IAEA-NS-IRRS-2024/02
ORIGINAL: English

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

IAEA

Vienna, AUSTRIA

30 September to 9 October 2024

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA

Integrated
Regulatory
Review Service

IRRS

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
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Mission dates:	*30 September to 9 October 2024*
Regulatory body visited:	*IAEA*
Location:	*Vienna*
Regulated facilities, activities, and exposure situations in the mission scope:	*radiation sources facilities and activities, waste management facilities, decommissioning activities, transport, emergency preparedness and response, occupational exposure, public exposure, interface with nuclear security*
Organized by:	*IAEA*

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IAEA-2024/02

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 International Atomic Energy (hereinafter referred to as 'The IAEA'), an international team of senior radiation safety experts met representatives of the IAEA management and the Radiation Safety and Nuclear Security Regulator (the Regulator) at its headquarters, from 30 September to 9 October 2024, to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this IRRS mission was to review the IAEA regulatory framework for radiation, transport and radioactive waste safety, as it is applied in the IAEA's internal work.

The review assessed the regulatory framework for radiation, transport, and waste safety against IAEA safety standards. The mission was also used as an opportunity to exchange information and experience between the IRRS team members and Regulatory counterparts in the areas covered by the IRRS.

This mission is the first IRRS conducted in an organization that does not belong to an IAEA Member State. While following the IRRS Guidelines, some criteria were adjusted to better understand the governance and legal system that covers and oversee the regulatory programme of the IAEA. To mirror a State organization, and to apply as best as possible the Safety Standards, for the purpose of this mission the Government includes the Director General (DG) of the IAEA and the Deputy Directors General (DDsG), and the licensees or authorized parties defined in the standards are for the purpose of this mission the Directors in Charge (DiCHs).

The IRRS team consisted of 10 senior regulatory experts from 10 IAEA Member States, two IAEA staff members and one observer.

The IRRS team carried out the review in the following areas: responsibilities and functions of the Government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, public and environmental exposure control, safety of radioactive sources; transport, waste management and decommissioning and the interface with nuclear security.

The IRRS mission also included the following regulatory policy issues for discussion: Participation on legal and non-legal binding international instruments and globalization of the Nuclear Community by the Regulator and Human Resources and Knowledge Management.

The mission included observations of regulatory activities and a series of interviews with the staff of the Regulator, discussions with some licensee personnel and management, for an objective assessment of the effectiveness of the regulatory system.

These activities included observation of an inspection at the Insect Pest Control Laboratory in Seibersdorf. The IRRS team members observed the working practices during inspection carried out by the Regulator, including discussions with the authorized parties. The team noted that relationships between the regulatory body and authorized parties were constructive and open.

The Regulator provided the IRRS team with comprehensive advanced reference material (ARM) and documentation including the results of the self-assessment exercise carried out for all areas within the scope of the mission, including the initial action plan for improvements of the regulatory infrastructure for safety established after the self-assessment exercise. The IRRS team commends the IAEA for the extensive self-assessment and detailed action plan.

The team noted that of the 8 recommendations 6 had already been identified in that self-assessment and of the 12 Suggestions 10 had also been identified. The IRRS team also identified 1 good practice and 2 good performances.

Throughout the mission, the IRRS team was extended full cooperation in its review of the regulatory framework for safety, and in the discussions of the technical and policy issues. The staff of the Regulator were very open, transparent, and professional in all of their discussions and provided full support and assistance.

The IRRS team made recommendations and suggestions to the Regulator where improvements will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards. The main areas for further improvement are:

To the Government (DG-DDsG) :

- to develop a comprehensive policy and strategy for safety that is tailored to the IAEA specific situation with a level of attention that meets the strategic and operational ambitions of the IAEA; they should promulgate this policy and strategy across the IAEA and ensure its implementation in accordance with a graded approach.
- to initiate a review of the resourcing at the IAEA-level with the aim of ensuring that the Regulator has sufficient human and financial resources for sustainable discharge of its assigned responsibilities, including the resources needed to continuously improve the regulatory framework and to enhance the competence of the regulatory staff
- to consider formalising arrangements to ensure regulatory independence
- to consider adopting formal arrangements for the Regulator to acquire in-house expert opinion and advice from IAEA business units, for example, by entering into specific interservice agreements, that include measures to prevent conflict of interest.
- to consider assessing events at the Agency Seat against the INES and reporting any events Level 2 and above to share learning with Member States.

To the Regulator:

- to consider establishing a systematic programme for training and knowledge management in order for the Regulator to carry out its regulatory functions effectively.
- to complete the documentation of the management system for formal adoption, and establish a mechanism for its regular independent review to ensure consistency and stability of control.
- to arrange for independent assessments at planned intervals to measure, evaluate and review its leadership for safety and safety culture, to improve the overall safety performance.
- to finalize and formally adopt procedures for authorization taking into account a graded approach.
- to develop an inspection programme and plan in accordance with a graded approach.
- to formally adopt a process for establishing, regulations and regulatory guides, including the frequency for reviewing the regulatory guides and a system to ensure that the development and implementation of regulations and guides is based on a graded approach
- to consider establishing, formalising and implementing a comprehensive enforcement policy that clarifies and expands the criteria for initiating and determining the level of the enforcement action.

The IRRS team acknowledged the following good pratice :

The Agency has demonstrated its commitment to the safety standards and made use of the peer review system designed for Member States for a review of its internal implementation of the safety standards, as

mandated by the IAEA Statue. This goes beyond what is required, is unique, and is replicable for other bodies if relevant to their mandate; it is thus considered a Good Practice.

Overall, the IRRS team concluded that the regulatory programme of the IAEA is well established, considering that it is an organization regulatory programme. The regulatory oversight of radiation, transport and waste safety is established. The IRRS team welcome the commitment of the Regulator to continue to progress its regulatory systems and to continually improve.

The IRRS team findings are summarized in Appendix I.

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

I. INTRODUCTION

At the request of the Director General of the International Atomic Energy IAEA (IAEA), an international team of senior safety experts met representatives of the regulatory body of the IAEA from 30 September until 9 October 2024 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the IAEA governance, legal and regulatory framework for nuclear and radiation safety. In October 2020, the DG decided to first conduct a systematic self-assessment prior to inviting an IRRS mission. A preparatory mission was conducted 22-23 January 2024 at IAEA Headquarters in Vienna to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in IAEA and their related safety aspects and to agree the scope of the IRRS mission. Where specific facilities and / or activities would not be included in the scope of the IRRS mission, the IAEA undertook to provide explanation for the exclusion.

The IRRS team consisted of 10 senior regulatory experts from 10 IAEA Member States, and 2 IAEA staff members (+1 observer). The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, public and environmental exposure control, safety of radioactive sources, transport of radioactive material, waste management and decommissioning. In addition, the IRRS mission also included the following regulatory policy issues for discussion: Participations on legal and non-legal binding international instruments and globalization of the Nuclear Community by the Regulator and Human Resources and Knowledge Management were discussed.

The Regulator conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics within the agreed scope through review of the IAEA advance reference material, conduct of interviews with management and staff from the IAEA's Headquarters and direct observation of the regulatory activities at regulated facilities in Seiberdorf. Meetings with the Director General of the International Atomic Energy Agency was also organized with the Team leader.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Host organization (the Regulator) radiation and nuclear safety governmental, legal and regulatory framework and activities against the relevant IAEA safety standards to report on effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Host Organization. It is expected this IRRS mission will facilitate regulatory improvements in Agency and serve as a model for other Member State, utilizing the knowledge gained and experiences shared between the Regulator and IRRS reviewers and the evaluation of the Host organization regulatory framework for nuclear safety, including its good practice.

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

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

b) providing the host organization (Regulator and DG and DDsG) with a review of its regulatory technical and policy issues;

c) providing the host organization(regulator and senior 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 organization 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 organization 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 IRRS TEAM

At the request of the Director General of The International Atomic Energy Agency, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 22 to 23 January 2024. The preparatory meeting was carried out by the appointed Team Leader Mr. Carl Magnus Larsson and the IRRS IAEA Team representative, Mr. Ronald Pacheco, Team Coordinator.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of IAEA, represented by DDG-NS Lydie Evrard and Mr. Hazem Suman Regulator for Safety and Security. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Predisposal management of radioactive waste.

Mr. Hazem Suman (The Regulator) made presentations on the organizational context, the current status of regulatory programme 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 Host organization in September 30th to October 10th, 2024.

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

The Liaison Officer for the IRRS mission was confirmed as Mr. Hazem Suman.

The IAEA provided the advance reference material (ARM) for the review at the end of June 2024, In preparation for the mission, the IAEA review team members reviewed the Host organization advance reference material and provided their initial impressions to the IAEA Team 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 VIII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday 29th September 2024, in the hotel, directed by the IRRS Team Leader and the IRRS IAEA Team 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 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 in the IAEA Headquarters on Monday 30th September 2024, with the participation of the IAEA's Director General, Mr. Rafael Mariano Grossi, Ms. Lydie Evrard, Deputy Director General and Head of the Department of Nuclear Safety and Security, other DDsG and Directors. Opening remarks were made by DG Grossi, Mr. Carl-Magnus Larsson, IRRS team Leader and Mr Ronald Pacheco, IAEA Coordinator, Mr. Hazem Suman gave an overview of the Host organization 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 the Host organization with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the legal, governmental, and regulatory framework for safety.

In addition to the review, discussions were to share views, experience and lessons learned between Host organization and the IRRS team on selected policy issues.

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

The IRRS exit meeting was held on Wednesday 9th October. The opening remarks at the exit meeting were presented by Mr Hazem Suman and were followed by the presentation of the results of the mission by the IRRS team Leader Mr. Larsson. Closing remarks were made by Ms. Lydie Everard, DDG, Department of Nuclear Safety and Security.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

The framework for safety laid out in the safety standards of the International Atomic Energy IAEA (IAEA) comprises radiation safety, nuclear safety, waste safety, transport safety, and emergency preparedness and response. Member States (MS) of the IAEA can request peer reviews, in the form of Integrated Regulatory Review Service (IRRS) missions, of their implementation the framework that cover some or all of the topical areas listed above, as well as the interface of safety with security.

This IRRS mission reviewed the implementation of the framework for safety within the organization that is the 'custodian' of the framework - the IAEA itself. This is the first time an IRRS mission has been carried out in a non-State. This is a manifestation of transparency as well as of the IAEA's willingness to subject its own activities to the same level of scrutiny - and following the same methodology – as applied in peer reviews of national frameworks requested by Member States. It provides valuable experience for other international organizations with comparable mandates and obligations, and for the safety community more broadly. The IRRS team considers this a Good Practice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IAEA is not a State, and the IRRS peer review methodology was not developed with the potential application to a non-State in mind. Nevertheless, the IAEA determined that an IRRS mission would offer an opportunity for a peer review of the implementation of the safety standards, in accordance with the IAEA Statute, in its own program of work. This is the first time an IRRS mission to a non-State has been requested and carried out.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally.*
(2)	**GSR Part 1 (Rev 1) para 3.2 states that** *"The features of the global safety regime include:* *(a) International conventions that establish common obligations and mechanisms for ensuring protection and safety;* *(b) Codes of conduct that promote the adoption of good practices in the relevant facilities and activities;* *(c) Internationally agreed IAEA safety standards that promote the development and application of internationally harmonized safety requirements, guides and practices;* *(d) International peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States;* *(e) Regular multilateral and bilateral cooperation between the relevant national and international organizations to enhance safety by means of harmonized approaches as well as to increase the quality and effectiveness of safety reviews and inspections, by means of sharing of knowledge and feedback of experience."*
GP1	**Good Practice: The IAEA has demonstrated its commitment to the safety standards and made use of the peer review system designed for Member States for a review of its internal implementation of the safety standards, as mandated by the IAEA Statue. This goes beyond what is required, is unique, and is replicable for other bodies if relevant to their mandate; it is thus considered a Good Practice.**

For the purpose of defining roles and responsibilities within the IAEA that correspond to the structure of a State, the Government is in this mission report represented by the Director General and Deputy Directors General (the DG and DDsG); the Regulatory Body by the Radiation Safety and Nuclear Security Regulator (the Regulator); and Registrants and Licensees by the Directors in Charge (DiCHs). These roles are mapped against the organizational structure of the IAEA in Figure 1.

