



DSA in Figures (2018)

- → Funding: 222 316 million NOK:
  - 109 610 million NOK from the Ministry of Health and Care Services
  - 23 150 million NOK from the Ministry of Climate and Environment
  - 66 942 million NOK from the Ministry of Foreign Affairs[1]
  - 12 895 million NOK from other sources
  - 9 719 million NOK is VAT related
- → Staffing: 114 employees
  - 64 female
  - 50 male
  - 10 nationalities
  - 68 have a master degree
  - 23 have a doctoral degree
- → Information provision:
  - 1257 media reports
  - 793 access requests
  - 177 189 online visits
- → Indicators of regulatory activities:
  - 152 inspections
  - 112 approvals following the Regulations on Radiation Protection
  - 30 permits following the Pollution Control Act

[1] including 39 million NOK in grant allocations from MFA

PRELIMINARY ACTION PLAN

No.	Chapter	Action
1	1 and 5	**Safety Policy** • Propose a national policy and strategy for safety. • Propose a national strategy and plan for radioactive waste management, including a decommissioning strategy for nuclear installations.
2	1 and 3	**Independent body** • Investigate whether the effective independence of DSA as the regulatory body for safety needs to be further ensured.
3	1, 3, 5, 7	**Competence** • Develop a strategy to ensure that DSA has the necessary competence. • Enhance the competence in the nuclear safety area, including decommissioning and management of radioactive and nuclear waste. • Enhance the competence in relation to the establishment of proton therapy in Norway.
4	1 and 3	**Resources** • Address the need for adequate resources to ensure that DSA can fulfil its statuary obligations. • Introduce a fee for regulating, including licensing and inspection, related to military vessels entering Norwegian waters and ports. • Address the need for proper financing from those responsible related to the SSDL laboratory at DSA. • Develop a policy and strategy for competence management including a human resource plan.
5	1,3,4,5,7	**Management system** • Finalize the development of an integrated management system. • Develop and implement an electronic case processing system.

No.	Chapter	Action
6	1, 3, 5, 6, 7, 9	**Legislation and Guides** • Propose formalizing the General Licence Conditions in the Nuclear Energy Activities Act. • Propose an approach for regulation connected to siting and design of nuclear facilities and develop associated regulatory documents and guidance • Propose inclusion of a provision in the Radiation Protection Regulations about authorization and accreditation of personal dosimetry laboratories. • Develop an approach for taking account of interdependencies in radioactive waste management. • Consider whether Nuclear Energy Activities Act should be included in the legislative basis for the Internal Control Regulations. • Consider whether the Radiation Protection Act should be included in the legislative basis for the offshore Health, Safety and Environment regulations.
7	7	**Inspection** • Further develop a long-term programme to provide the basis for more systematic planning of inspections.
8	8	**Enforcement** • Create an enforcement policy document.
9	5	**Transport** • Review the regulatory framework for transport.
10	11	**Chronic exposure and remediation** • Motivate increased measurement and mitigation actions in private homes. • Improve the protection strategy for areas with extreme radon levels.
11	10	**Emergency management** • Consider the need to define the different phases of emergency management and termination of emergency in regulations.

No.	Chapter	Action
12	11	**Medical exposure** • Strengthen cooperation with relevant authorities and parties, i.e. the Norwegian Directorate of Health, the Norwegian Board of Health Supervision and the Norwegian Medicine Agency. • Address the need for establishing learning objectives in radiation protection in the curriculums for relevant health personnel. • Address the need for formal education and national recognition of Medical Physicists.

1 RESPONSIBILITES AND FUNCTIONS OF THE GOVERNMENT

1.1 NATIONAL POLICY AND STRATEGY FOR SAFETY

Related to GSR Part 1 (Rev. 1): Requirement 1

1.1.1 Government policy and strategy

The Government has not established a single comprehensive document containing a complete national policy and strategy for safety. However, the principles and requirements for safety are stated in the following elaborated 'White Papers', three legal acts with their associated regulations, the Internal Control Regulations and the Constitution:

- → The Constitution of Norway, 17 of May 1814;
- → Act on Radiation Protection and Use of Radiation, 12 of May 2000 No.36. (RP Act);
- → Ot.prp. nr. 88 (1998-99) 'White Papers';
- → Act on Nuclear Energy Activities, 12 of May 1972 No. 28 (NE Act);
- → Ot.prp. nr.51 (1970-71) 'White Papers',
- → Act on Pollution Control, 13 of March 1981 No. 6 (PC Act);
- → Ot.prp. nr. 11 (1979-80) 'White Papers';
- → Internal Control Regulations (IC Regulations);
- → St. prp. nr. 1 - National Budget.

The country's long-term commitment to safety
The country's long-term commitment to the safety of people and the environment is stated in the Constitution section 112:

> "*Every person has the right to an environment that is conducive to health and to a natural environment whose productivity and diversity are maintained. Natural resources shall be managed on the basis of comprehensive long-term considerations which will safeguard this right for future generations as well.*
> *In order to safeguard their right in accordance with the foregoing paragraph, citizens are entitled to information on the state of the natural environment and on the effects of any encroachment on nature that is planned or carried out.*
> *The authorities of the state shall take measures for the implementation of these principles.*"

The fact that the environment is protected within the Constitution means that it is protected by binding provisions in the law of highest rank. The authorities must instigate measures to implement this provision, for example through legislation, and laws, regulations and decisions that are in accordance with the rights formulated in this section.

The Norwegian Government's Nuclear Action Plan sets up long-term goals for Norway's cooperation on nuclear safety and security with Russia, Ukraine and other countries in Eurasia. It is funded by allocations from the Norwegian Ministry of Foreign Affairs (MFA). The Plan was established in 1995 and has been revised regularly, most recently in 2018. The main aims are "*to reduce the risk of serious accidents and radioactive contamination; to prevent nuclear and other radioactive material from falling into the wrong hands*".

Fundamental safety objectives and safety principles
The fundamental safety principles set out in the legal framework mentioned above are:

- → The prime responsibility for safety and security rests with the undertaking responsible for facilities and activities that give rise to radiation risks.
- → The Norwegian Radiation and Nuclear Safety Authority (DSA) supervises compliance with provisions in the legal framework mentioned above, and may for this purpose make such individual decisions as are necessary.
- → All use of radiation shall be justified. This implies that the benefits of the radiation use shall outweigh the associated radiation detriments.
- → The use of radiation shall be optimized. This implies that the ionizing radiation exposure shall be as low as practically achievable, taking into account technological knowledge, social and economic factors.
- → Dose limits and limit values apply to individuals, workers and rescue workers exposed to radiation. Dose limits also apply to radon levels in kindergartens, schools etc.
- → In undertakings, the employees and other associated persons shall have such instruction or training as is necessary to ensure that they have sufficient qualifications or knowledge in respect of radiation protection and safe use of radiation.
- → The operator of a nuclear installation shall take all necessary measures to ensure that no damage will be caused as a result of radioactivity or other hazardous features of nuclear material or radioactive products. The operator shall take the necessary measures to ensure that the installation does not become a danger to public safety after closure of the installation.
- → The PC Act aims to protect the environment against pollution, to reduce existing pollution, to reduce the quantity of waste, and to promote better waste management. Further, it is stated that pollution and waste shall not result in damage to human health or adversely affect welfare, or result in damage to the productivity of the natural environment and its capacity to self-renewal. The Radioactive Pollution and Radioactive Waste Regulations makes this act applicable to radioactive pollution and radioactive waste. The Act is based on the Polluter Pays Principles, the Precautionary Principle and the Principle of Best Available Techniques. Guidance on the implantation of the law is given in section 2 of the law itself.
- → Every undertaking shall plan, organize, perform, ensure and maintain its activities in compliance with requirements set out in or pursuant to the legislation related to health, environment and safety (HES), and thus promote systematic implementation of measures to ensure that the objectives of the HES legislation are achieved. The principle of entities internal control of compliance with HES-legislation is an important principle in Norway, embedded in and specified in the IC Regulations.

1.1.2 Participation in and adherence to international conventions and instruments

Norway has for many years contributed to the global international safety and non-proliferation regime through a number of different means, through political commitments, allocation of funds and grant applications, bilateral and multilateral project implementation and active engagement internationally e.g. through leadership in fora regarding international cooperation.

The DSA works closely with the Ministry of Health and Care Services (HOD), the Ministry of Climate and Environment (KDL) and the Ministry of Foreign Affairs (MFA) advising on policy issues and taking part in international fora together with, or on their behalf.

Norway 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 Ionising Radiations.

Norway has also made a political commitment with regard to the Code of Conduct on the Safety and Security of Radioactive Sources, and the associated Supplementary Guidance on the Import and Export of Radioactive Sources, in addition to the Code of Conduct on the Safety of Research Reactors.

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

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

DSA has been heavily engaged in bilateral and multilateral projects for many years. There has been especially close cooperation between the Nordic countries. DSA has taken active part in international fora and projects to enhance nuclear safety regime in Norway and globally.

Norway is not a party to the EU nor to EURATOM, but DSA has, with some exceptions, implemented the EU Basic Safety Standards (BSS) in Norwegian legislation. In addition, Norway has cooperated with the EU Commission on the implementation of the BSS, especially related to radon and naturally occurring radioactive materials (NORM). Furthermore, Norway is an integrated part of the ECUIRE-system. Norway also take into account recommendations from ICRP (International Commission on Radiological Protection).

1.1.3 Need for and provision of human and financial resources

There are no specific provisions in legislation regarding funding of the regulatory body, staffing or training. DSA is funded by the Parliament through the annual national budget with contributions from the Ministry of Health and Care Services (HOD), the Ministry of Climate and Environment (KLD) and the Ministry of Foreign Affairs (MFA). These contributions are specified in detail in the annual Letter of Commitment (tildelingsbrev) from HOD and addendum from KLD and MFA (Proposition 1 S for 2018 and Letter of Commitment 2018). HOD and KLD have separate chapters about DSA in the national budget. MFA do not have a specific budget chapter for DSA but after application/suggestions by DSA, MFA allocates money to perform specific tasks in an special allocation letter/debit mandate (belastningsfullmakt). Fees paid by the operator funds the budget connected to DSA's regulation of the civilian nuclear sector. Fees are also being introduced for the regulatory work related to environmental protection (under the PC Act). In addition, DSA applies for funds under several programmes and other organizations such as research programmes under the Norwegian Research Council, Norwegian Grants, EC, in addition to applications for funding for specific tasks to different ministries. This means that part of the total budget is allocated for specific tasks, based on priorities and applications from DSA and is dependent on DSA performing these tasks. The budget contributions from the ministries are allocated to the topic areas for which each ministry is responsible. The Director General (DG) of DSA has the power to decide how many positions are needed to fulfil the authority's tasks, within the available budget provided by each ministry, i.e. the available budget from each ministry is used to fulfil the tasks within that ministry's area of responsibility. Consequently, the DG cannot re-allocate resources between the ministerial areas or other financial contributors, but can allocate the resources within each.

The prioritized assignments are initiated and described by DSA, upon request from the ministries as an input to the budgetary process, and is later formalized in the Letter of Commitment from the Ministries, based on the final national budget.

The DG has the mandate to employ (and discharge) the staff needed to conduct the tasks given by the Government. At the ministerial level there is no detailed human resource plan related to underlying directorates or regulatory authorities.

DSA plans its activities and allocation of resources in the annual Operation Plans, in accordance to the Strategic Action Plan. Annual inspection plans are performed in accordance to the DSA's Inspection Strategy. The detailed allocation of resources within DSA is decided at Management Group meetings. The external management dialogue between DSA and the three ministries is done in agency management meetings (minimum two each year), the annual letter of commitment from HOD, and through DSA's written reports to the ministries, in accordance with the annual Letter of Commitment.

1.1.4 Provisions for research and development

On 1 July 2017, the ministries, through HOD, instructed that DSA shall within its area of responsibility, have an overview of knowledge and shall continuously assess the need for increased or revised knowledge of current issues in order to support the administration through, for example, participation in national and international research. DSA is a partner in –the Centre for Environmental Radioactivity Centre of Excellence (CERAD (CoE)) at the Norwegian University for Life-sciences and several projects and PhDs are performed by DSA employees. Accordingly, DSA has wide access to research performed under CERAD. DSA also takes part in research within the Fram Centre, the High North Research Centre for Climate and Environment in Tromsø.

The ministers have also agreed to and funded Norway's participation in EURATOM's research programs. Norway takes part in the EURATOM cooperation on radiation protection research through an arrangement

for funding through the Norwegian Research Council. DSA is a partner in CONCERT, the European Joint Programme for the Integration of Radiation Protection Research, under Horizon 2020. DSA also participates in related projects, such as: CONFIDENCE (COping with uNcertainties For Improved modelling and DEcision making in Nuclear emergenCiEs), and TERRIORIES (To Enhance unceRtainties Reduction and stakeholders Involvement TOwards integrated and graded Risk management of humans and wildlife in long-lasting radiological Exposure Situations).

Through participation in relevant international processes, and work within its area of responsibility, DSA contributes to the implementation of Norway's international obligations and evaluates the implementation of international recommendations. This work also contributes to maintaining and further developing DSA's competence and national regulatory practices. This is further described in DSA`s International Strategy.

DSA is also responsible for collecting and communicating up-to-date knowledge to relevant authorities and the public. This is primarily done through monitoring and mapping, as well as databases, professional systems, journals and its own reports.

DSA monitors radioactivity and radiation with the aim of maintaining an up-to-date overview of radiation sources at home and abroad, concentrations of radioactivity and radiation, use and exposure of radiation in working life, daily life and the environment.

DSA monitors medical exposure through annually comprehensive activity and incident reports from both public and private entities. Regularly, the DSA collects doses and develops national dose reference levels for optimization purposes in diagnostic and interventional procedures.

DSA's overview of the state of knowledge provides a basis for management, supervision, emergency preparedness and for safeguarding national and international obligations. Further, DSA coordinates national surveillance of radioactive pollution in the environment, participates in coordinating national environmental data, collates and publishes relevant information about emissions and waste from Norwegian activities, as well as the occurrence and effects of radioactive material in the environment.

1.1.5 Consideration of social and economic development

According to the Royal Decree of 19 February 2016 about Assessment Instructions, (https://lovdata.no/dokument/INS/forskrift/2016-02-19-184) social and economic development shall always be taken into consideration by the Government when drafting new legislation or policy documents.

The regulatory body is expected to take factors of social and economic development into account when handling licensing decisions. This is explicitly stated in section 2 number 1 in the PC Act;

> *The Act shall be used to achieve a level of environmental quality that is satisfactory on the basis of an overall evaluation of human health and welfare, the natural environment, the costs associated with any measures implemented and economic considerations.*

Furthermore, it is generally recognized that the principle of proportionality applies to public authorities in their decision-making.

1.1.6 Promotion of leadership and management for safety

The Government signals its priorities on the areas of safety it considers to be important, through the national budget and the annual Letter of Commitment to DSA. The letter contains prioritized goals that are

linked to relevant indicators that DSA is required to report on yearly to monitor performance and development, within each of the areas for which the ministries are responsible.

A commitment to safety from managers at all levels in the organization is demonstrated through the Strategic Action Plan 2018-2020, decision-making processes, meetings, discussions and day-to-day activities. In order to protect humans and the environment from harmful effects from ionizing radiation, DSA focuses on safety in its role as a regulatory authority and uses international standards in the field. Policy documents for safety and security culture have been developed.

1.1.7 Graded approach to the implementation of the policy and strategy

The graded approach is taken into account when developing strategies within DSA, including the Strategic Action Plan. It is also taken into account in our inspection regime and inspection planning which is risk based. It is also embedded in our legislation and regulatory approaches. For instance, the PC and RP Regulations include criteria that are used to determine how different categories of waste are defined and regulated and on the control of radioactive sources, respectively. The graded approach is performed within the work areas associated with each responsible ministry.

1.1.8 Plans for improvement

The Government has not established a single comprehensive document containing a complete national policy and strategy for safety. However, legislation is established in the area, notably comprising the RP Act, the NE Act and the PC Act. The safety rationale for these acts, described in the 'White Papers' presented as proposals to the Parliament from the Government. The principle of the graded approach is implemented in the legislation and in regulatory practices according to the laws and regulations.

→ The Government should develop a national policy and strategy for safety, the implementation of which should reflect a graded approach that is commensurate with the radiation risks associated with facilities and activities.

1.2 ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

Related to GSR Part 1 (Rev. 1): Requirement 2 and GSR Part 3: Requirement 2

1.2.1 Elements of the legal framework for safety

The governmental legal and regulatory framework for safety comprises of three acts and associated regulations.

- → 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 RP Act and the NE Act are mainly based on the radiation protection and safety principles, established by IAEA and ICRP. The PC Act is based on central environmental principles (Polluter Pays Principle, BAT (Best Available Technology) and the Precautionary Principle). The ICRP protection principles were also taken into account in the regulations. These principles have, however, a high degree of similarity.

The RP Act regulates all uses of radiation sources and radiation protection. The NE Act regulates and requires a licence for nuclear installations and the use of nuclear substances, all handling of nuclear substances and radioactive product, including radioactive waste and radioactive contamination. The PC Act with regulations regulates all kinds of radioactive pollution, including nuclear waste and other radioactive waste.

1.2.2 Types of facilities, activities and exposure situations covered

The RP Act applies to any production, import, export, transport, transfer, possession, installation, use, handling and waste management of radiation sources. It also applies to human activities giving increased levels of naturally occurring ionizing radiation from the environment, and planning and emergency preparedness for incidents and accidents.

The NE Act covers issues related to constructing, owning or operating a nuclear installation, and manufacturing, owning, storing, handling, transporting, selling or otherwise holding or disposing of nuclear substances.

The PC Act regulates possessing, doing or initiating anything that may entail a risk of pollution. Activities that might lead to pollution require a permit from the Pollution Control Authority (DSA for pollution from radioactive substances). Further, it is said that the waste shall be managed in such a way as to minimize damage and nuisance and inter alia that all waste shall be managed safely and delivered to an authorized party. The PC Act also includes statutes for emergency preparedness etc., in case of accidents that might lead to pollution.

1.2.3 Establishment of a framework for safety

Scope of framework

Safety objectives for protecting people – individually and collectively – society and the environment from radiation risks, at present and in future, are established through scoping paragraphs of the RP Act , NE Act, and the PC Act, established by the Norwegian Parliament.

The RP Act section 1 states that the purpose of the Act is to prevent harmful effects of radiation on human health and contribute to the protection of the environment. Further, section 2 states that the Act applies to any production, import, export, transport, transfer, possession, installation, use, handling and waste management of radiation sources, and to human activities giving increased levels of naturally occurring ionizing radiation from the environment. The Act also applies to planning and emergency preparedness for incidents and accidents.

The NE Act section 4 states that it shall be unlawful to construct, own or operate a nuclear installation without a licence granted by the King. Section 5 states that it shall be unlawful to manufacture, own, store, handle, transport, sell or otherwise hold or dispose of nuclear substances without a permit from the ministry concerned. The NE Act holds the licence holder responsible for all safety and security issues at the site, and gives the responsibility for safety considerations in the licensing regime, and inspection and control to DSA.

According to the PC Act section 1, the purpose of the Act is to protect the people and the environment against pollution and to reduce existing pollution, to reduce the quantity of waste and to promote better waste management. The Act shall ensure that the quality of the environment is satisfactory, so that pollution and waste do not result in damage to human health or adversely affect welfare, or damage the productivity of the natural environment and its capacity for self-renewal. Further, the PC Act section 7 states that no person may possess, do, or initiate anything that may entail a risk of pollution unless this is lawful pursuant to section 8 or 9, or permitted by a decision (by DSA) made pursuant to section 11. DSA is assigned the role as the Pollution Control Authority in the Act in relation to radioactive pollution and waste.

Authorizations and involvement
The use of radiation sources requires authorization for a number of specified facilities and activities as stated in RP Regulations. Section 9, litra (a-t) and section 10, and registration according to Section 13.

Regarding nuclear activities, section 2, sections 4, 5 and 11 in the NE Act specify the necessary conditions to operate a “nuclear installation” and the need for a licence from the Government, based on a recommendation from DSA on all relevant safety and security issues, to own or operate a nuclear facility.

Regarding radioactive pollution, it is a general provision in the PC Act, section 7, which has a general requirement that pollution is forbidden for all types of activities unless a permit or exclusion/derogation is granted. Handling of waste also requires a permit and DSA can set the necessary conditions for all permits to avoid damage to people or the environment, in accordance with the graded approach.

The rationale for the authorization of new facilities and activities, as well as the applicable decision making process, is described in the ’White Papers’ and provisions in the acts (RP Act sections 5 and 6, NE Act sections 4 and 5, and PC Act section 7).

Provisions for the involvement of interested parties and for their input to decision making follows and is ensured from the general requirement laid down in the Planning and Building Act and the Public Administration Act, chapter IV and chapter VII. In the PC Act, there are also specific requirement for case-handling in chapter 36 in the pollution regulation which includes mandatory hearings of applications and advertising in the local media of new activities requiring a permit.

Legal responsibility for safety
The responsibility for safety is clearly allocated in the RP Act, NE Act, and the PC Act and associated regulations, to persons or organizations responsible for the facilities and activities. This allocation of responsibility is further ensured and identified via the specific authorization processes according to provisions in the RP, NE, and PC Acts, although the concept of the ‘responsible person or organization‘ is named differently in the three acts.

The RP Act uses the concept of an ‘undertaking’;

> RP Regulations section 9 (litra a-t): “*Undertakings planning to perform the following activities involving ionising radiation shall have an authorisation from the Norwegian Radiation Protection Authority*” and

Section 13 concerning registrations specifies:

> "*Undertakings that acquire, lease out, use or handle x-ray apparatus, accelerators and radioactive sources above the exemption limit values in the annex to this regulation, and that are not subject to authorisation under section 9 or 10, shall transmit registration to the Norwegian Radiation Protection Authority...*"

The NE Act uses 'nuclear installation operator' (licence holder/licensee);

> Section 1(g) nuclear installation operator: "*Anyone having obtained a license for operating the installation, or, in the absence of a license, anyone in control of the installation or whom the Ministry has designated, or, as far as installations abroad are concerned, anyone recognised as an operator in accordance with the legislation of the Installation State*".

The PC Act uses the term 'polluter/the person responsible for the pollution';

> Section 7 subsection 2: "*If there is a danger of pollution contrary to this Act or decisions made pursuant thereto, the person responsible for the pollution shall ensure that measures are taken to prevent such pollution from occurring. If pollution has already occurred, the said person shall ensure that measures are taken to stop or remove the pollution or limit its effects. The person responsible also has a duty to take steps to mitigate any damage or nuisance resulting from the pollution or from measures to counteract it. The duty laid down in this paragraph applies to measures that are in reasonable proportion to the damage and nuisance to be avoided.*"

If a permit with conditions has been obtained according to section 11 and 16 the person performing the permitted activities will be responsible.

Review and assessment of facilities and activities

The graded approach is implemented in the RP Act and the RP Regulations, see differentiation between authorization by licensing and authorization by registration, explained in more detail in Module 5.

The graded approach is also inherent in the NE and PC Acts, taking account of the risks involved and the specific conditions given in regulations or in each case or decision.

Licensing, according to the NE Act, is performed in a two-year process with review and assessments, which includes site visits, inspections, use of external experts etc., based on an application from the licensee. The application includes a safety analysis report (SAR) and when the licence is given the activities of the licensee shall be performed according to the SAR. Deviations from the SAR or new activities that might have safety significance must be authorized by DSA according to section 13 in the NE Act, before it is executed.

Preparation of regulation and guidance

The authority and responsibility of the regulatory body for promulgating regulations and preparing guidance for their implementation in the field of radiation protection are delegated to DSA, through section 18 of the RP Act.

According to the NE Act sections 10 and 13, DSA is the regulatory body and the highest specialist body as far as safety and security are concerned, and responsible for supervision.

Concerning the PC Act, DSA has been delegated the authority and responsibility to act as a regulatory body both in the regulations according to the Act and by delegation given on 30 December 2010 from the Ministry of Environment (now the Ministry of Climate and Environment).

If the need for regulatory revisions is identified, due to new scientific knowledge or international developments in the field, DSA will prepare a plan for revision of regulation(s), with the understanding of the ministries. Revision of regulations must follow the provisions laid down in the Public Administration Act chapter VII. Changes in regulations must be approved by the King in Council or the relevant ministry. If there is a need for changes in the laws themselves, DSA will present the issues to the ministries.

DSA has the authority to clarify the understanding of laws and regulations in guidance documents as needed. Some documents contain regulatory guidance based on specific regulations. Several guidance documents have been developed and issued by DSA, in dialogue with the facilities and activities involved.

Inspection of facilities and activities, enforcement and regulations
The RP Act section 18 provides DSA with the provisions necessary for inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach. This is further described in Chapter VII in RP Regulations.

Regarding the NE Act, the sections 13 and 14 provide the same provisions as mentioned above.

DSA has also been delegated the regulatory authority and responsibility to perform inspections according to the PC Act in the PC Regulations and by the delegation decision given on 30 December 2010.

DSA has established a strategy for inspections that describes the types of inspections, priorities, and inspection methodologies applied and reflects the graded approach.

Appeals against decisions
Provision for appeals against decisions of the regulatory body are imbedded as general provisions in the RP Act section 22 and the NE Act section 57a. For the PC Act, the Public Administration Act, section 28 as the general rule, regulates appeals. The ministries will decide appeals on decisions made by DSA; HOD is the responsible ministry regarding decisions based on the RP Act and NE Act, while KLD is responsible with reference to decisions based on the PC Act. The ministries have full competence in their appeal decisions. The only exception follows from the NE Act section 10, which states that DSA is the highest specialist body as far as safety and security are concerned. This is a legal constraint which means that considerations and decisions of safety (and security) significance made by DSA cannot by overruled by the ministry and that the Government cannot issue a licence against the recommendation from DSA.

Preparedness for, and response to, a nuclear or radiological emergency
The organization of nuclear emergency preparedness in Norway is based on the Crisis Committee for Nuclear Emergency Preparedness, mandated by a Royal Decree of 23 August 2013 pursuant to RP Act section 16. The Crisis Committee is responsible for handling the acute phase of the crises, and has the power according to the law to implement measures to reduce the impact and safeguard people and the environment. The DSA is the leader, a member and the secretariat for the Committee. As a member, DSA also represents both HOD and KLD areas of responsibility. The Committee consists of representatives from the DSA, the Norwegian Directorate for Civil Protection, the Norwegian Armed Forces, the Norwegian Directorate of Health, the Norwegian Coastal Administration, the Norwegian Food Safety Authority, the National Police Directorate and the Ministry of Foreign Affairs. Several other institutions are appointed advisors to the Committee.

Interface with nuclear security
The provisions for an interface with nuclear security are given in several acts and regulations as described in Module 11. DSA has a formalized cooperation with the Norwegian National Security Authority (NSM), the Norwegian Police Security Service (PST), Norwegian customs and the Police at local and national level.

Interface with the system of accounting for, and control of, nuclear material
Provisions for an interface with the system of accounting for, and control of, nuclear material is given in several acts and regulations, and regulation is according to the NE Act, as described in Module 11. In Norway, the IAEA system for accounting for and control of nuclear material –nuclear safeguards – is implemented based on regulation and an Additional Protocol with the IAEA, and performed in close cooperation with IAEA inspectors.

Acquiring and maintaining the necessary competence nationally for ensuring safety
The RP Regulation section 16 states that undertakings shall ensure that employees who install or work with radiation sources have sufficient competence in the field of radiation protection including safe handling of radiation sources. In addition, there are several requirements related to competence in RP Regulations Chapter VI concerning the medical use of radiation.

DSA has established a set of conditions it applies in forming its recommendations to the Government regarding licences to own and operate nuclear facilities in accordance with the NE Act. Condition 5.1 states that the licensee shall provide and maintain adequate financial and human resources to ensure the safe operation of the licensed facility. Furthermore, it is stated in condition 5.4 that the licensee shall at all times have sufficient personnel in possession of adequate expertise at all levels of the organization.

Permits according to the PC Act also include requirements on the necessary competence.

Management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities
Under the PC Act section 20, the authorities can set a requirement in the permits that any operator which needs a permit must have sufficient economic funding for decommissioning, closing and clean-up of an activity or a waste repository. The operators of the different repositories in Norway are therefore required to issue a financial guarantee to DSA that they will cover the costs of closing and remediation of the repository site, also in cases of bankruptcy. The Norwegian Government, and more specifically the Ministry of Trade and Fisheries, has stated it will take the overall economical responsibility to decommission the nuclear facilities that are currently operated by IFE, which is an independent research foundation. This is a special arrangement for the research reactors and their associated facilities.

The criteria for release from regulatory control
Both the RP Act and the PC Act and associated regulations include levels of activity that define when a licence or permit is needed. The authority may then set specific conditions, on a case-to-case-basis. Definitions of waste and limit values or clearance levels for waste are set in the PC Regulations.

The NE Act does not include limits for the release from regulatory control, which means that a licence is needed to construct, own or operate any nuclear installation . Further, it is unlawful to manufacture, own, store, handle, transport, sell or otherwise hold or dispose of any nuclear substances without a permit from the ministry concerned.

The specification of offences and the corresponding penalties
The RP Act section 23 states that anyone who wilfully or through negligence violates or contributes to the violation of provisions or orders made under the provisions of or pursuant to this Act, shall be punished by fines or imprisonment not exceeding three months. If the violation has or could have caused grave danger to health or environment, imprisonment not exceeding two years may be imposed. If the violation has resulted in insignificant harm or inconvenience, public prosecution will take place only at the request of the supervisory authority.

The NE Act sections 55, 56 and 57 include provisions about penalties, confiscation of nuclear material and fees for breaching the provisions of the Act.

According to the PC Act, any person that wilfully or through negligence breaches the provisions of the Act, will be fined or imprisoned, for unlawful waste management or pollution, according to sections 78 and 79. A proposal to strengthen the penalties for wilful and severe offences has recently been sent to the Parliament.

There is also a general offence in the penal code relevant to damage to the environment.

Import and export of nuclear material and radioactive material
MFA is the responsible authority for the control of exports from Norway of defence material, dual-use goods and related technology and services. Export licences are issued by the MFA under the Export Control Act. DSA has no legal role, but gives advice to MFA on nuclear issues. Import and export of nuclear material is also regulated under the NE Act and requires a licence or a permit. To nuclear materials, international safeguards commitments apply and transport is regulated. DSA is the State authority for safeguards. For radioactive sources, an approval for the undertaking for the use of the sources is a requirement. Export and import of waste is regulated under the Regulation of Waste Chapter 16, section 16-11 and 16-12.

1.2.4 Allocation of responsibilities of each authority

The Ministry of Health and Care Services (HOD) is the responsible ministry regarding the RP Act and NE Act. The RP Act regulates all uses of radiation sources and radiation protection. The NE Act regulates nuclear energy use, all handling of nuclear substances and radioactive product, including radioactive waste and radioactive contamination. Licences for nuclear installations are given by the Government (The King in Council). The Ministry of Climate and Environment (KLD) is the responsible ministry for the PC Act. The Ministry of Foreign Affairs (MFA) is responsible for, and finances, the Norwegian Government`s Nuclear Action Plan for Safety and Security (NAP) and is responsible for disarmament and non-proliferation. DSA administers the subsidy funds and is a specialist directorate for the Ministry. Thus, DSA has international tasks related to promoting radiation protection, nuclear security, nuclear safety, disarmament, non-proliferation and export control.

Other ministries are responsible within their fields:

- → The Ministry of Defence is responsible for the licensing and oversight of military nuclear powered ships. Based on the NE Act, DSA gives recommendations on licensing and sets conditions on safety and emergency preparedness related to military nuclear powered ships visits to Norwegian ports or waters.
- → The Ministry of Justice and Public Security has overall responsibility for civil protection and emergency preparedness. It is also responsible for the regulations related to transport of dangerous goods by road, including transport of radioactive material, but DSA is the specialist body.
- → The Ministry of Trade, Industry and Fisheries (NFD) is responsible for the regulation of transport of dangerous goods by sea, including transport of radioactive material. NFD is also responsible for legal metrology. NFD is further responsible for the newly established Norwegian Nuclear Decommissioning.
- → The Ministry of Transport and Communications is responsible for the regulation of transport of dangerous goods by air, including transport of radioactive material.

The legal and regulatory framework also includes other public authorities that have certain responsibilities concerning issues of radiation safety besides DSA:

- → The Norwegian Labour Inspection Authority has e.g. responsibility for regulation and supervision of the working environment that includes worker protection against radiation;
- → The Norwegian Directorate of Health works to strengthen the health of the population and develop good healthcare (justification issues in medical use of radiation);
- → The Norwegian Food Safety Authority aims to ensure that food and drinking water are as safe and healthy as possible for consumers and to promote plant, fish and animal health (including involvement in Codex Alimentarius, radioactivity in food, post Chernobyl management of food contamination, etc.);
- → The Norwegian Medicines Agency aims to evolve and safeguard public and animal health by ensuring the efficacy, quality and safety of medicines and to administer and enforce the medical devices regulation (radiopharmaceuticals);
- → The Norwegian Directorate for Civil Protection's overall task is maintaining an overview of various risks and vulnerability in general. Its responsibilities cover local, regional and national preparedness and emergency planning, fire safety, electrical safety, handling and transport of hazardous substances, as well as product and consumer safety (and is a partner in the Crisis Committee for Nuclear Preparedness).

1.2.5 Maintenance of the framework for safety

Generally, the Government gives the highest priority to safety issues in the legislative system and, to DSA, though the Letter of Commitment. The framework for safety is intended to ensure that the regulatory authorities for safety, such as DSA, are well organized and properly empowered to comply with the established legal framework, with specified purposes and tasks, and sufficient resources and competences to achieve them. The purpose and tasks assigned to DSA are specified in a dedicated chapter of the annual national budget- prop. 1 S, The ministries with responsibilities for safety, HOD, MFA and KLD, have regular bi-annual meetings with the DSA where safety issues are addressed.

In addition to the regular biannual meetings between the ministries HOD, KLD and MFA and DSA, regarding the maintenance for safety, there is always an 'open door' attitude. Communication between the involved ministries and DSA takes place whenever it is necessary, to raise new issues, problems and matters related to safety and security in the areas of radiation protection, nuclear safety and security, as safety matters have high governmental priority.

Referring to the national policies and strategies for safety, the relevant 'White papers' are now between 20 and 50 years old. Many aspects related to safety have changed significantly since they were written, both nationally and internationally.

1.2.6 Legislative basis for GSR Part 3 Requirements

Exemption and clearance, Requirement 8
The legislative basis for radiation protection and the regulation of radiation sources are the RP Act and the RP Regulation. Section 2 of the RP Regulations specify the sources and activities the regulations

apply to. This includes radon and other elevated levels of natural ionizing radiation in dwellings and holiday homes, radon levels in the workplace, transport of radiation sources outside a closed area and electrical appliances and components that unintentionally produce X-ray radiation under given levels. Smoke detectors, consumer products containing radioactive substances, welding electrodes containing thorium, or depleted uranium used as balancing weights or shielding material are exempted from registration duty, and requirements for a radiation protection coordinator, risk assessment and preventive measures. Radioactive sources with activity levels lower or equal to the exemption levels listed in the annex to the RP Regulations are exempted from the authorization requirement in section 9.

Almost all medical exposure situations require an authorization (by licencing) from the DSA. The exceptions are the acquisition and use of equipment for intra oral and panoramic (OPG) tooth examinations in dentist offices, and the use of simple X-ray equipment (typical X-ray examinations on limbs) in medical facilities (RP Regulations section 9). Dentists and medical practitioners must follow the requirements in the radiation protection legislation, even if their medical exposure activity do not require an authorization by DSA.

Radioactive sources exempt from the authorization requirement must notify DSA of their radiation sources according to the RP Regulations section 13.

The Regulations on the Application of the Pollution Control Act to Radioactive Pollution and Radioactive Waste (the PC Regulations) also specify exemption levels. Annex I (a) sets a lower level on the specific activity that is considered to constitute radioactive waste; and (b) defines the levels of total and specific activity above which radioactive waste is subject to additional requirements related to its disposal. Annex II defines the total and specific activities above which a permit is required to release radioactive substances.

Justification and optimization, Requirements 10-11, 37-38, 48
According RP Act, section 5 all production, import, export, transport, transfer, possession, installation, use, handling and waste management of radiation sources shall be justified to ensure that risks do not arise to those performing any such activity, to other persons or to the environment. In addition, human activities resulting in increased levels of naturally occurring ionizing radiation from the environment shall be justified. In the assessment of justification, importance shall *inter alia* be given to whether the benefits of the activity outweigh the risks associated with the radiation, and to whether the activity is arranged in such a way as to avoid acute injury to health and to minimize the risk of late injury as far as is reasonably possible.

All medical exposures must be justified on a principle, generic and individual level before a patient can undergo medical exposure through an examination or treatment. Medical exposure is considered to be justified if the total diagnostic or therapeutic benefits, for the individual and society, are higher than the disadvantages involved with the use of radiation. The benefits and risks connected to alternative methods with the same purpose, involving little or no exposure to ionizing radiation, shall be evaluated (RP Regulations section 39).

Undertakings have a duty to consider substitution and shall always assess alternatives to the use of ionizing radiation (RP Regulations section 23). If it is feasible without unreasonable cost or disadvantage to choose methods not involving ionizing radiation, these methods shall be used. For non-medical use of radiation, X-ray apparatus shall be utilized rather than radioactive sources when practically achievable. An example on non-justified use is the use of radioactive sources for blood irradiation. The use of ionizing radiation shall be continuously reassessed based on the latest available information and knowledge of relevance for the justification. In 2013, HOD and DSA took the initiative to phase out all the radioactive sources for blood irradiators in Norway and replace them with X-ray apparatus. The substitution was completed in 2014 and was an important contribution to security in, and around hospitals.

According to the RP Regulations, section 5, all use of radiation shall be optimized. This implies that the ionizing radiation exposure shall be as low as practically achievable, taking into account technological knowledge, social and economic factors. It is also stated in RP Regulations, sections 32 and 40, that undertakings shall ensure that all radiation exposure in both medical and non-medical applications are as low as practically achievable. In medical use, optimization includes *inter alia* choice of the method, apparatus and equipment, work procedures, assessment of radiation dose and dose distribution to the patient, image quality and the effect of therapy. The optimization shall be performed according to a multidisciplinary and continuous process, and be evaluated against existing national reference values or professional recommendations when available.

As part of ensuring optimized medical use of radiation, there are also requirements to perform quality assurance of equipment according to RP Regulations section 53. Radiation apparatus and equipment shall be subject to periodic quality controls and systematic maintenance, in addition to an initial acceptance test. The acceptance test, quality controls and maintenance shall be planned and documented properly.

Dose limitation, Requirement 12

The Government and DSA have established dose limits for occupational and public exposure, and have established requirements that registrants and licensees shall apply these limits. The effective dose to the public and non-occupationally exposed workers shall not exceed an effective dose of 1 mSv/year for ionizing radiation. The undertaking shall plan the use of radiation and protective measures to ensure that exposure of the non-occupationally exposed workers and the public, shall not be exposed to an effective dose exceeding 0.25 mSv/year (RP Regulations section 6). The effective dose for exposed workers, apprentices and students over the age of 18 shall not exceed 20 mSv/year, 20 mSv/y (equivalent dose to the lens of the eye). The equivalent dose to the foetus for pregnant exposed workers, apprentices and students shall not exceed 1 mSv for the remainder of the pregnancy (RP Reg. section 32).

Responsibilities specific to occupational exposure, public exposure in planned and existing exposure situations, Requirements 19, 29, 47 and 49

The Government and the regulatory body have established and enforced requirements for optimized protection and safety. This includes requirements for the radiation protection of humans on, for instance, dose limits and constraints, on competence and training and on design criteria of buildings and equipment, on rescue work (RP Act, RP Regulations, the Working Environmental Act).

Public exposure is regulated according to the PC Act and the RP Act and associated regulations. The RP Act specifies general requirements for optimization, justification, dose limits and dose constraints. Regulation of radioactive sources and consumer products is also based in this legislation.

The PC Act and associated regulations regulates radioactive discharges, radioactive waste management and remediation of contaminated sites. The PC legislation applies to radioactive substances which cause or may cause damage or nuisance to the environment including the public and their health. The legislation covers both radioactive pollution and non-radioactive pollution, and hence provides the basis for holistic regulation of pollution in Norway. In general, radioactive pollution, as for instance releases and contamination, is illegal unless it is exempt or authorized by DSA. Authorizations may specify conditions necessary to ensure safe and justified waste management.

The legislation provides DSA with a powerful regulatory framework for protection of public from radiation both in planned and existing exposure situations. DSA regulates both planned exposure situations, such as radioactive discharges and waste management as well as existing exposure situations such as remediation and protection of public from contaminated areas. Norway has, since the Chernobyl accident, regulated the contaminated areas and protected the public from effects from the contaminated areas.

Responsibilities specific to medical exposure, Requirement 34
Medical exposure is regulated under the RP Act and in the RP Regulations. DSA is responsible for controlling the implementation of these requirements, interpreting the articles, and for inspections and licensing. DSA is also responsible for administering the Internal Control Regulations within radiation protection.

Other relevant parties involved in regulating medical exposure activities are the Norwegian Board of Health, the Norwegian Directorate of Health, and the Labour Inspection Authority. The Norwegian Board of Health is the superior inspection authority for health services in Norway (Act on State Supervision of Health and Care Services, article 1). The Norwegian Directorate of Health is responsible for statutory interpretation, national professional guidelines related to health, issuing authorization of health professionals and issuing approvals for medical specialists. Other relevant acts and regulations related to health and medical exposure are the Specialized Health Services Act, the Health Personnel Act, the Patient- and User Rights Act, and the Working Environment Act.

Legislative basis for the regulation of source and environmental monitoring, Requirement 32; public exposure due to radon indoors, Requirement 50; exposure due to radionuclides in commodities, Requirement 51
Indoor radon involves several sectors of the society and is regulated under several acts: the RP Act, the Working Environment Act, the Public Health Act and the Planning and Building Act. In 2009, the Norwegian Government adopted a national strategy for reducing radon exposure [Strategy for the reduction of radon exposure in Norway, Norwegian ministries, Strategy, I-1144 E, 2010] and, in 2014, the strategy was extended until 2020. Since 2009, DSA has led a coordination group to implement the strategy. The members of the Coordination Group represent relevant public authorities, including those responsible for relevant regulations:

- DSA;
- The Norwegian Labour Inspection Authority;
- The Directorate of Health;
- Norwegian Building Authority;
- Department for Planning (Ministry of Local Government and Modernization);
- The Institute of Public Health;
- National Institute of Occupational Health;
- The Norwegian State Housing Bank;
- Geological Survey of Norway; and
- Representatives from the Municipalities: Oslo and Hamar.

1.2.7 Plans for improvement

The Internal Control Regulations (IC Regulations), issued under the Working Environment Act, plays a central role in the general policies for safety, and covers several acts related to safety (the HES legislation), including the RP Act and the PC Act. However, at present the NE Act is not covered by the IC Regulations, but similar requirements are included in the General Licence Conditions. In Norway, the responsibility for different areas of safety is clearly divided between three different ministries (HOD, KLD and MFA). The Government has allocated regulatory responsibilities to DSA under three relevant acts. Since 1993, DSA has been the sole regulatory body in the field of radiation and radioactivity, following the merger of the former regulatory bodies (SIS and SAT), which resulted in greater clarification of regulatory responsibilities. There was a further expansion of the regulatory mandate of DSA in 2010, when the regulatory functions related to radioactive waste and pollution, covered by the PC Act, resulted the further clarification of responsibilities in this area.

→ The Government should include the NE Act into the family of HES-legislation, making the IC Regulation applicable to facilities and activities regulated by the NE Act.
→ DSA should continue to identify possibilities for exchanging radioactive sources with X-ray apparatus when practically achievable.

1.3 ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Related to GSR Part 1 (Rev. 1): Requirements 3 and 4, and GSR Part 3: Requirement 2

1.3.1 Legal framework establishing the regulatory body

The Government has appointed DSA as the sole national regulatory body on radiation protection, nuclear safety and security, and safety of radioactive waste and radioactive discharges to the environment, regulatory control of natural radiation, and non- ionizing radiation. This is specified in section 18 in the RP Act and section 10 in the NE Act. Concerning the PC Act, a delegation decision in favour of DSA (then NRPA) was given on 30 December 2010.

1.3.2 Provision of competence and resources to the regulatory body

DSA is funded by the Parliament through the annual national budget with contributions from the three responsible ministries (HOD, KLD and MFA), and from fees connected to the NE Act and PC Act, and specified in more detail in the annual Letter of Commitment from HOD, KLD and MFA (Proposition 1 S for 2018 and letter of commitment 2018). Parts of the budget from the ministries are allocated for specific tasks, as specified in the annual letters from the ministries. The budget contributions from the ministries are allocated to the topical areas within the responsibilities of each ministry. The Director General (DG) has the power to decide how many positions are needed to fulfil the authority's tasks within the available budget limits from each ministry. The available budget from each ministry must be used to fulfil the tasks under the ministry's area of responsibility. Consequently, the DG cannot allocate resources between the ministerial areas but can, apart from allocated task-specific resources, freely allocate the resources within each.

1.3.3 Legal background and the functional manifestation of the legal independence of the regulatory body

In 1991, the organization of the two previously established inspectorates (State Atomic Inspectorate and State Institute for Radiation Hygiene) were reviewed in a parliamentary proposition. In 1993, this resulted in the merger of the two inspectorates into one regulatory body, DSA (then the NRPA). To ensure independence in its safety related decisions, DSA was organized as a directorate under the Ministry of Health (HOD). DSA currently serves the three ministries HOD, KLD and MFA. The Directive for DSA sets out the authorities and responsibilities of DSA and describes the governance dialogue with the involved Ministries. The governance dialogue encompasses the Directive for DSA, letters of commitment, letters concerning the delegation of authority and at least two biannual agency governance meetings.

However, from 1 January 2016, the Norwegian Government decided to organize the DSA (then NRPA) as an agency under the Norwegian Directorate of Health (NDH). This was partly implemented, but due to legal constraints, (especially section 10 in the NE Act), the NE Act and the PC Act remained within the authority of NRPA. In the spring 2016, the Norwegian Ministry of Health and Social Care Services (HOD) decided to

assess a further integration of NRPA within the NDH with the aim to increase and strengthen the effectiveness of the health sector and the emergency preparedness and response system within this sector. During the same period, Norway received the final report of the International Physical Protection Advisory Service (IPPAS) from the IAEA. One of the suggestions in the report was that Norway "*should reconsider its planned decision to reorganize NRPA under the Directorate of Health keeping in mind the objective of regulatory independence*." As part of the decision process, the Norwegian Ministry of Foreign Affairs (MFA) undertook an assessment of Norway's implementation of the international legal commitments that Norway has signed up to through various IAEA Conventions. Pertaining to the results of this assessment, and the advice from the IPPAS report, the Norwegian Government on 16 February 2017 decided the following, (which was reported to the CNS review meeting in 2017):

> "*A further integration of the NRPA within NDH is not going to take place. On the contrary, Norway will revert to the set-up where the NRPA exists as a professionally and financially independent regulatory body under the administrative authority of the Ministry of Health and Social Care Services. This decision will be implemented as soon as it is practically possible due to the need to amend laws and regulations and the necessary adaptations in the state budget. Furthermore NRPA is assigned to ask the IAEA to conduct an Integrated Regulatory Review Service (IRRS) in Norway. The NRPA and the NDH, as independent authorities, is assigned the task of assessing and proposing mechanisms for improved preparedness, civil protection and crisis management, including a proposal for the formalization of such cooperation*".

Consequently, from the 1 July 2017, NRPA (now DSA) was reestablished.

As a directorate, DSA is an independent decision-making authority, laid down under the legislative framework covering DSA's areas of responsibilities. However, there is some limitations in the independence of DSA. Fundamental and material issues linked to the performance of DSA's tasks, including actions that can influence the use of resources in the sector, and organizational changes, must be clarified with the relevant ministry.

The Ministry of Health (HOD) has the parliamentary responsibility for the health sector (including licensed hospitals) and the regulatory body (DSA) and a question of conflict of interest could be raised. However, licensed hospitals are generally organized as independent hospital trusts, which are governed by independent boards.

The RP Act, section 18, states that DSA is the dedicated authority to follow up compliance with provisions laid down in or pursuant to the RP Act and can, for this purpose, make such individual decisions as are necessary. DSA shall be given free access to perform supervision and shall be provided with information to perform its functions under the provisions of the RP Act. DSA shall be given access to undertake measurements and investigations.

The NE Act states, in section 10, that DSA is the highest specialist agency as far as questions of safety and security are concerned. It functions as the institution making recommendations and giving advice to the ministry concerned. DSA shall prepare and submit recommendations to the Government or the relevant ministry on all applications concerning licences under the NE Act, and shall on its own initiative put into effect all such measures as it deems necessary for safety reasons. It shall be the duty of DSA to ensure that all rules and conditions pertaining to safety precautions are complied with and put into effect, as well as such orders that are given in pursuance of the NE Act.

KLD has assigned DSA to act and fulfil its regulatory obligations for the control of facilities and activities under the PC Act, section 81. The regulations relevant to radioactivity under the Act and the delegation decision given on the 30 December 2010 gives DSA the legal authority necessary to enable it to fulfil its regulatory obligations for control of pollution and waste according to the PC Act.

1.3.4 Decision-making process and the absence of undue influence

DSA is an independent decision-making authority under the regulatory framework covering DSA's areas of responsibility. The RP Act, the NE Act and the PC Act give DSA the task of control, inspection and enforcement. In the NE Act section 10, it stated that DSA is the highest specialist agency as far as questions of safety and security are concerned. This is an important provision because it means that decisions on safety and security issues cannot be overruled by the ministry and, as such, is an important guarantee for the independence of DSA in its decision making.

