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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO THE

KINGDOM OF DENMARK

Copenhagen, Denmark

30 August to 8 September 2021

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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

IRRS TEAM

Integrated Regulatory Review Service

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
DENMARK

Mission dates:	*30 August to 8 September 2021*
Regulatory body visited:	*Danish Health Authority and Danish Emergency Management Authority*
Location:	*Copenhagen*
Regulated facilities, activities and exposure situations in the mission scope:	*Radiation Sources in Industrial and Medical Facilities, Waste Management Facilities, Decommissioning, Transport, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Monitoring.*
Organized by:	*IAEA*

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

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EXECUTIVE SUMMARY

At the request of the Government of the Kingdom of Denmark, an international team of senior nuclear and radiation safety experts met with representatives of the main regulatory authorities of radiation and nuclear safety, the Danish Health Authority (DHA) and the Danish Emergency Management Agency (DEMA), from 30 August to 8 September 2021, to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of Denmark´s national regulatory framework for nuclear, radiation, radioactive waste and transport safety. The review compared Denmark´s regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and Danish counterparts in areas covered by the IRRS. In addition to the main regulatory authorities, the scope of the mission included the following government ministries with regulatory responsibilities and functions: Ministry of Health: (Danish Health Authority, and its Divisions of Radiation Protection, and of Preparedness and Infectious Diseases), Danish Patient Safety Authority, Danish Health Data Authority, Danish Medicines Agency; Ministry of Defence (Danish Emergency Management Agency - Nuclear Division); Ministry of Higher Education and Science (Danish Agency for Higher Education and Science - Danish Decommissioning); Ministry of Employment (Danish Working Environment Authority); Ministry of the Interior and Housing (Danish Housing and Planning Authority); and Ministry of Business (Danish Maritime Authority).

The IRRS team consisted of 10 senior regulatory experts from 9 IAEA Member States, 3 IAEA staff members and an IAEA administrative assistant. The review covered the IRRS core modules 1 to 10, e.g., the responsibilities and functions of the government, the global safety regime, responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, regulations and guides, and emergency preparedness and response. The review also included the optional module 11 on nuclear safety and security interface. Facilities, activities and exposure situations covered included radiation source applications, waste management facilities, decommissioning, transport, occupational exposure, medical exposure, and public and existing exposure. The IRRS mission in Denmark was a full-scope Mission. The IRRS mission included discussion of three policy issues: Justification of Practices; Enhancement of Regulatory Effectiveness and Competence; and Regulatory Implications of Pandemic Situations.

The IRRS review mission included a series of interviews and discussions with key personnel at the DHA and DEMA. Several members of the IRRS team informed the representatives of the above-mentioned organisations on the purpose of the mission. Interviews were conducted and focussed mainly on responsibilities and functions of the government, on national policies and the regulatory framework for safety, the organisation and operation of the main Danish Authorities for radiation and nuclear safety, and Denmark´s contribution to the global safety regime.

The IRRS team also observed on-site inspections conducted by Danish Health Authority, Radiation Protection at various facilities: Rigshospitalet (radiotherapy and transport of radioactive materials for medical use), DTU Hevesy Laboratory, production, packaging and transport of radioactive materials, Thermo Fisher Scientific (NUNC Atom A/S) irradiator facility for sterilizing plastic materials, Danish Decommissioning, a government organisation aiming to dismantle the nuclear research facilities to receive, process and store radioactive waste from Danish users of radioisotopes (DEMA staff also participated at this specific inspection).

The IRRS team members reported very favourably on the professionalism of the DHARP and DEMA staff in the preparation and conduct of the inspections. During the site visits, open discussions took place with the management level of the authorized parties.

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

The IRRS team acknowledged as good practice the integration of relevant information from other national registers into DHARP's Customer Relationship Management system which provides an early warning on authorized parties capabilities and enables intervention prior to potential loss of control of radiation sources.

Several areas of good performances have been acknowledged including: the performance of focused inspection campaigns based on the assessment of findings from previous inspections, Denmark's capabilities and availability to provide international assistance in case of nuclear and radiological emergencies, as well as the well-established Nordic cooperation.

The IRRS team report includes a number of recommendations and suggestions to improve the Danish regulatory system and the effectiveness of the regulatory functions in line with IAEA safety standards. The IRRS team recognizes that most of its findings confirm the actions for further improvement that were identified in the self-assessment performed prior to the mission. The IRRS team concluded that the following issues are representative of those which, if addressed by the Government of Denmark, the DHA and DEMA, should further enhance the overall performance of the regulatory system.

The government should:

- develop policy and strategy for safety and revise the policy and strategy for the management of radioactive waste;
- review the framework for nuclear safety regarding Denmark plans to create new facilities for waste management.

DHA and DEMA should:

- review the regulations on public exposure, on emergency preparedness and response and on waste management in line with IAEA safety standards;
- improve their management systems.

Additionally, DHA should:

- develop a human resources plan including a training programme based on an analysis of the necessary competences and skills needed to perform its regulatory functions;
- revise or develop new guidance documents.

The IRRS team believes that the recommendations and suggestions, if acted upon, will enhance nuclear and radiation safety in Denmark.

To conclude, by inviting the IAEA to conduct this IRRS mission and providing a transparent self-assessment, the Government of Denmark and the regulatory authorities DHA and DEMA have demonstrated their commitment to continuous improvement.

The IRRS team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of the Kingdom of Denmark, an international team of senior safety experts met representatives from the Danish Health Authority, Radiation Protection from 30 August to 8 September 2021 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review Denmark's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Denmark in December 2016. An information meeting was held 5 to 7 February 2019 at the Danish Health Authority, Radiation Protection (DHARP) premises in Copenhagen to introduce the IRRS process and methodology followed by a self-assessment workshop to introduce the IAEA Self-Assessment methodology and SARIS tool. A preparatory meeting was conducted 8 to 9 October 2019 at DHARP to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Denmark and their related safety aspects and to agree the scope of the IRRS mission. As the mission had to be deferred for 2021 due to the COVID-19-pandemic, a second preparatory virtual meeting was held on 16 March 2021.

The IRRS team consisted of 10 senior regulatory experts from 9 IAEA Member States, 3 IAEA staff members and an IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response. The scope of regulatory activities reviewed during the mission covered radiation sources facilities and activities, occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning. The IRRS Mission to Denmark was a full-scope mission.

In addition, policy issues were discussed, including: "Enhancing Regulatory Effectiveness and Competence" and "Justification of Practices". Based on the IAEA "Proposal for the consideration of the Regulatory Implications of Pandemic Situations during the IRRS", a third topic on the "Effects of the pandemic in the regulatory functions for safety" was also included in the policy discussions.

DHARP together with other relevant Danish authorities conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During this full scope mission, the IRRS team performed a systematic review of all types of facilities and activities and exposure situations applicable to Denmark through review of Denmark's advance reference material, conduct of interviews with management and staff from the DHARP and Danish Emergency Management Authority (DEMA) and other relevant counterparts direct observation of regulatory activities at regulated facilities and meetings with the officials of the Danish Health Authority (DHA), DEMA and other regulated facilities and activities). It's worth to mention that most of the mission findings had been identified prior to the mission during the self-assessment process and relevant actions were included in the proposed action plan.

All through the mission the IRRS team received excellent support and cooperation from all participating organisation and mostly by the main authority the Danish Health Authority, Radiation Protection.

II. OBJECTIVE AND SCOPE

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

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

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

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements; and

k) providing feedback on the use and application IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Denmark, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 8 to 9 October 2019 and a subsequent vitual meeting on 16 March 2021. The Terms of Reference of the IRRS Mission were signed at the preparatory meeting and then revised and agreed at the end of the virtual meeting.

The preparatory meeting was carried out by the appointed Team Leader Patrick Majerus, the IAEA Coordinator Vasiliki Kamenopoulou, and the DHARP and DEMA representatives.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of DHARP represented by the Director Ms Mette Ohlenschlaeger, the Liaison Officer of this Mission Mr Kresten Breddam, Deputy Directors and staff. It was agreed that the mission would be a full-scope mission and therefore the regulatory framework with respect to the following facilities and activities and exposure situations would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning activities;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and environmental exposure control; and
- Selected policy issues.

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

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Denmark in 2021.

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

The Liaison Officer for the IRRS mission was confirmed as Mr Kresten Breddam.

Denmark provided IAEA with the advance reference material (ARM) for the review in March 2020; an update was provided in July 2021. In preparation for the mission, the IRRS team members reviewed the Danish ARM and provided their initial impressions to the IRRS Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 29 August 2021 in Copenhagen, directed by the IRRS team Leader and the IAEA Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 30 August 2021, with the participation of the senior management and staff of the Danish Health Authority and other relevant authorities. Opening remarks were made by the representative of Ministry oh Health Mr Svende Saerkjaer, the Director of DHARP Ms Mette Ohlenschlaeger and Mr Patrick Majerus, IRRS team Leader. Mr Soren Brostrom, Director General of DHA gave an overview of the Danish context, activities and the action plan prepared as a result of the pre-mission self-assessment.

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

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

The IRRS exit meeting was held on Wednesday, 8 September 2021. The opening remarks at the exit meeting were presented by Mr Soren Brostrom, Director General of DHA, and by Mr Andreas Jull Sørensen, Deputy Permanent Secretary of the Ministry of Health on behalf of the Ministry and were followed by the presentation of the results of the mission given by Mr Patrick Majerus IRRS team Leader. Closing remarks were made by by Mr Peter Johnston, the Director of the Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety and Security.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1 NATIONAL POLICY AND STRATEGY FOR SAFETY

The basic objective and principles of nuclear and radiation safety are codified in acts and executive orders, or declared in the explanatory notes, submitted to Parliament as part of drafted legislation for adoption. Explanatory notes are still available for public consultation once the act has been passed and serve as a contribution to the interpretation of the provisions in the Act.

Elements of the national policy on radiation safety are appearing in:

- The Finance Act section on tasks and objectives for the Danish Health Authority (DHA) states the long-term commitment to safety in a set of general objectives, one of them being "to ensure that workers, patients and the population as a whole, as well as animals and the environment, are protected against the harmful effects of ionising radiation"; and
- The explanatory note for The Radiation Protection Act that states that: "the act provides the basis for the protection of humans and the environment against the harmful effects of ionising radiation in connection with the use of man-made or natural radiation sources or in connection with exposure to radiation, whether planned or existing radiation situations or radiation caused by an emergency".

The main objectives of the framework for nuclear safety are described in Circular no. 9450/2020 on the application of regulatory control by the nuclear regulatory authorities regarding the nuclear safety of nuclear installations.

Although, a single comprehensive national policy document for radiation safety does not exist, several elements of a policy for safety are reflected in the legal and regulatory framework. For radiation protection, the graded approach is explicitly mentioned in the legal requirement concerning the safety assessment to be provided by applicants and inspections performed by DHA, but also reflected by the regulatory regime (exemption, notification or license) applicable to a regulated facility or activity, as well as in the legal requirements, however, there are no similar provisions in *the Nuclear Installation Act*, but nothing forbids licence conditions to follow a graded approach. Missing elements of a national policy and strategy for safety, as per GSR Part 1 (Rev.1), have been identified.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Some elements of a national policy and strategy for safety are included in the legislation, associated explanatory notes or executive orders. However, the Government has not promulgated any statement on national policy and strategy for safety expressing long term commitment to safety, including elements related to the need of provisions for human and financial resources, adequate mechanisms for taking account of social and economic developments, promotion of leadership and management for safety, safety culture.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 1, states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 (Rev. 1) para 2.3 states that** *"The National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:* *(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles;* *(b) Binding international legal instruments, such as conventions and other relevant international instruments;* *(c) The specification of the scope of the governmental, legal and regulatory framework for safety;* *(d) The need and provision for human and financial resources;* *(e) The provision and framework for research and development;* *(f) Adequate mechanisms for taking account of social and economic developments;* *(g) The promotion of leadership and management for safety, including safety culture".*
R1	**Recommendation: The Government should establish a comprehensive national policy and strategy for safety.**

1.2 ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

As Denmark is a member of the European Union (EU) and the European Atomic Energy Community (Euratom) the law and regulations have been amended in order to transpose into the national regulatory framework the Euratom Directives. EU regulations are directly applicable in Denmark.

Within the Danish national framework, in addition to *The Constitution*, the Danish legal hierarchy comprise:

- Acts (and Consolidation Acts) establishing authorities, obligations, prohibitions and framework of action. Acts are typically proposed (bills) by ministers, considered and eventually passed by Parliament. Consolidation Acts, adopted by the relevant minister, are administrative summaries of original acts and their subsequent amendments;
- Executive Orders setting administrative regulations based on one or more (consolidation) acts and issued either by a ministry or an appointed authority. An executive order may contain rules that are binding on both citizens and authorities;
- Circulars, issued by a ministerial department for example, setting administrative regulations, typically containing provisions aimed at hierarchically lower-ranking institutions such as authorities and agencies. Circulars, unlike executive orders, cannot directly bind citizens or authorised parties.

The Parliament can adopt Parliamentary Resolutions: these are policy decisions, but the Government is not constitutionally obliged to follow them. One example is *Parliamentary Resolution B103, 1985 on Energy Planning without Nuclear Energy*.

The legal framework for radiation and nuclear safety in Denmark essentially rests on *The Radiation Protection Act (2018), The Nuclear Installations Act* (1962) and *The Nuclear Safety Act* (1976, partially in force), while the general framework for emergency management, including a nuclear or radiological

emergency management, rests on *The Emergency Management Ac*t. Their provisions are further detailed in several executive orders, such as:

- Executive Order no. 669/2019 on Ionising Radiation and Radiation Protection;
- Executive Order no. 670/2019 on Use of Radioactive Substances;
- Executive Order no. 671/2019 on Use of Radiation Generators;
- Executive Order no. 993/2001 on Transport of Radioactive Material;
- Executive Order no. 315/1972 on the Peaceful Control of Nuclear Materials;
- Executive Order no. 278/1963, amended, on Protective Measures against Accidents at Nuclear Facilities;
- Executive Order no. 1762/2016 on Security Measures for Nuclear Material and Nuclear Facilities and Drafting of Security Plans.

The following three circulars are also of particular importance:

- Circular no. 9450/2020 on the application of regulatory control by the nuclear regulatory authorities regarding the nuclear safety of nuclear installations, etc;
- Circular no. 96542020 on the tasks of the Danish Health Authority and of the Danish Agency for Higher Education and Science concerning responsible and safe management of radioactive waste;
- Circular no. 9233/2021 on the Danish Health Authority's laying down rules on ionising radiation and radiation protection, on justification and optimisation, and on international cooperation.

The Radiation Protection Act, largely prepared by DHA applies to any activity and any exposure situation and by inference any facility in which an activity takes place, including nuclear facilities. This act includes the fundamental basis for a framework for safety: responsibility, justification of practices, optimization of exposure, limitation of doses, prevention of accidents and limitation of their consequences, training of workers, protective actions to reduce existing or unregulated radiation risks, administrative regimes, clearance of material, inspection, and appeals against regulatory decisions.

The act empowers DHA to lay down detailed rules for radiation protection, including requirements regarding the use of radiation sources, radiological monitoring, classification of workplaces, emergency procedures, quality assurance and categorization of workers engaged in activities in which they are or could be subject to occupational exposure. It also gives DHA the legal basis to perform inspections and to grant, amend, revoke or deny an authorization.

The types of facilities and activities regulated and their administrative regime (notification, license and license with conditions), activities and facilities exempted from regulatory control and, criteria for release from regulatory control, are further specified in *Executive Orders no. 669/2019*, *no. 670/2019* and *no. 671/2019*.

The Nuclear Installations Act complements *The Radiation Protection Act* by defining a nuclear facility, nuclear fuel and radioactive by products. It confers:

- The Minister of Health (originally the Prime Minister) the authority to grant or refuse a license for a nuclear installation or exempt an installation from such license;
- Jointly DEMA and DHA – the "Nuclear Regulatory Authorities" (NRA) – the authority to inspect and set license conditions or establish operational limits and conditions.

The few enacted sections of *The Nuclear Safety Act* entitle DEMA (initially the Danish Environmental Protection Agency) to monitor and assess factors of significance for nuclear safety, to initiate the implementation of research and development efforts for this purpose, and to cooperate with other authorities for nuclear safety matters.

Existing nuclear installations in Denmark are at a late stage of decommissioning and are operated by a single operator the Danish Decommissioning (DD). The Nuclear Installation and Nuclear Safety Acts are not appropriate to frame the siting, design, commissioning, operation, and decommissioning of a new nuclear installation and its regulatory oversight. The future updated storage facility and the disposal facility (see resolution B90) may be such new nuclear installations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The framework for nuclear safety relies on the Nuclear Installation Act, the Nuclear Safety Act and the Radiation Protection Act. The Nuclear Installation Act and the Nuclear Safety Act are not in line with IAEA safety standards.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 2 states that "***The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 2, para. 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:…"*
R2	**Recommendation: The Government should review the legal framework for nuclear safety and, as appropriate, bring it in line with the IAEA safety standards, taking into account the types of facilities present, planned or foreseen.**

Other acts also include provisions relevant to nuclear or radiation safety. For example:

- The safety of transport of radioactive substances is addressed in *The Road Traffic Act, The Railway Act, The Aviation Act, The Sea Act* and associated orders, such as the *Executive Order no. 828/2017 on Transport of Dangerous Goods by Road*;
- The framework for managing radon exposure is also set in *The Construction Act* and in *The Planning Act* and Building Regulations;
- The radiological surveillance of foodstuff and drinking water is primarily set in *The Food-Product Act.*

1.3 ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Regulatory Body for radiation and nuclear safety in Denmark is composed of several authorities, with specified roles and tasks. Although other organizations do have some regulatory roles on more specific or limited matters, the main regulatory authorities for radiation and nuclear safety are:

- The Danish Health Authority (DHA), one of eight authorities and agencies under the Ministry of Health;
- Danish Emergency Management Agency (DEMA), a civilian agency under the Ministry of Defence.

1.3.1 Regulatory body for nuclear installations

In accordance with *The Nuclear Installations Act*, once authorization is granted, the regulatory oversight of Danish nuclear facilities, all at Risø site, lies with the NRA formed by DHA and DEMA. During construction, operation and decommissioning, the nuclear installation is subject to inspection by NRA. NRA may impose such instructions as are necessary to ensure that the conditions for granting the licence are met, as well as any other conditions necessary for safety. If necessary, NRA may order that the installation ceases operation for a certain time.

DHA and DEMA jointly carry out regulatory activities (authorizing any modification of the Risø site Operational Limits and Conditions (OLC), inspection of facilities, etc) in accordance with their respective areas of authority, e.g., radiation protection and technical nuclear safety, as further specified in *Circular no. 9450/2020 on the application of regulatory control by the nuclear regulatory authorities regarding the nuclear safety of nuclear installations*.

Within DEMA, the Nuclear Department (NUC) is responsible for the oversight of nuclear facilities, physical protection of nuclear material (including during transport) and emergency preparedness for a nuclear or radiological emergency.

DEMA work is financed by the State Budget under the multi-year defence agreement, thus giving certainty on financial resources. IRRS team was informed that the resources currently allocated to the NUC department were found adequate

1.3.2 Regulatory authorities for other facilities and activities

The Radiation Protection Act and the Health Act empower DHA with the regulatory core functions:

- To promulgate regulations and issue guidance for their implementation. DHA prepares regulations issued by other authorities, such as the Ministry of Health;
- To regulate the use (manufacture, processing, holding, import, export, transfer, handling, application, control, technical safety inspection, storage, disposal, recycling, reuse, discharge and transport) of radioactive substances and ionizing radiation. Review and assessment powers are considered as an intrinsic part of the licensing process;
- To enforce *The Radiation Protection Act*, to perform inspections of use of radiation or exposure in accordance with a graded approach, to compile and publish the main results of inspection programs and inspection activities.

DHA has the duty to prohibit the use of radiation sources, revoke a license or amend the terms of a license and can require any responsible party to carry out urgent actions, which DHA deems necessary to ensure radiation protection and safety at that party's expense and risk.

Within DHA, the everyday duties for radiation protection are fulfilled by DHA Radiation Protection Division (DHARP). DHARP funding is ensured by 3 means:

- The State budget, as defined in the annual Finance Act, either with general purpose grants – distributed within DHA according to its own choices – or specific purpose grants to be exclusively used for the designated purpose;
- The annual fees payable by the authorized parties using radiation sources. The amount to be paid is established, following a graded approach, by the Minister of Health in *Executive Order no. 1111/2019*;

- Revenue funding, mostly from the provision of services of individual dose monitoring and, partly, radiation protection and safety courses organized by DHARP targeted at health professionals, future RPO's in the industrial field and other workers. This part of income is not used for funding the regulatory functions.

The annual Finance Act sets detailed grants for the upcoming fiscal year and indications for the next four years.

In 2014, DHARP documented a study on the human resources needed to perform its regulatory tasks. Its conclusion was that additional staff was needed, compared to the staffing available at that time. This study has not been updated despite the publication of the 2018 *Radiation Protection Act* and associated executive orders, even if the scope of DHARP duties has expanded and that numerous guidance have to be updated to become consistent with the current legally binding requirements or developed on new topics such as the safety assessment.

DHA routine tasks for authorizing and inspecting radiation facilities and activities are funded by the fees paid by some – but not all – of these authorized parties. However, special safety related projects (such as preparing new regulations or guidance) or activities related to non-licensed practices (e.g., radon in dwellings) have to be funded by the grants established in the State Budget for DHA, including specific purpose grants when applicable.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: For some proposed radiation safety related projects or activities, the requests addressed on behalf of the DHA for getting further funding have been rejected, affecting thus the projects or activities.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 3 states that** *"The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 4, para. 2.8 states that** *"To be effectively independent from undue influences on its decision making, the regulatory body:* *(a) Shall have sufficient authority and sufficient competent staff;* *(b) Shall have access to sufficient financial resources for the proper and timely discharge of its assigned responsibilities;…"*
(3)	**BASIS: GSG-13 para. 1.6 states that** *"The objective of this Safety Guide is to provide recommendations on meeting the requirements of GSR Part 1 on the regulatory body's core functions and the associated processes to implement those functions...The core functions … comprise:* *(a) The development and/or provision of regulations and guides;* *(b) Notification and authorization, including registration and licensing;* *(c) Regulatory review and assessment;* *(d) Regulatory inspection;* *(e) Enforcement;* *(f) Emergency preparedness and response;* *(g) Communication and consultation with interested parties."*
S1	**Suggestion: The Government should consider enhancing the existing funding**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	mechanisms to ensure that sufficient financial resources are available for DHA for the proper and timely discharge of its assigned responsibilities for radiation protection and safety taking into account the supporting justifications to be provided by DHA.

1.3.3 Independence of the regulatory authorities

The *Radiation Protection Act* explicitly states "*The Danish Health Authority exercises its functions under this Act with full professional independence*". This provision implies, among other things, that DHA is professionally independent of the governmental level. This ensures that DHA is able to make independent safety related decisions under its statutory obligations for the regulatory control of facilities and activities and that the Ministry of Health will not be able to issue instructions on the content of the regulations in relation to DHA's professional supervision.

Appeals against decisions made by DHA pursuant to *the Radiation Protection Act* or associated requirements may be lodged solely with the Minister of Health if the appeal pertains to legal technical matters. Other matters than cases of legal administrative character can only be either appealed to the Ombudsman or be subject of a lawsuit before the Danish courts.

The Ministry of Health and the DHA hold a large number of governmental and regulatory functions, including for strategic planning of hospital and associated equipment that may have implications on the use of radiation sources. However, the number of interfaces related to DHARP is small, as radiation protection is almost completely regulated by *The Radiation Protection Act;* and DHARP is the only division responsible for tasks in relation to this act. To illustrate a case where DHA is acting within several regulatory frameworks, the example of the new national Proton Therapy Centre was discussed with the IRRS team to show how the strategic planning made by DHA, the DHA decision to create the facility at a specific location and the license issued by DHARP for this new radiation facility were managed.

With respect to nuclear installations, the Ministry of Higher Education and Science is administratively responsible (as operating entity) for the nuclear facilities in Denmark: all Danish nuclear facilities are government property operated and decommissioned by DD, an institution under this ministry. There is therefore a clear separation in matters concerning the Nuclear Installations Act, as the DHA and DEMA report jointly (as NRA) to the minister of health.

Finally, *The Public Administration Act* provides rules in order to maintain impartiality, applying to all parts of public administration, including all cases subject to decisions by a regulatory authority.

1.4 RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The responsible parties are specified by *The Radiation Protection Act* such that whoever owns, holds right of use or right of disposal, is responsible for use of radiation sources or is responsible for workers using or being exposed, whether internal or external to this undertaking. *Executive Order no. 669/2019* explicitly states that "*the responsibility for fulfilling the requirements under The Radiation Protection Act, rules laid down pursuant to the Act rests with the undertaking, including where the undertaking is liable as an employer*." *The Radiation Protection Act* authorizes DHA to require persons or authorised parties having prime responsibility for the use of radiation or exposure to radiation, to comply with regulatory requirements.