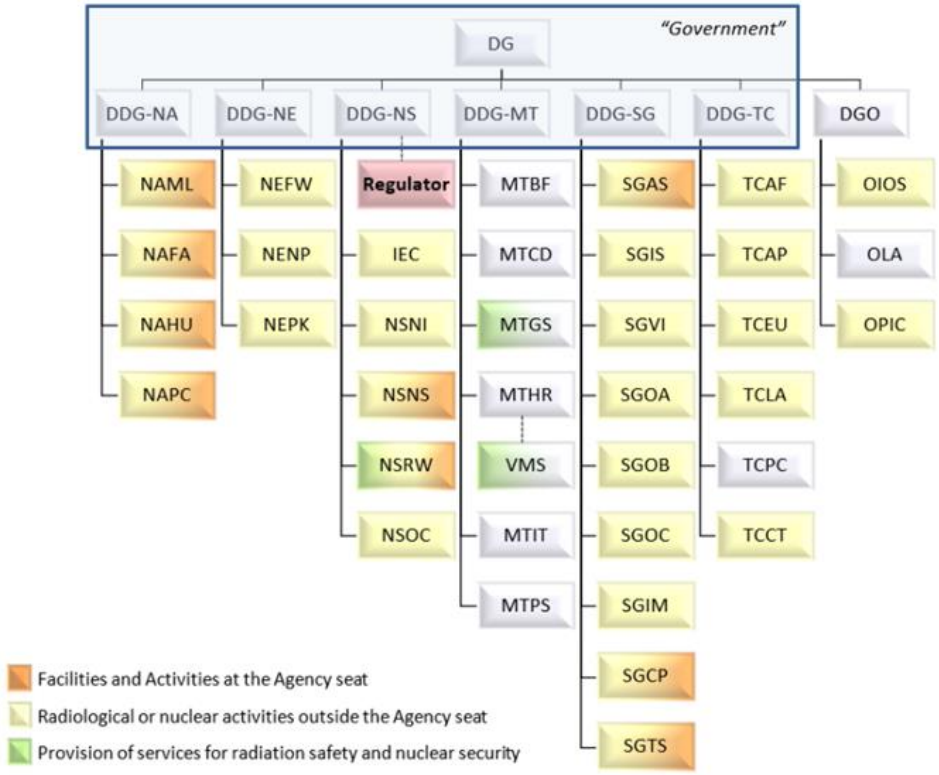

Figure 1. Mapping of 'State' roles and responsibilities across the organizational structure of IAEA.

1.1. POLICY AND STRATEGY FOR SAFETY

The Statute of the IAEA entered into force in 1957 and was latest amended in December 1989. Article III of the Statute establishes the functions of the IAEA and, *inter alia* (see Article III A.6), specifies that the IAEA is authorized to:

"…establish or adopt, in consultation and, where appropriate, in collaboration with competent organs of the United Nations and with the specialized agencies concerned, *standards of safety* [emphasis added] for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for these standards *to its own operations* [emphasis added] as well as to the operations making use of materials, services, equipment, facilities, and information made available by the Agency or at its request or under its control or supervision, and to provide for the application of these standards, at the request of the parties, to operations under any bilateral or multilateral arrangement, or, at the request of a State, to any of that State's activities in the field of atomic energy."

The IAEA's obligation to comply with the safety standards in its own operations are thus enshrined in the Statute. As part of the safety standards, the General Safety Requirements No. GSR Part 1 (Rev. 1) establishes (Principle 1) 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…", in which the intent of the Government and the commitment to long-term safety can be expressed.

The IRRS team considers that the obligation to comply with the safety standards, as well as the intent and commitment to safety are expressed in the Statutes and clearly stated in the objective and other sections of the IAEA-specific Radiation Safety and Nuclear Security Regulations (Administrative Manual Part X, referred to as "the Regulations"), which include the requirement for application of the safety standards to the Agency's own operations (Section I.1 2.c of the Regulations)).

The IRRS team considers that a comprehensive policy and strategy for safety aligned with Requirement 1 of GSR Part 1 (Rev. 1) would assist in highlighting the role of the Regulator, promoting the recognition of the significance of the Regulator as a resource for the entire IAEA, and stimulating ownership and collaboration on safety-related matters across the IAEA. It would also serve as a model for MSs in their national development and communication of safety-related policies. This has been recognized in the Advance Reference Material (ARM).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IAEA has given recognition to the obligation to comply with the safety standards in its own operations and clearly stated its commitment in that regard; however, there is no comprehensive written policy and strategy for safety as a commitment to safety at the highest level of the IAEA and internally communicated and known to all staff. This has been recognized in the ARM.	
(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.*
(2)	**BASIS: GSR Part 1 (Rev 1) para 2.3 states that** "*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."*
(3)	**BASIS: GSR Part 1 (Rev 1) para 2.4 states that** *"The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and*

	activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body."
R1	**Recommendation: The DG and DDsG should develop a comprehensive policy and strategy for safety that is tailored to the IAEA specific situation with a level of attention that meets the strategic and operational ambitions of the IAEA; they should promulgate this policy and strategy across the IAEA and ensure its implementation in accordance with a graded approach.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The framework for safety to be implemented and followed in all IAEA activities and endeavours consists of the safety standards (in accordance with the Statute, see section 1.1 of this report) and the Nuclear Security Series publications, applied through the Regulations. The Regulations allocate the prime responsibility for safety and nuclear security to the DiCH, while the DG retains the overall statutory function of establishing the standards and for making the necessary provisions for applying the standards to all IAEA operations and other endeavors as laid out in agreements and services or carried out through other activities and mechanisms.

The Regulations also delineate the functions, responsibilities, and powers of the Regulator. The Regulator reports to the DG through the Deputy Director General, Head of Department of Nuclear Safety and Security (DDG-NS), who has general responsibility for nuclear safety and security and also for certain radiation protection services provided directly to the Regulator. The arrangement may give rise to perceptions of conflict of interest with a potential impact on the perceived independence of the Regulator. Limited resources and the need to divert resources to other and/or urgent activities, different from the activities planned and carried out by the Regulator, may add to such perceptions. The potential for such conflicts, perceived or otherwise, must be identified and managed. *This has been addressed in S.1*.

The Regulations comprehensively outline the administrative requirements, general protection principles, requirements for safety and nuclear security, requirements for preparedness and response to an incident or emergency at the Agency Seat, and for activities outside the Agency Seat. The Regulations are to be reviewed at least once within a five-year interval; a review was carried out between 2021 and 2022 and the IRRS team was informed that the Regulations remain fit for purpose.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Regulator is established in accordance with the provisions of Regulations, which also define the functions and responsibilities of the Regulator and the reporting lines to the IAEA's senior management. Among other things, the Regulator oversees the implementation of the Regulations, liaises with the safety authorities of the States in which the IAEA is located, reviews and prepares revisions of the Regulations, issues safety guidelines, authorizes IAEA facilities and activities, approves Radiation Protection Programmes (RPPs) for activities outside the Agency Seat, conducts inspections and takes enforcement actions.

The Regulations include provisions to ensure independence in regulatory decision-making as well as functional separation from organizational units with responsibilities or interests that could unduly influence regulatory decision making. Although the Regulator is affiliated to the Office of the DDG-NS, which oversees activities and safety-related services, functional separation has been achieved in practice, despite the absence of formalized 'ground rules' for the interface of the regulatory team within the NS Department. Such formal rules would, however, be beneficial and facilitate consistent implementation of the provisions on effective independence and functional separation in the Regulations. In addition, completion and

implementation of the management system would serve to further strengthen effective regulatory independence, including functional separation. *See details on management system in Module 4.*

The Regulator is empowered to require the authorized party, being the DiCH, to provide safety-related information and to require access to premises, documents and other sources of information for the purpose of making inspections relevant to safety and nuclear security.

In addition, the Regulator is entitled to obtain technical and other professional advice or services from within the IAEA or from external experts. However, there is no formal process or agreements in place for acquiring in-house expert opinion and advice by the Regulator from IAEA business units. Every case needs to be negotiated individually, including specific provisions to manage possible conflicts of interest.

Specific provisions of the Regulations require the DG to provide the Regulator with the necessary resources and technical and administrative support, which is a challenge considering the many competing priorities the IAEA faces within its programme of work, and with finite resources. In practice, regulatory activities are funded through the IAEA programme and budget at the project level, where human resources are provided, while any other financial resources (e.g. for external technical support or external training) have to be negotiated on a case-by-case basis. In reality, this constrains the Regulator's ability to manage its budget and to appropriately allocate financial resources to its various regulatory tasks. By default, the Regulatory Activities project includes funds only for the human resources component. However, as regulatory oversight serves the entire IAEA, the DDG-NS may provide extra funding by reallocating funds from other projects and/or budget areas, when deemed justified.

The current level of staffing (two technical and one administrative members of staff) can support the discharge of core regulatory responsibilities, but not additional regulatory supporting functions that enable the regulatory body to implement its core functions effectively, such as:

- Administrative functions supporting the routine operations of the regulatory body (e.g. finance, management of documents and records, procurement and control of equipment);
- Technical functions directly relating to the effective implementation and execution of the core regulatory functions (e.g. legal support, research and development, the functions of advisory committees, external expert support, liaison with other governmental organizations, international cooperation and assistance).

The adequacy of human resources is regularly reviewed but it should be noted that some of the underlying assumptions for the initial staffing needs assessment carried out in 2015, such as the number of IAEA projects requiring regulatory involvement, are now outdated.

Some of the issues have recently been addressed at the level of the DDG-NS, where the administrative position in the regulatory team has been expanded from half-time to full-time. However, the IRRS team proposes a renewed systematic approach at IAEA level aiming to ensure adequate financial and human resources for its Regulator, with a timeframe for planning of 3 – 5 years. Details on provision of resources for the regulatory activities are also discussed in Modules 3 and 4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The resources of the Regulator are limited and just allows the Regulator to perform its core regulatory and support functions but constrain the ability to respond to unplanned requests for regulatory activities, to improve the regulatory framework with the view of strengthening its efficiency, effectiveness and sustainability, and to support the development of regulatory staff competence. This has been recognized in the ARM.	
(1)	**BASIS: GSR Part 1 Requirement 4, para. 2.8 (b) 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;"...*
R2	**Recommendation: The DG and DDsG should initiate a review of the resourcing at the IAEA-level with the aim of ensuring that the Regulator has sufficient human and financial resources for sustainable discharge of its assigned responsibilities, including the resources needed to continuously improve the regulatory framework and to enhance the competence of the regulatory staff.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Based on provisions in the Regulations, the independent decision-making and functional separation of the Regulator and the DDG-NS has been respected in practice, but there is no formally adopted arrangement between the Regulator and the DDG-NS in this regard.	
(1)	**BASIS: GSR Part 1 Requirement 4, states that** *"The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making*
S1	**Suggestion: The DDG-NS and the Regulator should consider formalizing arrangements to ensure regulatory independence.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no formally adopted arrangement in place for the Regulator to acquire in-house expert opinion and advice from other IAEA business units. This was recognized in the ARM	
(1)	**BASIS: GSR Part 1 Requirement 20, para. 4.18 states that** *"The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-technical in nature.* **BASIS: GSG 12, para. 4.38 states that** "The regulatory body may choose to give a formal structure to the processes by which expert opinion and advice are sought and provided.
S2	**Suggestion: The Regulator and relevant DDsG should consider adopting formal arrangements for the Regulator to acquire in-house expert opinion and advice from IAEA business units, for example, by entering into specific interservice agreements, that include measures to prevent conflict of interest.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Regulations assign the prime responsibility for safety of any facility or activity at the Agency Seat to the DiCH. In case of an activity that is organized, conducted or contracted outside the Agency Seat the DiCH has the responsibility to ensure, in cooperation with the Host State, that the requirements of the IAEA safety standards and IAEA nuclear security guidance are met.