Public administrative authorities, like DSA, perform all their functions and regulatory management in accordance to the Public Administration Act, the Freedom of Information Act and the Environmental Information Act, which all ensure an open and transparent public administration. Furthermore, it is stated in the NE Act that all information related to discharges or the danger of discharge shall be publically available.

In addition, all State employees must follow the Ethical Guidelines for the Public Service. This guideline covers the employees' duty of loyalty, transparency, impartiality and professional independence to maintain confidence in the public service.

1.3.5 Handling conflicts of interest

Conflicts of interest, impartiality and disqualification of State employees are covered in chapter II of the Public Administration Act, Ethical Guidelines for the Public Service and in DSA's local guidelines for employees (Short guidelines about the Public Administration Acts chapter about disqualification). A State employee shall, in general, be disqualified from preparing the basis for a decision or from making any decisions in an administrative case if she/he is a party to the case, in close relation (by blood, by marriage, is a guardian or agent) to a party, or if she/he holds a senior position or has economic interests in a company that is a party. The same is also valid for inspections of authorized parties. The State employee shall decide whether she/he is disqualified and a substitute shall be appointed or elected instead. The State employee must inform his/her leader about any disqualifications and conflicts of interests. If the State employee is not in the position to make the evaluation themselves, it will be performed by the nearest leader. Generally, if a leader (head of a section or department) is disqualified, all employees in the section or department are also disqualified.

HOD is responsible for evaluating if DSA can carry out its administrative duties in those cases where the Director General is disqualified. All evaluations and conclusions regarding disqualifications must be documented and saved together with the case documents for later reference. In addition, the State Employees Act regulates how state employees shall act if they are offered gifts (section 39). As a rule, state employees are not allowed to receive gifts, provisions, services or other contributions that can influence their independence in the performance of their duty. All decisions, documents and reports that are published by DSA are quality assured by at least two persons within the management line. All written decisions are signed by two persons, following established procedures (prosedyre for signering av brev). Authorizations and decisions on enforcement are signed by the Head of Section and Head of Department, while less important letters are signed by the executive officer and the Head of Section.

1.3.6 Plans for improvement

The mandates given to the regulatory body include inspection and surveillance of facilities and activities, enforcement of decisions and imposition of sanctions or coercive fines following violations against regulatory requirements or licence/registration conditions. It also explicitly states in the NE Act that DSA

is the highest authority on safety (and security) matters and by that, the safety decisions by DSA cannot be overruled at the ministerial level. The role and tasks for DSA are described and annually updated in the Parliamentary proposal document concerning the national budget (Prop 1S) in which the annual resources for DSA are also proposed to the Parliament. In the reestablishment of DSA, effective from 01 July 2017, DSA regained its independent status as a Directorate directly under HOD as the main ministry, and from 2019 with a new name; Directorate for Radiation and Nuclear Safety Authority (DSA). The rationale for this was to strengthen and enhance its role as an independent regulatory body according to Norway's international obligations and relevant international standards.

However, the process initiated by the Government to establish DSA as a subordinate body to the Health Directorate, clearly illustrates that there is a certain vulnerability to the effective independence of DSA as the regulatory body.

→ It should therefore be investigated whether the effective independence of the regulatory body for safety needs to be strengthened. The Government should investigate whether the effective independence of DSA as the regulatory body for safety needs to be further ensured.

The staffing and allocation of resources are, only to some extent, commensurate with the radiation risk associated with facilities and activities. There are no specific provisions in legislation related to organization, funding, staffing or training of the regulatory body. The maintenance of technical competence of regulators is recognized internationally as one of the most critical challenges to effective regulation of nuclear activities. For DSA this is a major challenge.

→ The Government should ensure that the regulatory body has the necessary resources and competence to fulfil its statuary obligations.
→ DSA should develop a policy and strategy for competence management and an operative human resource plan regarding organization, management, resource allocation and competences necessary to enable the regulatory body to fulfil its statuary obligations.

1.4 RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Related to GSR Part 1 (Rev. 1): Requirement 5 (Also related to GSR Part 2: Requirement 1)

1.4.1 Assignment of prime responsibility for safety of facilities and activities to persons or organizations responsible for them

The prime responsibility for safety for facilities and activities is specified in the RP Act, the NE Act and the PC Act, and the respective regulations. With respect to planned use of radiation sources in the medical, industrial, research etc., the 'undertaking' is the prime responsible actor (RP Act). The term 'undertaking', used in the RP Act, refers to the person or organization responsible for facilities and activities. For nuclear facilities and activities, the NE Act states that the "holder of the concession" (licensee) has the prime responsibility for safety. In the PC Act, "the polluter" is assigned the prime responsibility, and is referred to by different terms as "no person shall", "any person", "person responsible" and "polluter". The terms "undertaking", "holder of the concession" and "the polluter" used in the three acts have the equivalent meaning as being the person or organization responsible for facilities and activities. The responsibility for safety is absolute in all these acts – it cannot be transferred, delegated, outsourced, or contracted to any other party.

1.4.2 Legal basis of the authority of the regulatory body to require demonstration of compliance with the safety requirements

The empowerment of the regulatory body is given to DSA in RP Act section 18, in the NE Act section 10 and a delegation decision given on 30 December 2010, related to the PC Act. The processes used are evaluation and investigation of all information given by an applicant regarding an application for an authorization, registration, concession (licence) or permit. If the documentation provided shows that all regulatory requirements are fulfilled, the application is granted and confirmed. Otherwise, supplementary information is requested, or meetings are held with the applicant for clarification, or the application is rejected.

1.4.3 Governmental stipulation that requirements (regulations, guides) do not relieve responsible persons from their prime responsibility for safety

The prime responsibility for safety is set in the RP Act, the NE Act and the PC Act to the undertaking holding the licence, registration, concession, or permission under these acts. A person or organization, responsible for safety for a facility or activity, will need to document how safety issues and responsibilities are described in its organizational structure, management system and QA system. The general principle is that safety issues always shall be linked to the highest levels of management. DSA has published a number of guidelines describing how to comply or demonstrate compliance with the requirements. A major issue in all types of inspections is the review of compliance with regulatory requirements. Safety improvements, such as optimization of radiation protection and the application of BAT, as expressed in regulatory requirements, provide a continuing process for improvement that shall be documented and may be reviewed during inspections. If inspections identify deviations from the general regulatory requirements or conditions set in a specific licence or permit, the legislation enables DSA to order corrections and, if appropriate, sanctions to enforce corrective actions. In recent years, the focus of the inspection programme for the research reactors has been on the importance of building a strong safety culture within the licensed organization, as a prerequisite for maintaining responsibility for safety.

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

Related to GSR Part 1 (Rev. 1): Requirement 7

1.5.1 Distribution of responsibilities among the authorities with responsibilities in nuclear and radiation safety

The distribution of responsibility between the ministries HOD and KLD is closely connected to the management of the RP Act, the NE Act and the PC Act. DSA is the competent authority having responsibility for nuclear and radiation safety, but cooperates with other authorities with equivalent responsibility for safety within their field. The Government has worked for effective coordination between the various regulatory authorities and agencies for many years. This is achieved in a variety of ways, at the national, regional and municipal levels. Additionally, there are bilateral agreements on harmonization and cooperation among a number of regulatory authorities.

1.5.2 Coordination and cooperation among the authorities having responsibilities for safety

In planning for or handling a nuclear or radiological emergency, the Crisis Committee has a key role for coordination. The Crisis Committee consists of representatives from:

- → DSA;
- → Norwegian Directorate for Civil Protection;
- → Norwegian Armed Forces;
- → Norwegian Directorate of Health;
- → Norwegian Coastal Administration;
- → Norwegian Food Safety Authority;
- → National Police Directorate; and
- → Ministry of Foreign Affairs.

DSA is the leader and secretariat of the committee, mandated by a Royal Decree of 23 August 2013.

At the national level, a formalized cooperation (TSG) exists among six regulatory authorities and a non-governmental organization. These are:

- → DSA;
- → Norwegian Labour Inspection Authority;
- → Norwegian Environment Agency;
- → Norwegian Food Safety Authority;
- → Norwegian Board of Health Supervision;
- → Norwegian Industrial Safety Organisation;
- → Norwegian Directorate for Civil Protection;

All of these organizations have responsibilities for HES legislation, expressed in *inter alia* the Internal Control Regulations (IC Regulations), with responsibility in their particular area of work. A main goal with this cooperation is ensuring a harmonized implementation of the IC Regulations (based on eight different acts). Regular meetings and seminars are arranged and courses are held regarding education in inspection methodologies and strategies.

Furthermore, KLD stated, in the Letters of Commitment that DSA shall cooperate closely with the Norwegian Environment Agency in order to have a harmonized regulatory approach to the application of the PC Act.

Absence of conflicting requirements
The arrangements described above contribute to the elimination of gaps or overlap of responsibilities. Furthermore, they lay the foundation for avoiding situations where authorized parties might be subject to conflicting requirements by authorities responsible for different aspects of HES legislation.

1.5.3 Plans for improvement

Coordination among different authorities has existed for many years in many fields related to safety and security both in the radiation and nuclear sector and beyond this sector. In a radiological or nuclear emergency, the Crisis Committee has the prime coordinating role. It is also an advantage that DSA is the primary regulatory authority in the nuclear safety and security and radiation protection areas, which reduces the need for coordination with other authorities within these areas of competence.

→ DSA should continue its cooperation with other authorities, including preparation of further cooperation agreements with particularly closely related authorities, *i.a.* the Norwegian Directorate of Health, the Norwegian Board of Health Supervision and the Norwegian Medicine Agency.

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

Related to ***GSR Part 1 (Rev. 1): Requirement 9***
GSR Part 3: Requirement 2, paragraph 2.26 and Requirements 47-49

1.6.1 System to identify situations and protective actions to reduce undue radiation risks associated with existing exposure situations

According to the RP Act section 1, the purpose of the Act is to prevent harmful effects of radiation on human health and contribute to the protection of the environment. In the scope of the Act, section 2, paragraph 2 and 3, it is stated that the Act also applies to human activities giving increased levels of natural ionizing radiation from the environment. The Act also applies to planning and emergency preparedness for incidents and accidents.

Thus, provisions are available to implement protective actions to reduce undue radiation risks associated with unregulated sources (of natural and artificial origin) and contamination from past activities or events.

When protective actions are considered on the basis of the RP Act, the principles of justification and optimization are an integrated and full part of the actions, given that these principles are explicitly stated in both the RP Act (sections 5 and 13), and the RP Regulations (sections 5, 11, 39 and 40).

Several examples exist where protective actions have been implemented in Norway, considering justification and optimization. Historically, during the fallout period of atmospheric A-bomb testing in late 1950s and early 60s, dietary advice was issued regarding the intake of milk and water in some affected areas, based on monitoring and measurements of food and water samples. During the acute and late phase of the Chernobyl accident, several protective actions were and still are implemented, based on the justification and optimization principles. Other examples due to natural sources are planned, including handling:

- → Mineral tailings from disused mines with high concentrations of thorium (Søve mines/ Fen-field);
- → Waste repositories for scale waste from oil and gas production in the North Sea; and
- → Storage/waste facilities for alum-shale arising from, for example, building and construction sites/industries and which contain sufficient levels of activity to be classified as radioactive waste.

It is a basic requirement for the regulatory body to provide input to protective action decisions, and if appropriate, in cooperation with other authorities. This makes it necessary to have the competence, research and monitoring of exposure situations in order to be able to determine where protective actions might be feasible. An example that demonstrates the involvement of several authorities and interested parties is the evolution and deployment of the National Radon Plan. As part of this plan, authorities with responsibilities in the areas of health, building, geology and radiation protection routinely participate and cooperate with construction and building industry.

1.6.2 Arrangements for regaining control over abandoned, lost, misplaced, stolen, etc. radioactive sources (orphan sources)

DSA is the competent body, and has on the competence to monitor and manage radioactive sources. For example, members of staff have competence and equipment both for measuring radiation and for shielding, and such equipment is always available. When it comes to orphan sources, economy is not regarded as a limiting factor for regaining control of that source. If necessary, DSA will ask the Norwegian Civil Defence, the Coast Guard or Emergency Services for assistance with measuring radiation levels around the source and securing the area. The Institute for Energy Technology (IFE) may also provide assistance in measuring radiation levels and retrieving an orphan source.

If the radioactive source is registered in the electronic registration system, DSA can trace the source back to its origin based on its serial number. If the radioactive source is not registered, and its origin cannot be traced, DSA assumes responsibility for the source under the PC Act. Section 7 of the Act states that the responsible party's duty is to avoid pollution and to take measures to prevent further pollution. The orphan source is thereafter handled as radioactive waste, to be delivered to an appropriate radioactive waste disposal site. If necessary, DSA also has the possibility to store radioactive sources in a dedicated storage room, with necessary equipment and shielding, located at DSA's premises at Østerås.

DSA can receive notifications of radioactive sources that have been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorization through various canals. Processes are in place to ensure that competent and responsible personnel within DSA are notified, and that immediate action is taken. These cases are given high priority. DSA usually receives the notification in one of two ways:

a) DSA may be contacted through its emergency contact number, which is manned 24-hours a day, 7 days a week. The officer on duty will notify DSA´s section for emergency preparedness and response. It will then be decided whether the case should be solved by this section or whether it will be directed to another section within DSA. Usually, the case will then be directed to one of three sections (Section for Source Security, Radiation Applications and UV, Section for Medical Applications or Section for Nuclear Safety and Pollution Control). The referral is determined in a case-by-case manner, depending on the type of source, its location and the severity of the case.
b) The notification can also come directly to a case handler. The case handler will then, in collaboration with the head of section, decide whether the case can be dealt with directly, or if it should be directed to section for emergency preparedness and response or to another section within DSA.

Independently of how DSA was notified of the orphan source, all relevant personnel within DSA are informed, including Heads of section, Directors of the departments, the DG and staff in the Communication Unit.

DSA is currently working on developing an holistic procedure for handling orphan sources in the management system.

1.6.3 Arrangements for monitoring for the purpose of detecting orphan sources

DSA has the authority to monitor at appropriate checkpoints, and has monitoring equipment installed at several sites in Norway. For instance, there is a permanent portal for detecting radioactive material monitoring vehicles crossing the border from the Russian Federation to Norway at Storskog. DSA's other permanent checkpoints are used to measure radioactive air pollution. DSA can, however, organize or carry

out measurements if notification is received about orphan sources or industrial radiation sources that have been lost or are missing, as described above.

Portals are also installed at scrap metal yards and waste management sites. DSA will receive notification if an alarm at such portals are triggered.

1.6.4 Plans for improvement

Both the RP Act and the PC Act have legal provisions to implement actions to reduce radiation risks associated with unregulated sources of natural or artificial origin and contamination from past activities or events. There are several examples where such provisions have been useful in such situations.

A characteristic feature of situations where protective actions are relevant concerning unregulated sources (natural or artificial), or contamination from past activities, is that these might involve several authorities and categories of stakeholders (for example large and small undertakings, local societies, environmental organizations, individuals and indigenous population groups).

The PC Act has specific regulatory requirements, including mandatory public hearings. This also applies to cases of clean-up and remediation of legacy sites or contamination from past activities. Section 2 of the Act gives further guidance on the application of the Act and the main principles for its implementation.

- → DSA should adopt a more systematic procedure for handling orphan sources;
- → DSA should continue documentation of experience gained from implementation of measures to reduce radiation risks associated with unregulated sources of natural or artificial origin and contamination from past activities or events, in order to improve decision-making regarding any future measures or actions concerning similar situation and to provide the basis for sharing experience from such situations internationally.

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

Related to ***GSR Part 1 (Rev. 1): Requirement 10***
GSR Part 3: Requirements 2 and 31
GSR Part 5: Requirements 1, 2 and 6
SSR Part 5: Requirement 1
GSR Part 6: Requirements 4 and 5

1.7.1 Regulatory basis for decommissioning

The regulatory body, DSA, has the responsibility to regulate decommissioning of Norwegian facilities with regard to radiation and radioactivity. This authority is given in the NE Act section 10, in the PC Act section 81, the Regulation on Radioactive Waste and Pollution section 4, the Waste Regulations chapter 16, and a letter of delegation from the Ministry of Climate and Environment dated 10 December 2010. Central requirements and the main regulatory basis for the closure of a facility or the cessation of an activity is section 20 in the PC Act and section 15 in the NE Act. Requirements related to handling of waste, waste reduction, reuse and recycling can be decided based on section 33 of the PC Act.

The use of the PC Act provides a holistic and flexible regulatory framework for dismantling, waste reduction and handling of all kinds of radioactive discharges and radioactive waste, regardless of origin. The framework also makes it possible to address radioactive discharges (or pollution) and radioactive waste with the same approach and stringency as chemical discharges (or pollution) and non-radioactive waste. It is also an important and effective tool for remediation and clean-up of contaminated sites.

DSA gives advice on licences and grants permits according to the NE Act and the PC Act. The licences and permits generally include specific conditions to have and to update decommissioning plans at certain intervals. In addition, point 9 in the General Licence Conditions (GLCs), used in licensing and for assessing applications for a licence under the NE Act, states that the owner of a facility must have decommissioning plans in place at every phase in the facility's lifetime. In order to obtain a licence under the NE Act, any operator must adhere to the conditions in the GLC.

1.7.2 Government policy and strategy on waste and spent fuel management

The Government has not yet adopted a holistic national strategy for decommissioning or on the management of spent fuel and radioactive waste. The Government commissioned an impact assessment (KVU), followed by quality assurance reports (KS-1 and KS-2), on decommissioning and waste handling, which were published in 2016 and provide the basis for the Government's current strategy. The key recommendations arising from these studies were as follows:

- → Ensure safe interim storage of spent nuclear fuel;
- → Assess the possibility of repatriation of spent nuclear fuel;
- → Initiate the consideration of reprocessing of spent nuclear fuel;
- → Assess other possible options for spent fuel other than reprocessing;
- → Establish an independent radioactive waste management organization:
- → Ensure the application polluter pays principle in relation to the management of spent nuclear fuel and radioactive waste;
- → Initiate the planning of increased capacity of the LILW repository;
- → Assess the possibility for international cooperation on deep geological repository for the spent nuclear fuel;
- → Assess alternative repository solutions in Norway.

The Government has made a decision to take the economic responsibility for decommissioning of nuclear facilities, to develop a strategy that involves the development of sufficient disposal capacity to address the increased volumes of waste that will arise from decommissioning. The Government has also established an organization that will be responsible for the management of decommissioning and radioactive waste management from the nuclear sector Norwegian Nuclear Decommissioning (NND) (KS-1).

Further work is in progress and DSA has been requested to provide inputs into this process through the most recent Letters of Commitment.

The regulations on radioactive waste and pollution which defines radioactive waste and what discharges need a permit, and the waste act, which gives the legal basis, for how radioactive waste is handled, covers the expectations even though no formal strategy on radioactive waste are developed by the Government.

1.7.3 Legal provisions, regulatory control and assignment of responsibilities for facilities and activities

At present, no specific regulatory provisions exist in the NE Act regarding a decommissioning plan at the design stage. The Government (HOD) has, for the 2019 budget term, mandated the DSA to develop a comprehensive proposal under the NE Act with regard to necessary regulatory changes in these acts or other relevant regulations as a preparation for the decommissioning of the Halden research reactor facility.

1.7.4 Governmental provisions for financial resources

In the national budget for 2018-2019, the Government has stated that the State of Norway will take the economic responsibility to follow up the two Quality Assurance reports from 2016 regarding decommissioning of the Norwegian research reactors and their associated facilities. The cost estimate for these activities is 15 BNOK over several decades, however, with considerable uncertainty. For the present budget for 2018-2019, the Government has allocated 280.4 MNOK.

In 2019, the main focus of activity are: to build the new organization, Norwegian Nuclear Decommission (NND), prepare plans for the decommissioning of the Halden reactor, evaluate alternatives for treatment of national inventory of nuclear spent fuel, consider a new storage and deposal for low- and intermediate level radioactive waste, while maintaining the safety of the nuclear facilities in Norway.

1.7.5 Provisions for research and development programmes

DSA monitors radioactivity and radiation. The monitoring programme involves maintaining an up-to-date overview of radiation sources at home and abroad, concentrations of radioactivity and radiation, use and exposure of radiation in working life, daily life and the environment. DSA's overview provides a basis for management, supervision, emergency preparedness and for safeguarding national and international obligations. Further, DSA coordinates national surveillance of radioactive pollution in the environment, participates in national environmental data coordination and develops, and publishes, relevant knowledge about emissions and waste from Norwegian activities, as well as the occurrence and effects of radioactive material in the environment.

DSA is a partner in the Centre for Environmental Radioactivity, Centre of Excellence (CERAD (CoE)) at the Norwegian University for Life Sciences, which provides research and development input to relevant DSA work programmes, as appropriate. The need for additional research and development capabilities associated with decommissioning and the development of expanded and/or additional facilities for the storage and disposal of radioactive waste will be determined, in accordance with the national strategy, which is currently under development.

1.7.6 Interdependences of steps in the predisposal management of radioactive waste and the impact of the anticipated disposal option

The owner of a disposal facility is responsible for the facility after closure and DSA may assign a period for the maintenance of institutional control of the facility after closure in its licence or permit, and has done so for the combined facility for storage and disposal or low and intermediate level radioactive waste at Himdalen.

DSA gives permits to disposal facilities in accordance with the PC Act sections 11 and 16. Section 16 states that the authority may lay down further conditions with which the holder of a permit must comply. One such condition for disposal facilities is that the owner of the facility must plan for environmental monitoring and maintenance of the facility for a specified time period after closure, and a financial guarantee is required. Before closure, the owner must provide a plan for closure and present it to DSA for approval. DSA can also inspect the facility when needed. The newly established public entity, Norwegian Nuclear Decommissioning, will have a key role regarding the maintenance of institutional control over nuclear disposal facilities after closure.

1.7.7 Plans for improvement

There are ongoing processes to develop a national strategy for decommissioning and radioactive waste management, including planning for enhancing the national capacity for the disposal of low and intermediate radioactive waste in preparation for decommissioning of Halden research reactor. The newly established public entity, Norwegian Nuclear Decommissioning (NND), will have a key role regarding the maintenance of institutional control over radioactive waste facilities after closure.

- → Develop a comprehensive governmental policy and strategy for all radioactive waste, including that from decommissioning of nuclear facilities and management of spent fuel, taking into account the diversity in the types of radioactive waste and the radiological characteristics of radioactive waste and spent nuclear fuel.
- → Implement the changes needed to harmonize clearance levels for waste in the PC Act and the NE Act to be able to take a site out of regulatory control.
- → DSA need to further develop and finalize the guide on 'Regulatory Requirements for Decommissioning of Facilities' and to decide on the regulatory approach and strategy.

1.8 COMPETENCE FOR SAFETY

Related to GSR Part 1 (Rev. 1): Requirement 11

1.8.1 Government provisions for ensuring sustainable competence of all parties.

The specification of competences of the regulatory body is effectively defined by the tasks allocated to it by the ministries (HOD, KLD, MFA) and is reflected in the organizational structure of the regulatory body. If new competences or needs are identified, this will normally be reflected in the budgeting processes.

The competence of authorized parties having responsibilities relating to the safety of facilities and activities may be required either through the licensing process (to fulfil the competence requirements according to the RP Regulations), or by laying down competence conditions in the specific licences and permits (NE Act section 8 and PC Act sections 11 and 16).

1.8.2 Requirements on competence levels and provisions for qualified and experienced staff

In the RP Act it is stated in section 7 that:

"In activities covered by the Act, employees and other associated persons shall, to the requisite extent, have education or training, ensuring that they have sufficient qualifications or knowledge in the area of radiation protection and safe use of radiation".

For the NE Act and PC Act, there are no legal provisions describing the meaning of "*sufficient qualified and experienced staff*". However, in both cases the authority may set specific conditions in the specific licences and permits.

1.8.3 Arrangements for professional training and for periodic verification of competence of authorized parties

Normally, it is expected that the relevant radiation protection personnel complete a three-day course at a private enterprise or at the University of Oslo.

There are variations between educational institutions in the content and scope of radiation protection training provided for the health professionals, and this is often less extensive than is recommended by the EU and the ICRP. The radiation protection content in the curricula for radiographers, specialists in nuclear medicine and professionals in the dental health service is satisfactory, and in line with the international recommendations. For most specialist physicians, there is very little radiation protection included in their education and the formal competence in radiation protection among health personnel, on completion of their education, is not up to the recommendations of the EU and the ICRP. Justification and optimization have been identified as two of the radiation protection themes that must be strengthened in educational programmes. The level of radiation protection competence among newly-qualified health personnel has been found not to correspond to the health authorities' expectations for safeguarding radiation protection for both patients and personnel.

Nordic nuclear safety research (NKS) is a platform for Nordic cooperation and competence in nuclear safety, radiation protection and emergency preparedness. Its purpose is to carry out joint activities producing seminars, exercises, scientific articles, technical reports and other types of reference material. NKS is financial supported by Nordic authorities, companies and other organizations.

1.8.4 Requirements and provisions for appropriate research and development programmes

DSA monitors radioactivity and radiation. As indicated above, this programme provides information necessary to provide a basis for management, supervision, emergency preparedness, and for safeguarding national and international obligations. This programme also provides an input to determining whether and which further research and development activities are necessary, for example related to the occurrence and effects of radioactive material in the environment.

1.8.5 Periodic verification of the technical competence of authorized parties

Verification of competences of persons working for authorized parties is an integral part in the authorization processes, the first time of application, upon renewal or change in authorizations, and during various types of inspections.

1.8.6 Plans for improvement

The need for necessary competence, relating to safety of facilities and activities, is imbedded in regulatory requirements (RP Regulations) or as specific competence conditions in licences or permits (NE Act and PC Act)

Competence in radiation protection is a key requirement for health professionals under the RP Regulations. However, surveys among health professionals of education in radiation protection have demonstrated many and lasting shortcomings.

→ The need for establishing learning objectives in radiation protection in the curriculums for relevant health personnel should be addressed.

1.9 PROVISION OF TECHNICAL SERVICES

Related to ***GSR Part 1 (Rev. 1): Requirement 13***
GSR Part 3: Requirement 2, paragraph 2.23

1.9.1 Government provisions for technical services relating to safety

Since 1958, DSA has offered a personal dosimetry service (PDS) to all types of undertakings in Norway that have workers exposed to ionizing radiation at work. The DSA personal dosimetry service has of the order 9000 users, and is the dominant provider of PDS in Norway. In 2018, DSA established an official national personal dose registry covering all exposed workers in Norway.

DSA, has, as one of its primary functions, operation of the secondary standard dosimetry laboratory (SSDL) in Norway. The rationale for the establishment of this laboratory was the need to have proper dosimetry regarding the medical use of radiation. DSA participates, when relevant and appropriate, in different international inter-comparison campaigns and projects regarding dosimetry, personal dosimetry and environmental monitoring and sampling.

Since the period with fallout from atmospheric A-bomb testing in the late 1950s and early 1960s, the Government established various environmental monitoring programs via DSA to monitor air, water, food and agricultural samples with regard to fallout and discharges to the environment. DSA currently operates high volume air sampling and measurements at 5 locations (Østerås, Svanhovd, Skibotn, Ørlandet and Sola). Background gamma-measurements are organized in a network 'RADNETT', which consists of 27 stations located throughout the country.

Operators or regulated facilities and activities that give rise to radioactive discharges or radioactive wastes are generally required to undertake environmental monitoring under the conditions of their permits, depending on the type of facility or activity.

DSA has laboratory facilities for environmental monitoring for gamma-, alpha- and beta-emitting radionuclides using a variety of sampling techniques. DSA's facilities include a dedicated radon laboratory.

1.9.2 Authorization of technical services

There are at present no formal regulatory requirements regarding authorization of DSA's technical services, but in practice QA procedures are developed for the technical services based on the ISO 17025

standard. Parts of the laboratory services (Gammaspektrometrilaboratoriet and Beredskapsenheten Svanhovd) are accredited by Norsk Akkreditering.

1.9.3 Plans for improvement

DSA's Personal Dosimetry Service (PDS) is the main provider of personal dosimetry to occupationally exposed workers in Norway. Similarly, DSA provides services related to environmental monitoring for measuring gamma-, alpha- and beta-emitting radionuclides, using a variety of sampling methods. DSA's facilities include a dedicated radon laboratory. Some of these services have national or international accreditation.

- → DSA should prepare for and seek accreditation for all technical services it offers;
- → DSA should propose the inclusion of a provision in the RP Regulations about authorization and accreditation of personal dosimetry laboratories in Norway.

1.10 CONCLUSIONS AND ACTIONS

Norway has established an effective legal framework for safety. Prime responsibility for safety is clearly allocated to the organization responsible for the activity or operation. The responsibilities of those responsible for regulation are clearly allocated and the effective independence of the regulatory body is stated through legislation and the annual Parliamentary proposal document concerning the national budget (Proposition 1S).

As a consequence of the most recent reorganization of DSA, effective from 1 July 2017, DSA regained its independent status as a Directorate, to strengthen its role as an independent regulatory body authority according to international standards. Good coordination among different authorities has existed for many years, within the many fields related to societal safety and security. In a radiological or nuclear emergency, the Crisis Committee is responsible for coordinating the response.

1.10.1 Actions

- → It is necessary to investigate whether the effective independence of DSA as the regulatory body for safety needs to be further ensured;
- → A national policy and strategy for safety should be developed in accordance with the Safety Fundamentals;
- → The inclusion of the NE Act into the family of HES legislation should be considered, making the IC Regulation applicable to facilities and activities regulated by the NE Act;
- → A comprehensive governmental policy and strategy for decommissioning of nuclear facilities and the management of radioactive waste and spent fuel should be developed;
- → The need for a provision in the RP Regulations for authorization and accreditation of personal dosimetry laboratories in Norway should be considered.

2 GLOBAL NUCLEAR SAFETY REGIME

2.1 INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATIONS

Related to GSR Part 1 (Rev. 1): Requirement 14

Norway has for many years contributed to the global international safety regime through a number of different means. This is done through various channels:

- → Political commitments;
- → Allocation of funds and grant applications for nuclear safety internationally and in specific regions of interest to Norway;
- → Bilateral and multilateral project implementation, specifically in the region of interest (especially Russia and Ukraine, but also Eastern European- and Central Asian countries);
- → An active engagement internationally e.g. through leadership in fora regarding international cooperation on nuclear safety.

The role of the Norwegian Radiation and Nuclear Safety Authority (DSA), as a directorate for the Ministry of Foreign Affairs (MFA) on nuclear safety and security issues is described in a specific agreement between the Ministry of Health and Care Service (HOD) and the MFA prepared in 2005. DSA works closely with MFA advising on policy issues and taking part in international fora together with, or on behalf of, the MFA. This work has shown to be an effective way of implementing the MFA policy on global nuclear safety issues and for providing an active part in implementing Norwegian official positions.

A similar agreement exists with the Ministry of Environment and Climate Change (KLD) from 2005, where DSA acts as a directorate for KLD in the area of environmental protection from radiation.

2.1.1 International Conventions and other political commitments

Norway 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 Ionising Radiations.

Norway has also made a political commitment with regard to the Code of Conduct on the Safety and Security of Radioactive Sources, and the associated Supplementary Guidance on the Import and Export of Radioactive Sources, in addition to the Code of Conduct on the Safety of Research Reactors.

2.1.2 Promotion of International Cooperation and Assistance

Since 1995, Norway has established a Governmental Nuclear Action Plan (NAP) with strategic goals and yearly funding to enhance nuclear safety in Russia, Ukraine and other Eurasian countries. Until 2014, this plan focused mainly on activities in Northwest Russia, but now Ukraine, Belarus and other Eurasian countries are also included. After 2014, the focus on Ukraine increased. The Norwegian Prime Minister, Erna Solberg, announced at the Nuclear Security Summit in 2014 that Norway would assist Ukraine on nuclear safety and security issues.

The Nuclear Action Plan has, over time, been approved by a number of different Governments in Norway, showing the long-term political will to focus on this area. The plan, with strategies and goals, has been revised several times. Strategies and funds for the Nuclear Action plan are described in the yearly allocations of tasks and budget to DSA.

Norway allocates funds through different financial mechanisms to enhance global nuclear safety regime e.g.; IAEA extra budgetary funds for peaceful uses of nuclear energy; The Norwegian Government Nuclear Action Plan; the European Economical Area (EEA) and Norway Grants and allocation of funds through international mechanisms such as the European Bank for Reconstruction and Development (EBRD).

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

- → International Atomic Energy Agency (IAEA);
- → Heads of European Radiological Protection Competent Authorities (HERCA);
- → Organisation 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).

2.1.3 International, multilateral and bilateral cooperation programmes

DSA has, for many years, been heavily engaged in bilateral projects to reduce the risks from nuclear and other radioactive materials in Russia from, for example, decommissioned nuclear submarines, nuclear power plants, waste storages and Radioisotopic Thermoelectric Generators. These projects have been funded through the Nuclear Action Plan mentioned above. Dealing with the nuclear legacy after the Cold War has been an essential part of this work, and cooperation between regulatory authorities in Norway (DSA) and in Russia has been an important aspect.

The cooperation projects in Ukraine are also funded through the Nuclear Action Plan, and cover areas such as safety and security at nuclear power plants, waste management, emergency response and border

control. The cooperation has been both bilateral and multilateral (in cooperation with Sweden, United States and Germany). Norway also supports different funds administered by EBRD: e.g. the rehabilitation of the Chernobyl site (NSF), nuclear safety in Northwest Russia (NDEP-Nuclear window) and rehabilitation of Uranium legacy in Central Asian countries (ERA). EBRD. Norway, together with US partners, has taken initiative to establish an international coordination group (ISI) among the countries with nuclear safety and security programmes in Ukraine. The first meeting was arranged in Oslo in 2016 during the Ukrainian presidential visit to Norway.

Norway has been an active member of the G7 Global Partnership since 2003. This work is closely connected to cooperation with Russia and Ukraine on nuclear safety and non-proliferation, and has been of great importance for the international community.

In Central Asian countries, Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan, DSA is actively engaged in improving the regulatory regime to deal with their nuclear legacy. This is achieved through cooperation between regulatory authorities and by implementing international recommendations from IAEA into the national legislation and recommendations. Due to its long-term bilateral cooperation with Central Asian authorities on nuclear legacy issues, DSA was asked to lead the IAEA's newly established EuCAS (European Countries and Central Asia) network in 2016, to deal with nuclear safety issues in Eastern Europe and Central Asian Countries.

In 2016, Norway, Finland, Sweden and Belarus signed a cooperation agreement on nuclear safety. This cooperation aims to support the regulatory authorities in Belarus in the areas of nuclear safety, radiation protection and emergency preparedness and response. This cooperation is partly governed by the Nuclear Action Plan.

DSA cooperates closely with countries in Eastern Europe (Romania, Slovakia, Ukraine and Lithuania) on nuclear safety, security and emergency preparedness through the EEA Grants arrangements. The DSA has gathered significant experience from EEA projects over the years and is committed to continue this in the future.

There is also close cooperation between the Nordic countries through: the Nordic Nuclear Safety Research (NKS); the Nordic Group on Industrial Use of Radiation (NORGIR); the Nordic Meeting with General Directors of Radiation and Nuclear Regulators; the Nordic Working Group of Emergency Preparedness (NEP) and the Nordic Pubic Cooperation Group (NNPC).

2.1.4 IAEA Safety Standards and International Peer Reviews

DSA staff participate in the development of IAEA safety standards through participation in the IAEA's Safety Standards Committees (NUSSC, WASSC, RASSC, TRANSSC, NSGC and EPReSC), and in consultancy meetings for the development of safety standards. When developing licence conditions, requirements and guides, the IAEA safety standards are one of the main bases.

Norway also has invited IAEA to perform the following missions to Norway:

- → 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 has provided experts to several international IAEA missions, such as IRRS, IPPAS, Advisory Missions and INSARR, and also participated in the EU Topical Peer Review on aging management of nuclear power plants and research reactors in 2017/2018.

2.2 SHARING OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Related to GSR Part 1 (Rev. 1): Requirement 15

DSA has made many arrangements for sharing regulatory experience and for dissemination of lessons learned. In 2014, DSA established an International Strategy for DSA with goals and procedures for how to work and how to make use of the information and the lessons learned from the international activities. It also includes procedures for how to update the overview of DSA's international activities and how to share information internally. The Governments Nuclear Action Plan (NAP) also describes how DSA's international work should be used domestically, e.g. in relation to emergency preparedness and information exchange.

DSA also uses IAEA Safety Standards as guidelines when national laws and regulations are developed, reviewed and updated. DSA has established internal procedures describing how to work in the IAEA Standards Committees and how to share information and coordinate DSA work related to the different committees. DSA also make use of recommendations from international missions such as IPPAS, INSARR and IRRS, when regulations, procedures and guidelines are developed.

Employees have access to established procedures for DSA's international work, including procedures on participation in and follow up following international fora and meetings. Reports of such meetings are posted on the internal webpage, and are distributed to the ministries and other relevant partners, as appropriate.

DSA participates in several international networks, fora and cooperation projects, to both share and receive information and international experience. The results of this information exchange are taken into account in the regulatory work and procedures of DSA. One example is the way in which DSA shared information with Japan after the Fukushima Daiichi accident, on the countermeasures in place in Norway after the Chernobyl accident. The information and international experience received by DSA is shared with national operators, users and stakeholders as deemed necessary, although there is no specific procedure for how this should be done.

2.3 CONCLUSIONS AND ACTIONS

Norway contributes to the global international safety regime through a number of different means, including political commitments, allocation of funds and grant applications for nuclear safety, which are implemented through international, bilateral and multilateral projects (especially in Russia and Ukraine, but also Eastern European and Central Asian countries). Norway also maintains active international engagement through leadership in fora related to nuclear safety. Norway takes part in IAEA peer review missions and supports implementation work in other countries related to follow up of peer review missions, for instance in Romania, Ukraine and Russia.

Norway has signed, ratified and implemented all relevant conventions in the area of nuclear safety and security and radiation protection. The Norwegian international obligations are implemented through many different national and international activities. Through the Governments Nuclear Action Plan, Norway puts

extensive efforts into enhancing the nuclear safety regime in Russia, Ukraine and Central Asian Countries. DSA applies international knowledge and experience into our regulatory regime and practice resulting from participation in international fora and bilateral and multilateral cooperation programmes. The close contact between the relevant ministries and the regulatory body ensures an effective implementation of strategic political goals as well as priorities for radiation protection and nuclear safety and security. DSA established an International Strategy in 2014, followed by new procedures in the quality management system, which enhanced the focus of DSA's international activities and the effectiveness of sharing information and lessons learned from international work to strengthen our own regulatory regime and regulatory practice.

In conclusion, the self-assessment shows a high degree of compliance with the GSR Part 1 Requirements 14 and 15.

3 RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

The Norwegian Radiation and Nuclear Safety Authority (DSA) is the responsible national regulatory body for the use of radiation sources, radiation protection, nuclear safety, security, safeguards, emergency preparedness, transport, radioactive waste and radioactive discharge to the environment, natural radiation, and non-ionizing radiation. DSA's authority and responsibilities as a directorate for the Ministry of Health and Care Services (HOD), the Ministry of Climate and Environment (KLD) and the Ministry of Foreign Affairs (MFA) are described in the Directive for the Norwegian Radiation Protection Authority, adopted by the Ministry of Health and Care Services on 1 July 2017. The primary legal basis for DSA's regulatory work is the Act on Radiation Protection and Use of Radiation (RP Act), the Act on Nuclear Energy Activities (NE- Act) and the Act on Pollution Control (PC Act) and their underlying regulations. DSA is responsible for regulatory control, while the three respective ministries are responsible for administrative appeals.

In addition, DSA act as an authority connected to Ministry of Defence for regulatory work, including the licensing process, inspections and emergency preparedness arrangements, for military reactor powered vessels entering Norwegian waters or ports.

Concerning nuclear emergency preparedness in Norway, DSA is by Royal Decree given the responsibility to provide a secretariat for the national Crisis Committee. The Director General (DG) of DSA is chairs the Committee, which has the mandate to handle the acute phase of the crises, and has the power according to the law to implement measures to reduce the impact and safeguard people and the environment.

The Government has also given DSA a key role in the implementation of international conventions, agreements, governmental strategies that Norway has ratified, signed or developed and additional tasks and responsibilities are provided in a number of international conventions and agreements.

In addition to being a directorate for HOD, KLD and MFA, DSA is also the competent body with responsibilities for authorization and inspection of transport of nuclear material according to the NE-act with regulations. Radioactive material class 7 is regulated in the ADR/RID regulations on transport of hazardous material on land and the IMO/MDG code at sea. The ADR/RID Regulations are primarily administered by the Norwegian Directorate for Civil Protection (DSB), which reports to the Ministry of Justice and Public Security, but DSA is a specialized agency for radioactivity. DSB, the Police and the Norwegian Road Administration and the Norwegian Custom are responsible for control of transport on road and rail.

DSA is also responsible for coordination and inspection related to the security of appointed protected objects that fall within DSA's areas of responsibility according to the NE Act. These facilities are regulated under the Act relating to protective Security Services (Security Act) and the underlying regulation. The Security Act is administered by The Norwegian National Security Authority (NSM), which reports to the Minister of Defence and Minister of Justice and Public Security.

DSA has responsibilities and tasks in addition to those it undertakes as as a regulatory body. DSA is mandated by an agreement with The Norwegian Metrology Service (JV) to operate a secondary standard dosimetry laboratory (SSDL) to implement and maintain the SI-units Gray, Sievert and Becquerel according to the Act on Measuring Units, Measurement and Standard Time. The responsible ministry for this Act is the Ministry of Trade, Industry and Fisheries (NFD). DSA also provides a personal dosimetry service (since 1958) under the mandate from HOD.

3.1 ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

Related to GSR Part 1 (Rev. 1): Requirement 16

3.1.1 Organization and decision-making process

The current organization of DSA has been operative since 2018. The last reorganization was driven by the DSA Strategic Action Plan for 2018-2020, with the objective of being able to perform the prioritized responsibilities and tasks more effectively. Organizational changes must be cleared with the ministries (HOD, KLD and MFA) according to the Directive for DSA (Instruksen).

DSA has two departments responsible for topical subject areas and one department responsible for planning and administration (POA).

The Department of Radiation Protection and Measurement Services (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. ASM is also responsible for measurement services (personal dosimetry, SSDL and measurements of radon and radioactivity in people and the environment). The ASM comprises three sections.

The Department of Nuclear Safety and Environmental Protection (AOM) is responsible for the regulation of nuclear safety and security, transport of nuclear materials, 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). AOM is also responsible for nuclear and radiological emergency and preparedness, the control of exposures from radon and for supporting international cooperation and support on nuclear safety and security. The AOM comprises five sections.

The DG of DSA is appointed by the Government and the employment time has no limitations. The DG reports to the three ministries (HOD, KLD and MFA). There is no Board at the DSA and the decisions are made in formal biweekly meetings of the Management Group, which consists of the DG, Heads of Departments, the Head of the Communication Section and a secretary. The DG has the authority to administer the budget in accordance with the annual Letter of Commitment (Tildelingsbrev). The DG may also delegate authority to persons responsible for established functions or executive leaders in the organization. The DG has the mandate to employ in accordance with the Working Environment Act (Arbeidsmiljøloven) and the Government Employee Act (Statsansattloven).

Work within DSA is organized in a holistic manner that provides an effective delivery of tasks within the responsibilities associated with different ministerial sectors. The management of these responsibilities within a single organization has proven to be more effective than the divided responsibility between different organizations. This has had the result of strengthening the regulatory work in nuclear and radiation safety and environmental protection and enhanced international cooperation. This arrangement has facilitated a more efficient use of resources and good coordination among the different sectors.

3.1.2 Financing and allocation of resources

DSA receives funding according to an annual budget that is decided by the parliament, based on proposals from the relevant ministries (HOD, KLD and MFA) and taking account of the overall priorities established in the national budget. These proposals are developed taking account of input from DSA on the risk-based

priorities for its work programme over the next year. Following parliamentary agreement on the budget, the ministries allocate the budget and assign specific tasks within their areas of responsibility (for health, including nuclear safety, environment issues and international work) to DSA in the annual letter of commitment (Tildelingsbrev). In addition, resources are available from fees in connection with the NE Act and the PC Act. The budget and associated tasks are then distributed within DSA in December each year, according to an established internal process, and following agreement at the relevant Management Group meeting.

The tasks DSA performs for the Ministry of Defence (FD), in relation to access of nuclear powered vessels to Norwegian ports and waters, has increased significantly over the last years. Such access constitutes an increased risk of accidents and accordingly the work burden on DSA to consider safety issues, environmental monitoring and emergency planning, including communication with local and regional authorities, has increased. Although FD gives the licence based on DSA proposals and advice, no fee for this activity, or inspections, is paid either by the operator or those representing the operator. Consequently, the financing is inadequate. In contrast, DSA's work on licensing and inspection of the research reactors and associated facilities are funded entirely by fees from the operator.

DSA is responsible for operation of the secondary standard dosimetry laboratory (SSDL). The activities at SSDL is the basis for implementation of the SI-units Gray, Sievert and Becquerel and calibration of dosimeters and related instrumentation, traceable to primary standards. There is no external funding for these activities at present.

The areas prioritized in the Strategic Action Plan are based on the risk associated with the activities or practices. The available budget provided by each ministry must be used to fulfil the specified tasks that fall under the areas for which the ministries are responsible. The DG has the power to decide how many positions are needed to fulfil the authority's tasks within the available budget limits from each ministry. After DSA has given an input to the Government, based on DSA's risk-based prioritizations, and after the Government proposal for budget and the parliament's decision, there are some limitations in the use of the resources based on the allocations for different sectors and the available fees. The allocation of staff and resources, including the fees, within each of the areas for which the ministries are responsible reflects the view of the associated radiation risks. However, it would be helpful to implement a more formal documented procedure, which includes assessments of the radiation risks associated with facilities and activities, to inform the allocation of resources at Management Group meetings. This would help to ensure that available resources are more systematically allocated in accordance with a graded approach. It has also been identified that some of the areas for which HOD is responsible seem to be under-financed, based on the risk associated with the involved activities and practices.

3.1.3 Planned improvements

- → The staffing and the available resources under the Ministry of Health and Care Services are only to some extent commensurate with the radiation risk associated with facilities and activities and the budget should be strengthened in accordance with a graded approach.
- → The assistance given by DSA to Ministry of Defence regarding visits from military submarines and ships in Norwegian ports should be funded adequately.
- → DSA should address the need for proper financing from the relevant responsible ministries related to the SSDL laboratory at DSA.
- → DSA should establish a formal documented procedure, which includes assessments on the radiation risks associated with facilities and activities, when allocating its resources.

3.2 EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Related to GSR Part 1 (Rev. 1): Requirement 17

3.2.1 Preservation of effective independence and cooperation

DSA is an independent decision-making authority under the provisions of the RP Act, the NE Act and the PC Act (for the financial resources c.f. Proposition 1 S for 2018). In principle, within their areas of responsibility, different ministers may make decisions and issue instructions to the authority on a general basis and also on specific cases but this is usually avoided. However, the NE Act effectively recognises the primary authority of DSA on issues related to nuclear safety and security (article 10 NE Act). This ensures 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 could result in a conflict of interest. However, in practice, the licensed hospitals are generally organized as independent hospital trusts, which are governed by independent boards, such that this problem does not arise.

DSA is also a user of radiation sources, an employer of staff who receive occupational exposures, and a producer of radioactive waste and discharges. In order to avoid possible conflicts of interest, the Ministry of the Environment has agreed that permits under the PC Act, for relevant DSA activities, in special circumstances, may be granted by the Ministry or another appointed authority. Similar agreements are not in place 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. The authorizations are transferred to other sections not responsible for the sources and activities applied for.

DSA participates in research and 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. There is no formal procedure dealing with DSA independence in these circumstances. However, in the new integrated management system that is under development, such procedures will be included.

3.2.2 Preservation of integrity of regulatory staff and resolving conflicts of interest

Public administrative authorities, like the DSA, perform their functions and regulatory management in accordance to the Public Administration Act (PA Act) and Freedom of Information Act (FoI Act), which ensure an open and transparent public administration (Forvaltningsloven, Offentlighetsloven og statsansatteloven). In addition, all State employees must follow the Ethical Guidelines for the Public Service (Etiske retningsliner for statsansatte). This guideline covers the employees' duty of loyalty, transparency, impartiality and professional independence. Public administration and decisions made by DSA are open and transparent and the general rule is that all documents are open to the public. Cases concerning national security, international relations, commercial relations and the individual's right to privacy are typically classified and not available to the public.

To preserve and enhance the public's confidence in the public administration service, it is important to be an independent authority. Conflicts of interest, impartiality and the grounds for disqualification of State employees are covered in chapter II of the PA Act, Ethical Guidelines for the Public Service and in DSA's local guidelines for employees (Short guidelines about the Public Administration Acts chapter about disqualification). This act and guidelines regulate when and in which cases a state employee is disqualified

from service. The responsibility for identifying and notifying the employer about any disqualifications or possible conflicts of interests rests with the state employee. All evaluations and conclusions regarding disqualifications must be written and recorded together with the case documents. In addition, the State Employees Act (statsansatteloven) regulates how state employees shall act if they are offered gifts (§ 39); State employees are not allowed to receive gifts, provisions, services or other contributions that can influence the performance and their independency of their duty.

The 'National Governmental Personnel Manual' (chapter 10.13) regulates the possibility for employees to have outside or second jobs, in other companies and organizations. Normally, outside and second jobs are accepted, but this right is not unlimited. All outside and second jobs, directorships or other paid assignments that are not compatible with the legitimate interests of the State as an employer, that may lead to any conflict of interest, disqualification of state employees, unfair competition and in any way influence the independence of the employee and trust in the public service, are not accepted.