The Nuclear Installations Act complements *The Radiation Protection Act* by defining a nuclear facility and setting the basic responsibilities related to safety. Pursuant to *The Nuclear Installations Act*, the license indicates the responsible holder – and the approval is granted on the terms and conditions deemed necessary for reasons of safety and other essential public interests. Hence, the regulatory body is granted comprehensive authority. Furthermore, *Circular no. 9450/2020* states that the regulatory control by NRA is intended to ensure compliance with established safety conditions.

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

Decisions under *The Radiation Protection Act* are entirely within the authority of DHA and other organizations do not have any roles in DHA decision-making process. However, other authorities do perform tasks that are tied with decisions made by the DHA. For example, according to the *Executive Order no. 993/2001*, there may be several authorities involved in authorizing a particular type of transport. In this case, however, the responsibilities of each authority are clearly specified, and authorisation typically takes place through a chain of organizationally separate decisions, rather than by the authorities negotiating a joint decision. Nevertheless, where more than one authority is involved in the decision-making process, decisions are worked out in cooperation and collaboration prior to any contact to a given interested party.

With regard to the oversight of the nuclear facilities at Risø, the IRRS team was informed from both DEMA and DHA that effective and fluid working relations were in place, at staff, manager and director general levels.

Principles or provisions for coordination and cooperation between authorities may be specified either in executive orders, official circulars or in formal (Memorandum of Understandings) or less formal agreements. Not mentioning the NRA case, examples of formal coordination mechanisms include:

- *Circular no. 9654/2020.* It allocates responsibility and provides for coordination between DHA and the Danish Agency for Higher Education and Science with respect to ensuring responsible and safe management of radioactive waste;
- *Circular no. 3151/1964.* DHA manages regulatory matters on radiation protection of workers, while the Danish Working Environment Authority (WEA) handles any other matters of worker protection. The cooperation between DHA and WEA is further based on a formal agreement of cooperation (1980);
- *Executive Order no. 993/2001*. It clarifies interfaces between DHARP and the Danish Road Traffic Authority, the Danish Civil Aviation and Railway Authority, the Danish Maritime Authority.

For emergency preparedness and response purposes, DEMA has concluded agreements with a number of governmental institutions.

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

DHA has identified the following existing exposure situations:

- Exposure to radon (workers at workplaces and members of the public in buildings);
- Exposure to external gamma radiation from building materials;
- Exposure from radionuclides in food and drinking water;
- Exposure of air and space crews to cosmic radiation.

Provisions governing such situations have been set in various Acts and associated Executive Orders.

Should an incident or accident occur, the responsibilities for review and establishing criteria for remedial actions (including for any legacy site, should any exist) are assigned to DHA in all instances where remedial actions involve management of radioactive material under regulatory control. Should a liable party not be identified, the municipalities would be the responsible organization for carrying out local remedial actions. Based on *The Radiation Protection Act*, DHA may lay down specific requirements to have the person or organization responsible for post-remediation control measures establish and maintain an appropriate programme, including any necessary provision for monitoring, to verify the long term effectiveness of the completed remedial actions.

Although disused sealed sources are to be either returned to the manufacturer/supplier, or transferred to another authorized party and, ultimately, to DD (*Executive Order no. 670/2019*), disused sealed sources are, on rare occasions, detected by monitoring systems typically installed at major scrap yards. In accordance with *Executive Order 669/2019*, DHA must be notified immediately in such cases so that appropriate actions can be readily implemented.

According to *The Finance Act*, the Minister of Defence and the Minister of Health can, in all cases of nuclear accidents or radiological emergencies, bear all necessary expenses to counteract them, including all expenses incurred in providing assistance to other countries

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

The Danish policy for safe management of radioactive waste is currently established in Parliamentary Resolutions. The Government has made initial provisions for the safe decommissioning of the nuclear facilities at the Risø site, the safe management and disposal of radioactive waste, and the safe management of spent fuel by the adoption of Parliamentary Resolution B48 (2003) and Parliamentary Resolution B90 (2018):

- Parliamentary Resolution B48 on the decommissioning of the nuclear facilities at Risø forms the basis for the current policy on decommissioning and management of the waste from decommissioning activities at the site. In this resolution, the Parliament agrees that the Government ensures the decommissioning of the nuclear facilities at Risø Research Center under the independent undertaking DD, in order to release the areas for unrestricted use within a timeframe of up to 20 years. Pursuant to this resolution, the Parliament also gives its consent that the Government starts preparing a basis for decision for a Danish final disposal facility for low- and medium-level waste.

- Parliamentary Resolution B90 on a long-term solution for Denmark’s radioactive waste aims to implement a long-term solution for Denmark's radioactive waste with a view to continue safe storage until the waste is placed in a final disposal facility. It states that long term safe management is to be achieved through storage of waste, for a period of up to 50 years, before disposal of all waste in a geological disposal facility. It facilitates – in the medium term – geological studies in order to identify possible sites for a deep geological final disposal facility in Denmark. It provides management options and decision points for management of waste streams with reference to international instruments and fundamental principles for safety. It expresses the need for assurance of sufficient human and financial resources. The resolution also includes provisions for financing of decommissioning and establishment of a deep geological final disposal facility for commissioning by 2073. Funding is provided through dedication of financial reserves in *The Finance Act* for these activities.

A national strategy (programme) was originally established in response to Parliamentary Resolution B48/2003. Executive Order no. 670/2019 specifies requirements for radioactive waste management, discharges and disposal, applicable to any use of radioactive materials subject to licensing. Circular no.

9654/2020 allocates responsibility and provides for coordination between DHA and the Danish Agency for Higher Education and Science to ensure responsible and safe management of radioactive waste and delegate tasks in relation to the design, establishment and updating of a national policy and a national programme (strategy) for safe and responsible radioactive waste management.

In 2020, a comprehensive update of the above-mentioned strategy was established to match the specific interim and end targets of Parliamentary Resolution B90/2018. The updated strategy was prepared by DHA and by the Danish Agency for Higher Education.

All radioactive waste related to the decommissioning activities as well as radioactive waste from institutional users in Denmark is stored at Risø site, within facilities operated by DD. NORM waste originating from off-shore oil- and gas activities is currently stored by authorised parties in the oil and gas industry. Management of this NORM waste until disposal is not specifically included in existing policies and strategies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although Parliamentary Resolution B90 and a national programme have been issued, Denmark has not established a comprehensive governmental policy and strategy on decommissioning and on the management of all types of radioactive waste and spent fuel, e.g., long term management of NORM waste is not yet addressed.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 10 states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel."*
(2)	**BASIS: GSR Part 5 Requirement 2 states that** *"To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments" conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste"*
(3)	**BASIS: GSR Part 5 Requirement 2, para. 3.6 states that** *"The national strategy for radioactive waste management has to outline arrangements for ensuring the implementation of the national policy. It has to provide for the coordination of responsibilities. It has to be compatible with other related strategies such as strategies for nuclear safety and for radiation protection"*
R3	**Recommendation: The Government should revise the policy and strategy for radioactive waste management so that all types of radioactive waste are included.**

1.8 COMPETENCE FOR SAFETY

The requirements for acquiring, maintaining and updating the necessary competence for ensuring appropriate radiation protection is specified in *The Radiation Protection Act*. Provisions stipulating the necessary level of competence for authorized parties and supporting providers for technical services or advice can be found in *Executive Orders no. 669/2019, no. 670/2019* and *no. 671/2019*. They provide for knowledge, skills and

competencies of radiation protection officers, radiation protection experts and medical physics experts. They also require individual workers to have sufficient knowledge, skills and competences, updated as necessary (for example when new or updated technologies and techniques are introduced), before they may work independently with radiation sources.

The IRRS team was informed that the number of qualified experts, whose advice is required according to the new legislative framework, is low for the needs identified, particularly for advising applicants or authorized parties on the safety assessments. DHA approves qualified experts based on their academic qualifications and experience, but it was pointed out that most of them are working only in the medical field, with very few available and knowledgeable in other areas.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The number of qualified experts in the country is low for the needs identified and they are mainly involved in the medical field. As such, other areas using radiation sources, e.g., industrial applications, transport have difficulties in accessing qualified experts.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 11, para. 2.36 states that** *"The government (…) shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties"*
(2)	**BASIS: GSR Part 3 Requirement 4, para. 2.46 states that** *"The relevant principal parties shall ensure that qualified experts are identified and are consulted as necessary on the proper observance of these Standards."*
(3)	**BASIS: GSR Part 1 (Rev. 1) Requirement 11, para. 2.34. states that** *"As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available".*
S2	**Suggestion: The Government should consider establishing a plan to increase the number of qualified experts in the country.**

There is a number of courses tailored to specific health profession educations and their specific needs for technological competence building. The courses are offered to people, who are enrolled in specific educational programs in order to obtain an academic degree. Beyond health professionals there is also a limited number of general – and some highly specific – courses on radiation protection and use of radioactive material available nationally, organized by DHA, by universities or private companies.

With respect to medical exposure, provisions on knowledge, skills and competencies of health professionals with responsibilities in relation to medical exposure can be found in executive orders issued under *The Authorization Act* (on the authorization of healthcare professionals and on health care practice), for instance *Executive Order no. 1252/2010 on Special Education for Medical Physicist*s.

For nuclear installations, *Circular no. 9450/2020* specifies that the NRA shall ensure that their construction, operation and decommissioning is undertaken subject to the utilization of necessary and adequate human, financial and competence resources, the latter including contractors and subcontractors, and the requisite continuing education and other necessary instruction being duly arranged for any individual who has bearing on the security and safety conditions prevailing when a nuclear installation is established, operated or decommissioned.

For civil servants, competence is typically managed at local level: it is the responsibility of the management of DHA and DEMA to ensure adequate competences for their staff. In addition, two circulars highlight the

need to acquire and maintain the necessary regulatory competence for ensuring nuclear safety, including safe management of radioactive waste: *Circulars no. 9450/2020* and *9654/2020*.

Should national courses not be available, foreign or international courses may also be of interest. For instance, in order to build competence within the field of decommissioning DHARP staff has attended courses and summer schools at the Argonne National Laboratories (Facility Decommissioning Training Course) and Cambridge (Christs College, Decommissioning and Radioactive Waste Management, Summer School). Likewise does DEMA staff participate in relevant international training and competence building. However, formal educational arrangements in the field of radiation protection and safety have not been made with other States or international organizations.

Apart from *The Radiation Protection Act* and its executive orders, there are no particular requirements and provisions for research and development programmes in radiation protection and safety. However, as an EU Member State, Denmark contributes annually to financing Euratom's research program. Research and development may also be supported by financing projects in nuclear safety through the Nordic Nuclear Safety Research forum (NKS).

1.9 PROVISION OF TECHNICAL SERVICES

Although the basis is not yet assured in an administrative regulation, DHARP provide the following national technical services by operating:

- A personal dosimetry laboratory. It is by far the largest personal dosimetry provider nationally;
- A standards dosimetry laboratory;
- A measuring laboratory for inspection and emergency samples.

This ensures the availability of technical services since not all of these services are offered by commercial or non-governmental providers.

Pursuant to *The Radiation Protection Act*, technical services are licensed if performing technical safety inspection of radiation sources subject to licensing themselves. Likewise, technical services must notify DHA if performing technical safety inspection of radiation sources subject to notification. Dosimetry services must abide to the provisions given in *Executive Order 669/2019*.

1.10 SUMMARY

A governmental, legal and regulatory framework for safety has been established, including the designation of effectively independent regulatory authorities and provisions to address exposure situations. The legislation governing radiation protection have been recently updated. Technical services for dosimetry and calibration are available, as well as some national training courses relevant for radiation protection or nuclear safety.

However, the following topics warrant further work:

- The development of a comprehensive national policy for safety and an enhanced national policy for radioactive waste management;
- The review of the adequacy of the legislation governing the safety of future nuclear installations;
- The financing of DHA safety related activities to ensure it is consistent with the needs, justified by DHA, for performing the core regulatory functions;
- The availability of an adequate number of qualified experts to provide advice to the authorized parties.

2. THE GLOBAL SAFETY REGIME

2.1 INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

In the field of nuclear and radiation safety Denmark has ratified the international conventions and agreements listed below:

- 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 the Physical Protection of Nuclear Material and its Amendment;
- Convention concerning the Protection of Workers against Ionising Radiations (No. 115);
- Convention on Environmental Impact Assessment in a Transboundary Context;
- UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters;
- Convention for the Protection of the Marine Environment of the North East Atlantic;
- Convention on the Protection of the Marine Environment of the Baltic Sea Area.

Denmark is a member of EU and Euratom. As a consequence, Denmark implements the Euratom regulations and directives and participates in several Euratom fora including:

- European Nuclear Safety Regulators Group (ENSREG) and associated Working Group 1 (on nuclear safety) and Working Group 2 (on waste management and decommissioning);
- The Article 31 Expert Group. This group advises the European Commission on radiation and nuclear safety issues, including for new or updated legally binding EU texts (such as a Directive);
- The Article 35/36 Group. This group advises the European Commission on matters related to the monitoring of radioactivity in air, water and soil;
- The Article 37 Expert Group. This group advises the European Commission on matters related to the disposal of radioactive waste.

Denmark also subsidizes Euratom's research program and takes part in two European associations: Heads of European Radiological Protection Competent Authorities (HERCA) and Western European Nuclear Regulatory Association (WENRA).

Regionally, Denmark is an active participant in the Nordic cooperation, for example by participating in the Nordic Chiefs Group, Heads of the Nordic Radiation and Safety Authorities, the Nordic Emergency Preparedness (NEP) group, the Nordic Medical Applications group and several other fora established under the Nordic Chiefs Group. In addition, the Nordic Safety Research (NKS) group, which finances research projects related to nuclear safety, radiation protection and emergency preparedness. The IRRS team acknowledges this Nordic cooperation and identified it as an area demonstrating good performance.

Denmark is a member of the Nuclear Energy Agency of the Organization for Economic Cooperation (OECD/NEA) and is an IAEA Member State. Denmark participates in the development of the IAEA Safety Standards through participation in RASSC, WASSC, TRANSSC and in EPReSC committees and has also well-established relations with the IAEA Incident and Emergency Centre and makes capacities available for IAEA Response and Assistance Network (RANET). Denmark made political commitments concerning the

Code of Conduct on the Safety and Security of Radioactive Sources and its associated Guidance on the Import and Export of Radioactive Sources and Guidance on the Management of Disused Radioactive Sources.

With regards to nuclear safety, Circular no. 9450/2020 acknowledges the value of participation in international reviews, international conferences and other international cooperation, in particular in relation to the development of international standards. Concerning radiation protection, Circular no. 9233/2021 includes specific provisions on international cooperation during emergencies or following an emergency and in a case of loss, theft or discovery of radioactive sources or radioactive material.

Finally, Danish experts take part in international peer reviews of the regulatory control and safety of facilities and activities, including EU topical peer reviews. Hosting safety related peer reviews is an obligation established in Circular no. 9450/2020 and Circular 9654/2020) - regarding waste management.

2.2 SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

DHARP and DEMA participate in several international networks, fora and cooperation projects, to both share and receive information and international experiences within Nordic countries and Europe as well as worldwide, as identified above. For example:

- DHARP participates in HERCA board and working groups and in the Nordic Working Groups established by the Nordic Chief Group: staff members from the Nordic authorities within the same working area meet up to twice a year to optimize and harmonize radiation protection and nuclear safety as well as to exchange experience;
- DEMA participate in the Nordic Chief Group and its underlying working groups, such as NEP (emergency preparedness) and NPC (public communication). It works actively with the IAEA Incident and Emergency Center. It is a member of RANET and takes part in international ConvEx exercices.

Key information gathered during these meetings are shared in DHA and DEMA, as the case may be, primarily during staff meetings. In addition, DEMA and DHA store documents related to each international meeting, including any official meeting report or meeting notes by DEMA representative in the IT system (Workzone), as required according to DEMA internal procedures. DEMA may forward relevant information to DD and DEMA may also forward information of relevance to DHA, and vice versa.

The information from these international meetings is taken into account, if deemed necessary, in the regulatory work and procedures.

With regard to emergency preparedness and response, DEMA uses ARGOS decision support system. ARGOS was originally developed by PDC-ARGOS and DEMA and has been continuously developed since 1996. DEMA takes part in PDC-ARGOS user group, consisting of emergency preparedness organizations from approximately 14 countries. This user group gives input to the development of the system, and acts as a professional network for knowledge exchange, not only about ARGOS software but also about all matters concerning emergency preparedness.

DEMA also organizes an annual meeting on emergency preparedness and response for the Nuclear Contact Group which consists of representatives from relevant sectors, facilities and governmental bodies in Denmark. The aim of the meeting is to ensure contact and collaboration between the relevant sectors. In addition to ad hoc meetings, when necessary, this annual meeting is an opportunity to share information on lessons learned.

Even if DHARP staff participate in international events and fora, the IRRS team was informed that dissemination of information could be further improved.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Information and feedback of experiences collected by DHARP staff when participating in international cooperation fora were usually shared during DHARP section or division meetings, but not systematically documented nor systematically shared with relevant stakeholders. No specific DHARP procedure or policy addresses this sharing and dissemination of such information.	
(1)	**BASIS: GSG 12 para. 3.20 states that** *"Information and knowledge are part of the corporate memory of the regulatory body and should be managed as a key resource that is embedded in the regulatory body's processes, activities and functions (see Table A-19 in the Annex)…. Effective management for safety will take into account the knowledge and information resulting from both positive and negative experiences (e.g. good practices and bad practices). Examples of information and knowledge relevant for regulatory bodies include the following:* - *…* - *Feedback of experience from other authorities and national and international bodies;* - *Operating experience in authorized facilities and activities in the State and in other States."*
(2)	**BASIS: GSG 12 para. 4.54 states that** *"The regulatory body should also serve as the national point of contact for international systems for the exchange of safety related information and should join dedicated regional organizations in order to ensure the quality of information provided to such systems and to ensure the effective communication of information to and from authorized parties and other governmental organizations."*
S3	**Suggestion: DHARP should consider improving the processes for the dissemination of information and feedback of experiences from international cooperation, for their use by DHARP, authorized parties, other authorities and stakeholders concerned.**

2.3 SUMMARY

Denmark participates in and adheres to relevant binding international conventions, treaties and other instruments related to radiation and nuclear safety. Denmark is a member of IAEA and Euratom. Denmark actively participates in groups established by these organisations, but also in more informal groups such as HERCA, WENRA and the Nordic Chiefs Group, Heads of the Nordic Radiation and Safety Authorities. Denmark is also contributing to international peer reviews.

However, an area for improvement concerns the systematically sharing, within the DHA and with relevant stakeholders, of information obtained during international cooperation activities.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Considering the regulatory infrastructure in Denmark and information provided in self-assessment, the IRRS team has focused its review on DHA and DEMA, the two main regulatory authorities which mandates are summarized in Module 1, while recognizing that other entities have also some roles in the regulatory control system.

3.1 ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

DHA has the power to structure most of its organizational divisions, counting the Executive Secretariat and the nine (9) specialized divisions, headed by a director, including DHARP. DHA is managed by a full time Executive Board consisting of the Director General, the Deputy Director General and the division Directors. Divisions are typically subdivided into Sections, each managed by a Deputy Director.

The mission of DHARP is to protect humans and environment from the harmful effects of ionizing radiation in the use of, or exposure to, human-made or natural radiation sources, whether in planned, existing or emergency exposure situations. The Director of DHARP establishes the more specific goals, objectives and plans for radiation safety and protection. DHARP is divided into two main sections handling regulatory core functions: Section for Medical uses (MED) and Section for Industrial uses, Research and Environment (IFM). Each section is responsible for authorization, review and assessment, and inspection of facilities and activities in the industrial and medical fields. An independent Project Secretariat Office provides expert assistance and professional advice to DHARP management and employees and provides professional competencies when necessary. DHARP actually employs 38 employees and 3 students. The IRRS team was informed that even if new tasks have been integrated in the regulatory system, such as exposure to radon in workplaces and dwellings, building materials and NORM facilities, the number of staff is not increased, and the regulatory functions cannot be covered adequately. **Recommendation 4 in Section 3.3** addresses this issue**.**

Within the sections of MED and IFM the responsibilities are distributed according to the type of facility to be authorized. Staff performs authorization, review and assessment, and inspection. There is no specific procedure for formally authorizing the personnel to conduct a specific activity such as inspection or authorization. **Recommendation 7 in Section 4.5** addresses this issue.

Regarding the use of its resources, DHARP applies a graded approach. For example, a graded approach is taken into account in the inspection process by the allocation of the respective manpower based on the risk of the activities and facilities.

In DEMA the Director of NUC refers to the Operations Divisions Director who in turn refers to the DG of DEMA. NUC manages the country's radiation monitoring system and jointly with DHARP inspects, reviews and assesses the nuclear facilities. In NUC there are 12 employees, 4 of them are directly involved in the regulatory processes of authorization, review, assessment and inspection of nuclear facilities, while other employees, e.g., nuclear legal experts or EPR-officers, are involved when needed. The financial resources are determined through the budget of Ministry of Defense and are established on multi-year basis. No fees are foreseen for the nuclear facilities' regulatory actions. The IRRS team was informed that the funding is appropriate taking into account the situation of the few remaining nuclear facilities in Denmark and the other activities of the Nuclear Department.

For nuclear installations, DEMA and DHA jointly carry out regulatory activities in accordance with their respective areas of authority, i.e. technical nuclear safety and radiation protection respectively, although a number of issues will constitute a matter for both regulatory authorities. In such cases, decisions are only taken when there is agreement between DHA and DEMA. In practice, most of the activities conducted during

decommissioning and waste management fall solely under *The Radiation Protection Act*, e.g., inspection, licensing, and other regulatory activities, these are therefore handled by DHA alone.

The IRRS team was informed that in the performance of the regulatory functions for nuclear installations there is an effective coordination between DEMA and DHA.

3.2 EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The Radiation Protection Act explicitly states the effective independence of DHA in the decision making process. Moreover, to avoid any conflict of interest, DHA:

- Has established policies (e.g., DHA Conflict of Interest Policy, 2020) and procedures on impartiality;
- Is requiring impartiality declarations at all managerial levels;
- Is introducing all new staff to The Public Administration Act and the principles therein.

The government has made provisions for technical services (such as calibration, individual monitoring and environmental measurements) to be available in the country. These services are provided by DHARP. However, the fact that the calibration laboratory is part of the MED Section, could potentially create a conflict of interest between the regulatory functions of the MED, responsible for the authorization and inspection of medical facilities, and the calibration laboratory which provides services to these medical facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: DHARP Section of Medical use (MED), responsible for the regulatory control of medical facilities, provides also the service of calibration of equipment. This scheme could lead to a potential conflict of interest in the exercise of DHARP's regulatory functions for medical facilities.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 13, states that** *"The government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 13, para. 2.41 states that** *"Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services."*
(3)	**BASIS: GSR Part 1 (Rev. 1) Requirement 17, para. 4.7 states that** *"The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework."*
S4	**Suggestion: DHARP should consider formal and operational separation between the calibration laboratory and the performance of the regulatory functions to avoid any potential conflict of interest while maintaining the provision of such services.**

Regarding DEMA, the effective independence is not stated in the legislation but, in practice, there is no conflict of interest with the Ministry of Defense or the relevant stakeholders such as the DD or nuclear technology organizations.

There are no special provisions for the staff recruited in DHA or DEMA coming from the authorized parties. DHA is encouraged to implement the action already identify to address this issue. DEMA is not facing such an issue as the nuclear activities in the country are very few. The potential conflict of interest in these cases is dealt with in accordance with the general legal rules on impartiality (provisions in the Public Administration Act).

3.3 STAFFING AND COMPETENCE OF THE REGULATORY BODY

The management system of DHA foresees that the necessary knowledge for radiation protection and safety is pursued through maintenance of knowledge and continuous development of the employees' competences in the field. Although DHA strategy expresses the need for adequate competences, it does not specify the necessary number of staff nor the necessary knowledge, skills and abilities in radiation protection and safety. The new staff attend training courses on fundamentals of radiation protection. Moreover, DHARP staff participates in courses in Nordic countries, European or other international workshops.