Further, in accordance with the Regulations, the DiCH shall:

- Ensure the safety and security of the IAEA facilities and activities under their management in accordance with the Regulations, IAEA safety standards and IAEA nuclear security guidance, and any conditions attached to the authorizations;
- Establish clear lines of responsibility and accountability for safety and security in the IAEA facilities or activities under their supervision;
- Ensure that managers at all levels in the IAEA facilities or activities under his or her supervision are aware of, and are committed to their roles and responsibilities for safety and security.

The IAEA is obliged to apply the IAEA safety standards in its operations, as stipulated in its Statute and in the Regulations. Therefore, although there is no provision in the Regulations stipulating explicitly that compliance with the Regulations does not relieve the DiCH from their prime responsibility for safety, this is implicitly established through the above mentioned overarching requirements.

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

Provisions are in place in the Regulations for coordination between the Regulator and other organizational units of the IAEA with responsibilities for safety. Within the IAEA structure such coordination involves:

- The Division of Radiation Transport and Waste (NSRW) with regard to their services for safety;
- The Incident and Emergency Center (IEC) with regard to their role in notifications of internal events;
- The Division of General Services (MTGS) with regard to their role in Emergency Preparedness and Response (EPR) and nuclear security at the site area of the Agency Seat;
- The IAEA Central Security Coordinator (CSC); and
- The VIC Medical Service with regard to their role in health surveillance of Occupationally Exposed Workers (OEWs) and medical response in case of radiation events.

Where appropriate, such coordination is based on formal procedures.

Coordination with relevant authorities of the Host States is based on the Headquarters agreements with Austria and Monaco, and on specific technical agreements related to operation of the Seibersdorf facilities.

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

The Regulations, safety standards and nuclear security guidance include provisions aimed at reducing radiation risks associated with unregulated sources.

Appropriate procedures and protective actions are in place for risks associated with radiation incidents and emergencies – measures after discovery of unaccounted radioactive source in a laboratory are the responsibility of the respective DiCH; safeguards equipment returned from the field are subject to radiological monitoring and decontamination if needed; IAEA sealed sources returned from the field must

be checked for integrity, including a leak-test prior to re-use at the Agency seat; radiation monitoring is conducted at access gates to Seibersdorf facility by MTGS; radiation monitoring is conducted at VIC access gates by UN Safety and Security Service. IAEA provides technical support (testing & calibration) through MTGS and response to alarms by the IEC. Formal procedures exist for all situations described above.

The IAEA is obliged to apply the safety standards in its operations, as stipulated in the Statute and in the Regulations, therefore the application of justification and optimization is a requirement with regard to the system of protective actions against unregulated risks.

The Host States' laws and regulations for radon are applicable to the IAEA according to the Headquarters Agreement with Austria and Monaco, since no regulations in this area have been established by the IAEA.

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

Section II.2 of the Regulations assigns the prime responsibility for safety to the DiCH of an IAEA facility or activity at the Agency Seat. For IAEA activities that are conducted outside the Agency Seat, the prime responsibility for safety does not rest with the IAEA, and the DiCH of an IAEA activity has the responsibility to ensure, in cooperation with the host country, that the requirements of the IAEA safety standards and the recommendations of the IAEA nuclear security guidance that are relevant to the IAEA activity of concern, are met. The Regulations include several provisions relating to the radioactive waste management and disposal. Furthermore, disposal of sealed sources is handled by the IAEA through agreements with suppliers and for legacy sources, directly with Nuclear Engineering Seibersdorf (NES).

Requirements for decommissioning are included in the Regulations, including provisions for future decommissioning (preliminary decommissioning plans) that are part of the requirements for authorization of IAEA facilities and activities.

Although the Regulations provide provisions for the management of waste and decommissioning, the IAEA does not have an over-arching policy and strategy for decommissioning and waste. The IAEA does however have agreements with Austrian Authorities and NES captured in Article V of the Technical Agreement on Safety that includes provisions for the disposal of radioactive waste from normal operations and decommissioning.

The cost of radioactive waste management is part of the operational costs included in the IAEA budget. For decommissioning, there are no explicit financial provisions but Article V of the Technical Agreement on Safety sets obligations on the IAEA, and the clearance of radioactive material for disposal is captured in paragraphs 41 and 42 of the Regulations. Authorized facilities under the IAEA control have in place, or are working to put in place, clearance procedures that have been developed with the Host State authorities.

In recent decommissioning cases (such as Safeguards Analytical Laboratory (SAL) and decommissioned laboratory rooms of the Nuclear Sciences and Applications Department), funds were made available through a variety of well-established mechanisms in the IAEA. Funding for decommissioning activities has not delayed these activities or the disposal of radioactive waste; however, funding should be allocated by the IAEA earlier in the life cycle of facilities.

Interim targets and end states for radioactive waste are proposed in applications for authorization, and preliminary and final decommissioning plans. The Regulator issues authorizations for decommissioning and includes provisions within the authorization for reporting on the end state, which can be verified and inspected by the Regulator. *The recommendation to develop the IAEA's policy and strategy for safety is included in R1*.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no requirements on the authorized DiCH to have financial assurance for decommissioning.	
(1)	**BASIS: GSR Part 6, Requirement 5, Para 3.3 states that** *" Establishing requirements for the licensee's financial assurance for decommissioning and requirements for a mechanism to ensure that adequate resources will be available when necessary for safe decommissioning, in the case where the government has delegated these responsibilities to the regulatory body*;"
(2)	**BASIS: GSR Part 6, Requirement 4, Para 3.2 states that** "*The responsibilities of the government shall include:* *…* *— Establishing a mechanism to ensure that adequate financial resources are available when necessary for safe decommissioning and for the management of the resulting radioactive waste."*
S3	**Suggestion: The DG and DDsG should consider establishing requirements and developing a mechanism to ensure that adequate financial resources are guaranteed at the time of decommissioning.**

1.8. COMPETENCE FOR SAFETY

According to the provisions of the Regulations, the DiCH responsible for a facility or an activity involving ionizing radiation shall ensure that those who work in the facility or carry out an activity have the necessary competence and are generally suitable to carry out work tasks that are important for radiation safety. The level of radiation safety competence required is normally determined as part of the recruitment process, usually by the responsible manager.

The Regulations require each DiCH to provide adequate training and periodic refresher training to their staff. In addition, staff with specific responsibilities for emergency response must be provided with appropriate training and retraining in this area. Similarly, DiCHs are responsible for providing adequate training to Radiation Protection Officers (RPOs). The DiCH and MTGS must ensure that emergency response personnel receive regular training. The DiCHs are required to ensure adequate training for OEW who may be exposed to radiation during duty travel.

In addition, on-the-job training is provided for specific positions (e.g. radiation protection training for OEWs, and specific training for RPOs). Refresher training is also required.

As part of the IAEA's human resources management, staff performance criteria and development objectives are evaluated on an annual basis. This general process also applies to staff working in the regulatory team and supporting units. The same process applies to staff working for authorized parties. In addition, training programmes are provided at DiCH or Departmental level. Such training programmes are usually included in the RPPs approved by the Regulator.

1.9. PROVISION OF TECHNICAL SERVICES

The Regulations provide requirements related to provision of technical services for safety. It is required that provision of individual monitoring services and calibration services, as well as any other services that have significance for safety, shall be subject to authorization. In fact, the provision of individual monitoring services and the calibration services provided by NSRW are duly authorized by the Regulator.

1.10. SUMMARY

This is the first time an IRRS mission has been requested by a non-State. The IRRS team commended IAEA's initiative to invite a peer review of its framework for safety, considering that the IAEA is obliged to apply the safety standards to its own operations. *This was recognized as a Good Practice*.

The IRRS team concludes that the IAEA Statute and the Regulations lay out the obligations of the IAEA in accordance with the safety standards. A Regulator has been established to carry out the regulatory functions, including to supervise the activities of the authorized parties (the DiCHs). While this infrastructure exists, the IRRS team identified a number of areas where the regulatory actions and documentation should be strengthened. This includes core regulatory concepts such as a graded approach, and formal adoption of regulatory processes and procedures in the Management System. These observations are in subsequent Modules of this Report.

The Regulator consists of two technical and one administrative members of staff. It is affiliated with the NS Department. The IRRS team recommends that an assessment is made for resourcing the Regulator at the IAEA-level, considering that the Regulator is a resource for, and serves, the whole of the IAEA. This assessment should focus on the long-term sustainability of the regulatory functions, including entering into formal agreements regarding, e.g. its interaction with the NS Department and regarding access to advice and services, and to further develop and formally adopt its management system.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Due to its specific status, the IAEA plays an active and crucial role in the global safety regime.

The IAEA through the DG is the depositary for several international instruments such as safety conventions (the emergency conventions, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, the Nuclear Safety Convention, etc.). In addition, the IAEA prepares and establishes the international safety standards and codes of conduct, frequently in collaboration with other international organizations, offers peer review services for Member States, organizes and/or participates in multilateral and bilateral cooperation with States and other regional and international organizations and networks.

The IAEA is not a contracting party to any legal instruments developed under its auspices. These instruments assign specific roles to the DG and the IAEA Secretariat, including the depository function and the facilitation or servicing of meetings of the Contracting Parties.

With regard to the Code of Conduct on the Safety and Security of Radioactive Sources (CoC), it is not an international treaty. While the CoC assigns certain roles to the IAEA, these roles are similar in nature to those assigned under the aforementioned international treaties, including the facilitation of meetings among IAEA Member States.

In practice, this means that the IAEA, through its NS Department, supports meetings and may provide technical input as necessary. Where appropriate, the Regulator may participate and provide technical input.

Based on the foregoing, there is no legal basis within international legal instruments developed under the IAEA's auspices for the formal "participation" of the Regulator. However, the Regulator may attend meetings as part of the IAEA's support to the Early Notification and Assistance Conventions, or related to the CoC, and may be invited to share relevant experiences at such meetings.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The IAEA's extensive involvement in international instruments and collaboration does not fully extend to the Regulator, who is rarely formally involved or actively participating in activities relating to the global safety regime. Like other IAEA staff members, the regulatory team members have the possibility to attend some of the IAEA activities or meetings (such as the Senior Regulators Meeting, meetings of the safety standards committees, seminars and webinars). This is predominantly done on an ad-hoc basis rather than in the capacity as a regulator. In practice, this participation is constrained by the high workload and the limited ability to allocate the necessary resources. The importance of this issue was recognized by the IAEA during the self-assessment and it was also addressed in the policy discussions during the mission. In this discussion, one of the tools identified to remedy this situation is the use of a systematic approach by the Regulator to establish means for its engagement in international activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Regulator has limited resources to engage and participate in international cooperation activities to enhance safety. This has been recognized in the ARM.	
(1)	**BASIS: GSR Part 1 Requirement 14, para 3. 4 states that** *"The regulatory body shall establish and maintain a means for receiving information from other States, regulatory bodies of other States, international organizations and authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience. The regulatory body shall require appropriate corrective actions to be carried out to prevent the recurrence of safety significant events. This process involves acquisition of the necessary information and its analysis to facilitate the effective utilization of international networks for learning from operating experience and regulatory experience"*
S4	**Suggestion: The Regulator should consider establishing a strategy to contribute and benefit from international cooperation amongst Member States and with other organizations that provides the means for sharing regulatory experience to enhance safety.**

POLICY DISCUSSION ON PARTICIPATION IN LEGAL AND NON-LEGAL BINDING INTERNATIONAL INSTRUMENTS AND GLOBALIZATION OF THE NUCLEAR COMMUNITY

The policy discussion was on whether the Regulator should become engaged in international activities and if so, what the benefits might be and whether the Regulator would benefit from participating in international instruments. It was recognized that the Regulator comprises only two technical staff who have a wide range of tasks to fulfil. A key consideration for IAEA's involvement is prioritization of both the Regulator's workload to allow time for engagement, and the type of international groups it should be involved in.