3.2.3 Recruitment of staff

Employment and recruitment of DSA staff follows formal internal procedures and are regulated by the SE Act (statsansatteloven). This act covers the employment process, which is based on the qualification principle, and how to deal with dismissal. To help ensure the confidence of public in the administrative agencies, specific legislation exists regulating the transition for state employees to private companies that could be associated with any conflict of interest (The Act on duty of information, quarantine and prohibition of politicians, officials and Government employees (Quarantine Act) (chapter 4) and underlying regulations). There is no formal procedure at DSA describing how to ensure the avoidance of conflicts of interest 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. The necessary time period is decided from case to case.

Training of newly recruited staff follows internal procedures, but a need to make them more formal has been recognized. 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 shortly after employment.

3.2.4 Authority to intervene in connection with any significant risk

DSA has the authority, through the provisions in the RP Act, the NE Act and the PC Act, to intervene towards any facility or activity that presents a significant risk at any time and irrespective of costs to the authorized party. DSA may also require the authorized party to improve the situation in order to be in accordance with the regulations and, if the radiation risk is significant, immediate actions such as closure or clean-up can be demanded. If the public authority intervenes, the costs, damage or losses incurred may be claimed from the person responsible for the pollution of waste problems, according to the PC Act section 74.

3.2.5 Planned improvements

→ DSA should develop quality assured internal procedures in the (new) integrated management system to ensure independence regarding situations when DSA staff participate in research, national quality assurance cooperation, or projects with undertakings or institutions that might need

licences, permits or registrations normally issued by DSA. This might include arrangements with the ministries on delegation of authorities to other bodies to enable them to issue the necessary permits or licences.

3.3 STAFFING AND COMPETENCE OF THE REGULATORY BODY

Related to GSR Part 1 (Rev. 1): Requirement 18

3.3.1 Staffing

The Director General (DG) of DSA has the power to employ the necessary staff within the budgetary frames 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 that is fully commensurate with the nature and number of facilities and activities regulated.

The external reorganization of governmental health authorities (including DSA) initiated by the ministry of Health and Care Services (HOD) had an impact on the staffing situation at DSA. This external reorganization was part of the Government's efficiency programme with the aim to reduce costs and to streamline the public sector. In this process, in 2016, DSA (then NRPA) was reorganized and became an agency with a separate General Director and budget under the Norwegian Directorate of Health, under HOD. In addition, support functions such as the library, archive and IT were outsourced and centralized over the time period from 2016-2018, Public authorities (including DSA) were also instructed to reduce their workforce by 5% and a recruitment freeze was introduced. In July 2017, the reorganization of DSA was reversed following an assessment by the Norwegian Ministry of Foreign Affairs (MFA) and in order to fulfil DSA's obligations and recommendations under the International Conventions signed and ratified by the Government of Norway.

On 1 July 2017, DSA was re-established as an independent directorate directly under HOD to ensure its status as an effectively independent regulatory body according to international standards. However, the instructions to reduce the workforce and outsourcing of support functions were not reversed. DSA fulfilled the workforce reduction by natural departures of staff, mainly through retirement. In this way, the reduction in the workforce was random with respect to loss of competences, vacant positions were not replaced, and many sections became understaffed (HOD area). To cope with this situation, DSA decided to reorganize and the new organization came into effect 1 January 2018. The main changes were to close the section responsible for research and to reallocate staff from research to regulatory tasks. However, this process was challenging due to the staff competence profiles. The outsourcing of IT support functions to the Norsk Helsenett (NHN) has cost DSA significantly more than estimated. Despite this, no additional budgetary resources have been provided by the responsible ministry (HOD) and the additional costs must be taken from the ordinary budget. This has resulted in a new recruitment freeze in 2019 within HOD area with the result that it is still not possible to fill existing vacant positions, with exception of a few identified key positions. The effects of the external reorganization and the out-sourcing of support functions (like IT) has not yet been fully evaluated. DSA has identified a need to perform an evaluation of this process that takes into account its effect on budgetary frames and staffing level. As of June 2018, DSA had a full-time equivalent of 112 employees. The average age was 48 years. Approximately two employees retire every year. The staff turnover rate was 6.6 % during 2017.

The current organization of DSA consists of the Director General, a Communication Unit, the Department of Planning and Administration and two operational Departments; the Department of Nuclear Safety and

Environmental Protection, with five underlying sections, and the Department of Radiation Protection and Measurement Services, with three underlying sections.

Administration and Communication
The Department of Planning and Administration consists of seven persons and is responsible for human resources, finance, quality management, reception/switchboard operator and the administrative support to the Director General. As indicated above, support functions like the library, archive and IT have been outsourced and centralized during a time period from 2016-2018 as part of the Governments efficiency programme for the public health sector. The Communication unit consists of four persons and is responsible for all communication-related activities and the development and maintenance of DSA's intranet and external web-pages.

The Department of Nuclear and Environmental Protection
The Department of Nuclear Safety and Environmental Protection, is organized in five sections and has 61 employees in total. The Department regulates nuclear safety and security issues in the nuclear sector in Norway and the discharges to the environment and radioactive waste management activities, the measurement of activity in the environment, strategies for the control of radon exposure and emergency preparedness and response.

The nuclear sector in Norway comprises two research reactors, and associated fuel cycle facilities, and radioactive waste management facilities including interim storage facilities and the national repository for intermediate and low level waste. The Department also regulates the use of radiation sources at nuclear facilities, transport of nuclear materials, safeguards and decommissioning of the research reactors and remediation activities. Further, in the nuclear sector, the Department is responsible for regulatory work including the licensing process, inspections and emergency preparedness arrangements for military reactor powered vessels entering Norwegian waters or ports. This work has increased considerably over the last years from an average of less than 10 to about 30 -40 yearly, with higher values in some years. An increasing number of locations is also being visited, adding to the regulatory workload. To do this work, 6.5 persons are allocated per year for the nuclear sector under the NE act, of these 1.5 persons deal with the nuclear military sector. The civilian nuclear safety work is fully financed by fees from the operator. However, there is currently no fee charged for regulatory work for the military nuclear sector and this work is currently funded under the budget from HOD.

The Department is responsible for the national emergency organization (the Crisis Committee), which is a cross sector organization established with a national mandate, established though a royal degree on the basis of the RP Act. The Crisis Committee is led by DSA, and DSA provides the secretariat. To achieve this, and to deal with other emergency response tasks directly connected to DSA including the emergency part of DSAs two laboratories in the high north, 9 person years are funded from the ordinary budget and 1.5 from extra budgetary fund after yearly applications to HOD. HOD has, in recent years, increased funding available which has been allocated to emergency preparedness.

Four people are involved in the control of exposure from radon. Assessing and monitoring trends in the exposure of the public, involves 1.5 person years funded by the HOD budget. The environmental monitoring programme undertaken for KLD involves an additional 4 person years.

The work on international nuclear activities, such as non-proliferation verification, including managing the support programme for North West Russia, Ukraine and Eurasia, is funded according to a yearly decision by the Ministry of Foreign Affairs (MFA). DSA does not have a budgetary chapter in the national budget for work for this ministry, as it has for work with HOD and KLD. DSA provides input to MFA on the programme of work under the International Nuclear Safety Action Plan on an annual basis and receives funding accordingly. There are 9 persons working in this area.

The Department's work in the area of environmental regulation is funded by KLD in the national budget. This work involves 12 members of staff and includes permitting activities associated with releases of radioactive material to the environment, licensing of repositories of non-nuclear waste, and licensing of nuclear waste and environmental assessment under the PC Act . Work is in progress to apply the polluter pays principle by establishing a fee system for this work. At present, a total of 130 such permits have been granted.

In addition to the above, work is also funded on the basis of time-limited funds provided after applications to funding organizations such as the Norwegian Research Counsel, EU, Nordic cooperation, EØS mechanism for funding projects in EU countries and other *ad hoc* funding programmes. The funding for a total of 13 persons in the Department is obtained in this way.

In addition, the Department includes 2 administrative personnel, one is funded under the ordinary budget and one after external applications to the Research Council.

A number of shortcomings in the regulation and performance of nuclear safety and security and related to radioactive waste and decommissioning in the nuclear sector where identified in 2014 and 2015 with the result that deficiencies in the competence of both the regulator and the operator were identified. There continues to be a severe lack of competence and resources in some areas of nuclear safety, security, and decommissioning. KLD has provided significantly increased funding to DSA from 2019 to cover the handling of decommissioning and radioactive waste, in their area of responsibility.

Department of Radiation Protection and Measurement Services
By June 2018, the Department of Radiation Protection and Measurement Services had 44 employees. The Department works with authorization and management of all types of activities involving radiation and is responsible for the technical support laboratories. The Department is divided into three sections: Section for Medical Applications (12 employees), Section for Source Security, Radiation Application and UV (11 employees) and Section for Radiation Measurements (15 employees). The Department also has a staff of three people to support the Head of the Department. In total 10 full-time equivalent positions are involved in regulatory management and inspections of activities associated with ionizing radiation.

The Section for Source Security, Radiation Application and UV has three full-time equivalent positions working with regulatory issues of all types of non-medical application of ionizing radiation sources (industrial, research, etc.) and 6.5 full-time equivalent positions that work with all types of non-ionizing radiation (non-medical applications, research and public protection from UV).

The Section for Medical Application has 7 full-time equivalent positions working with regulatory issues of all medical applications of ionizing (and non-ionizing) sources. In addition, the Section is responsible and serves as the secretariat for the National Program on Quality Assurance in Radiotherapy (KVIST) mandated by Ministry of Health and Care Services (HOD). Three part-time employees work within this program. Personnel working with regulatory issues cover all aspects including issuing authorizations, inspections, reviewing annual reports for the undertakings, and answering questions from all relevant stakeholders (public, responsible parties, governmental authorities and ministries).

The Section for Radiation Measurements is responsible for all the technical support laboratories associated with radiation measurements and surveillance-programs. These laboratories consist of the secondary standard dosimetry laboratory (SSDL) designated as the national reference laboratory, personal dosimetry service, measurements of optical radiation and UV-network, and laboratories for radon and environmental radioactivity measurements.

The Department of Radiation Protection and Measurements Services has issued in total 875 authorizations related to the use of ionizing and non-ionizing radiation, 755 of these are related to the use of ionizing

radiation. Some of these are expired and not renewed. The highest number of authorizations are issued within the area of industrial radiography (187), X-ray in diagnostics (191) and to distributors of radiation sources (122). At present, 9640 ionizing radiation sources and 6658 non-ionizing radiation sources are registered as 'in use' in the DSA's electronic database for radiation sources. All these practices and sources are regulated according to the Department's regulatory management programme. When it comes to the technical support laboratories, approximately 1200 samples are analyzed annually by alpha, beta or gamma spectrometry. The SSDL performs 60-100 calibrations a year andthe personal dosimetry service has about 6000 users. The radon laboratory performs about 150 analyses of radon in water annually while measurements of indoor radon using track detectors varies from a few hundred to 2500 a year, depending on running projects.

The staff-situation in the Department has become critical during the last years due to many vacancies, which has made the Department vulnerable. For the Section for Source Security, Radiation Application and UV, strict prioritizing of inspections has been necessary, due to the limited number of staff with the necessary competence available. On-site inspections have mainly been performed on high-risk sources. To be able to cover inspections of facilities operating low- and medium-risk sources (like facilities operating control- sources and veterinary use of X-rays), inspections through electronic questionnaires has been increased. For Section on Medical Applications, the number of facilities and authorizations has increased (mainly due to an increase in the number of dental CBCT and chiropractors). In addition, two proton therapy facilities are under planning (for the first time in Norway) and three to four hospitals are planning to establish new photon beam radiotherapy facilities. The staff situation at the different measurement laboratories (like SSDL, personal dosimetry, UV-lab and measurements and surveillance of radioactivity) is also challenging and vulnerable (some laboratories are operated by only one person). The laboratories have an vital function in supporting the management of radiation sources, for estimating the exposure of workers, the public and the environment, in monitoring the radioactive pollution of the environment and the quality control of medical exposure like radiation therapy.

The Ministry of Health and Care Services (HOD) finance all activities performed by the Department of Radiation Protection and Measurement Services. The Department is understaffed, vulnerable and operates under a very tight budget, resulting in hard priorities. The available resources and staffing-level financed under the HOD for the areas for which the Department is responsible are only to some extent commensurate with the radiation risk associated with facilities and activities. This situation has made it difficult to maintain an effective and safe regulatory management programme and to perform an adequate inspection regime regarding the many licenced facilities and activities in the medical, industrial and research sector for planned use of radiation sources. The Department does not have a sufficient number of qualified staff and available resources to carry out its functions and discharge its responsibilities in a justifiable way.

3.3.2 Competence of the regulatory body

DSA has highly educated and qualified staff. As of June 2018, 19 % of the employees had a PhD, 58 % had a Master degree, 21 % had a Bachelor degree and 2 % had completed secondary high school. The employees' level of education and competence is generally commensurate with the types of tasks they fulfil. However, DSA covers a broad, and at the same time deep area 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. DSA needs to develop a formal human resource plan that identifies the number and the necessary qualifications and competence of staff as an input to reducing the authority's vulnerability further.

In the field of medical applications, there is no medical doctor among the staff. Considering the volume of facilities and activities regulated in medical sector, and that most of DSA's regulatory actions are motivated by protection of health for workers, patients and the general public, recruitment of medical competence should be considered.

In the nuclear field, recruiting competent personnel with the necessary qualifications is very difficult due to the limited scale of the nuclear programme in Norway and to the relatively few candidates with relevant expertise. Due to this, DSA has recently recruited employees from other European countries with the necessary knowledge and experience, but with a language challenge, accordingly. The available resources allocated to this area are also limited to those available from the fees payed by the operator, particularly given that no fees are available for work within the military sector.

DSA has initiated a process to map the competencies of the employees and the competency needs of each department and section. The outcome of the competence mapping will be used to identify areas where competencies are lacking, to see if there are any specific competencies among the current staff that can fill these gaps or whether recruitment is necessary. The results of this analysis will be continuously updated, as part of the new integrated management system, which is under development. Succession planning could also be improved as part of this process, for example by identifying and formally documenting areas where the DSA is potentially vulnerable in its dependence on key individuals.

3.3.3 Human resource and succession planning

DSA is now in the process of considering establishing a human resource plan that will identify the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions and other tasks necessary to discharge DSA's responsibilities. The human resource plan will take account of the nature and number of facilities and activities regulated by DSA and will be guided by the more systematic application of a graded approach that reflects the associated risks. DSA also intends to develop a formal process, including a training programme, for developing and maintaining the necessary competence and skills of its staff. The human resource plan, system of knowledge management and training programme will be included in the new integrated management system, which will facilitate its frequent review and updating.

3.3.4 Knowledge management and regulatory training

DSA has an established formal recruitment process in accordance to the State Employees Act. However, the transfer of knowledge from employees leaving DSA is not formalized and is dependent on the staff involved and the Head of the Section. DSA does not currently have a formal training program for newly hired staff. Training is based on internal training under the responsibility of the leader, delegation of an experienced colleague and relevant courses, chosen on an ad-hoc basis. However, it is obligatory for inspectors to attend an external inspection course organized through a collaboration between the regulatory authorities in Norway.

3.3.5 Planned improvements

→ There is a need to increase the competence within DSA's organization in relation to the challenging process of entering into a decommissioning phase of Norway's nuclear program and in supporting the development of a national strategy for spent fuel and radioactive waste and the associated regulatory processes.

- → There is need to increase the competence within DSA's organization in relation to the introduction of proton therapy in Norway and to establish the regulatory program for this new activity.
- → DSA should develop an operative human resource plan regarding organization, management, resource allocation and competences necessary to enable the regulatory body to fulfil its statuary obligations. In this work, it is recommended to consult the resource document, IAEA General Safety Guide No GSG-12, "Organization, Management and Staffing of the Regulatory Body". In this process, DSA should finalize the mapping the competencies of the employees against the competency needs of each department and section to identify gaps.
- → DSA, together with the responsible ministry (HOD), should develop a detailed plan on how to ensure that DSA employs a sufficient number of qualified and competent staff that is commensurate with the nature and number of facilities and activities regulated, and to carry out the full range of its functions and discharge its responsibilities. This plan should be based on DSA's human resource plan (to be developed).
- → DSA should develop a system for knowledge management, including a formal training program for newly hired staff, to ensure the development and maintenance of the necessary competence and skills of its staff.
- → Procedures and relevant documents related to the planned human resource plan, competence mapping, knowledge management, training program and succession planning should be available in the integrated managements system that is under development.

3.4 LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

Related to GSR Part 1 (Rev. 1): Requirement 20

3.4.1 Advisory bodies

An independent expert Advisory Committee on Nuclear Safety and Radioactive Waste Management has been established to provide advice in the field. The Terms of Reference of the Committee includes the review of relevant work undertaken by DSA or for DSA under framework agreements made with External Support Organizations. As indicated below, the arrangement with external support organizations has been established to cover the functions of a Technical Support Organization (TSO). As an example, the Committee reviewed draft statements on nuclear safety and security culture and draft guidance on the General Licence Conditions for nuclear facilities, used in the establishment of the most recent licence under the NE Act.

There is also comprehensive cooperation on nuclear and radiation issues with other regulatory bodies and professional organizations, which gives valuable input to DSA decision-making. DSA has formal agreements on cooperation with most of the relevant Norwegian authorities and the need to formalize cooperation with the remaining relevant authorities has been identified. The main purpose of the formal agreements is to ensure information exchange and coordination between authorities with regulatory responsibilities for the same undertaking. In addition, there are informal dialogue meetings with relevant professional organizations.

In questions related to medical exposure, DSA usually seeks advice from the professional organizations for different health professionals, the Norwegian Directorate of Health, the Norwegian Board of Health

Supervision and Board for Ethics for Doctors (underlying the Norwegian Association for Medical Doctors). DSA has established a national quality assurance (QA) program in radiotherapy (KVIST). The program was initiated by the Ministry of Health and Care Services (HOD) to facilitate the implementation of QA activities in the hospitals. The KVIST Reference Group (RG) is the DSA's advisory body for this purpose and consists of radiotherapy experts from all nine radiotherapy hospitals. The RG identifies radiotherapy challenges and helps KVIST prioritize, prepare and implement evidence based guidelines in radiotherapy. Through the KVIST program, the number of severe errors in radiotherapy in Norway has decreased during the last 15 years or so.

DSA relies on the competence within the organization to make informed decisions on the use of external advice or assistance. When DSA seeks advice from advisory bodies, like the expert Advisory Committee and other authorities and organizations, it is made clear that their advice is used solely as an input to the decision-making process and does not alter the responsibilities of DSA for performing regulatory actions.

3.4.2 Arrangements with External Support Organizations

DSA often uses External Support Organizations (e.g. consultancy services) to fulfil the function of a TSO to support implementation of regulatory functions related to nuclear safety and security (e.g. review and assessment of authorization applications, inspections of nuclear facilities and activities). These activities are administered through a contract framework that has been established following an internal DSA process to identify the additional competences necessary to support its work. This process is documented and was based on a widely advertised call for applications. The call for proposals described the criteria that would be used to assess the proposals. These criteria were used in performing an objective evaluation of the suitability and competence of the various individual and groups of consultancy companies that submitted proposals. The successful contractors have since been used on a regular basis.

3.4.3 Avoiding conflicts of interest

The potential for conflicts of interest was taken into account in the evaluation of proposals from consultant companies in the establishment of framework arrangements. In addition, members of the Advisory Committee on nuclear safety and radioactive waste management were requested to submit a statement of any potential conflicts of interest in advance of their appointment. A formal procedure to avoid and deal with any conflicts of interests should be developed in the new integrated management system that is under development.

3.4.4 Planned improvements

→ DSA should consider establishment of advisory bodies in relevant areas other than nuclear safety and waste management.

3.5 LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Related to GSR Part 1 (Rev. 1): Requirement 21

3.5.1 Communication with authorized parties

DSA, as a regulatory body, 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), which relates to procedures for all public administration bodies. According to section 11 of the PA Act, DSA has a general duty to provide guidance within its sphere of competence. According to section 11 d of the PA Act, a party which has due cause to do so shall be given the opportunity to communicate orally with a public official employed at the administrative agency that is dealing with the case. According to section 6 of the PA Act, a public official shall be disqualified from preparing the basis for a decision or from making any decision if he/she is impartial. The Freedom of Information Act (FoI Act) also facilitates an open and transparent public administration and communication with the authorized parties. The main rule of the Act (section 3) states that documents, archives and registers of an administrative agency are public, and that any person may apply for access to these documents.

3.5.2 Fostering constructive liaison

DSA's Communication Strategy commits it to take an active role in communicating its regulatory practices with licensees, registrants and other stakeholders (Communication Strategy). 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. According to the Radiation Protection Regulation, all undertakings must appoint a radiation protection officer (RPO). The RPO serves as the contact point and has an important role in the dialogue with DSA. 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. Additionally, DSA publishes articles, notes, and commentaries in journals, magazines and news media, as appropriate.

As further examples. formal and informal dialogue is established with the main operator in the nuclear sector, IFE, and with the new Norwegian Nuclear Decommissioning organization (NND) and agreements have been reached on the different types of commination, meetings etc. that are needed. DSA has also established an annual dialog meeting with radiation protection coordinators involved in medical use of radiation. Professional or representative industry organizations are also consulted to foster broader sector-specific communications on general regulatory issues. For example, different health professionals and medical ethics committees are consulted regarding medical exposure issues, and oil and gas industry organizations are consulted regarding the issues related to the regulation of NORM discharges and wastes.

Authorized parties are also consulted when establishing or updating guidelines. Informal communication with authorized parties is performed at all levels at DSA, as necessary, including discussions or guidance in informal meetings, e-mails and phone calls.

3.5.3 Justification and explanation of decisions

The PA Act regulates the way in which the justification and explanation of DSA's regulatory decisions are communicated to authorized parties, as for all public authorities. Under this Act, affected parties must be given the opportunity to speak to an official from the administrative agency (DSA), if necessary. It also requires that all regulatory decisions made shall include an explanation or reasoning for the decision (PA-act section 24)

The formal requirements for decisions made by the DSA are implemented through the use of procedures and templates (that include the formal requirements according to the PA Act) and quality assured by the chain of command, requiring two signatures for any decisions made by the responsible DSA staff. The procedures and templates are established, and will be incorporated in the integrated management system, which is under development.

As an example, in its licensing process under the NE Act, DSA provides detailed feedback in the form of a covering letter to authorized parties that explains in the basis for its decisions, including detailed justification of the licence conditions and references to all relevant Norwegian laws and other regulatory requirements. The authorized party is informed that this letter will be copied to interested parties (including municipalities and other local authorities and, where relevant, the Norwegian Environment Agency) and it is made publicly available on the DSA website.

3.5.4 Planned improvements

→ DSA should ensure that the new integrated management system contains quality assured processes and procedures to cover Requirements 20 and 21 concerning liaison functionalities.

3.6 STABILITY AND CONSISTENCY OF REGULATORY CONTROL

Related to GSR Part 1 (Rev. 1): Requirement 22

Norwegian administrative bodies, like the DSA, must follow the decision making and transparency processes outlined in the PA Act and the Archive Act. In addition, all decisions made by DSA are anchored in one or more of the acts and regulations that fall within its area of responsibility (RP Act, NE Act and PC Act and associated regulations). All relevant laws and regulations are available to the public and are 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 have been given to paragraphs where it is considered necessary. DSA has also developed a set of best practice guidelines, which describe how to meet the regulatory requirements. Furthermore, various application forms for different user groups are available at the DSA's website. These acts, regulations and guidelines provide the basis for a stable and consistent regulatory practice.

DSA has developed, through several decades, a functional, applicable and predictable regulatory framework that has been developed and maintained to ensure consistency with international standards, best practice and recommendations, such as the recommendations of the ICRP, IAEA standards including the IAEA Basic Safety Standards and relevant EU Directives, as far as possible.

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 (Safety Culture Policy Statement and Nuclear Safety Culture Policy Statement).

3.6.1 Procedures for implementation of regulatory processes

At present, DSA operates two parallel management systems containing all 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 merging of procedures etc. will further enhance the stability and consistency of DSA's regulatory activities towards the responsible parties. See Module 4 for more information.

3.6.2 Avoiding of subjectivity in decision making

There is a robust mechanism in use at DSA to prevent subjectivity in decision-making processes. This is achieved through the implementation of the PA Act and the internal QA-procedures covering all types of regulatory decisions. The QA procedures ensure that several members of staff are involved in the 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.

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.

3.6.3 Process for issuing new or revised regulatory requirements

Making modifications to the established regulatory regime at DSA can be initiated by new international recommendations in the field, experience gained from audits and inspections, new areas of use of radiation sources or new focus areas triggered by accidents, incidents or risks related to possible malicious acts. Before new regulatory requirements can be implemented, a risk assessment, cost-benefit and consequence analysis must be performed, according to the PA Act (Chapter VII). In addition, a public hearing must be conducted. Relevant parties are asked for 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. New regulatory requirements must also be approved at the political level. 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.

3.6.4 Planned improvements

- → Establish the policy for safety and security for all working areas and personnel within DSA in the integrated management system.
- → Include the NE Act to the family of Health, Environment and Safety (HES) legislation in the Internal Control regulations

3.7 SAFETY RELATED RECORDS

Related to GSR Part 1 (Rev. 1): Requirement 35

3.7.1 Provisions for establishing and maintaining safety records

Documents related to all DSA's regulatory activities are stored in DSA's archive software system (called Public 360), and in accordance with the Archives Act. The information is generally available to DSA staff and the public, unless the information is confidential (regulated by the Freedom of Information Act).

Documents related to the safety of facilities and activities, except the system of accountancy and control (SSAC) of nuclear material (Safeguards), are stored in the archive and are normally linked to the authorization/licensing process. The same is true for records that might be necessary for the shutdown and decommissioning (or closure) of facilities. For example, it is a requirement in the licence that licensees of nuclear facilities periodically update their decommissioning plans or their plans for closing a repository. Results from inspections are documented in inspection reports, which are stored in the archive and made available to the public on the DSA's web pages.

Authorized parties must report unintended events and accidents to DSA, according to the Radiation Protection Regulation (§ 20), Pollution Control Act (section 39) and the Act of Nuclear Energy Activities (section 16). Information regarding all reported events are kept in the DSA's archive. Events related to use of radiation sources, regulated under the Radiation Protection Regulation, are also registered in an Excel sheet, allowing statistics and analyses. For an event that triggers the emergency organization, information on the event is also stored in a separate archive for emergency events (CIM).

Electronic system for declaration of waste

Inventories of radioactive waste and records of discharges are required as part of the requirement for yearly reporting to the DSA and are kept in the archive. Furthermore, a national system for electronic 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 (www.avfallsdeklarering.no)

Safeguards

DSA is the State System of Accountancy and Control (SSAC) for nuclear material. The associated records are kept in a separate secure archive (Safeguard) and form the basis for the inventory of spent fuel.

In addition to keeping records of documents in the archive, DSA has the following systems to ensure that adequate records related to safety of facilities and activities are maintained:

Electronic registration system for radiation sources (EMS)
Any ionizing radiation source used in Norway, with the exception of exempted radioactive sources, shall be registered in DSA's web-based electronic registration system 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. For sealed radioactive sources, the return scheme for disposal of the source shall be registered, allowing DSA to review that a return scheme exists prior to authorizing the use of a radioactive source. EMS gives DSA the possibility to generate reports and statistics at a national, regional and local level. The undertakings have the possibility to get statistics and analysis for their own registered 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 responsible undertaking is responsible for keeping the inventory updated according to RP Regulation section 13.

Records of occupational doses
An electronic web-based national dose register for occupational doses was launched in September 2018. The national register provides DSA with a national overview and surveillance of occupational doses, and statistics and analyses are used to protect workers from unintended exposure and to prevent health damage. This register replaces the previous manual system of occupational exposure records stored in the archive. All responsible parties must report occupational doses to the national dose register yearly, according to the Radiation Protection Regulation § 34. DSA runs the largest personal dosimetry service in Norway (TLD-based), and dose records from this service are automatically reported to the national dose register. Undertakings making use of other personal dosimetry services must report their dose records to the National dose register at least yearly.

In addition, together with the Norwegian Environment Agency, DSA has established an electronic database for the declaration of content from the producers of hazardous and radioactive waste.

At present, most of the safety-related records are stored in DSA's archive in a way that does not support easy statistics or analysis. DSA has identified the need for developing an electronic case handling system linking all relevant records related to authorized facilities and activities (authorizations, inspections, reported events/accidents, relevant documents for safety, etc.). The Government has placed a high priority on the digitalization of the public sector and an electronic case handling system would increase the efficiency of regulatory processes. DSA has therefore initiated a process of procurement of such a system.

3.7.2 Maintenance and management of other safety related records by the authorized parties

The obligation of the regulated or authorized party to keep and maintain records necessary for the safe operation of facilities and the safe conduct of activities follow from the general provisions of RP Act, NE Act and PC Act and their associated regulations. Specific requirements for keeping and maintaining records can also be given as conditions in authorizations and permits.

All responsible parties are also required to undertake systematic measures to ensure that they plan, organize, perform, secure and maintain all their activities in accordance with the requirements given in the health, environmental and safety legislation, according to the Internal Control Regulation (IC Regulation) (Internkontrollforskriften). Both the RP Act and the PC Act is included in the family of Health Environment and Safety legislation governing the IC Regulation. This is not the case for responsible parties regulated by the NE Act and the duty of the operators of nuclear facilities related to the internal control system is given as a licence condition. The duty of responsible parties to perform internal controls is a strong tool for systematic improvement of their work and systems ensuring safe operation of facilities and safe conduct of activities.

3.7.3 Planned improvements

→ DSA to ensure a robust verifiable and efficient administrative procedure DSA should develop and implement an electronic document management and case processing system that is integrated with the archive system, and that supports statistics and analysis of regulatory information with the responsible party.

3.8 COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Related to *GSR Part 1 (Rev. 1): Requirement 36*

GSR Part 2: Requirement 5

Involvement and consultation with interested parties is a key part of the decision making process in accordance with the PA Act (Public Administration Act). Chapter IV of the Act contains provisions for preparation of regulatory decisions:

- → Section 16 establishes that interested parties shall be given advance notification before decisions are made and be given the opportunity to express their concern within a stipulated time limit. Advance notification can be omitted under certain circumstances (section 16 letters a-c);
- → Section 17 establishes that the administrative agency shall ensure that the case is clarified as thoroughly as possibly before decisions are made;
- → Sections 18 establishes the right of interested parties to obtain access to relevant documents, with certain restrictions.

In addition, there are provisions for communication with interested parties within the acts that fall within DSA's areas of responsibility, and associated procedures have been developed. Hearings are performed for licensing and are mandatory under the PC Act for permits etc. For example, under the PC Act, applications for authorization are reviewed to ensure that they are appropriate and complete. The application and the DSA response are then 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 to ensure that interested parties have an opportunity to participate.

3.8.1 DSA communication strategy

Mechanisms and legal provisions are in place for DSA to inform and consult 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 Freedom of Information Act is also an essential mechanism for ensuring the public access to information.

DSA aims to be a transparent and credible authority, by actively communicating knowledge within its 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. DSA is also available for inquiries and dialogue with the different target groups.

The authority´s website is an important tool for communication to the public and other interested parties. As part of the DSA's Communication Strategy, reports and information of interest to the pubic 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 keeps a proactive dialogue with the media, and provides several national auditoria offices with news.

According to the Directive from the Ministry of Health and Care Services for the NRPA (DSA), DSA has a responsibility to disseminate updated knowledge to relevant authorities and the public. The Communication Strategy also includes communications with relevant ministries and governmental

agencies/authorities, as well as counties and municipalities. DSA`s communication strategy is under revision and is expected to be finalized in May 2019.

3.8.2 Planned improvements

→ 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 CONCLUSIONS AND ACTIONS

Norway has established a regulatory system that provides a solid foundation for the regulation and supervision of radiation protection and nuclear safety. The regulatory framework provides a stable and consistent basis for regulation.

The regulatory body, DSA, has undergone recent changes to ensure its effective independence and it is acknowledged, in law, to be the highest authority on issues related to nuclear safety and security.

A tradition of openness and integrity in public service and administration, applicable to DSA, is incorporated into both the laws and working practices. Provisions are in place to ensure that decision-making is not influenced by conflicts of interest or undue influence from third parties. There is good cooperation with other organizations with related responsibilities and there are arrangements for independent review of technical inputs to decision-making, where appropriate.

Overall, there is a high level of compliance with IAEA Standards. However, it is necessary to enhance competence planning, based on mapping the necessary competences against those available, to improve human resource and succession planning. The need to enhance capacity and competence in two key areas has been identified, resulting from recent developments in Norway. One of the two research reactors is entering the decommissioning phase, making further competence in both decommissioning and radioactive and nuclear waste management essential. Furthermore, plans to develop proton therapy units at hospitals in Norway, makes relevant competence in that area also necessary.

The changes in the civilian nuclear sector have significantly increased regulatory development work at a time when an increase in the number of nuclear powered vessels visiting Norwegian waters has also increased the licensing work for the military sector. Licensing in the civilian nuclear sector is fully funded by operator fees, but regulatory development work is funded from the core budget. In the absence of fees for licensing the military sector, this core budget is also used to cover this work, although it should be funded by the operator or those representing the operator.

3.9.1 Actions

→ DSA should develop a policy and strategy for competence management to enable it to fulfil its statuary obligations.

→ DSA should continue development of coordination and cooperation with other authorities, including further cooperation agreements with relevant authorities.

→ DSA should continue documenting experience from implementing measures to reduce radiation risks from unregulated sources and contamination to improve future decision-making.

→ DSA should introduce a fee for regulating, including licensing and inspection, associated with military vessels entering Norwegian waters and ports.

→ DSA should address the need for proper financing of the SSDL laboratory at DSA.

→ DSA should adopt a more systematic procedure for handling orphan sources.

→ DSA should prepare for and seek accreditation for all technical services it offers.

4 MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1 RESPONSIBILITY AND LEADERSHIP FOR SAFETY

Related to GSR Part 2: Requirement 2

Safety is an integral part of all DSA activities and the framework of legislation related to radiation protection, nuclear safety and pollution control in Norway is extensive, forming an efficient framework for DSA's activities and management processes. The main bases for DSA's responsibilities as a regulatory body are the Radiation Protection Act (Strålevernloven), the Nuclear Energy Activities Act (Atomenergiloven) and the Pollution Control Act (Forurensningsloven), with their associated regulations. The objectives of this legislation are in accordance with the IAEA-SF-1 Safety Fundamentals. These three acts and associated regulations form the basis for handling all types of permits, audit activities and monitoring programs. Moreover, according to the Public Administration Act (Forvaltningsloven), DSA has an obligation to provide the basis for all decisions that give rights or obligations to entities or persons. Consequently, external parties are informed of decisions affecting them and the basis for these decisions is documented according to an established process.

Safety also forms an important basis for the NPRA Strategic Action Plan 2018-2020 (Strategisk Handlingsplan 2018 -2020), DSA Inspection Strategy (2016-2020) and DSA International Strategy (2019-2023). It also forms the basis for decision-making processes, meetings, discussions and day-to-day activities.

The Department of Nuclear Safety and Environmental Protection has established quality management system following ISO 9001, and taken into account GSR Part2, GSG-12, GSG-13, GS-G-3.1, that includes procedures and templates for regulatory control related to the safety and security of nuclear facilities and materials and environmental protection (https://tqm1.tqmenterprise.no/nrpa). The Department of Radiation Protection and Measurement Services has documented procedures for regulatory control related to safety and security of radiation sources and their use, e.g., medical and industrial use. Development of the latter system started in 2009. Although different in scope and structure, these two systems form the basis of the new integrated DSA management system that is under development. There are also established procedures for DSA as a whole, e.g. related to inspections, emergency preparedness, laboratory work and to DSAs international activities. The main elements of the process framework in the new integrated management system and their associated procedures have been described. However, the description of the top-level processes, safety policy and goals are under development. These initiatives demonstrate the awareness of the need for a management system for DSA as a whole.

4.2 MANAGEMENT FOR SAFETY

Related to GSR Part 1 (Rev. 1): Requirement 19 and GSR Part 2: Requirements 3, 4 and 5

In 2018, DSA management decided to establish a management system for DSA as a whole for quality (following ISO 9001, Bnotat Quality Management System). The decision was expanded to address the requirements listed in IAEA GSR Part 2 for an integrated management system (Bnotat Integrated Management System). The intention is that requirements in the IAEA Standards will take precedence over ISO 9001. The integrated management system will be hosted on a cloud-based, electronic platform provided by TQM partner (https://tqm1.tqmenterprise.no/nrpa/). In this system, roles and responsibility will be defined according to the DSA organization and existing lines of authority for making decisions. The system will include a case-handling module, which will allow the management to more easily assess process

performance and make any necessary adjustments to processes and procedures, thus facilitating continuous improvement.

Currently, the main safety goals are given by the Parliament through legislation; it is the responsibility of the Norwegian Government to ensure that legislation is followed. The Government delegates this responsibility for each law to a Ministry. The Ministry can then delegate this responsibility to a Directorate, such as DSA. This process is described in more detail in Module 3. The goals, including those related to safety in the case of DSA, are further defined in the management dialogue between the Ministries and DSA through an Instruction Letter (Instruks), Allocation Letters of Commitment (Tildelingsbrev and Belastningsfullmakt,), and dialog meetings. DSA has a Strategic Action Plan (Strategisk Handlingsplan 2018 - 2020) which describes goals and plans for thematic areas, as well as an Inspection Strategy and an International Strategy. These plans are updated on a regular basis.

DSA has not yet established a safety policy for the whole organization. However, for the nuclear sector, safety and security culture statements have been established. Once the integrated management system has been established, safety goals, strategies, plans and objectives will be in compliance with IAEA's Safety Standards.

4.3 THE MANAGEMENT SYSTEM

Related to GSR Part 2: Requirements 6, 7 and 8

DSA has procedures that cover all aspects of health, environment and safety (HES) work that are readily available for all employees on DSA's intranet. DSA is required to follow the Working Environment Act under Norwegian law, which has the intention to secure the working environment for employees in Norway and to provide the basis for a healthy and meaningful working situation. The Working Environment Act also states that the working environment should be the result of a cooperation between employees and the employer. The HES procedures will be accessible through the new management system, which will ease case handling and traceability of decisions and arrangements related to health, safety and environment issues.

The Director General (DG) of DSA has the overall responsibility for the Directorate's safety, health, security, quality, human and organizational factors, and societal and economic elements of the working environment. The DG manages these responsibilities in consultation with the management group (comprising the three Department Directors and the Director of Communications), which meets every two weeks. In these meetings, decisions are made with safety as an important priority. Minutes from the meetings are archived through the archive system, Public 360 (http://dokumentix4.nrpa.local/BlankWebPartPage.aspx) and is available for all personnel. Topics for the management group meetings are predefined in an annual plan (Årshjulet), which integrates different aspects of safety into the internal management dialogue within DSA. In addition, each of the three departments at DSA has a safety representative with respect to the working environment. The elected leading safety representative and union representatives have quarterly meetings with the DG and the senior management (the working environment committee) to discuss and decide upon safety, health and environment issues with respect to the working environment.

DSA or the Ministry of Health and Care Services (HOD) can make decisions regarding the internal organization of DSA. A reorganization can result from the sharing and merging of entities, or changes to the organization. Currently there are no procedures for independent review prior to organizational changes that focus on safety issues.

DSA is obliged to follow a 'Basic Agreement' ('Hovedavtalen'), which regulates the basic rules of staff in government employment. This includes the general provisions on negotiation and cooperation between

employers and employees. It also defines employees' right of co-determination of internal organizational changes by negotiation between management and employee representatives, labour unions, in the event of major changes that are expected to be permanent. There is also a management prerogative (styringsrett) that implies that management also has the right to reassign staff to other positions within the organization or to assign other tasks, if necessary.

The new integrated management system, with its documented policies, goals and procedures will improve systematic application of a graded approach with respect to safety, notably on processes such as authorization and inspections.

DSA currently operates a document management system for records through the archive system Public 360 (http://dokumentix4.nrpa.local/BlankWebPartPage.aspx), which is used by most organizations in the health management sector. All official documents are loaded into Public 360 according to NOARK 5.0, which is the Norwegian standard for documentation management. If not classified as graded documents, documents are then made public through the portal einnsyn. Moreover, DSA follows the central governmental administration system (Forvaltningssystemet), which is operated in accordance with legislation including the Public Administration Act (Forvaltningsloven), the Freedom of Information Act (Offentleglova, https://lovdata.no/dokument/NL/lov/2006-05-19-16), the Archive Depot Act (Arkivlova, https://lovdata.no/dokument/NL/lov/1992-12-04-126) and Auditor General Act (Lov om Riksrevisjonen, https://lovdata.no/dokument/NL/lov/2004-05-07-21). Nevertheless, DSA is in the process of developing a fully documented management system that fully complies with the requirements specified in IAEA GSR Part 2.

The Letter of Instruction (Instruksen) specifies that the DG can delegate authority to parts of the organization and to managers within DSA. This letter also specifies explicitly that such delegation decisions and the management of the organization should be documented. Decisions of delegation made by the DG are documented in the Organization Decision Document (Organiseringsbeslutningen 2012 and Organiseringsjusteringer from 2018, attached), Signature Decision Document (Underskriftsfullmakter, attached) and the Acting Management Document (Fungeringsoversikt, attached). Organizational structures are also documented. The position of DSA in the central government administration system is specified in e.g., the Letter of Instructions (Instruksen), while the internal organization of DSA and minutes of the management group meetings are archived through Public 360 (http://dokumentix4.nrpa.local/BlankWebPartPage.aspx), and are accessible to all employees..

The integrated management system will include a document module with automatic document management system including automatic version control, automatic generated headings, full log history and automatic notification to the person responsible for the document.

4.4 MANAGEMENT OF RESOURCES

Related to GSR Part 2: Requirement 9

Determining the requirements for competence in general is a dynamic and continuous process where senior management considers if DSA has the required competence to handle all tasks for which it has been delegated responsibility. Senior management consult the Heads of Sections who have the detailed knowledge of the competence needed and available. If the competence exists in the organization, resources (time and economic) are allocated in the Operating Plans. Management ensures that the required in-house competence is maintained or acquired by allocating resources for training in the Operating Plan, or by hiring new staff, e.g., if new tasks are assigned to the DSA or if employees leave or are transferred to other tasks.

In some cases, senior management decides to acquire competence from external sources. In doing so, the DSA must follow the Public Procurement Act (Anskaffelsesloven, https://lovdata.no/dokument/NLO/lov/1999-07-16-69) and the Public Procurement Regulations (Anskaffelsesforskriften, https://lovdata.no/dokument/SF/forskrift/2016-08-12-974).

In 2019, DSA plans to undertake an inventory of competence (Bnotat Mapping of Competence) to provide senior management with a complete competence profile of all staff, in order to identify gaps and implement training or recruitment measures in the necessary topical areas and sections within the organization

Managers are offered courses in management, usually a course of their own choice. In addition, senior managers participate in development programs as a group every few years. However, there are at present no specific requirements with respect to competence for leadership at management levels. However, at present, the Management Group is taking part in a senior management course provided by the Direktoratet for forvaltning og ikt (DIFI), the Agency for Public Management and eGovernment.

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When the decision was made by DSA management to develop a new management system (MS), a MS group was formed and was given the mandate to coordinate the work across the organization. The group consists of five members, representing the DSA's three departments and led by the Department for Planning and Administration (POA). In addition, a representative from the laboratory occasionally participates to ensure integration of the new management system and the laboratory management system, which is based on the ISO 17025 standard. DSA management has emphasized the importance of involving staff at all levels and securing necessary resources via the annual planning process (Virksomhetsplan or VP). Consequently, most DSA staff are involved in the MS development project, describing process, procedures, guideline etc.

Regulatory staff involved in inspections, attend an inspection course, which is common to all regulatory bodies in Norway. Attendance is mandatory and new employees usually participate as trainees in the first period. In previous years, DSA had more extensive program for regulatory staff, which included in-house courses. However, the scope of this training program has been significantly reduced in recent years due to the lack of internal resources. However, DSA is currently revising the competence requirements for staff members conducting inspections. Newly hired staff are trained in tasks such as assessing applications for authorization and enforcing regulatory requirements through general in-house training. All new employees are assigned a colleague with experience in the same field to act as mentor during the first few months of employment.

4.5 MANAGEMENT OF PROCESSES AND ACTIVITIES

Related to GSR Part 2: Requirements 10 and 11

The document module of the new integrated management system will allow processes to be easily visualized. It will also allow responsibility for processes and documents and their revision to be assigned and distributed. The integrated management system will be a process-based system with three levels of documentation:

- → Level 1. Documents describing policies, goals, organization structure etc;
- → Level 2. Description of DSA processes, interactions between the processes and responsibilities;
- → Level 3. Detailed description of procedures, instructions, guidelines and checklists need to perform DSA processes.

Three of DSA's laboratories operate fully developed and implemented management systems following the requirements of ISO/IEC 17025. In accordance with the standard, processes and procedures are documented and documentation is controlled and periodically reviewed. Records of administrative communications and results are archived through Public 360 (http://dokumentix4.nrpa.local/BlankWebPartPage.aspx). The laboratories are either in the process of, or have recently completed, the transfer of their management systems to an electronic platform provided by TQM partner (https://tqm1.tqmenterprise.no/nrpa/).

Products and services supplied to DSA that influence safety include ionizing radiation sources (radiation sources and X-ray equipment) and their associated safety systems; metrology equipment; and Information and Communications Technology (ICT) equipment, systems and services.

Since 1 Jan 2017, DSA is no longer responsible for the management of procurement. As a consequence of the reorganization of the Norwegian health administration, procurements are managed through Norsk Helsenett (https://www.nhn.no/, agreement archived in Pubic 360), which acts as a procurement office in accordance with Public Procurement Regulations (Anskaffelsesforskriften, https://lovdata.no/dokument/SF/forskrift/2016-08-12-974). Technical requirements for procurements, however, continue to be defined by technically competent personnel at DSA, who then specify the scope and standard of a required product or service and determines whether the product or service meets applicable safety requirements.

Both Norsk Helsenett and DSA are obliged to follow the Public Procurement Act (Anskaffelsesloven, https://lovdata.no/dokument/NLO/lov/1999-07-16-69) and the Public Procurement Regulations (Anskaffelsesforskriften, https://lovdata.no/dokument/SF/forskrift/2016-08-12-974). DSA makes arrangements for specifying, managing and monitoring the supply of items, products and services delivered, but processes and procedures for ensuring that all such arrangements are in place for all procurements are in the process of being developed as part of the development of the new management system.

4.6 CULTURE FOR SAFETY

Related to GSR Part 1 (Rev. 1): Requirement 19 (para 4.15.)
GSR Part 2: Requirement 12

A commitment to safety from managers at all levels in the organization is demonstrated through the Strategic Action Plan 2018-2020 (Strategisk Handlingsplan 2018 -2020), decision-making processes, meetings, discussions and day-to-day activities. The allocation of economic resources is clear through the Allocation Letter (Tildelingsbrev). Allocation of human resources is documented through a yearly Operating Plan (Virksomhetsplan). Roles and responsibilities are made clear through regular meetings and communications from senior management, and through the Organization Decision Document (Organiseringsbeslutningen 2012 and Organiseringsjusteringer from 2018), Signature Decision Document (Underskriftsfullmakter) and the Acting Management Document (Fungeringsoversikt). Day-to-day work is undertaken by individual members of staff acting as case handlers, which provides ownership and responsibility for tasks at all levels of the organization.

DSA recognizes the importance of safety culture and, for the nuclear sector, safety and security culture statements have been established. However, DSA would benefit from a more systematic approach to safety culture, including the establishment of a common safety policy (aligned with a national safety policy), which is actively promoted by all levels of management.

4.7 MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Related to GSR Part 2: Requirements 13 and 14

Assessment and improvement are an important part of management decisions within DSA and relevant procedures have been established for some parts of the organization. However, systematic written procedures that apply to the whole organization to ensure that safety performance is measured, assessed and improved, have not yet been established. The three accredited laboratories operate systems for systematic handling of deviations following ISO/IEC 17025.

The new management system includes a case-handling module for deviation that interacts with the document module, which will hold all process and procedures. Consequently, implementation of this system will provide DSA's management with a powerful tool to measure the organization's performance and to provide the basis for taking actions for improvement, where necessary. In addition to documenting all actions associated with registered deviations, the case-handling module includes elements for evaluating the effect of actions taken, the possibility of performing a risk analysis and for identifying problem areas in the organization's processes, using statistical analysis where appropriate.

When the decision was made to develop a management system following the requirements in ISO 9001:2015, a goal was set to obtain ISO certification, which would involve an independent review process. Although it was later decided to expand this to decision to apply the requirements included in IAEA safety standards for the establishment of an integrated management system, the ISO system will form the framework in the new management system. Therefore, DSA intends to seek ISO certification since both the process and any independent feedback would be of value.

4.8 CONCLUSIONS AND ACTIONS

The different departments of DSA currently operate separate management systems and procedures but the need for an integrated system has been recognized. Such a system is under development, which incorporates elements of the existing systems. This will improve management processes in the future and will fully comply with IAEA requirements.

The self-assessment of module 4 clearly indicates that the DSA management system only partially complies with IAEA requirements related to an integrated management system. In short, the current DSA management system fulfils some of IAEA requirements with respect to leadership and commitment to safety by senior management (Requirement 2 of GSR Part 2) and Requirements 9 of GSR Part 2 related to management of resources. With the latter, however, it is recognized that DSA should strengthen some its training programs and establish systematic procedures for assessment of competence, considering DSA as a whole. Although it is difficult to demonstrate, DSA maintains a strong safety culture according to Requirement 19 (para 4.15) and GSR Part 2, Requirement 12, although these should be documented in a systematic manner and safety and security statements are currently under development.