DHARP has the authority to employ the necessary staff within the allocated budget by DHA DG, and the fees from authorized parties. However, there is no specific process for developing and maintaining the necessary competence and skills of the staff. An assessment of the required personnel and the staffing levels was performed in 2014, but this process was never repeated afterwards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In DHARP there is no systematic procedure for the development and maintenance of competence and skills of staff. There is no training programme based on a gap analysis nor a human resource plan with the number of staff and their necessary qualifications and competence needed to perform its regulatory functions.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.11 states that** *"A human resource plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities."*
(3)	**BASIS: GSR Part 2 Requirement 9, para 4.21 states that** *"Senior management shall make arrangements to ensure that the organization has in-house, or maintains access to, the full range of competences and the resources necessary to conduct its activities and to discharge its responsibilities for ensuring safety at each stage in the lifetime of the facility or activity, and during an emergency response"*
R4	**Recommendation: DHARP should develop a human resource plan including a training programme based on an analysis of the necessary competences and skills needed to perform its regulatory functions.**

DEMA, has no specific training procedure in place for the new staff. The recruitment of the staff is performed based on staffing criteria relevant to the organization's needs. Experience has been gained for regulatory

control issues during the previous years when the nuclear facilities in Denmark were in operation or were being decommissioned. However, the IRRS team was informed that the decision regarding the siting of the waste management facility has been taken and that DEMA has started identifying the technical aspects for such a facility. DEMA was awarded additional funds to build competences and enhance the knowledge of the relevant technical aspects.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: DEMA currently reviews and assesses the safety of the nuclear installation being in late stage of decommissioning. To be prepared for the review and assessment of new waste management facilities, DEMA has initiated a gap analysis where it has been identified that additional competences are needed for this purpose.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities".*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18 para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
S5	**Suggestion: Taking into consideration Denmark's plans for new waste management facilities, DEMA should consider finalising the identification of competences required for the review and assessment of the safety of such facilities, and ensuring all competences are available in due time.**

3.4 LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

DHARP is assisted by a permanent external advisor who is a medical doctor specialized in the health effects of ionizing radiation and typically assists in cases where there is an investigation of exceeding the dose limit or possible overexposure of workers.

The use of external advisory support is possible through a contract agreement. However, the IRRS team was informed that as this possibility is not used, many emerging issues are handled within the Nordic countries and the European or international working groups.

The approval of dosimetry services is performed by DHARP according to a specific procedure based on the provision of the Executive Order 669.

DEMA, has not asked for external advice and, as IRRS team was informed, their knowledge on the regulatory issues has been so far considered sufficient.

3.5 LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

DHARP in exercising its regulatory functions applies several formal and informal mechanisms of liaising with authorized parties, including meetings, mail or phone correspondence, various types of proactive or reactive inspections. The authorized parties are also invited in a formal or informal consultation procedure for the development of regulations and guides. For example, the IRRS team was informed that thematic meetings were held to inform the authorized parties for the change in the legislative framework and the new requirements to be implemented within this framework. Moreover, the IRRS team was informed that the

relationship between the authority and the authorized parties is based on mutual respect and constructive dialogue.

Prior to issuing a license, the draft license is sent to the applicant for review and may, if deemed appropriate by DHARP, be modified prior to formal issuance.

Pursuant to Public Administration Act when there is a need to justify decisions for authorized parties, DHARP refers to specific sections of relevant executive orders or legislation in order to explain the nature of a non-compliance and the basis for this decision. In many cases such statements are supplemented with a reference to relevant existing guidance. The IRRS team was informed that there are not many cases where the authorized parties ask for justification of DHARP's decisions.

3.6 STABILITY AND CONSISTENCY OF REGULATORY CONTROL

DHARP has developed policies, procedures and instructions to efficiently manage its core regulatory functions. A Customer Relationship Management database system (CRM) is used which enables staff to manage the documentation submitted by the applicants as well as the records related to the authorized parties.

DHARP evaluates, at a maximum interval of 5 years, whether a revision of regulations in the field of radiation protection and safety is needed. The evaluation is to ensure that the regulations remain comprehensive and complete, consistent with the new or amended Danish legislation as well as with the European and international standards taking into account reported incidents and accidents, the development of new technologies or new applications of existing technologies, and feedback from relevant stakeholders.

The IRRS team was informed that one of the goals of DHARP is to seek the continuous improvement of the regulatory system. In this direction, DHARP organizes a series of meetings conducted every two weeks at section or higher level where the staff is informed about possible changes and can propose areas of improvement.

Regarding the prevention of subjectivity and according to a graded approach, inspections for high risk facilities are usually performed by two inspectors who can discuss and agree on potential non compliances.

The authorization process is handled by the staff member who is responsible for the specific area (for example for nuclear medicine facilities or industrial, etc). In case of a new practice or when there is a lack of specific competence, as it was the case with the new proton therapy facility, DHARP seeks information usually within the Nordic or neighboring countries.

3.7 SAFETY RELATED RECORDS

DHARP manages and maintains safety related records for the authorized parties using the following data systems:

- The CRM which contains the source registry and information on facilities and activities, such as contact details, central company registration number, location, type and category of the source, activity, type of use, data of the Radiation Protection Officer (RPO) as well as invoices, reminders, and other mailing records;
- The Dose Registration System (SRP) where information regarding external and internal doses (operational and accident) for all exposed workers are kept;
- WorkZone which contains all records related to the safety and security of facilities and activities– including safety assessments, authorizations, emergency plans, security plans, inspection records, records of events etc.

A similar system for record keeping (WorkZone) is used in DEMA.

3.8 COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The Planning Act, the Environmental Impact Assessment Act as well as the Parliamentary Resolution B90/2018 include provisions for the involvement of interested parties and for their input to decision making process. An example of implementation of such an involvement is the public consultation on the decommissioning of the nuclear facilities at Risø which took place on the 18th of May 2005 organized by DD. Upon the decision to decommission the nuclear facilities at Risø, DD agreed to inform the public about possible radiation risks associated with the decommissioning and release of cleared material. The involved authorities informed the public on the applied control regime at the same occasion.

At DHA level, a Communication Strategy has been established setting as a priority the dialogue and cooperation with stakeholders and interested parties, while at the same time maintaining the regulatory position of DHA. When new acts or orders are developed or revised, the drafts undergo a hearing process and are submitted for public consultation on a national website with public access. The purpose of this phase is to provide public with the opportunity to comment on the draft regulations. For the development of guides the procedure include a series of meetings between DHARP and stakeholders. Depending on the specific context and content, interested parties may consist of ministries, authorities, authorized parties, trade associations, unions, medical interest organizations, environmental organizations, universities.

Pursuant to the Radiation Protection Act, DHA summarizes and publishes the most important results of its inspection programs and activities. For radiation safety, these results are included in the annual report, prepared by DHARP, covering information of the core regulatory activities e.g.: the role and work of the regulatory body, the framework of regulatory control, an overview of annual doses, incidents and accidents, participation in national and international forums, courses and teaching, and publications. In addition, due to past public interest, on transport of radioactive substances a report in this respect is since that time included in the annual report.

3.9 POLICY ISSUES DISCUSSION

The policy issue discussions took place on 3rd September 2021. All staff of the DHARP, senior staff of the DEMA, a representative of the Ministry of Health and the IRRS team participated in the discussions. The host counterpart wished to collect the international experience and views of the IRRS team regarding the topics of (1) justification of practices and (2) enhancement of regulatory effectiveness and competence. A third topic on the effects of the pandemic in the regulatory functions for safety, was also included. Background information in the three topics was attached to the Summary Report of the IRRS Advance Reference Material.

Justification of practices

In Denmark, the Radiation Protection Act states that the use (including processing, holding, import, application, storage, etc.) of radiation sources and exposure shall take place solely if the health, financial, societal or other benefits of that use or exposure outweigh any detriment, i.e. it must be justified. Further, it states that the DHA is competent on making decisions on justification. DHARP have formal processes, established policies, principles and associated criteria that assist in the assessment of justification of a practice. For both new and existing practices, DHARP in the assessment considers the advantages and the disadvantages for the user of the radiation sources, for society and if relevant for individuals, but also considers the alternatives.

The topics discussed were related to the assessment of benefits weighted against the potential radiological risks concerning new technologies in industry, medicine and on the borderline between medical and non-medical imaging; experiences on the means of implementation of the justification principle were exchanged. The outcomes of discussions are:

Cooperation of various organisations and expertise is needed to cope with the justification of practices. The assessment of justification within industry and research is solely performed by DHARP although expertise not related to radiation is limited. The use of advisors would make the assessment more complete. The changes in the life-style and the use of practices with radiation for judicial purposes have brought a lot of concerns including some ethical ones.

It was discussed if the justification for use of radiation sources for age determination for medical or security purposes could be treated differently.

Some team members reported problems on the implementation of the justification of some practices, such as the panoramic radiography in dentistry, when used excessively.

Which are the pros and cons of a list with justified practices? Is there room for further international guidance on the issue?

In Luxembourg, all existing practices are justified. An internal procedure has recently been established for the assessment justification for new practices in the medical and industrial field. If needed, external advice is requested to examine specific cases. A prosecutor needs to order scanning for security purposes e.g., check for drugs in the human body. Age determination for medical or security purposes is presently not a justified practice.

In Portugal the applications are examined on a case - by - case basis. An advisory commission is formed by the regulatory body to provide the needed competence. A separate license is needed when a medical facility is used for judiciary or forensic purposes.

In France there is a separate approach for medical and non-medical practices. Justification for medical practices is according to the 3 level approach. For non-medical practices, there is no generic justification: it depends on the practice and the needs of the applicant. For low risk practices which are regulated under the notification regime justification is presumed as benefits outweigh risks. For moderate or higher risk practices, a concrete justification is needed together with an explanation why an alternative (with no radiation) method cannot be used.

In summary, regulating and implementing the justification principle is an issue of common concern that needs contribution of various expertise. There is also an understanding that the justification for use of radiation sources for age determination for medical or security purposes could be treated differently. Some team members reported problems on the implementation of the justification of some practices. Considerations on the ethical part of some practices using ionizing radiation and the added values are shared. The question on how to quantify the risks and the benefits remains open. Additional advice in the form of guidance is considered useful for the implementation of the justification principle on all its levels.

Enhancement of Regulatory Effectiveness and Competence

Denmark recognizes that establishing, maintaining and developing regulatory effectiveness and competence is a multifaceted challenge involving overarching organizational processes and goals, and introduces uncertainties regarding means of evaluating status and progress. At a national level, regulatory effectiveness may refer to the mechanisms for collaboration, exchange of experience and information etc. between entities of the regulatory body, each exercising regulatory functions within separate fields of competence. At the organizational level of each entity in the regulatory body, regulatory effectiveness may to a larger extent refer

to aspects related to in-house resource planning, knowledge management, workforce competencies and training and development, but also pertains to the "mission statement" or "strategy" of the organization. As such, it is proposed that regulatory effectiveness and competences may be addressed at an overarching, national level and at the level of individual entities constituting the regulatory body

The topics discussed were related to the development and implementation of a national policy and its associated strategy, to the assessment of competences required for the regulatory body to implement the strategy and achieve the policy goals; the experience on the means to progress towards achievement of goals and the ways to evaluate their effectiveness were also shared.

In Portugal, a public consultation mechanism could be used before defining a policy and strategy.

In Greece, the regulatory body drafts the policy and strategy; the government advises to consult all ministries involved. In general, it is a lengthy process.

In Luxembourg, a strategy and policy and strategy for safety has recently been adopted by the government. This governmental commitment strengthens the role of the regulatory body and helps to implement safety requirements.

Regarding the means to enhance efficiency it was reported that in general, it is done step by step, surveys are performed, and studies to show the progress achieved.

In Sweden, the means used are surveys, strategies, recruitments, definition of roles, assessment if the goals are achieved.

In France there may be mixed feelings on some of the performance indicators (e.g. number of inspections performed, number of incidents reported, number of licenses issued) or their use. It is believed that the indicators need to cover the whole scope of the regulatory body missions, for this reason, other indicators such as press-releases, number of guidelines issued, number of national EPR exercises etc. are also used. However, it is important to know how to correctly interpret the figures as there are limitations or bias in some indicators. For example, whether licence application are processed in due time is depending both on the initial contents, time needed to request for additional information, time needed to receive answer from the applicant. For the use of resources, prioritization is applied, however, there are may be different views within the regulatory body on the definition of priorities. There are processes to build consensus, involving various managers' committees, and, ultimately, by the Director General or the board of commissioners.

In Slovenia, the performance of the core functions and the respective numbers are used as indicators. Even if these numbers are verified annually, the message that these numbers brings is carefully analyzed.

In Greece, studies and statistics using specific mostly technical indicators for different fields indicate the evolution of the implementation of the strategies for radiation safety.

Effects of the pandemic in the regulatory functions for safety

Denmark passed through different phases of lockdown due to the COVID-19 pandemic. Initially on 11 March 2020, the government of Denmark enforced a lockdown of large parts of the Danish society. A part of this lockdown was to close many public workplaces and send all non-essential public sector employees home, including most of the personnel at DHARP. However, as most users of radiation sources in medicine, industry and research continue to work, it was essential for DHARP to continue to function as a regulatory authority. Much of the work performed at DHARP could continue from home, including communication with users and keeping the registries up to date. The challenge was mostly on performing regular inspections: DAHRP carried out a number of virtual inspections. When on-site inspections started, there were still problems of access in the hospitals. There has not been a need for any reactive inspections during this period, but had that been the case, physical inspections would have been prioritized. Some laboratories in DHARP continued to

provide services (e.g., dosimetry). Other problems that DHARP faced concerned the interactions with third parties' interactions, the increasing waste volume within facilities as the waste facility was closed and the users' training on radiation protection prior to start working with radiation sources, as the institutions providing this training were closed. Regarding EPR, all functions were up-kept, and Denmark added that security in relation to transport of nuclear material through the country was one of the issues that required physical presence at DEMA.

The participants shared their experience on how the regulatory bodies in their countries faced the consequences of the pandemic during its different phases. The discussion focused on the performance of inspections and the efficiency of the virtual inspections, meetings, and every-day work.

All reviewers reported that within their respective regulatory bodies, work from home option was introduced due to lockdown. The performance of regulatory inspections was the most affected function; virtual or hybrid inspections replaced face-to-face inspections. Additionally, it was reported that:

In Portugal the EPR was also an issue because of some difficulties to ensure the logistic needs of the response. Problems for access and maintenance within the regulatory body premises were identified. Regarding authorization, a Law to automatically extend licenses, and extension of all administrative deadlines (including radiation facilities and activities) was issued and implemented.

In France, there was specific provisions put in place to ensure staff availability for EPR (duty roaster to man ASN emergency centre). Drafting guidance and regulations from home, didn't work well as a lot of interaction is needed and this was not very effective virtually. The training of the new employees was also a challenge as usual training (in physical courses) and on-the job training were not possible: training modalities had to be modified significantly to rely mainly on self-training and some virtual meetings. The function of the review and assessment was overall well performed remotely.

In Greece, the duration of the authorizations was automatically extended. The dosimetry laboratory continued to provide services. Relevant instructions regarding the adaptions needed were continuously given to the interested parties through the regulatory body's webpage.

In Luxembourg, the dosimetry lab continued to work, the audit for accreditation purposes was performed virtually, but the implementation of the IRRS action plan was put on hold as the responsible staff were devoted to the crisis management.

In summary, the way of work within regulatory bodies was affected by the pandemic and adaptions we made. Work from home option was introduced due to lockdown. The performance of regulatory inspections was the most affected function; virtual inspections replaced face-to-face inspections. Other sectors that encountered difficulties, are the waste management, the transport of radioactive material, the meetings that need to be face-to-face, and the EPR arrangements.

3.10 SUMMARY

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

- Potential conflict of interest regarding provision of one technical service in DHARP;
- Human resource plan for DHARP;
- Identification of additional competences at DEMA for regulating new nuclear installations.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

In Denmark the core regulatory functions for radiation and nuclear safety are performed by DHA and DEMA. For this reason, the management systems of both these organizations are included in the scope of the mission. The ARM and SARIS self-assessment questionnaire included information on the management system of DHA and DHARP. Regarding DEMA, some information on its management system was given during the IRRS mission interviews.

4.1 RESPONSIBILITY AND LEADERSHIP FOR SAFETY

DHA senior managers demonstrate leadership and commitment to safety; the DG holds regular bilateral meetings with DHARP Director twice a month to discuss matters of radiation safety or framework issues.

DHARP has set goals for safety and is actively seeking information on safety performance within its area of responsibility and demonstrating commitment to improving safety performance. Individual and institutional expectations are set out in policies and procedures in the management system. The expectations are expressed by the vision and mission policy and the policy for the responsibility of the management.

Based on the institutional values developed, DHA has cultivated an open-minded and dialogue-oriented working method, both internally and externally, as a way of seeking out new methods and solutions. As it is stated in the competency management strategy, DHA promotes a learning attitude that supports a flexible development and efficient application of competences across the organization. The learning environment comprises both the individual tasks as well as the employee's interaction with colleagues, managers and external collaborators. DHA is continuously working on developing and strengthening the learning environment, including concrete methods for learning in practice, such as new assignments, peer training, mentoring, teamwork, facilitation and collegial feedback.

4.2 RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The management system of DHA is supported by the platform D4 InfoNet where its policies, procedures and instructions are managed. In addition, the CRM database is used for the management, inter alia of the authorized parties, their locations, activities, facilities, the responsible persons, radiation sources, inspections, and inspection follow-up. Furthermore, WorkZone is used to for the record keeping of each authorized party registered in CRM.

DHA senior management has established the goals and strategy in such a manner that safety is not compromised by other priorities. Moreover, the Director of DHARP has specified these goals, objectives and plans in the area of radiation safety and protection.

Although the strategic plan of DHA and the supporting documents include elements of a safety policy, the policy itself is not identified in the management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: DHA has developed a set of policies, but the organizational safety policy is not defined explicitly in the management system.	
(1)	**BASIS: GSR Part 2, Requirement 3, para 4.2 states that** *"Senior management shall be*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	responsible for establishing safety policy."
R5	**Recommendation: DHA should define its safety policy in its management system, in line with GSR Part 2.**

The DG, the deputy DG and the division Directors are actively involved in coordinating the development, application and maintenance of the management system.

The management system is governed by the Quality Forum comprised by the quality system manager, the head, the secretary and the legal adviser of the executive secretariat, and a quality coordinator from each division of the DHA. Quality Forum meetings for the entire authority are held at least 3 times per year and a course for people assigned with editorial rights is held once a year.

At DHARP level, the management team has in its agenda the management system at every third meeting – i.e. every 6 weeks, where the current issues with significance for the optimization of the management system are discussed; at least every 15 months an evaluation is carried out by the DHARP management.

4.3 THE MANAGEMENT SYSTEM

DHA has established and is applying an integrated management system. Although in its title the system addresses the quality component, the IRRS team noted that in everyday practice its elements, such as safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic ones, are integrated.

Arrangements in the management system for the resolution of conflicts arising in decision making processes are primarily embedded in the management hierarchy. NRA decisions are always taken jointly by DHA and DEMA, and are only issued when the substance and wording of the decision is agreed between the two authorities. Situations, where individual authorities have disagreements are typically managed through meetings and correspondence between the relevant authorities until solutions that satisfy both parties are reached.

The organizational structures, processes, responsibilities, accountabilities, levels of authority and regulatory body interfaces are partially specified in the management system. DHA applies procedures to manage the interface with other organizations. The IRRS team was informed that there are no provisions in the management system for managing those organizational changes that could have significant implications for safety.

The regulatory decision-making process is guided by procedures and instructions. The management system includes detailed process flowcharts and decision trees displaying the planned and systematic actions necessary to provide confidence that all requirements are met. In cases of higher technical or legal complexity, it is common for DHARP staff members to use peer or legal supervision as well as the relevant Section Leader in the decision-making process. In cases without precedent, the management or at times a member of the Executive Board may be involved in the decision-making process as relevant.

The management system reflects a graded approach based on the magnitude of the risk as well as on the complexity of the authorized parties. These are reflected by the number and detail of the procedures and instructions applicable to the areas of the medical and industrial sections.

The IRRS team noted that the documentation of the management system is not complete, since there are processes for some of the core functions, which are not documented. **Recommendation R7 in Section 4.5** addresses this issue**.** The documentation of the management system is controlled, and version tracked. Documents can only be created and revised by people assigned with editorial rights. All revised documents undergo a re-approval procedure in the same way as for the first release.

Based on the Archives Act and its executive order, the statutory requirements for retention of records are identified in the management system policy.

The IRRS team was informed that DEMA has established some elements of its management system, such as manuals, guidelines, and uses the executive order carrying out their task.

Graded approach is implemented in the authorization process and in updating of safety assessment. However, independent verification of safety assessment in line with graded approach is not addressed in Regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Some provisions of GSR Part 2 are in place in DEMA's management system. DEMA has not completed the establishment and implementation of its management system, regarding the regulatory functions for safety. It does not include all the necessary elements relevant to safety (e.g., identification of processes - authorization, inspection and review and assessment - graded approach, documentation of the records and procedures, determination of competence and resources, measurement and assessment of the effectiveness of the management system and for leadership for safety).	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 19 states that** "The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."
(2)	**BASIS: GSR Part 2 Requirement 3. states that** *"Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety."*
R6	**Recommendation: DEMA should complete the establishment and implementation of its management system regarding the regulatory functions for safety, in line with GSR Part 2.**

4.4 MANAGEMENT OF RESOURCES

Policies and procedures are in place to ensure that DHARP has in-house, or maintains access to, the range of competences and resources necessary to conduct its activities and to discharge its responsibilities. The recruitment process ensures that the candidate's education, professionalism, experience with similar jobs or subjects and other competences meet the needs of the division's competence, to the highest degree possible. The IRRS team was informed that despite of this, DHARP has not enough competences and resources

necessary to carry out all the activities of the organization, thus it is a challenge which they face. **Suggestion 1 in Section 1.3.2** addresses this issue**.**

In accordance with a management system procedure, new employees are trained to work in accordance with DHARP policies, goals and requirements in general. It is the responsibility of the Section Leader, to prepare a training program for the new employee. The training program includes introductions to DHA organization, the management system, the document management system (WorkZone) as well as the obligations arising from The Public Administration Act, and the Public Information Act. In the preparation of the training program, the suitability and availability of radiological courses are considered. During their first year of employment, new employees participate in several courses organized by DHARP concerning the fundamentals of radiation protection. The IRRS team was informed that except of the training program for the new employees, there is no formal system, and no training plan for conducting trainings for all individuals.

4.5 MANAGEMENT OF PROCESSES AND ACTIVITIES

Processes necessary for the performance of regulatory core functions are basically identified on the basis of the requirements of the legislation. These are developed, modified, managed and documented in the management system. However, the IRRS team noted, that not all processes are identified, documented or properly updated in the management system. Examples are given in the respective sub-sections of this report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Not all processes are identified, documented or properly updated in the management system of DHA, such as: the issuing of license by members of the staff of DHARP; the management of organizational changes; the evaluation of authorization applications for workplaces with high radon exposure where an authorization is required; the review and assessment of information (including the occupational exposure, waste management, decommissioning and clearance/release from regulatory control) submitted by the applicant for notification or licensing purposes; the performance of reactive inspections; sharing, evaluating and implementing lessons taken by the on-site training and exercises; conducting training to sustain the required levels of competence.	
(1)	**BASIS: GSR Part 2, Requirement 8, para 4.16. states that** *"The documentation of the management system shall include as a minimum: policy statements of the organization on values and behavioral expectations; the fundamental safety objective; a description of the organization and its structure; a description of the responsibilities and accountabilities; the levels of authority, including all interactions of those managing, performing and assessing work and including all processes; a description of how the management system complies with regulatory requirements that apply to the organization; and a description of the interactions with external organizations and with interested parties."*
(2)	**BASIS: GSR Part 2, Requirement 10, para 4.28. states that** *"Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained. It shall be ensured that process documentation is consistent with any existing documents of the organization. Records to demonstrate that the results of the respective process have been achieved shall be specified in the process documentation."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 2 Requirement 6, para 4.13. states that** *"Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed."*
(4)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24, para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures…"*
(5)	**BASIS: GSR Part 3 Requirement 19, para. 3.72 states that** *"Before authorization of a new or modified practice, the regulatory body shall require, as appropriate, and review supporting documents from the responsible parties that state:* *(a) Design criteria and design features relating to the exposure and potential exposure of workers in all operational states and in accident conditions;* *(b) Design criteria and design features of the appropriate systems and programmes for monitoring of workers for occupational exposure in all operational states and in accident conditions."*
(6)	**BASIS: GSR Part 7 Requirement 25, para 6.30 states that** *"…The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained."*
(7)	*BASIS: GSR Part 2, Requirement 9, para 4.23. states that "Senior management shall ensure that competence requirements for individuals at all levels are specified and shall ensure that training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence. An evaluation shall be conducted of the effectiveness of the training and of the actions taken."*
R7	**Recommendation: DHA should ensure that all processes relevant to safety are identified and documented in the management system.**

Consistency and effective interaction between internal processes is promoted by passing approval of management system procedures (both new and revised documents) through the same section leaders – who should thus be able to detect conflicts.