As well as formal engagement with international groups, informal engagement with counterparts in Member States was recognized as a good way to develop learning and share work practices; it is acknowledged that being involved in international groups will help foster relationships that can be called upon for informal engagement.

The discussion also noted that one of the barriers to international engagement may be that the Regulator has limited visibility internally and externally. Even when the IAEA is arranging meetings and inviting

international organizations, it does not routinely include its own Regulator. This IRRS mission could be used to raise awareness of the existence and role of the Regulator when interacting with the global safety regime.

It was noted that provision 30 of the CoC assigns the role of the IAEA in particular with the implementation of these provisions. The Regulator has never been invited to the open-ended meetings to discuss and share information related to the implementation of the CoC provisions, in the same manner as other international organizations.

The discussion concluded that it would be beneficial for the Regulator and the IAEA as whole if given the opportunity to engage with relevant international groups and this would be feasible with appropriate prioritization of resources. Participation would also benefit Member States, in particular those with only a small number of regulatory staff.

2.3. SUMMARY

The IAEA through the DG is the depositary for several international instruments. In addition, the IAEA prepares and establishes the international safety standards and codes of conduct, offers peer review services, organizes and/or participates in multilateral and bilateral cooperation with States and other regional and international organizations and networks. The Regulator's staff attend some of the IAEA activities or meetings on an ad-hoc basis. However, the ability of the Regulator to maintain and further enhance its international engagement seems to be restrained by financial and human resources. Establishing a strategy for international engagement that provides the means for sharing regulatory experience that allows for the Regulator's effective allocation of its limited resources.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Regulator role was established in 2007 by the DG. The Regulations were most recently revised in 2017 and define the Regulator's mandate to exercise regulatory functions in the safety and security fields. The Regulator's functions include overseeing the implementation of the Regulations, reviewing their effectiveness, issuing necessary safety and security guidelines, and liaising with relevant authorities to ensure compliance with applicable safety and security requirements in the States hosting the Agency Seat.

The Regulator conducts regulatory oversight of the IAEA's facilities and activities, which include the management of radiation sources and radioactive material at the Agency Seat and the transport of radioactive materials when the IAEA is the consignor. This regulatory oversight extends to activities conducted outside the Agency Seat, such as those in Member States under safeguards agreements, external shipments of radioactive materials, contracted activities involving radiation exposure, emergency assistance missions, and other organized activities that may involve occupational exposure for IAEA personnel or participants.

The DG appoints the Regulator and provides them with the authority, resources, as well as technical and administrative support to fulfill these obligations. This appointment is for individuals and not for a unit or department, meaning the regulatory functions are performed on an individual basis. Consequently, there is no existing organizational structure for the Regulator.

The Regulations authorize the Regulator to propose the designation of an acting regulator to the DDG-NS to cover absences. The acting Regulator has the authority to perform all the regulatory functions. The Regulator trained four staff members from different parts of the department of safety and security for this role while ensuring there was no conflict of interest. This approach is reflected in the draft Quality Manual.

After hiring a new staff member for the Regulator, the Regulator relied, to the extent possible, solely on them to cover these activities. The maintenance of training and competency for these staff to ensure sustainability of regulatory functions is important.

The Regulator reports to the DG through the DDG-NS. The Regulator provides the DG with a comprehensive Annual Report, which includes information on the management of the regulatory system, developments in regulations and guidelines, regulatory oversight, coordination and cooperation, updates on the assessment of overall radiation safety and nuclear security, a summary of the layout of the regulatory program, and staffing needs analysis. The Annual Report also includes the implementation status of open corrective actions, and events that occurred in the year covered by the Report. The report is sent to the DG for information; in some instances, specific feedback on the information provided in the report was received.

The IRRS team observed that the current role of the Regulator in the IAEA has limited visibility beyond authorized parties and other interested parties such as the providers of technical services for safety. This limits opportunities for working together with other parties on improving regulatory functions.

The IRRS team was informed that a staffing needs analysis and planning was conducted in 2015 to identify resource needs; however, since then, no formal re-evaluation has been undertaken to estimate the required resources in terms of staffing, other than what has been stated in the Annual Reports. Subsequently, there has been a growth in regulatory activities including additional assignments such as preparation for and receiving the IRRS mission, and for upgrading the Regulatory Authority Information System (RAIS) from version RAIS 3.4 to version RAIS+, both of which have consumed significant resources due to technical and other challenges.

Resourcing has emerged as a significant challenge, with only two technical staff members and one administrative staff member available. This resourcing level has occasionally contributed to prolonged processes that impact the activities of authorized parties and hinder the Regulator's effectiveness, as well as limits the capacity to respond to unforeseen increases in requests for regulatory functions and compensate for staff absence or departure. It also offers little opportunity for further improvement of the regulatory system, such as developing and formally adopting internal management system documentation or regulatory guides. Additionally, one of the two technical positions is funded by the Program Support Cost (PSC), creating uncertainty regarding long-term availability.

The IRRS team observed that the Regulator does not manage a separate budget; instead, it relies on the regular budget and extrabudgetary funds for salaries and projects. The Regulator operates under the umbrella of the IAEA as an international organization and regulatory costs provided are not charged to the IAEA business units.

Over the past three IAEA programme and budget cycles, the Regulator has requested but not received additional funding for carrying out various projects to support the regulatory functions, limiting the ability to execute those function in a timely manner. *This has been addressed in R.2.*

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The IRRS team noted that the organizational structure of the Regulator under the DDG-NS might lead to questions or perceptions about the independent implementation of regulatory mandates and raise concerns about potential conflicts of interest. Only the Regulator is empowered to make regulatory decisions, including authorizations, inspections, and other regulatory activities. The IRRS team was informed that there had been no interference from successive DDG-NS in regulatory actions. *This has been addressed in S.1.*

While the Regulations recognize that a potential conflict may arise with a Host State during the implementation of the Regulations or the application of the Host State's laws, there are provisions for resolving such conflicts.

In terms of decision-making processes for the regulatory functions, flow charts are in place; however, detailed procedures have not been formally adopted into the Management System.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

Within the regulatory function, a systematic training program for administrative personnel is provided in the draft Quality Manual, however no such program exists for technical staff. The IRRS team was informed that the two technical staff members have not received any formal training related to their technical areas. The regulatory officer who joined in 2018 has only received on-the-job training from the Regulator and had 15 years of experience in regulatory functions prior to joining, while the job description requires only 5 years. Furthermore, the IRRS team was informed that, the recruitment process is utilized to ensure staff have the relevant competence and experience.

This situation presents a challenge for the Regulator's knowledge management in case of staff turnover. Currently, the regulatory functions of review and assessment, authorization, inspection, and enforcement are carried out by both staff members, with a peer review process in place. Due to the nature of the Regulator's work and limited resources, no specific roles have been assigned to each of the two staff members. When specific competencies are not available within the regulatory team, the Regulator approaches other divisions within the IAEA for support. This process is informal and handled on a case-by-case basis.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no systematic training for qualifying the regulator's staff, for example the training on inspection or other technical areas and incomplete arrangements for knowledge management.	
(1)	**BASIS: GSR Part 1 Requirement 18, para. 4.11 states that** *"4.11. 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.* ***4.12.*** *The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff.* ***4.13.*** *A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills.* *The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements.*
S5	**Suggestion: The Regulator should consider establishing a systematic programme for training and knowledge management in order for the Regulator to carry out its regulatory functions effectively.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The IRRS team noted that the Regulations establish the foundation for liaising with support organizations. Specifically, the Regulations empower the Regulator with the authority to obtain technical and professional advice or services as necessary, either from within the IAEA or from external experts, to support the regulatory functions. Moreover, when requesting such advice or services, the Regulator must ensure that there are no conflicts of interest among those providing assistance and that the Regulator remains responsible for all regulatory actions and decisions derived from this advice or assistance.

The Regulator primarily relies on IAEA resources for expert opinion and advice, which depends on the ability of other departments to provide the requested support. The IRRS team was informed that, in one instance, an authorized party had approached the same individual for technical support who provided support to the Regulator on the same issue, which raised concerns. As a result, the Regulator decided not to seek expert opinion and advice from that individual on the issue of concern.

3.5 LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There are several interfaces between the Regulator and authorized parties, occurring both formally and informally. The IRRS team was informed that the Regulator participates regularly in round table sessions for the RPOs and DiCH four times a year. During these sessions, the Regulator is given time to discuss their regulatory updates in a section called "Regulator's Corner". For example, at the last round table session, the Regulator provided an update on the transition to the RAIS+ system and informed about the upcoming IRRS mission. Also, the Regulator shared with authorized parties and the IAEA management how the Regulator played a vital role in making significant changes between the years 2015 and 2017 (when the IAEA regulatory system was relatively young) and how these changes had a significant positive impact on safety.

Additionally, the Regulator holds its own coordination meetings with authorized parties as required to discuss relevant regulatory matters such as the interpretation of regulations or practices that affect the regulated facilities and activities. Information is shared either formally through Interoffice Memoranda (IOM) or as presentations in meetings (e.g. about notification of events and contents of Annual Safety Reports). The communication of regulatory decisions is conducted through formal communication.

The Regulator follows the safety standards development process and involves consultations with authorized parties and the Host State, when creating its own regulations and guides. However, this approach has not been formally adopted.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

Currently, the Regulator has issued one regulation and three regulatory guides. The Regulator reviewed the Regulation between 2021 and 2022 and identified areas for improvement. The IRRS team was informed that the Regulations remain fit for purpose. The general flowcharts related to functions such as authorization, inspection, enforcement, and investigation of the Regulator are in place; however, they have not yet been adopted in the Management System. The Regulator partly applies a graded approach within its regulatory functions for review, assessment, and inspection, although in the case of inspections, there is no grading of identified non-compliance.

3.7. SAFETY RELATED RECORDS

One of the functions of the Regulator is to establish and maintain records related to the fulfilment of its regulatory functions, including regulatory decisions and their bases. The Regulator maintains these records through various means, which includes a dedicated shared drive where all regulatory documents are scanned and saved electronically in a structured manner, and the RAIS+ system. RAIS+ also contains an inventory of sources and event reports, and provides a range of data analysis and reporting tools. Transfer to the RAIS+ is done by limited number of countries and the Regulator made huge efforts to use the updated version and they succeeded in transferring 95% of their data. **The IRRS team considers this a good performance.**

The Regulator presented an Excel spreadsheet to the IRRS team, which is used to track correspondence, ensuring all incoming and outgoing communication is maintained and accessible to regulatory team members. While hard copies were previously maintained, working practices were modified during the pandemic, leading to a fully paperless system.

Authorized parties are also required, as per the Regulations, to maintain their records. The DiCH is responsible for establishing and maintaining safety-related records.

The maintenance of dose records has been assigned to a service provider. See Module 5 for further information.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The draft Quality Manual identifies the areas of communication and consultation with interested parties. The Regulator has specified the stakeholders in their draft manual, which include the DiCH and their representatives (such as RPOs), DDsG, the DG, internal providers of expert opinion and advice, the Office of Legal Affairs, and personnel at large. Additionally, the IRRS team was informed that the Host State is also considered a stakeholder for the Regulator.

There has been no communication arrangement to inform interested parties, including agency staff, about the radiation risks associated with facilities and activities authorized by the regulator and its processes.

The Regulator does not provide access to information regarding authorized parties, such as events, inspections, and authorizations to interested parties. Nonetheless, the Regulations and regulatory guides are shared and consulted with all interested parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: Access to information regarding authorized parties, such as events, inspections, and authorizations is not always available to interested parties.