4.8.1 Actions

- → DSA should finalize the implementation of the integrated management system describing all DSA processes and their interactions, with a focus on safety;
- → The management system currently under development should integrate the requirements specified in the IAEAS Safety Standards requirements and ISO

9001:2015 according the decisions made by DSA management in January 2018 and January 2019, in which the IAEA standard supersedes ISO 9001;

→ DSA's management should establish a documented safety policy for the whole organization in line with national policies, with safety goals, strategies, plans and objectives in line with the safety policy, and measurable indicators that provide the basis for periodic reviews and appropriate actions, if corrections are needed;

→ The integrated management system under development should include systematic procedures to review, maintain and enhance competence across the organization to enhance safety.

5 AUTHORIZATION

5.1 GENERIC ISSUES

DSA ensures that facilities and activities are authorized in advance, under one or more of three Acts (the Act on Radiation Protection and Use of Radiation (RP Act), the Act on Nuclear Energy Activities (NE Act and the Pollution Control Act (PC Act)), broadly in accordance with IAEA standards and guidance. Procedures are in place for application of authorizations and a range of guidelines are available that specify, in general terms, the information applicants need to submit in support of applications for an authorization. Where appropriate, this includes a requirement to submit a safety assessment.

The applications and assessments are reviewed by DSA and the level of review depends upon the level of risk involved with the facility or activity. If sufficient information is provided to demonstrate that risks are below required levels, authorizations are granted.

The three general principles of radiation protection, concerning justification, optimization of protection and limitation of risk – as expressed through IAEA's Fundamental Safety Principles no. 4, 5, 6 and 10 – are fully implemented in the Norwegian regulatory framework, notably in the Radiation Protection Regulations (RP Regulations), as described in more detail in Module 1.

5.1.1 Roles and responsibilities

The Ministry of Health and Care Services (HOD) is the responsible ministry for the RP Act and the NE Act. The RP Act is the basis for regulating the use of radiation sources and radiation protection. The NE Act is the basis for regulating the use of nuclear substances and for licensing nuclear facilities. The Ministry of Climate and Environment (KLD) is responsible for the PC Act, which is the basis for regulating radioactive discharges, radioactive waste and radioactive contamination. Both ministries thus have responsibilities related to the regulation of nuclear facilities. Other ministries are responsible within their fields, as outlined in more detail in Module 1.

The Government has appointed the Norwegian Radiation and Nuclear Safety Authority (DSA) as the sole national regulatory body on radiation protection, nuclear safety and security, and safety of radioactive waste and radioactive discharge to the environment, regulatory control of natural radiation, and non-ionizing radiation (see Module 1).

Regulatory processes within the three areas related to the use of radiation, nuclear energy and radioactive waste and pollution are conducted by different sections of DSA, reflecting to some extent that there are separate acts (RP Act, NE Act, PC Act) governing these processes.

DSA is a member of a formalized cooperation group of six regulatory authorities and a non-governmental organization that have responsibilities for health, safety and environmental protection. One of the main goals of this cooperation is to ensure that implementation of the Regulations relating to Systematic Health, Environment and Safety Activities in Enterprises Internal Control (The IC Regulations) is harmonized to the extent possible. Additionally, there are bilateral cooperation agreements between some regulatory authorities (see Module 1).

5.1.2 Graded approach to authorization

The Norwegian regulatory regime for use of radiation sources, use of nuclear technologies, and for management of radioactive waste and pollution control, is governed by the following three acts:

- → Act on Radiation Protection and Use of Radiation, No.36, of 12 May 2000. (RP Act)
- → Act on Nuclear Energy Activities, No. 28, of 12 May 1972 (NE Act)
- → Act on Pollution Control, No 6, of 13 March 1981 (PC Act)

The requirement for authorization has its legal basis in the three acts and in the corresponding Regulations.

The NE Act includes provisions for two forms of authorization:

- → Permits to manufacture, own, store, handle, transport, sell or otherwise hold or dispose of nuclear substances (Norwegian: godkjenning/løyve/tillatelser/driftstillatelse); and
- → Licence to construct, own or operate a nuclear installation (Norwegian: konsesjon).

Licences are granted by the Government, based on advice from DSA and the associated review and assessment work. The NE Act also specifies that DSA is the highest specialist agency as far as questions of safety and security are concerned.

The RP Regulations distinguish between activities requiring authorization (referred to using the terms “authorization" in RP Regulations and “approval” in RP Act), which are specifically listed in the regulations, and activities requiring authorization by registration (referred to simply as “registration” in RP Regulations and as “notification” in RP Act). The duty of registration applies to undertakings that acquire, lease out, use or handle x-ray apparatus, accelerators or radioactive sources above the exemption limits, included in an annex to these regulations.

DSA has responsibility for supervising compliance with the provisions of the RP Act and for setting conditions for authorizations under the associated regulations. These regulations apply to “*any manufacture, import, export, transfer, possession, installation, use, acquisition, storage, disposal, handling and extraction of radiation sources*” (RP Regulations).

Under the PC Act, pollution – including releases and contamination – is illegal unless the activity is below the exemption values given in Annex II in Regulations on the Application of the Pollution Control Act to Radioactive Pollution and Radioactive Waste (PC Regulations), or the pollution control authority (DSA) has granted a permit. Similarly, all waste management of radioactive waste with activity above the exemption values given in Annex I in the same regulation require a permit. The requirements for both the content of application and requirements given in the permit are graded, commensurate with the potential risk of the release or waste. The regulatory system covers all types of radioactive waste and pollution, including NORM and nuclear wastes. The requirements for the information to be included in an application and the specific requirements in an authorization are graded, commensurate with the potential risk.

In addition, throughout the PC Act, the different sections specify that requirements should be graded. For instance, section 2 Guidelines states that “*The Act shall be implemented in accordance with the following guidelines.... The Act shall be used to achieve a level of environmental quality that is satisfactory on the basis of an overall evaluation of human health and welfare*”,

5.1.3 Justification and duty to consider substitution

The justification principle is implemented in both the RP Act and Regulations. All use 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 (section 5 in both RP Act and Regulations).

Consistent with the justification principle, and according to the RP Regulations section 23, the undertaking shall assess alternatives to the use of ionizing radiation. The 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 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.

Only justified practices are granted authorizations from DSA. Justification is typically considered in connection with applications or during the authorization period, i.e. if new technology becomes available.

According to the PC Act, DSA can, based on an application, issue according to section 11 a special permit for any activity that may cause pollution. When the pollution control authority (DSA) decides that a permit may be granted and lays down conditions pursuant to section 16, it shall pay particular attention to any pollution-related problems arising from the project as "compared with any other advantages and disadvantages so arising". A pollution permit should be justified, taking into account section 2;

> *"The Act shall be used to achieve a level of environmental quality that is satisfactory on the basis of an overall evaluation of human health and welfare, the natural environment, the costs associated with any measures implemented and economic considerations".*

Furthermore, the application shall be based on an environmental impact assessment. In that assessment (section 13) alternative locations, production processes, purification measures and ways of recovering waste and reasons for the solutions chosen by the applicant shall be evaluated. Accordingly, substitution of raw materials in the production process might be considered and conditions might be set to reduce the potential pollution.

5.1.4 The authorization process

Procedures are in place for applying for authorizations and a range of guidelines are available on the DSA website for applications according to the different acts and types of facilities. These specify, in general terms, the information applicants need to submit in support of such applications. Where appropriate, for example for nuclear facilities, this includes a requirement to submit a safety assessment.

The applications and assessments are reviewed by DSA and the level of review depends upon the level of risk involved with the facility or activity. If sufficient information is provided to demonstrate that risks are acceptable and adequately handled, authorizations are granted.

The authorizations often include standard conditions on reporting, operations, competence and, where appropriate, conditions related to the discharge or disposal of radioactivity that are specific to that facility. These authorizations may be time-limited or unlimited. They all include the requirement that the

DSA is informed in the event of significant changes that may affect the authorization and, if required by DSA, the authorized parties may be required to reassess and apply for a modification to the authorization. Such changes may include significant stages in the duration of the activity or stages in the life stage of a facility (e.g. decommissioning and closure) but these are not currently specifically specified in all authorizations.

The authorization process does not uniformly apply to site evaluation, design and construction, although the NE Act applies to the latter of these stages and the RP Act and Regulations apply to some aspects of facility design. The PC Act applies from the operational stage. However, DSA is specifically identified as the competent authority for impact assessments, under the Building Act for nuclear power plants and facilities for processing, storage and disposal of spent nuclear fuel and radioactive waste. Involvement in these processes involves review and approval of assessments.

According to the Polluter Pays Principle, assessing applications for authorizations according to the PC Act and the NE Act is funded by fees.

5.1.5 Formulation and recording regulatory decisions

DSA is subject to the requirements of the Public Administration Act of 10 February 1967 (PA Act), which applies to all Norwegian regulatory authorities. An authorization is an 'individual decision', which is an administrative decision made in the exercise of a public authority, which generally or specifically determines the rights or duties of one or more private persons (individual persons or other private legal persons).

An individual decision made by DSA shall be carried out immediately or in line with deadlines stated in the decision. With some exceptions, the parties to any case concerning individual decisions have a right to see the documents pertaining to the case. Furthermore, DSA has a general duty to provide guidance and responses to questions regarding procedural matters and other regulatory matters that are relevant to a case.

All documentation related to DSA's regulatory activities is stored in DSA's archive system. Documents to be stored are regulated by the Act on Archives. The information is generally available to DSA staff and the public, unless the information is classified (regulated by the Freedom of Information Act).

Involvement and consultation with interested parties
As described in more detail in Module 1, involvement and consultation with interested parties is a key part of the decision making process in accordance with the PA Act. The PA Act requires DSA to clarify an application for authorization before it is granted. This includes a public hearing of applications where any questions or concerns may be raised. DSA will, as part of assessing the application, consider any concerns raised during the hearing process.

Furthermore, there are provisions for communication with interested parties within the three acts that fall within DSA's areas of responsibility, and associated procedures have been developed. For example, hearings are performed for licensing and are mandatory under the PC Act.

5.1.6 Processes of appeal, amendment, renewal, revocation

Those affected by an individual decision, such as an authorization, must be notified and there is a right of appeal. The authorized party, or others with legal right of appeal, may appeal to the Ministry of Health and Care Services or the Ministry of Climate and Environment. The appeal is assessed by DSA and sent to the

appropriate ministry for decision. The time period for lodging an appeal and for obtaining a decision are specified in the PA Act. Requirements on the form and content of the appeal and the response are also given in this Act.

DSA has the authority to amend, renew, suspend or revoke authorizations. In practice, applications to amend or renew an existing permit undergo re-evaluation of the authorization. Suspension or revocation of the authorization is decided on a case-by-case basis.

5.1.7 Planned improvements

- → While established authorization processes are in place, these could be further improved by the development of processes valid for all types of authorization processed by DSA. The development of such a process is ongoing. The development of an integrated process and procedures applicable for all facilities and activities would help to improve consistency and a more systematic application of a graded approach. The procedures should include a systematic procedure for periodic review and subsequent amendment, renewal, suspension or revocation of the authorizations.
- → More detailed guidance on the information required to support authorization applications, and the criteria that are used in reviewing such applications, would help applicants and the regulatory review work.
- → Review and, if appropriate, develop recommendations for modifying laws and regulations and associated guidance to ensure that regulatory processes (legislation, regulations and associated guidance) cover all life stages of all types of facilities. The situation regarding siting, design and construction, in particular, requires further review and clarification. The review should take into account the scope of each of the Acts and Regulations, including the impact assessment regulations.
- → Identify specific hold points, and the way in which these should be addressed, within the authorization process. This would require a review of the relevant legislation, regulations and guidance and revision, as necessary [GSR Part 1 (Rev. 1), para 4.35].
- → Develop an integrated process and procedures for authorization valid for all types of authorization process at DSA [GSR Part 1 (Rev. 1), para. 4.33]. This would improve consistency of approach and ease the regulatory workload in the long term. These processes and procedures are being developed as part of DSA's new integrated management system. The procedures should include any subsequent amendment, renewal, suspension or revocation of the authorization (licensing or registration) for a facility or an activity.
- → Further develop and apply a systematic graded approach to regulation. This would involve internal review and preparation of proposals for implementing a graded approach and the development of internal guidance and procedures, review, consultation and hearings, as appropriate.
- → Clarify expectations in external guidance regarding applications for authorization, including criteria for review and assessment, taking account of the application of a graded approach to regulation.

5.2 AUTHORIZATION OF NUCLEAR INSTALLATIONS

Related to SSR-3: paragraphs 3.4 – 3.5 and Requirements 1 to 6

NS-R-3
GSG-13

5.2.1 Developments in the regulation of nuclear installations

In the period 2014 - 2016, DSA (then NRPA) performed a system audit of the nuclear facilities operated by the Institute of Energy Technology (IFE), the only civilian nuclear site operator in Norway. The system audit revealed a number of discrepancies, related to management of responsibilities, human resources and expertise to deal with security, safety, the role of the safety committee, and management of deviations, knowledge transfer and document management. The DSA supervisory team concluded that there were serious shortcomings in the management system and especially in the management of the business and the follow-up of deviations. The business appeared to be fragmented, and thus an impression was given that there was no comprehensive management-controlled safety culture at the licensee. At the operating level, the safety work was more established and systematic. However, it was considered necessary, also in light of the challenging economic situation at IFE, to place IFE under intensified supervision. Through the intensified supervision, DSA followed up the correction of the identified discrepancies and concluded that the preventive safety culture had been strengthened.

Following the system audit in 2014, the DSA, as part of the intensified supervision, has regularly monitored the safety work at IFE through the attendance at meetings of IFE's safety committee, with the assistance of external expertise.

As a consequence of the intensified supervision, a long-term work programme was also initiated to improve the regulatory supervision of the operator. This included measures to:

- → Follow international regulations, safety standards and best international practice more closely;
- → Improve the competence and capacity of DSA staff;
- → Enhance the quality of and systematic approach to the implementation regulatory functions;
- → Improve the operators' understanding of the regulatory requirements related to nuclear facilities and activities.

DSA therefore implemented the following actions and measures:

Actions towards the operating organization:

- → Intensification of the number of inspections of operating organization facilities and activities in order to establish the level of the operator's understanding and attitude to comply with international standards and their understanding of the role of regulatory body.
- → Introduction of intensified supervision including regular supervision of the operating organization's safety committee.

Internal organizational changes (completed or in progress):

- → Establishment of the Advisory Committee for Nuclear Safety and Radioactive Waste, involving international experts and representatives from the regulatory bodies of other countries.

- → Reassignment and recruitment of human resources, working towards strengthening the supervision of nuclear facilities and activities based on graded approach. This work is on-going.
- → Extended use of external consultancy services to fulfil the Technical Support Organization function to support implementation of regulatory functions (e.g. review and assessment of authorization applications, inspections of nuclear facilities and activities). This involved establishing framework contract arrangements with a range of consultancy companies with the necessary competencies.
- → Development of a management system with clear and defined processes and procedures to implement regulatory functions in a systematic manner to assure quality, to follow international regulations, safety standards and best international practice and to improve safety culture at DSA. This work is still in progress but the improved review and assessment and authorization processes helped DSA staff to follow international regulations, safety standards and best international practice more closely in the most recent licensing process, in December 2018.

Improved regulatory framework to meet international practice:

- → Development of General Licence Conditions (GLCs), with the intention that these will be applicable to all nuclear installations in Norway that are subject to licensing under the NE Act. The GLCs are closely linked to both the NE Act and international standards. The GLCs are intended to be comprehensive in the safety and other requirements included, but not prescriptive in how safety should be achieved. The GLCs clarify the regulatory requirements related to nuclear facilities and activities and are intended to facilitate the operators' understanding of regulatory expectations.
- → The Licence Conditions are site-based, rather than installation-based, following international practice. The GLCs are published and are publicly available on the DSA web page.
- → General Guidance and Specific Guidance are also under development to provide guidance on the application of Generic Licence Conditions that can be used by: the relevant operating organizations in carrying their responsibilities as licensees; the regulatory body (DSA) in carrying out responsibilities in oversight of compliance with licence conditions; and other stakeholders who may have an interest in nuclear safety. This guidance is, among other things, intended to describe and explain what the regulator anticipates will be included in support of a licence application, e.g. in terms of the content of a safety case

5.2.2 Licence to hold nuclear substances and to own and operate nuclear installations

Nuclear installations are defined in the NE Act, section 1(e), and includes both research reactors and fuel cycle facilities. In addition, in order to obtain a permit to hold nuclear substances, a legal person must submit an application to the Ministry of Health and Care Services (HOD), in accordance with section 5 of the NE Act. Following a request from HOD, DSA shall, as the highest specialist agency with regard to safety issues (section 10 of the NE Act), review and assess the application and its supporting documentation. On the basis of this review, DSA will make a recommendation to the Ministry regarding the application and, if it is acceptable, HOD will issue a permit.

In order to obtain a licence for the operation of a nuclear installation, a legal person shall submit an application to the King (the King in the Council, Government), in accordance with section 7 and 11 of the NE Act. Following a request from HOD, DSA shall review and assess the application and its supporting documents and make a recommendation in accordance with Section 10 of the NE Act. If the application is potentially acceptable, HOD takes this matter to the King in the Council of Ministers, the Government, and a licence is issued.

Thus, the authorization of nuclear installations in Norway involves handling of licence application, e.g. to construct, own and operate nuclear installations. It also includes regulatory oversight during operation, e.g. authorization of operation of nuclear installations or authorization of modifications relevant to safety in the construction, operation or management of the installation, which constitutes a departure from the licence conditions.

Section 4 of the NE Act requires that the King in Council (the Government) shall license anyone who constructs, owns or operates nuclear installations. The nuclear installation definition is stated in the section 1 (e) of the NE Act. The operator of the nuclear installation, in order to get or extend the licence for nuclear installation operation, shall submit an application to the King in the Council (the Government) for a licence in accordance with section 7 and 11 of the NE Act.

Licence application
The licence application, in accordance with section 11 of the NE Act, should contain as minimum the following:

- → Safety Analysis Report;
- → Emergency preparedness plan;
- → Management system description.

In general, the owner of a nuclear installation applies for licence for a period of 10 years. The operator describes the technical status of the nuclear installation and how these installation will be operated safely during the requested licence period in the safety report. The safety report is part of the application and it is central to documenting how operations will be carried out safely. It describes both the operation of the nuclear installation and other necessary infrastructure.

Process of licence application at DSA
DSA handles licence application in accordance with developed procedures on authorization and review and assessment. The outcome of the authorization process is a Recommendation report, which is submitted to the Ministry for Health and Care Services (HOD).

DSA's assessment is based on the documents submitted with the licensee's application, information obtained at meetings between DSA and operator, audits performed, applicable regulations and international recommendations.

DSA thus makes an assessment to determine whether the licence application is in compliance with:

- → National legislation and regulations requirements;
- → The General Licence Conditions;
- → International recommendations and safety standards, international standards, primarily IAEA Safety Standards.

The General Licence Conditions (GLCs) are based on IAEA and other international recommendations and specify the conditions with which licensees must comply. The GLCs will provide the basis for reviewing any application for a licence under the NE Act ('Generelle vilkår for vurdering av søknader om konsesjon etter

atomenergiloven'). The GLCs were available in an initial form at the beginning of 2018 and were used in the most recent licensing process for the IFE Kjeller site. During the licensing procedure, DSA made the initial form of the licence conditions available to IFE as part of its clarification of expectations regarding the content of a licence application. The finalized GLCs were subsequently used in the review and assessment of the final licence application, before being specified as the conditions associated with the revised site licence.

After receiving a request from HOD and the licence application and associated documents, DSA and the operator hold a start-up meeting, where the operator presents the justification for and details of the licence application. DSA describes how the application will be processed and meetings and inspections related to the application are planned.

During the licence application review and assessment process, DSA carries out further meetings with the operator to clarify any issues identified, and to discuss progress of review and assessment process. DSA carries out inspections to clarify safety issues based on a graded approach.

To strengthen the review and assessment process, DSA uses technical support from independent external consultants. The consultants may assist DSA in inspections in order to clarify identified safety issues. If relevant, DSA also uses information from external contributors, such as IAEA missions, and evaluation or peer review reports in safety, security and safety culture areas.

Stakeholder involvement
According to section 17 of the Public Administration Act (PA Act), the administrative agency (DSA) must ensure that a case, such as an application for authorization, is as informed as possible before a decision is made. In order to secure a basis for its own recommendation, and the basis for further processing and decisions, DSA requests relevant stakeholders to come forward with views on the authorization (or licence) application. Stakeholders include state authorities, national organizations, municipalities' councils and the general public. Licence application documents are published on the DSA website.

DSA summarizes all consultation feedback and provides results in its Recommendation Report, which is submitted to HOD, as described below.

DSA Nuclear Safety and Radioactive Waste Advisory Committee
When the results and the conclusion of the licence application review and assessment process are clear, DSA presents its proposals to the DSA Nuclear Safety and Radioactive Waste Advisory Committee, in line with international recommendations and practice. The members of the Committee include international experts in the field and representatives from regulatory bodies of other countries. The Committee may give advice on the authorization process and provide recommendations on licence conditions, and may provide advice to DSA on supervision of nuclear installation (e.g. to intensify the inspection process, to issue orders for operator for strengthening safety etc.).

Recommendations Report for Licensing to HOD
Based on findings, observations and comments from the review and assessment process, feedback from external stakeholders, and the DSA Advisory Committee, DSA prepares a Recommendation Report, which is submitted to HOD. In accordance with section 10 of the NE Act, DSA makes recommendations to HOD on whether to grant or renew the licence to own and operate the nuclear installation. DSA also provides recommendations on licence conditions, in accordance with section 8 of the NE Act. This advice will includes reference to the GLCs and proposals for any additional licence conditions that are specific to the facility.

Based on DSA's Recommendation Report, the King in Council (the Government) decides whether to grant or renew a licence to construct, own or operate the nuclear installation and issues the licence, if appropriate.

5.2.3 Authorization for operation of nuclear installations

If the licence is granted, DSA must grant approval for operation before the licensee may start operation, according to section 11.2 of the NE Act. The operator of the nuclear installation approaches DSA directly and provides the necessary supporting information for such an authorization. According to section 11.2 of the NE Act, the regulator shall, before authorization, is granted ensure that:

- → The nuclear installation's technical standard, operating regulations, safety measures and emergency response plan are safe;
- → The nuclear installation's management and personnel have the necessary qualifications and clear responsibilities;
- → Warranty is provided pursuant to section 35 of the NE Act, cf. section 37.
- → All other approvals are available from the competent authorities in accordance with the legislation.

In accordance with Section 11.4 of the NE Act, DSA may, if it believes this will assist it in its evaluation of the installation, give separate consent to a limited trial operation, subject to such conditions as may appear necessary. DSA issues the authorization for operation of a nuclear installation directly to the operator of installation, and may withdraw it if necessary.

5.2.4 Authorization for different stages in the lifetime of a facility

A licence is required to construct, own and operate a nuclear installation (NE Act, section 4). The NE Act, section 4 also includes the requirement that the applicant must submit details of the building site.

The DSA procedures on review and assessment and authorization cover all stages in the lifetime of a nuclear facility at a specified location. The review and assessment procedure covers all safety documentation submitted to DSA, independent of the stage in the lifetime of the facility. The procedure for authorization applies to the handling of applications for authorization of the nuclear installation, concerning all stages in the lifetime of a facility until its release from regulatory control.

There are no specific regulations or guidance for specific hold points at which a separate licence is required for specific stages in the lifetime of a facility (e.g. decommissioning). As indicated above, a licence is required to construct, own and operate a nuclear installation (NE Act, section 4), but there are no specific licence requirements in the NE Act for siting, or extended shutdown.

5.2.5 Factors considered in authorization and licensing

Qualification and training of staff and operating personnel
According to the NE Act section 11.2, the regulator shall be satisfied that the nuclear installation's management and personnel have the necessary qualifications and clear responsibilities, before the installation is granted an authorization to operate.

According to General Licence Condition number 17.5, the licensee shall ensure that no operations are carried out which may affect safety except under the control and supervision of suitably qualified and experienced persons appointed for that purpose by the licensee.

Authorization of modifications and changes to the SAR, OLC and other documentation
Authorization for modifications is described in section 12 of the NE Act. All safety important modifications to the installation, operating organization or management changes, changes in the Safety Analysis Report and operational limits and conditions (OLCs) must be authorized by DSA. According to the NE Act, section 11, item 2, if an operator proposes to make a modification in the construction, operation or management of the installation, which constitutes a departure from the conditions on which authorization was granted,, and which may affect safety, the matter must be submitted to DSA for authorization before the alteration is made. DSA handle such requests from the operators in accordance with Authorization Process, including the Review and Assessment Process. DSA authorizes such cases directly to operator.

Requirements on safety policy, safety analysis report and safety assessment, and on the management system
According to the General Licence Conditions (number 15), the licensee of a nuclear facility is required to establish a management system, including a written safety policy that places safety paramount within the management system, overriding all other demands.

According to the General Licence Conditions (number 6), the operating organization must have a Safety Analysis Report (SAR) which must be updated. The General Guidance specifies the expected content of the SAR. Furthermore, the General Guidance for this licence condition states that the licensee should make adequate arrangements for periodic and systematic review of the SAR at intervals specified by DSA.

The SAR and the description of the management system is main part of the documentation required to support an application for authorization for operation of a nuclear installation, in accordance with section 11 of the NE Act.

Requirement for a safety committee
The licensee of a nuclear installation shall establish and maintain a Safety Committee, with an established mandate and procedures approved by DSA (General License Conditions, number 10).

Currently, the licensee (IFE) had established a mandate for a Safety Committee, but as part of the licensing process for the Kjeller site in 2017-18, it became clear that the mandate needed to be updated. Therefore, one of the specific licence conditions was to present a revised mandate and procedure for the Safety Committee to DSA before 1 May 2019.

5.2.6 Planned improvements

The following actions have been identified:

- → DSA should further elaborate its authorization process specific to nuclear installations within the framework of the DSA management system.
- → DSA should improve formalization and application of the graded approach to the authorization process for nuclear installations.

5.3 AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Related to GSR Part 5: Requirements 3 and 4

5.3.1 Radioactive waste management in Norway

National strategy for radioactive waste
Norway is in the process of formalizing its national strategy for the management of spent fuel and radioactive waste in order to address, among other things, the options for the continued storage, conditioning and disposal of spent fuel and longer-lived radioactive wastes, and the increased volume of radioactive wastes that will arise during decommissioning of the research reactors. Current estimates indicate that wastes from decommissioning would result in the existing capacity at KLDRA Himdalen being exceeded, leading to the need to develop extended or new facilities for the disposal of radioactive waste. The regulatory requirements and processes related to the development of new waste management facilities will therefore need to be further developed to address such developments.

Holistic legislative framework for protection of public and the environment
According to chapter 2 of the Pollution Control Act (PC Act), the term 'pollution' "means:

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..."

The PC Act is thus the basis for, *inter alia*, regulating both radioactive and non-radioactive discharges and waste management facilities and activities. Thus, the PC Act, together with its associated regulations, provides a holistic legislative framework for regulating waste management and discharges in Norway. The Norwegian Environment Agency (NEA) regulates non-radioactive pollution and DSA and NEA work closely in regulating facilities, especially in authorization. For example, authorization conditions and the review and assessment processes are harmonized between the two regulatory bodies, where appropriate.

The PC Act and the Regulations on the Application of the Pollution Control Act to Radioactive Pollution and Radioactive Waste (referred to in this document as the PC Regulations) concern radioactive substances which cause or may cause damage or nuisance to the environment including the public and their health. The requirements for authorizations, according to the PC Act, hence shall ensure protection of both public health and protection of the environment.

Chapter 16 in the Regulations Relating to the Recycling of Waste (Waste Regulations) specifies the requirements for radioactive waste management. Radioactive waste must be managed in a sound and justifiable manner and sent to a licensed facility as soon as possible, and at least once a year. Facilities for radioactive waste management require an authorization. Waste management of category 1 waste, which is also classified as hazardous waste, and where there are no radioactive discharges, is only required to have authorization related to its hazardous properties, whereas other types of waste management require an authorization from DSA.

Any relevant information should follow the radioactive waste in a joint declaration form for radioactive waste and hazardous waste.

Graded approach
According to the PC Act, pollution including discharges and contamination, is illegal unless its activity is below the exemption values given in Annex II in the PC Regulations or a permit has been granted by DSA. Similarly, all management of radioactive waste with activity above the exemption values given in Annex I in the same regulation require a permit.

The regulatory system covers all types of radioactive waste and pollution, covering the full range from NORM to nuclear materials. The requirements on the information to be included in an application and the specific conditions included in the authorization are graded commensurate with the potential risk associated with the discharge or waste.

Authorization of repositories for radioactive waste
DSA has authorized five repositories for the disposal of radioactive waste:

- → The combined facility for the storage and disposal of low/intermediate level (L/ILW) waste (KLDRA) at Himdalen;
- → NOAH Langøya;
- → Borge massedeponi;
- → Heggvin Alun; and
- → Gulen NORM repository.

All of these are either surface or near-surface facilities. Only KLDRA, may accept LLW and ILW of nuclear origin and waste containing other manmade radionuclides. The other waste facilities are designed to accept NORM wastes of different origins.

Given their limited number, disposal facilities are regulated on a case-by-case basis under the relevant legal requirements in the NE Act, the PC Act, the Waste Regulations. Detailed regulatory requirements are expressed in the conditions included in permits and licences for the individual facilities. The KLDRA site at Himdalen is currently the only waste disposal facility licensed under the NE Act (in addition to permits under the Pollution Control Act), which can accept waste that originates from nuclear facilities, in addition to low and intermediate level waste from other industries, research activities and hospitals.

Radioactive waste containing NORM
Wastes containing levels of NORM above the exemption levels given in the PC Regulations are defined and handled as radioactive waste. Such wastes constitute the largest volume of radioactive wastes arising in Norway. These wastes would typically be defined as VLLW/LLW under IAEA classifications. Their chemical properties are also taken into account in permitting under the PC Act. The permits for repositories that accept NORM wastes take account of the characteristics of the repository and the waste form to maintain the appropriate level of regulatory control over these wastes.

The radioactive waste containing NORM mainly constitutes waste from NORM industries as well as acid forming rocks containing radionuclides. Hence, four of the five repositories with an authorization for the disposal of radioactive waste accept only NORM wastes:

- → Gulen NORM-repository – may accept radioactive waste from NORM industries;
- → NOAH Langøya – is the main repository for hazardous waste which may also accept radioactive waste with activity below 10 Bq/g from oil and gas industry, mining and acid forming rocks;
- → Borge massedeponi – may accept acid forming rocks and radioactive waste from mining;
- → Heggvin Alun– may accept acid forming rocks and radioactive waste from mining.

5.3.2 Authorization of waste management facilities under the Pollution Control Act

Radioactive waste management facilities and disposal facilities are subject to authorization according to the Pollution Control Act (PC Act) and, for nuclear waste, the Nuclear Energy Activities Act (NE Act).

The DSA issues permits under the PC Act for activities and facilities giving rise to radioactive discharges (releases) and for the management of radioactive waste (including disposal) exceeding the exemption limit in the PC Regulations. Permits issued according to the PC Act authorize planned and controlled discharges during the commissioning, operational and closure /decommissioning phases, including remediation. These permits include conditions on reporting, operations, competence and, where appropriate, conditions related to the discharge or disposal of radioactive waste. DSA has the authority to amend, renew, suspend or revoke authorizations.

DSA may issue separate permits for closure or decommissioning of facilities under the PC Act. Currently, Norway has no national experience in the closure/decommissioning of disposal facilities, and has not yet issued a permit for decommissioning nuclear facilities. However, permits for decommissioning offshore oil and gas installations, including management of radioactive waste, have been granted. In the case of issuing separate permits during the lifetime of a facility, each stage of operation and closure will be subject to review and assessment before issuing a permit for the next phase.

DSA does not authorize siting, design or construction under the PC Act. However, DSA is specifically identified as the competent authority for impact assessments, under the Building Act for nuclear power plants and facilities for processing, storage and disposal of spent nuclear fuel and radioactive waste. Involvement in these processes involves review and approval of assessments and thus may effectively perform many of the same functions as authorization. Nevertheless, it would be helpful to clarify the regulatory process for siting, design and construction in order to identify whether and which modifications to current legislation and regulations would be necessary to authorize the early stages of the development of new facilities.

Applications for permits pursuant to the PC Act are sent to relevant governmental agencies and authorities, interested parties and NGO for consultation. The documents are made public on the DSA's webpages, and in local or national newspapers. DSA forwards any statements or concerns to the applicant for comments, and these are addressed in the final decision.

Stakeholder engagement
According to section 17 of the Public Administration Act (PA act), the administrative agency (DSA) must ensure that a case, such as an application for authorization, is as informed as possible before a decision is made. In order to secure a basis for further processing and decision. DSA requests relevant stakeholders to come forward with views on the authorization application through a hearing process. The application is published on DSA website and information is sent to interested parties. The interested parties include local county administration, relevant other authorities such as Norwegian Environment Agency or Petroleum Safety Authority, NGOs such as environmental protection organizations or local organizations. If relevant, DSA will also participate in public meetings on specific applications. All information is taken into account during DSA's assessment of the application.

Import and export of radioactive waste
According to the Waste Regulations both import and export of radioactive waste require a licence. A licence for export of radioactive waste may only be given under certain conditions:

- → It is necessary to ensure environmental sound waste management;
- → Authorities in the country of destination have given authorization for import;

- → It may be documented that the waste management is environmentally sound in the country of destination;
- → The exporting company is fully responsible for the waste until it is accepted by the waste management facility in the county of destination.

Similarly, a licence for import of radioactive waste may only be given if:

- → Well-grounded reasons are present;
- → Environmentally sound solutions exists for waste management in Norway;
- → Waste management facilities required have the necessary authorizations and capacity.

For import or export of offshore oil and gas installations, which contains both hazardous waste and radioactive waste, the authorization is harmonised with the Norwegian Environment Agency. The majority of import and export authorizations have been either offshore installations or parts of offshore installations containing radioactive waste from the North Sea area, which has been sent onshore for waste management or decommissioning.

5.3.3 Authorization of waste management facilities under the Nuclear Energy Activities Act

Radioactive waste management facilities and disposal facilities are subject to authorization according to the Pollution Control Act (PC Act) and, for nuclear waste, the NE Act.

According to the NE Act, a licence is required for the construction, commissioning and operational stages in the lifetime of a nuclear installation. The Government, through the relevant Ministry (Health and Care Services), grants, revokes or modifies licences. According to section 10, DSA shall make recommendations on all applications for licences under the NE Act. The recommendation normally includes the results of DSA's review and assessment of the application and proposals for licence conditions, as described in more detail in Section 5.2 on the authorization of nuclear installations.

5.3.4 Regulatory requirements and procedures for development of radioactive waste management facilities

The PC Act and the PC Regulations apply to radioactive substances, which cause or may cause damage or nuisance to the environment including the public. The PC Act shall be used to achieve a level of environmental quality that is satisfactory on the basis of an overall evaluation of human health and welfare, the environment, the costs associated with any measures implemented and economic considerations. According to the PC Act, any pollution is in principle forbidden, unless it is authorized. For activities and facilities that may involve serious pollution at a new site or significant developments of a new character at a site where there is existing activity shall at an early stage of the planning process notify the pollution control authority. The pollution control authority may decide that an environmental impact assessment shall be carried out. Provisions for emergency response plans, inspections, application of the Polluter Pays Principle and enforcement are established.

In addition to the provisions of the PC Act, specific regulations pertaining to the management of radioactive waste are given in the Regulation on Waste (chapter 16). The Regulation on Waste requires operators of radioactive waste facilities to properly manage radioactive waste to ensure that the risk of pollution or harm to humans and animals is minimized. Radioactive waste must be sent to an authorized facility and the waste producer shall provide sufficient information about the origin, content and characteristics of the waste to enable the further handling of the waste to take place in a proper manner.

The NE Act contains the legal provisions for authorization and supervision of nuclear installations, and for permitting any activity related to nuclear substances, including disposal. These provisions and requirements are described in more detail in Section 5.2 on the authorization of nuclear installations. It is, however, relevant to note that before a licence is granted, preliminary approval may be given for the site and/or other aspects of the application for the licence.

The authorization process for the PC Act and the NE Act is covered in processes in the DSA internal management system. However, there is ongoing work to develop harmonised processes, which will include all DSA's authorizations, including those for radioactive waste management facilities.

5.3.5 Planned improvements

- → DSA should clarify whether and which modifications to current legislation and regulations that are necessary to ensure that the early stages of the development (siting, design and construction) are regulated according to IAEA standards.
- → DSA should develop and publish guidance on the regulatory requirements and review procedures for the various stages of licensing radioactive waste management facilities.
- → DSA should develop and publish guidance on the regulatory requirements for preparation and maintenance of a safety case, during the development and operation of a radioactive waste facility.
- → DSA should develop more detailed guidance on the criteria and conditions to be included in authorizations for different types of facilities for managing radioactive waste. This would include making explicit linkages between the packaging and closure conditions and the safety case.
- → The provisions for the regulatory control of closure and closed repositories should be clarified.

5.4 AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Related to ***GSR Part 1 (Rev. 1): Requirements 23 and 24***
GSR Part 3: Requirements 6, 7 and 8

5.4.1 Specificities of authorization of radiation sources applications

Requirement for authorization of facilities and activities by DSA
Any activity involving ionizing radiation sources (with the exception of activities involving exempted radioactive sources, as described below) is subject to a requirement of authorization.

Exemption
According to section 2 of the RP Regulations, radioactive sources with total activity (Bq) or activity concentration (Bq/g) lower than or equal to the exemption limit values in the annex of the Regulations are exempted from the requirements of:

- → Registration (section 13);
- → Appointing an RP-coordinator (section 17);
- → Preparing a written risk assessment (section 18); and

→ Handling unsealed radioactive sources in an isotope laboratory of type A, B or C (section 27).

Smoke detectors containing less than 40 kBq Am-241, other permitted consumer products containing radioactive substances, welding electrodes containing thorium, and depleted uranium used as balancing weights or shielding material are also exempted from the requirements listed above.

Radioactive sources with activity below the exemption limits are also exempted from the requirement of authorization for trading or leasing the sources (RP Regulations, section 9, letter r). The remaining regulatory requirements apply also to the exempted sources. There is no process for clearance from all regulatory control within the Norwegian regulatory framework.

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. 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. Any undertaking subject to a requirement for authorization shall appoint a Radiation Protection (RP) coordinator, in order to comply with the competence requirements in the RP Regulations, section 17. The RP Coordinator is the undertaking's contact person with DSA.

Authorization by licensing and demonstration of safety by applicants
Licensing is generally 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 Regulations, section 9, letter a-r. The categorization of activities in section 9 of the RP Regulations allows the application and licensing processes to be adapted to the type of activity in question, consistent with the principle of a graded approach.

Undertakings 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. The application forms request information relevant to the facility or activity in question, typically including specification of activity and type of radiation sources, documentation of personnel qualifications, return arrangements for radioactive sources, security arrangements, instructions and procedures for source handling, emergency arrangements, safety equipment and other equipment for source handling.

Undertakings 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, section 18. If the relevant activity *is* subject to licensing, the applicant must in most cases – depending on the type of activity and associated application form –- either confirm that a risk assessment has been performed and documented, or submit the risk assessment as an attachment to the application.

Every licence that is issued by DSA is given a unique identification number and saved in DSA's archive along with all the information supplied by the applicant and all relevant correspondence pertaining to the case. 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.

Authorization by registration
Authorization by registration is required for any activity involving ionizing radiation sources that is not subject to licensing, cf. the RP Regulations, section 13. Registration is performed using DSA's web-based electronic registration system, which is termed EMS (https://ems.dsa.no/). All the radiation sources and their return arrangements shall be 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. A written risk assessment shall be prepared for activities requiring authorization by means of registration, but the risk assessment is not submitted as part of the application due to the low risk generally associated with activities that do not require licensing.

Whenever the status of a radiation source is changed, e.g. because it is sold, leased out or disposed of, the owner shall register this electronically in EMS in accordance with the requirements of sections 13 and 14 of the RP Regulations. An appropriate case handler at DSA is automatically informed. Once the case handler has approved the registered change, the undertaking's RP Coordinator is automatically informed that the update has been confirmed by DSA. 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.

Conditions in licences
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, cf. the RP Regulations, section 11. For example, licences may include conditions related to the type of radiation sources that can be used, activity limits for radioactive sources, competence requirements, requirements for quality control and maintenance of equipment, for notification of changes such as change of RP Coordinator, change in the status of radiation sources, and so on. 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. Requirements to register all radiation sources in EMS and to keep the information in EMS updated, are normally set as conditions in the licence. Hence, the purpose of EMS is to establish a complete registry of radiation sources used in Norway, comprising all X-ray apparatus, accelerators or radioactive sources with activities above the exemption limits.

5.4.2 Import and Export of Sealed Radioactive Sources

Import and export of high-activity sealed radioactive sources require a licence pursuant to section 9, letter p, of the RP Regulations. However, the Regulations do not prescribe explicit limits to establish what is meant by "high activity". In practice, the Regulation has been interpreted such that "high activity" for sealed sources implies an activity corresponding to $2 \cdot 10^6$ times the exemption limits. This interpretation is consistent with the requirement for licensing according to section 9, letter m of the RP Regulations, to acquire and use high-activity sealed radioactive sources with activity exceeding $2 \cdot 10^6$ times the exemption limits. The criterion also ensures that a licence is generally required for import or export of radioactive sources in Category 1 and 2 (with reference to Table II.1 in Schedule II of IAEA Safety Standards Series No. GSR Part 3), although the IAEA categorization scheme has not been directly adopted.

Import of sealed radioactive sources with activities below the limit for an import licence requires either a confirmation from DSA that the source has been registered in EMS, in accordance with section 13 of the RP Regulations, or a licence according to section 9, letter r, for trade and/or leasing of radioactive sources. Since the requirement for registration does not apply to exempted radioactive sources, authorization for importing such sources is not required.

For international undertakings, e.g. companies conducting offshore radiography or well logging activities in multiple countries, DSA normally issues a licence for import/export of high-activity sources (RP Regulations section 9, letter p) along with the licence for either industrial radiography (section 9, letter a) or well logging activity (section 9, letter c). Transportation of the radiography or well logging sources between States is then not subject to further assessment by DSA.

5.4.3 Justification of practices and optimization of protection and safety

According to section 5 of both the RP Act and the RP Regulations, all use of radiation sources shall be justified and optimized. In the assessment of justification, it shall be determined whether the benefits of the activity outweigh the risks associated with the radiation, and whether the activity is arranged in such a way as to minimise the risk of radiation-induced injury. The ionizing radiation exposure shall be as low as practically achievable, taking into account technological knowledge, social and economic factors. Moreover, section 23 of the RP Regulations states that undertakings shall assess alternatives to the use of ionizing radiation, and choose methods that do not involve the use of ionizing radiation if feasible without unreasonable disadvantage. A reassessment shall be performed when new information emerges relating to the justification of existing areas of use and methods.

For most practices, the relevant application forms do not request applicants to explicitly demonstrate justification of their use of radiation. Since the practices that are subject to the licensing requirement are normally well established and considered to be beneficial to society, the focus is rather on the applicant's demonstration of optimization of protection and safety, e.g. through documentation of personnel qualification, risk assessment, radiation protection procedures, safety equipment, emergency and security arrangements. Hence, if the use of radiation is optimized and well established, it is implicitly considered to be justified. However, if new alternative technologies emerge that are feasible and entail less risk, the applicant is required to consider substitution according to section 23 of the RP Regulations. Section 23 also states that for non-medical use of radiation, X-ray apparatus shall be utilized rather than radioactive sources, when practically achievable. On this basis, blood irradiators using radioactive caesium chloride were substituted with X-ray irradiators at all 13 Norwegian facilities in the period 2013-2015. An assessment of alternatives to the use of radioactive sources is included as part of the licence application form for irradiation facilities (RP Regulations section 9, letter b).

Applicants must also demonstrate justification when applying for authorization of new types of practices or equipment. The demonstration shall contain a description of why the practice is necessary, that alternatives to the use of ionizing radiation have been considered and found not to be feasible without considerable disadvantage, and an assessment of risk, including estimates of radiation doses to employees and the public. Three recent examples where justification was an important issue in the authorization process include use of X-ray based body scanners to detect internally concealed objects for anti-smuggling purposes, use of X-ray imaging for age determination (to settle the age of asylum seekers), and authorization for importing and selling handheld X-ray inspection equipment. In the latter case, DSA considered the demonstration of justification to be insufficient, and the application for authorization was rejected.

5.5 AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Related to GSR Part 6

5.5.1 Specificities of authorization related to decommissioning

The regulatory body, DSA, has the responsibility to regulate decommissioning of Norwegian facilities with regard to radiation and radioactivity. This authority is given in the Regulation on Radioactive Waste and Pollution section 4, the Waste Regulations chapter 16, the NE Act section 10, and the Letter of Delegation from the Ministry of Climate and Environment, dated 10 December 2010, as described in more detail in Modules 1 and 3. The use of the PC Act provides a holistic and flexible regulatory framework for handling all kinds of radioactive discharges and radioactive waste, regardless of origin. The framework also makes it possible to address radioactive discharges (or pollution) and radioactive waste with the same approach and stringency as chemical discharges (or pollution) and non-radioactive waste.

DSA gives advice on licences and grants permits according to the NE Act and the PC Act. The licences and permits generally include specific conditions to have and to update decommissioning plans at certain intervals. In addition, point 9 in the General Licence Conditions (GLCs), used in licensing and for assessing applications for a licence under the NE Act, states that the owner of a facility must have decommissioning plans in place at every phase in the facility's lifetime. In order to obtain a licence under the NE Act, any operator must adhere to the conditions in the GLCs.

The Regulation on Impact Assessment (2017) requires that an operator intending to construct or decommission nuclear facilities or facilities for fresh or spent fuel or repositories for radioactive wastes, must undertake an impact assessment. This requirement also applies to predisposal waste facilities for NORM waste, such as scale, arising from offshore installations (appendix II g).

In addition to the above legal requirements, DSA is in the process of clarifying its regulatory expectations related to the decommissioning of nuclear facilities, in the document 'Regulatory Requirements for Decommissioning of Facilities, which is currently under development. At present, this document is mainly focused on nuclear facilities, due to the imminent decommissioning of one of the research reactors. However, at a later stage, the requirements for non-nuclear facilities will also be included, providing a graded approach which will be suitable for, for example NORM facilities and hospitals . This document will provide instructions and guidelines on authorization for decommissioning for nuclear and non-nuclear facilities at all life stages. .

Nuclear facilities

Owners of nuclear substance (NE Act section 1 c) must have a licence to own nuclear substances (NE Act section 5). Licensing includes setting required conditions to ensure safety (NE Act section 8). Even if the licence to operate the research reactor facilities is revoked, the owner of the facility would still need a licence for as long as they own nuclear substances, i.e. also during decommissioning. Licences under the NE Act are given by the Norwegian Government, based on advice from DSA. DSA also advises the Government on what the conditions and requirements licences should include. The GLCs have been prepared to provide a generic basis for licensing for all nuclear facilities. DSA, as the Norwegian authority, will amongst other actions perform inspections, review and assess the facility's plans such as decommissioning plans, annual reports on operations, discharges and waste handling.

When the decision has been made by either the Government (through not renewing the operational licence), or the operator of the facility, to permanently shut down and decommission the licensed facility, DSA will receive the final decommissioning plan for review and assessment. This plan must be approved by DSA before decommissioning can commence. At present, the decommissioning plans for the Norwegian research reactors and their associated licensed facilities are in the process of being revised and updated based on the initial decommissioning plans. At present, the operator (IFE) has announced that one of the research reactors (at Halden) will be permanently shut down and will be decommissioned. The facilities licence to own nuclear material expires in 2020 and the operator is required to apply for a new licence by September 2019. The decommissioning plan will be evaluated in the process, but before decommissioning,

the operator must deliver a final decommissioning plan to DSA, which has to be approved before decommissioning may commence. In addition, decommissioning is likely to require changes in both the licence under the NE Act and the permit granted under the PC Act. Any decommissioning action, which may alter the safety of the facility or affect safety systems, cannot be performed without approval from DSA.

The licence to own nuclear materials, and the permit to discharge radioactive substances and handle radioactive waste, which are needed to perform decommissioning, will be retracted when the decommissioning work has been completed and the licensee can prove that the goal of the decommissioning has been reached (probably green field).

Non-nuclear facilities
DSA regulates decommissioning of non-nuclear facilities, including NORM facilities, according to PC Act, under the same regulatory framework as nuclear facilities.

An authorization for decommissioning will be given based on the plan for closure and decommissioning. The authorization includes requirements on safe and environmentally sound decommissioning, waste management and protection against releases.

Several offshore installations for oil and gas extraction have been decommissioned under DSA regulations. The decommissioning of offshore installations for oil and gas extraction is also regulated by the regulations specific to the regulation of health, safety and the environment (HES) in the petroleum industry. According to these, a cessation plan must be developed, which includes all relevant information for the cessation. In addition, according to the management regulations applying to such facilities (Regulations relating to management and the duty to provide information in the petroleum activities and at certain onshore facilities), the operator must submit an application for consent for any major changes during the lifetime of an installation, including decommissioning. The consent for applications is coordinated by the Petroleum Safety Authority and the application is sent to all relevant HES authorities, including DSA. The consent will then include any requirements the HES authorities specify for the decommissioning of the installation.

There are ongoing works to establish proton therapy facilities at a few hospitals in Norway. These facilities will give rise to radioactive waste in the form of activated matter in building structures and equipment. There is a requirement in DSA's permits to these activities that the proton therapy facilities develop initial decommissioning plans for review and approval by DSA. In order to be involved at an early stage, DSA has established dialogue with the company that builds hospitals (Sykehusbygg) in order to be able to ensure that the operators consider decommissioning during the planning and construction period and that they deliver initial decommissioning plans as early as possible.