Documentation related to the processes are kept in CRM and Workzone databases. In order to avoid compromising safety, only electronic documents are valid. Physical copies are invalid as they may be out-dated. In order to avoid changes that conflict with the overall goals and objectives any change proposal must be approved by a section manager or by the quality system manager. Modifications of processes are automatically documented by the management system audit history routine. Changes of documents are subject to the same level of approval as newly developed documents.

DHA specifies the scope and standard of a required product or service and assess whether the product or service supplied meets the applicable safety requirements. DHARP retain responsibility for safety when contracting out any project and when receiving any item, product or service in the supply chain. In the management system there are requirements for purchased critical goods and services (also data handling) are specified in accordance with the overall policy for the procurement of critical goods and services. The regulatory body specifies the scope and standard of a required product or service and assess whether the product or service supplied meets the applicable safety requirements.

4.6 CULTURE FOR SAFETY

The safety culture at DHA is maintained by the continuous use of the management system, section meetings and meetings in small subgroups for the exchange of information and knowledge. All meetings are performed in an open and trustful atmosphere, supporting that all matters are discussed. During the training of new staff, the section heads give a general introduction to the concept of safety culture. The management system establishes a working environment in which staff can raise safety issues without fear of harassment, intimidation, sanction or discrimination. DHA strategy sets an example with the inclusion of "cooperation" and "presence" in the set of core values. Furthermore, the organizational willingness to self-evaluate and improve is expressed by the biannual ALT-evaluations (Work environment, Management and Well-being) as well as by the annual Staff Development Talks MUS, in which every single staff member has the opportunity to have a face-to-face conversation with the nearest leader.

Internal communication is further organized through the well working intranet system. It provides among others information on daily work, gives access to minutes from all relevant meetings (e.g. meetings between DG, DDG and divisions directors) and other relevant information related to the performance of DHARP, including safety related aspects.

4.7 MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The management system is constantly monitored for inadequate, expired or irrelevant documents, and is expanded with amendments or new documents to make it more efficient and improve safety. DHARP management evaluates the performance of its processes and procedures, including those of the accredited laboratories with an approximately 15 months interval.

The functions and use of the management system D4 InfoNet are regularly assessed by the quality system manager. In accordance with the management system policy self-assessments of the management system are conducted every 15 months by the division management.

The IRRS team was informed, that independent assessment of the management system is conducted by the national accreditation body DANAK, focusing on accredited laboratories and hence it does not fully cover the management system of DHARP. The IRRS team noted, that independent assessment of the entire management system is not conducted regularly to evaluate its effectiveness and to identify opportunities for its improvement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: Independent assessment of the management system is conducted by the national accreditation body DANAK, focusing on the laboratories and hence it does not cover the management system of DHARP in a comprehensive manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 2, Requirement 13., para 6.4. states that** *"Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any resulting significant changes shall be analysed for their implications for safety.*
S6	**Suggestion: DHA should consider conducting regularly independent assessment of the DHA management system components related to DHARP to evaluate its effectiveness and identify opportunities for improvement.**

4.8 SUMMARY

DHA has established and implements an integrated management system. The IRRS team has identified the following areas of improvement:

- The identification and documentation of all regulatory processes;
- The development of a policy statement in alignment with its safety goals;
- The performance of regularly independent assessments.

DEMA has not completed the establishment and implementation of its management system, for its regulatory functions for safety in line with GSR Part 2.

5. AUTHORIZATION

5.1 GENERIC ISSUES

The Radiation Protection Act provides for the DHA to establish regulatory requirements regarding notification and licensing of the use of radiation sources and to set license conditions. Other ministries and authorities are also responsible for a few associated legal provisions in the authorisation process, most notably on nuclear facilities for which the provision for authorization is set out in the Nuclear Installations Act.

The concepts of exemption, and authorization by "notification" or licensing broadly represent a graded approach to regulatory control based upon the levels of risk or the nature of the facility or activity. However, it is important to mention that 'notification' in the context of the Danish regulatory system is very similar to 'registration', as defined in the IAEA safety standards. Furthermore, registration, as a simpler form of authorization according to IAEA safety standards, is not recognized as such in the legal framework of Denmark. Instead, the registration process provide relevant information on radiation sources and facilities in the DHA's Registry of CRM. Depending on the type of facility and activity, different types of information need to be included.

The procedures for notification and licensing and a procedure for submission of applications for the renewal and/or amendment of the license are described in the DHA management system.

DHARP has implemented a web-based system to apply for the authorization. Within the framework of General Data Protection Regulations (GDPR) provisions, the system continuously retrieves relevant information from other national registers, e.g., register of companies and personal social security numbers. The initial form to be used by an applicant contains basic data related to the facility or activity. The system implemented by DHARP allows an applicant to select the purpose or request as either notification or a license, independent from the practice that is to be carried out. The web-based system was demonstrated to the IRRS team. Herby, the IRRS team noted that the applicant for licensee who would accidently apply for the notification, instead of applying for the license, might use sources without authorization for a short-period of time, namely a week until DHARP reviews and assesses the application and informs such applicant that a license is needed for such practice and the applicant should refrain to exercise the activity without license. The IRRS team noted a potential risk associated with the present IT solution and advised DHARP to take adequate steps to minimize such risk by addressing such possibility in the procedure on review and assessment of applications for authorization. The issue is addressed in a more general context **in Recommendation 7 in Section 4.5 and Recommendation 8 in this Section.**

The legislation provides for different types of license for the different stages in the lifetime of a facility or the duration of an activity: from cradle to grave. However, if new activities are initiated, there is no requirement that the organization shall submit to the regulatory body a notification about its intention to operate a facility or conduct an activity that involves the use of radiation sources. DHA is encouraged to assess whether a multi-step licensing process for some facilities and activities would be more appropriate.

DHA may revoke a license or amend the terms of a license for the use of radiation sources if it is deemed not to be justified or optimised from the point of view of radiation protection on the basis of technological advances or new knowledge. The license is issued for an indefinite period of time.

The applicant is required to submit a safety assessment to demonstrate safety, in support of the application to DHA. The safety assessment has to be made prior to the application for a license, as specified in the Executive Order 669/2019. It is the responsibility of the licensee to update the safety assessment in accordance with the current circumstances and activities taking place. However, the full list of documents to be submitted in support of the application for authorization, in addition to a safety assessment, is not specified in any regulatory document. This list could include, according to IAEA safety standards, information on the

responsibilities and organisational arrangements for protection and safety, staff qualification and training, design features of the facility and of radiation sources, management system, occupational radiation protection programme, emergency arrangements, management of disused sources, quality assurance programme, etc.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The applicants for authorization of a facility or an activity are required to submit a demonstration of safety in support of their application. However, the list of documents to be submitted is not specified in any guidance document.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24, para. 4.34. states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization."*
(2)	**BASIS: GSG 13, para. 3.102. states that** *"The extent of the information to be submitted to support an application for authorization should take into account the type of facility or activity. The scope of the information required should depend on the stage in the lifetime for which the authorization is being considered. The information should include…"*
R8	**Recommendation: DHA and DEMA should develop further guidance on the format and content of the documents to be submitted by the applicants in support of an application for authorization.**

The regulatory framework for clearance of material is established in the Executive Order 670. The same values of activity concentration, as for the exemption, may be applied as standard for clearance of radioactive material.

5. 2 AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Facilities for predisposal waste management (including storage) are subject to authorization in accordance with the provisions of Executive Order 670/2019, which specifies the levels of regulatory control and the requirements regarding authorization. In Denmark, a license for waste storage (as part of "use") is required as per provisions described above. Storage for more than one year may be approved by DHA (Executive Order 670). This applies to NORM waste as well.

No disposal facility is in operation in Denmark. However, paragraph 6 (11) of the Executive Order 670/2019 states that operation of a disposal facility is subject to a requirement for licensing and hence subject to requirement of undertaking a safety assessment, prior to commencement of disposal, which is requires in section 20 (1) of the Executive Order 669/2019. However, the planning, site-selection, design and construction phases may not be subject to licensing nor notification. The IRRS team has observed that the requirements regarding the development of a disposal facility for radioactive waste taking into account the different stages of the licensing process (siting, design, construction, operation, closure and post-closure) should be established. **Recommendation 12 in Section 9.2** addresses this issue**.**

In advance of any use of radiation sources or exposure subject to licensing under the Radiation Protection Act a safety assessment must be compiled, commensurate with the nature, scale and complexity of the radiation sources or exposure. This is also applicable to radioactive waste and decommissioning and is further described in section 5.1. One difference from the general description in Section 5.1 when applied to radioactive waste management facility, is that the application is used without predefined forms on the web. Also, a full list of documents which should be submitted in support of the application for authorization, in

addition to a safety assessment, is not specified in any regulatory document. **Recommendation 8 in Section 5.1** addresses this issue.

DHA may issue terms to a license, pursuant of the Radiation Protection Act. OLC have been issued for the nuclear facilities at the Risø site, pursuant of the nuclear installations act. The contents of OLC correspond to terms in a license under the Radiation Protection Act. One document is addressed to DD containing detailed requirements for the waste management facilities at Risø together with requirements for the decommissioning of the nuclear facilities at Risø. The OLC are established jointly by DHA and DEMA.

5.3 AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The applicable types of authorization for facilities and activities with radiation sources follow a graded approach including notification, license and license with conditions. Prior authorization is required from the DHA before a radiation source is acquired. The DHA is authorised to determine which facilities or activities are to be exempted from the provisions in the Radiation Protection Act and associated Executive Orders, using as the basis for this determination the criteria for exemption specified in the Executive Order 670/2019, in Annexes 2-4. Furthermore, the DHA may exempt the use of radioactive material from the requirement for licensing or notification according to defined criteria in Executive Order 670/2019. Radiation generators which are subject to the requirement of notification are listed in Executive Order 671/2019.

Prior to the use of radioactive material, a license from the DHA shall be obtained for the following specific types of use: production of radionuclides and sealed radioactive sources, deliberate administration of radionuclides to patients or animals, acceptance and performance testing of medical equipment, inspection of sealed radioactive sources and equipment, recovery of radioactive material, recycling of radioactive material, injection into geological layers and disposal. In addition, a license is required for use of radioactive material with higher activity contents and/or activity concentrations as defined in Annex 1 of Executive Order 670/2019. In case of a radiation generator, a prior license is required if the use relates to manufacture, modification, installation and technical safety inspection of radiation generators, as well as acceptance and performance testing of radiation sources for medical purposes.

For nuclear medicine and brachytherapy facilities a license is always required, as these constitute administration of radionuclides to patients. Medical applications of radiation generators require a license, except for uses of conventional dental X-ray, where notification is sufficient.

In the case of import or export of sources, DHA follows the IAEA Import and Export Guidance. An agreement from the supplier to take back the source at the end of its useful life must be in place prior to issuing a license for a high activity sealed radioactive source. As of June 2021, the total number of radiation generators in Denmark, was 10.400, including 6825 dental, 246 CT scanners, 57 accelerators for radiotherapy, 11 cyclotrons, 1 proton therapy center (3 gantries), 1 irradiator facility (50 PBq Co-60), 15 blood irradiators (2 based on x-ray), 68 industrial radiography gamma sources (224 based on x-ray) and 715 process control units.

In 2020, the total number of issued new or renewed licenses and received notifications was 347, 256 of these are new licenses/notifications whereas 91 are amendments. However, a large number of the new licenses covers previously registered radiation sources, moved into a new control category. This is a result of the implementation of the updated levels of control, introduced with the Radiation Protection Act, which transfer a large number of radiation generators from a ‘preceding control category’ to licensing.

The process addressing safety assessment has been introduced in legislation recently. Graded approach is implemented in authorization process and in updating of safety assessment. However, independent verification of safety assessment in line with graded approach is not addressed in legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Independent review of safety assessment is not foreseen in the regulations.	
(1)	**BASIS: GSR Part 4 Requirement 21 states that** *"The operating organization shall carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body."*
R9	**Recommendation: DHA should introduce a requirement for independent verification of the safety assessment in line with graded approach.**

The IRRS team was informed that an active integration of relevant data from different national systems into the DHARP CRM database is in place, which enable it to have instant information of different kinds regarding the status of authorized parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The active integration of relevant data from the National CVR Register (Central Business Register), the National CPR Register (Central Person Register), the National SOR Register (Health Services Organisations Register) and the National Authorisation Register (Register of Authorised Health Professionals) - into the DHARP CRM database provides an early warning on authorized parties capabilities that warrants additional regulatory attention and enables intervention prior to potential loss of control of radiation sources.	
(1)	**BASIS: GSR Part 3, Requirement 30, para. 3.127 states that:** "*Registrants and licensees, for sources under their responsibility, shall establish, implement and maintain:…* *(d) Provision for suitable and adequate resources (including facilities, equipment and services) for the protection and safety of members of the public, commensurate with the likelihood and magnitude of exposures.*"
(2)	**BASIS: Code of Conduct on the Safety and Security of Radioactive Sources, item 22 states that** *"Every State should ensure that its regulatory body: ….* *(b) ensures that arrangements are made for the safe management and secure protection of radioactive sources, including financial provisions where appropriate, once they have become disused;".*
(3)	**BASIS: Guidance on the Management of Disused Radioactive Sources, item 17 states that** *"Each State should ensure that the regulatory body: …..* *c. Establishes provisions for unforeseen circumstances that may require the management of a radioactive source as a disused source, such as abandonment of a radioactive source or bankruptcy of the user;"*
GP1	**Good Practice: The active integration of relevant information from other national registers into DHARP's Central Record Management provides an early warning on authorized parties capabilities that enables intervention prior to potential loss of control of radiation sources.**

5.4 AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Decommissioning activities are regulated in the same way as any other use of radioactive material. A separate license is required in order to undertake decommissioning. Since parts regarding decommissioning activities are in close relationship with waste management facilities, Section 5.2 covers the parts that are applied to both areas.

For decommissioning, the safety assessment will be based on a decommissioning plan and prepared before the decommissioning activity starts. As for the other licensing procedures, a full list of documents which should be submitted in support of the application is not specified.

The final stage of decommissioning activities for the Risø site are planned to be "green-field" and the criteria for clearance of materials and release of buildings and sites from regulatory control are provided by the Executive Order 670.

5.5 AUTHORIZATION OF TRANSPORT

DHA is the competent authority for safe transport of radioactive material in Denmark, for the specific regulations for each mode of transport according to the Executive Order no. 993/2001 on Transport of Radioactive Material and for the supervision and control of shipments of radioactive waste and spent nuclear fuel. The Executive Order993/2001 is based on the superseded edition of the IAEA Regulations for the Safe Transport of Radioactive Material, 1996 Edition, Revised, No. TS-R-1 (ST-1 Revised). The need to up-to date the Executive Order 993/2001 is addressed in **Recommendation 13 in Section 9.5.**

According to the same executive order, all applications for approvals are submitted to DHA. Application for approval of shipment by sea or by air shall be submitted to DHA that, after a technical evaluation, forwards it to the authority responsible for the mode of transport respectively the Danish Maritime Authority (sea) and the Danish Transport, Construction and Housing Authority (air) for issuing the approval.

Validation of foreign certificates of approval of package designs are issued according to the DHA management system procedure that focuses on applications regarding packages containing UF6 and non-irradiated fresh nuclear fuel elements. The procedure for the validation of a certificate of package of foreign origin should be revised to address the validations of package designs for all the packages that need a "multilateral approval".

No active manufacture or design of packages or material requiring competent authority approval is performing in Denmark. Should this change, guidelines for applicant on how to apply for approval of manufacture or design of packages for transport of radioactive material should be established as part of the compliance assurance programme. Moreover, there is no procedure in place for such an approval process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: DHA issues validations of foreign certificates of package design, that need multilateral approval. The instructions for the application and the procedure for validation concern only packaging for transport of fissile material (UF6 and non-irradiated fresh fuel).	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 33, para. 4.34 states that** "*The regulatory body shall issue guidance on the format and content of documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: Safety Guide No. TS-G-1.5 (4.2) states that** *"In determining the national programme for compliance assurance, the competent authority should take into account not only the quantities and type of packages being transported, but also the size and complexity of the industry for which it has responsibility, as well its own resources. In all circumstances, compliance assurance should include, as a minimum, the following three fundamental activities:* *(a) Activities relating to review and assessment, including the issuing of approval certificates;* *(b) Activities relating to inspection and enforcement;* *(c) Activities relating to emergency response*
(3)	**BASIS: SSR-6 (Rev.1) para 840** states that*"Multilateral approval may be by validation of the original certificate issued by the competent authority of the country of origin of the design or shipment. Such validation may take the form of an endorsement, annex, supplement, etc by the competent authority of the country through or into which the shipment is made"*
S7	**Suggestion: DHA should consider establishing a procedure for the validations of foreign certificates of package designs for all the packages that need a "multilateral approval".**

The approval of the radiation protection programme for special use of vessels should be clarified in terms of the requirements for approval and the role of the Danish Maritime Authority and the Danish Emergency Management Agency that can be involved in the process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Guidance material and a procedure to manage the approval of a radiation protection programme for special use of vessel are not in place and the role of the Danish Maritime Authority and DEMA are not defined.	
(1)	**BASIS: SSR-6 (Rev.1) para 802(d)** states that *"Competent authority approval shall be required for the following: Radiation protection programme for special use vessels (see para. 576(a))"*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33, para. 4.34 states that** "*The regulatory body shall issue guidance on the format and content of documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process"*
(3)	**BASIS: Safety Guide No. TS-G-1.5 (4.2) states that** *"In determining the national programme for compliance assurance, the competent authority should take into account not only the quantities and type of packages being transported, but also the size and complexity of the industry for which it has responsibility, as well its own resources. In all circumstances, compliance assurance should include, as a minimum, the following three fundamental activities:* *(a) Activities relating to review and assessment, including the issuing of approval certificates;* *(b) Activities relating to inspection and enforcement;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(c) Activities relating to emergency response.
S8	**Suggestion: DHA and the relevant agencies should consider establishing guidance material and a procedure to manage the approval of the radiation protection programme for special use of vessel.**

5.6 AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

DHARP assesses information on exposed workers through the information submitted in the safety assessment that is to be presented by the undertaking if it intends to carry out a practice subject to licensing. General requirements for the contents of this safety assessment are established in a DHA guide which also involves the advice of a qualified expert to determine the classification of areas, the categorization of workers, and the dose monitoring programme.

The IRRS team was informed that the number of Qualified Experts is low for the needs identified, particularly for advising authorized parties on the safety assessments. This issue is addressed in **Suggestion 2 in Section 1.8.** DHA approves qualified experts based on their academic qualifications and experience. Further, the IRRS team was informed that most of qualified experts are working only in the medical field, with very few being available and knowledgeable in other areas. This is partly due to the fact that it's a recent requirement in the regulatory framework.

Dosimetry services must be approved by DHA, under Executive Order 669/2019. For dosimetry services performing individual monitoring not based on the use of personal dosemeters, approval of the method must be obtained by DHA. Dosimetry services performing individual monitoring based on the use of personal dosimeters or supplying dosimetric data must be approved by DHA and must document that the method conforms to the requirements of ISO 17025 or equivalent standards. Procedures and requirements for evaluating monitoring programmes involving internal dosimetry have not yet been fully implemented by DHA, partly due to unavailability of human resources. **Suggestion 1 in Section 1.3, Recommendation 4 in Section 3.3 and Recommendation 7 in Section 4.5** address these issues.

There are requirements for informing, training and instructing workers, with the Radiation Protection Officer having responsibilities in such matters. Details on workers training and information is not part of an authorization application but are instead addressed in the safety assessments to be submitted.

A reference level for occupational exposure to radon in workplaces has been established, and there are requirements in place so that a notification or license is required if, once above the reference level, the effective dose exceeds 1 or 6 mSv/year, respectively. However, compliance with the reference level is not systematically verified, and therefore not enforced adequately. Furthermore, for buildings constructed before 2010, the value has the status of a recommendation. The DHA in collaboration with the Danish Housing and Planning Authority are encouraged to establish a mechanism for the employers to systematically verify compliance with the reference level for radon in workplaces.

If the exposure to radon is liable to result in an effective dose to the workers that is greater than 6 mSv/year, then it is subject to authorization from DHA. However, no procedures for evaluating such license applications or notifications have been established, due to unavailability of resources. **Recommendation 7 in Section 4.5. and Suggestion 1 in Section 1.3.** address this issue.

For air and space crews that are liable to receive an effective dose greater than 1 mSv/year from exposure to cosmic radiation in flight or in space, the requirements for justification, optimisation, dose limitation and

monitoring are applicable, including requirements for provision of information and instruction to workers and for continuous radiological monitoring of crews. Dose monitoring is carried out in accordance with a monitoring programme that is submitted by the employer and has to be approved by DHA. However, procedures for such approval of the monitoring programme are not yet established and do not yet address the methodology to be used (e.g., codes), due to lack of resources. **Recommendation 7 in Section 4.5. and Suggestion 1 in Section 1.3.** address this issue. The employer must, nevertheless, submit information on doses to DHA's Personal Dose Registry (SRP).

5.7 AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

GSR Part 3 requires patient dosimetry to be carried out under the supervision of a medical physicist. The requirements for calibration of dosemeters used for dosimetry for patients are not defined in the regulations, including the traceability to a standards dosimetry laboratory.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Within the regulations there are no provisions for calibration of dosimeters used for dosimetry of patients, including the traceability to standards dosimetry laboratory.	
(2)	**BASIS: GSR Part 3 Para 3.167 states that** *"in accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.*
R10	**Recommendation: DHA should establish provisions for the calibration of dosimeters used for patient dosimetry and for the traceability to a standards dosimetry laboratory.**

National diagnostic reference levels (DRL) for CT, nuclear medicine and conventional radiology are defined based on exposure records collected on a national level. Guidance documents on diagnostic reference levels are published on the website of DHA, except for interventional radiology, which are not prepared yet. DRLs have been established in 1996 and revised periodically since then. However, there is not a documented procedure in place for the periodic review of DRL's. This issue is addressed in **Recommendation 7 in Section 4.5**

Dose constraints for carers and comforters and criteria for the release of patients who have undergone therapeutic radiological procedures using unsealed sources are established in Executive Order no 670/2019. Dose constraints for volunteers participating in a programme of biomedical research are established in guidelines issued by the National Committee on Health Research Ethics.

Executive Orders 669/2019, 670/2019 and 671/2019 set requirements for justification and optimization of medical exposure, including pediatric and pregnant or breast-feeding patients, radiological reviews and records. The requirement that patients or their legal representatives are informed on the benefits and radiation risks to the patient before the exposure is set in the Executive Order 903/2019 (The Health law). The access of carers and comforters to radiation safety instructions is provided for, but there is no specific requirement for them to indicate an understanding of the received instructions.

Unintended or accidental exposures of patients are reported to the database of the Danish Patient Safety Authority, according to the Health Act. Based on a formal agreement, DHA has periodic access to an anonymized review of reported incidents. If the incident led to an overdose for personnel and/or a dose that may cause deterministic effects for the patient, DHA is directly informed by the undertaking. Executive Order 995/2018 has provisions that radiological medical practitioners inform patients or their legal representatives of any unintended or accidental medical exposure.

5.8 SUMMARY

DHA has an authorization system in place which covers all facilities, activities and exposure situations not explicitly exempted in the legal framework. The system is in accordance with the principle of a graded approach.

The following areas for further improvement have been identified:

- Development of guidance material on content of document to submit for an authorization;
- Establishment of a system to perform an independent verification of safety assessment according to a graded approach;
- Improvement of procedure for validation of foreign certificate of approval of packages for transport of radioactive material;
- Establishment of provisions for the calibration of dosemeters used for patient dosimetry including traceability.

6. REVIEW AND ASSESSMENT

6.1 GENERIC ISSUES

The following subsections apply to activities and facilities regulated by DHA; the case of nuclear installations is addressed in Subsection 6.2.

6.1.1 MANAGEMENT OF REVIEW AND ASSESSMENT

DHA performs review and assessment of safety relevant information to determine if the applicant for authorization or the authorized party complies with relevant regulatory requirements. Review and assessment are performed over the lifetime of a facility or activity, before an authorization is issued or changed and whenever a regulatory inspection is performed.

An applicant for authorization is required to submit relevant information using standard forms available on DHA's webpage, which list some of the required information, or in some cases by email or letter. When an application is received, the completeness of submitted information is verified.

The extent of the information to be submitted by the applicant to support the application for authorization takes into account the type of facility or activity. DHA requires that the submitted safety assessment is commensurate with the radiation risks associated with the facility or activity and is updated during the lifetime of it. The outcome of the safety assessment has to be documented and presented to DHA as part of the application process for licenses. Additional documentation, including construction and layout details of facilities, management for safety, number, competencies and training of safety related staff, classification of areas, categorization of workers, dose monitoring, work plans and instructions concerning prevention of accidents and incidents, may be submitted either as integrated into the safety assessment or as separate documents.