(1)	**BASIS: GSR Part 1 Requirement 36, para. 4.66 (X) states that** *"Requirement 36:* *The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.* *4.66. The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision making process. This communication shall include constructive liaison such as:* *(a) Communication with interested parties and the public on regulatory judgements and decisions;* *(b) Direct communication with governmental authorities at a high level when such communication is considered necessary for effectively performing the functions of the regulatory body;* *(c) Communication of such documents and opinions from private or public organizations or persons to the regulatory body as may be considered necessary and appropriate;* *(d) Communication on the requirements, judgements and decisions of the regulatory body, and on the bases for them, to the public;* *(e) Making information on incidents in facilities and activities, including accidents and abnormal events, and other information, as appropriate, available to authorized parties, governmental bodies, national and international organizations, and the public.*
S6	**Suggestion: The Regulator should consider making information related to authorized parties available to interested parties, as appropriate.**

Policy Discussion: Human Resources and Knowledge Management

The Human Resource and Knowledge Management policy discussion included strategies to prevent the loss of knowledge upon staff departure from the IAEA regulatory team and strategies to follow that minimizes resources needed for enhancing document management and for finalizing the management system.

The IAEA has a general knowledge management procedure in place and the Regulator takes action towards capturing existing knowledge. Nevertheless, the Regulator faces several challenges to its knowledge management, such as the IAEA's rotation policy of limiting assignments to a maximum of 7 years, and the policy to not allow overlapping assignments.

To address the knowledge transfer of the Regulator, several options were discussed, including the following:

- Increase staff knowledge through both formal (e.g., training and conferences; information gathering mission to another State regulator) and informal initiatives (e.g. learning sessions with State regulators and IAEA staff, virtually or in-person)
- Staff schedule and engage in knowledge transfer sessions over time prior to staff departure
- IAEA seeks experienced external advisors to assist in instituting a knowledge management process
- IAEA institutes a hiring plan and recruit staff with regulatory experience, designate staff as critical resources, and consider conducting exit interviews at various intervals well in advance of staff departure to gather knowledge.

The IAEA currently has a program specific to knowledge management in the Safeguards department with strategies to gather departing staff knowledge to support knowledge transfer. Establishing this program to target knowledge transfer for the Regulator team would be beneficial. The policy discussion ended with several strategies for enhancing knowledge management and finalizing the management system, including the following:

- Accomplish document management activities over time to facilitate knowledge management;
- Capitalize on internal knowledge of the IAEA to fill gaps in writing procedure;
- Identify the root causes, provide stability for staff, and implement preventive measures to minimize risk of staff departing early;
- Develop formal procedures and utilize current IAEA staff to fill knowledge gaps and contract retired staff to support knowledge management;
- Seek experience from external advisors to provide advice to enhance the management system related to knowledge management and transfer;
- Implement a strategy to undertake a small project within 1-2 years to enhance the management system focused exclusively on knowledge management

3.9. SUMMARY

The Regulator, established in 2007, operates under the Regulations set by the DG, with revisions made in 2017. The Regulator's role includes overseeing safety and security compliance with the Regulations within the IAEA's facilities and activities, both within Agency Seat and in Host States. The Regulator reports to the DG through DDG-NS.

Resource constraints have emerged as a challenging issue, resulting in difficulties to adequately manage its responsibilities, including in training personnel and sharing knowledge effectively.

The existing informal arrangement allows the Regulator to seek expert opinion and advice while ensuring no conflicts of interest, making the Regulator responsible for subsequent decisions. The Regulator primarily relies on internal IAEA resources for this support.

While a number of documents have been developed and used in practice, they have not been finalized and formally adopted in the Management System. Without a standardized approach to manage regulatory functions, the Regulator's ability to maintain stable and consistent operational capacity is reduced.

The Regulator has established and maintains a comprehensive records systems related to its regulatory functions, utilizing various systems for effective documentation management. The Regulator has transitioned to a paperless system. Furthermore, 95% of data has successfully been transferred to the RAIS+ platform, ensuring accessibility, retrieving and maintaining safety related records.

Communication with authorized parties is conducted through various meetings and channels, and there is a formal approach in place for communicating with the Host States. However, transparency in sharing relevant information with the interested parties other than authorized parties remains insufficient and needs improvement.

4. MANAGEMENT OF THE REGULATORY BODY

4.1. RESPONSIBILITY

The Management of IAEA demonstrates leadership and commitment for safety by defining the organization's values and goals. The IAEA values and goals are contained in its mission statement, strategic and annual plans and made available to staff through various means that include the website, and intranet (InSite). The DDG under whom the Regulator falls expresses commitment to safety and promotes safety values though regular interaction with staff and other interested parties.

The Regulator is responsible for the development and continuous improvement of their management system and regularly reports on its performance and areas of suggested improvement during team meetings and through Annual Reports to the DG. Although the management system contains several elements for promoting safety and a culture of safety, the Regulator has not developed a safety policy to underscore that safety is the main priority in all its operations. The IRRS team was informed by the DDG-NS on the possibility of developing an overall safety policy of the IAEA which the Regulator could incorporate into their management system, *as recommended in R1*.

4.2. THE MANAGEMENT SYSTEM

The Regulator operates under the overall guidance of the IAEA's Administrative Manual. Efforts have been made to document the core regulatory processes in a draft Quality Manual to be used by the regulatory staff and RPOs, accessible through the IAEA communication systems. The draft Quality Manual contains general descriptions of processes, workflows showing the interfaces between processes as well as individual job descriptions. The draft Quality Manual incorporates a graded approach with priority given to core processes with an impact on safety. The IRRS team noted that the draft Quality Manual requires further development and finalization to ensure consistency and stability of control.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Development of the Regulator's Management System is in progress, and a draft Quality Manual has been developed to integrate all elements. Several core regulatory processes require finalization before the manual can be formally adopted for use by regulatory staff. This has been recognized in the ARM.	
(1)	**BASIS GSR Part 1 (Rev.1) Requirement 19: state 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 *1* Requirement *19 para (4.14)*.14.state that** "The regulatory body shall establish and implement a management system whose processes are open and transparent. The management system of the regulatory body shall be continuously assessed and improved "
(3)	**BASIS: GSR Part 2 Requirement 8 states that *"The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.***

R3	**Recommendation: The Regulator should complete the documentation of the management system for formal adoption, and establish a mechanism for its regular independent review to ensure consistency and stability of control.**

4.3. MANAGEMENT OF PROCESSES AND ACTIVITIES

The Regulator has established and implemented several processes such as review and assessment, authorization and approvals, inspection and enforcement. For issuing Regulations and guides, the Regulator follows the IAEA process for developing safety standards. Workflows guiding the processes and interfaces have been partially developed but not yet formally adopted. The IRRS team observed that while process implementation is underway, documentation is critical to ensure consistency especially considering the rotational nature of IAEA employment contracts. The Regulator is responsible for the management of all processes due to the size of the regulatory body.

4.4. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The Regulator conducts reviews of its work performance through daily interactions, team meetings held fortnightly as well as the annual performance/ personal development evaluation. Performance is reviewed against targets set in the planning period. The Regulator submits a comprehensive annual report to the DG for information, highlighting key performance matters. The IRRS team was informed that the individual performance review of the regulatory staff identifies areas of improvement and suggests interventions.

4.5. LEADERSHIP AND CULTURE FOR SAFETY

4.5.1. FOSTERING AND SUSTAINING LEADERSHIP AND CULTURE FOR SAFETY

The Regulators' safety culture is maintained through the ongoing application of elements of the management system that guides staff when making decisions. Daily engagements by the two regulatory staff enables the team to provide feedback on the implementation of processes and on their own performance. This promotes openness and engagement in decision-making and ensures that safety remains an overriding priority. In addition, the Regulator assesses the safety culture of licensees during each inspection which is highlighted in the report. The IRRS team was shown a typical inspection report to verify this.

4.5.2. MEASUREMENT, ASSESSMENT AND IMPROVEMENT OF LEADERSHIP AND CULTURE FOR SAFETY

The Regulator has not conducted an independent assessment of its leadership for safety and for its safety culture. The IRRS team noted that the Regulator could select available methodologies/ approaches for safety culture assessment that suit its size and resources while providing valuable insights on its work.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Regulator has not commissioned assessments of its leadership for safety and of its safety culture.	
(1)	**BASIS: GSR Part 2 Requirement 14 states that** *"Senior Management shall regularly commission assessments of leadership for safety and of safety culture in its own organization.* *6.10. Senior management shall ensure that an independent assessment of leadership for*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	safety and of safety culture is conducted for enhancement of the organizational culture for safety.
R4	**Recommendation: The Regulator should arrange for independent assessments at planned intervals to measure, evaluate and review its leadership for safety and safety culture, to improve the overall safety performance.**

4.6. SUMMARY

The Regulator has established and implements some elements of the management system which include core regulatory processes. The development and documentation of the management system requires completion and adoption to ensure the integration of safety. A system of internal assessment and evaluation is in place allowing for continuous improvement. No arrangements have been made for the external assessment and evaluation of the leadership for safety and safety culture of the Regulator. Limited financial and human resources have impacted the development of the management system of the Regulator.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The Regulations empower the Regulator to issue authorizations for facilities and activities, subject to any condition that may be required in the opinion of the Regulator; and to revoke at any time, any such authorizations, if the Regulator considers the facility or activity is not in compliance with the required standards or levels of safety. An authorization can only be granted on the condition the party seeking authorization submits all relevant information which the Regulator considers necessary. If an initial review of an application reveals that information is inadequate, applicants are requested to submit the additional details.

According to the Regulations, the Regulator shall specify those facilities and activities for which notification is sufficient. The Regulator has established internal criteria for determining whether notification is sufficient, however this is not available to potential applicants. Where applicable, the decision whether full authorization is required, is taken on a case-by-case basis with due consideration of a graded approach, although no formal procedures have been adopted by the Regulator.

Stages in the lifetime of facility that require authorization are listed in the draft Quality Manual, and are defined as the following:

- Facility design (if specific safety related structures, systems and components are needed, e.g., active ventilation system, shielding, etc.)
- Commissioning or acceptance testing of radiation generators or equipment containing radioactive sources
- Use of radiation sources or operation of a facility
- Storage of radioactive material in certain cases
- Decommissioning

The Regulations also require the Regulator to determine which stages in the lifecycle of a facility, or the duration of an activity, necessitate formal authorization. This requirement is addressed in the draft Quality

Manual. A formal document on the authorization process specifying the stages in the lifetime of an IAEA facility or activity that require an authorization and outlining the form and contents of an application for authorization has not been fully developed. *This has been addressed in R.3 and R.8.* This information is provided to the applicants through presentations and meetings with the RPOs.

When an authorization is granted, an authorization certificate is issued. Each authorization certificate contains the scope of authorized activities and facilities, specification of the involved radiation sources, the location of the authorized activities, a list of additional limits and conditions specified by the Regulator, as well as validity date of the authorization. As part of an authorization, the applicant is required to submit a safety assessment on an annual basis, which is reviewed and assessed by the Regulator. All authorizations are valid for five years, independent of the source category. A renewal of an authorization verifies the information in the safety case, as well as takes into consideration events and non-compliances over the previous authorization period.

The Regulations establish a mechanism for the DiCH to appeal different types of regulatory decisions, including denial of authorization and imposed operational limits and conditions.

The detailed technical report prepared by the Regulator when reviewing and assessing an application for a renewal of an authorization is sent to the applicant together with authorization or rejection as appropriate. The report includes among others the detailed Regulator's assessment of a history of compliance of the applicant and lessons learned. **The IRRS team considers this to be good performance**, as it promotes safety and transparency of the regulatory decisions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Regulator does not have formally adopted procedures for authorization that take into account a graded approach. This has been recognized in the ARM.	
(1)	**BASIS: GSR Part 1 Requirement 24, para. 4.33 (X) states that** "Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [9], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."
R5	**Recommendation: The Regulator should finalize and formally adopt procedures for authorization taking into account a graded approach.**

The Regulator analyses submissions for approval of RPOs. Although, the analysis is performed by considering a graded approach, there are no formal procedures where the criteria for analysis are established.