The Regulation on Impact Assessment (2017) states that anyone that constructs or decommissions nuclear facilities or facilities for the storage of fresh or spent fuel or repositories for radioactive wastes must have an impact assessment. This also applies for predisposal waste facilities for offshore installations that may generate NORM waste such as scale (appendix II g). DSA has the responsibility for reviewing and assessing such assessments, within the context of the NE Act and the PC Act.

In addition to the above legal requirements, DSA is in the process of developing additional specific guidance that explains its regulatory expectations with regard to decommissioning. The first draft of this document focuses on nuclear facilities due to the imminent decommissioning of one of the research reactors. However, the requirements and expectations for decommissioning non-nuclear facilities, such as NORM facilities, will be included at a later stage.

5.5.2 Regulatory requirements related to decommissioning

More detailed guidance on regulatory requirements for decommissioning will be provided in the document 'Regulatory Requirements for Decommissioning of Facilities', which is currently in the process of being developed. This document will describe information required on decommissioning strategy, plans and management. The document will need to be further developed, reviewed and appropriately endorsed.

Provisions for retention of institutional knowledge
Knowledge management is a considered under in the draft document on 'Regulatory Requirements of Decommissioning of Facilities'.

5.5.3 Responsibilities for financial provisions for decommissioning

Under section 20 of the PC Act, authorities can set a requirement in the permits that the authorized party must have sufficient funding for decommissioning.

Following a requirement in the permit under the PC Act, the operator of the nuclear facilities (IFE) has set aside 3 million NOK the last 3 – 4 years, which is far less than the estimated cost of decommissioning. IFE is a state owned independent foundation. The research at the facility has provided revenue to Norway. The Attorney General has assessed that the Norwegian Government may be the responsible party, under the PC Act section 7, if IFE becomes bankrupt. By extension, the Norwegian Government (the Ministry of Trade and Fisheries) has stated it will take the economic responsibility to decommission the nuclear facilities. This is a special arrangement for the research reactors and their associated facilities.

5.5.4 Planned improvements

- → To fulfill IAEA requirements, DSA need to clarify the regulatory approach and strategy for regulating decommissioning by further developing and finalizing the 'Regulatory Requirements for Decommissioning of Facilities' document, which is currently in draft form.
- → To fulfil DSA's regulatory obligations on decommissioning of facilities DSA requires further competence and capacity.

5.6 AUTHORIZATION OF TRANSPORT ACTIVITIES

Related to SSR-6

5.6.1 Specificities of authorization related to transport

With regard to transport by road or railroad, DSA is the supervisory and competent authority for class 7 – radioactive material according to section 7 of Regulations on Transportation of Dangerous Goods by Land, No. 384, of 1 April 2009. ADR/RID is formally a part of these Regulations, cf. section 2. Similarly, the IMDG code and ICAO Technical Instructions are incorporated into the regulations for transport of dangerous goods by sea and air (viz. Regulations on Dangerous Goods on Norwegian Ships, No. 944, of 1 July 2014, and Regulations on the Transport of Goods in Aircraft (BSL D 1-7), No. 41, 11 January 2003). However, these regulations do not explicitly state that DSA is the competent authority for transport of radioactive material by sea and air, respectively.

Although the national Competent Authority for all modes of transport of radioactive materials is not currently explicitly identified, in accordance with the item 207 of the IAEA SSR-6, the provisions of section 10 of the NE Act specify that DSA is the highest specialist agency as far as questions of nuclear safety (and security) are concerned. Hence, in practice, DSA acts as the national competent authority in issuing approvals covering all modes of transportation of nuclear substances, except transportation of radioactive sources. In performing this role, DSA applies national legal acts, based on ADR, RID, IMDG, ICAO-TI regulations, requirements and IAEA Specific Safety Requirements SSR-6.

In accordance with the NE Act section 5, it shall be unlawful to manufacture, own, store, handle, transport, sell or otherwise hold or dispose of nuclear substances without a permit from the ministry concerned. However, a specific permit is not required to the extent that activities mentioned here are covered by a licence, granted in accordance with Section 4.

Radioactive sources, radioactive material, other than nuclear substances, are transported along Norwegian roads, but the sources present in Norway do not currently require approval from DSA for transport according to SSR-6.

5.6.2 Requirements on approval and notification related to package design and shipment

DSA has not implemented detailed authorization processes requiring approval for design and shipment of various package types, special arrangements for fissile materials, or special forms of radioactive material but, in practice, assessment and authorization of submitted applications follows national legislation and the requirements of SSR-6 .

5.6.3 Planned improvements

- → There would be benefit in evaluating the regulatory system in Norway. This should be performed to make sure that DSA is legally the only competent authority in Norway for all modes of transport for any purpose in connection with regulations SSR-6 and to further develop a systematic regulation.
- → Consideration of the need to develop further regulations and guidance for transport of radioactive material;
- → Further development of processes for regulation of the transportation of radioactive materials, to be included in the integrated management system that is currently under development.

5.7 CONCLUSIONS AND ACTIONS

DSA ensures that facilities and activities are authorized in advance, under one or more of the three Acts. Procedures are in place for application of authorizations, and a range of guidelines are available that specify, in general terms, the information applicants need to submit in support of applications for an authorization. Where appropriate, this includes a requirement to submit a safety assessment.

The applications and assessments are reviewed by DSA and the level of review depends upon the level of risk involved with the facility or activity. If sufficient information is provided to demonstrate that risks are below required levels, authorizations are granted. The authorizations include conditions on reporting, operations, competence and, where appropriate, conditions related to the discharge or disposal of radioactivity. The authorizations may be time-limited or unlimited. They all include the requirement that DSA is informed in the event of significant changes that may affect the authorization. If required by DSA,

the authorized parties shall reapply for a modification to the authorization. Such modifications may include significant stages in the duration of the activity or stages in the life of a facility (e.g. decommissioning and closure), but specific stages are not specified in all authorizations.

The authorization process does not uniformly apply to site evaluation, design and construction; although the Nuclear Energy Activities Act applies to the latter of these stages, and the Radiation Protection Act and Regulations apply to some aspects of facility design. The Pollution Control Act applies from operation. However, in the Impact Assessment Regulations (No. 854, 21 June 2017), pursuant to the Planning and Building Act, DSA is specifically identified as the competent authority for impact assessments for nuclear power plants and facilities for processing, storage and disposal of spent nuclear fuel and radioactive waste. DSA's involvement in the impact assessments may effectively perform many of the same functions as authorization. Nevertheless, the process should be clarified to identify whether modifications to current legislation and regulations are necessary regarding authorization of the early stages of the development of new facilities.

Furthermore, DSA's established authorization processes could be improved by developing an integrated process applicable for all facilities and activities regulated by DSA. This would improve consistency and ensure a more systematic application of a graded approach, which would also reduce the regulatory workload in the long term. The integrated process should include a systematic procedure for periodic review and subsequent amendment, renewal, suspension or revocation of the authorizations.

It is also clear that more detailed guidance on the information required to support authorization applications, and the criteria that are used in reviewing such applications, would help applicants and the regulatory review work.

DSA regulates facilities and activities broadly in accordance with IAEA standards and guidance. This area has been regulated in Norway since 1938, and the legislation and regulatory practice are ever evolving and improving. To keep the Norwegian regulation and licensing to the high standard required, DSA requires further competence in some areas, as well as further resources.

5.7.1 Actions

- → DSA should further improve its authorization process to provide a systematic procedure for applying the graded approach;
- → DSA should develop and provide more detailed guidance in some areas on the information required to support authorization applications;
- → DSA should propose an approach for regulation connected to siting and design of nuclear facilities and develop associated documents and guidance;
- → DSA should develop an approach for taking account of interdependencies in waste management, including repository design, packaging and closure conditions;
- → DSA needs to clarify the regulatory approach and strategy for regulating decommissioning;
- → To perform sound regulation of decommissioning of facilities DSA require both further competence and resources;
- → DSA should propose that the regulatory framework for transport should be reviewed.

6 REVIEW AND ASSESSMENT

6.1 GENERIC ISSUES

6.1.1 MANAGEMENT OF REVIEW AND ASSESSMENT

Related to ***GSR Part 1 (Rev. 1): Requirements 25 and 26, paragraphs 4.40 – 4.48***
GSR Part 3 Requirement 13
GSR Part 4 (Rev. 1): Requirements 1 – 4

Responsibilities for review and assessment

Under the provisions of the Public Administration Act (PA Act), DSA is required to ensure that all aspects of the authorization are clarified as thoroughly as possible before a decision is made.

The level of detail and the resources allocated to reviews and assessments of the documents submitted in support of authorization applications is broadly determined according to the complexity and risk associated with the facility or activity, in line with a graded approach.

The specific requirements related to the acts under which DSA grants authorizations are described in detail in the sections below.

Scope and types of documents reviewed
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-These guidelines are available on the DSA website.

Applicants applying for an authorization under the Pollution Control (PC Act) are required to include information specified in guidance available on DSA's website, as explained in more detail below.

Applicants for authorization under the Nuclear Energy Activities Act (NE Act) are required to submit details of the site, the purpose, nature and size of the installation and an account and evaluation of the safety features of the installation.

Applications for authorization under the Act on Radiation Protection and Use of Radiation (RP Act), for example for the use of radiation sources, may be in the form of a letter or an application form. Guidelines and the relevant forms specify the information required on the most relevant safety aspects, as explained in more detail below.

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, according to established internal procedures. The guidelines for applicants are used as a checklist for assessing the completeness and adequacy of the application. The level of review depends on the complexity and risk associated with the facility or activity.

Applications for licensing under the NE Act are handled in accordance with the recently developed 'Review and Assessment Procedure'. This procedure was prepared and used for the licensing process in 2018 for the Institute for Energy Technology (IFE) Kjeller site and the fuel workshop in Halden, as explained in more detail below.

6.1.2 BASES FOR REVIEW AND ASSESSMENT

Related to GSR Part 1 (Rev. 1): Requirements 23 and 24, paragraphs 4.33 – 4.34; Requirements 25 and 26, paragraphs 4.40 – 4.41
GSR Part 4 (Rev. 1): Requirements 14 – 15

As indicated above, 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. These guidelines are available on the DSA website. These guidelines provide one of the bases for reviewing the completeness and adequacy of submitted materials.

For nuclear facilities, draft guidance is under development on the application of the General Licence Conditions that were developed for the licensing process in 2018 for the Institute for Energy Technology (IFE) Kjeller site and the fuel workshop in Halden. The intention is to finalize this guidance and to use it in assessing licence applications under the NE Act in the future.

Further clarification of expectations in external guidance regarding applications for authorization, including criteria for review and assessment, taking account of the application of a graded approach to regulation.

6.1.3 PERFORMANCE OF REVIEW AND ASSESSMENT

Related to GSR Part 1 (Rev. 1): Requirements 25 and 26, paragraphs 4.43 – 4.48
GSR Part 4: Requirements 2 – 21

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, according to established internal procedures. The guidelines for applicants are used as a checklist for the completeness and adequacy of the application. The level of review depends on the complexity and risk associated with the facility or activity.

Applications for licensing under the NE Act are handled in accordance with the recently developed 'Review and Assessment Procedure'. This procedure was prepared and used for the licensing process in 2018 for the Institute for Energy Technology (IFE) Kjeller site and the fuel workshop in Halden, as explained in more detail below.

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. The requirement to undertake periodic reviews of health, safety, and environmental protection provisions is also required as part of the Internal Control Regulations (IC Regulations). Furthermore, for nuclear facilities, the General Licence Conditions include a requirement for the authorized party to undertake periodic assessments of safety. These assessments are reviewed by DSA, as appropriate.

6.2 REVIEW AND ASSESSMENT FOR NUCLEAR INSTALLATIONS

Related to SSR-3: Requirements 1 and 5

6.2.1 General Review and Assessment for Nuclear Installations

Review and assessment of information relevant to safety for nuclear installations and activities are performed in authorization processes and through inspections. Technical and other information relating to safety is reviewed, in order to verify the adequacy of the proposed safety measures as part of the authorization process, and to determine whether the facility or activity complies with regulatory requirements and the authorization. The review and assessment is performed to support the authorization processes, for example in reviewing licence applications or in performing regulatory oversight activities. The input to review and assessment process could be:

- → Licence application to own or operate a nuclear facility, in accordance with section 7 of the NE Act;
- → Application from a licensee to authorize operation or safety important modifications, in accordance with section 11.2 or 12 of the NE Act;
- → Annual reports. The licensee of a nuclear installation is required, through a licence condition, to submit an annual report.

Review and assessment of a licence application is a comprehensive task, which could take 1.5 year to complete. In addition to reviewing the technical and other information, an important part of the review and assessment of licence applications is consideration of the appropriate licence conditions and whether the period applied for is appropriate.

DSA makes review and assessment of submitted documents against:

- → National legislation and regulations requirements;
- → The General Licence Conditions;
- → International recommendations and safety standards, international standards, primarily IAEA Safety Standards.

If the information provided by the applicant is found to be insufficient, DSA will request the necessary supplementary information for processing the application. If necessary, during application review and assessment process, DSA holds meetings with the applicant to clarify issues identified and to discuss progress of review and assessment process.

Conducting inspections is an important method to clarify safety issues, to verify that the information provided by licensees in their applications and annual reports is correct, and that the licensee complies with the regulatory requirements.

The review and assessment for nuclear installations is implemented in accordance with an established 'Review and Assessment Procedure'. This process consists of the following activities:

(1) Nomination of a responsible employee to organize and manage review and assessment activities;
(2) Review and assessment of documents, using checklists and implementation of inspections on site to clarify identified issues, if necessary;
(3) Collection, integration and documentation of review and assessment results;
(4) Development of a review and assessment report, including proposed authorization conditions;
(5) Submission of feedback to the authorization process.

To strengthen the review and assessment process, DSA uses technical support from the Nuclear Safety and Radioactive Waste Advisory Committee (described in section 5.2), as well as independent external consultants as necessary. These consultants may also assist DSA in inspections to clarify safety issues related to the review and assessment.

The information from external contributors, such as IAEA audit and evaluation or Peer reviews reports in safety, security and safety culture areas are used as well. Feedback on operating experience of the nuclear installations and outputs from other regulatory processes (e.g. inspection results, previous reviews and assessment results) are also used.

6.2.2 Assessment during lifetime of a nuclear installation

The review and assessment of information is performed throughout the lifetime of a facility, or periodically as determined by the duration of the licence. According to the General Licence Conditions, and in accordance with the NE Act, section 13, it is anticipated that, as the need arises, further review and assessment will need to be undertaken, for example relating to developments in the Safety Analysis Reports for Kjeller, before the end of the current licensing period.

DSA continually assesses the safety of licensed nuclear installations, based on reports from the operator, DSA's own supervisory activities, international safety standards, internal national practices and national requirements from other organizations such as IAEA, as well as assistance from external consultants.

In accordance with Section 12 of the NE Act, all safety important installation modifications, operating organization or management changes, for example changes in Safety Analysis Report, must be authorized by DSA. DSA handles such requests in accordance with its internal procedure on Authorization and Review and Assessment.

6.2.3 Review and assessment related to Periodic Safety Review, to SAR and to the applicable acceptance criteria

The regulatory body requires authorized parties to routinely evaluate operating experience and to periodically perform comprehensive safety reviews of facilities, such as periodic safety reviews through the General Licence Conditions. A licence condition for periodic safety review was first established in the licence for the Kjeller site and the Fuel Instrumentation Workshop in Halden for 2019-2028. Thus, in the future, DSA will need to review and assess the results of comprehensive periodic safety reviews, which will be submitted in accordance with the General Licence Conditions.

6.3 REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Related to GSR Part 5: Requirements 13 – 16, SSR-5: Requirements 11 – 14

6.3.1 Review and assessment for different stages in development waste management facilities

The provisions for siting and design are to some degree regulated according to the Act on Planning and Building Activities and the Regulation on Impact Assessments. According to the Regulation on Impact Assessments, DSA determines the plan for the impact assessment and undertakes an assessment, review and approval of the assessment performed by the operator. DSA has not yet established specific guidance on the scope of the impact assessments required for the development of predisposal and waste management facilities or the review and assessment process but this work is planned.

Prior to authorizations according to the Pollution Control Act (PC Act), including modifications to existing authorizations, DSA reviews and assesses relevant information in the application, including the supporting

documents and assessments, to determine whether the facilities and activities comply with regulatory requirements.

Requirements for the information that needs to be included in the application are specified in the Pollution Control Regulations (PC Regulations, chapter 36), and complementary information is specified in the document 'Guidelines for application'. A procedure for applications and authorizations under the PC Act (procedure SB-P-0001) describes the activities of the regulatory body when assessing an application. The procedure describes the process that is followed once an application is received by DSA. The development of a further more detailed written procedure for review and assessment would help to improve consistency and a more systematic application of a graded approach.

The following information is required in applications for authorization under the PC Act and associated regulations:

- → Description of the given facility/activity;
- → Information on the competence of staff concerning radioactive waste handling and radioactive discharges;
- → Description of measures to ensure proper handling of radioactive waste;
- → Internal control system, including relevant procedures and risk assessments for radioactive discharges and radioactive waste;
- → Description of the discharge and a proposed environmental monitoring program; and
- → Safety assessments including dose evaluations for normal operation and incidents/accidents.

All waste management facilities, including repositories, are required to report annually to DSA. The annual report shall follow guidelines provided on DSA's website and any facility-specific reporting requirements. The reports shall include information about: radioactive waste accepted, managed or disposed of; monitoring of discharges and environment; any incidents (in addition to any reported severe incident or accident which should be reported immediately); or non-compliances, including how they are managed and how BAT (Best Available Technique) is implemented. Annual reports are reviewed and assessed

According to the Nuclear Energy Activities Act (NE Act), a licence to construct, own or operate a nuclear installation is needed, and is based on a safety case. DSA undertakes a detailed assessment and review of the safety case and gives its recommendations to the relevant ministry (Ministry of Health and Care Services). The Government issues the licence.

Before a licence is given, a preliminary approval may be given for the site and other aspects of the application for the licence. DSA shall ensure that licence conditions are complied with and that any necessary safety measures are implemented, including the safety measures described in preliminary safety reports. Before any operation of nuclear installations, the operator must have an operating licence from the DSA. These various stages of licensing imply that DSA would review and assess the evolving safety case, at each stage in its development.

The General Licence Conditions for nuclear facilities serve as requirements on the information and assessments that a licence application under the NE Act must include. In addition, guidelines, providing a more detailed explanation of the General Licence Conditions (GLCs) and DSA's regulatory expectations, are currently under development. Draft versions of these are available (General Guidance for the Application of the General License Conditions' and 'Specific Guidance for the Application of the General License Conditions'). The review and assessment of the documentation related to licences under the NE Act is made with reference to the GLCs and the NE Act itself. DSA reviews and assesses technical and other documents

submitted by the applicant in accordance with the 'Review and Assessment Procedure' to determine whether the facility or activity complies with the relevant objectives, principles and associated criteria for safety.

Any changes in the construction, management or operation of a facility that constitute a departure from the original conditions in the licence, shall be approved by the DSA. The General Licence Conditions require that modifications that might significantly affect the safety of a facility or activity shall be subject to DSA approval if so specified.

6.3.2 Review and assessment related to Periodic Safety Review

Licensees of nuclear facilities are required, according to the General Licence Conditions (GLCs) No.22, to carry out a periodic safety review as necessary or at intervals specified by the DSA. The GLCs were recently established, and therefore review and assessment of a periodic safety review has not yet been performed.

For radioactive waste facilities that are not nuclear facilities, there are currently no requirements to perform a periodic safety review. However, authorized parties are not permitted to deviate significantly from the conditions specified in their authorization application and there is generally a condition in permits to notify DSA in advance of any such changes or modifications. Furthermore, the permit may be withdrawn or altered if it is more than 10 years since it was issued. These situations may result in the need to re-apply for an authorization, which would be supported by a revised assessment. This process would involve DSA assessment, review and approval.

6.3.3 Review and assessment extending beyond the operational phase

According to the permits, granted under the PC Act, disposal facilities are required to present a post-closure plan well in advance of closure. The DSA has not yet established specific guidance on the scope of the post-closure plan or the associated review and assessment process.

6.3.4 Planned improvements

- → DSA should consider clarifying the process to identify whether and which modifications to current legislation and regulations would be necessary to authorize the early stages of the development of new facilities. This should, include a formalized regulatory framework that provides for disposal facilities to be developed, operated and closed in a series of steps.
- → DSA should consider requiring periodic safety review for authorized non-nuclear facilities/activities associated with the management of radioactive waste.
- → DSA should develop and publish guidance on the regulatory requirements related to the preparation and maintenance of a safety case, during the development and operation of a radioactive waste facility. This should ensure that safety cases are prepared (for all types of waste facility, in accordance with IAEA-SSR-5).

6.4 REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Related to GSR Part 1 (Rev. 1): Requirements 23, 25 and 26

Review and assessment of information relevant to safety for radiation sources facilities and activities are performed in connection with licence applications, with 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 (see description of EMS in section 5.4).

6.4.1 Review of licence applications

DSA has formalized general processes for review and assessment of licence applications. For most categories of radiation sources facilities and activities, there are specific application forms. The application forms are designed such that the questions cover the requirements in the RP Regulations relevant for the facility/activity in question. As such, the information provided through the completed application forms (and submitted attachments) will 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 expert 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 emphasize on reviewing the applicant's demonstration of justification, as described in section 5.4.

If the information provided by the applicant is found to be insufficient, DSA will request the supplementary information that is deemed necessary for processing the application. According to the Public Administration Act, section 17, DSA shall ensure that the case is clarified as thoroughly as possible before any administrative decision is made.

For large high-risk facilities, such as radiotherapy centres, the application and licensing process are more comprehensive, and DSA reviews parts of the project, e.g. the design and shielding of laboratories and radiotherapy treatment rooms, at 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 (Section 9, letter n), radiotherapy facilities (Section 9, letter f), and irradiation facilities involving high-activity radioactive sources (Section 9, letter b), it is part of DSA's regulatory practice to inspect the location or site at the planning stage.

The conditions included in a licence vary with the type of activity or facility that is authorized, consistent with the principle of a graded approach. It is therefore an important part of DSA's review and assessment to determine the conditions that are relevant and necessary to limit the risks that are identified as most important for a particular activity or facility.

6.4.2 Annual reports

For a number of practices, a requirement for annual reporting is included as a condition in the licence. For instance, vendors of radiation sources (RP Regulations, section 9, letter r) shall report records of radiation sources that have been sold, and the recipient of each source. Facilities with a licence for comprehensive

use of radiation for research (Section 9, letter d), or for type A isotope laboratory (section 9, letter n), need to report the quantities of unsealed radioactive sources purchased and used, in addition to descriptions of ongoing research projects, updated lists of radiation protection officers and isotope laboratories, and results from dose monitoring and internal radiation protection controls. Companies with a licence for performing tracer studies (section 9, letter l) shall report records of all tracer studies carried out and the amount of radioactive material used.

For medical facilities, annual reports are typically divided into the three fields of nuclear medicine (section 9, letter e), radiotherapy (section 9, letter f) and general radiology (section 9, letter g). The reports include information about the organization of radiation protection within the facility, activity data, any incidents and results from internal revisions regarding radiation protection. The annual reporting for radiology is currently being revised because of the requirements to establish a system for automatic reporting of patient exposure data by 2020 (RP Regulations, sections 56 and 64).

To assess optimization of patient doses in diagnostic radiology, DSA has collected local diagnostic reference levels (LDRL) (most recently in 2017). Facilities that exceed the national DRL significantly are followed up by inspections.

6.4.3 Review through inspections

Conducting inspections is the most reliable way for DSA to verify that the information provided by licensees through applications and annual reports is correct and that the licensee complies with the regulatory requirements. When planning, inspections of the following are prioritized: new undertakings, high-risk and high-dose facilities or activities, undertakings that have reported incidents or accidents, and medical facilities that have been exceeding the national diagnostic reference levels. More details on how inspections of radiation sources facilities and activities are carried out and followed up are given in Module 7.

6.4.4 Monitoring of the status of radiation sources

EMS has report functions that enable DSA to monitor relevant transactions involving radiation sources, such as whether the source is in use, in storage, sold, leased out, or disposed of. Whenever the status of a radiation source is updated in EMS, DSA is automatically notified and details concerning the update is sent to a case handler in DSA for review and confirmation.

6.5 REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Related to GSR Part 6: paragraph 3.3

6.5.1 Review of decommissioning strategies and plans

The decommissioning plans for the research reactors are reviewed as part of the licensing process and by instruction after a given amount of time. The General Licence Conditions, paragraph 9, state that decommissioning plans must be reviewed and submitted for approval by DSA at least once every 5 years. DSA is in a process of developing a document that will be applicable to all facilities that has either a licence or a permit under the NE Act, the PC Act or the RP Act with regard to decommissioning. This document will address in full expectations of regulatory requirements for decommissioning, including review given in GSR

part 6, WS-G-2.1 and other relevant documents. This will include conditions for review and eventual approval by DSA.

In practice, DSA reviewed the ongoing decommissioning plans from the operator of the nuclear facilities provided in December 2016. The review of the decommissioning plans performed by DSA compared the content and quality of the decommissioning plan against demands in Norwegian legislation as well as IAEA GSR Part 6 and IAEA WS-G-2.1. Based on these analyses, DSA gave feedback to the operator and instructions on how to increase compliance with Norwegian legislation and GSR part 6 and WS-G-2.1. Revised decommissioning plans were delivered to DSA in 2018, which are currently being reviewed by DSA.

6.5.2 Review and assessment of methods and reports

Review and assessment of novel decommissioning methods has not been performed in Norway, but it is anticipated that review and assessment of novel methods will be handled in the same way as other, more well-established methods. However, when any operator wants to use methods that are novel for the facility, even if the method itself is well known in other facilities or industries, the operator must undertake a safety assessment to demonstrate that the method is safe. Novel methods may require more documentation.

6.6 REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

Related to SSR 6

In practice, there is currently only one nuclear operator in Norway, the Institute for Energy Technology (IFE), which is licensed, in accordance with requirements of section 4 of the NE Act (to construct, own and operate nuclear installations). In this case, the operator's licence also permits IFE to hold (and transport) nuclear substances. IFE has designed manufactured, maintained and repaired packages for the transportation of radioactive waste. IFE performs all transportation operations (preparation, packaging, loading, carrying and unloading) for nuclear materials in Norway. IFE transports radioactive materials by land, using road transport only.

6.6.1 Management system assessment

An operator must submit a description of its management system as part of its licence application, in accordance with section 11 of the NE Act. DSA systematically assesses and reviews this document throughout the life cycle of nuclear installations, during relicensing process and operational supervision inspections.

6.6.2 Review and assessment of package design

It is the operator's responsibility to demonstrate that package designs comply with the applicable SSR-6 requirements. DSA undertakes a review and assessment to determine whether the information submitted adequately demonstrates such compliance. DSA checks statements, calculations and assessments made by the operator, for example by performing independent calculations or tests, if necessary. DSA approves the design of packages in accordance with SSR-6 requirements, and issue a certificate if appropriate.

6.6.3 Continuous review and assessment

The operator's compliance with the authorization is granted and relevant information associated with the transport approvals is assessed during the validity period of the transport approvals (e.g. permit or licence conditions, package design certificate.) during operational supervision inspections.

6.7 CONCLUSIONS AND ACTIONS

The regulatory body performs review and assessments to determine whether facilities and activities comply with regulatory requirements and the conditions specified in authorizations. DSA also has formalized processes for review and assessment of applications for each of the relevant Acts. DSA is also in the process of developing a procedure for review and assessment that would apply to all relevant processes.

DSA is therefore generally in compliance with IAEA standards.

The procedure for review and assessment would be improved by the development of written procedures specifying relevant requirements in accordance with graded approach. This would ensure more systematic review and assessment. The processes should also be extended to include periodic review and assessment of facilities and activities throughout their lifetime and the way in which relevant information is processed.

6.7.1 Actions

→ DSA should consider requiring periodic safety review for authorized non-nuclear facilities/activities associated with the management of radioactive waste.

→ DSA should develop and publish guidance on the regulatory requirements related to the preparation and maintenance of a safety case during the development and operation of a radioactive waste facility. This should ensure that safety cases (for all types of waste facility)

7 INSPECTION

7.1 GENERIC ISSUES

Related to GSR Part 1 (Rev. 1): Requirements 27 – 29, paragraphs 4.50 and 4.53

The Ministries instruct DSA to highly prioritize inspections in all regulatory areas, for example, inspections were specifically mentioned in the Ministries' Letters of Commitment for each year in the period 2016-2019. The number of yearly inspections is used as a key performance indicator in DSA's reports to the different ministries. DSA also report on any deviations from the requirements in legislation, permits and licences uncovered in this process. Inspection is a key focus area for DSA.

7.1.1 Legal basis for DSA's inspections

Norwegian legislation provides the necessary legal basis for inspection activities covering all areas that DSA regulates. DSA may perform both announced and unannounced inspections. According to the Pollution Control Act (PC Act), the Radiation Protection Act (RP Act) and the Nuclear Energy Activities Act (NE Act), DSA shall be given free access to all relevant information and to sites, facilities and activities.

DSA's legal basis for performing inspections is given in:

- → Radiation Protection Act, section 18;
- → Radiation Protection Regulations, section 60;
- → Pollution Control Act, sections 48 and 50;
- → Regulation on Recycling of Waste, sections 16-13;
- → Internal Control Regulations, section 7;
- → Nuclear Energy Act, sections 13, 14 and 51.

7.1.2 Internal control principle

Internal control is defined in section 3 of the Internal Control Regulations (IC Regulations) as:

> *"systematic measures designed to ensure that the activities of the enterprise are planned, organized, performed and maintained in conformity with requirements laid down in or pursuant to the health, safety and environmental legislation".*

Facilities and undertakings have an obligation to maintain internal control, with active participation from employees. The principle of internal control establishes that the undertaking has an independent responsibility to assess and control Health, Environment and Safety (HES)-related risks and verify compliance with the requirements of the HES-legislation. Hence, it also ensures that regulatory inspections do not diminish the authorized party's prime responsibility for safety.

The similar system is the key also to regulations relating to HSE in the offshore petroleum industry and at associated land-based facilities, which are also subject to DSA supervisory authority according to the PC Act.

7.1.3 Norwegian HES-authorities and their guidelines

To ensure coordination and harmonized regulation among the Norwegian HES-authorities , a formalized cooperation group has been established. These authorities are;

- → Norwegian Radiation and Nuclear Safety Authority;
- → Norwegian Labour Inspection Authority;
- → Norwegian Environment Agency;
- → Norwegian Industrial Safety Organisation;
- → Norwegian Directorate for Civil Protection;
- → Norwegian Food Safety Authority;
- → Petroleum Safety Authority Norway; and
- → Norwegian Board of Health Supervision.

A main goal with this cooperation is to ensure that inspections are carried out as uniformly and in as coordinated a manner as possible.

The authorities cooperate through the group of Directors General to coordinate strategic plans for inspection. The authorities also cooperate through the Coordination Group, which has established joint guidelines for inspections, a database for coordinating inspections and joint training of inspectors. The joint HES-guidelines for inspections is implemented in the DSA processes and templates for inspections.

The training constitutes of a 4-day course on performing inspections according to the IC Regulations, through the HES joint guidelines. The course covers the basics of audits and inspections. The HSE authorities have also established additional courses, for example in communication related to inspection and on performing risk-based inspections. All DSA inspectors attend the HES training in addition to in house training in DSA processes for inspection.

7.1.4 DSA's Inspection Strategy

DSA has developed an inspection strategy for the period 2016-2020. The strategy ensures implantation of IAEA requirements for performing inspections. The strategy has four ambitions for the period:

1. The inspections shall be risk-based,
    a. The choice of facilities and activities to inspect shall be risk-based,
    b. The frequency of inspections shall be risk-based through annual plans and longer general plans for long-term focus and goals, and
    c. The choice of inspection form shall be risk-based.
2. The inspections shall be of high quality,
    a. The inspectors shall be well trained,
    b. DSA shall have a training programme for inspectors,
    c. The performance of inspection shall be evaluated,
    d. DSA shall have updated processes for inspection of high quality, and
    e. Sanctions shall be used uniformly and consistent.
3. DSA inspections shall follow the Norwegian HES-authorities' joint guidelines and be coordinated with other inspections performed by other HES-authorities.
4. The number of inspections shall be adequate to ensure compliance in facilities and activities.

7.1.5 Graded approach to inspections of facilities and activities

As indicated above, DSA's Inspection Strategy states that inspections shall be risk-based, both with regard to the frequency of inspections and to the facilities or activities inspected. For some areas, target frequencies of on-site inspections have been established based on an evaluation of associated risk and IAEA recommendations. For other areas, the selection of inspection frequencies and objects is based on long-term plans and expert judgement. The actual frequency of inspections has been lower than DSA's target frequencies for several areas. This discrepancy is mainly due to a lack of resources.

7.1.6 DSA's Inspection Group

DSA has established an Inspection Group to coordinate DSA's inspection work, including the annual inspection plans. Each section decides which facilities and activities to inspect the following year and reports to the inspection group, which maintains and coordinates the annual plan to, among other things, ensure that a facility or activity is not inspected several times by different inspection teams.

The inspection group helped to prepare the inspection processes and templates, as well as the Inspection Strategy. The group also helps to keep DSA's inspections in accordance with the DSA Inspection Strategy and HES-guidelines.

7.1.7 DSA's processes for inspection

DSA has developed processes for inspections according to each of the three acts under which DSA regulates. There is ongoing work to harmonize the processes to cover all DSA's inspections. The processes include inspection guidelines, procedures and templates.

The inspection procedures describe the practical inspection activities, including the responsibilities of inspectors, case handlers and the Section Head. The procedures also include templates for writing notice letters and inspection reports, and PowerPoint templates for opening/closure meetings. Within most areas, checklists and question lists have also been established, but these are not yet available in the DSA quality management system. The checklists are adapted to each inspection. During inspections, DSA typically looks into the management/quality system, technical solutions, accident handling and risk assessments, competence, education and training, quality controls, and the radiation protection organization.

DSA performs several different types of inspections, which includes programmed and reactive inspections, both announced and unnanounced. Relevant inspection types include:

- → Revision/audit – systematic review of a facility's internal management system;
- → Inspection – systematic review of one or several topics;
- → Thematic inspections – a systematic review of several facilities or activities on a specific topic;
- → Unannounced inspection – review which has not been announced to the facility in advance;
- → Follow-up inspection – review to verify rectification of non-compliance;
- → Web-based inspection – mandatory digital questionnaire;
- → Ad hoc/incident-inspection – review due to knowledge or suspicion of non-compliance. Reactive inspections are not part of programmed inspections.

Programmed announced inspections are the most common type. The inspection processes follow the guidelines from the HES-authorities, and comprise of the following steps:

- → Planning of an inspection;
- → Notification of the facility or activity, in writing at least 6 weeks in advance;
- → Review of documentation, both from the archive and new information from the facility or activity;
- → Opening meeting with presentation of the inspection;
- → Interviews and on-site control of the facility or activity;
- → Closing meeting where any non-compliance or suggestions for improvement are presented;
- → A written inspection report is sent to the facility, specifying any non-compliance with a deadline for rectification;
- → Non-compliances are closed when the facility demonstrates rectification. See Module 8 for a detailed description of potential enforcement actions that DSA may use if deadlines are exceeded);
- → The inspection is formally closed by DSA;
- → The inspection report is published on DSA's website.

DSA inspectors

There are no full-time inspectors at DSA. Most inspectors are designated case handlers who are also involved in the authorization, review and assessment of the inspected facilities or activities and generally spend significantly less than 50% of their time undertaking inspection activities. There are just over 20 employees working as inspectors at DSA.

The case handlers, who also work as inspectors, generally have relevant education, mainly within natural sciences or in law, at master- or PhD-level. The inspectors are usually specialized in a specific area/field. Within their first year at DSA, inspectors participate in the joint HES-authorities' four-day course for inspection personnel . The course covers the basics of audits and inspections under the terms of the IC Regulations. All inspectors also have in-house training in performing inspections by experienced staff. Additionally, some of the inspectors have taken a 2-day communication course, which is also offered through the cooperation between the HES-authorities, or university level training in performing inspections. The Agency for Public Management and eGovernment (Difi) offers optional, short web courses in the Public Administration Act and the Freedom of Information Act.

Teams of 2-3 inspectors typically carry out DSA's inspections. One of the inspectors will leadthe inspection, and the role of inspection leader is normally rotated. New inspectors will initially be paired with experienced personnel, who lead the inspection. The most important part of any inspector's training is participating in inspections under the supervision of more experienced inspectors.

Inspection in connection with authorization, review and assessment and enforcement

Inspection may be, but is not commonly, used in the authorization process of facilities, although inspections have been performed as a part of a licensing process for nuclear installations. Inspections are primarily performed in order to review and assess how the facilities comply with legislation and requirements specified in the licence or permit.

For enterprises applying for use of radioactive sources, and especially high-risk radioactive sources, DSA normally inspects first time applicants before an authorization is granted, for security reasons. The main purpose of this routine is to verify by inspection that the applicant is trustworthy and not a fictitious enterprise.

Results from inspections during the licence period are considered when reviewing applications for the renewal of a licence. In addition, information submitted by the authorized party in its licence applications is considered during, and in the preparation for, inspections. Both statistical information collected through DSA's inspection activity, e.g. from web-based inspections covering a large number of enterprises, and experience from on-site inspections, are valuable sources of information used for optimization of the regulatory system, by making changes in regulations and guides and in modifying the inspection programme.

Facilities and activities without a licence may also be inspected if DSA suspects a breach of legislation.

If non-compliance is found during an inspection, the enforcement process is part of the follow up after an inspection. See further information in Module 8.

Inspection techniques
The inspection techniques used are evaluation of written documents and comparison with regulatory requirements (including those specified in the licence or permit) and the operators' internal standards (if applicable). The findings identified in the review of documentation can be verified by either individual or group interviews. Other issues may be addressed during such interviews. An inspection can also include a tour of the facility and the inspectors may check on-site documentation, such as the description of waste, access records and so on. The inspectors may use instruments or samples to verify the level of radioactive substances present, the absence of contaminants or other similar issues, if applicable.

In accordance with the DSA inspections procedures, a closing meeting is held at the end of the inspection. At this meeting, non-compliances are presented. The operator is given the opportunity to comment on the findings, to identify and resolve any misunderstandings or factual errors. A written inspection report, comprising general impressions and findings, and deadlines to correct non-compliances is sent to the operator as soon as possible after the inspection. . Findings are followed up, according to the regulatory practice within the different regulations. When finalized, the inspection report is published on the DSA website.

If the authorized party fails to meet a deadline for complying with an order of rectification, a coercive fine, decided by DSA, may be applied. Stronger enforcement actions are also available. If necessary, DSA may revoke the licence, confiscate substances or equipment, prohibit import or sale, or close the facility. For further details, see Module 8.

Joint inspections with other authorities and invited experts
Occasionally, DSA includes experts in the inspection team to strengthen the team's expertise. The experts generally contribute to specific evaluations, but they will not lead the inspection nor have a formal role as authority.

DSA occasionally performs joint inspections with other authorities, where more than one authority regulates different aspects of the same facility or activity. In recent years, DSA has performed joint inspections with *i.a.* the County Governor, the Norwegian National Security Authority, Norwegian Labour Inspection Authority, Norwegian Directorate for Civil Protection, Petroleum Safety Authority Norway, Norwegian Board of Health Supervision, Customs and the Norwegian Environmental Agency.

Inspections under the PC Act may be performed together with the Norwegian Environmental Agency or the County Governor, which are authorities for regulating non-radioactive discharges and waste, according to the PC Act. For example, these authorities also have responsibilities for regulating disposal sites for alum shales and discharges from the oil and gas industry, which result in both radioactive and non-radioactive releases.

Sometimes DSA also participates in coordinated inspection campaigns with the other Norwegian HSE-authorities.

Selection of facilities and activities to inspect
The risk-based selection of inspection objects focuses mainly on comparisons within different sectors/areas rather than the entire area of DSA responsibility. The risks associated with radiation sources are not compared to the risks associated with nuclear facilities or radioactive discharges and waste, when selecting the objects for inspection. It is, however, reflected when the allocation of resources available for inspection is decided, taking into account the possibility of collecting inspection fees.

The selection of inspection objects and the frequency of inspections for different activities is, in practice, decided according to a graded approach, based on information from yearly reports, new practices, incidents, type of activities etc. Designated case handlers select the inspection objects based on their specific knowledge, experience and an overview of the objects within a specific activity. The frequency of inspecting a specific facility or activity is mainly based on experience and judgment of DSA staff, and the available resources. For some areas, a planned frequency for inspections necessary to secure safety has been determined. Nevertheless, DSA could improve its inspection planning by developing a written procedure that specifies criteria for selecting of inspection objects and the frequency of inspections, based on a more systematic application of the graded approach.

There are general plans for identifying long-term focus and goals. For example, in the hospital sector, PET production facilities will be the focus of more inspections in the coming years, based on an evaluation of risk within the hospital sector concerning radioactive discharge and waste. Long-term plans for inspections of offshore installations have also been developed, where the biggest contributors to radioactive discharges were selected, based on risk and graded approach. The long-term plan has also meant that all waste recipients on land have been inspected and the repository for NORM waste (Wergeland-Halsvik) has been inspected several times.

7.1.8 Planned improvements

- → DSA should further develop its programme of inspections to include more systematic planning of inspections. This should include:
  - Stipulation of the frequency of inspections and the areas and programmes to be inspected and criteria for determining which type of inspection is appropriate and detailed processes for planning and undertaking each type.
  - Processes to ensure that inspections of facilities and activities are commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.
- → DSA should strengthen the work of its Inspection Group by developing an integrated systematic process for performing inspections and providing feedback that covers all DSA inspections. The process should include a description of appropriate actions to undertake in the event of contraventions to regulatory requirements, and references to the relevant enforcement processes.
- → DSA should work to resolve the legislative challenges associated with inspections. For instance, the legislation for Health Safety Environment and Quality (HSEQ) in offshore oil and gas industry is not based on the Radiation Protection Act, as it is for Pollution Control Act. It should be evaluated whether the HSEQ legislation should also be based on Radiation Protection Act.

→ The Internal Control Regulation is not based on Nuclear Energy Activities Act. Similar conditions have been implemented in the General Licence Conditions. However, there would be value in evaluating whether the Internal Control Regulations also should be modified to make reference to the Nuclear Energy Activities Act.
→ DSA requires further competence in certain areas and further resources to perform justifiable and sufficiently frequent inspections, according to an established inspection programme.

7.2 INSPECTION OF NUCLEAR INSTALLATIONS

Related to SSR-3 paragraphs 3.13 – 3.16, NS-R-5, paragraphs 3.11 – 3.12

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

7.2.1 Specificities of inspections of nuclear installations

DSA has the authority to perform inspections of nuclear installations according to the NE Act, sections 13, 14 and 51. According to section 13, nuclear installations shall be subject to continuous supervision by DSA and section 14 states that DSA may at any time demand access to a nuclear installation and the surrounding area. Safeguards inspections are covered in section 51 of the Nuclear Energy Act.

DSA charges a fee for licence applications and inspections (NE Act section 57).

7.2.2 DSA inspections under the Nuclear Energy Activities Act

Normally DSA perform 15-20 inspections per year under the NE Act. In 2018, DSA performed 14 inspections at IFE's nuclear installations under this Act. Two of the inspections were of the research reactors, and one was at a fuel cycle facility. Eight inspections were safeguards inspections. In 2018, there was one inspection to observe the functioning of IFE's Safety Committee, which involved 10 individual visits.

Nuclear installations are currently under a period of intensified inspections due to several breaches in safety. Inspections are being performed in order to assess whether the operator has performed the necessary steps to improve safety at the facilities.

7.2.3 Inspection Plan for nuclear installations

DSA normally develops an annual inspection plan at the beginning of each year for objects regulated under the NE Act. The inspection plan and the frequency of inspections are based on experience, and the authority's organization and resources. The plan is often shared with the operating organization. The inspection plan is adjusted during the year, as needed. DSA has not yet established a systematic inspection programme stretching beyond the annual planning.

7.2.4 Scope of inspections

Under the NE Act, there are inspections in the areas of nuclear safety, nuclear security, safeguards, waste, and emergency preparedness. The areas of inspection to be included in the inspection plan are selected based on the experience and judgment of DSA staff. When the inspection plan is developed, the areas of inspection are general, covering a specific facility or activity. The details for each inspection are developed in the period before the inspection. The facilities associated with the highest risks are prioritized, and that might relate to age or the status of the facility, incidents at the facility or the planning of special operations or changes. Focus of inspections the recent years has, however, also focused on the management system, the internal control and the safety and security culture of the operator, including the work of its safety committee, as part of the intensified inspection regime, which was initiated in 2014. Several inspections have also been performed in relation to the licensing process.

7.2.5 Inspection reports and follow-up

Based on inspection findings, if there is evidence of a reduced level of safety or, in the event of serious violations, DSA could use enforcement measures to require the operating organization to stop its activities and to take any further actions necessary to restore an adequate level of safety (NE Act, section 13.2).

7.2.6 Planned improvements

- → DSA should further elaborate the inspection process specific to nuclear installations within the framework of the DSA management system.
- → DSA should improve formalization and application of the graded approach to the inspection process for nuclear installations.

7.3 INSPECTION OF WASTE MANAGEMENT FACILITIES

Related to GSR Part 5: paragraphs 4.22, 5.14, 5.15, 5.20
SSR-5: paragraphs 3.15, 3.48, 5.19

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

7.3.1 Specificities of inspections of waste management facilities

Inspections of waste management facilities include both announced and unannounced inspections, which are performed according to the PC Act and, for nuclear waste, according to the NE Act in addition.

7.3.2 Strategy, planning and graded approach

Long-term plans have been developed for inspections of waste management facilities, to facilitate a long-term focus within selected areas. Decisions on which facilities to inspect are made based on an assessment of potential risks and on expert judgment according to graded approach. The activities are chosen on the basis of an evaluation of associated risks, with higher risks being given highest priority.

For example, in the hospital sector, PET production facilities will undergo more inspections in the coming years, based on an evaluation of risk within the hospital sector concerning radioactive discharge and

waste. Long-term plans for inspections offshore have also been developed. As part of the long-term plan, all waste recipients on land have been inspected, and the repository for NORM waste (Wergeland-Halsvik) has been inspected several times.

Inspections of the repositories and waste management facilities for radioactive waste are given a high priority. However, due to shortage of resources, inspections are not performed as often as intended. Inspection of waste management facilities will become even more important with the approaching decommissioning of research reactors and further competence in this area will be necessary.

7.3.3 Results of inspections and their use for further development of regulatory processes

Results from inspections may, if deemed relevant, be used as an input to DSA's further regulatory activities for a given site and as a basis for advising the Ministries. Results may also lead to changes in regulation of specific industries or types of facilities and corresponding changes in authorizations, if necessary.

Inspections of waste management facilities have led to the discovery of non-compliances at such facilities but DSA has identified that, for NORM facilities, compliance has generally improved in subsequent inspections, through the inspection process and associated follow-up measures. The value of the inspection process has also been demonstrated by the fact that a severe non-compliance at KLDRA, Himdalen was identified during an inspection and has resulted in intensified inspections and follow-up including enforcement activities, according to the processes described in Module 8.

7.3.4 Implementation of inspection process for waste management facilities

Inspections of waste management facilities follow the general structure and procedures for DSA's inspections. There are specialized checklists and a list of standard questions for inspections for most waste management facilities. It is not compulsory to use these but they are an aid to the inspection team.

Most inspections of waste management facilities are planned and announced inspections, but planned unannounced inspections and reactive inspections are also performed.

Inspections of waste management facilities usually inspect areas such as waste acceptance, management and storage, records of stored and managed waste, potential for exposure of personnel or the public and environment, control and management systems, including procedures and training of personnel.

7.3.5 Enforcement actions

Non-compliances found during an inspection may lead to application of the DSA enforcement process. According to the PC Act, DSA may revoke a licence or permit, impose coercive fines and may arrange for immediate implementation of measures and claim reimbursement from polluter. The NE Act states that DSA may revoke a licence and may, if deemed necessary, enforce any safety measures to ensure that the operation of the facility is safe, stop operation of the facility, for a shorter or longer periods, and impose both violation and coercive fines. According to all the Acts under which it regulates, DSA may also notify the police for further actions, and if relevant, prosecution. Further details are given in Module 8.

7.3.6 Inspectors for waste management facilities

There are just over 10 inspectors performing inspections of waste management facilities. As indicated above, the inspectors are case handlers who also performs inspections as part of their work. The inspectors all have relevant masters or PhD degrees in natural sciences or law in addition to HES-training and in-house training.

7.4 INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Related to GSR Part 1 (Rev. 1): Requirements 27 – 29 and GSR Part 3: Requirement 3

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

7.4.1 Inspection of facilities and activities - strategy and planning

Inspections of radiation sources, facilities and activities cover both medical and non-medical applications, and are conducted primarily under the terms of the RP Act, the RP Regulations and the IC Regulations.

DSA carried out 303 on-site inspections in the years 2012-2016, of which 60% were in the areas “Industrial and research applications” and “Medical applications” (StrålevernRapport 2018:8). By comparison, there are about 250 licensees for industrial or research applications of ionizing radiation sources, and about 200 licensees for medical applications (hospitals and X-ray institutes). In addition, 418 web-based inspections were carried out by DSA in the same period. About 30 on-site inspections related to radiation sources facilities and activities were conducted in 2017 and 2018.

There are two sections at DSA that are responsible for supervision of radiation sources, facilities and activities, viz. Section for Source Security, Radiation Applications and UV (i.e., industrial and research applications) and Section for Medical Applications. Combined, the two sections have about 20 employees (case handlers), with 10-12 of these employees participating in inspections of radiation sources, facilities and activities on a regular basis. In each of the sections, a plan for inspections throughout the year is suggested by the case handlers, and approved in dialogue with the Head of Section. Occasionally, the two sections conduct joint inspections (e.g., inspections of isotope laboratories at medical facilities).