For submissions related to notification, DHA reviews the completeness of submitted documentation and assesses whether the submission under the requirement for notification is appropriate.

To support the implementation of the legal framework, DHA published a guide on safety assessments that explains how the safety assessment can be designed to adequately document radiation protection. The guide also addresses justification, optimisation and dose limitation. It contains four templates to facilitate the preparation of information relevant to determine compliance, namely, templates for process control through sealed sources, industrial radiography inside facilities, radiation generators for chiropractic examinations and radiation generators for veterinary medical examinations. As stated, there are other guides to be prepared. Since the publication of the guide on safety assessments, three additional templates have been prepared and made available on the website: templates for radiation generators for dental examinations, service of radiation generators and service of sealed sources.

The DHA has established a general procedure for review and assessment following a graded approach covering all facilities and activities subject to licensing. The review and assessment procedure for licensing is described in the DHA management system.

The priorities in performing reviews and assessments follow the prioritization of inspection activities, in line with the inspection policy. Similarly, the outcome of the review and assessment of an application is used as the basis for planning and conduct of inspections.

In some cases, a pre-operational inspection is carried out before issuing a license and is used for verifying if the safety framework presented by the applicant is in place and adequate. For medical exposure, such an

inspection is performed before the license is granted in the case of new facilities for nuclear medicine or radiotherapy.

6.1.2 ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

Usually, review and assessment is carried out by an individual staff member from the industrial or medical use sections at DHARP. In case of high risk practices, or a new type of practice, a review panel, comprising of several staff members at DHARP is established to review the application.

Where in-house specialized knowledge is not sufficient, DHARP may seek advice from TSO's or from an external independent expert. Any assignment of external assistance requires the approval of the management according to procedures that have been established.

Documents sent to the DHARP in support of the application are produced by the applicant in cooperation with a qualified expert. Especially in the case of high risk facilities or activities, the comprehensiveness, quality and completeness of the documents for review and assessment by the DHARP rely on the expertise provided to the licensees by the qualified experts. **Suggestion 2 in Section 1.8** addresses the issue of the availability of qualified experts in the country.

6.1.3 BASES FOR REVIEW AND ASSESSMENT

The legal framework determines that DHA is responsible for establishing rules regarding the preparation of a safety assessment. The applicant has to prepare a safety assessment that reflects the nature, extent and complexity of the intended use of radiation sources before starting the operation of any facility or activity that requires a licence. The assessment must be updated regularly, for the different stages in the lifetime of a facility, including commissioning, operation, shutdown and decommissioning.

6.1.4 PERFORMANCE OF REVIEW AND ASSESSMENT

The comprehensiveness and quality of the documents and information submitted by the applicant are verified by DHARP. This verification is partly automatically in the case of web-based submission. Findings of the review and assessment of applications are assessed; when modifications or additional measures are required from an applicant, a reference to the relevant requirement in regulations is provided. Additionally to the general processes associated with safety review, there is a need to further detail the procedures and decision criteria for the review of the safety assessments submitted by applicants; this issue is addressed in **Recommendation 7 in section 4.5**.

6.2 REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Waste management operations and associated facilities and equipment are included in the regulatory review and assessment, as described in Section 6.1. However, in this case, the application is not based on the use of web forms.

For the waste management and decommissioning operations conducted at the nuclear facilities of the Risø site, DD is required to maintain a complete set of records relating to safety, including all facilities and activities that must be updated periodically and submitted to DHARP and DEMA for review and assessment.

Furthermore, for the waste management and decommissioning operations at the Risø site, there are OLC for the operation and decommissioning activities performed by DD. The review of the OLC is performed by DHARP and DEMA whenever necessary. The review takes place before a new revision of the OLC takes place and is based on what the NRA has identified as needs of change or whatever change is proposed by

DD. IRRS team was informed that a documented procedure for this review is yet to be established, but a practical process is in place for reviewing, including co-operation between DHARP and DEMA, and consultation with DD for comments. **Recommendation R7 in Section 4.5** addresses this issue.

According to the Nuclear Installations Act, a preliminary safety report should be compiled and approved by the NRA prior to the construction of a facility. Additionally, a safety assessment has to be compiled. Pursuant to the Radiation Protection Act, hence safety assessments are evaluated by the DHARP as basis for a licensing decision. Regulatory provisions are in place that require DD to upgrade the storage facilities at the Risø peninsula and plan that the storage will last for 50 years until all radioactive waste can be placed in the disposal facility. The IRRS team was informed that, for the future, reviewing of documents for the development of disposal facilities for radioactive waste taking into consideration the different stages of the licensing process (siting, design, construction, operation, closure and post-closure) will be considered. **Recommendation 7 in Section 4.5** addresses this issue.

6.3 REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The review and assessment is conducted as part of the authorization process. For facilities and activities for which licence is required, the regulations require that a safety assessment includes all aspects of safety and radiation protection and it is kept up to date. DHARP guides specify when this updating is needed (mostly after changes occur). The information submitted is reviewed and assessed by DHARP.

The so-called complex or regular inspections, conducted in line with the annual inspection plan and performed on-site, are used as an additional source of information for the review and assessment.

The IRRS team noted that comprehensive procedures on how to perform review and assessment of all information relevant to determine whether facilities and activities comply with regulatory requirements are not in place. This issue is addressed in **Recommendation 7 in Section 4.5.**

Furthermore, as the radiation protection regulations were recently updated, with these enhanced requirements for review and assessment, this task requires a sufficient number of qualified and competent staff. The issue is addressed in **Recommendation 4 in Section 3.3**.

6.4 REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Decommissioning requires a license and a safety assessment as described in Section 5.4 and the reviewing process of these are performed in-line with the description of reviews in Section 6.1 aside from the fact that the application is not using web forms. The decommissioning plan and safety assessment for decommissioning are reviewed by DHARP or the NRA in case of nuclear facilities. The final decommissioning report will be reviewed by DHARP in order to evaluate if the stated end-point for decommissioning is reached.

The different decommissioning projects or sub-project descriptions that are performed at the Risø site have specific working plans which DHARP has not explicitly reviewed but use as a base of information for inspections which ensure the status of the decommissioning process and timeline.

The OLC of DD for the decommissioning activities are reviewed, as described in Section 6.2.

6.5 REVIEW AND ASSESSMENT FOR TRANSPORT

Applications for the approvals are reviewed by DHARP according to the management system procedures. Applications for transport as a special arrangement are reviewed according to a specific procedure. The documentation to be provided by the applicant is in accordance with the modal international regulations for

road, rail, and sea transport, and is reviewed and assessed by DHARP, following the provisions in the international requirements ensuring that the scope of and the requirements to obtain approvals of special arrangement are in line with these. Applications for validation of package design certificates of foreign origin are reviewed according to a specific procedure as well. The process for issuing certificates of validation does not foresee an independent assessment of the package safety report, but includes checks of package certificate, verification that the payload is within the authorized content, the insurance coverage, transport route and dates. When transport carries fissile material of category I, II or III the validation of the certificate of the package design is sent to the DEMA for the approval of the transport security plan.

Approvals of package design and material are not covered by existing procedures as manufacture of models or prototypes of packaging or material do not take place in Denmark. Reassessment of transport notifications and approvals, as required by the Executive Order 993/2001, is carried out along with inspections of companies transporting radioactive material.

Doses of workers, including drivers, are communicated to the SRP. IAEA Regulations SSR-6 (Rev.1) require that the competent authority shall arrange periodic assessments of the radiation doses to the public due to the transport of radioactive material. DHARP is encouraged to perform such periodic assessments to evaluate the effectiveness of the Transport Regulations as part of the compliance assurance activities. This will also contribute to achieving and maintaining public confidence.

6.6 REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

Occupational exposure issues, including classification of areas, categorization of workers, dose monitoring programme, especially in connection with the need for individualized measurement programs, are addressed in safety assessments that must be submitted with the application for a license. The IRRS team was informed that DHARP does not have comprehensive procedures for the review of the safety assessment submitted by the applicant. This issue is addressed in the **Recommendation 7 in Section 4.5.**

The IRRS team acknowledged that DHARP has procedures in place within SRP to, review every 2 weeks and, if needed, take actions with the authorized parties, regarding the occurrence of anomalous dose measurements in any of their workers that are reported to the database. IRRS team considers this process of the systematic review of occupational doses at short intervals as an area of good performance.

In workplaces where indoor exposure to external gamma radiation from building materials exceeds the reference level, optimising measures need to be taken to reduce the exposure as much as is reasonably achievable. Before marketing building materials emitting gamma radiation, which may cause doses exceeding the reference level, the activity concentration of the radionuclides concerned must be determined and the measurement results and the corresponding activity concentration index must be made available to DHARP. Given that it is a recent requirement, and due to the unavailability of resources, DHARP is still developing procedures for the review and assessment of this information. **Recommendation 7 in Section 4.5** addresses this issue.

Additionally, it was noted that studies supporting the reference level for radon in workplaces require an update. The IRRS team encourages DHARP to update these studies, as is addressed as well in **Suggestion 11 in Section 9.8**.

6.7 REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

The review and assessment for medical exposure facilities and activities is performed by the Medical Applications Section of DHARP.

To assess the optimization of patient doses in radiology, DHARP collects information on diagnostic reference levels (DRL) for each relevant facility and reviews this information. Those facilities that significantly exceed the national DRL are identified as requiring an inspection. DHARP has issued guides for clinical professionals for the collection and assessment of doses to patients.

During inspections, DHARP reviews a series of factors relevant to the medical exposure control: the procedures for evaluation of justification, the referral procedure and content, the guides for referrals, the availability and appropriateness of procedures for quality control of sources and equipment, a regular performance of required quality control tests, authorized parties' tests (e.g., acceptance, performance and constancy testing), results of internal audits and other reviews, and finally the delegation of responsibilities within the organization/hospital/department is evaluated to verify whether all relevant duties and functions as specified in relevant executive orders are duly taken into consideration.

DHARP has an agreement with the Danish Patient Safety Authority whereby it has access to performing periodic reviews of adverse incidents with implications for the field of radiation protection to draw learning points from the radiation protection aspects of those incidents. However, this information consists only of general observations and incident class statistics. DHARP has the opportunity to categorises the incidents to identify general trends and adapt its inspection programme and procedures accordingly. The review of incidents is usually performed three times a year.

6.8 REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Issues on public exposure, including review and assessment, are addressed in further detail in section 9.8.

6.9 SUMMARY

DHARP performs review and assessment of safety relevant information to determine authorized parties and applicants' compliance with safety requirements. Review and assessment are performed over the lifetime of a facility or activity, before an authorization is issued or updated and whenever a regulatory inspection is performed.

DHARP has established general procedures for review and assessment following a graded approach.

However, the establishment of comprehensive processes and procedures for review and assessment covering planned and existing exposure situations is an area for further improvement.

The systematic review of occupational doses at short intervals that DHARP performs, allowing quick feedback to the authorised parties, is considered as an area of good performance.

7. INSPECTION

7.1 GENERIC ISSUES

The Act on Ionising Radiation and Radiation Protection empowers DHA to conduct inspection "of the use of radiation sources and exposure". The Nuclear Installation Act empowers DEMA and DHA to perform and carry out inspections of nuclear facilities and activities. Those Acts also ensure DHA and DEMA unlimited access to nuclear installations, and for DHA unlimited access to facilities and activities with radiation sources. DHARP conducts inspections of facilities and activities with radiation sources as planned in the annual programme which is prepared in line with the relevant DHARP procedure. The facilities or activities to be inspected are identified in the annual plan. IRRS team was informed that the majority of inspections are announced, however unannounced inspections are conducted when there is a particular reason to do so, e.g., checking if the RPO is available during summer holidays. Reactive inspections are conducted as appropriate. Several different types of inspections are defined in the Inspection Strategy, e.g., general inspections, administrative inspections, complex inspections and follow-up inspections. Administrative inspections are not conducted on site, but data on undertaking's sources are inspected. During complex inspections the undertaking's administrative tools such as management system, staff education and qualifications are inspected. Usually, the inspections are announced about few weeks before the on-site visit using e-mail. Complex inspections are announced by secure e-mail. As a rule, two inspectors conduct complex inspections.

The annual plan includes inspections to be conducted by both DHARP sections, MED and IFM; 150 inspections have been performed in 2019. Graded approach is demonstrated as the plan is addressing high risk facilities and activities. Four on-site inspections per year are foreseen to inspect industrial irradiators and three inspections of radiotherapy facilities selected among eight such departments. 25 on-site inspections of industrial radiography are planned inspections. IRRS team received data on on-site inspections of industrial radiography, e.g., in 2017 there were 19 inspection, 16 in 2018 and 16 in 2019. Due to pandemic only 12 inspections were conducted in 2020.

DHARP procedure for conducting inspections describes all phases of inspections: preparation, conducting and termination. Practice specific inspection check-lists to be used by inspectors and questionnaires for interviewing personnel are prepared for inspecting different types of facilities or activities.

Conclusions of inspections are presented orally at the end of the inspection. The inspection report, prepared using a template in the DHARP document system, is sent at a later stage. If non-compliances are not identified, the inspection is terminated by sending the letter to the applicant or authorised party. If this is not the case, the corrective actions are required in the inspection report or so-called "letter of requirements", e.g., an order sent by DHARP requiring from the authorised party to conduct corrective actions, is sent. DHARP has a tracking system related to the corrective actions and deadlines. When the documentation on corrective actions is received and evaluated, the inspector terminates the case or performs a follow-up inspection.

The number of inspectors at DHARP is around 20. The inspectors are also dedicated to other tasks, e.g., authorizations. There is not specific examination or training programme of inspectors but all of them receive the standard training on radiation protection.

7.2 INSPECTION OF WASTE MANAGEMENT FACILITIES

DHARP and DEMA conduct inspections of the waste management in existing facilities as well as decommissioning activities at the Risø site where DD is the licensee. The inspections are performed according to the DHARP procedure for conducting inspections.

An annual inspection plan is describing the activities that DHARP and DEMA plan to perform at the Risø

site. The inspections are performed jointly by the two authorities with different focus area based on their mandate/focus area. The overall planning includes a minimum of one inspection to each facility or activity per year.

IRRS team was informed that one example of an ad-hoc inspection might be a follow up inspection on an earlier finding or when a particular issue is identified. Unannounced inspection is an opportunity, mentioned as inspection without notification in the mentioned procedure, and these will be conducted primarily if serious non-compliances have been identified or if the DHARP doesn't get any response to communication. The majority of performed inspections are announced. The IRRS team encourages the DHARP and DEMA to systematically perform unannounced inspections of the DD.

7.3 INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The inspections of radiation sources facilities and activities are conducted in line with the annual plan. The inspections are performed according to the procedures. However, the IRRS team noted that there is no procedure on inspecting some specific facilities and activities such as industrial irradiator and there is no procedure how to use radiation equipment and how to perform measurements on site and document them. The IRRS team noted that there is no procedure to address reactive inspections. The lack of procedures is addressed in **Recommendation 7 in Section 4.5.**

To perform inspectors tasks the newcomers are trained through informal on-the-job training. Informal training on the use of DHARP radiation equipment is performed in-house from time to time. In addition, DHARP pays attention that newcomers when started working as inspectors, they perform inspections of low or medium risk facilities or activities. The IRRS team was informed that there is a challenge to recruit newcomers in the field and to assure competences of inspectors, adequate for all types of existing facilities and activities. **Recommendation 4 in Section 3.3**. addresses this matter.

7.4 INSPECTION OF DECOMMISSIONING ACTIVITIES

Since inspections of decommissioning activities are conducted at the Risø site, the inspections for both waste management facilities and decommissioning activities are described in sub-section 7.2

7.5 INSPECTION OF TRANSPORT

DHARP performs inspections of parties authorized to use radioactive material including transport, according to Executive Order 670/2019 as well as parties that have notified DHA about their transport activities and undertaking responsible for transit storage facilities according to Executive Order 993/2001. Inspections include auditing of undertaking management system as well as handling, stowage, documentation of packages and other activities that are important to safety at the consignor, carrier and consignee.

DHARP performs on-site inspections, administrative inspections and on the road inspection of transport transit through Denmark in cooperation with the Police that is empowered to stop the vehicle. Due to the lack of human resources only five on-site inspections are planned for the year 2021. On-site inspections include auditing of the authorized party's management system as well as the handling, stowage, documentation, maintenance procedures of packages and other activities that are important to safety at the consignor, carrier and consignee. Administrative inspections are conducted by the review and assessment of documentation of parties authorized or notified for transport of radioactive material.

7.6 INSPECTION OF OCCUPATIONAL EXPOSURE

The inspection procedures established by DHARP for planned exposure situations include preparations that involve a review of the results of dose monitoring of workers according to written procedure. As a rule,

during walk downs the DHARP inspectors interview workers and check the measures related to occupational exposures.

There are no procedures for inspection of compliance with requirements for protection of workers in existing exposure situations. This issue is addressed in **Recommendation 7 in Section 4.5**.

7.7 INSPECTION OF MEDICAL EXPOSURE

Inspections of medical facilities and activities are performed by the MED. Nine persons cover both authorization and inspection in nuclear medicine, radiotherapy, and diagnostic radiology. Inspection planning in MED is performed annually for the upcoming year and revised after six months according to the necessities. In addition to planned inspections conducted on regular basis, MED performs reactive inspections to verify issues during the licensing process or addressing other specific ones. Unannounced inspections are seldomly performed, but they may happen if deemed necessary. Only new facilities for nuclear medicine and radiotherapy are inspected before issuing the license.

Each year MED establish the main area of interest for performing a series of inspections in a specific thematic area (campaign), based on the findings of previous years. Interventional cardiology was the focus in 2020 and will, together with veterinary applications be considered main areas of interest in 2021. The IRRS team acknowledges the performance of focused inspection campaigns based on the assessment of findings from previous inspections.

One of the main purposes of inspections of medical exposures concerns conditions related to testing, e.g., acceptance, performance and constancy testing, conducted by authorized parties in support of a use of radiation generators.

Requirements imposed as a result of an inspection were consequently aimed to further enhance optimization of the radiation protection. The results of inspection findings are made public in the DHA annual report.

7.8 INSPECTION OF PUBLIC EXPOSURE

No issue is reported.

7.9 SITE VISITS:

IRRS team members observed regulatory inspections performed by DHARP staff.

- Two inspections at the Risø site, e.g., at the inspection of waste management at the Waste Management Plant and follow-up inspection of decommissioning activities at DR 3 reactor complex. All background information was well documented. In this inspection DEMA inspectors participated as well;
- An inspection in the DTU Hevesy Laboratory, dedicated to the shipment of three Type A packages containing unsealed source of Fluorine -18 by the DTU Hevesy Laboratory as the consignor of the shipment and inspection of the carrier on the premises of the consignor. Inspectors performed measurements of the surface dose rates and measurements of the surface contamination and checked Transport Index of the packages;
- An inspection of an industrial irradiator at Thermo Fischer NUNC in Roskilde. Each inspector had a specific task to be conducted, i.e. the leading inspector conducting interviews and review of documentation and one observed visual and sound alarms, labels, signs and notices. During the walkdown, the inspectors performed measurements and conducted interviews. Tests of the emergency procedure and start up sequence were also demonstrated;

- Two inspections, at the radiology and the brachytherapy departments of the Rigshospitalet. The inspections included observation of radiation protection arrangements and interviews with several workers.

All inspections were well prepared using documentation already available and performed in line with the envisaged programme. The inspections started with the entrance meetings, followed by the planned activity, e.g., inspection of documentation and walk downs as appropriate. The inspectors used detailed checked lists and questionnaires, as appropriate, and performed measurements when needed. At the end of the inspection all findings were orally presented to the inspected parties while the inspection reports will be prepared at a later stage.

After the inspection IRRS team members interviewed the representatives of inspected parties who confirmed the good relationship and the collaborative attitude of regulatory authorities. However, they pointed out the difficulty of understanding the new requirements related to the safety assessment and the need for more detailed guides.

7.10 SUMMARY

DHA and DEMA conduct inspections professionally and competently. However, the inspection process could be improved in particular regarding inspection procedures related to specific facilities and activities, managing reactive inspections and inspections of occupational exposure in existing exposure situation. DHA faces a challenge to recruit newcomers in the field and to assure competences of inspectors, in order to be adequate for all types of existing facilities and activities. The DHA and DEMA are encouraged to perform unannounced inspections at DD. The IRRS team acknowledged the performance of focused inspection campaigns based on the assessment of findings from previous inspections.

8. ENFORCEMENT

8.1 ENFORCEMENT POLICY AND PROCESS

The Radiation Protection Act and its executive orders provide enforcement powers to DHA. The enforcement actions, that DHA may take depend on the degree of non-conformity of breach of law.

The enforcement policy of the DHA applies a graded approach reflecting the risk evaluation. The range of enforcement actions are specified in a management system procedure. Enforcement actions by the DHA may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization.

Enforcement actions are grouped in three categories according to the risk. DHA has a procedure addressing prohibition as well as responding time for corrective actions:

- Category 1: non-compliances that cause the use of radiation sources to be stopped immediately;
- Category 2: non-compliances where the continued use of radiation sources is justified if corrected within 1-2 weeks (Short term);
- Category 3: non-compliances where the continued use of radiation sources is justified if corrected within 1 month (Long term).

Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance.

Provisions on enforcement also exist in the Nuclear Installation Act, where enforcement power is given to NRA.

8.2 ENFORCEMENT IMPLEMENTATIONS

As a rule, any non-compliance is identified at the on-site inspections. If identified otherwise, e.g., during review and assessment, DHARP either sends an order to the interested party or conducts an inspection. Based on the severity of non-compliances, enforcement actions are in line with the DHA internal policy.

In relation to inspections of DD at the Risø site, where DHARP and DEMA conduct inspections jointly, enforcement actions are coordinated between both authorities. That is also relevant to deadlines listed in the instruction regarding enforcement.

DHARP is empowered to prohibit the operation of facilities or to continue activities with radiation sources. The relevant procedure gives a list of examples of non-compliances which call for a prohibition, e.g., missing license or notification, or update of these after changes in use.

The IRRS team has been informed that the enforcement actions, implying for example the payment of a fine or a prosecution, are rarely applied: only two cases happened during the last 3 years. In such cases the DHARP inspector reports the findings to the director and the enforcement actions are taken on a case-by-case base; DHARP staff can consult with DHARP lawyers on the selection of the appropriate enforcement actions. In some cases, DHARP lawyers are leading the enforcement action. There is no procedure stating the involvement of legal experts in the enforcement process. This issue is addressed in **Recommendation 7 in Section 4.5.**

Appeals against decisions made by the DHA pursuant to Radiation Act or rules pursuant thereto may be lodged solely with the Minister for Health if the appeal pertains to legal administrative matters.

8.3 SUMMARY

The legal framework provides enforcement powers to the DHA and DEMA.

DHARP has developed and implemented a policy for determining actions when a non-compliance is identified. Furthermore, DHA has established a number of enforcement actions, depending on the degree of the non-compliances identified.

9. REGULATIONS AND GUIDES

9.1 GENERIC ISSUES

Based on the provisions of the Radiation Protection Act, DHA is authorized to prepare and issue regulations and is responsible for developing regulatory guides. The Danish regulations for radiation safety have recently been revised, and DHA has prepared and issued several executive orders, namely:

- Executive Order no. 669/2019 on Ionising Radiation and Radiation Protection;
- Executive Order no. 670/2019 on Use of Radioactive Substances;
- Executive Order no. 671/2019 on Use of Radiation Generators;
- Executive Order no. 672/2019 on Transboundary Shipments of Radioactive Waste and Spent Nuclear Fuel;
- Executive Order no. 993/2001 on Transport of Radioactive Material.

In addition, several more executive orders have been issued by other relevant authorities that have regulatory roles, for instance Executive Order no. 1252/2010 on Special Education for Medical Physicists issued by Ministry of Health, Executive Order no. 10/2018 on Medical Examinations Pertaining to Potential Occupational Exposure to Ionising Radiation issued by Working Environment Authority and Executive Order no. 1762/2016 on security measures for nuclear material and nuclear facilities and drafting of security plans issued by Ministry of Defence.

To ensure that regulations remain comprehensive and complete, the DHARP management team, together with legal advisors, review at intervals of 5 years, the regulations and analyse whether a revision is needed. The process is documented in the DHARP management system. The basis for review primarily considers changes in Euratom Directives or Danish legislation, or development of new technologies in the field. Feedback and experience of DHARP staff during the implementation of the regulations and feedback from relevant stakeholders are continuously collected and analysed.

DHA has established a set of legally non-binding guides that elaborate the provisions in regulations, covering safety aspects of regulated practices, as well as, prescribing some regulatory processes. The revision of existing guides and the establishment of additional guidance document is an ongoing process. DHA has published 14 regulatory guides based on newly issued executive orders. These guides represent the outcome of a first phase in the process of revision and re-structuring of all guidance documents to be performed in the framework of the newly implemented Radiation Protection Act and pursuant regulations.