The IRRS team noted that IAEA has a large pool of experts in a broad spectrum of radiation and nuclear safety as well as nuclear security. However, the recognition of qualified experts has not been addressed in Regulations and therefore no qualified experts are formally recognized. In addition, the role of qualified experts in establishing and maintaining regulatory framework for safety and security at IAEA has not been addressed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although the IAEA has a pool of experts consulted by the Regulator and authorized parties, there are no requirements in the regulations to recognize the qualified experts and identify their responsibilities	
(1)	**BASIS: GSR Part 3 Requirement 2, para. 2.21 states that** *"The government shall ensure that requirements are established for:* *(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;* *(b) The formal recognition of qualified experts;* *(c) The competence of organizations that have responsibilities relating to protection and safety."*
S7	**Suggestion: The DG and DDsG should consider ensuring that requirements are established for the formal recognition of qualified experts.**

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Waste management facilities have not been established under the control of the IAEA, as authorizations are limited to activities being conducted at the Agency Seat. As part of their operation, radioactive waste undergoes predisposal at the laboratories and is transferred to waste management facilities operated in Austria in accordance with established criteria.

Appropriate management of radioactive waste resulting from operations or decommissioning activities is evaluated during the review and assessment of the facility safety demonstration. In the specific context of the IAEA, it is required for the management of radioactive waste to follow the requirements of the Host State, as established in the Regulations. This also applies to the waste generated during decommissioning and any resulting material that might be subject to clearance. The disposal of radioactive waste resulting from operation (or decommissioning) of the IAEA Laboratories in Seibersdorf is made through NES on contractual basis. There are established transport procedures between both adjacent sites. (i.e., IAEA laboratories in Seibersdorf and NES).

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The regulatory system within the IAEA includes adequate provisions for protection and safety in all facilities or activities involving the use, storage, or handling of radiation sources. While primarily focused on the Agency Seat these provisions also extend to activities conducted outside of the IAEA, such as the procurement of sources for States or placing IAEA-owned sources in Member States' facilities. Currently, there are twelve facilities at the Agency Seat authorized by the Regulator.

The Regulations and current regulatory arrangements ensure the following:

- Control the transfer of sources between IAEA facilities and activities, ensuring that only authorized facilities can receive sources.
- Control the transfer of sources to external facilities (e.g., safeguards operations, return to supplier, or disposal as waste).
- Control the procurement of sources for use by the IAEA.

5.4. AUTHORIZATION OF DECOMMISSIONING OF FACILITIES

According to the Regulations, decommissioning is one of the stages in the lifetime of any IAEA facility and requires separate authorization. Therefore, all requirements regarding radiation safety are applicable also for decommissioning.

Initial provisions for future decommissioning are part of the standard safety demonstration required by the Regulations to support any application for authorization. Each of the decommissioning authorization certificates contain specific conditions requiring the DiCH to provide a final report summarizing the safety issues encountered during the decommissioning process and confirming its completion, i.e. achieving the end state specified in the authorization. In addition, records relevant for decommissioning and release from regulatory control must be kept for the lifetime of the facility or until its release from regulatory control.

The Regulator has the authority to conduct inspections and enforce corrective actions for decommissioning activities. The Regulator also requires, and approves if needed, that appropriate institutional controls that may be applied in the period between the closure of the facility and decommissioning.

In practice, the Regulator has established criteria for authorization of decommissioning activities through informal means; however, the process and specific information required for authorization of decommissioning activities are not formally adopted. *This has been addressed in R.3*. The Regulator is able to request additional information, if needed to make a decision on authorization. The Regulator should develop guidance on the format and content of the documents to be submitted by the applicant *This has been addressed in R.8.*

A detailed decommissioning plan is required for authorizing the decommissioning activities. In addition, the authorized party prepares for decommissioning throughout the lifetime of the facility, as initial provisions for future decommissioning (i.e. preliminary decommissioning plans) are part of the standard safety demonstration required to support any application for authorization.

There are no explicit requirements in the Regulations for periodic updates of the decommissioning plans. However, authorizations for operation of facilities are issued for a period of five years, which requires the licensees to revise the entire safety demonstration at this frequency, or on request by the Regulator. This offers an opportunity to require a review of the preliminary arrangements for decommissioning when applying for renewal of an authorization.

5.5. AUTHORIZATION OF TRANSPORT

The agreements between the IAEA and the Republic of Austria and the Government of Monaco establish the authority of the IAEA to make regulations, operative within the Agency Seat, for the purpose of establishing requirements and oversight for transport. The Regulator exercises oversight over the DiCH for compliance with SSR-6 and the transport regulations accordance with the Regulations.

The competent authority in the country of origin of the shipment is responsible for issuing approval for package designs and activities covered by SSR-6. The Austrian competent authority for transport is the competent authority for transport where the IAEA is the consignor of the shipment from the Agency Seat in Austria. Transport carriers transporting radioactive material are required in the contracting process to comply with the requirements in SSR-6 and the Agreement concerning the international carriage of dangerous goods by road (ADR). The carrier is responsible to apply for authorization for transport activities conducted through or into each country in accordance with SSR-6. The Regulator verifies that documentation from the relevant authorities has been obtained.

The International Laboratory of Marine Radioactivity in Monaco is engaged only in transport activities involving exempted sources.

5.6. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The Regulations establish comprehensive requirements for occupational exposure in planned exposure situations. The DiCHs are responsible for controlling occupational exposure in their respective facilities or activities. For occupational exposure control purposes, the manager of an IAEA worker is considered the employer. When the DiCH and the manager are different, cooperation is required. A regulatory guide "Application of the Regulatory Requirements in Cross-Divisional Activities" was established in 2021 to facilitate this cooperation.

The DiCHs of facilities and activities must establish and maintain a RPP. This program outlines arrangements for compliance with regulations, including information on activities, risks, organization, monitoring, health surveillance, personal protective equipment, incident response, training, recording, reporting, and program auditing. The program requires approval from the Regulator as part of the authorization.

IAEA and outside workers must comply with regulations and safety measures, cooperate with the DiCH and RPO, and refrain from harmful actions. Workers must participate in training, use monitoring equipment properly and report unusual conditions, or incidents to the DiCH, immediate supervisor, or RPO.

Female IAEA workers should notify the DiCH and their immediate supervisor if they are pregnant or breastfeeding. The DiCH must adapt working conditions to ensure the protection of the embryo, fetus, or infant, which might involve adjusting work tasks, limiting exposure, or providing alternative work arrangements.

The IAEA has established a policy for occupational health and safety, which covers *inter alia* radiation safety. This policy establishes a health and safety committee, in which the Regulator is a member.

The health surveillance guide from 2013 is not fully implemented and requires revision. It provides limited information on the content of medical examination and health surveillance programs. Additionally, health surveillance for non-routinely monitored Occupationally Exposed Workers (OEWs) is not clearly addressed. To improve the effectiveness of health surveillance, the guide should be updated to include all OEWs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The health surveillance guide does not adequately address all OEWs. This has been recognized in the ARM.	
(1)	**BASIS: GSR Part 3 Requirement 25, para.** *3.109 states that "If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a source that is not under the control of their employer, the registrant or licensee responsible for the source shall, as a precondition for the engagement of such workers, make with the employer any special arrangements for workers' health surveillance that are needed to comply with the rules established by the regulatory body or other relevant authority.* **BASIS: GSG 7, para. 10.1***"the management should ensure that all workers engaged in activities in which they could be subject to occupational exposure are provided with the necessary workers' health surveillance and health services".*

S8	**Suggestion: The Regulator should consider, in cooperation with the VIC Medical Service, reviewing and updating the health surveillance guide as required to include all Occupationally Exposed Workers.**

The Regulations do not explicitly address occupational exposure in certain existing exposure situations such as exposure to Radon in the workplaces. According to the Headquarters Agreements, the laws and regulations of the Host States are applicable in such cases, but this is not explicitly stated in the Regulations.

The IAEA Radiation Safety Technical Services Unit (RSTSU) provides radiation protection services in compliance with the Regulations. These services include individual monitoring, workplace monitoring, emergency response, and equipment calibration. The RSTSU also provides Radiation Protection Training Course for OEWs in-person and online. The RSTSU is an ISO/IEC 17025 accredited testing services, demonstrating its technical competence and impartiality, and is authorized by the Regulator.

While the RSTSU provides technical services to the Regulator and other parties, no formal service level agreement has been established with the Regulator.

The Regulator should consider establishing and implementing a service level agreement with the RSTSU. that outlines the specific services provided by RSTSU, the performance expectations, and the mechanisms for addressing any issues or disputes. *This has been addressed in S.2*

For certain activities outside the Agency Seat, external service providers may monitor occupational doses of IAEA workers and participants under specific conditions. In these cases, arrangements ensure that dose records are provided to the IAEA and kept by RSTSU. However, these external doses are not currently integrated into the dose records held by RSTSU for their own results.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: For certain activities outside the Agency Seat, external service providers may monitor occupational doses of IAEA workers and participants under specific conditions. In these cases, arrangements ensure that dose records are provided to the IAEA and kept by RSTSU. However, these dose records are not currently integrated into the dose register held by RSTSU. This has been recognized in the ARM.	
(1)	**BASIS: GSR Part 3 Requirement 20, para.** *3.73. (e)* **states that** *"The regulatory body shall be responsible, as appropriate, for:* *(e) Provision for maintaining exposure records and results of the assessment of doses from occupational exposure*
(2)	**BASIS: GSR Part 3 Requirement 3, para. 2.35 states that** "*The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to facilities and activities. These records shall include:* *…— Records of doses from occupational exposure; …"*
(3)	**BASIS: GSG-7 para. 7.265. states that** *"Consideration should be given to the establishment of a national dose registry as a central point for the collection and maintenance of dose records. The storage of information at the national dose registry should be such as to allow workers, during and after their working life, to retrieve information on the doses they received while occupationally exposed..."*

S9	**Suggestion: DDG-NS in collaboration with the Regulator should consider expediting the finalization of a central dose register at the RSTSU with the integration of doses from external providers into their existing records.**

5.7. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

Each DiCH is responsible for ensuring that public exposure from authorized facilities and activities under their management, including personnel not designated for occupational exposure, remains within the specified dose limits. Additionally, a dose constraint of 0.3 mSv per year must be applied to public exposure resulting from any authorized facility or activity.

In accordance with the Regulations, the DiCH is responsible for assessing predicted discharges and the proposed safety measures to demonstrate that these discharges remain below the limits set by the Host State, ensuring that the dose constraint to the public is not exceeded during routine operations. This assessment is reviewed by the Regulator during the authorization process, and operational limits and conditions are established or approved based on the evaluation, although there is no specific authorization of public exposure situations. Discharges are an area of interface with the Host State's authorities, as described by the Technical Agreement between the Austrian authorities and the IAEA.

All safety measures related to public exposure control are reviewed during the authorization process, as well as through ongoing oversight activities, including the review and assessment of mandatory annual reports and inspections.

5.8. SUMMARY

There are clear regulatory requirements in the Regulations for the authorization of the facilities and activities at the Agency Seat. In practice, there is an approach in place for authorization which takes into consideration the associated radiation risks in accordance with a graded approach. Currently, it is not formally adopted how the Regulator considers a graded approach in authorization.

In cooperation with the VIC Medical Service, the Regulator should ensure that all OEWs are adequately considered in the health surveillance guide. Additionally, doses from external providers should be integrated in a central dose register at the RSTSU, which is under development.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

According to the Regulations, the review and assessment process involves the Regulator examining the application for authorization and its supporting documents against the Regulations, and relevant IAEA standards and guides. Once satisfied with the demonstrated adequacy of safety and security measures and compliance with the Regulations, an authorization certificate is issued by the Regulator. If the review raises reasonable doubts about the adequacy of safety and security or compliance with regulations, the Regulator may deny authorization or request additional information. This decision will be communicated to the DiCH and the relevant DDsG with appropriate justification.