7.4.2 Graded approach to inspections of facilities and activities

DSA has established target frequencies of on-site inspections for various radiation sources, facilities and activities according to the principle of a graded approach and in agreement with DSA’s Inspection Strategy. The activities that are given highest priority, based on an evaluation of associated risks, include: industrial radiography, irradiation facilities, well-logging companies, type A isotope laboratories, treatment centres and production facilities for radiopharmaceuticals, radiotherapy and brachytherapy facilities, and interventional radiology facilities. Ideally, these activities/facilities should be inspected every 1-3 years but, in practice, the frequency is about once in every 3-5 years for most of these activities, with even lower frequencies in some cases. The discrepancy between target frequencies and actual frequencies is mainly due to a lack of resources.

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

7.4.3 Types of inspection of facilities and activities

DSA has internal procedures for preparing, conducting and reporting for inspections of radiation sources, facilities and activities. Checklists have been developed for inspections within selected areas, e.g. industrial radiography, isotope laboratories and industrial nuclear gauges.

The inspections follow the general format for DSA's inspection processes described in section 7.1. The most common on-site inspections related to radiation sources, facilities and activities are 1-day inspections lasting for 3-6 hours. However, for larger facilities, e.g. major hospitals, DSA in some cases performs audits. Such audits include a systematic review of the facility's management system. Audits may last for several days and involve a thorough review of relevant documentation, several interviews and additional verification activities.

Typical topics investigated during an inspection are: management system and internal control, radiation protection organization, education and training of staff, technical solutions, maintenance routines, safety culture, results of dose monitoring, emergency preparedness and accident handling. If relevant, the application of special precautions and dose limits related to pregnant and breastfeeding women are inspected, cf. RP Regulations, sections 32 and 46. For inspections of facilities involving the use of high-activity radioactive sources, there has been an increasing focus on security in recent years, implying that routines for physical verification of source inventory, access control, detection and alarm systems, structural barriers, and response capabilities are typically inspected.

As outlined in section 7.1, non-compliances are presented in a closing meeting, where the authorized party is given the opportunity to comment on the findings and address potential disagreements. In accordance with section 60 of the RP Regulations, a written inspection report comprising general impressions and findings is sent to the authorized party as soon as possible after the inspection, and deadlines to correct non-compliances are set. The authorized party is also given the opportunity to comment on the report within a given deadline. When finalized, the inspection report is published on DSA's web site.

7.4.4 Enforcement actions

In the event that an authorized party ignores a deadline for complying with an order of rectification, DSA may apply a coercive fine, in accordance with the RP Act, section 21. Stronger enforcement actions are also available. If necessary, DSA may revoke the licence, confiscate substances or equipment, prohibit import or sale, or close the facility. In case of serious non-compliances, implying a material risk to health, the practice may be closed on-site at the inspection, cf. the RP Act, section 19. Further details are given in Module 8.

7.4.5 Web-based inspections

Web-based inspections are a new type of inspection, which employs mandatory questionnaires. Such inspections can cover a large number of companies and are useful for keeping an overview of low-risk undertakings, or as a supplement to on-site inspections to obtain increased overview of medium- or high-risk activities with many licensees. A web-based inspection of more than 180 companies registered as users of industrial gauges and other types of medium activity sealed sources was carried out in 2016. A number of non-compliances were uncovered and subsequently corrected by the companies. For instance, 52 undertakings were found to not comply with the requirement of keeping a written inventory of their radioactive sources. A web-based inspection of all 70 undertakings with licences for industrial radiography was conducted in 2015, identifying 22 non-compliances from 17 undertakings.

7.4.6 Use of inspection results for development of regulatory processes

Results from inspections may, if deemed relevant, be used as input to recommended revisions of the RP Regulations or as a basis for advising the Ministries. As discussed also in Module 5, all 13 Norwegian facilities involving blood irradiators using radioactive caesium chloride were substituted with X-ray irradiators in the period 2013-2015. The phase-out process was initiated by DSA and supported and further enhanced by the Ministry of Health and Care Services, which is the owner of the hospitals and blood banks. DSA's recommendations to the Ministry were partly based on joint inspections of blood irradiator facilities with The Norwegian National Security Authority (NSM), which revealed insufficient security measures at major hospitals.

7.5 INSPECTION OF DECOMMISSIONING ACTIVITIES

Related to GSR Part 6: paragraph 8.5

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

7.5.1 General basis for inspection of decommissioning

Inspections of decommissioning activities have so far been limited to inspections of the decommissioning plans and compliance with these plans, since no nuclear decommissioning activities are currently being performed. However, inspections have been undertaken of facilities decommissioning oil and gas installations.

Decommissioning is regarded as any planned activity, which may cause radioactive discharges and will produce radioactive waste. Inspections of decommissioning actions will therefore follow the procedures established for other inspections under the NE Act, the PC Act, the Waste regulations or the IC Regulations.

The decommissioning plans for facilities at the IFE site at Kjeller were inspected as a part of the licencing process in 2017. The documents were evaluated for compliance with Norwegian legislation and compliance to GSR part 6 and WS-G-2.1. In 2018, an inspection of the preparations for entering the transition phase of decommissioning was performed with special emphasis on knowledge management. DSA plans to undertake an inspection of compliance with the decommissioning plans at IFE Halden in 2019.

7.5.2 Routines for performing inspections on decommissioning activities

Inspections on decommissioning follow the same procedure as any other inspection under the PC Act, the NE Act and the IC Act and is described in detail in sections 7.1 – 7.3.

Inspection results are presented to the operator as described in 7.1

The inspections and deviations are reported to the ministries as mentioned in 7.1. If an operator does not demonstrate a sufficient degree of safety and security, DSA uses inspections and instructions to make the operator work to increase their safety and security.

7.5.3 DSA's authority and ability to perform inspections on decommissioning activities

For decommissioning projects, any inspector with experience in inspections under the PC Act, The NE Act or the Waste Regulation may attend inspections. At present, there are 10 DSA employees working in this area, but in practice, 4 – 5 employees have so far been involved in inspections related to decommissioning. All inspectors are required to attend courses developed for the HES authorities, as described in 7.1. The training of the inspectors also includes on-the-job training, for example by attending inspections led by other team leaders on other topical areas, either as observers, secretaries or as team members.

Enforcement is performed through legally binding documents such as the inspection reports, or instructions if appropriate, as described in Module 8.

7.6 INSPECTION OF TRANSPORT ACTIVITIES

Related to SSR-6: paragraphs 302, 306, 503,582, 801

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

7.6.1 Specificities of inspections on transport of radioactive material

DSA has established an inspection process to verify that holders of a permit or licence, issued under the NE Act are in compliance with the DSA requirements and with the conditions specified in the authorization. In accordance with inspection process requirements, an annual plan for inspections of facilities and activities is developed in respect of a graded approach. Inspection areas cover the transportation of nuclear substances. More information about inspections of nuclear installations is provided in section 7.2.

DSA performs inspections of licensees that are handling, using, shipping or receiving radioactive sources, such as industrial radiography and well logging companies, vendors/suppliers and users of nuclear gauges and these inspections cover transport activities. The inspections, and the follow-up of non-compliances detected during inspections, are performed according to DSA's established procedures for inspections.

If high-activity sealed radioactive sources are to be imported or exported, the consignor or consignee must apply to DSA for a licence for import/export. The licence requirement allows DSA to assess the plans for transportation, depending on the risk associated with the shipment.

7.6.2 Planned improvements

→ Further developing a program for inspections to assess whether transportation of radioactive materials is performed according to the requirements in legislation and licenses or permissions.

7.7 INSPECTION OF OCCUPATIONAL EXPOSURE

Related to GSR Part 3: Requirements 19-24, 27, 28 and 52

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

7.7.1 Inspection of occupational exposure

The RP Act and Regulations include provisions on occupational exposure. In addition, there are provisions in Regulations concerning the Performance of Work, section 15-4, regarding medical examination of employees who may be exposed to ionizing radiation. The Norwegian Labour Inspection Authority is the regulatory authority for Regulations concerning the Performance of Work.

Occupational exposure is normally included as part of the inspections DSA performs, following the inspection processes described in section 7.1. See also sections 7.2 -7.7 for more information about DSA's inspection activities within the different areas.

During inspections, the DSA inspectors may review, verify or control the following:

- → The undertaking's review and classification of workers in category A and B;
- → Procedures and routines regarding use of personal dosimeters or other dosimeters, and if the employees can easily check their own dose readings;
- → Controlled and supervised areas;
- → Routines and procedures for the use of shielding equipment;
- → Arrangements for proper use, calibration, testing and maintenance;
- → Equipment for measuring radiation;
- → Competence and training programs;
- → Dose readings/reports and compliance with dose limits; and
- → Routines for dealing with pregnant workers and under-age persons.

7.7.2 Existing exposure situations

The requirements regarding occupational exposure in the RP Regulations apply to aircrew. However, DSA does not actively control the protection of aircrew. It is the responsibility of the Norwegian Labour Inspection Authority, to undertake inspections regarding radon in workplaces.

7.7.3 Offering of benefits as substitutes for safety measures

DSA employees have not been offered benefits as substitutes for safety measures.

7.8 INSPECTION OF MEDICAL EXPOSURE

Related to GSR Part 3: Requirements 34-40

Related to GSR Part 1 (Rev. 1): Requirement 29, paragraphs 4.51 and 4.52

7.8.1 Inspection of facilities and activities associated with medical exposures

The planning of inspection is part of a yearly scheduled activity planning for the upcoming year. Hospitals with high-risk facilities, facilities where DSA suspects non-compliance, and facilities where the last inspection was a long time ago, are prioritized. The number of inspections are planned according to available resources, and may be revised according to changes in budgets and personnel status. While the IAEA recommends an inspection frequency of every year, DSA has established an ideal frequency of every third year based on the available resources. The actual frequency of inspection is lower for some medical

facilities, due to lack of personnel and financial resources. Inspections with a full systematic audit of large hospitals, serving many patients, are prioritized over smaller facilities. Sometimes DSA performs a series of inspections with a smaller, common agenda. This approach enables the inspection team to cover more facilities in a shorter period of time.

The results of inspections may highlight areas for improvement in both the RP Regulations and their accompanying guidelines, or the need for guidelines in new areas of medical exposure. For example, if some of the articles in the regulations or wording in the guidelines are difficult to understand, or can be misinterpreted, this can be demonstrated during inspections. Results may also affect DSA's considerations on risk areas and the facilities that should be prioritized in the future.

In the medical field, there are seven inspectors divided in groups of two or three that cover respectively nuclear medicine-, radiotherapy- and radiological facilities (including dental and chiropractic facilities). Inspections are always performed by two inspectors, where one is appointed leader of the inspection. The inspectors have competence in radiation protection from relevant education as a physicist or radiographer, previous clinical experience, national and international meetings and courses within their respective fields

7.9 CONCLUSIONS AND ACTIONS

DSA routinely carries out both announced and unannounced inspections in order to verify that authorized parties are in compliance with regulatory requirements and the conditions specified in their authorizations. Inspections are conducted under the terms of the three Acts and associated regulations under which DSA regulates. Annual Letters of Commitment from the Ministries frequently request DSA to perform more inspections to verify compliance with regulatory requirements. The number of inspections is used as an indicator of performance and the outcome of the inspections is reported to the Ministries on an annual basis.

DSA has established an Inspection Group, which coordinates DSA inspection work and has, among other things, developed an Inspection Strategy for the period 2016-2020. This strategy specifies that inspections should be risk-based and adapted to the level of risk and complexity associated with the authorized facilities or activities. DSA inspections are based on common guidelines from the group of Norwegian HES -authorities, and all inspectors have training based on these guidelines.

Annual inspection planning processes are rarely integrated; inspections for different types of source or activity prepare annual inspection programmes within a given sector. These decisions are risk-based.

DSA performs inspections according to established processes, broadly related to each of the relevant Acts. However, there is ongoing work to develop common processes that will cover all types of DSA's inspections.

DSA has generally developed annual plans for inspections, although plans for longer periods have been developed for some areas. While the inspection strategy includes a commitment to prepare longer-term inspection programmes, this has not yet been implemented for all areas.

There may be benefit in further developing the DSA programme of inspections to ensure long-term planning, stipulating the frequency of inspections, in accordance with a graded approach, and to include criteria for determining which type of inspection is appropriate, in order to further ensure that inspections are commensurate with the risks associated with the facilities or activities involved.

7.9.1 Actions

- → DSA should further develop its programme of inspections to include more long-term systematic planning of inspections.
- → DSA should strengthen the work of the Inspection Group by developing an integrated systematic process for performing inspections and providing feedback that covers all DSA inspections.
- → DSA should evaluate whether further legal developments are necessary and, if necessary, determine how to manage legislative challenges for DSA inspections.
- → DSA requires further competence in certain areas and further resources to perform justifiable and sufficiently frequent inspections, according to an established inspection programme.

8 ENFORCEMENT

8.1 ENFORCEMENT POLICY AND PROCESSES

Related to GSR Part 1 (Rev. 1): Requirements 30 and 31, paragraphs 4.54, 4.57 – 4.60

8.1.1 Legal basis for DSA's enforcement

The Public Administration Act (PA Act) regulates how administrative agencies, including DSA, may secure compliance through enforcement. The Act specifies the requirements for how government and municipal administrative bodies must prepare and handle cases connected to individuals or groups, in the form of individual decisions, regulations and other forms of administration. Enforcement provisions follow the same requirements as for other individual decisions, which includes pre-notification and the possibility for appeal. Appeals are sent to DSA for assessment and then forwarded to the Ministry of Health (HOD), or the Ministry of Climate and Environment (KLD), for final decision. If there is an urgent risk to health or the environment, stronger and more immediate enforcement actions can be taken.

According to the PA Act, an administrative sanction is a negative reaction that may be applied by an administrative agency in response to an actual breach of an act, regulation or individual decision including a licence. In addition, coercive fines may be imposed, to ensure compliance with obligations pursuant to an act, regulation or individual decision, such as a licence.

The responsible party may be a person or company who has breached an act, regulation or a licence. The responsible party may or may not have a licence.

The Act on Radiation Protection and Use of Radiation (RP Act), the Act on Pollution Control (PC Act) and the Act on Nuclear Energy Activities (NE Act), with their associated regulations, specify the enforcement provisions are available to DSA in the event of non-compliance with requirements given in that legislation or decisions made thereto.

The RP Act states that DSA may impose a coercive fine in the form of a one-time fine or cumulative daily fine, revoke a licence, or prohibit the import or sale of any product, substance or item that may involve a risk to health or the environment due to radiation. If a material risk to health exists, DSA may halt the activity in question, confiscate substances or equipment in whole or in part, or by other means, ensure discontinuation of further use.

The PC Act states that DSA may revoke a licence, impose coercive fines and may arrange for immediate implementation of measures and claim reimbursement from polluter.

The NE Act states that DSA may revoke a licence and may, if deemed necessary, enforce any safety measures to ensure that the operation of the facility is safe, stop operation of the facility for a shorter or longer timespan and impose both violation and coercive fines.

For all Acts DSA may also notify the police for further action in serious cases, and if relevant, prosecution.

The PA Act has recently introduced regulations on the use of administrative fines in the public sector, and HOD has started working on a more detailed regulation according to the NE Act on the use of administrative fines.

8.1.2 DSA's enforcement process

Non-compliance may be identified through inspections, review of annual reports, information from the public or in dialogue with the responsible party.

There are internal enforcement processes, which govern how DSA imposes enforcement provisions. As part of developing the DSA integrated management system, there is also ongoing work to develop a harmonized enforcement process that covers all DSA's work. The existing processes ensure that DSA's enforcement is in line with legal requirements, IAEA guidelines and that the severity of the enforcement provisions are commensurate with the severity of the non-compliance, according to a graded approach.

There are processes that govern how DSA in general regulates compliance with requirements in the licences and legislation. These processes govern the dialogue between DSA and licensees, as well as the guidance given to licensees. During ordinary regulatory dialogue, potential non-compliance or non-compliance may be detected or the licensee may ask whether an activity is in compliance or not. If the non-compliance is identified as not being severe or easily rectified, recorded verbal or written guidance and assistance is given to help the licensee rectify the non-compliance.

These cases are performed by the case handlers/inspectors in dialogue with the Section Head and Department Head. Guidance and regulatory dialogue may be verbal, but details are nevertheless recorded in the DSA archives. Communications regarding non-compliance are, however, normally in written form. All such communications are also archived.

If the non-compliance is deemed to be more severe, DSA will follow the process for enforcement. The process constitutes four main steps, according to the legal basis established in the PA Act. Each of the steps has an identified responsible person associated with it: for example the inspector/case handler, Section Head, Department Head and DSA lawyer. The process includes templates for written correspondence between DSA and the responsible party. In general, the responsible party is made aware of the non-compliance and given a deadline to rectify the non-compliance. The process includes guidance on ensuring that the enforcement provisions are commensurate with the severity of non-compliance, according to graded approach. If the non-compliance entails material risk to health or the environment, stricter and more immediate enforcement actions may be taken.

The processes for enforcement comprises four main steps:

1. DSA may order a responsible party to supply information.

   DSA has both a right and a duty to gather all necessary information prior to making an administrative decision. All three acts state that DSA shall be given free access to perform supervision, and shall be provided with all information necessary to perform its functions. According to the PA Act, DSA has a duty to collect all necessary information, under the requirement that administrative agencies shall ensure that a case is clarified as thoroughly as possible before any administrative decision is made.

   In accordance with the PA Act, the responsible party shall be informed of its right of appeal in connection with an order to supply information. The appeal must normally be lodged within 3 days. The requested information shall be supplied within a stipulated time limit, which DSA may set based on its evaluation of the urgency of the matter and/or the complexity of retrieving the requested information.

   Alternatively, DSA conducts an inspection or visit to confirm a suspected non-compliance, or a non-compliance that has been identified as part of a programmed inspection (as described in

Module 7). The subsequent steps and enforcement actions are normally the same regardless of how the non-compliance was identified (unless there is material risk to health or the environment, which warrants stronger and more immediate enforcement actions to be taken).
This step is performed by the inspector/case handler, DSA lawyer and Section Head. There are templates for communication with the responsible party

2. Advanced notification of an administrative decision of order for rectification

When a non-compliance has been identified, DSA issues an advance notification to the responsible party with information on enforcement of the non-compliance, in accordance with the PA Act. The notification shall explain the nature of the case, and contain such information as considered necessary to enable the responsible party to protect its interests in a proper manner. The advance notification shall give the responsible party an opportunity to express its opinion within a stipulated time limit. DSA sets the deadline. The advance notification usually specifies relevant the enforcement provisions.

This step is performed by inspector/case handler in dialogue with DSA lawyer and the written order is signed by Section Head and Department Head. There are templates for communication with the responsible party.

In practice, the responsible parties often correct non-compliances, and document this to DSA within the time limit given in the advance notice. DSA therefore often does not need to make a decision to issue an order of rectification or other enforcement actions.

3. Administration decision of order for rectification

The order for rectification is a legally binding administration decision/individual decision. DSA may demand rectification of any activity that conflicts with provisions laid down in the RP Act, NE Act and PC Act with associated regulations, or with any individual decision or condition set by DSA.

The order of rectification shall contain reference to the particular legal provision or individual decision that has been violated. The order shall describe as precisely as possible what needs to be rectified such that the relevant legal provision can be considered to be fulfilled. The order for rectification specifies a deadline for rectification. The order shall also specify the enforcement provision if compliance is not demonstrated.

This step is performed by inspector/case handler in dialogue with DSA lawyer and the written order is signed by Section Head and Department Head. There are templates for communication with the responsible party.

4. Enforcement provisions

There are several enforcement provisions available, both administrative sanctions and coercive fines. The specific provisions available are given in each of the acts, i.e. the RP Act, the NE Act and the PC Act. The provisions may be imposed for non-compliances to that act, regulations to that act and decisions made thereto. The choice of enforcement provisions shall be commensurate with the severity of non-compliance with regard to safety, according to graded approach.

a. Administrative sanctions

A violation fine may be imposed as an administrative sanction. The PA Act states that, for assessment of violation fines, consideration should be given to the extent and effect of the breach, the advantages that have or could have been gained by the breach, as well as the offender's fault and financial means. Pre-notification may be omitted when the fine is imposed, for example during an inspection.

DSA may arrange for immediate implementation of orders pursuant to non-compliance to the duty to avoid pollution or to orders to clear up waste. The cost of these measures may then be claimed from the responsible party.

DSA may revoke a licence if conditions set, or orders are materially or repeatedly ignored. This may include cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of a non-compliance.

DSA may refuse the import or sale of any product or substance and any item that may involve a risk to health or the environment due to radiation, provided that this is not in conflict with international agreements to which Norway has acceded.

If non-compliance is deemed to be severe, DSA may halt an activity or demand closure of a facility. DSA may also confiscate substances, equipment or nuclear material.

DSA may also request public prosecution. Each of the acts specifies what types of penalties non-compliance may entail, normally fines or imprisonment.

b. Coercive fines

A coercive fine may be imposed as an incentive for the responsible party to rectify a non-compliance. The fine may be given in the form of a one-time fine or a cumulative daily fine until compliance is demonstrated. The coercive fine shall be fixed either at the time the order is made or when a new deadline is set for compliance.

8.2 ENFORCEMENT IMPLEMENTATIONS

Related to GSR Part 1 (Rev. 1): Requirement 31, paragraphs 4.55 – 4.56

8.2.1 Decision-making process

As described in Module 7, DSA's case handlers also act as inspectors, and will often be responsible for both identifying and following up non-compliances. There are internal procedures for how and when to issue orders to supply information, issue advance notifications and orders of rectification, and for imposing a coercive fine. In addition, there are internal procedures for how to follow up inspections. Whenever an enforcement action is taken, the order is signed by both the Head of Section and the Director of the Department. The case handlers normally consult DSA's lawyers concerning appropriate enforcement actions to take.

8.2.2 Confirmation process

Any non-compliance identified through DSA's review and assessment activities is followed up through written correspondence with the authorized party. Each non-compliance is identified along with its legal

basis, and a time limit for rectification is stipulated in the written communication. Each non-compliance is closed (i.e., no longer subject to follow-up from DSA) only when the authorized party has transmitted documentation to DSA that the non-compliance has been corrected. The correspondence is saved in DSA's archive along with all information supplied by the authorized party.

8.2.3 Appeal

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

8.2.4 Training

Inspectors/case handlers have in-house training in working according to DSA's management system with processes including enforcement, regulation and inspections, also described in Module 4. In addition, inspectors have training in the general inspection guidelines from the Norwegian HES-authorities, as described in more detail in Module 7. The enforcement process states that inspectors/case handlers shall consult DSA lawyers when ensuring enforcement.

8.3 CONCLUSIONS AND ACTIONS

There are enforcement provisions available for DSA under each of the three Acts (the RP Act, the PC Act and NE Act). There are some differences in the enforcement mechanisms available.

In 2018, a process was performed to harmonize the different enforcement mechanisms in the legal system. This includes changes to the PA Act, which are relevant for the whole public sector. However, a uniform enforcement policy covering all the three Acts has not yet been implemented. A harmonized practice according to the PC Act has, however, been developed taking account of the Norwegian Environment Protection Agency's strategy for sanctions.

In general, DSA complies with IAEA requirements but some areas for improvement have been identified.

The integrated management and QA-system, which is currently under development (see Module 4 for more information), will be a useful tool for updating existing and building a new enforcement policy and processes.

8.3.1 Actions

- → DSA should create a unified, more consistent and harmonized enforcement policy, covering all the three Acts. This should include the development and establishment of criteria for corrective actions to ensure that enforcement and corrective actions are commensurate with the significance for safety of the non-compliance, in accordance with a graded approach.
- → DSA should develop integrated processes for enforcement and corrective actions for all of DSA's areas of responsibility in the internal DSA management and QA-system, which is currently under development.

9 REGULATIONS AND GUIDES

9.1 GENERIC ISSUES

Related to *GSR Part 1 (Rev. 1): Requirements 32 – 34, paragraphs 4.61 – 4.62*
GSR Part 3: Requirement 3

9.1.1 Development and review of regulations and guides

The Ministries have responsibility for developing regulations related to the acts for which they are responsible, the Act on Radiation Protection and Use of Radiation (RP Act), the Act on Nuclear Energy Activities (NE Act) and the Act on Pollution Control (PC Act). DSA provides input to the Ministries regarding the need for and content of relevant regulations. Regulations are published on DSA's webpage and the official webpage for Norwegian legislation (www.lovdata.no).

DSA has responsibility for developing and publishing any supporting guidance. Guidance documents are published on DSA's webpage.

Regulations and guides exist under each of the relevant Acts listed above. These regulations are different in structure and content. They are reviewed and revised, as appropriate.

The Public Administration Act (PA Act) regulates how regulations shall be developed and published. There is a general requirement to provide guidance, a right to call on assistance or advocate, obligations to clarify the case before issuing a regulation, and requirements to notify interested parties in advance and to seek their opinion. In addition, there are requirements on the form and publication of regulations.

9.1.2 Promotion of regulations and guides

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 (www.lovdata.no).

The Ministries are responsible for the promotion of regulations. In developing regulations, opinions are sought from interested parties through hearing processes and meetings with relevant parties, including industry organizations, non-governmental organizations (NGOs) and other regulatory bodies. Information on regulations is also given to other interested parties, including the public.

DSA is responsible for the promotion of guides. When developing guides, drafts are normally made available to interested parties through a hearing process. In addition, guides are generally sent in a draft form to the interested parties for whom the guides are particularly relevant. For example, the review of Guide for Management of Radioactive Waste and Discharges was sent to all operators in the Norwegian oil and gas industry and the associated industry organization. Once a guide is approved, information is also sent to relevant parties.

Both regulation 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.

9.1.3 Graded approach in development and revision of regulations and guides

The graded approach is included in DSA regulation through the requirements in the regulation. Regulations and guides are developed to serve as a framework for regulatory requirements and conditions and prioritization of the development of further guidance is determined by, among other things, the risk associated with topic area and the potential of guidance to reduce those risks. For example, at present, guidance is under development to elaborate the General Site Licence Conditions for nuclear installations and to clarify the regulatory expectations for decommissioning.

9.1.4 Description of regulations and guides

There are several regulations associated with the relevant Acts (the RP Act, the NE Act and the PC Act).

Regulations based on the NE Act are:

- → Regulations on the Physical Protection of Nuclear Material and Nuclear Facilities, no. 1809, 2 November 1984; and
- → Regulations on the Possession, Sale and Transport of Nuclear Material and Multipurpose Goods, No 433 12 May 2000.

Regulations based on the PC Act relevant to the regulation of radioactive waste and discharges are:

- → Regulations on the Application of the Pollution Control Act to Radioactive Pollution and Radioactive Waste (PC Regulations) No. 1394, 1. November 2010;
- → Regulations Relating to the Recycling of Waste (Waste Regulations) No. 930 1 June 2004; and
- → Pollution Regulation No. 931 1 June 2004.

The regulations based on RP Act are:

- → Regulations on Radiation Protection and Use of Radiation (RP Regulations) No. 1659 16 December 2016.

The Internal Control Regulations (IC Regulations) under the umbrella of the Health, Environmental, and Safety (HES) legislation, is also a key part in the safety regulation. The regulations are based on several acts in the area of health, environment and safety, including the PC Act and RP Act. The IC Regulations require the person responsible for an enterprise to ensure that requirements set out in the Acts on which it is based are complied with in a systematic manner. Similarly, there are a set of HES-regulations for the oil and gas industry specifying relevant HES-requirements for the offshore oil and gas industry and some onshore facilities.

DSA has published thirteen guides that further specify the requirements in the legislation. These are described under each of the topic areas below. In addition, there are four published 'Guidelines for application' for:

- → Annual reports to be submitted by authorized parties with a permit for radioactive waste management and discharges;
- → Reporting discharges from the oil and gas industry;
- → Application for permit for radioactive waste management and discharges; and
- → Use of ionizing radiation in medical and biomedical research.

In addition, general guidance and information to licensees and the public is published on the DSA webpage, and associated webpages for specific areas such as www.environment.no/www.miljøstatus.no, where the Government and authorities presents relevant information on environmental status.

9.2 REGULATIONS AND GUIDES RELATED TO NUCLEAR INSTALLATIONS

Related to SSR-3: paragraphs 3.1 to 3.4 and NS-R-5

9.2.1 Regulations and guides related to the regulatory supervision nuclear installations

The NE Act provides the framework for the regulatory requirements and conditions incorporated into individual authorizations or applications for authorization.

There are two regulations based in the NE Act, as indicated above:

- → Regulations on the Physical Protection of Nuclear Material and Nuclear Facilities, no. 1809, 2 November 1984; and

- → Regulations on the Possession, Sale and Transport of Nuclear Material and Multipurpose Goods, No 433 12 May 2000.

The Institute of Energy Technology (IFE) is currently the only licensee under the NE Act, such that additional guidance on the application of the Act are generally included in organization, site or facility-specific communications. Most recently, the licence for the IFE Kjeller site, and the Fuel Instrumentation Workshop in Halden, was renewed in December 2018, with a number of general and specific licence conditions. IFE also holds a licence for other facilities at the Halden site for the period 2015-2020, which also contains a number of specific licence conditions.

General Licence Conditions for nuclear installations ("Generelle vilkår for vurdering av søknader om konsesjon etter atomenergiloven") were developed during 2018 and were published in December 2018. This document specifies the conditions on licence applications under the NE Act. The General Licence Conditions were developed on the basis of relevant international safety standards, technical standards and relevant experience. An initial version of this document was provided to IFE in the early stages of the review and assessment process of its most recent application for a licence. The final version of the conditions was also included as part of the licence issued in December 2018.

DSA is currently developing guidance on these conditions in the form of 'General Guidance to the General Licence Conditions' and the 'Specific Guidance to the General Licence Conditions'. The guidance will specify the principles, requirements and associated criteria for safety upon which DSA's regulatory judgements, decisions and actions are based. The Specific Guidance will further strengthen the framework for the regulatory requirements, by providing additional guidance for particular types of facility that are, or could be, licensed under the NE Act (e.g. research reactors and radioactive waste management facilities). These guidance documents are currently available in draft form.

The above-mentioned regulations and guides cover all regulatory activities. There are no particular regulations and guides for the separate regulatory activities, such as authorizations, review and assessment processes, inspections and enforcement.

The guidelines include different stages in the life cycle of a research reactor, such as construction, commissioning, operation and decommissioning.

9.2.2 Planned improvements

- → DSA should review and revise the General and Specific Guidance documents and propose that they should be elevated to the rank of a regulation.
- → DSA should review, revise and extend the legal and regulatory framework for the regulatory supervision of research reactors and fuel cycle facilities to address additional elements required by the respective IAEA safety standards.

9.3 REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Related to GSR Part 5: Requirements 2, 6, 8, 9, 10, 11 and 12
SSR-5: Requirements 5, 7, 10, 15, 19, 20, 22 and 26

There are three relevant regulations according to the PC Act, as indicated above:

- → Regulations on the Application of the Pollution Control Act to Radioactive Pollution and Radioactive Waste (PC Regulations) No. 1394, 1. November 2010;
- → Regulations Relating to the Recycling of Waste (Waste Regulations) No. 930 1 June 2004; and
- → Pollution Regulation No. 931 1 June 2004.

These regulations apply to any release of radioactive substances or management of radioactive waste. Radioactive waste incudes both waste containing naturally occurring radioactive materials (NORM), radioactive waste arising from, for example, industry, research activities and hospitals, and nuclear waste, e.g. spent fuel.

The Ministry of Climate and Environment (KLD) is responsible for the development and publication of regulations under the PC Act. However, the content of regulations related to radioactive pollution and radioactive waste is based on DSA's input and experience. The regulations are published on www.DSA.no and www.lovdata.no.

The PC Regulations apply to radioactive substances that may cause damage to or nuisance to the environment, including human health. The PC Regulations include exemption values, which effectively define what is considered to be radioactive waste. The Regulations also describe a three-tier approach to the regulation of waste, by the categorization of waste into three types; non-radioactive waste and two categories of radioactive waste, that may be disposed of in different types of facility, based on activity concentrations, according to the graded approach. The Regulation also includes exemption values that specify the levels above with discharges are regulated as radioactive and hence require an authorization. In Norway, releases are illegal unless they are exempt or authorized.

The Waste Regulations include requirements for all kinds of waste. Chapter 16 contains requirements for the management of radioactive waste. Radioactive waste must be: sent to licensed facility at least once per year and managed in a sound and justifiable manner. Under these Regulations, it is the responsibility of the operator of a waste facility to ensure that waste received meets the waste acceptance criteria, specified in the permit. It is the responsibility of the waste producer to provide sufficient information about the waste to enable further handling of the waste in a proper manner (section 16-9 and 16-10). There is a common electronic system for declaring radioactive and/or hazardous waste in use. This is a cooperation between DSA and the Norwegian environment agency (NEA) (https://www.avfallsdeklarering.no/). Any import or export of radioactive waste also requires a licence.

The Pollution Regulation contains several parts related to different kinds of pollution. Chapter 36 includes provisions on assessing applications under PC Act and chapter 39 provides provisions for fees to the Treasury for work with permits and control pursuant to the PC Act.

DSA has developed and published a set of guides to provide guidance on how to meet the requirements of the PC Act and associated regulations and associated criteria for discharges of radioactive material and radioactive waste management. The guides provide explanatory information on the requirements of the Act and Regulations. It is not mandatory to follow the guides but it is expected that deviations from them will be explained and approved by DSA.

There is a guidance document on the management of radioactive waste and radioactive discharges from the oil and gas industry. The guide describes how radioactive waste may be managed, and criteria for measuring discharges and waste.

In addition, there is guidance on how to sample alum shale and a general guidance document on alum shales. Guidance on the classification of wastes has also been developed to support the General Licence Conditions for nuclear installations.

9.3.1 Planned improvements

→ Develop further guidance on the regulation of waste management facilities

9.4 REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Related to GSR Part 1 (Rev. 1): Requirements 32-34

Acting as the regulatory body for the RP Act, DSA is the initiator for establishing and revising the RP Regulations. The purpose of the RP Regulations is to ensure the proper use of radiation, prevent harmful effects of radiation on human health and contribute to the protection of the environment. The RP Regulations apply to any manufacture, import, export, transfer, possession, installation, use, acquisition, storage, disposal, handling and extraction of radiation sources. The RP Regulations also apply to human activities that elevates levels of natural ionizing radiation. This includes radon in existing buildings and premises where people may reside.

The RP Act and RP Regulations state the requirements and associated criteria for various uses of radiation and are available to public at both DSA's web-site www.dsa.no and at www.lovdata.no.

DSA has developed and published a set of guides to provide guidance on how to meet the requirements and associated criteria for use of radiation given in the RP Act and Regulations,. The guides are based on the requirements included in the RP Regulations, and aim to give comprehensive guidance in the safe use of radiation. The relevant requirements in the RP Regulations form the basis on which application for authorization are assessed, whereas the guides provide information to the licensee or registrant on how to meet the relevant requirements. The following guides are available at DSA's web-site, www.dsa.no:

- → No. 1 – Guidance for industrial radiography (issued 2004/last updated 2017);
- → No.2 – Code of practice for the use of unsealed radioactive material in laboratories (issued 2004/last updated 2018);
- → No. 3. – Guidance to tanning studio owners and others offering indoor tanning services (issued 2012/last updated 2018);

- → No. 4 – Guidance to distributors and importers of tanning appliances for cosmetic purposes (issued 2013/last updated 2017);
- → No. 5 – Guidance for use of medical X-ray and MR-equipment (issued 2005/last updated 2018);
- → No. 6 – Guidance for radiation protection in radiotherapy (issued 2005/last updated 2018);
- → No. 7 – Guidelines for the safe application of UVC-radiation (issued 2005/last updated 2017);
- → No. 8 – Guidelines for the use of optical radiation therapy in medical and cosmetic procedures (issued 2006/last updated 2012);
- → No. 9 – Code of practice for the use of nuclear gauges (issued 2012/new update about to be released 2019);
- → No. 10 – Guidance on nuclear medicine (issued 2008/last updated 2016);
- → No. 12 – Guideline for strong laser pointers (issued 2011/last updated 2016);
- → No. 13 – Guideline for radioactive pollution and radioactive waste from oil and gas industry (issued 2011);
- → No. 14 – Guidance for the use of radiation within odontology (issued 2017).

The guides provide specific information on the various uses of radiation, and are based on the graded approach. They include information on how to use common radiation sources in a safe manner within the relevant field, including specific practical examples of how the requirements in the RP Act and Regulations can be fulfilled. Reference to relevant guides is always given upon granting authorization by licensing and during inspections. However, the undertakings are not obliged to follow the guides directly, as long as they can demonstrate that they meet the requirements and associated criteria in the RP Act and Regulations.

A considerable part of the content of these guides is based on input from interested parties, such as undertakings within the relevant field. Revisions of the guides generally reflect the experience gained through DSA's continuous contact with undertakings, such as inspections, meetings and other communication. Interested parties are consulted whenever regulations and/or guides are significantly revised.

9.5 REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

Related to GSR Part 6

9.5.1 Regulations and guides related to regulatory supervision

Discharges and waste management are regulated under the PC Act, PC Regulations, and the Waste Regulations (chapter 16). Any discharge above the exemption levels given in the PC Regulations appendix II must are subject to a permit. Permits are given under the PC Act and it is a condition in the permit that the operator of the nuclear facilities must have a decommissioning plan.

The NE Act section 8 also states that the licence or permit shall have conditions necessary to secure safety requirements. When the decision to decommission is taken, the operator will need a licence under the NE Act. It is also a condition in the licence issued under the NE Act that the operator must have decommissioning plans. The licence to decommission will include conditions for safety. The regulations issued under the NE Act will also be relevant for decommissioning, notably the Regulations on Nuclear Materials and the Regulations on Exemption from the Nuclear Energy Activities Act.

The RP Regulations and the PC Act regulate exposure of workers, the public and the environment during decommissioning, as a planned exposure situation. Dose limits are established in the RP Regulations for the public and workers.

The General Licence Conditions (GLCs) will also apply to any site or facility that is licensed under the NE Act. The GLC No. 9 relates to the need for decommissioning plans. Other documents which is relevant for decommissioning is under development and are in draft form; the Specific Guidance for the General Licence Condition (SGGLC), Regulatory Requirements for Decommissioning of Facilities (RRDF) and Regulatory Requirements for Research Reactors (RRRR).

9.5.2 Provisions to ensure retention of key staff and institutional knowledge

The GLCs give conditions which must be fulfilled in order to obtain a licence. Condition 5 (especially 5.1 and 5.4) states that the operator must have necessary personnel with the right competence at all times.

9.5.3 Approval for restrictions on release from regulatory control

If the facility cannot be released for unrestricted use due to the presence of nuclear or radioactive substances, the owner of the site or the facility would need a permit or licence after the NE Act or PC Act. This licence or permit would specify the conditions which must be fulfilled.

9.5.4 Planned improvements

- → DSA should implement the identified changes needed to harmonize clearance levels for radioactive and nuclear waste in the two relevant acts;
- → The Government should establish a decommissioning strategy for the existing research reactor, including clarifying the policy for the reuse of the two sites.

9.6 REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

Related to SSR-6

The transport of dangerous goods in Norway is predominantly regulated through the following three regulations:

- → Regulations on Transportation of Dangerous Goods by Land, No. 384, of 1 April 2009, pursuant to the Act Relating to Fire and Explosion Prevention, No. 20, of 14 June 2002. According to section 2 of these Regulations, ADR/RID is a part of the Regulations;
- → Regulations on Dangerous Goods on Norwegian Ships, No. 944, of 1 July 2014, pursuant to the Act Relating to Ship Safety and Security, No. 9, 16 February 2007. The IMDG and INF codes, among others, are incorporated into these Regulations;
- → Regulations on the Transport of Goods in Aircraft (BSL D 1-7), No. 41, 11 January 2003, and the Regulations are made pursuant to the Act Relating to Aviation, No. 101, 11 June 1993. According to these Regulations, dangerous goods shall be transported in accordance with the requirements of the ICAO Technical Instructions.

Norwegian regulatory requirements pertaining to transport activities are generally consistent with the requirements of IAEA's Regulations for the Safe Transport of Radioactive Material (SSR-6) through the implementation of ADR/RID, IMDG and ICAO TI codes as part of Norwegian regulations.

The Acts and Regulations listed above are available to users and applicants through the public web-site www.lovdata.no. The ADR/RID regulations are available from the web-site of the Norwegian Directorate for Civil Protection (DSB), www.dsb.no.

DSA has not published any guides specifically pertaining to transport or transport regulations. However, DSB has developed a number of guides to communicate regulatory principles and requirements to interested parties involved in the transport of dangerous goods by road or railroad. These include, among others:

- → Web-based guide to approvals or certificates related to ADR;
- → Industry Guidelines for the Security of the Transport of Dangerous Goods by Road;
- → First responders handbook – Hazardous Materials – CBRNE;
- → Digital dangerous goods archive (may look up substance by substance name or UN-number).

The guides are available from DSB's web pages.

The provisions of the NE Act and the RP Act also apply for the transport of nuclear substances and radioactive material. The former contains requirements for obtaining a permit to manufacture, own, store, handle, transport, sell or otherwise hold or dispose of nuclear substances, and provisions regarding transport liability. The latter contains general provisions regarding e.g. justification, instruction and training, and undertakings' duty to take necessary measures to protect employees, other associated persons and the environment against radiation.

The RP Regulations do not, in general, apply to transport of radiation sources outside a closed area, cf. section 2. However, in the event of accidents or incidents, undertakings shall immediately notify DSA, and a written report shall be sent within 3 days, cf. section 20. Incidents include, among others, events that cause or may have caused unintended exposures of employees or the public; loss, theft or sabotage of radiation sources; or unintended discharges of or contamination with radioactive material. Generally, there is a requirement to notify DSB in case of an accident or incident involving transport of dangerous goods by road or railroad, cf. section 6 of Regulations on Transportation of Dangerous Goods by Land. In DSB's guidance to these Regulations, reference is made to the notification requirement in the RP Regulations for incidents involving Class 7 radioactive material.

9.6.1 Planned improvements

- → The legal and regulatory framework for transport of radioactive material should be reviewed and revised, and any necessary changes to fulfil the IAEA recommendations should be proposed.

9.7 CONCLUSIONS AND ACTIONS

Regulations and guides under each of the relevant Acts, i.e. the RP Act, PC Act and NE Acts, have been published - and reviewed and revised - where appropriate. The Regulations are different in structure and content. Additionally, the IC Regulations under the umbrella of the Health, Environmental and Safety legislation, is a key part in the regulation of safety.

The PA Act regulates the development and implementation of regulations in general. The Government or authority has an obligation to clarify a case and seek opinion from interested parties before developing a regulation, as well as give advance notification. The Ministries have responsibility for developing regulations related to the three Acts. DSA provides input to the Ministries regarding the need for and content of relevant regulations. DSA has responsibility for developing and publishing any supporting guidance.

There are some legislative challenges. For instance:

- → The legislation for Health, Safety, Environment and Quality (HSEQ) in offshore oil and gas industry is not based on the RP Act, as it is for the PC Act.
- → The NE Act is not part of the legislative basis for the IC Regulations. Conditions similar to those in the IC Regulations have, however, been implemented in the General Licence Conditions for nuclear installations and activities.
- → The IC Regulations do not apply on Svalbard nor to activities associated with exploration for and exploitation of natural resources in the seabed or its substrata, such as offshore petroleum activities. For the latter type of activities, requirements related to health, safety and the environment are given in Regulations relating to health, safety and the environment in the petroleum activities and at certain onshore facilities (the Framework Regulations), No. 158, 12 February 2010.

With regard to regulations and guides related to radiation sources facilities and activities, the Norwegian regulatory framework is generally in good compliance with the requirements of IAEA's Framework for Safety and International Basic Safety Standards. However, there may be a need for additional regulatory provisions regarding protection and safety in the handling of deceased persons that are known to contain radioactive sources, and for establishing dose constraints related to use of ionizing radiation for human imaging for purposes other than medical diagnosis or treatment.

9.7.1 Actions

- → Consider whether the NE Act should be included as a legal basis for the Internal Control Regulations, or whether the current practice of including specific criteria for HSEQ in the General Licence Conditions for nuclear facilities and activities is sufficient (see also Module 7).
- → Consider whether the RP Act should be included in the legislative basis for the offshore HES regulations (see also Module 7).
- → Evaluate the need to develop regulatory provisions (in regulations or guides under the RP and/or PC Act) concerning protection and safety in the handling of deceased persons or human remains that are known to contain sealed or unsealed radioactive sources, and if necessary do so.
- → Establish dose constraints for the use of ionizing radiation for human imaging for purposes other than medical diagnosis, medical treatment or biomedical research.
- → Develop further guidance on the regulation of waste management facilities.

- → DSA should develop guidance on establishing waste acceptance criteria and the confirmation of conformance with the acceptance criteria, including provisions for identifying, assessing and dealing with waste that do not meet process specifications.

→ DSA should consider strengthening the provisions for stored waste, including retrieval and monitoring, and formalizing criteria for storage for decay and subsequently clearance.

→ DSA should implement the outstanding changes that has been defined to harmonize clearance levels for radioactive and nuclear waste in the two relevant acts.

10 EMERGENCY PREPAREDNESS AND RESPONSE

A risk based management system applies in Norway rather than a rule-based compliance management system. The Internal Control Regulations (IC Regulations) describe the systematic health, environmental and safety activities that must be implemented in all enterprises, which covers risk assessments for unwanted incidents/accidents and any associated actions necessary to reduce these risks. The IC Regulations state that "Internal control shall be documented in the form and to the extent necessary in the light of the nature, activities, risks and size of the enterprise" and, as such, requires that a management system shall be used by all enterprises in Norway, no matter what other acts and regulations also apply to the enterprise. Many of the detailed IAEA requirements on operating organizations' management and quality assurance systems are covered by the IC Regulations (although in a risk based manner rather than rule-based compliance), and thus are not repeated in other regulations, such as those specifically addressing nuclear safety and radiation protection. DSA is one of the national authorities that are supervisory authorities under the IC Regulations.

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

Related to *GSR Part 7: Requirements 2, 20 and 25*
GSR Part 1 (Rev. 1): Requirements 16, 26 and 27

10.1.1 Scope of authority and responsibilities of the regulatory body

DSA has been assigned the sole and full authority and responsibility to regulate on-site radiological and nuclear emergency arrangements of the operating organizations. This is stated in the Act on Radiation Protection and the Use of Radiation (RP Act), the Act on Nuclear Energy Activities (NE Act) and the Pollution Control Act (PC Act). This role includes developing, or advising on regulations and guides and verification of compliance for notification, approval, instruction and training, protective measures, radioactive waste, internal control, radiation protection, and planning and response to radiological and nuclear emergencies.

The DSA approach to EPR regulation is based on a graded approach where most effort and resources are given to regulation of the two research reactors operated by the Institute of Energy Technology (IFE). The regulatory regime in place for IFE facilities, including requirements for EPR is executed through:

- → Review and assessment of documentation during the licensing procedure (renewal every 10 years);
- → Inspections of the EPR plans and arrangements; and
- → Observation and evaluation of emergency preparedness exercises.

The EPR plans and arrangements, as well as the scope of exercises, includes both safety and security for radiological and nuclear issues and the interface with other organizations with specific responsibilities in the general security field. A Government Forum for the Protection of Nuclear Installations and Nuclear Fuel in Norway was established in 2016 based on recommendations from the IAEA's IPPAS (International Physical Protection Advisory Service) mission to Norway 2015. This is further described in Section 11 on the interface with nuclear security.

DSA reviews IFE's emergency plan as part of the licencing process and subsequently if/when IFE suggests revisions to the plan. DSA specifies additional requirements to be included in the EPR plan if necessary. However, DSA does not formally approve the operators' EPR plans. This is intentional since it is the duty of

the operating organization to ensure that any potential risk posed by their operations or activities are covered by an adequate emergency preparedness plan and arrangements. This duty follows from the Acts stated above as well as the IC Regulations.

10.1.2 Coordination among relevant organizations with authority and responsibilities for regulating EPR

In the annual budget from the ministries, resources are allocated specifically for EPR purposes and for nuclear safety. Staff from the EPR section work with those dealing with nuclear safety to ensure that IFE is compliant with the regulations on EPR, since safety and EPR are closely related issues (e.g. licensing, inspections, evaluation of exercises).

Staff in several sections at DSA perform inspections of operations of organizations other than IFE related to various aspects of the RP Act and the PC Act. Inspections on EPR-related activities and arrangements are performed as part of the overall inspections and the inspection team may be composed of members of staff from several sections.

DSA has an EPR section of 12 persons operating on a daily basis and a 24/7 officer-on-duty service with the involvement of staff from several sections. In the event of a radiological and nuclear incident or accident, this level of staffing may be increased to up to 80 persons, all of whom have been trained and exercised to perform specific functions.

The Communication Unit at DSA consists of four persons who also have specific functions in emergency preparedness and response.

10.1.3 Application of a graded approach

Regulation is based on a graded approach and greater effort is directed towards the regulation of the operator IFE than on operators using industrial or medical radiation sources. However, all authorizations granted under the RP Act to industrial and medical operators include requirements on risk assessment and EPR plans. The relevant documentation is reviewed during the authorization process and additional requirements may be specified if necessary, e.g. if EPR plan or arrangements are not considered to be satisfactory. EPR may also be included as one of the elements in inspections on site. DSA does not observe or evaluate exercises performed by industrial and medical operators but does participate in the notification exercises they perform.