Processes regarding developing and revising regulations and guides involve informal consultation with relevant parties followed by an official consultation process, providing relevant parties, public, and organizations. This offers an opportunity to influence the final text, as well as transparency in the development process. To support the transparency and involvement of relevant parties, public consultation is announced on the DHA website and information on the consultation is sent directly to relevant stakeholders. In addition, draft regulations and guides are made publicly available on an official web portal for consultation. Guides are developed using a generic document template, providing scope and references to the legislative and regulatory basis for the particular guide.

The IRRS team was informed that approximately 50 new or revised guides are either under consideration or are in planning stages or under preparation. The IRRS team was informed that implementation of this activity is a challenge for DAHRP, due to lack of a formal process that includes adequate resources needed for revision and development of guides. **Recommendation 11 in Section 9.1** addresses this issue.

Even if an important number of guides have been issued, taking into account the significant changes in the regulatory framework, which among others introduce new requirements, such as establishment of new roles and responsibilities of the relevant parties, and requirements for licensees to provide a safety assessment to demonstrate safety, IRRS team considers that a thorough revision of the regulatory guides are needed. This issue was also highlighted by authorized parties during the discussions that took place during the inspection to the hospital. An appropriate system of guides will help authorized parties to comply with the provisions of the Act and regulations and will help the DHA to maintain consistency in the regulatory control.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The newly established legislation and regulation for radiation safety requires the development of additional guides to be used by the authorized parties in meeting regulatory requirements. There are significant number of guides that are either under consideration, or in planning stages or under preparation, but DHARP resources pose a challenge in fulfilling this responsibility timely and efficiently.	
(1)	***BASIS: GSR Part 1 (Rev 1) Requirement 33 states that*** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
(2)	***BASIS: GSG 13 para. 3.20 states that*** *"The overall purpose of guides is to advise authorized parties on how to comply with laws and regulations, and on how to implement the regulatory requirements, thus improving effectiveness and efficiency and enhancing safety."*
(3)	***BASIS: GSG 13 para. 3.63 states that*** *"The process used by the regulatory body to establish regulations and guides should include the following steps:* *…* *(d) Determining the resources necessary to develop the regulations or guide. The development of regulations and guides requires sufficient suitably qualified, competent and experienced people to be available, as well as adequate financial and other resources."*
R11	**Recommendation: DHA should ensure the timely revision and development of guidance documents, following a prioritisation.**

9.2 REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

In Denmark, the framework for management of radioactive waste is given in Executive Order 670/2019. Since DD is the only operator of a nuclear facility in Denmark, based on the principle of graded approach no general guidance has been issued addressing decommissioning of nuclear facilities. Instead, DHA and DEMA have established OLC for the operation and decommissioning activities of DD.

The IRRS team observed that the OLC for the operation and decommissioning activities of DD include details that could appear in regulations based on IAEA Safety Standards for predisposal management of radioactive waste and decommissioning. Since DD is the only licensee in this area, the IRRS team believe that compiling of and use of OLC is in line with applying graded approach in regulation.

In Denmark there are no disposal facility for radioactive waste in operation. The Parliamentary Resolution B90 gives provisions for the establishment of a final disposal facility for commissioning by 2073 at the latest. The existing requirements, relevant to safe disposal of radioactive waste and development of disposal facility, are general and are found in the Executive Order 670/2019, which requires that a disposal facility has a licence from DHA, and in Executive Order 669/2019 addressing safety assessment. DHA has a guide "Safety Assessments in connection with use of radiation sources" which provides instructions on how to design a safety assessment. The IRRS team was told that this guide is currently used to support discussions with DD, as DD is preparing a safety assessment for the new storage facility as well as for the decommissioning activities. However, the guide does not include any details regarding decommissioning. **Recommendation R11in Section 9.1** addresses the issue regarding revision and development of guidance documents.

In order to develop a safe disposal for radioactive waste, specific regulations for the safety of disposal facilities for radioactive waste have to be established as addressed in **Recommendation 11 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: At the latest in 2073 a final disposal solution for radioactive waste should be in place in Denmark based on the Parliamentary Resolution B90. Even if general requirements for disposal facilities are found in two executive orders, there are no specific requirements regarding the development of disposal facilities for radioactive waste taking into consideration their lifetime and the different stages of the licensing process.	
(1)	**BASIS: SSR - 5 Requirement 2,** *"The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."*
R12	**Recommendation: The regulatory body should establish regulations for the development of disposal facilities for radioactive waste taking into consideration the different stages of the licensing process (siting, design, construction, operation, closure and post-closure).**

9.3 REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Regulations related to the safety of radiation sources are provided in section 9.1 above. The DHA publishes guidance on how licensees may meet the requirements stipulated in the Act and executive orders. The guides are published on the DHA webpage.

While essential regulatory provisions concerning radiation safety for facilities and activities with radiation sources are in place, providing a comprehensive set of guidance documents remains a priority and is requiring a substantial effort. This issue is addressed in **Recommendation 11 in Section 9.1.**

9.4 REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

Since regulations and guides for decommissioning activities are applied in the same way as for waste management facilities, both areas are described in subsection 9.2.

9.5 REGULATIONS AND GUIDES FOR TRANSPORT

The transport of radioactive material in Denmark is regulated by the Executive Order n. 993/2001. This order is based on the superseded edition of the IAEA Regulations for the Safe Transport of Radioactive Material (1996 Edition). The international modal regulations for transport ADR (road), RID (rail), IMDG Code (sea) and ICAO TI (air), implementing the last edition of the IAEA Regulations SSR-6 (Rev.1), 2018 Edition for transport of Class 7 of dangerous goods, are also applied in Denmark.

Guides are published by DHA on application of a radiation protection programme in transport of radioactive material and to provide information to the first responders on how to handle transport incident or accident involving radioactive material.

Guides on the use of sealed and unsealed sources containing specific paragraphs dedicated to the transport of those sources are also published. This guidance material for authorized parties and shipping companies explains the requirements applicable to the transport of sealed and unsealed sources for all modes of transport. However, there is no detailed guidance on applying for or issuing approvals based on the SSR-6 (Rev.1), such as package design or material approvals. **Suggestion 7 in Section 5.5** addresses this issue.

For packages not requiring competent authority approval, the consignor needs to provide documentary evidence of the compliance of the package design with all applicable requirements of the IAEA Regulations SSR-6 (Rev.1). Guidance material that explains the requirements of SSR-6 (Rev.1) for those packages would be beneficial for designer and/or user, in demonstrating compliance with the provisions of SSR-6 (Rev.1) and the modal regulations applicable to the respective package type.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is a misalignment between the Executive Order no. 993 and the modal regulations and this create inconsistencies with the requirements and provisions applicable to the transport of radioactive material.	
(1)	**BASIS: GSR Part 1 Requirement 33, states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
R13	**Recommendation: DHA should revise the Executive Order no. 993 to be in compliance with the SSR-6 (Rev.1) and the international modal Regulations for transport of dangerous goods.**

9.6 REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

Regulations addressing occupational exposure in planned exposure situations are in place. However, for the occupational exposure due to existing exposure there is a need to provide regulatory guidance, e.g., regarding exposure to radon and for aircrews. **Recommendation 11 in Section 9.1** addresses this issue.

There are regulations in place concerning the training and approval of qualified experts and radiation protection officers, as well as the training of workers. Training requirements for exposed workers follow a graded approach: for the facilities or activities presenting higher risks, a course on the fundamentals of radiation protection approved by DHA is required, according to Executive Orders 669/2019 and 670/2019.

Monitoring and recording of occupational doses are prescribed in regulations, specifying that, at any time, the undertaking must be able to document doses for its workers for the last five calendar years. In case of accidental exposure, including occupational exposure and emergency occupational exposure, a record must also be retained of the circumstances of such exposures and of the corrective measures taken. Furthermore, regulations address the recording of worker doses at the national level by DHA. There are also guides addressing the transfer of information from approved dosimetry services to SRP.

Regulations include special arrangements for protection and safety of female workers, e.g., requirements for monitoring during pregnancy and by setting restrictions to work with a significant risk of internal or external contamination with radioactive material during breastfeeding. These also address the classification of persons under 18 years old as exposed workers.

9.7 REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The Health Act states that health professionals must be authorized. The Authorization Act regulates the authorization of medical practitioners of all relevant specialities (radiology, nuclear medicine, radiation therapy, dentistry, cardiology, orthopaedic surgery, neurosurgery, etc.), along with radiologists, oncologists, radiographers and radiation therapists.

The Danish Society for Medical Physics administrates the education of medical physicists and grants the formal educational approval. Executive Order no. 1252/2010 on Special Education for Medical Physicists establishes provisions for knowledge, skills and competencies for medical physicists. Medical physicists are not recognized as an authorized health professional in Denmark and the regulations do not allocate responsibilities for this profession.

Justification of medical exposure, of new practices and individual justification, are addressed in Executive Order 669/2019. Each medical exposure must be requested by a referring medical practitioner in a referral including the clinical context. It is also requested that both referring and radiological practitioners are bound to consider alternative techniques before performing every radiological procedure. The hospitals implement local referral guidelines. Clinical audits analyse the referral content and procedure and also the high-dose examinations.

Optimization of all medical exposure is set out in Executive Order 669/2019 and patient dosimetry should be performed for all examination, except for dental intraoral exams. Guides on national reference levels for diagnostic radiology, CT and nuclear medicine are available on the DHA website.

9.8 REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

Responsibilities of relevant parties specific to public exposure are established in Danish regulatory system. Requirements for optimization are established and dose limits for public exposure that are in compliance with GSR Part 3 are established and enforced.

DHA requires the applicants for a licence to assess, as part of the required safety assessment, the exposure of member of the public resulting from the operation of the facilities and/or activities for which the authorization

is requested. Where needed, authorizations establish operational limits and conditions related to public exposure, including authorized discharge limits.

In relation to the application of requirements for members of the public accessing as visitors controlled or supervised areas, while according to Danish regulations only individuals whose presence in the area is necessary for the use of radiation sources or exposure may be granted access to a controlled area, and some additional provisions are considered in practice specific requirements, the IRRS team considers that existing provisions are not comprehensive enough to cover all potential situations when access of some members of the public to a controlled or supervised area can legitimately occur.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While regulations establish, for controlled areas, that only individuals whose presence is necessary for the use of radiation sources or exposure may be granted access to the area, provisions for the control of public exposure for visitors to a controlled area or a supervised area are not explicitly established.	
(1)	**BASIS: GSR Part 3 Requirement 30 para. 3.128 states that** *"Registrants and licensees, in cooperation with employers where appropriate:* *(a) Shall apply the relevant requirements of these Standards in respect of public exposure for visitors to a controlled area or a supervised area;* *(b) Shall ensure that visitors are accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area;* *(c) Shall provide adequate information and instructions to visitors before they enter a controlled area or a supervised area, so as to provide for protection and safety for visitors and for other individuals who could be affected by their actions;* *(d) Shall ensure that adequate control is maintained over the entry of visitors to a controlled area or a supervised area, including the use of signs for such areas."*
S9	**Suggestion: DHA should consider establishing requirements, in line with GSR Part 3, specific to the control of public exposure for visitors to a controlled or a supervised area as appropriate.**

Criteria for the control of discharges of radioactive material to the environment are established in Danish regulations and are enforced by DHA. Danish regulations require the implementation of, as needed, source monitoring and environmental monitoring programmes. The results from the monitoring are recorded and are made available.

Requirements for the control of consumer products are established. The IRRS team was informed that these requirements are not fully implemented and enforced in practice and actions are foreseen by DHA to address this issue.

DHA has identified existing exposure situations that may be of concern from the point of view of radiation safety. As evaluations of the contribution to public exposure of identified existing exposure situations were performed but their basis may no longer fully reflect current existing exposure situations and these evaluations need to be complemented and updated. Reference levels for controlling exposure due to radionuclides in construction materials, food and feed, and in drinking water have been established. For building materials, established reference levels are based on assessments done in the 80's and therefore they

do not consider the whole spectrum of building materials that are being currently in use in construction industry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Evaluations of the contribution to public exposure of identified existing exposure situations were performed on a basis which may no longer fully reflect current existing exposure situations. Reference levels established for building materials do not consider some of building materials that are currently in use.	
(1)	**BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection."*
(2)	**BASIS: GSR Part 3 Requirement 51 para. 5.22 states that** *"The regulatory body or other relevant authority shall establish specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv."*
S10	**Suggestion: DHA should consider updating the evaluations of the contribution from the existing exposure to the public and the assessment of compliance with the reference levels for building materials.**

In Denmark, no existing exposure situations resulting from past accidents or situations leading to legacy sites have been identified. The exposure to radon of Danish population has been assessed and proactive measures to inform the public of the risk from radon in dwellings are available in a dedicated web page. Radon levels in Denmark are generally quite low. However, the radon reference level adopted in Danish regulations for controlling public exposure of radon in dwellings is based on a reference level set for workers exposed to radon at work places.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The reference levels specific for the control of public exposure to radon are not established and implemented in a comprehensive manner.	
(1)	**BASIS: GSR Part 3 Requirement 50 para. 5.20 states that** *"Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered….., the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings, which includes:* *(a) Establishing an appropriate reference level for 222Rn for dwellings and other buildings with high occupancy factors for members of the public, with account taken of the prevailing social and economic circumstances, that in general will not exceed an annual average activity concentration due to 222Rn of 300 Bq/m3;* *……"*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 7 states that "***Where several authorities have*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."
S11	**Suggestion: DHA in cooperation with other relevant authorities should consider, based on an updated assessment of the levels of radon indoors and the associated health risks, establishing and implementing comprehensive reference levels specific for the control of public exposure to radon and the associated health risks, in line with GSR Part 3.**

The government has established an action plan to reduce long term effects of exposure to radon indoors. This plan, with a duration of three years, was prepared and entered into force in 2018, with actions to be completed within 3 years. Therefore, the plan is now considered effectively expired.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Radon action plan entered into force in 2018, and the described initiatives had a predefined duration of 3 years, after which time no described initiatives within the framework of the plan exist. Effectively the plan has expired.	
(1)	**BASIS: GSR Part 3 Requirement 50 para. 5.20 states that** *"Where activity concentrations of radon that are of concern for public health are identified on the basis of the information gathered….., the government shall ensure that an action plan is established comprising coordinated actions to reduce activity concentrations of radon in existing buildings and in future buildings,….*
(2)	**BASIS: GSR Part 3 Requirement 50 para. 5.21 states that** *"The government shall assign responsibility for:* *(a) Establishing and implementing the action plan for controlling public exposure due to 222Rn indoors;* *……"*
R14	**Recommendation: The Government should assign responsibilities to ensure the continuous update and implementation of the national radon action plan.**

9.9 SUMMARY

DHA has established regulations specifying the principles, requirements and associated criteria for safety upon which the regulatory decisions and actions are based. The existing set of regulations is mostly in accordance with the nature and extent of the facilities and activities to be regulated.

DHA has established a set of legally non-binding guides that elaborate the provisions in regulations, covering safety aspects of regulated practices, and prescribing some regulatory processes. There is a need to ensure that guides are reviewed and revised and are consistent with the regulations.

DHA has established processes for the development of regulations and guides which involves consultation with interested parties, including the public.

The IRRS team has identified opportunities for improving the regulatory framework and bring it in line with IAEA Requirements on specific topics, related to the waste management, transport of radioactive materials, medical exposure control and control of public exposure in planned and existing situations.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The Nuclear Installation and Radiation Protection Acts assigns the responsibility for the on-site Emergency Preparedness and Response (EPR) to the authorized party.

The authority to regulate emergency preparedness arrangements on-site at nuclear facilities and activities is assigned to two separate authorities, DHA and DEMA, collectively denominated as "Nuclear Regulatory Authorities" (NRA). The authority to regulate emergency preparedness arrangements on-site at facilities holding radiation sources is assigned to DHA.

The authorization process of the facilities and activities include an obligation that an on-site emergency response arrangement should be established, and for high activity sealed sources, it's specifically required that the emergency response plan shall be approved by the DHA before acquisition of a source. Also, if substantive amendments from the point of view of radiation protection are made to the emergency response plan, the DHA shall approve the amended plan.

The regulations do not require that the on-site emergency response plans from the authorized parties should be coordinated with the relevant off-site emergency arrangement of the response organizations, nevertheless, the IRRS team was informed that for facilities with high activity sources, there are arrangements in place ensuring coordination with the competent off-site emergency response organizations.

The IRRS team was also informed that during the training of first responders a better articulation between on-site and off-site responders for facilities and activities which use radioactive sources is encouraged, so that the off-site response organisations are aware of the EPR arrangements on-site.

DHA applies a graded approach in regulating the EPR arrangements based on source category. DEMA has, in accordance with the Emergency Management Act, developed a national Nuclear Emergency Plan which is revised every four years. The current version addresses three scenarios as part of an assessment of existing threats that must be taken into account in the dimensioning and planning of EPR in all relevant authorities. The scenarios contain description of the nature of the threat as well as the possible consequences. Nevertheless, the country lacks a comprehensive, robust, cross sector hazard assessment to provide a sound basis for a graded approach and for the definition of a protection strategy. For a justified and optimized response, hazards shall be identified, and potential consequences of an emergency shall be assessed to provide a basis for establishing arrangements for preparedness and response for a nuclear or radiological emergency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The emergency preparedness and response arrangements lack a comprehensive hazard assessment for a nuclear or radiological emergency for facilities or activities classified in the emergency preparedness categories III, IV and V.	
(1)	**BASIS: GSR Part 7 Requirement 4 states that** *"The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 Requirement 4, para 4.18 states that** *"Hazards shall be identified and potential consequences of an emergency shall be assessed to provide a basis for establishing*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	arrangements for preparedness and response for a nuclear or radiological emergency. These arrangements shall be commensurate with the hazards identified and the potential consequences of an emergency."
R15	**Recommendation: The Government should ensure that comprehensive hazard assessment is performed for nuclear and radiological emergencies in line with GSR Part 7.**

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

The preparedness for radiological and nuclear emergencies only concerns facilities or activities classified in Emergency Preparedness Categories (EPC) III, IV and V, as per IAEA categorization. No facilities of EPC I and II exists in the country.

According to the Executive Order 670/2019, the authorized party should keep the arrangements for emergency preparedness and response up to date.

The Radiation Protection Act, together with the Executive Order 669/2019, define clear legal basis for the protection of emergency workers for all facilities and activities. The Executive Order 669/2019 establishes dose limits and reference levels for emergency occupational exposure. Even if no definition was found for "Helpers" and no arrangements are in place for the protection of helpers in a nuclear or radiological emergency, the IRRS team was informed that "Helpers" assisting in an emergency are formally considered "Emergency Workers" pursuant to Executive Order 669. The IRRS team was informed that several authorized parties maintain a reserve of personal dosimeters to supply to the emergency workers.

No criteria are established for transition from an emergency exposure situation to an existing exposure situation or to a planned exposure situation, or for the termination of an on-site or off-site emergency. **Recommendation 16 in Section 10.3** addresses these issues.

Executive Orders 669/2019 and 670/2019, require that EPR on-site must be carried out in accordance with an effective management system and following a graded approach and tested at suitable intervals. Pursuant to the obligations mentioned above, authorized parties shall immediately contact the 24/7 Expert Service at DHA for advice in the event of emergencies, accidents or incidents of significance from the point of view of radiation protection and safety.

The NRA has issued operational limits and conditions for the operation and decommissioning of the DD facilities including EPR matters. Guides are also issued by DHA for authorized parties and first responders, to be used in emergencies involving radioactive sources.

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

The authorized parties should provide for the training of their employees for emergency situations and also conduct periodic exercises on emergency response on-site and off-site. DEMA and DHA have the competence to evaluate and observe exercises conducted by the authorized parties. The action plan recognizes the fact that DHA has not established a comprehensive process for sharing lessons learned from on-site training drills and exercises conducted by the authorized parties. **Recommendation 7 in Section 4.5** addresses this issue.

The IRRS team further observed that some arrangements for EPR in Denmark are not in compliance with GSR Part 7. For example, there is no comprehensive protection strategy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Some of the requirements for emergency preparedness and response are not in compliance with the requirements of IAEA safety standards GSR Part 7, such as the protection strategy; the arrangements for the definition of criteria for the termination of an emergency; the national policy and strategy for radioactive waste management generated in a nuclear or radiological emergency.	
(1)	**BASIS: GSR Part 7 Requirement 5 states that** *"The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 Requirement 18 states that** *"The government shall ensure that arrangements are in place and are implemented for the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of social and economic activity."*
(3)	**BASIS: GSR Part 7 Requirement 15, para 5.84 (a) states that** *"The national policy and strategy for radioactive waste management shall apply for radioactive waste generated in a nuclear or radiological emergency,…"*
R16	**Recommendation: The Government should ensure that the framework for emergency preparedness and response is in line with GSR Part 7.**

The IRRS team was informed that a revision of the Nordic Flag Book is being prepared in cooperation with the other Nordic countries and will address these subjects for off-site emergencies.

The legal framework does not state that the DHA or DEMA has the obligation to perform inspections to the facilities or activities after an emergency has occurred. Nevertheless, the IRRS team was informed that depending on the severity of the emergency, an inspection will take place.

The IRRS team was informed of insufficient human resources for the discharges of the competences in radiological EPR of the DHA. **Recommendation 4 in Section 3.3** addresses this issue.

During the discussions there was also mentioned the benefits of a thorough peer review mission on EPR such as the IAEA Emergency Preparedness and Response Review Service (EPREV).

10.4 ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

The national emergency response system in Denmark, which applies to radiological and nuclear emergencies, is specified in the Emergency Management Act. This emergency response system relays on the principle of sector responsibility, any authority upholding a given function on a day-to-day basis retains that same responsibility in the case of emergencies. In the case of a nuclear or radiological emergency, DHA and DEMA have separate responsibilities and provide advice and expert services within their respective field of competence.

Denmark has put in place the National Operative Staff (NOST). NOST is an all-hazards coordinating body established by the Government, with no decision capacity for the response to emergencies, but allowing the coordination between all the relevant sectors for the response to an emergency. The IRRS team considers the creation of the NOST as a good performance.

During a nuclear or radiological emergency, DHA can provide for the dose assessment of the emergency workers.

Both DHA and DEMA operate their own dedicated emergency support centres, with staff members that ensure duty officer functions 24/7 hours. The IRRS team was informed that internal procedures of DHA and DEMA ensures the coordination between the two centres.

DEMA possess adequate capabilities in place for operational use in case of a nuclear or radiological emergency, including the real-time national radiological monitoring network, mobile and aerial measurement teams, decisions support systems, etc.

DHA has guidance for regional arrangements for providing medical response in a nuclear or radiological emergency. Nevertheless, the IRRS team encourage DHA to establish arrangements to raise awareness in medical personnel, both general practitioners and emergency medical staff, of the symptoms of radiation exposure in patients and notification procedures, in routine situations.

Denmark is a Party to the IAEA "Convention on Early Notification of a Nuclear Accident", and "Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency". DEMA has the competency of being the National Warning Point, Competent Authority for Emergencies Abroad and Competent Authority for Domestic Emergencies for these conventions and assumes the role of INES National Officer. DEMA, as member, and DHA as alternate, ensure the representation of Denmark on the Emergency Preparedness and Response Standards Committee of the IAEA. Denmark supply monitoring data to IRMIS.

Denmark is a small non-nuclear country that is actively engaged in a very pro-active manner in international cooperation, with good arrangements in place to providing and receiving international assistance under the "Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency" and with registered capabilities in RANET. These arrangements have allowed Denmark to promptly provide assistance with the deployment of a DEMA field assistance team to Lebanon, under the scope of a RANET Mission requested following the Beirut's explosion in 2020. The IRRS team acknowledges the participation of Denmark in the RANET Mission and considers it as a good performance.

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

Denmark also has established several bilateral agreements related with EPR with several countries, namely: Sweden, UK, Germany, Russian Federation, and Singapore.

10.5 SUMMARY

Denmark has put in place an adequate operational emergency preparedness and response capability for radiological and nuclear emergencies and established a comprehensive bilateral and multilateral exchange with the neighbouring countries.

The IRRS team considers the creation of the NOST and the participation of the DEMA at the RANET mission to Lebanon in 2020, as an area demonstrating good performance.

The IRRS team observed that some of the requirements for emergency preparedness and response are not in compliance with the requirements of GSR Part 7, mainly:

- A comprehensive process for sharing, evaluate and implement lessons taken by the on-site exercises;
- A protection strategy;
- A comprehensive hazard assessment for nuclear and radiological emergencies.