The review and assessment process is comprehensive and is applicable to initial authorization, renewals, annual safety reports, radiation events, modifications in the authorization conditions, changes in the scope of the authorized activities and other information from third parties such as RSTSU. In practice, the depth of the review is proportionate to the radiation risks; however, the application of a graded approach is not formally adopted. *This has been addressed in R.5*. The Regulator may require the DiCH to implement corrective actions for identified areas of improvement, with follow-up activities conducted by the Regulator.

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

There are no dedicated waste management facilities at the Agency Seat. However, the Regulator does authorize waste management activities that are included in the authorized facilities.

The Regulations include the necessary requirements in order to review and assess waste management facilities, and the process for conducting the review and assessment is captured in section 6.1.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Safety-related information is periodically required through the renewal of authorization and through the submission of an annual safety report by the DiCH. Every five years, the safety demonstration must be updated by the applicant and reassessed by the Regulator as part of authorization renewal.

Following the review of annual safety assessments, a report is compiled, which is uploaded into a shared drive and accessible to all regulatory staff, and is sent to the facility. Depending on the significance of the findings related to safety and security, the following control measures are applied:

- Mandatory Improvements: Deadlines for implementation are included as part of the review and assessment report or the authorization conditions.
- Progress Reporting: Necessary improvements are noted in the review report, and the authorized party is required to report on progress in the subsequent annual report.

In certain cases, a combination of these approaches may be applied.

The scope and depth of the review and assessment is proportional to the associated radiation risks, following a graded approach. Although, there is no internal guidance for the Regulator on the procedures to be followed in the review and assessment process, and the safety objectives to be met. *This has been addressed in R.3.*

6.4. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The Regulator conducts reviews and assessments of preliminary and detailed decommissioning strategies and plans. These strategies and plans are prepared by the authorized party in accordance with GSR Part 6.

Authorized parties submit a final decommissioning report to the Regulator for review following the completion of authorized decommissioning activities. These activities are also summarized in the annual reports submitted by authorized parties for review and assessment by the Regulator.

6.5. REVIEW AND ASSESSMENT FOR TRANSPORT

The primary activities related to transport are conducted within the IAEA facilities for onsite movements. Most shipments are either in excepted packages or in Type (A) packages. In accordance with the Regulations, the DiCH is required to notify the Regulator prior to each shipment of radioactive material in packages other than excepted packages. In addition, the DiCH is required to submit a list of shipments of radioactive material in the excepted packages to the Regulator on a quarterly basis.

Shipment of sources in Type (A) packages and excepted packages do not require approval by the Regulator. Transports with quantities greater than the exempted limits requires the DiCH to submit a comprehensive description of proposed transport arrangements to the Regulator as part of the application for authorization. The Regulator reviews transport arrangements for compliance with all of the specific safety requirements outlined in SSR-6 and possession limits authorized on the radioactive material license.

The IAEA has procedures for acceptance of transport packages containing radioactive materials in quantities great than the exempted limits. The RSTSU is available to support transport activities including individual monitoring, calibration of radiation monitor device, workplace monitoring and to issue the certificate for the results of the radiation surveys.

6.6. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

The review and assessment process comprehensively evaluates the organizational, procedural, and technical measures implemented to protect OEWs within facilities. This information is documented in the RPP, a mandatory component of the application for authorization. The review encompasses individual monitoring, area designation, workplace monitoring, clear delineation of responsibilities for DiCHs, RPOs, and OEWs, and the provision of comprehensive safety related training.

The review and assessment process is applied to all annual safety reports prepared by the DiCHs on radiation protection in their respective activities. This review and assessment is part of the compliance monitoring process. For occupational exposure, the Regulator reviews and assesses all information received, including radiation events, facility modifications, changes in authorized activities, and doses exceeding investigation levels.

6.7. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

According to the Regulations, each DiCH establishes a monitoring and surveillance program to demonstrate that discharges of radioactive substances to the environment are minimized and comply with the relevant laws and regulations of the Host State, as well as the conditions specified in the authorization certificates issued by the Regulator. The DiCH is also responsible for maintaining the related records.

Since the IAEA has no specific regulations regarding reference levels for radionuclides in commodities, Host State’s regulations apply in such cases. In addition to the laboratories' monitoring programs at the Agency Seat, environmental monitoring in the Seibersdorf area is conducted by Austrian institutions, with financial contributions from the IAEA. The results of this monitoring are included in the Annual Safety Reports and are presented to Austrian authorities during the annual safety review in Seibersdorf.

6.8. SUMMARY

The Regulator conducts a comprehensive review and assessment process. This process is applied to all authorizations and annual safety reports prepared by DiCHs regarding radiation protection in their respective activities.

The IRRS team observed that to enhance the efficiency and transparency of the regulatory process, the Regulator should consider adopting a formal procedure for review and assessment. This procedure would outline the specific steps involved, the criteria for evaluation, and the expected outcomes.

7. INSPECTION

7.1. GENERIC ISSUES

The Regulations give the Regulator authority to conduct inspections of authorized facilities and activities to verify compliance with the Regulations and the conditions outlined in the authorizations.

Inspections include the following sequential steps: preparation, conduct, analysis of findings, documentation, and reporting. However, these steps are not formally adopted in a written procedure. Most of the conducted inspections are full scope, covering all applicable safety and security areas, including the management and leadership for safety, record keeping, and safety and security culture.

All the inspections are conducted without their own survey meters or other measuring equipment, including inspections for category 1 or 2 sources. The outcome of the inspections is documented in a formal inspection report, which is sent to the inspected facility. The IRRS team noted that implementation of corrective actions is followed up and recorded by the Regulator.

The priority and frequency of inspections reflect the risk associated with the radiation source and the complexity of the facility or activity. Currently, there are no formally established criteria to define the frequency of inspections, nor is there a formal inspection programme or plan in place by the Regulator. Furthermore, the Regulations allow the Regulator to perform both announced and unannounced inspections. However, in practice, only announced inspections have been carried out.

Additionally, there is no formal training programme for inspectors. *This has been addressed in S.5*.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Regulator has not formalized an inspection programme or plan. - This was recognized in the ARM.	
(1)	**BASIS: GSR Part 1 Requirement 28, states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and unannounced."*
(2)	**BASIS: GSR Part 1 Requirement 29 para. 4,50, states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections) and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(3)	**BASIS: GSG 13 para. 3.218, states that** "*The priority and frequency of inspections should reflect the risk associated with the radiation source and the complexity of the facility or activity, as well as the possible consequences of an*

	accident and the type and frequency of any regulatory non-compliances found by inspections"
(4)	**BASIS: GSG 13 para. 3.240, states that** *"Planned inspections, either announced or unannounced, should be carried out in fulfilment of a predetermined inspection plan developed by the regulatory body to provide sufficient confidence that regulatory requirements are being met (baseline inspection plan)…"*
R 6	**Recommendation: The Regulator should develop an inspection programme and plan in accordance with a graded approach.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Inspections follow clear steps in the preparation, conduct, analysis of findings, documentation and reporting. However, these steps are not documented in a written procedure. and it does not include the identification of the necessary equipment for the inspection. This has been recognized in the ARM.	
(1)	**BASIS: GSG-13, para. 3.262 (X) states** that "The regulatory body should issue internal guidance for its inspectors on performing regulatory inspections in order to ensure a consistent approach to inspection while allowing sufficient flexibility for inspectors to take the initiative in dealing with new concerns that arise. Each inspector should be given adequate training in following this guidance."
(2)	**BASIS: GSG-13, para. 3.263 states that** "The guidance for inspectors should include the following: (a) Policies of the regulatory body regarding inspections. (b) The legal basis for regulatory inspection and the scope of the inspector's authority. (c) The use of regulatory requirements, regulations, guides and standards. (d) The development of an inspection programme. (e) The implementation of the inspection programme, including: (i) Facilities (or areas of the facility) or activities to be subject to inspection; (ii) Method of inspection to be used; (iii) Methods for selection of inspection samples; (iv) Use of relevant technical information; (v) Use of inspection questionnaires; (vi) Follow-up on inspection findings. (f) Reporting requirements and practices for inspectors. (g) Standards of conduct of inspectors. (h) The enforcement policy, procedures and practices".
(3)	**BASIS: GSG-13 para. 3.267, states that** "Preparation includes the identification of the necessary documentation and equipment for the inspection. Depending on the particular circumstances and the nature of the facility or activity these may include: ... (d) Appropriate survey meters or other necessary measuring equipment..."
(4)	**BASIS: GSG-13 para** 3.221**, states that** "Specific responsibilities of the regulatory body with respect to inspection should include the following: … (i) Developing procedures and directives as necessary for the effective conduct and administration of the inspection programme;"
S10	**Suggestion: The Regulator should consider formally adopting procedures for inspections.**

Site Visit to the Insect Pest Control Laboratory

The IRRS team observed the inspection at the Insect Pest Control Laboratory in Seibersdorf. The inspector briefed the IRRS team on the preparation for the inspection, namely the review of documentation related to

the authorization process and preparation of the checklist before the inspection. The inspection followed the checklist that included an entrance meeting, interviews with laboratory personnel, and a visual observation of sources and equipment. The IRRS team noticed that the inspector did not use a survey meter during the inspection.

During the exit meeting, the main findings were shared with the laboratory personnel, following which the inspection ended. The IRRS team observed that the inspector displayed professional behaviour throughout the inspection. After the closing meeting, the IRRS team met with the inspected team. The IRRS team was informed that this was the first inspection in this laboratory since 2015 when the current RPO was appointed. The RPO stressed to the IRRS team that more frequent inspections would be beneficial. The RPO informed the IRRS team that it is easy to contact the Regulator, both by phone and email. When questioned about the authorization process, the RPO pointed out that there was frequent communication at the beginning of the authorization process and a prescribed guide on the application content would be very helpful because it is not clear which documents should be included in the applications as well as details on the necessary information to be provided. The RPO informed the IRRS team that guides would be very useful, including a guide on nuclear security. The laboratory staff were not aware of the three guides that the Regulator has already published.

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

There are no dedicated waste management facilities at the Agency Seat. However, the Regulator does conduct inspections of waste management activities that are included in the authorized facilities. *This has been addressed in section 7.1.*

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Prior to 2022, an average of one planned inspection per year was conducted. In 2022, the initiative was taken to increase the number of planned inspections to two per year.

The Regulator's decision on which facilities to inspect considers factors such as the radiation risks posed by the facility, the date of the last inspection, and the facility's performance and compliance history.

7.4. INSPECTION OF DECOMMISSIONING ACTIVITIES

Focused inspections on decommissioning activities have not been conducted, and decommissioning is only considered as part of a routine planned inspection, if applicable. Decommissioning activities are limited in the authorized facilities; however, a graded approach to inspection should be applied and take into consideration the potential inspection of future decommissioning activities and should be included in the inspection programme and plan. *This has been addressed in R.6.*

7.5. INSPECTION OF TRANSPORT

The Regulator is responsible to verify compliance with the regulations for safe transport of radioactive materials. IAEA responsibility for transport is limited to activities inside the Agency Seat. The Regulator is empowered to have access to transport documents and activities. The Host State through which a shipment is travelling is the competent authority for transport activities outside of the Agency Seat.

The Regulator conducts transport inspections as an element of each inspection that is conducted at each laboratory. During the site inspection, a random verification of shipment records is conducted for discrepancies with the shipment notifications provided to the Regulator. The Regulator documents findings in a report and provides them to the DiCH of the site. The report clearly identifies non-compliances found during the inspection and requests corrective actions within a prescribed time. The corrective actions are

required to be commensurate with the significance for safety and security of the non-compliance, in accordance with a graded approach.