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

Related to ***GSR Part 7: Requirements 2 and 8***
GSR Part 1 (Rev. 1): Requirement ***2***

10.2.1 Regulations and guidance on emergency arrangements

In all EPR work in Norway the following four EPR principles are fundamental ('White Paper' to the National Assembly (Stortingsmelding) number 10 (2016-2017) :

- → Responsibility: the organization responsible for a service is also responsible for necessary preventative measures, emergency preparedness measures and the implementation of actions in the event of a crisis;
- → Similarity: there shall be as much similarity as possible between the organization in day-to-day operations and when a crisis occurs (the organization which performs a task during daily operations is best placed to also handle these tasks during a crisis);
- → Subsidiarity: crises shall be handled at the lowest level possible;
- → Collaboration: organizations have an independent responsibility for collaborating with relevant actors in the work on prevention, preparedness and crisis management.

These four principles combined with the Internal Control regime provide the model for the EPR work within both the nuclear and radiological fields.

Several regulations and guidelines have been developed for operating organizations with radiation sources. The regulations specify the requirements that must be followed (perform risk assessment, prevent, prepare and respond to emergencies, notify the regulatory body etc.) while the guidelines elaborate on the expectations related to the risk assessment approach, the expected content of EPR plans and the EPR arrangements to be in place by the operator. The guidelines include expectations on:

1. Procedures for alerting and notification;
2. Organization for EPR;
3. Defined responsibilities in EPR;
4. Emergency plans and procedures in place which describe protective measures;
5. Procedures for gaining an overview of the situation;
6. Routines for internal communication;
7. Description of personal protective gear and its location;
8. Routines for following-up affected personnel;
9. Routines for communicating with authorities;
10. Routines for communicating with the public.

No specific EPR guidance has been issued for nuclear operators since IFE is the only operator in Norway . Instead, guidance is included in the licence tailored specifically to their needs.

10.2.2 Scope of authority and responsibilities assigned to operating organizations

The RP Act, the NE Act and the PC Act, and the associated regulations, all describe requirements for the operating organizations to promptly notify the regulatory body, declare the emergency and take all necessary mitigating actions on-site to counteract an escalation of an emergency situation. This authority and responsibility remains with the operating organization at all times.

DSA requires EPR plans to be part of the documentation given by the operator before a licence or authorization is given and every time a change in the activity takes place that requires a revised licence or authorization.

The list of IAEA requirements for the operating organization`s EPR plans and arrangements is very comprehensive and detailed. This is appropriate for nuclear installations, but is not appropriate for operators with only radiation sources. Such operators are required to:

- → Have a quality management system;

- → Perform risk assessment;
- → Take preventive measures to mitigate those risks;
- → Develop and maintain an EPR plan;
- → Have suitably trained personnel; procedures for notification of the regulatory body (and other responders if necessary);
- → Have necessary equipment;
- → Establish means of communication;
- → Decide on and take mitigatory actions on-site; and
- → Manage radioactive waste etc.

The number of elements included for each operator is chosen to be commensurate to the potential risk, according to a graded approach. As such, the number of requirements/provisions given by DSA will vary according to the type of operator. For IFE, almost all the provisions listed by IAEA are addressed by DSA. There is one exception: DSA does not give specific provisions to the operator for protecting emergency workers responding on the site.

10.2.3 Planned improvements

- → Specific requirements to the operator on protecting off-site emergency workers responding on the site should be included in the licensing procedure.

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

Related to ***GSR Part 7: Requirements 2 and 25***
GSR Part 1 (Rev. 1): Requirements 26-31

10.3.1 Processes to verify adequacy of on-site EPR

The adequacy of the operators' EPR plans and arrangements is verified through review and assessments of documents sent in support of the licensing or authorization process, through inspections on-site and by evaluating emergency exercises. However, there is room for some improvement, for example by the development of checklists for:

- → Review of EPR plans;
- → EPR arrangements in the licencing/authorization procedure.

The number of inspections of EPR plans and arrangements at other operators than IFE is very low.

As stated under 10.1, DSA does not approve the operator`s emergency plan since it is the duty of the operating organization to ensure that any potential risk posed by their operations or activities are covered by an adequate emergency preparedness plan and arrangements. DSA can require the operator to include additional elements in their EPR plan during the licensing or authorization process, if it is not considered to be satisfactory.

10.3.2 Scope of regulatory body to enforce corrective actions

DSA can, in the case of non-compliance, give individual decisions for the operator to rectify the fault or deficiency within a given deadline. In cases involving a significant risk to health, DSA may halt the activity

in question, confiscate substances or equipment in whole or in part, or by other means ensure discontinuation of further use. DSA may demand the closure of an undertaking that does not possess the required licence/authorization or has not submitted the required notification.

DSA may impose a coercive fine on an undertaking that ignores a deadline for complying with an order. Severe violations can also be penalized by fines or imprisonment. All of these enforcement instruments are laid down in the RP Act.

10.3.3 Integration of on-site and off-site emergency arrangements

Integration between on-site arrangements and those of relevant off-site response organizations is one of the questions raised in the safety-related inspections of operating organizations. For IFE, more detailed plans and procedures are in place under DSA requirements and through the cooperation with first responder organizations. However, there is room for improvement to make sure that operators also address security issues adequately in their EPR plans.

10.3.4 Planned improvements

- → DSA should consider the need to do more inspections on EPR at operators other than IFE, according to a graded approach;
- → DSA should produce improved written procedures (check-lists) related to EPR to be in full accordance with the IAEA requirements;
- → DSA should ensure that security issues are sufficiently addressed in the operators` EPR plans.

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

Related to ***GSR Part 7: Requirements 2, 20-26***
GSR Part 1 (Rev. 1): Requirements 3 and 8

10.4.1 Assigned role of DSA in a radiological or nuclear emergency

According to the Royal Decree on Nuclear Preparedness, DSA is assigned the role of chair of the Crisis Committee for Nuclear and Radiological Emergency Preparedness and Response. If a nuclear or radiological accident or incident has either occurred or cannot be ruled out, and such an event can affect either Norwegian territory or Norwegian interests, the Crisis Committee shall ensure that the incident is addressed with coordinated measures and coordinated information to the public. DSA is the chair, a member of and the secretariat for the Crisis Committee, as stated in the Royal Decree.

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 Authority; and

→ Directorate for Civil Protection.

During the acute phase of a nuclear or radiological event, the Crisis Committee is mandated to decide on implementation of early mitigating measures to protect life, health, environment and important societal interests. The decision-making power rests with the Crisis Committee in the acute and intermediate phase.

The Government has decided on six defined nuclear and radiological dimensioning scenarios[2], which the Crisis Committee must be able to manage. These are:

1. Large airborne release from foreign facility;
2. Large airborne release from domestic facility;
3. Local event with mobile source;
4. Local event that develops over time;
5. Release (or rumour of release) to the marine environment;
6. Serious accident abroad that can affect Norwegian interests, but not territory.

The Norwegian preparedness organization as a whole consists of the Crisis Committee for Nuclear and Radiological Emergency Preparedness and Response, its Advisors[3] and the secretariat, with the County Governors acting as the Committee's regional representatives. The Royal Decree further stipulates that the County Governors shall establish the necessary regional forum for coordination, with participation from all the agencies concerned, and establish a set of plans for their functions in nuclear preparedness. The County Governors shall help ensure that regional and local agencies and services, which are under the County Governors' general coordinating and organizational responsibility have established satisfactory plans for nuclear incidents as part of a coordinated set of plans. They shall also regularly report about such planning to DSA as the Crisis Committee's secretariat.

DSA is the national and international competent authority and warning point (NCA, NWP) for all radiological and nuclear events. DSA is required to maintain a round-the-clock On-Duty Officer system in order to be able to convene the Crisis Committee. The Secretariat (DSA) alerts the Crisis Committee's Chair, members, advisors, information officers, as well as the County Governors, ministries, and other relevant authorities or enterprises.

During events encompassed by the Crisis Committee's mandate, the secretariat shall:

→ Assist the Crisis Committee make its assessments;
→ Assist institutions and authorities at all levels address relevant issues;
→ Manage smaller incidents in line with guidelines provided by the Crisis Committee; and
→ Run the operations centre and its communications system.

The roles and responsibilities of all the members of the Crisis Committee are clearly defined in the 'Plan for the Crisis Committee'. The sections in this plan also cover:

→ Preparedness levels;
→ Notification, summoning and attendance;
→ Accident/incident management;
→ Competence, training and exercises; and

[2] The six dimensioning scenarios are general descriptions of nuclear and radiological accidents/incidents/events that may occur and affect Norwegian territory or Norwegian interests abroad. The Government has stated that the Norwegian radiological and nuclear emergency preparedness organization should be able to respond to any such scenario, should it occur. The national EPR plans should thus cover all of these scenarios and resources and capabilities should be in place to respond adequately.
[3] 14 organizations from universities, research institutes, and public directorates

- → Detailed descriptions of tasks and responsibilities of each member in the Crisis Committee.

One deficiency in the Norwegian regulations on emergency response is that: different phases in emergency management and the termination of an emergency are not defined in the Norwegian regulations.

10.4.2 Information and communication during emergencies

The Secretariat of the Crisis Committee (DSA) is responsible for ensuring that adequate information resources are available for managing incidents within the Crisis Committee's mandate. The Secretariat is required to seek cooperation with other agencies and directorates that have tasks within information preparedness, with the intent of organizing and coordinating the information work within the various preparedness areas.

During the acute phase, the Crisis Committee can strengthen the Secretariat's Information Unit by requesting professional assistance and supplementing resources from the information pool set up and administered by the Directorate for Civil Protection. During an acute incident, the Communication Unit at DSA shall:

- → Assist the Crisis Committee by developing communication strategies adapted to the incident at hand;
- → Suggest and implement communication measures for the Crisis Committee in the various phases of the incident; and
- → Assist the Crisis Committee to disseminate coordinated information to the general public and media.

In its continuous work, the Secretariat shall:

- → Assist the Crisis Committee to develop information strategies;
- → Participate in the continuous work on preparedness of disseminating information;
- → Carry out measures to raise competency;
- → Draft standard information materials; and
- → Facilitate, participate in, and enable learning from drills and exercises.

The Crisis Committee has both a communication strategy and communication plans for each of the six dimensioning scenarios. The Crisis Committee's communication strategy will be revised in 2019.

The information that the Crisis Committee provides must be:

- → Coordinated, fast and as comprehensive as possible;
- → Relevant and adapted to the target groups;
- → Help to maintain and strengthen the Crisis Committee as the preferred source of information.

The Crisis Committee's communication units have jointly developed a communication plan for each dimensioning scenario, with an explanation of the roles and responsibilities among the various communication units within the Crisis Committee member organizations. These communication plans are aimed at target groups, the media and the public and are structured according to the same template:

- → Scope and possible consequences of the scenario;
- → Context and framework conditions;
- → Objectives;
- → Target groups;
- → Primary messages;
- → Communication channels;
- → Communication activities and initiatives within each scenario;
- → Clarification of roles and responsibilities among the Crisis Committee agencies for communication;
- → Coordination between the Crisis Committee agencies' joint primary messages and each individual agency's communication follow-up on technical issues.

10.4.3 Capabilities of DSA

In normal situations, the preparedness for radiological or nuclear events is the responsibility of the Section for Emergency Preparedness in the Department of Nuclear Safety and Environmental Protection. The section is responsible for the operation of a 24/7 officer-on-duty system manned by staff from the whole DSA organization. Both in normal and crisis situations, DSA uses the Crisis Information Management (CIM) software as their main emergency response assistance system. The emergency operations are embedded in the CIM software; all plans, procedures, information exchange, contacts, incident logs etc. are included in CIM. All internal exercises are conducted and logged in CIM, and members of staff from the section hold training sessions for new staff and to keep others updated. All functions in the emergency staffing are formulated in written procedures in the DSA emergency plan. The Plan for the Crisis Committee is also hosted in CIM.

When an event occurs, the Crisis Committee Chair (the Director General (DG) of DSA) declares a higher level of emergency according to a graded approach, according to three pre-defined emergency levels. The DG's decision converts DSA into an emergency staff organization (different from the normal organization of DSA) that operates the Crisis Committee's operations room and the Situation Centre for the Crisis Committee's secretariat (at DSA Headquarters). Around 80 employees at DSA take part in this emergency staffing. They are trained in their respective roles and participate in exercises every year.

To assist the Secretariat in preparing advice for the Crisis Committee on protective actions, DSA has several capabilities. The ARGOS decision support system provides atmospheric dispersion and fallout prognosis for releases from any given nuclear power plant (NPP) in Europe and adjacent areas. It calculates inhalation doses and external doses during plume passage and after fallout has occurred, and internal doses from ingestion of contaminated foodstuffs. The RADNETT early warning system consists of thirty three stations for the measurement of ambient dose rate with an alarm function that notifies the officer on duty when radiation levels increase above a certain threshold. DSA also has six air filter stations, three advanced laboratories, , a mobile laboratory with whole body counter capabilities and a range of mobile and portable instruments for field application, car borne surveys and air borne surveys. DSA has, together with the Food Safety Authority, a food monitoring network with ten laboratories. Agreements for assistance in radiation measurements, decontamination and medical treatment of exposed people have been made with several of the Crisis Committee's members and advisors. DSA coordinates the joint Norwegian capacities for radiation measurement in case of emergencies. DSA also participates in various international networks for radiation monitoring and is the Norwegian counterpart for the IAEA RANET capabilities.

10.4.4 Ensuring no conflict with regulating safety

DSA has not been assigned responsibilities in response to an emergency that might compromise or conflict with discharging of its responsibility for regulating the safety of facilities and activities. The operator is responsible for any mitigating actions on-site, while DSA and the Crisis Committee are responsible for mitigating actions off-site.

10.4.5 Planned improvement

- → Specific requirements to the operator on how to protect off-site emergency workers should be included in the licensing procedure;
- → DSA should consider the needs to do more inspections on EPR of operators other than IFE, according to a graded approach;
- → Written procedures (check-lists) related to EPR should be improved to be in full accordance with the IAEA requirements;
- → DSA should ensure that security issues are sufficiently addressed in the operators` EPR plans;
- → Different phases in the emergency management and the termination of an emergency should be defined in the Norwegian regulations.

10.5 CONCLUSIONS AND ACTIONS

The Government has given DSA sole authority as the regulatory body to regulate on-site nuclear and radiological EPR of operating organizations. A clear regulatory framework exists with acts, regulations and guides related to nuclear and radiological EPR. Compliance in operating organizations is verified through document review and assessment during licensing or authorization, inspections and evaluation of exercises. Most resources are dedicated to the regulation and review of the EPR plans and arrangements for the only nuclear operator in Norway (IFE) and less to operators that use radiation sources, according to a graded approach.

DSA has legal instruments to enforce corrective actions in case of non-compliance such as orders, coercive fines, fines and imprisonment, as well as imposing a halt to activities and confiscating material.

In case of emergencies, the operator is responsible for any mitigating actions on-site, while DSA and the Crisis Committee are responsible for mitigating actions off-site. There are no conflicts or compromises related to the roles and responsibilities between the regulatory body and the operators.

The Crisis Committee for nuclear and radiological emergencies has been given a clear mandate for cross-sectorial collaboration and decision making during emergencies. In addition, the Government has decided on six defined nuclear and radiological dimensioning scenarios, which the Crisis Committee must be able to manage. Each of these six scenarios has its own communication plan. DSA has been assigned clear roles and responsibilities when managing nuclear and radiological events. For minor incidents, DSA as the sole regulatory body is responsible for managing the incident at national level. For larger emergencies, the Director General at the DSA chairs the Crisis Committee for Nuclear and Radiological Preparedness, which has a clear mandate through a Royal Decree for nuclear and radiological EPR.

10.5.1 Actions

→ Different phases in the emergency management and the termination of an emergency should be defined in the Norwegian regulations.

10.5.2 Intentional non-compliance

DSA does not approve the operator`s emergency plan. It is the duty of the operating organization to ensure that any potential risk posed by their operations or activities are covered by an adequate emergency preparedness plan and arrangements. DSA can require the operator to include additional elements in their EPR plan during the licensing or authorization process, if it is not considered to be satisfactory.

11 CONTROL OF MEDICAL, OCCUPATIONAL AND PUBLIC EXPOSURES

11.1 CONTROL OF MEDICAL EXPOSURES

Medical exposure is regulated under the Act on Radiation Protection and Use of Radiation (RP Act) (chapter III, §§ 13-14) and the Radiation Protection Regulations (RP Regulations) (chapter VI, §§ 39-59). DSA is the sole regulatory body for medical exposure (both patient and occupational). The Medical Applications Section comprises 11 employees, of whom 7 full-time equivalent persons work with regulatory issues, 3 part-time employees work within the secretariat for the National Program on Quality Assurance in Radiotherapy (KVIST), mandated by HOD, and the head of Section.

11.1.1 Responsibilities of the Government specific to medical exposure

Related to GSR Part 3: Requirement 34, paragraph 3.147-3.149

Authorization of relevant parties to assume their roles and responsibilities
The undertaking has the overall responsibility for medical exposure. The RP Regulations specify these responsibilities and define who can take the role as radiological medical practitioners (section 47), referring medical practitioners (section 42), medical radiation technologists (section 48) and medical physicists (section 50). Only authorized health professionals can take on the role and responsibilities as radiological medical practitioners, referring medical practitioners and medical radiation technologists. In addition, the role and responsibilities of the Radiation Protection Officer (RPO) is regulated in section 17 and the responsibility of the regional committees for health and research ethics (REK) in justification of biomedical research is regulated in section 39 c).

Norway has a national system for authorization of health professionals and specialist education of physicians (radiology, cardiology, etc.), under the responsibility of the Norwegian Directorate of Health. The roles and responsibilities of authorized health professionals is regulated under the Health Professional Act (ref: Helsepersonelloven). All authorized health professionals are registered in the Register for Health Personnel (Helsepersonellregisteret) which is continually updated. There is formalized education for all authorized health professionals, provided by high schools, colleges or universities. However, a survey performed by DSA in 2014 revealed that there was a lack of radiation protection (RP) covered in the curriculums for most health professionals and large variations between educational institutions for the same group of health professional (ref: StrålevernRapport 2014:5 (In Norwegian)). Radiographers, specialists in nuclear medicine and staff involved in dental use of radiation, generally demonstrated a sufficient level of competence in RP. Otherwise, the level of competence in RP amongst health professionals is generally lower than recommended by ICRP and EC, and almost absent for general practitioners, cardiologists, gastrologists, orthopaedists, etc. Health professionals involved in radiation therapy were not included in the survey. DSA and the Ministry of Health and Care Services (HOD) followed up this survey by providing the educational institutions and professional organizations with defined learning outcomes to be implemented in their curriculums, but do not have the authority to enforce the implementation. The Ministry of Education and Research, which is responsible for education, has been informed about the situation. In 2017, the RP Regulations were strengthened by implementing requirements on competence in radiation protection among health professionals (sections 47-48) to compensate for lack of RP in basic education.

There is no formalized educational system for medical physicists and no system for national recognition. However, there is an internal certification system by the Norwegian Association of Medical Physicists,

which most working physicists apply. This system is supported by DSA. Medical physicists are not defined as health professionals in Norway, and are not included in the established system for authorization of health professionals. DSA is investigating alternative possibilities for national recognition of medical physicists on assignment from HOD (work in progress). Educational requirements are given in the RP Regulations (section 50), and medical physicists need to have a scientific competence to master's degree level in the relevant discipline of medical physics (X-ray, nuclear medicine, radiotherapy, MR). The responsible medical physicist shall have further clinical experience of two years.

Service engineers must have consent from the Norwegian Directorate for Civil Protection (DSB) to be able to perform service and repairs on medical equipment that emits ionizing radiation according to Regulations on electrical companies and qualification requirements for work related to electrical installations and electrical equipment, articles 6, 7 and 8.

There is no national recognition of RPOs related to medical exposure to ensure proper knowledge, education and training, but DSA evaluates the education of RPOs during the licensing process and keep an updated list of RPOs involved in the control of medical exposure.

The regional ethics committees (REK) are responsible for evaluating the ethics in relation to biomedical research the justification of research protocols. DSA has provided REK with a guideline for evaluation of the justification of biomedical research, but the role and responsibilities and cooperation between DSA and REK is not formalized.

Relevant parties are informed of their role and responsibilities through the licensing process for activities and the registration process for sources, and through the RP Regulations and the associated RP-guidance (no. 5, 6, 10 and 14).

Establishment of diagnostic reference levels (DRLs)
DSA is responsible for establishing national DRLs, but this responsibility is not formally stated in the regulatory framework, although it is indirectly defined in the RP Regulations (section 45). National DRLs are normally set by the DSA without consultation with the Health Authority and relevant professional bodies. DSA have until now established national DRLs for 7 conventional X-ray procedures, 11 CT examinations, 5 interventional procedures and 8 diagnostic nuclear medicine procedures, most of these are indication based. DRLs (including revisions) are published in a publication series called 'StrålevernInfo' (Information from the DSA). The need for a more formal format of publication of legal binding DRLs is identified.

National DRLs are based on national surveys and are updated on regular basis. The latest revision for nuclear medicine was in 2010 (based on survey in 2007-2008), while the DRLs for radiology and interventional procedures were updated in 2018 (based on survey in 2017). Image quality is taken into account by providing a lower level (25 percentile of national dose distribution) as a trigger level for the responsible parties to ensure that image quality is sufficient. There is currently no national DRLs for pediatric patients, but DSA is participating in an ongoing Nordic project to establish Nordic DRLs for paediatric patients. The DRLs will be set as dose-weight curves and will be adopted as national DRLs (work in progress). DSA has the legal right to ask for the necessary dose parameters to obtain national dose distributions for the establishment of DRLs (RP-regulation, Section 52).

Establishment of dose constraints
The concept of dose constraints for carers and comforters, and volunteers participating in a programme of biomedical research, is not fully implemented in the RPRegulations. DSA has the authority to give specific conditions in the licence, but this is not done in practice. However, the general requirement on justification takes into account doses to carers, comforters and volunteers participating in biomedical research (Section 39). The Radiation Protection Guideline 10 on nuclear medicine has adopted the recommendations

on a dose constraint for carers and comforters related to the release of patients treated with I-131 provided by the European Commission (RP publication 97).

Establishment of criteria and guidelines for the release of patients

Neither the RP Regulations nor other Norwegian regulations contain explicit dose criteria for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who retain implanted sealed sources (the latter procedure is not performed in Norway). Hence, no legal binding release criteria for the release of patients has been established. DSA has no legal responsibility to ensure that criteria for release of patients are established other than to state it as a condition in the licence (RP Regulations, article 11). This has not been done. In general, hospitals are responsible for setting their own release criteria of patients to be in compliance with general requirements in the RPRegulations, such as dose limits for members of the public (ref: Guideline for NM). The Norwegian Directorate of Health has also published national recommendations on release criteria for patients treated with I-131, but DSA was not consulted in the development and the guideline has not been formally adopted by DSA.

Planned improvements

- → The need for establishing learning objectives in radiation protection in the curriculums for relevant health personnel should be addressed;
- → Formal education and national recognition of medical physicists should be addressed;
- → The role and responsibility of the regional committees for health and research ethics (REK) for evaluation of radiation protection and justification should be properly addressed in the regulatory framework for biomedical research;
- → The concept of dose constraints and release criteria within medical exposure should be implemented in the RP regulatory framework.

11.1.2 Responsibilities of the regulatory body specific to medical exposure

Related to GSR Part 3: Requirement 35, paragraph 3.150

The RP Regulations regulate who can take the role as radiological medical practitioners (section 47), referring medical practitioners (section 42), medical radiation technologists (section 48) and medical physicists (section 50). Only authorized health professionals can take the role as radiological medical practitioners, referring medical practitioners and medical radiation technologists. In addition to being authorized health professionals, the RP Regulations require that radiological medical practitioners must have competence in radiation protection to be responsible for justification and optimization (section 47) and medical radiation technologists (section 48) must have adequate competence in radiation protection to safely operate the equipment. All personnel involved in medical exposure must perform documented annual training in radiation protection and dedicated training on the equipment (section 49). Proper education and knowledge in radiation protection is a pre-condition to obtaining an authorization for activities associated with medical exposure. DSA also verifies compliance with the regulation during inspections.

11.1.3 Responsibilities of the registrants and licensees specific to medical exposure

Related to GSR Part 3: Requirement 36, paragraph 3.151-3.154

The RP Regulations give detailed requirements to registrants and licensees to ensure that no person incurs a medical exposure unless there has been an appropriate referral (section 42), responsibility has

been assumed for ensuring protection and safety (section 39 and 40), and the person subject to exposure has been informed as appropriate of the expected benefits and risks (section 43). The RP Regulations require that the justification of biomedical research is evaluated by a REK (section 39 c).

Section 43 of the RP Regulations and the Act on Patient and User Rights (article 3-2) regulate information provided to carers and comforters. The concept of dose constraints is not implemented for carers and comforters, but doses to carers and comforters are covered by the general requirement on justification (section 39).

The RP Regulations require that the number of radiological medical practitioners (section 47) and medical physicists (section 50) must be in accordance with the extent, size and complexity of the activity and to be commensurate with the given tasks and responsibilities for justification, optimization and dosimetry, quality assurance/quality control of equipment. DSA addresses the issue during inspections, by verifying if responsible parties have an appropriate number of staff to perform the required tasks. There are many acts and regulations regulating the quality of care, and to fulfil these requirements, the licensees must also ensure that there is the appropriate number of qualified staff. This topic is also addressed in inspections by the Norwegian Board of Health Supervision.

The RP Act states that all use of radiation must be justified (section 5) and the Act on Health Professionals states that health professionals must practice within agreed norms of propriety (section 4). In general, responsibilities provided through Acts and regulations cannot be delegated, but the associated tasks can be delegated. The Act on Health Professionals regulates the use of assistants (section 5). There is no direct requirement in the RP regulation that delegations need to be documented, but it is the normative understanding.

11.1.4 Justification of medical exposure

Related to GSR Part 3: Requirement 37, paragraph 3.155-3.161

The RP Act (section 13) and RP Regulations (section 39) regulate justification of medical exposure. Requirements on justification is in full compliance with GRS Part 3.

Generic justification
The registrants and licensees must document that new methods and applications in medical use of radiation is evaluated to be justified on a general basis before such methods and applications are taken into general clinical use. Existing areas of use and methods must be reassessed when new information emerges concerning their justification (Section 39 a).

Norway established a National System for Managed Introduction of New Health Technologies within the Specialist Health Service in 2013 (called Nye Metoder). This system ensures the systematic use of health technology assessment (HTA) as a tool for decision-making regarding new methods. HTA is performed on a national level (rapid- and full-HTA) and at a local level at the hospital (mini-HTA). HTA-assessments always address the benefits and risks associated with the method, but can also address ethical, organizational, economical and social aspects. The system ensures that there is a broad cooperation among relevant responsible parties and DSA. The role of DSA is to ensure that the principle or generic justification and radiation protection issues are properly addressed in the HTA-assessment. 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. Further, this system brings together all involved authorities, assessments and evaluations in one decision-making process. In this way, generic justification becomes part of a coordinated evaluation process. In addition, conflicting conclusions from separate authorities and evaluations is avoided. The weakness of this approach is that the system only covers the introduction of

new methods in the specialist health service. Generic justification of new methods in private practice and primary health service need to be performed by a case-by-case evaluation, but DSA use the concepts from Nye Metoder in the evaluation of generic justification in these situations. HTA-reports demonstrating compliance with the Nye Metoder criteria is considered to be sufficient documentation to demonstrate generic justification. The registrants and licensees also have the possibility to demonstrate generic justification in other ways, and the provided documentation has to be assessed and evaluated by DSA on a case-by-case basis.

Individual justification
Individual justification is regulated under the RP Regulations (section 39 b, section 42 and section 46). Medical exposure can only be carried out if a proper referral from an authorized health professional exists. The radiological practitioner is responsible for ensuring that the examination is justified and to choose the most appropriate examination based on applicable guidelines, standardized procedures and/or referral criteria. Alternative methods involving little or no exposure to ionizing radiation and previous relevant patient information and radiological images must be taken into account in the justification process. Special attention shall be given for the justification of examination of pregnant and breastfeeding women.

To ensure proper individual justification, the Norwegian Directorate of Health has issued national guidelines, covering the total patient pathway and gives recommendations on cancer diagnosis (including medical imaging), treatment (including radiation therapy and nuclear medicine) and control and follow-up regimes (including medical imaging). There is not a single set of national referral criteria for medical imaging implemented in Norway. The Norwegian Health Directorate has published national guidelines for medical imaging for non-trauma muscle- and skeleton diseases (from 2014). The Office of the Auditor General of Norway (Riksrevisjonen) performed an investigation of the use of medical imaging for outpatients (focus on CT and MR). This investigation revealed several issues including:

- → Geographic variation;
- → Justification and appropriateness;
- → High frequency of retakes due to unavailability of previous images;
- → Quality of referrals;
- → Lack of national referral criteria;
- → Differences between public and private sector.

In 2016, HOD gave the Norwegian Directorate of Health an assignment to establish a national strategy for efficient use of medical imaging. DSA participated in this work and the strategy is now being evaluated by HOD. To be able to implement the proposed strategy, there is a need to establish an action plan and national coordination and financing from the Government.

DSA has identified the need to formalize the cooperation with the Norwegian Directorate of Health to prepare guidelines, referral criteria and to initiate actions that have an influence on justification.

Justification of health screening programmes
Screening programmes involving medical exposure are regulated according to the RP Regulations (section 51). The requirements for screening programmes making use of ionizing radiation are very strict and DSA has the authority to inspect to assess compliance with these requirements. All screening programmes must also be notified to DSA.

The National Cancer Strategy for 2018-2022, prepared by HOD, gives national goals and a vision of how Norway shall approach different aspects related to cancer, including screening programmes. The Norwegian Directorate of Health is the responsible authority for giving advice to HOD and to the Government regarding national screening programmes. The national guidelines for cancer, issued by the

Norwegian Health Directorate, also give recommendations about screening (if relevant) and conclusions on the status of national implementation of screening programs.

HOD gave an assignment to the Norwegian Health Directorate to describe the present system for governance and to suggest a strategy for national screening programmes in 2013 involving relevant parties (DSA was not involved). In parallel with the development of this strategy, the National System for Managed Introduction of New Health Technologies within the Specialist Health Service (Nye Metoder) was introduced in 2013. In the mandate of 'Nye Metoder', the system also covered the introduction/changes and out phasing of screening programmes (generic justification). The drafted report on governance and strategy was subject to public hearing in 2014 and, as part of this process, DSA addressed the need to implement and address the requirements provided in the RP Regulations and to clarify the borderline between the proposed strategy and 'Nye Metoder'. Unfortunately, a final strategy has not been published and the suggested governance and strategy were not implemented.

At present, HOD gives recommendations on the introduction of new screening programmes and the final decision is made by the Parliament through the national budget. HOD bases its recommendations on comprehensive investigations and reports performed by the Norwegian Directorate of Health, which comprise an updated summary of the evidence-based knowledge, organization of the screening programme and a health economic analysis of the suggested screening programme. These issues are also evaluated in a HTA-assessment performed in the system 'Nye Metoder'.

DSA has identified a need for a formal strategy on implementation of new screening programmes, to clarify the role of 'Nye Metoder', and the process for properly involving DSA for screening programmes involving medical exposure to radiation. There is also a need to formalize the cooperation between DSA and the Norwegian Directorate of Health regarding the implementation of screening programmes involving medical exposure.

Justification of asymptomatic individuals

Medical exposure of asymptomatic individuals is addressed in the RP Regulations to ensure that the exposure is justified and that the individual is properly informed about the associated risks and benefits. Medical exposure of asymptomatic individuals can only be performed if there is a written referral and the examination is evaluated as justified. It is emphasized that, for asymptomatic individuals, the referral must contain information about the family history, identified risk factors and the cause for the examination. The concept of self-referral (to refer patients to a clinic where the referring physician has economic interests) must be performed with care, especially when referring asymptomatic individuals.

DSA has made considerable efforts to establish regulatory control over individual health assessments by use of mammography outside the public Mammography Screening Programme and the use of CT calcium scoring for cardiac diseases and other imaging tests offered by the private sector. All advertising now makes it clear that a referral from a referring practitioner is needed. However, DSA is aware of a problem with *pro forma* referrals, where the individual can request to be referred in order to undergo an otherwise unjustified x-ray examination. Inspections of such activities has been identified as an area where joint inspections with the Norwegian Board of Health Supervision (Helsetilsynet) would be effective.

There are no national referral guidelines for use in diagnostic imaging from national health authorities of professional organizations. Referrals for examinations of asymptomatic individuals must therefore be carefully documented in the referral. DSA consults national health authorities (mainly the Norwegian Heath Directorate) and relevant professional organizations when expert statements are needed for questions related to diagnostic imaging of asymptomatic individuals.

Justification of biomedical research

The regulatory framework for biomedical research consists of a number of Acts and regulations and is in accordance with the Helsinki Declaration. The Health Research Act regulates all biomedical research. All biomedical research programmes require a responsible person, a project manager and a research protocol (section 6), and the programme must be approved by a regional committee for health and research ethics, REK (section 9). The establishment of REK and their role and responsibilities are regulated in the Act on Ethics and Integrity in Research. In addition, the RP Regulations require that biomedical research involving medical exposure is evaluated by REK. DSA has provided REK with a guideline for evaluation of the justification, which is based on the recommendations by ICRP and EC. REK are advised to consult DSA in the evaluation of justification if doses to the individual may exceed 50 mSv. However, DSA has no authority to instruct REK and the cooperation between REK and DSA is not formalized. DSA is not aware if radiation protection issues are properly addressed by REK and DSA has not been consulted as recommended. The concept of dose constraints is not implemented for biomedical research, but doses to volunteers participating in biomedical research programmes are covered by the general requirement on justification (section 39). REK is working with an approach to provide DSA with statistics about biomedical research involving medical exposure. There is an identified need to formalize the cooperation between REK and DSA and to update the guideline.

Planned improvements

- → Measures should be put in place to ensure that relevant authorities involved in the evaluation of justification of medical exposure are effectively coordinated, that their responsibilities are unambiguously allocated and their cooperation is formalized.
- → The formal adaptation and adoption of a set of referral criteria for medical imaging for national use in the justification process should be considered, including their implementation in clinical decision support systems to increase their use.
- → The development of IT-systems that allow easy access to previous radiological images should be considered to reduce the need for retakes of radiological examination revealed by the Office of the Auditor General (Riksrevisjonen).
- → Development of a formal strategy on implementation of new screening programmes (including out phasing), should be considered. This would inclue clarifying the role of 'Nye Metoder', and involvement of DSA for screening programmes involving medical exposure. There is also a need to formalize the cooperation between DSA and the Norwegian Directorate of Health regarding implementation of screening programmes involving medical exposure.

11.1.5 Optimization of protection and safety

Related to GSR Part 3: Requirement 38, paragraph 3.162-3.174

Optimization of medical exposure are regulated under the RP Act (section 13) and the RP Regulations (section 40). In summary, optimization shall include choice of method, apparatus and equipment, working procedure, assessment of radiation dose and dose distribution to the patient, image quality and the effect of therapy.

Design considerations

Medical equipment is primarily regulated under the Medical Equipment Act and the Medical Equipment Regulations (ME Regulations) administrated by the Norwegian Directorate for Civil Protection (DSB). The ME Regulations article 2-4 states that medical equipment shall be CE-marked, which is a sign of quality

according to European standards such as the 'Council Directive 93/42/EEC of 14 June 1993 concerning medical devices'. DSB is also responsible for vigilance reports associated with medical equipment. DSB also performs market control and systematic inspections and can prohibit a type of equipment and take it off the market if it does not fulfil the safety requirements in the regulations.

Operational considerations
The RP Regulations require that radiation apparatus and equipment for medical use is adapted to the areas of use and comply with acknowledged acceptance criteria (section 53). In absence of national acceptance criteria, European and international criteria should be used as a guidance. The undertaking must also have written procedures for examinations and treatments, and these shall be regularly updated (section 41). A multi-disciplinary team consisting of the radiological medical practitioner, the medical radiological technologist and the medical physicist are responsible for performing optimization (section 40). In diagnostic radiology and nuclear medicine, optimization is driven by the ALARA principle (as low as reachable available) and by balancing the dose versus image quality. Use of diagnostic reference levels is an important tool in the optimization of radiology and nuclear medicine. For radiotherapy, optimization is driven by delivering the correct dose to the target volume and minimizing the dose to organs at risk. Special attention should be given in optimization of exposure to female patients that are pregnant or breastfeeding, to reduce the exposure of the embryo or fetus and breastfeeding infants (section 46).

Calibration
The RP Regulations regulate calibration (section 54). For radiotherapy, the undertaking shall have a reference instrument for dose measurement and it shall be calibrated every second year against the national standard. Further, radiation sources used in radiation therapy shall be calibrated against the reference instrument for the radiation qualities used clinically. On a regular basis, all devices that show a measure of radiation dose in X-ray diagnostics and nuclear medicine, shall be calibrated and controlled.

Calibration of radiation sources shall be performed during the acceptance test, after maintenance of significance for dosimetry and in accordance with planned routines. Calibration shall be carried out in compliance with acknowledged international or national protocols where applicable. All calibrations must be performed under the responsibility of a medical physicist (section 50).

Dosimetry of patients
The RP Regulations require the undertaking to establish typical doses for patients for common procedures radiological and interventional procedures (section 45). Radiation therapy must be planned and performed according to accepted national procedures, defining descriptions of target volume, organ at risk, fractionation and doses. Individual treatment plans must be authorized by an oncologist and a medical physicist prior to treatment. The treatment plan must be followed and documented (section 57). For nuclear medicine, the undertaking must determine and verify the amount of radioactivity to be administered to the patient, and for treatments, they must perform individual dose planning. Administration of radiopharmaceuticals must be documented in the patient journal (section 58). All dosimetry of patients must be performed under the responsibility of a medical physicist (section 50).

Diagnostic reference levels
The RP Regulations require the undertaking to regularly compare their typical doses for radiological and interventional procedure, and typical administered activities for nuclear medicine, against the national diagnostic reference levels (DRLs) published by DSA. If the dose values significantly deviate from the national reference values, the undertaking shall investigate the causes and consider implementing measures to reduce or increase the doses.

Quality assurance for medical exposure
The RP Regulations require that an undertaking has a documented system for quality assurance for medical exposure covering proper quality control (acceptance test and periodic tests) and system for

maintenance of the equipment. All parameters affecting the dose and image quality must be controlled. The acceptance tests, quality controls and maintenance must be planned, systematic and documented properly (section 53). Quality controls of equipment must be performed under the responsibility of a medical physicist (section 50).

In 2000, DSA established a national quality assurance (QA) program in radiotherapy (KVIST). The program was initiated by HOD to help undertakings through a planned, extensive increase in radiotherapy capacity in Norway. This QA program, organized and run for this purpose is, as far as we know, unique for QA in radiotherapy. The KVIST team is multi-disciplinary, employed in permanent positions at DSA, working solely with national radiotherapy QA projects. Relevant national projects are identified in collaboration with the radiotherapy department representatives. Several national consensus documents have been prepared; systems for incident handling and activity reporting have been established and clinical audits have been implemented in Norwegian radiotherapy. Guidelines for quality controls of equipment and the performance of radiotherapy for various diagnoses have also been prepared in collaboration with National Cancer groups. Records of radiotherapy activity, quality controls, incidents and accidents are sent to the DSA annually. The KVIST programme has been very well received in the Norwegian radiotherapy community, and has succeeded in creating a safety culture, a positive attitude towards QA and improved the communication between centres and the various professions (Hellebust et al 2012).

Dose constraints
The concept of dose constraints in medical exposure are not fully implemented in Norway and there are no requirements in the RP Regulations for dose constraints. Doses to carers and comforters and individuals taking part in biomedical research must be considered through the general concepts of justification and optimization (section 39 and section 40). However, the RP guides give some advice on dose constraints for use in optimization of medical exposure.

11.1.6 Pregnant or breast-feeding female patients

Related to GSR Part 3: Requirement 39, paragraph 3.175-3.177

Exposures to pregnant and breast-feeding female patients are regulated under section 46 in the RP Regulations. The requirement is general and states that special attention must be given these patients to protect the unborn child/foetus/embryo and breast-feeding child. There is no requirement to display signs to inform the patients to notify the staff if they are pregnant or breast-feeding, but the licensees must have procedures to identify these patients and have available procedures to ascertain the pregnancy status and to estimate the dose and to take this into account in the justification process of the examination/procedure. The licensees must also have procedures to follow-up unintended exposure of the unborn child/foetus/embryo, to estimate the dose and to report the incident and corresponding dose if the dose to the foetus exceeds 20 mSv. Further information is given in the comments and guidelines to the RP Regulation, such as recommendations for interrupting breast-feeding after administration of radiopharmaceuticals in routine use.

11.1.7 Release of patients after radionuclide therapy

Related to GSR Part 3: Requirement 40, paragraph 3.178

DSA has not established national release criteria for the release of patients after radionuclide therapy. There are some guidelines on release criteria for I-131 patients, but these are not harmonized. The RP-guide No. 10 (on nuclear medicine) states that it is the licensee's responsibility to set release criteria under the boundary of the general dose limits to the public and staff. The RP Regulations give general

requirements on information and guidance to the patients and other relevant persons and detailed recommendations are given in the guidelines for nuclear medicine.

11.1.8 Unintended and accidental medical exposure

Related to GSR Part 3: Requirement 41, paragraph 3.179-3.181

The responsibilities of the undertakings related to minimization of unintended and accidental medical exposure are regulated under the RP Regulations section 55. The registrants and licensees must perform actions to minimize the risk for unintended and accidental medical exposure. A deviation system to register, analyze and follow-up accidental and unintended medical exposure must be implemented. Finally, if necessary based on the analysis, corrective actions to prevent repetition must be performed.

To reduce the possibility for unintended and accidental events, the undertakings must perform a risk assessment and, based on this assessment, implement corrective actions to reduce the risks (section 18). All employees must be informed about the identified risks associated with their tasks and receive adequate training to perform their tasks at minimal risk. Risk assessment and systems for detecting problems and safety issues are also required by the Internal Control Regulations (IC Regulations), article 5 pts. 6 and 7.

Undertakings must promptly notify DSA about accidental or unintended events according to the criteria given in the RP Regulations section 20. A written report must be sent to DSA within 3 working days. The report must, at a minimum, contain a brief description of the event, its possible cause and estimated doses to involved persons. All received reports of accidental and unintended events are followed-up by DSA to ensure that the responsible party has initiated corrective actions, if necessary. Based on the nature and severity of the event, DSA can also decide to perform an on-site inspection. The risk assessment associated with the practice involved in the event must be updated if necessary. DSA keeps records of unintended and accidental events and informs registrants and licensees of important events that are of general interest, to enable other to learn from the mistake.

Within the KVIST mandate, all radiotherapy departments report yearly to DSA on all events that are registered in their local deviation system. All events are categorized according to a national guideline developed within the mandate of KVIST and all the events are analyzed and discussed among all radiotherapy centres in annual meetings. An overview of all reported events is published in a DSA publication, approximately every 5 years.

The licence for vendors includes a specific requirement to ensure that the consumer receives information about errors, and faults in the equipment. Vigilance reports and other safety information that the vendor receives from the producer or from the Norwegian authorities must be provided to the customer.

11.1.9 Review and records

Related to GSR Part 3: Requirement 42, paragraph 3.182-3.185

Review

The registrants and licensees must regularly perform internal control to ensure that the practice is performed in a justifiable way and in accordance with relevant acts and regulations, particularly the RP Act and Regulation. The duty to perform internal control is specified in the IC Regulations, and in the RP Regulations section 16. The IC Regulations article 5 pt. 8, requires that the undertaking must review the internal control regularly (i.e. procedures instructions etc.) to ensure it is functioning as intended. For medical exposure, the internal control must contain a review of how the principles of justification and

optimization are implemented in daily practice. If needed, corrective actions should be identified and performed.

In addition, clinical audits must be performed regularly within medical exposure (RP Regulations, section 44). Systems for clinical audits are developed for radiotherapy within the KVIST mandate and the same principles may be applied within radiology and nuclear medicine. There is no external body performing clinical audits, but external audits may be performed by peers from other hospitals or departments. Dosimetric audits within radiotherapy are also performed within the KVIST mandate.

Records
According to the RP Regulations, registrants and licensees must keep the following records:

- → Training in radiation protection of personnel (section 49);
- → Calibrations, quality controls and maintenance (section 52 and 53);
- → Dosimetry of patients (section 52, 56, 57, 58);
- → Typical doses for common radiological, interventional and nuclear medicine procedures together with review against national DRLs (section 45);
- → Documentation related to quality assurance (section 53).

In addition, records of medical exposure must be kept within diagnostic radiology and interventional procedures (section 56), radiation therapy (section 57) and nuclear medicine (section 58). Records related to investigations for unintended and accidental medical exposures are regulated in section 55.

DSA is working together with the Norwegian Directorate of Health to establish a national system of surveillance of medical exposure. This system is based on automatic reporting of activity- and dose data from all practices related to medical exposure that are subjected to authorization. The facilities will report the data to the Norwegian Patient Register (NPR) and NPR will provide DSA with aggregated data on activity and doses. In the future, this national system will yearly collect activity- and dose data to provide the basis for establishing the national dose distributions and revising national DRLs, and to estimate the contribution of medical exposure to collective dose. In addition, this system will allow practices with the potential for optimization and patient groups of high risk to be identified.

11.2 CONTROL OF OCCUPATIONAL EXPOSURES

Related to GSR Part 3: Requirements 12, 19-21, 23-25, 28 and 52

Different activities and facilities require authorization as described in more detail in Module 5. DSA does not require specific authorizations regarding occupational exposure situations, but there are provisions on occupational exposure to ionizing radiation in the RP Regulations, sections 32–34. According to these sections, the undertaking shall:

- → Ensure that all radiation exposure are as low as practically achievable, and below the dose limits listed inn section 32
- → Perform a systematic surveillance of exposed workers in category A and ensure the determination of individual doses for exposed workers in category B, as described in section 33;
- → Annually report dose data to the national dose register at DSA, as described in section 34.

These requirements apply to any manufacture, import, export, transfer, possession, installation, use, acquisition, storage, disposal, handling and extraction of radiation sources.

11.2.1 Justification and optimization

Requirements on justification and optimization are stated in both the RP Act and the RP Regulations.

The scope of the RP Act is broad, it applies to all exposure situations, i.e. production, import, export, transport, transfer, possession, installation, use, handling and waste management of radiation sources. It also applies to human activities giving increased levels of naturally occurring ionizing radiation from the environment. Hence, all activities involving radiation exposures to persons shall be justified and optimized according to regulations.

11.2.2 Compliance with dose limits

According to RP Regulations section 32, the undertaking shall, if a worker might have exceeded the dose limits, immediately make an investigation and if possible find the cause, and initiate measures to avoid repetition.

Compliance with dose limits is mainly controlled by DSA through inspections, annual reporting or through the DSA dosimetry service. Doses to workers shall be reported to DSA at least annually, (ref. RP Regulations section 34). However, most licensees in Norway use DSA's personal dosimetry service. In cases where doses readings are above dose limits or significantly higher than expected for the relevant occupation, the undertaking will be contacted to examine the cause, and the case will be followed up by inspection if deemed necessary.

Recommended action levels above which an assessment of the exposure of a staff member should be performed are given for various practices in DSA guidelines.

11.2.3 Female workers and persons under age

The following Acts and Regulations have provisions related to female workers and persons under age:

- → The Regulations on the Performance of Work;
- → The Radiation Protection Regulations;
- → The Radiation Protection Act;
- → The Working Environment Act;
- → The Organization, Management and Employee Participation Regulations;
- → The Regulations on physical and chemical agents in the working environment and infectious risk groups for biological factors.

According to the RP Regulations section 32, the equivalent dose to the foetus for pregnant exposed workers, apprentices and students shall not exceed 1 mSv for the remainder of the pregnancy, i.e. after the pregnancy is known. For apprentices and students between the age of 16 and 18 years who are using radiation sources as part of their education, the dose limits of respectively 5, 15 and 150 mSv per year applies. Pregnant and breastfeeding workers, apprentices and students shall not work with assignments, which might imply a significant risk of intake of radionuclides or contamination.

According to the Regulations on the Performance of Work (section 7-4), employers shall 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.

The Working Environment Act, section 11-1, states that no persons under 18 years of age must perform work that may be detrimental to their safety, health, development or schooling.

According to the Organisation, Management and Employee Participation Regulations, section 12-6a, no persons under the age of 18 shall perform work that entails exposure to ionizing radiation. The only exception, stated in section 12-7, is for young people aged between 16 and 18 who are not required to go to school may perform work as mentioned above when the effective dose equivalent does not exceed 5 mSv over a period of 12 months.

Requirements regarding the transfer of pregnant women, medical practitioners' notification duty, employers' duty to register etc., are included in the regulations on physical and chemical agents in the working environment and infectious risk groups for biological factors.

For further details on dose limits and provisions related to female workers and persons under age, see the acts and regulations mentioned above.

11.2.4 Inspection of occupational exposure

Occupational exposure is normally included as part of the inspections DSA performs, following the inspection processes described in section 7.1. See also sections 7.2 -7.7 for more information about DSA's inspection activities within the different areas.

During inspections, the DSA inspectors may review, verify or control the following:

- → The undertaking's review and classification of workers in category A and B;
- → Procedures and routines regarding use of personal dosimeters or other dosimeters, and if the employees can easily check their own dose readings;
- → Controlled and supervised areas;
- → Routines and procedures for the use of shielding equipment;
- → Arrangements for proper use, calibration, testing and maintenance;
- → Equipment for measuring radiation;
- → Competence and training programs;
- → Dose readings/reports and compliance with dose limits;
- → Routines for dealing with pregnant workers and under-age persons.

In addition to provisions on occupational exposure in the RP-Act and Regulations, there are provisions in Regulations concerning the Performance of Work, section 15-4, regarding medical examination of employees who may be exposed to ionizing radiation. The Norwegian Labour Inspection Authority is the regulatory authority for Regulations concerning the Performance of Work.