11. INTERFACE WITH NUCLEAR SECURITY

The only nuclear installations, the former research reactors at the Risø-site, are in the late stage of the decommissioning phase. Most of the spent fuel from the operation period was returned to the USA in 2002. The IRRS team was further informed that a relatively significant number of carriers transit nuclear material through the country, mainly fresh nuclear fuel and UF6. Sea vessels operating under Danish flag are also under control of the Danish regulatory authorities when carrying nuclear and radioactive material, even if those operations occur beyond the "territorial waters" of Denmark.

11.1 LEGAL BASIS

Following the Emergency Management Act, DEMA regulates and monitors the operators' obligations regarding use, storage or transport of nuclear material for peaceful use in terms of measures against theft or other unlawful taking of the material as well as against sabotage (nuclear material and facilities). DEMA has laid down a set of detailed regulatory requirements on security measures for nuclear material and nuclear facilities and on the drafting of security plans by the operators.

With regard to radiation source users, pursuant to The Radiation Protection Act, DHA has the authority to oversight and enforce requirements for safety and security. Based on a graded approach, DHA has established security requirements on radioactive sources for all radioactive materials, which emphasize that security measures must not compromise radiation protection and must not impede emergency response. These requirements, primarily aimed at high activity radioactive sources, are based on IAEA Nuclear Security Series No. 11.

11.2 REGULATORY OVERSIGHT ACTIVITIES

DHA and DEMA exercise their mandate through inspections and control and, if necessary, issue orders to ensure that requirements and conditions are met. Most employees of the Nuclear Department of DEMA deal with both safety and security. Concerning security measures for radioactive sources, DHA inspectors examine both security and radiation safety aspects.

With respect to transport of nuclear materials through Denmark or with a Danish vessel, DHA has obligations as Radiation Protection Authority and DEMA has obligations as the authority for security measures – physical protection. While DHA issues the carrier license, DEMA reviews and approves the security plan. Given that the security plan is based on a comprehensive risk assessment, not limited to security hazards, safety-security interface is addressed and considered when assessed by DEMA.

If a regulatory authority detects failure to comply with requirements and/or (attempted) violation of security measures this can be treated as a criminal offence. According to legislation, notification of criminal offences should be given to the police, which will initiate investigation. If investigation leads to prosecution, the case will be handled by the Prosecution Service.

11.3 INTERFACE AMONG AUTHORITIES

There is a close collaboration and exchange of information between DEMA and DHA, ensuring that both safety and security measures are implemented without compromising one another.

Coordination between the regulatory processes regarding safety and security at the nuclear installations at the Risø-site is ensured in an appropriate manner. The IRRS team has been informed of specific examples, including access in case of fire for which a coordination between regulatory processes on safety and security

has been necessary. In those cases, DEMA defines applicable procedures in consultation with other concerned organizations or authorities, namely police, local authorities and fire fighter brigades. On a regular basis, DEMA associates the police to inspections with the main goal to familiarize the police with the access to the site in case of an emergency.

The Radiation Protection Act includes specific responsibilities for the liaison with law enforcement agencies. For example, upon request from DHA the police provide assistance to conduct inspections.

With respect to transport of nuclear materials, no formalized procedure exists between DHA and DEMA to coordinate their respective field of competence. However, the frequent exchanges between both authorities ensure consistency. Furthermore, DEMA internal procedures entails that security plans for transport of nuclear material are shared with the national police and that DEMA informs the national police of time schedules for - and contents of - specific transports. In addition, operators must be in direct contact with the police when transporting category 1 nuclear material. The IRRS team was further informed that on a regular basis, tabletop drills are performed with the involvement of all concerned organizations and authorities with the main goal to test the communication channels and thus to ensure coordination of agencies, including those responsible for safety and security.

11.4 SUMMARY

Based on the legal and regulatory framework, both regulatory authorities (DHA and DEMA) adequately consider safety and security interface in the execution of their regulatory oversight functions related to nuclear installations, nuclear and other radioactive material. The IRRS team acknowledged the effective collaboration and coordination between the relevant authorities.

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INTERFACES WITH NUCLEAR SECURITY	
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APPENDIX III MISSION PROGRAMME

DAY	Sunday	Monday	Tuesday		Wednesday		Thursday	Friday	*Saturday*	*Sunday*		Monday	Tuesday	Wednesday
DATE	29-aug	30-aug	31-aug		01-sep		02-sep	03-sep	*04-sep*	*05-sep*		06-sep	07-sep	08-sep
08:00			Transport	*SITE VISITS*	Transport	*SITE VISITS*	Transport	Transport				Transport	Transport	
08:30														
09:00			Interviews with counter-parts		Interviews with counter-parts	*Rigshospitalet (sources, exposure), DD open-ended, Hevesy (transport)*	Follow-up interviews	Report Cross Reading (team)	*Finalisation of First Draft of the Report*		*Draft Report Review and Commenting (Host)*	TL & TC drafts Executive Summary and Presentation	Team Meeting for Report Finalisation	
09:30		Entrance Meeting												
10:00										Transport				Exit Meeting
10:30							Recomm. & suggestions Finalisation			***Social Event*** *The Hermitage & Royal Hunting Lodge, Traditional Lunch at Peter Lieps.*				
11:00														
11:30														
12:00		Transport	Lunch		Lunch		Lunch	Lunch	*Lunch*			Lunch	Lunch	
12:30		Lunch												
13:00	Initial Team Meeting		Interviews with counter-parts	*Thermo Fisher (NUNC ATOM), Danish Emergency Management Agency*	Interviews with counter-parts	*Rigshospitalet (sources, exposure), DD open-ended*	Report writing (team)	Policy Discussions	*Finalisation of First Draft of the Report*			SIS Finalises review and submit comments	Team Meeting for Report Finalisation	
13:30		Interviews with counter-parts												
14:00														
14:30														
15:00												Team Reviews Host Comments and Finalises Report		
15:30								Individual Review of the full Report (team)						
16:00					Daily Team Meeting								**Report Submission**	
16:30														
17:00		Daily Team Meeting	Daily Team Meeting				Daily Team Meeting						Transport	
17:30														
18:00							Transport	Transport				Transport		
18:30		Transport											Transport	
19:00			Transport		Transport								Farewell Dinner (Team and Counterparts)	
19:30														
20:00		Writing the Report (Team)					Finalisation of First Draft of the Report	Individual Review of the full Report (team)	*TL & TC Draft Report Edit*			TL and TC Finalises Draft Report Editing		
20:30			Writing the Report		Draft of Preliminary Findings (Team)									
21:00														
21:30														
22:00														
22:30														
23:00														

APPENDIX IV SITE VISITS

Rigshospitalet
Rigshospitalet is a highly specialised hospital, entailing activities and facilities such as radiology, radiation therapy, nuclear medicine and isotope production (cyclotrone).

Thermo Fisher Scientific (NUNC Atom A/S)
Thermo Fisher Scientific operates the highest activity irradiator facility in Denmark, producing and sterilizing plastic materials for a range of uses, especially medical.

Danish Decommissioning (DD)
DD is a government organisation, under the auspices of the Ministry of Higher Education and Science. DD is tasked with1) dismantling the nuclear research facilities at Risø by 2023 2) receiving, processing and storing radioactive waste from Danish users of radioisotopes and 3) participating in the process leading to a long-term solution for the radioactive waste by 2073 – until then, storing the waste.

Danish Technical University - Hevesy Laboratory
The aim of the Hevesy Laboratory is to a) Carry out research, development and production of radioactive drugs for diagnostics and treatment, b) Produce radioactive isotopes for use in research and with applications in industry and medicine and c) Carry out research in radioecology and perform radiometric analyses of environmental samples and food

Danish Emergency Management Agency
The Danish Emergency Management Agency is a civilian agency under the auspices of the Ministry of Defense. The Danish Emergency Management Agency is responsible for a number of tasks in the field of operational nuclear preparedness, including radiation monitoring in Denmark and Greenland, as well as the preparation and revision of the national nuclear emergency response plan. Additionally, DEMA is one of the Nuclear Regulatory Authorities in Denmark, jointly with DHA. DEMA is also regulatory authority for the physical protection of nuclear material and nuclear facilities.

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	The Government should establish a comprehensive national policy and strategy for safety.
	R2	The Government should review the legal framework for nuclear safety and, as appropriate, bring it in line with the IAEA safety standards, taking into account type of facilities present, planned or foreseen
	S1	The Government should consider enhancing the existing funding mechanisms to ensure that sufficient financial resources are available for DHA for the proper and timely discharge of its assigned responsibilities for radiation protection and safety taking into account the supporting justifications to be provided by DHA.
	R3	The Government should revise the policy and strategy for radioactive waste management so that all types of radioactive waste are included.
	S2	The Government should consider establishing a plan to increase the number of qualified experts in the country.
2. GLOBAL SAFETY REGIME	S3	DHARP should consider improving the processes for the dissemination of information and feedback of experiences from international cooperation, for their use by DHARP, authorized parties, other authorities and stakeholders concerned.

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S4	DHARP should consider formal and operational separation between the calibration laboratory and the performance of the regulatory functions to avoid any potential conflict of interest while maintaining the provision of such services.
	R4	DHARP should develop a human resource plan including a training programme based on an analysis of the necessary competences and skills needed to perform its regulatory functions.
	S5	Taking into consideration Denmark's plans for new waste management facilities, DEMA should consider finalising the identification of competences required for the review and assessment of the safety of such facilities, and ensuring all competences are available in due time.
4, MANAGEMENT SYSTEM OF THE REGULATORY BODY	R5	DHA should define its safety policy in its management system, in line with GSR Part 2.
	R6	DEMA should complete the establishment and implementation of its management system regarding the regulatory functions for safety, in line with IAEA Safety Standard GSR Part 2.
	R7	DHA should ensure that all processes relevant to safety are identified and documented in the management system.
	S6	DHA should consider conducting regularly independent assessment of the DHA management system components related to DHARP to evaluate its effectiveness and identify opportunities for improvement.

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
5. AUTHORIZATION	R8	DHA and DEMA should develop further guidance on the format and content of the documents to be submitted by the applicants in support of an application for authorization.
	R9	DHA should introduce a requirement for independent verification of the safety assessment in line with graded approach.
	GP1	The active integration of relevant information from other national registers into DHARP's Central Record Management provides an early warning on authorized parties capabilities that enables intervention prior to potential loss of control of radiation sources.
	S7	DHA should consider establishing a procedure for the validations of foreign certificates of package designs for all the packages that need a "multilateral approval.
	S8	DHA and the relevant agencies should consider establishing guidance material and a procedure to manage the approval of the radiation protection programme for special use of vessel.
	R10	DHA should establish provisions for the calibration of dosemeters used for patient dosimetry and for the traceability to a standards dosimetry laboratory.
6. REVIEW AND ASSESSMENT		

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
7. INSPECTION		
8. ENFORCEMENT		
9. REGULATION AND GUIDES	**R11**	**DHA should ensure the timely revision and development of guidance documents, following a prioritisation.**
	R12	**The regulatory body should establish regulations for the development of disposal facilities for radioactive waste taking into consideration the different stages of the licensing process (siting, design, construction, operation, closure and post-closure).**
	R13	**DHA should revise the Executive Order no. 993 to be in compliance with the SSR-6 (Rev.1) and the international modal regulations for transport of dangerous goods.**
	S9	**DHA should consider establishing requirements, in line with GSR Part 3, specific to the control of public exposure for visitors to a controlled or a supervised area as appropriate.**
	S10	**DHA should consider updating the evaluations of the contribution from the existing exposure to the public and the assessment of compliance with the reference levels for building materials.**
	S11	**DHA in cooperation with other relevant authorities should consider, based on an updated assessment of the levels of radon indoors and the associated health risks, establishing and implementing comprehensive reference levels specific for the control of public exposure to radon and the associated health risks, in line with GSR Part 3.**

Area	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	R14	**The Government should assign responsibilities to ensure the continuous update and implementation of the national radon action plan.**
10.EMERGENCY PREPAREDNESS AND RESPONSE	**R15**	**The Government should ensure that comprehensive hazard assessment is performed for nuclear and radiological emergencies in line with the GSR Part 7.**
	R16	**The Government should ensure that the framework for emergency preparedness and response is in line with the GSR Part 7.**
11.INTERFACE WITH NUCLEAR SECURITY		

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

Overview of references used in both the SARIS and the ARM Summary reports. Please note: Titles listed in SharePoint folders indicate references only available in Danish (DA).

Treaties (English titles)

- Consolidated version of the Treaty establishing the European Atomic Energy Community (Euratom) (2016/C 203/01)

Council Regulations (English titles)

- Council Regulation (EURATOM) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States
- Commission Implementing Regulation (EU) 2016-6 of 5 January 2016 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station
- Commission Implementing Regulation (EU) 2017/2058 of 10 November 2017 amending Implementing Regulation (EU) 2016/6 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima power station
- Council Regulation (EC) No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station
- Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products
- Council Regulation (EURATOM) No 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency

Council Directives (English titles)

- Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation
- Council Directive 2013/51/EURATOM of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.
- Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations
- Council Directive 2014/87/EURATOM of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations

- Council Directive 2011/70/EURATOM of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste
- Council Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel
- Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage
- Council Directive 2013/51/EURATOM of 22 October 2013 laying down requirements for the protection of health of the general public with regard to radioactive substances in water intended for human consumption
- Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods.
- Council Directive 89/106/EEC
- of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products

Commission Recommendations (English titles)

- 1999/829/Euratom: Commission Recommendation of December 6 1999 on the application of Article 37 of the Euratom Treaty

ICRP Publications (English titles)

- Cost-Benefit Analysis in the Optimisation of Radiation Protection, ICRP Publication 37
- The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103

International conventions/provisions (English titles)

- European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), provisions 6.4.23.15, 1.8.3.3 and 1.7.2
- European Agreement concerning the International Carriage of Dangerous Goods by Rail (RID), provisions 6.4.23.15, 1.8.3.3 and 1.7.2
- International Maritime Dangerous Goods Code (IMDG), provisions 6.4.23.15 and 1.5.2
- Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO-TI/IATA DGR), provision 6.2

Acts (English titles)

- Act no. 23 of 15 January 2018, on Ionising Radiation and Radiation Protection (The Radiation Protection Act)
- Act no. 170 of 16 May 1962, on Nuclear Installations (The Nuclear Installations Act)
- Act no. 244 of 12 May 1976 on Safety and Environmental Conditions at Nuclear Facilities, etc. (The Nuclear Safety Act)
- Consolidation Act no. 145 of 24 February 2020 on Access to Public Administration (The Public Information Act)

- Act no. 502 of 23 May 2018 on supplementary provisions for a regulation on the protection of individuals with regard to the processing of personal data and on the free exchange of such information (The Data Protection Act)
- Act no. 686 of 27 May 2015 on Railway Traffic (The Railway Act)
- Consolidation Act no. 1157 of 1 July 2020 on Planning (The Planning Act)
- Consolidation Act no. 790 of 10 September 2002 on the Central Management of the Health System (The Central Management Act)
- Consolidation Act no. 903 of 26 August 2019 on Health (The Health Act)
- Consolidation Act no. 314 of 3 April 2017 on Emergency Management (The Emergency Management Act)
- Consolidation Act no. 731 of 8 July 2019 on the authorization of healthcare professionals and on health care practice (The Authorization Act)
- Consolidation Act no. 973 of 25 June 2020 on Environmental Impact Assessment of Plans and Programs and of Specific Projects (EIA) (The EIA Act)
- The Finance Act, 2019, § 16.11.11 including text annotation 2
- Consolidation Act no. 433 of 22 April 2014 on Public Administration (The Public Administration Act)
- Consolidation Act no. 1218 of 25 November 2019 on Environmental Protection (The Environmental Protection Act)
- Consolidation Act no. 674 of 25 May 2020 on Working Environment (The Working Environment Act)
- Consolidation Act no. 1083 of 15 September 2017 on the Management of Research Ethics in Health Science Research
- Consolidation Act no. 645 of 8 June 2011 on the Equal Treatment of Men and Women concerning Employment
- Consolidation Act no. 282 of 27 March 2017 on Soil Pollution (The Soil Pollution Act)
- Consolidation Act no. 938 of 10 September 2019 on the Administration of Justice (The Justice Act), §§ 742-743
- Consolidation Act no. 1178 of 23 September 2016 on Construction (The Construction Act)
- Consolidation Act no. 999 of 2 July 2018 on Food-products (The Food-product Act)
- Consolidation Act no. 1505 of 17 December 2018 on the Sea (The Sea Act)
- Consolidation Act no. 1650 of 17 November 2020, The Criminal Code, §§ 114 and 192 b
- Consolidation Act no. 1324 of 21 November 2018 on Road Traffic (The Road Traffic Act)
- Consolidation Act no. 1149 of 13 October 2017 on Aviation (The Aviation Act)
- Consolidation Act no. 1201 of 28 September 2016 on Archives (The Archives Act)

Parliamentary resolutions (English titles)

- Parliamentary Resolution B103, 1985 on Energy Planning without Nuclear Energy
- Parliamentary Resolution B48, 2003 on the Decommissioning of the Nuclear Facilities at Research Station, Risø
- Parliamentary Resolution B90, 2018 on a Long-Term Solution for Denmark’s Radioactive Waste

Royal Resolutions (English titles)

- Royal Resolution of 28 June 2015 on Ministerial Resort Changes

Executive Orders (English titles)

- Executive Order no. 669 of 1 July 2019 on Ionising Radiation and Radiation Protection
- Executive Order no. 670 of 1 July 2019 on Use of Radioactive Substances
- Executive Order no. 671 of 1 July 2019 on Use of Radiation Generators
- Executive Order no. 672 of 1 July 2019 on Transboundary Shipments of Radioactive Waste and Spent Nuclear Fuel
- Executive Order no. 278 of 27 June 1963 on Protective Measures against Accidents at Nuclear Facilities, ect. - as changed according to Executive Order no. 502 of 10 January 1974
- Executive Order no. 1111 of 7 November 2019 on Fees for Danish Health Authority Inspection and Guidance (in Danish)
- Executive Order no. 971 of 28 June 2016 on planning of health care (in Danish)
- Executive Order no. 1252 of 11 November 2010 on Special Education for Medical Physicists (in Danish)
- Executive Order no. 1762 of 27 December 2016 on Security Measures for Nuclear Material and Nuclear Facilities and Drafting of Security Plans
- Executive Order no. 315 of 27 June 1972 on the Peaceful Control of Nuclear Materials
- Executive Order no. 1399 of 12 December 2019 on Building Regulations (BR18) (in Danish)
- Executive Order no. 359 of 4 April 2019 on information and consent in connection with treatment and in the transmission and gathering of health information ect. (in Danish)
- Executive Order no. 530 of 24 May 2018 on Authorized Health Professionals´ Patient Records (in Danish)
- Executive Order no. 10 of 5 January 2018 on Medical Examinations Pertaining to Potential Occupational Exposure to Ionising Radiation
- Executive Order no. 1229 of 3 November 2015 on Resort Changes between Ministers (in Danish)
- Executive Order no. 1070 of 28 October 2019 on Water Quality and Inspection of Water Supply Plants (in Danish)
- Executive Order no. 157 of 27 February 2018 on Occupational Safety and Health Conditions for Crew Members While serving on Aircraft and for Their Employers (in Danish)
- Executive Order no. 993 of 5 December 2001 on Transport of Radioactive Material
- Executive Order no. 828 of 10 June 2017 on Transport of Dangerous Goods by Road (in Danish)
- Executive Order no. 543 of 12 June 2012 on Safety Advisers for Dangerous Goods Transport (in Danish)
- Executive Order no. 796 of 22 August 2000 on the Manufacture, Marketing and Import of Food and Food Ingredients Treated with Ionising Radiation - (The Irradiation Order)
- Executive Order no. 763 of 11 July 2008 on Transport of Dangerous Goods by Air (in Danish)
- Executive Order no. 1234 of 29 October 2018 on the Execution of Work
- Executive Order no. 9 of 5 January 2018 on Medical Examinations Pertaining to Potential Occupational Exposure to Ionising Radiation in connection with offshore oil and gas activities, etc.
- Executive Order no. 591 of 26 June 2003 on public archives and public records business

- Executive Order no. 1349 22 of 110 December January 2019 2021 on import of food and feed, animal by-products and derived products for animal feed and food-contact materials with special restrictions etc. and on penalties for infringement of various EU acts, which implements a number of EU regulations

Circulars and Circular Letters (English titles)

- Circular no. 15105 of 22 December 1975 on the 24/7 Expert Service at the Danish Health Authority, Radiation Protection
- Circular no. 3151 of 26 November 1964 on the Cooperation between the Danish Health Authority and the WEA
- Circular no. 9450 of 9 July 2020 on the application of regulatory control by the nuclear regulatory authorities regarding the nuclear safety of nuclear installations, etc.
- Circular no. 9654 of 18 September 2020 on the tasks of the Danish Health Authority and of the Danish Agency for Higher Education and Science concerning responsible and safe management of radioactive waste.
- Circular no. 9233 of 12 April 2021 on the Danish Health Authority's laying down rules on ionising radiation and radiation protection, on justification and optimisation, and on international cooperation.

Programmes (English titles)

- National Programme for the Responsible and Safe Management of Radioactive Waste, Denmark, 2020.

Guides (English titles)

- Guide on transfer and shipment of radioactive material – Receipt and delivery, 2021
- Guide on the use of x-ray in chiropractic practices, 2021
- Guide on radiation protection in industrial radiography, 2021
- Guide on application of a radiation protection program in transport of radioactive materials, 2021
- Guide on use of unsealed radioactive sources – Non-medical purposes, 2020
- Guide on use of sealed radioactive sources – Non-medical purposes, 2020
- Guide on safety assessments – In connection with the use of radiation sources, 2020
- Guide on radiation generators – For service companies, 2019
- Guide on handheld radiation generators, 2019
- Guide on self-shielded radiation generators, 2019
- Collection of patient doses for radiographic examinations of children, 2018
- Guide on intraoral radiographs – Application of X-rays in dental practice, 2019
- Guide on acceptance and performance testing for digital orthopantomographs and cephalostats, 2019
- Guide on testing of X-ray diagnostic monitors, 2018
- Guide on approved isotope courses, 2020
- Guide on reference levels for radiographic examination of the lumbar spine by chiropractors, 2017
- Guide on radioactive substances in scrap, 2002

The Management System D4 (English titles)

- D4 2952 General instructions for 24/7 Expert Service calls
- D4 2953 Introducing new employees
- D4 3065 Calls regarding transport
- D4 3069 Staff
- D4 3071 Handling of mail etc.
- D4 3072 Responsibility of the Management
- D4 3073Vision and Mission
- D4 3104 Calibration of own equipment
- D4 3105 Conduction of management's evaluation of QMS
- D4 3109 Processing of complaints against accredited laboratories
- D4 3158 Quality Management Policy, DHARP
- D4 3159 Maintenance and document management in the quality management system
- D4 3189 Check of workers personal doses
- D4 3202 Report doses to National Dose Registry
- D4 3240 Processing of sealed source registration forms
- D4 3299 Enforcement including requirements and deadlines
- D4 3317 Overall Objective with QMS
- D4 3326 Review of inquiries, offers and contracts
- D4 3333 Organisation
- D4 3335 DHARP Tasks
- D4 3342 Requirements for qualifications, education and authorization
- D4 3343 Use, etc. of radiation sources at DHARP
- D4 3364 Improvements and corrective actions
- D4 3370 Procurement, externally delivered products and services in accredited areas
- D4 3381 Complex System Inspections at oncology departments
- D4 3500 Management of retrieved radioactive sources
- D4 3740 Regulatory processing in connection with transport as special arrangement
- D4 3819 Involvement of the public
- D4 3821 Access to documents
- D4 3837 Conflict of interest policy and procedures for declaration of conflict of interest
- D4 3840 Answering inquiries
- D4 3841 Mail guideline
- D4 3850 Retrieval of data regarding elevated personal doses
- D4 3855 Quality management policy
- D4 3896 Work procedure under 2006/117/EURATOM Council Directive of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel
- D4 3900 Method of validating package construction in transport of fissile materials
- D4 3912 Inspection of industrial radiography
- D4 3977 Procurement, contracts and tenders, including the use of consultants and expert advisors

- D4 3990 Inspection of companies using unsealed radioactive sources
- D4 3996 Use of radiological monitoring data for inspection purposes
- D4 4106 Media strategy
- D4 4003 Management of deviations in accredited laboratories
- D4 4068 Competency management strategy
- D4 4107 Danish Health Authority's strategy 2016
- D4 4110 Help for WorkZone
- D4 4117 Communication strategy
- D4 4130 Confidential information at DHARP
- D4 4273 CRM data outside D4
- D4 4289 Recruitment of employee
- D4 4341 Package transport by road
- D4 4362 Update of National Dose Registry doses
- D4 4382 Staff Development Talk
- D4 4451 DHARP, Inspection Strategy
- D4 4454 Establishing an annual inspection plan
- D4 4457 Exposure of Harshaw TL Cards for system calibration.
- D4 4577 Retrieval of data regarding annual statistics for personal doses
- D4 4630 Check for late or non-returned dosimeters
- D4 4667 Procedure for hiring external advisors at the Danish Health Authority
- D4 4742 Submission of cases for management approval
- D4 4770 Danish Health Authority's emergency management policy
- D4 4899 Isotopelab 1.04 Instructions for the disposal and discharge of radioactive waste
- D4 4982 Generic Division Competencies
- D4 4983 Licenses and notifications of radiation generators
- D4 4987 Radiation generators, license
- D4 4988 Radiation generators, notification
- D4 5200 Data processing agreement
- D4 5258 Unsealed sources, license
- D4 5259 Unsealed sources, notification
- D4 5260 Sealed sources, license
- D4 5261 Sealed sources, notification
- D4 5378 Principles for journalising in the Danish Health Authority
- D4 5392 NORM, license
- D4 5446 Management Structure of the Danish Health Authority
- D4 5447 Ministry of Health's basis for leadership
- D4 5617 Competence requirements, DHARP laboratories
- D4 5661 Presentation of cases for Executive Board meetings
- D4 5909 Personal Dosimetry, Critical items

- D4 5912 Procedure for conducting inspections
- D4 5914 Assessment of license application
- D4 5920 National and international collaboration
- D4 5961 Assessment of competence of designated expert individuals
- D4 5992 Receiving and handling results from dose monitoring of employees at DHARP
- D4 6000 Evaluation of need for revision of executive orders
- D4 6001 Evaluation of need for revision of DHARP guides
- D4 6027 Regulatory control and enforcement policy
- D4 6108 Notification and license for transport of radioactive material
- D4 6120 Loading of personal doses from dosimetry services
- D4 6153 Ensuring impartiality between SIS government functions and technical support organizations
- D4 6205 National cooperation in the field of radiation protection
- D4 6206 International cooperation in the field of radiation protection
- D4 6237 Guides from DHARP
- D4 6320 Prioritisation of inspections
- D4 6461 Inspection of transport of radioactive material
- D4 6495 Regulatory cooperation on transport of radioactive substances
- D4 IFM unsealed sources - flowchart
- D4 MED nuclear medicine - flowchart

Annual Reports

- Radiation Protection, Danish Health Authority Annual Report 2019, (2020)
- Rigshospitalet, Annual Report (2020)

Miscellaneous (English titles)

- IAEA Country Factsheets regarding Kingdom of Denmark
- List of Interested Parties for Consultance wrt Executive Orders (in Danish)
- List of interested Parties for Consultance wrt Guides (in Danish)
- IAEA List of States – code of conduct etc. 2019
- Nordic guidelines for dose reduction in conventional radiography and fluoroscopy, 2019
- Radioactivity in the Risø District January-June, 2019
- Ministry of Finance 2015: Seven Central Duties for Civil Servants in the Central Administration
- Foundation of the Radiation Hygiene Laboratory 1953 – 1961 (DHARP 47181961)
- General requirements for the competence of testing and calibration laboratories (DS/EN ISO/IEC 17025:2017)
- Operational Limits and Conditions for Danish Decommissioning (OLC) 2018
- Communication of August 2015 to the Commission pursuant to Council Directive 2011/70 / EURATOM : National policy and strategy framework for the responsible and safe management of spent fuel and radioactive waste

- Protective measures in early and intermediate phases of a nuclear or radiological emergency - Nordic Guideline and Recommendations 2014
- Danish Transport, Construction and Housing Authority: www.radonguiden.dk (now at the Danish Housing and Planning Authority)
- DHA Inspection Report -Complex System Inspection (Cardiology Department, Aalborg University Hospital) 2019
- DHA Inspection Report - Complex System Inspection (Danish Centre for Particle Therapy)
- DHA Inspection Report – Inspection - (Industrial Radiography at NSK) 2019
- DHA Inspection Report - Inspection - (Irradiator at NUNC)
- NRA Inspection Report - Inspection Danish Decommissioning (DD) 2018
- Inspection Check List - Radiation Generators in Industrial Radiography 2019
- Interview Guide - Complex System Inspection Medical X-ray
- WEA response to the IRRS questionnaire of July 3 2019
- Guidelines for actions at CBRNE-incidents and accidents (DEMA), 2016
- DEMA and DHA, July 2001: Handling of incidents and accidents with radioactive substances
- Guidelines for emergency response management (DEMA), 2018
- NUNC-exercise 2018
- DEMA observations Fire Exercise 2019
- DEMA observations Flooding Exercise 2019
- Analysis of the Emergency Preparedness Needs of Danish Decommissioning, by the Norwegian Institute for Energy Technology 2010
- Factsheet Nuclear Division's tasks (DEMA)
- DEMA organizational chart
- National Emergency Management RNE-exercise 2018
- Danish Transport, Construction and Housing Authority: National Radon Action Plan 2018 (now at the Danish Housing and Planning Authority)
- Radon-Dwellings-Radiation Dose-Lung Cancer Risk, DHA 1987 (in Danish)
- Radon in Danish Dwellings, DHA 2001 (in Danish)
- Radon-95: A study of methods for reducing the radon concentration in Danish single-family dwellings 1997 (in Danish)
- SBI-2019-07 Compliance with building regulations on Radon (in Danish)
- Thoron Measurements for Identification of Soil Gas Pathways to Indoor Climate, The Danish Environmental Protection Agency 2012 (in Danish)
- REFLAB (Environmental Protection Agency's Reference Laboratory for Chemical and Microbiological Environmental Measurements): Indicative dose for drinking water
- General Data as called for under Article 37 of the Euratom Treaty, Danish Health Authority 2003
- Calculation of upper limits for radioactive material discharge for the Cyclotron Unit at the Department of Clinical Physiology at Herlev Hospital 2010
- Radioactive Substances in Danish Building Materials, DHA 1980 (in Danish)
- Natural Radiation in Danish Dwellings, DHA 1987 (in Danish)

- Radon in recent naturally ventilated single-family dwellings, DHA 1994 (in Danish)
- Danish Health Authority, Radiation Protection: Ionising Radioation , Exposure Pathways in Denmark – general information (The Radiation Guide) 2019
- Orientation on the Transport of Radioactive Substances, DHA 2018
- Joint convention on the safety of spent fuel management and on the safety of radioactive waste management, national report from the unity of realm Denmark Greenland, 6th review meeting, 2017
- Danish Health Authority, Radiation Protection: Investigation into terrestrial radioactive contamination at Thule and assessment of radiation doses 2011
- Danish Health Authority, Radiation Protection, 2011: Thule Accident - Assessment of Radiation Doses from the Terrestrial Radioactive Contamination.
- Adoption of the international code for the safe carriage of packaged irradiated nuclear fuel, plutonium and high-level radioactive wastes on board ships (INF Code) (27 May 1999, resolution MSC.88(71))
- Ministry of Energy: Note on the safeguard administration in Denmark 1993
- European Commission, Safeguards & Non-Proliferation: Arrangements for the implementation and information flow for the additional protocol in Denmark 2005
- Arrangements for Additional Safeguards Protocol 2005
- The Danish Energy Agency: Conditions for possession of nuclear material 2007
- Emergency Management Agency: Note on authority responsibility for licenses, conditions, inspection, etc. regarding the establishment and operation of nuclear facilities in Denmark and Greenland 2019
- Overview of IFM and MED Inspections in 2019
- NRA Inspection Report of 20 December 2018, Inspection Danish Decommissioning
- Note on the Cooperation between the DHA and the WEA, 1980 (in Danish)
- Radon at Workplaces, DHA 1987 (in Danish)
- Radioactive Substances in Drinking Water, DHA 1987 (in Danish)
- Radioactive Isotopes in Danish Drinking Water, 2006
- "The Nordic Manual" (Co-operation, Exchange of Information and Assistance between Nordic Authorities in Nuclear or Radiological Incidents and Emergencies, 2015)
- Cooperation agreement btw DHA and the Customs Authority (SKAT) (D2494648)

WorkZone - Electronic case and document management system (English titles)

- DD – Facility, Waste management Plant
- DD – Facility, Fuel Fabrication
- DD – Safety Documentation
- DD - High tide maximum level in Roskilde Fjord
- DD – Facility, New Upgraded Storage
- DD - SIS presentation at Scientific Visit, Croatia 7-11 October 2019 (IAEA's technical cooperation program)
- National Contact Forum on long-term solution for radioactive waste – tasks pursuant to B90
- Roskilde Contact Forum on long-term solution for radioactive waste – tasks pursuant to B90
- Clinical physiological and nuclear medicine department HI

- Industrial radiography outside facility at Dana-Tank A/S

Paper files/journals (English titles)

- Accreditation by DANAK of the clearance function at Danish Decommissioning 2019

Licenses (English titles)

- DHA License of 10 January 2018 for use of unsealed radioactive sources – Hospital of Herlev and Gentofte, Clinical Physiological and Nuclear Medicine Department (AAKTIL-00000815)
- DHA License of 22 January 2020 for use of radiation generators – Copenhagen University Hospital, Department of Oncology, Division of Radiotherapy (RTGTIL-00001080)
- DHA License of 25 March 2019 for use of sealed radioactive sources – NUNC, Roskilde, Denmark (LUKTIL 00000982)

Web forms (English titles)

- DHARP Web Guidance, Dose Monitoring – PHE guide on extremity dosemeters (from DHA webpages)
- DHARP Web Guidance, Dose Monitoring – PHE guide on Neutron dosemeter (from DHA webpages)
- DHARP Web Guidance, Dose Monitoring – Price list
- DHARP Web Guidance, Dose Monitoring with full body personal dosemeters
- DHARP Web Guidance, for applying for license from DHA (bioashes)
- DHARP Webform Guidance for registration of lending devices
- DHARP Webform Guidance for registration of sources or facilities in connection with permission of sealed radioactive sources
- DHARP Webform Guide for applying for a permit or notification regarding open radioactive sources
- DHARP Webform Guide for the cancellation of a license or facility regarding unsealed radioactive sources
- DHARP Webform Guidelines for application of sealed radioactive sources
- DHARP Webform Guidelines for completing the registration of radiation generators
- DHARP Webpage (English titles)
- DHARP Webpage on bioashes
- DHARP Webpage on dose monitoring
- DHARP Webpage on radiation generators
- DHARP Webpage on sealed radioactive sources
- DHARP Webpage on unsealed radioactive sources

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006)

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Research Reactor, IAEA Safety Standards Series No. SSR-3, IAEA, Vienna (2016).

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. SSR-4, IAEA, Vienna (2017)

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Disposal of Radioactive Waste, IAEA Safety Standards Series No. SSR-5, IAEA, Vienna (2011).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Site Evaluation for Nuclear Installations, IAEA Safety Standards Series No. SSR-1, IAEA, Vienna (2019).

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. SSR-4, IAEA, Vienna (2017).

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-2, IAEA, Vienna (2011).

[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, IAEA Safety Standards Series No. GSG-6, IAEA, Vienna (2017)

[17] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018)

[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).

[19] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Arrangements for Preparedness for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-G-2.1, IAEA, Vienna (2007).

[20] ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, Arrangements for the Termination of a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-11, IAEA, Vienna (2017).

[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, IAEA Safety Standards Series No. SSG-40, IAEA, Vienna (2016).

[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. SSG-41, IAEA, Vienna (2016).

[23] INTERNATIONAL ATOMIC ENERGY AGENCY, Operating Experience Feedback for Nuclear Installations, IAEA Safety Standards Series No. SSG-50, IAEA, Vienna (2018).

[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Commissioning of Research Reactors, IAEA Safety Standards Series No. NS-G-4.1, IAEA, Vienna (2006).

[25] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Occupational Radiation Protection, IAEA Safety Standards Series No. GSG-7, IAEA, Vienna (2018).

[26] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Infrastructure for Radiation Safety, IAEA Safety Standards Series No. SSG-44, IAEA, Vienna (2018)

[27] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATION, PAN AMERICAN HEALTH ORGANIZATION AND INTERNATIONAL LABOUR OFFICE, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46, IAEA, Vienna (2018)

[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Environmental and Source Monitoring for Purposes of Radiation Protection, IAEA Safety Standards Series RS-G-1.8, IAEA, Vienna (2005)

[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources, IAEA Safety Standards Series No. RS-G-1.9, IAEA, Vienna (2005)

[30] INTERNATIONAL ATOMIC ENERGY AGENCY, Licensing Process for Nuclear Installations, IAEA Safety Standards Series No. SSG-12, IAEA, Vienna (2010)

[31] INTERNATIONAL ATOMIC ENERGY AGENCY, Classification of Radioactive Waste, IAEA Safety Standards Series No. GSG-1, IAEA, Vienna (2009)

[32] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radioactive Discharges to the Environment, IAEA Safety Standards Series No. GSG-9, IAEA, Vienna (2018).

[33] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. SSG-47, IAEA, Vienna (2018).

[34] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, IAEA Safety Standards Series No. SSG-40, IAEA, Vienna (2016)

[35] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. SSG-41, IAEA, Vienna (2016)

[36] INTERNATIONAL ATOMIC ENERGY AGENCY, Remediation Process for Areas Affected by Past Activities and Accidents, IAEA Safety Standards Series No. WS-G-3.1, IAEA, Vienna (2007).

[37] INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Sites from Regulatory Control on Termination of Practices, IAEA Safety Standards Series No. WS-G-5.1, IAEA, Vienna (2006)

[38] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, IAEA Safety Standards Series No. WS-G-5.2, IAEA, Vienna (2009)

[39] INTERNATIONAL ATOMIC ENERGY AGENCY, Storage of Radioactive Waste, IAEA Safety Standards Series No. WS-G-6.1, IAEA, Vienna (2006).

[40] INTERNATIONAL ATOMIC ENERGY AGENCY, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. SSG-26, IAEA, Vienna (2014).

[41] INTERNATIONAL ATOMIC ENERGY AGENCY, Code of Conduct on the Safety and Security of Radioactive Sources, IAEA/CODEOC/2004, IAEA, Vienna (2004).

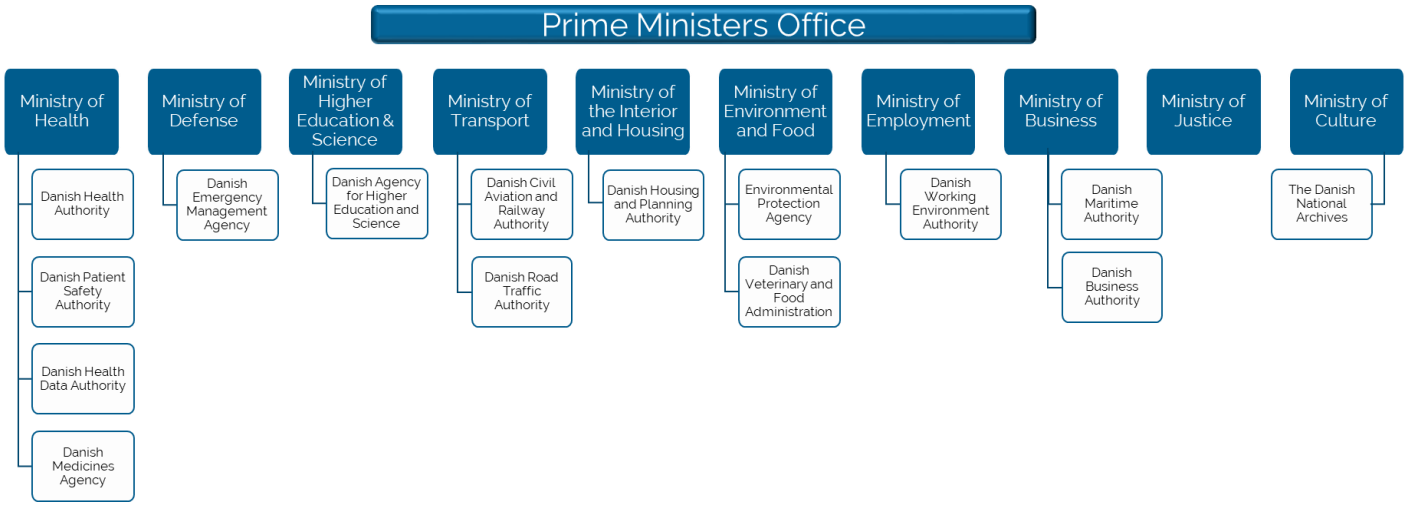
[42] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidance on the Import and Export of Radioactive Sources, IAEA, Vienna (2012).

[43] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidance on the Management of Disused Radioactive Sources, IAEA, Vienna (2018)

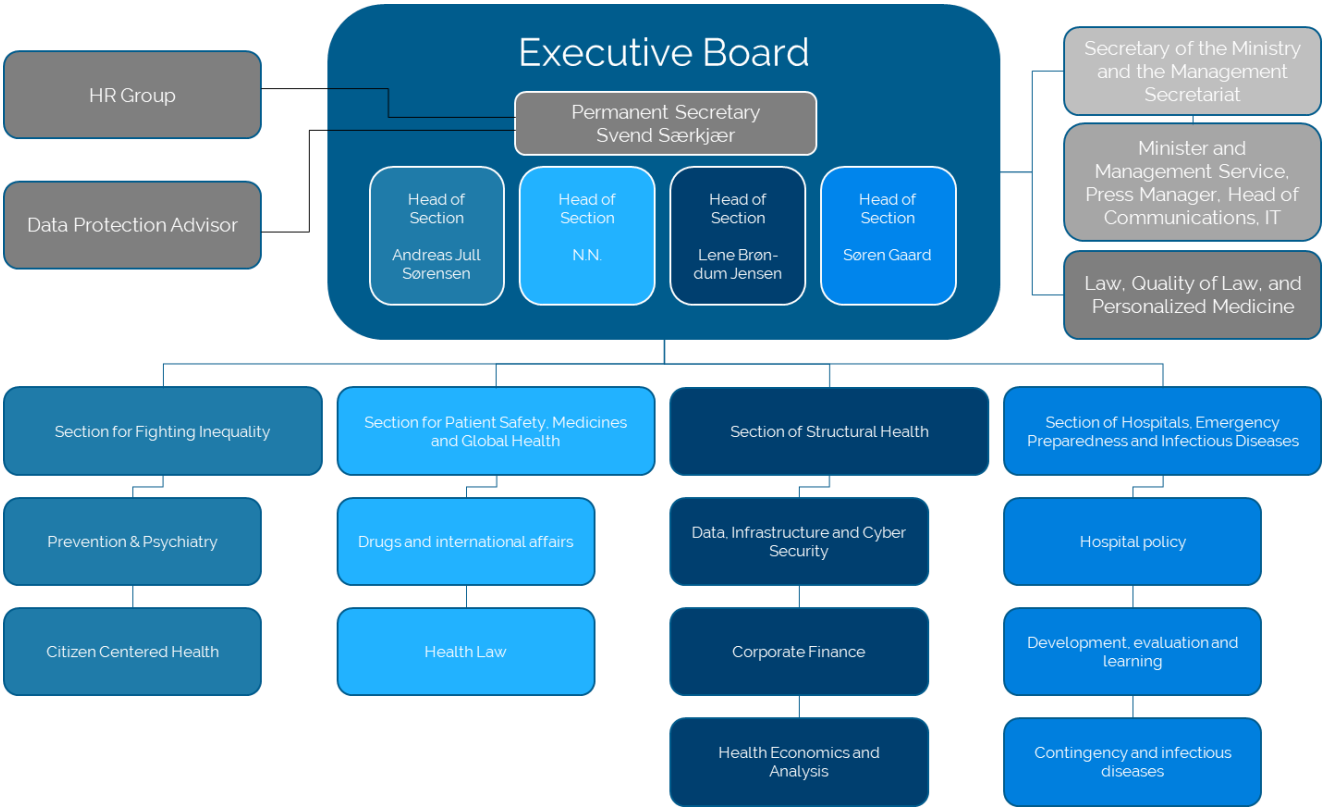
[44] INTERNATIONAL ATOMIC ENERGY AGENCY, SARIS Guidelines, IAEA Services Series No. 27, IAEA, Vienna (2014).

[45] INTERNATIONAL ATOMIC ENERGY AGENCY, IRIS Guidelines, IAEA Services Series No. 28, IAEA, Vienna (2014)

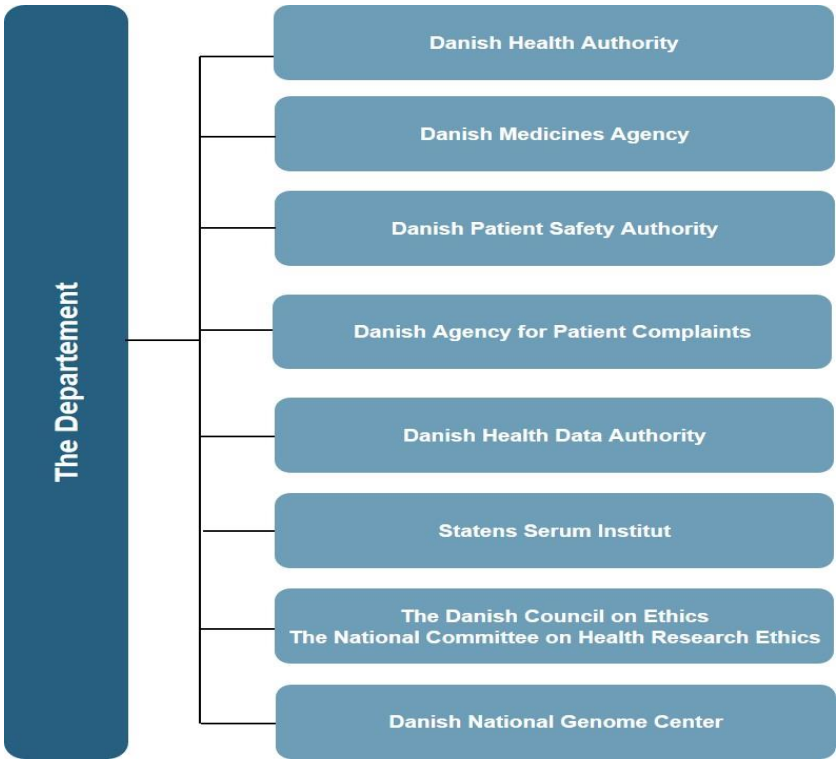
APPENDIX VIII ORGANIZATION CHARTS



1. Regulatory Framework, Ministries and underlying authorities of relevance

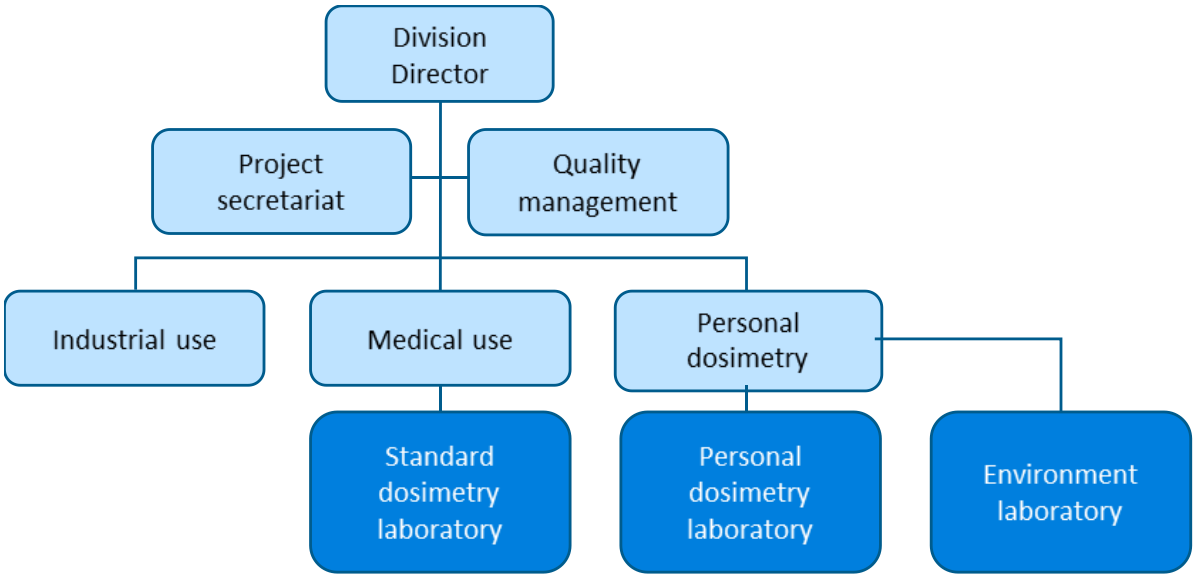


2. Organisation of the ministerial Department, Ministry of Health



3. The authorities under the Ministry of Health.

4. The divisions of the Danish Health Authority under the Ministry of Health



5. Organisation of the Radiation Protection Division (Danish Health Authority, Radiation Protection)