11.2.5 Existing exposure situations

The provisions on occupational exposure to ionizing radiation also apply to aircrew (RP Regulations, sections 30–34). DSA does not actively regulate the protection of aircrew.

As far as occupational exposure is concerned, the act of remediation is regulated as a planned exposure situation, and hence requirements to ensure protection in the working place are included in the licence to perform remediation activities. These requirements are based on the general requirements in the RP Act relating to protection in working place and a graded approach commensurate with the potential risks.

Radon in workplaces is regulated in the Working Environment Act, section 4-1, requiring the employer to provide a fully satisfactory working environment, and section 3-1, requiring systematic health, environment and safety work. There are no legally binding limits for radon in workplaces (except for schools and kindergartens), but it is recommended that the DSA general recommendation (100 and 200 Bq/m^3) should be taken into account (See the section on radon exposures for more information).

11.2.6 Review and assessment for occupational exposures

The RP Regulations, section 30-34, sets requirements on classification of areas, categorization of occupationally exposed workers, dose limits and dose reporting.

The review and assessment of occupational radiation doses is mainly done by DSA in connection with inspections, assessment of the authorized parties' annually reported doses or through the DSA dosimetry service, see above. Doses to workers shall be reported to DSA at least annually, according to the RP Regulations section 34. The reporting is now done through the newly (2018) established national dose register. DSA will review occupational exposure reports, classification of areas and monitoring programmes.

The review and assessment of the classification of areas is reviewed and controlled thorough the authorization and inspection process. In the application forms for different categories of radiation sources, facilities and activities, the applicant is required to answer questions about the requirements in the RP Regulations, sections 30–34.

According to the Internal Control Regulations (IC Regulations), the undertaking has an independent responsibility to assess and control HES-related risks and to verify compliance with the requirements of the HES-legislation, and it is the undertaking's responsibility to fulfil the requirements in the RP Regulations.

Recommended action levels for when an assessment of the exposure of a staff member should be performed are given for various practices in the DSA Guidelines, see above. On inspections, DSA will check compliance with the requirements in the RP Regulations, sections 30–34 (see Module 7 for more information).

11.2.7 Cooperation, Information, instruction and training

The responsibility for the radiation protection of workers is placed on undertakings that acquire and use, lease out or handle ionizing radiation sources, such as x-ray apparatus, accelerators and radioactive sources. This responsibility is specified in detail in a set of requirements in the RP Act and Regulations and in the Working Environment Act, as described in detail in Section 11.2.1. More specific requirements related to cooperation between the authorized party and employees and the provision of appropriate information, instruction and training are described below.

Cooperation and employee participation
Radiation protection shall be a part of the internal control system, and undertakings shall prepare instructions and work procedures in writing that ensures proper radiation protection (RP Regulations, section 16). Employees shall contribute to the introduction and exercise of the internal control, according to IC Regulations, section 2. Employees shall cooperate on the design, implementation and follow-up of the undertaking's systematic work on health, environment and safety (Working Environmental Act. section 2-3). Section 33 in the RP Regulations states that workers shall contribute to the monitoring of dose.

Information, competence and training
According to section 7 in the RP Act, undertakings are responsible for ensuring that workers have sufficient competence and training to carry out their tasks safely. Visitors and others with access to the undertaking shall, where necessary, in the interest of radiation protection, be provided with information about precautions that must be taken (RP Act section 7). Undertakings shall take necessary measures to protect the employees, other associated persons and the environment against radiation (RP Act, section 8).

The RP Regulations section 16 states that undertakings are required 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, including safe handling of radiation sources and competence regarding measurement and protective equipment.

Requirements related to competence, risk assessment and emergency preparedness are further specified in the RP Regulations sections 18, 19, 48, 49.

When persons other than the employer's own employees, including workers hired from temporary work agencies or other companies perform tasks in connection with the employer's activities or installations, the employer shall ensure that his own activities and those of his own employees are performed safely (Working Environment Act, section 2-2). The principal undertaking shall be responsible for coordinating the health, environment and safety work of each undertaking (Working Environment Act, section 2-2).

Assessment of occupational exposure and workers' health surveillance
According to the RP Regulations section 33, the undertaking shall perform a systematic surveillance of exposed workers in category A and B. Employees who work within a controlled or monitored area shall carry a personal dosimeter or ascertain their personal radiation exposure by other means (Regulations on Performance of Work, section 15-3). Undertakings shall make an assessment and categorize occupationally exposed workers in category A or B depending on the presumed annual exposure (RP Regulations, section 31).

Undertakings that have occupationally exposed workers who can be exposed to significant internal radiation must identify these workers. The undertaking must establish a suitable surveillance system for workers who can have a significant exposure via internal irradiation (RP Regulations, section 33). Furthermore, undertakings shall provide workers with information about dose records and implement measures when needed (RP Regulations, section 33).

According to the Regulations on Performance of Work, section 15-4, the employer shall ensure that employees who are to work under conditions where radiation may lead to a dose of more than 6 mSv per year, or an equivalent dose of more than 3/10 of the dose limits set out in the Regulations concerning Action and Limit Values, undergo medical examinations before they are assigned such work. Subsequently, such workers shall undergo medical examinations every three years or more frequently if advised by a medical practitioner. The medical examinations shall seek to determine whether there are medical reasons why the employee should not work, or continue to work, with ionizing radiation or whether special measures are required.

If individual dose readings show that an employee has been exposed to radiation doses exceeding the dose limits for physical and chemical agents set out in the Regulations concerning Action and Limit Values, the employee shall be referred to a medical practitioner for a medical examination. Such a medical examination shall also be conducted if requested by the employee on special grounds, or if the medical practitioner has decided that the employee needs to be examined.

The employer shall ensure that the medical practitioner has all the exposure information that may be of importance to the medical examination and the employee shall be informed about the result of the medical examination.

Employees who have a medical certificate stating that they cannot work with ionizing radiation shall be transferred to work in which there is no occupational exposure to ionizing radiation.

Prohibition of offering benefits as substitutes for measures for protection and safety
Registrants and licensees are not permitted to offer benefits to the worker as a substitute for measures for radiation protection and safety. This would be in breach of the purpose of all the radiation protection requirements in the RP legislation and the Working Environment Act.

Persons who are particularly sensitive to radiation (low age, pregnant, other reasons) shall either be assigned tasks that do not involve exposure to radiation, or be protected by other appropriate measures (RP Act, section 8).

11.2.8 Personal dosimetry services in Norway

DSA offers a personal dosimetry service to all types of undertakings in Norway that have employees exposed to ionizing radiation at work. The DSA personal dosimetry service has of the order 9000 users, and is the dominant provider of personal dosimetry to occupationally exposed workers in Norway. There are at present no formal regulatory requirements regarding authorization of DSA's dosimetry laboratory. See section 1.9 for further information.

11.2.9 Regulations and guides related to occupational exposures

- → Radiation Protection Act;
- → Radiation Protection Regulations;
- → Regulations on the Performance of Work;
- → The Working Environment Act;
- → Organisation, Management and Employee Participation Regulations;
- → Regulations of 6 December 2011 no. 1358 on physical and chemical agents in the working environment and infectious risk groups for biological factors;
- → Regulations concerning Action and Limit Values;
- → Internal Control Regulations.

The topic *occupational exposure* is addressed in most of DSA's guidelines on radiation protection. See Module 5 for a complete overview.

11.2.10 Planned improvements

- → The need for a provision in the RP Regulations for authorization and accreditation of personal dosimetry laboratories in Norway should be considered.

11.3 CONTROL OF PUBLIC EXPOSURES

Related to GSR Part 3: Requirements 12, 29-30, 33, 45 and 47

An introduction to the level of doses experienced by members of the public in Norway is provided to give some context to the relevant regulatory requirements and associated processes.

DSA has published an assessment of the general public's total exposure to ionizing radiation from natural and artificial sources. The assessment is summarised in NRPA Report 2015:13 'Radiation Doses to the Norwegian Population' (https://www.dsa.no/publikasjon/straalevernrapport-2015-13-radiation-doses-to-the-norwegian-population.pdf). An updated assessment is scheduled for 2020.

The mean dose to the general public was estimated to be 5.2 mSv/year, of which near 50% is due to radon inhalation. The second largest contribution is medical examinations at 21%, followed by natural external radiation (incl. cosmic), radioactivity in food, and inhalation of radionuclides other than radon (at 16, 10 and 4%, respectively).

The assessment of the average dose from inhalation is based on national data on radon and thoron concentrations in indoor air and other radionuclides in outdoor air. Estimates of ingestion doses has been made based on statistics from national dietary surveys and best estimates of national activity concentrations of fourteen anthropogenic and naturally occurring radionuclides in different food products and drinking water. The assessment of external exposure to cosmic radiation, as well as external gamma radiation both indoors and outdoors, are also based on national conditions and data. Dose estimates for external radiation and inhalation of radon and thoron has been made taking into account Norwegian statistics on indoor occupancy. The average exposure to medical ionizing radiation from diagnostic radiological examinations was also included in the assessment. Ranges of exposure is presented for most exposures, when data is available.

11.3.1 Legal basis for public exposure

The Pollution Control Act (PC Act) and the Radiation Protection Act (RP Act) with their associated regulations are the basis for regulation of public exposure to radioactive materials.

The RP Act and Regulations specify the responsibilities for control of public exposure. Dose limits and a dose constraint for members of the public are also specified along with the requirements for optimization of protection and safety for situations in which individuals are or could be subject to public exposure. Consumer products are also regulated under this legislation.

The PC Act and associated regulations are the basis for regulating any radioactive discharge, release or waste management. The PC Act applies to both non-radioactive and radioactive release and waste management. The Regulations on the Application on the Pollution Control Act to Radioactive Pollution and Radioactive Waste (PC Regulations) specify exemption values for radioactive waste and discharges. Remediation of contaminated and legacy sites is also regulated under the PC Act and Regulations.

11.3.2 Radiation Protection Principles

Dose limits and constraints
Dose limits and dose constraints for public exposure are given in RP Regulations. The dose to a member of the public shall not exceed 1 mSv/y. The equivalent dose to eye lens shall not exceed 15mSv/y and for the skin the dose limit is 50mSv/y. These values are in accordance with the requirements given in IAEA GSR Part 3, Schedule III. An enterprise using ionizing radiation shall plan the use of the source and shielding measures so that the dose to the public does not exceed 0.25mSv/y.

Optimisation and justification
All use of ionizing radiation shall be optimized, according to RP Regulations. This means that the exposure shall be kept as low as possible, taken into account technological knowledge, social and economic factors.

According to RP Regulations, the undertaking must have sufficient shielding and other safety equipment available and technical arrangements in place to prevent unintended exposure, were this is necessary.

The use of radiation sources must be operated such that the risk of unintended exposure of users, patients and other persons is as low as possible, according to the RP Regulations. The Regulations also specify that only justified use of radiation sources and equipment are allowed and the undertaking must use methods that do not involve ionizing radiation when practically possible.

11.3.3 Planned exposure situations

Control of discharges, materials for clearance
Discharges of radioactive materials are regulated under the PC Act and associated regulations. The same general regulatory framework applies to both radioactive and non-radioactive releases. Hence, there is a holistic approach to protection of human health and environment. Non-radioactive discharges are regulated by the Norwegian Environment Agency. For facilities with an authorization from both authorities, the authorizations and follow-up are coordinated and harmonized. Hence, all discharges from a facility are regulated in a harmonised and coordinated manner.

The PC Act states that any radioactive discharge or pollution is illegal unless it is below the exemption values or it is authorized by the pollution control authority (DSA, in that case of radioactive pollution and radioactive waste). Applications for permit for radioactive discharges are required to include a radiological impact assessment for the public and the environment, for instance taking into account the state of the recipient environmental medium. A permit is only granted if it has been demonstrated that the impact is low for both humans and the environment. In addition to a limit on discharges, a permit includes conditions such as a requirement to implement Best Available Techniques (BAT), to optimize protection related to the use of radiation and to limit radioactive discharges.

In making an application for a permit under the PC Act, the operator applies for a certain discharge, specified in terms of the radionuclides and activity involved. If the associated impact assessment adequately demonstrates that public exposures are insignificant and that BAT has been implemented, a permit for applied discharge will be given. A discharge permit also generally includes specified conditions, including the requirement for both source and environmental monitoring and for reporting the data to DSA annually. Most facilities are not required to report estimated doses to DSA, although the operators of nuclear facilities and some repositories are expected to do so.

Discharges of naturally occurring radioactive materials (NORM) are regulated in the same manner as other radioactive discharges. Discharges of NORM exceeding exemption values are subject to similar requirements as those of other radioactive discharges. In fact, radioactive discharges from the Norwegian oil and gas industry constitute the largest discharges of radioactive material in Norway, including the Norwegian Continental Shelf, and hence the regulation of these discharges is a priority for DSA.

Applications for permits for radioactive discharges follow the same regulatory framework but the conditions given in a discharge permits is graded commensurate with the potential for harmful effects of the discharge. Hence, a facility with a larger discharge will have stricter conditions associated with its permit compared to one with a smaller discharge, for example associated with source and environmental monitoring.

Source and environmental monitoring data are submitted to and reviewed and assessed annually by DSA. The assessment influences further work and priorities. DSA also performs independent monitoring of Norwegian marine, freshwater and terrestrial environments and estimates doses to the Norwegian public to

evaluate the impact on public and the environment (see above). Data from the independent monitoring programme and estimated doses are published as a DSA report and updated routinely.

Shielding calculations

Activities involving ionizing radiation require an authorization from DSA, according to the RP Regulations. Depending on the type of radiation source and their use, DSA is involved in approval of the location and planning, according to a graded approach. For diagnostic radiation equipment like CT, fluoroscopy, dental imaging etc. general shielding recommendations are given in DSA guideline No. 5. In the areas using the strongest sources, like radiotherapy and nuclear medicine, the undertaking must obtain a consent from DSA before they can start building a facility. As part of the application for authorization for use of such equipment, the undertaking must demonstrate that the plans comply with the dose requirements listed above by shielding calculations and design sketches. DSA carries out separate shielding calculations, based on the provided floor plan and information about the source and its use. There are guidance documents (Guideline No. 1, No 6. and No. 10) gives detailed guidance. For industrial radiography, the established practice is that the general requirement that the general public shall not be exposed to more than 0.25 mSv/y is considered to be fulfilled if the dose rate outside the site of exposure does not exceed 7.5 µSv/h (Guideline No. 6 and No.10 give detailed guidance on this topic). The shielding calculations must be verified by measurements as soon as the source is installed, and a report must be sent to DSA. For industrial radiography, dose levels at the barriers cordoning off the area should be checked with a measuring instrument, and special attention should be paid with regard to the primary beam (Guidance No. 1 for industrial radiography (issued 2004/last updated 2017). If the radiography is performed at site (not shielded enclosure), the licence for industrial radiography requires that radiography shall be performed by at least two operators to ensure that no unauthorized personnel enters the site of exposure. Thus, it ensures that the public exposure is as low as possible.

Consumer products

Smoke detectors containing less than 40 kBq Am-241 and other permitted consumer products containing radioactive substances are not subject to authorization through registration, according to the RP Regulations section 2.

Authorization through licensing for trade and leasing of radiation sources is not relevant for the smoke detectors and consumer products or for radioactive sources with total activity lower or equal to the exemption levels listed in the annex to the regulations.

The Directorate for Civil Protection is the national authority regarding product and consumer safety and has a coordinating role for competent authorities for different types of consumer products. DSA is the competent authority on matters for consumer products containing radioactive substances.

11.3.4 Existing exposure situations and control of chronic exposures (Radon, NORM and past practices) and remediation

DSA has identified the following existing exposure situations in Norway:

- → Radon, legacy sites;
- → NORM industries;
- → NORM and radon rich areas;
- → Radioactive substances in food and drinking water;
- → Areas contaminated by radioactive material deriving from previous nuclear emergencies; and
- → Exposure of aircrew to cosmic radiation.

The existing exposure situations have been evaluated to determine which public exposures are of concern from the point of view of radiation protection, and sound regulation has been secured in all the areas, with exception of aircrew.

Radon

The number of lung cancer cases attributable to radon in Norway has been estimated to be 373 cases per year (confidence interval 145-682), or around 12 % of all lung cancer cases. [Lung cancer prevalence associated with radon exposure in Norwegian homes, Hassfjell C. et al. (2017), https://tidsskriftet.no/en/2017/08/original-article/lung-cancer-prevalence-associated-radon-exposure-norwegian-homes].

Indoor radon involves several sectors of the society and is regulated in several acts: the RP Act, Working Environment Act, Public Health Act and Planning and Building Act.

DSA has issued general recommendations on radon in all buildings with high occupancy that are intended to promote optimization of exposures. Radon levels in all buildings should be as low as reasonably achievably and within recommended limits, action limit of 100 Bq/m^3 and maximum limit of 200 Bq/m^3 [The Norwegian Radiation Protection Authority's recommendations concerning radon in Norway. Stråleverninfo 25:09].

In 2009, the Norwegian Government adopted a national strategy for reducing radon exposure [Strategy for the reduction of radon exposure in Norway, Norwegian ministries, Strategy, I-1144 E, 2010], and in 2014, the strategy was extended until 2020. Since 2009, DSA has led a coordination group to follow up the strategy. The members of the Coordination Group represent relevant public authorities, including those responsible for relevant regulations:

- DSA;
- The Norwegian Labour Inspection Authority;
- The Directorate of Health;
- Norwegian Building Authority;
- Department for Planning (Ministry of Local Government and Modernization);
- The Institute of Public Health;
- National Institute of Occupational Health;
- The Norwegian State Housing Bank;
- Geological Survey of Norway; and
- Representatives from the Municipalities: Oslo and Hamar.

Under the framework of the national radon strategy, two new regulations with legally binding limit values for indoor radon concentrations have been introduced. In the RP Regulations, legally binding limit values for indoor radon in schools, kindergartens and rental accommodation were introduced in 2011. The limits are 100 Bq/m^3 (action level) and 200 Bq/m^3 (maximum level). New building regulations, with two mandatory anti-radon measures and a legally binding limit value for indoor radon, 200 Bq/m^3, were introduced in 2010.

The municipalities can perform inspections in schools, kindergartens and rental accommodation according to the Public Health Regulations. The legally binding radon limits should be taken into account in these inspections. DSA, in cooperation with the Directorate of Health, has established a system for the municipalities to perform inspections. DSA can also perform inspections. [Guide to the monitoring of radon in schools, preschools and rental properties, Guide, IS-2409, NRPA and Directorate of Health, 2016].

DSA provides radon information to the general public and to local and national authorities, primarily through the DSA website.

DSA also provides guidance on specific radon issues, like measurement protocols (dwellings, schools and kindergartens), how the municipalities can include radon when considering relevant risk factors in connection with land planning, national susceptibility maps for radon and recommendations for gravel and other materials for use under buildings.

DSA also refers to the SINTEF Building Research Design Guides for guidance on radon reduction in existing buildings and radon prevention in new buildings.
[https://www.byggforsk.no/dokument/648/tiltak_mot_radon_i_eksisterende_bygninger and https://www.byggforsk.no/dokument/326/sikring_mot_radon_ved_nybygging]

DSA has been conducting various kinds of national surveys for many years for example in existing dwellings, new built schools and kindergartens. Based on a national survey of 29 000 dwellings in 2000/2001, the average level of radon in Norwegian homes is assumed to be 88 Bq/m^3 and in 9 % of the dwellings the radon levels exceed 200 Bq/m^3 (action level at the time) [Straalevernrapport-2001-6-kartlegging-i-114-kommuner].

Prior to the change of the DSA general radon recommendations in 2009, DSA carried out an analysis of the costs related to different strategies for new and existing buildings, including setting a reference level or giving recommended radon limits. In 2010, DSA undertook an analysis of the cost related to the new radon limits included in the RP Regulations for kindergartens, schools and rental accommodation, as well as for Norwegian dwellings in general [StrålevernRapport 2010:6]. DSA also carried out an assessment of the cost-effectiveness of the existing and potential radon prevention and remediation strategies [RADPAR WP 7, Cost-effectiveness. Analysis of cost effectiveness and health benefits of radon control strategies. May 2012].

During the implementation period of the strategy, DSA has conducted several surveys. One of them was a survey of radon in newly built homes. The overall result shows a considerable reduction in radon concentrations after the implementation of the new building regulations from 2010 [Radon i nye boliger. Kartlegging i 2008 og 2016, NRPA Report 2017:3]. DSA has also carried out other radon surveys, such as an investigation of the long-term effectiveness of radon mitigation techniques in dwellings [DSA-rapport 01 2019. Varighet av radonredusernde tiltak i boliger 15 år etter tiltak], and seasonal variations in schools and kindergartens with balanced mechanical ventilation [Teknisk dokument 6 2015. Årstidsvariasjoner i radon i skoler og barnehager med balansert mekanisk ventilasjon]

A national radon map has been developed, in a cooperation between DSA and the Geological Survey of Norway (NGU) [http://geo.ngu.no/kart/radon_mobil/]. DSA conducts population surveys on regular basis, and through these surveys, DSA obtains information about the population's knowledge about radon. [NIVI Survey 2017 on the population´s knowledge and opinions on radiation protection and preparedness survey 2017].

Radon in workplaces is regulated under the Working Environment Act, which requires the employer to provide a fully satisfactory working environment. The Norwegian Labour Inspection Authority, as the responsible authority for regulating the working environment, gives guidelines and recommendations that the DSA general recommendation on radon, action level and maximum level in buildings with human occupancy (100 and 200 Bq/m^3), should be taken into account.

Guidance on radon in underground workplaces is provided by the Labour Inspection Authority. The guidelines give advice on how employers should manage radon and propose a graded approach based on given advisory exposure limits.

Reference levels and exposure limits for radon in workplaces are not legally binding (except in schools and kindergartens), and radon measurements are not mandatory, even for underground workplaces.

Legacy sites/remediation
Only a few legacy sites have been identified in Norway. The two most relevant are a disused niobium-mine in Telemark County and a site where alum shale has been illegally disposed of outside Oslo. Both are under regulation, and there is ongoing work to remediate the sites.

The PC Act states that no person may possess, do or initiate anything that may entail a risk of pollution unless it is exempted or permitted, and that if pollution has already occurred, measures must be taken to stop or remove the pollution or limit its effects. DSA may instruct the responsible person to prepare a plan for remediation which DSA may approve. The act of remediation is regulated as a planned exposure situation and thus requires a permit. The permit then ensures that the remedial and protective actions are justified and that protection is optimized. An instruction to remediate will include requirements for post-remediation control measures, if appropriate.

DSA will review and may accept plans for remediation, application for the act of remediation, annual reports and reports at every significant step in the process, including a report when the remediation is finalized and post-remediation control measures have been performed.

The PC Act provides the basis for the regulation of remediation of sites due to radionuclides as well as other pollutants. This provides a useful basis for a harmonised approach to regulation and remediation of sites that are contaminated with both radionuclides and other pollutants. Remediation of non-radioactive contaminated sites is regulated by Norwegian Environment Agency and DSA works in cooperation with the Environment Agency, where appropriate. For example, for sites contaminated with both radioactive and non-radioactive contamination, both authorities may require remediation, and the conditions and subsequent follow-up of remediation regulation are coordinated.

The regulation of remediation follows an established process comprising specific steps. A written procedure for the regulation process has, however, not yet been established. Such a procedure is under development as part of the development of the DSA integrated management system.

Exposure of aircrew to cosmic radiation
The provisions for occupational exposure to ionizing radiation, related to sections 30–34 of chapter 4 in the RP Regulations applies to aircrew. However, DSA does not actively regulate the radiation protection of aircrew.

Areas contaminated by radioactive material deriving from nuclear emergency in the past
The radiocaesium fallout from the Chernobyl nuclear accident has caused long-term challenges for traditional animal husbandry in parts of Norway. The vast pastures in mountain and forest areas cannot be decontaminated, and various other actions have instead been implemented to sustain livelihood and animal production within the permissible levels in these areas; administration of caesium binders to the animals, clean feeding of animals and live-monitoring controls before slaughter.

In Norway, there are some areas where continuous monitoring of radioactivity levels in animals and food is still performed, along with implementation of various countermeasures to sustain traditional production of milk and meat. Human internal exposure levels are measured every second year for Sami people involved in reindeer herding, which helps people make living in the affected areas sustainable. In these areas, providing guidance on safe radiation levels and practical advice on reducing contamination levels has contributed to better living conditions and increased transparency in decision making and helped to strengthen trust in authorities. For example some actions that helped management of the situation included:

a) The authorities allowed higher radiocaesium concentrations in traded reindeer meat (not consumed by the reindeer herders themselves) to relieve the serious long-term consequences of the Chernobyl

fallout for reindeer herding, based on calculation of doses to the general public from consumption of reindeer meat;

b) DSA implemented various remedial actions and procedures for live monitoring of animals to avoid slaughtering of animals that would not meet the permissible level (and should instead be clean fed); and

c) A programme of whole-body monitoring was implemented to ensure personal control of contamination levels and providing the affected population with an opportunity to speak directly to representatives of the authorities (Averted doses to Norwegian Sami Reindeer Herders after the Chernobyl accident, Skuterud and Thørring 2012; How long is long-term? Reflections based on 20 years of post-Chernobyl management in Norway, Liland and Skuterud 2013)

Control of animals and foods is now the responsibility of the Norwegian Food Safety Authority. In addition to the food control, whole-body monitoring is offered to population groups with significant intake of the most contaminated products, whose intake may result in annual ingestion doses exceeding the reference level of 1 mSv/year. The whole body monitoring is the responsibility of DSA.

11.3.5 Relevant commodities, construction materials, food and drinking water.

There are no specific statutory or regulatory reference values for radionuclides in building materials in Norway. However regulatory requirements for radon indoors can be perceived, by implication, to be a form of requirement for building materials. Furthermore, DSA has issued *a recommendation* on radioactivity limits in gravel and sand to be used under the building foundations https://www.dsa.no/publikasjon/straaleverninfo-6-2015-radon-fra-tilkjoerte-masser-under-bygg-anbefalt-grenseverdi.pdf. Regulations on technical requirements for construction works sets standard for the indoor climate. The Norwegian Building authority regulates the requirements.

Food

Norway received substantial contamination during the Chernobyl accident, and consequently regulatory limits for Cs-134 and Cs-137 have been introduced in foodstuffs placed on the market. The maximum permitted levels are given in the Ministry of Health and Care Services' Regulation on Certain Contaminants in Foodstuffs (§4) [forskrift om visse forurensende stoffer i næringsmidler (in Norwegian], which is administered by the Norwegian Food Safety Authority. The maximum permitted level in infant food and milk is 370 Bq/kg. For meat and meat products of semi-domesticated reindeer, game and wild freshwater fish the maximum permitted level is 3000 Bq/kg, while for basic foodstuffs it is 600 Bq/kg for total caesium (Cs-134 + Cs-137).

There are statutory rules that deal with national regulations on labelling semi-domesticated reindeer and game meat containing radioactive caesium between 600 and 3000 Bq/kg, which can only be traded in Norway [Forskrift om særlige regler for gjennomføringen av offentlig kontroll av produkter av animalsk opprinnelse beregnet på konsum (animaliekontrollforskriften)(in Norwegian)].

Countermeasures are still performed in contaminated districts to reduce the cesium-137 concentration in sheep and semi-domesticated reindeer below the maximum permitted levels. A separate regulation has been prepared on the division of land into free zones [Forskrift om soneinndeling ved nedforing (in Norwegian)], action zones and security zones using live animal measurements during August / September. In action zones, the average content (median value) of radioactive caesium in the meat is higher than 600 Bq per/kg, and clean feeding must be performed before the animals are slaughtered. The Security Zone is a zone type that is mainly used for cattle. In these zones, the content of radioactive caesium in the meat is on average less than 600 Bq/kg. However, special feeding measures are required to prevent levels from rising above the reference level of 600 Bq/kg. The regulations are administered by the Norwegian Food Safety Authority.

The values laid down in the current regulation were based on the dietary intake in the average population. Therefore, the Norwegian Food Safety Authority also provides dietary advice to persons with a very high consumption of natural products containing high levels of radioactive caesium, such as semi-domesticated reindeer, game and freshwater fish from areas contaminated after the Chernobyl accident. Owners/herders of semi-domesticated reindeer are particularly advised to follow this advice as they traditionally have large intake of reindeer meat.

The Norwegian Food Safety Authority advice, developed on the basis of input from DSA, specifies the following:

- → Total dietary intake of radioactive caesium should not exceed 80,000 Bq per year;
- → Total intake of pregnant and breast-feeding women and children under two years should not exceed 40,000 Bq per year; and
- → No one should eat any food containing more than 20,000 Bq/kg.

There are no statutory or regulatory limits or dietary advice for radionuclides in foodstuffs other than Cs-134 and Cs-137. However, in the event of an accident, the national Crisis Committee would have the authority to set limits for all the radionuclides as necessary, principally in accordance with guidelines of maximum levels for foodstuffs and drinking water given in the Nordic Guidelines and Recommendations 2014, 'Protective Measures in Early and Intermediate Phases of a Nuclear or Radiological Emergency.

It should be noted that there are currently discussions among the relevant authorities whether the management of radioactive caesium in food should be revised. Among the proposed changes is to repeal the regulation on maximum permitted levels in food described above. These discussions are taking place after the Norwegian Scientific Committee for Food Safety published an assessment on the health risks associated with radioactivity in food [Risk assessment of radioactivity in food].

Drinking water
National maximum permitted levels for drinking water have been laid down by the Ministry of Health and Care Services in the Regulation on Certain Contaminants in Foodstuffs [forskrift om visse forurensende stoffer i næringsmidler]. The regulations are administered by the Norwegian Food Safety Authority. The maximum permitted level of both radon and tritium in drinking water from waterworks is 100 Bq/L, and the maximum permitted total indicative dose is 0.1 mSv/year (not including tritium, K-40, radon and the short-lived radon decay products).

It has been estimated that 5-10% of the population is supplied by private wells drilled in bedrock. A national survey and other data shows that radon levels are generally higher in private wells than in public supplies, and the risk of exceeding the recommended limit for radon is quite high. Separate advice has been included on radon measurement and remediation aimed at home and cabin owners with their own water supply. For these water supplies, DSA recommends that remediation be carried out if the water has a radon concentration of more than 500 Bq/L.

Representative data for naturally occurring radionuclides other than radon in groundwater sources, such as polonium-210, lead-210, uranium and radium isotopes are not available.

11.3.6 Planned improvements

- → DSA should reassess whether regulation of consumer products should be assigned a higher priority, and further develop DSA's regulation in the area if necessary.

- → DSA should consider further development of a systematic review and assessment process that is commensurate with the radiation associated risks in accordance with an established graded approach.
- → DSA should develop procedures and/or guidance with defined steps for the regulatory control of remediation, including criteria for remediation of a site;
- → DSA should collect data on radon in buildings with high occupancy , including hospitals and care homes;
- → DSA should propose ways to strengthen incentives for members of the public to mitigate radon levels in existing homes;
- → DSA should establish training and quality control program for radon measurement and mitigation;
- → DSA should fill the knowledge gaps on radon in workplaces in order to be able to decide on the need for further regulation, possibly including legally binding limits and requirements for measurements.

11.4 CONCLUSIONS AND ACTIONS

Norway's regulatory framework, DSA's regulatory processes for the control of medical, occupational and public exposure are, in general, in compliance with IAEA recommendations.

There is an extensive body of legislation in place to safeguard human health from exposure to ionizing radiation. These requirements are given in RP Act and Regulations and the PC Act and associated regulations. The RP Regulations establish dose limits and dose constraints for occupational and public exposure and the requirements for justification and optimization. The RP Regulations also provide the regulatory basis for the control of medical exposures. Nevertheless, some improvements have been identified.

There is regulation for consumer products in Norway and legal basis in the RP Regulations. At present, there is no production of consumer products containing radioactivity in Norway and very few consumer products on the market. Consequently, DSA has not prioritized regulation of consumer products highly. It would be useful for DSA to reassess whether regulation of consumer products should be given a higher priority.

DSA generally fulfils the IAEA requirements for remediation of contaminated areas. However, the regulatory processes could be improved with the development of more systematic written procedures.

The national radon strategy is a powerful tool for the control of radon exposures in Norway. However, in existing homes, significant problems persist in areas with very high levels of radon. This situation may be improved if stronger incentives for remediation were provided.

There is a knowledge gap on the levels of radon in general workplaces and public buildings with high occupancy other than schools and kindergartens. Therefore, the basis for establishing requirements for such places has not yet been established.

11.4.1 Actions

Medical exposures

- → Provisions should be in place to ensure that all relevant parties have sufficient competence in RP in their curriculums to assume their role and responsibilities in controlling medical exposures;

→ A formal curriculum and national recognition for medical physicists should be established;

→ The role and responsibilities of the regional committees for health and research ethics (REK) for evaluation of radiation protection and justification is properly addressed in the regulatory framework for biomedical research.

→ DSA should ensure that the concept of dose constraints and release criteria within medical exposure are implemented in the RP regulatory framework.

→ DSA should address the need for IT-systems that allow for easy access to previous radiological images to reduce the need for retakes of radiological examinations.

Occupational exposures

→ A provision in the RP Regulations about authorization and accreditation of personal dosimetry laboratories in Norway should be considered.

Public exposures

→ DSA should reassess whether regulation of consumer products should be assigned a higher priority, and further develop DSA's regulation in the area if necessary.

→ DSA should propose ways to strengthen incentives for members of the public to mitigate radon levels in existing homes;

→ DSA should fill the knowledge gaps on radon in workplaces in order to be able to decide on the need for further regulation, including legally binding limits and requirements for measurements.

12 INTERFACE WITH NUCLEAR SECURITY

12.1 LEGAL BASIS

Related to GSR Part 1 (Rev. 1): Requirement 12, paragraph 2.39

The legal framework for all nuclear activities, including interfaces of nuclear safety with arrangements for nuclear security are regulated by three legal instruments (including regulations):

- → The Nuclear Energy Activities Act (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;
- → The Act on Radiation Protection and Use of Radiation (RP Act);
  - The Regulation on Radiation Protection and Use of Radiation;
- → The Security Act.

12.2 REGULATORY OVERSIGHT ACTIVITIES

Related to GSR Part 1 (Rev. 1): Requirement 12, paragraphs 2.39 – 2.40

Module 1 covers the governmental framework, including a description of the regulatory organizations. The above-mentioned Acts and regulations on nuclear and radiation protection are briefly described here.

12.2.1 **The** Nuclear Energy Activities Act

The NE Act is the basis for DSA's supervision, and licensing of the Institute for Energy Technology's (IFE's) nuclear facilities at Kjeller, Halden and Himdalen. The main points of the Act relevant for the interface between safety and security are the provisions on:

- → Licences for entry, ownership and operation of nuclear facilities, as well as permits to produce, own, store, process, transport, trade or hold nuclear substances, any other nuclear fuel or radioactive product than nuclear substances;
- → Control and oversight tasks of DSA;
- → Preparedness and control of peaceful utilization of nuclear energy.

The NE Act clearly states that DSA is the highest professional body in terms of "sikkerhet", which in the Norwegian language encompasses both safety and security. Under the Act, DSA has the authority to take the measures it considers necessary for safety and security reasons on its own initiative. Before a nuclear installation is put into operation, the operator must have a licence. Prior to such a licence being granted, DSA must prepare and submit a recommendation to the Ministry of Health and Care Services (HOD) regarding the safety standard of the plant, operating regulations, security measures and contingency plans.

The NE Act states that if an operator intends to make a change in the construction, operation or management of the plant, which differs from that which was the basis for licensing and which may affect

safety or security, the operator is obliged, before the change is made, to bring the matter before DSA for approval.

12.2.2 Regulations on the Physical Protection of Nuclear Materials and Nuclear Facilities

These regulations specify the framework for the facility operator and the authority's obligations regarding physical protection.

The purpose of the regulation is to facilitate the minimization of the potential for theft of nuclear material or from sabotage against nuclear facilities.

The regulations state that the operator must establish and maintain a system for physical protection of reactor facilities and nuclear materials that are undergoing storage, processing or transportation, which at least shall be able to withstand the threat represented by the design basis threat.

It should be noted that nuclear materials and nuclear installations that fall under the Regulations on the Physical Protection of Nuclear Materials and Nuclear Facilities are by default classified as a '*national asset*' for protection. This means that the Security Act, and regulations issued pursuant thereto, shall apply to the object. Due to the special nature of the assets, DSA has the coordinating role in the supervision and exercise of authority in respect to national assets, subject to the NE Act. The Ministry of Justice and Public Security administers the Security Act and the Act is under the supervision of the Norwegian National Security Authority (NSM), a cross-sectoral authority within the protective security services in Norway.

In 2017, the Ministry of Trade, Industry and Fisheries (NFD) asked IFE and DSA for a new valuation and damage assessment so that they could independently assess the classification of IFE as a 'national asset' (according to the Security Act) (letter to NRPA 31.10.17). HOD has decided the current classification of IFE. The initiative by NFD may indicate a more direct role in security other than to follow up. If the accountability for security resides at the NFD, which also deals with budgetary matters concerning research and development in the field of nuclear energy, it may violate an essential element of a State's nuclear security regime according to NSS 20 Chapter 3.3 (d).

12.2.3 Regulation on Possession, Transfer and Transportation of Nuclear Material and Dual-use Equipment

The regulation states that the possessor shall keep account of the amount of nuclear material in their possession. A report on the amounts and accountancy shall be sent to the safeguards authority (DSA) and the records shall be kept according to common rules for ordinary accounts.

12.2.4 The Act on Radiation Protection and Use of Radiation

The RP Act constitutes the legal basis for regulating the use of ionizing and non-ionizing radiation and radiation protection requirements, in the medical/ non-medical fields and in contingency planning. The Act itself establishes the framework, which is elaborated in the Regulations on Radiation Protection and Use of Radiation (RP Regulations).

The purpose of the RP Act is to prevent harmful effects of radiation on human health and contribute to the protection of the environment. The Act applies to any manufacture, import, export, transport, transfer, possession, installation, use and handling of radiation sources. The Act also applies to human activity

causing increased natural ionizing radiation from the surroundings, and to planning and preparedness for accidents.

The RP Act and regulations contain primarily safety regulations. There is no separate regulation that solely covers security of radioactive material. HOD has ordered DSA to assess whether there is a need to impose stricter security requirements related to the use of radioactive sources.

12.2.5 The Regulations on Radiation Protection and Use of Radiation

Pursuant to the RP Act, one set of regulations have been adopted, which covers every area of use of radiation. The sections related to both safety and security aspects are included in the general provisions and provisions on ionizing radiation in the RP Regulations.

Undertakings that are planning to perform activities involving radioactive sources, listed in the regulations, shall have an authorization from DSA. Depending on the amount of activity used or administered, the authorization certificate specifies additional conditions regarding security measures that must be in place. Undertakings that trade radioactive sources must assure that the buyer has an appropriate authorization to use the sources. Sources that do not require an authorization must be registered in the DSA source database. This requirement is also set as a condition in the authorization, for sources that require one. There is also a requirement that the undertaking must have overview and control of their sources.

The regulation also states that enterprises involved with radioactive sources, must conduct a risk assessment of the activity including consideration of both safety and security. Adequate security measures to secure the radioactive sources against theft and sabotage must be considered. The regulations also state that radioactive sources must be secured against unauthorized access.

The requirement in the RP Regulations regarding actions to ensure security of the radioactive sources are general. Hence, in the DSA guidelines measures to prevent thefts and sabotage of the sources are elaborated, for example in Guideline no.1 on Industrial Radiography, Guideline No. 9 on Control sources Guideline no. 6 on Radiotherapy. When applying for an authorization on acquisition and use of sources, the undertaking must declare compliance with the requirements in the RP Regulations. When planning for instance a radiotherapy facility containing a radioactive source for brachytherapy or external beam therapy with Gammaknife, the undertaking must provide shielding calculations and descriptions of the security measures taken before an authorization is granted. Special conditions regarding security given in the authorization are set according to a graded approach and based on the IAEA guideline for security of radioactive sources of different categories (IAEA Nuclear Security Series No.11). When inspecting a facility containing radioactive sources, security of the sources is a focus area. DSA performs inspections according to a graded approach, and prioritizes the areas using the strongest sources. DSA has regular contact and dialogue with the Radiation Protection Officers (RPOs) of the undertakings where information about relevant radiation protection topics is shared. Information about requirements for security of radioactive sources is also provided to the relevant undertakings, such as industrial radiography companies.

12.3 INTERFACE AMONG AUTHORITIES

Related to GSR Part 1 (Rev. 1): Requirement 12, paragraphs 2.39 – 2.40

Based on recommendations from the 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 among national authorities and agencies and to produce, summarize and disseminate knowledge about how best to secure nuclear installations and nuclear fuel in Norway. The members of the forum share knowledge concerning preventive security work relevant to the protection of nuclear installations and nuclear fuel. The forum is also required to identify security challenges and issues for further investigation and possible interaction.

The Government Forum consist of representatives of the Police Security Service (PST), the Norwegian National Security Authority (NSM)), the Police Directorate (POD), Local Police force, Directorate of Norwegian Customs and DSA. If necessary, other authorities and organizations may participate in the forum.

The forum discusses and share information on:

- → Security management and administrative and organizational security;
- → Personnel safety;
- → Physical security;
- → Information security;
- → Data security (Cyber security);
- → Object security;
- → Threats in general and threatens especially against nuclear installations and nuclear fuel in Norway;
- → Audit activities;
- → International cooperation in the field.

The Government Forum is required to, through dialogue, work to ensure that the security of Norwegian nuclear facilities is safeguarded, including:

- → Following up on the International Physical Protection Advisory Service (IPPAS) report;
- → Informing each other about changes in the threat;
- → Assisting in the development of Design Basis Threat (DBT);
- → Providing input to DSA in the development of contingency plans;
- → Assisting in revising regulations.

The meeting activities may vary according to needs and the current security situation but at least two meetings of the Forum are held each year.

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.

To ensure efficient, rapid management during the acute phase of a nuclear incident, and to ensure satisfactory expert management during the continuous work on preparedness, a special Crisis Committee for Nuclear Preparedness has been appointed. The King's authority pursuant to Section 16, paragraph two, of the RP Act is delegated to the Crisis Committee for Nuclear Preparedness (ref. Royal Decree of 23 August 2013). The Director General of DSA chairs the Committee.

The composition of the Crisis Committee for Nuclear Preparedness is comprised of representatives from:

- → The Norwegian Radiation and Nuclear Safety Authority;
- → The Norwegian Directorate for Civil Protection;

- → The Norwegian Armed Forces;
- → The Police Directorate;
- → The Norwegian Directorate of Health;
- → the Norwegian Coastal Administration;
- → The Norwegian Food Safety Authority;
- → The Norwegian Ministry of Foreign Affairs.

The nuclear preparedness organization has been established in order to have expertise available in order to manage nuclear incidents and to ensure the swift implementation of measures that aim to protect life, health, the environment, and other important public interests. Nuclear incidents include accidents and incidents that follow from intended actions in peacetime, from security crises, and from armed conflict.

The emergency preparedness and response (EPR) plans are described in Module 10.

12.4 CONCLUSIONS AND ACTIONS

Adequate 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.

The legal and governmental framework includes specific responsibilities for:

- → Assessment of the configuration of facilities for the optimization of safety, taking into account factors relating to security and the system of accounting for, and control of nuclear material;
- → Oversight and enforcement of arrangements for safety, security and the system of accounting for, and control of nuclear material;
- → Liaison with law enforcement agencies;
- → Integration of emergency response arrangements for both safety related and nuclear security related incidents.

There are some measures in place to ensure that safety and security measures are designed and implemented in an integrated manner, but there is room for improvements in this area.

12.4.1 Actions

- → DSA should assess whether there is a need to impose stricter security requirements related to the use of radioactive sources.
- → Clarify the role of Ministry of Trade, Industry and Fisheries concerning security and make certain that it does not violate an essential element of a State's nuclear security regime according to NSS 20 Chapter 3.3 (d).

ATTACHMENTS REFERRED TO IN THIS REPORT

egal Documents

File number	Title
[2]	Act on Nuclear Energy Activities (1972)
[1]	Act on Radiation Protection and Use of Radiation (2000)
[218]	Act on State Supervision of Health and Care Services
[15]	Act relating to procedure in cases concerning the public administration (Public Administration Act)
[142]	Act relating to Protection against Pollution and concerning Waste (1981)
[115]	Act relating to the right of access to documents held by public authorities and public undertakings (Freedom of Information Act)
[208]	Archive Depot Act
[207]	Auditor General Act
[217]	Export Licence Act
[210]	Government Employee Act
[29]	Internal Control Regulation
[133]	NRPA licence recommendation for IFE/Kjeller, including General Licence Conditions, December 2018
[20]	Nuclear Preparedness: Central and Regional Organization, Royal Decree of 23rd August 2013
[240]	Ot.prp.nr.11 (1979-1980) Regarding the Pollution Control Act
[239]	Ot.prp.nr.51 (1970-1971) Regarding the Nuclear Energy Act
[238]	Ot.prp.nr.88 (1998-1999) Regarding the Radiation Protection Act
[221]	Patient- and User Rights Act
[125, 126]	Planning and Building Act
[117]	Proposition 1 S for 2018, Chapter 747 and 3747
[206]	Public Procurement Act
[205]	Public Procurement Regulation
[134]	Regulations on Dangerous Goods on Norwegian Ships, No. 944, of 1 July 2014
[30]	Regulations on impact assessments
[5]	Regulations on Possession, Transfer and Transportation of Nuclear Material and Dual-use Equipment
[6]	Regulations on the Physical Protection of Nuclear Materials and Nuclear Facilities
[136]	Regulations on the Transport of Goods in Aircraft
[135]	Regulations on Transportation of Dangerous Goods by Land

File number	Title
[194]	Regulations relating to health, safety and the environment in the petroleum activities and at certain onshore facilities (the Framework Regulations)
[143]	Regulations relating to management and the duty to provide information in the petroleum activities and at certain onshore facilities (the Management Regulations)
[222]	Regulations relating to the Recycling of Waste
[132]	Regulatory Requirements for Decommissioning of Facilities
[4]	Security Act
[215]	Short guidelines about the Public Administration Acts chapter about disqualification
[219]	Specialized Health Services Act
[209]	The Act on duty of information, quarantine and prohibition of politicians, officials and Government employees (Quarantine Act)
[214]	The Air Traffic Act
[216]	The Fire and Explosion Protection Act
[220]	The Health Personnel Act
[204]	The Norwegian Constitution, 17 May 1814
[3]	The Regulations on Radiation Protection and Use of Radiation
[137]	The Ship Safety Act
[67]	Working Environment Act

Agreements

File number	Title
[200]	Agreement between the Ministry of Health and Care Service (HOD) and the MFA prepared in 2005
[203]	Agreement with Norsk Helsenett
[198]	Agreement with the Ministry of Environment and Climate Change (KLD) from 2005
[199]	Agreement with the Norwegian Metrology Service
[202]	Basic agreement for the civil service purpose of the agreement and intentions of the parties, 2017-2019

Directives and Allocation/Letters of Commitment

File number	Title
[213]	Allocation Letter of Commitment (118.01/118.71)
[212]	Allocation Letter of Commitment (118.21/118.70)
[31]	Directive for the Norwegian Radiation Protection Authority, Adopted by the Ministry of Health and Care Services on 1 July 2017
[32]	Letter of Commitment, Norwegian Radiation Protection Authority 2018

Strategy Documents

File number	Title
[116]	DSA Communication Strategy
[174]	DSA Inspection Strategy 2016-2020
[190]	DSA International Strategy 2019-2023
[21]	DSA Strategic Action Plan 2018-2020
[121]	Nuclear Safety and Security – The Norwegian Government's Action Plan 2018-2022
[57]	Strategy for the Reduction of Radon Exposure in Norway, Norwegian Ministries, Strategy, 2010

DSA Documents

File number	Title
[44]	Acting Management Document
[120]	Advisory Committee on Nuclear Safety and Radioactive Waste Management - Terms of Reference
[153]	Bnotat Integrated Management System
[38]	Bnotat Mapping of Competence
[41]	Bnotat Quality Management System
[40]	DSA Annual Plan
[233]	DSA Nuclear Security Culture Policy Statement
[43]	DSA Organization Decision Document 2018
[42]	DSA Organization Decision Document 2012
[25]	DSA Organization Chart 2018

File number	Title
[234]	DSA Procedure for signing letters
[232]	DSA Safety Culture Policy Statement
[83]	Guideline no. 6 on Radiotherapy
[106]	Guideline No. 9 on Control of Sources
[104]	Guideline no.1 on Industrial Radiography
[54]	Operating Plan for Department of Nuclear Safety and Environmental Radioactivity 2018
[55]	Operating Plan for Department of Radiation Applications 2018
[39]	Signature Decision Document

Other Documents

File number	Title
[56]	Ethical guidelines for the public service 2005
[11]	Integrated Safety Assessment of Research Reactors (INSARR) at the Institute for Energy Technology in 2007
[12]	Integrated Safety Assessment of Research Reactors (INSARR) at the Institute for Energy Technology in 2010 (follow-up) and 2017
[231]	National Governmental Personnel Manual
[17]	Norway's Topical Peer Review report 2017
[72]	Report to the National Assembly (Stortingsmelding) number 10 (2016-2017)

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1 DSA-rapport 01-2019
Varighet av radonreduserende tiltak i boliger

2 DSA-rapport 02-2019
Nasjonal UV- og hudkreftstrategi

3 DSA-rapport 03-2019
Stråleterapi i Norge - Generelle trender 2001-2015

4 DSA-rapport 04-2019
Årsrapport med årsregnskap 2018

5 DSA-rapport 05-2019
Nasjonal tilsynskampanje med solarievirksomheter i 2017

6 DSA-rapport 06-2019
IRRS ARM Summary Report Norway 2019

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