7.6. INSPECTION OF OCCUPATIONAL EXPOSURE

The scope of all inspections related to occupational exposure includes the responsibilities of the DiCH for controlling occupational exposure in their respective facilities or activities. The RPP includes arrangements for compliance with the Regulations, covering activities, risks, organization, monitoring, health surveillance, personal protective equipment, incident response, training, recording, reporting, and program audits.

7.7. INSPECTION OF PUBLIC EXPOSURE

The Regulator conducts public exposure inspections as an element of each inspection that is conducted at each laboratory.

7.8. SUMMARY

The IRRS team noted that the Regulator has the legal basis in place for the conduct of inspections.

The inspection process includes the following sequential steps: preparation, conduct, analysis of findings, documentation, and reporting; however, some areas for improvements were identified. There is no written procedure for how to prepare and conduct the inspections. There are no formally established criteria to define the frequency of inspections, nor is there a formal inspection programme or plan in place. Additionally, there is no formal training programme for inspectors. The IRRS team findings were supported by the site visit where they observed an inspection conducted by the Regulator at the Seibersdorf site.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The Regulations provide a legal basis for the Regulator to take enforcement actions. The Regulator shall require corrective action to be taken by the authorized party in the event of non-compliance with the Regulations or with the conditions attached to authorizations, or in the event that risks are identified, including risks that were unforeseen in the authorization process. The Regulations give the authorized party the right to appeal an enforcement decision.

In the event of failure of an authorized party to meet the obligation to implement corrective action, the Regulator is empowered to undertake enforcement actions ranging from notifying the respective DDG; imposing additional regulatory limits or conditions on the operation of a facility or activity; or ultimately suspending or revoking the authorization. The responsible DDG shall take the necessary measures to ensure that the corrective actions are implemented, to investigate the failure to comply on the part of the DiCH, and to make arrangements to prevent a recurrence. The enforcement actions take into account the specific differences between facilities and activities at the Agency Seat on one hand, and activities conducted outside the Agency Seat on the other hand.

The Regulator does not have a comprehensive enforcement policy contained in a single document, but the Regulations provide its major elements. This enables the Regulator to take the appropriate enforcement action in order to make authorized parties to implement the necessary corrective action and return to compliance. The Regulator has not documented specific criteria for determining the appropriate enforcement action in accordance with a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Regulations provide basic elements of an enforcement policy. However, some elements are missing, such as specific criteria initiating an enforcement action and determining the level (severity) of the enforcement actions in accordance with a graded approach.	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 30 states that *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization".*
(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.55 states that *"Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the noncompliance".*
S11	**Suggestion: The Regulator should consider establishing, formalizing and implementing a comprehensive enforcement policy that clarifies and expands the criteria for initiating and determining the level of the enforcement action.**

8.2. ENFORCEMENT IMPLEMENTATIONS

The Regulator requires corrective action to be taken by the authorized parties in the event of non-compliance. Each DiCH shall inform the Regulator on the implementation of the corrective action. The Regulator then verifies and, if satisfied, confirms the completion of the corrective action in writing.

Since 2017, the Regulator has taken 3 enforcement actions. All enforcement actions led to the return to compliance.

In practice, the Regulator applies an approach to enforcement based on the escalation of non-compliances through line management. Non-compliances identified during an inspection are captured in inspection reports that are provided to the authorized party. The primary means of enforcement by the Regulator is informing the authorized party of non-compliances. This correspondence is recorded and tracked by the Regulator. Should the authorized party fail to implement corrective actions within a reasonable time frame, the Regulator escalates enforcement action by raising the non-compliant findings through line management. In practice, this approach to escalated enforcement has resulted in the authorized parties taking the appropriate corrective actions.

There is an escalation of enforcement action with revocation of the authorization at the top, but there is also an escalation based on hierarchical level with the DG at the top. The Regulator demonstrated the effectiveness of escalation based on a hierarchical level through a recent example of a non-compliance identified related to the need to conduct exercises and drills at Seibersdorf. The Regulator also has other enforcement tools such as imposing additional conditions within the authorization.

8.3. SUMMARY

The Regulations provide basic elements of an enforcement policy. However, some elements are missing, such as specific criteria for initiating an enforcement action and determining the level (severity) of the enforcement actions in accordance with a graded approach. Establishing and implementing a comprehensive enforcement policy will clarify and expand the criteria for initiating and determining the level of the enforcement action.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The DG has established the Regulations. The current version was issued in May 2017. The Regulations specify the principles, requirements, and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.

The Regulations establish requirements for:

a. The protection of people and the environment;

b. the protection of persons, property, and the environment from harmful consequences of a nuclear security event;

c. the application of IAEA safety standards to the IAEA's operations making use of materials, services, equipment, facilities, and information made available by the IAEA, at its request, or under its control or supervision; and

d. the compliance with relevant provisions of the legislation and regulations of the States hosting IAEA facilities and activities.

The development of the Regulations followed a consultation process with IAEA staff, which included two rounds of formal review (commenting and resolution of comments). Resolutions were posted on a dedicated SharePoint site, and the drafts were presented to staff in two public sessions. However, this process is not documented in the management system, as demonstrated in the draft Quality Manual, chapter 4.9., "The Process of Development of Regulations and Guide".

The Regulations should be reviewed at intervals not exceeding five years or sooner as required. A review was carried out between 2021 and 2022 and the IRRS team was informed that the Regulations were found to remain fit for purpose.

Although three regulatory guides have been published by the Regulator, the IRRS team observed a lack of guidance provided to applicants regarding the presentation of applications for facilities and activities. This lack of clear direction can lead to inconsistencies and challenges in the application process. Furthermore, a graded approach should be considered in the development of the Regulations and associated documents.

Several other areas have been identified where regulatory guides would enhance the effectiveness of implementing the regulations. Such guides could be useful for capturing operational experiences and securing knowledge management.

Interested parties are informed of new or updated guides via circulated emails.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A process for establishing regulations and regulatory guides has been applied but not formally documented. The process does not consider the frequency for reviewing the regulatory guides and a system to ensure that the development and implementation of regulations and guides is based on a graded approach. This was recognized in the ARM	
(1)	**BASIS: GSR Part 1 Requirement 32, states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*

(2)	**BASIS: GSR Part 1 (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.."*
(3)	**BASIS: GSG-13 para. 3.9 states that** "*The regulatory body should establish a system to ensure that the development and implementation of regulations and guides is based on a graded approach, such that the application of regulatory requirements is commensurate with the radiation risks associated with the type of facility or activity."*
R7	**Recommendation: The Regulator should formally adopt a process for establishing, regulations and regulatory guides, including the frequency for reviewing the regulatory guides and a system to ensure that the development and implementation of regulations and guides is based on a graded approach.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Guidance has not been developed and provided, as a separate dedicated document, to the applicants regarding the submission of applications for authorizations.	
(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."***
R8	**Recommendation: The Regulator should issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for authorization.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The Regulations include the necessary provisions for authorization of waste management facilities. The Regulator does not have formal guidance related to waste management facilities; however, waste management activities are included in current authorizations with disposal of radiological waste handled by NES, under the regulatory control of the Host State.

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The Regulator is empowered to issue regulatory guidance to support the implementation of the Regulations. To date, three regulatory guides have been developed: "Cross-Divisional Activities", establishment of recording levels, and notification to the IEC of safety and security systems malfunctions. Although a process for establishing regulatory guides has been established but not yet formally documented in writing as mentioned in Section 9.1.

9.4. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The Regulations require an applicant to provide information in order to demonstrate the adequacy of measures for safety and security related to provisions for future decommissioning.

The Regulator does not have guides related to decommissioning activities, and in practice, applicants seeking authorization for decommissioning activities have applied past experiences and direct discussions with the Regulator in order to seek clarification on information requirements. As decommissioning activities are conducted infrequently, guides would be beneficial to knowledge management and to secure preservation of operational experience.

9.5. REGULATIONS AND GUIDES FOR TRANSPORT

The IAEA conducts transport of radioactive material under their management in accordance with the relevant regulations and international agreements, including the following as applicable:

- IAEA Specific Safety Requirements No. SSR-6 (Rev.1);
- The European Agreement concerning the International Carriage of Dangerous Goods by Road;
- The International Air Transport Association's Dangerous Goods Regulations;
- Austrian national transport regulations for shipments from the IAEA laboratories at Seibersdorf or from the Vienna International Centre;
- Regulations concerning the International Carriage of Dangerous Goods by Rail.

9.6. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The Regulator is empowered to issue regulatory guidance to support the implementation of the Regulations. Three regulatory guides have been developed and the following two are related to occupational exposure:

- "Application of the Regulatory Requirements on Cross-Divisional Activities": this guide provides clarification of the roles and responsibilities of the DiCH of cross divisional activities, the role and responsibility of the Managers of the participating cross assigned IAEA workers, and recommendations for the implementation of the requirements set in the Regulation in case of Cross-Divisional Activities.
- "Establishment of recording levels for individual monitoring": this guide establishes the values of recording levels for individual monitoring of external exposure to any type of radiation and for individual monitoring of internal exposure owing to intake of H-3, Cs-134 or Cs-137.

9.7. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

In accordance with the Regulations, the DiCH is responsible for assessing predicted discharges and the proposed safety measures to demonstrate that these discharges remain below the limits set by the Host State, ensuring that the dose constraint to the public is not exceeded during routine operations. The Regulator has not published a guide for public exposure, however the protection of the public outside the Agency Seat is covered by the Host States.

9.8. SUMMARY

The Regulations provide a foundation that supports development of a comprehensive framework for radiation safety and nuclear security.

The IRRS team identified needs to develop processes for the establishment, review and update of Regulations and regulatory guidance, and expand the current guidance as necessary to include applicable IAEA safety standards in line with a graded approach. In addition, areas for improvement related to developing and updating guidance, templates, and checklists were identified.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The Regulation provide requirements for preparedness and response for radiation incidents and emergencies at the Agency seat, including details on specific functions and powers.

The IAEA's human resources for regulating EPR are two members of staff who make up the Regulator and who are responsible for the review of emergency plans, review of lessons learned from testing and for providing advice amongst their other regulatory activities. The Regulator has to be available 24/7 to discharge its duties in the event of an emergency so additional members of staff have been trained to fulfil the Regulator role; in addition, the two full-time regulatory staff co-ordinate their vacations to ensure they are not both absent at the same time.

The emergency arrangements are coordinated with the Austrian authorities. The arrangements cover provisions of first responders for firefighting, medical support, and as necessary, law enforcement. The RPOs and RSTSU will provide radiation protection advice to emergency responders. The RSTSU provides support to the emergency response by providing a member of staff to be available 24/7 to support the Seibersdorf laboratories for investigation, dosimetry, personal and environmental monitoring. The emergency services participate in exercises and use the lessons learned to develop their response plans. For example, at one exercise it was found that the assembly point was not fully fit for purpose, so the plans have been amended to identify a more suitable location. Fire fighters in Seibersdorf are volunteers who have been provided with radiation protection training and dosimetry.

Initial assessment of the severity of an event is the responsibility of the DiCH; in practice the Emergency Controller will work with the relevant RPO to provide advice to the DiCH. A report is submitted to the Regulator for all events and incidents including 'near miss' events with the potential for radiological consequences. More serious events are also notified to the IEC. The criteria for which events are reported to the IEC are set out for each facility in the emergency plans. The notification form for the IEC is a standard form established in the IAEA Response Plan for Incidents and Emergencies (REPLIE) and usually included in the emergency plans for each facility.

The IEC will support the initial emergency response by communication within the IAEA including to the DG's Office and will make a recommendation to the DG for communication with the Austrian authorities where there are actual, perceived or potential off-site consequences; but the IEC has no role in other response actions. An agreement has been developed with the Austrian authorities on the type and scale of event that they want to be informed of and how they want to be informed. This includes events that have no radiological impact but may cause public or political concern such as a fire in a non-radiological area. This communication has not been tested yet, but there are plans for a test this year via the Unified System for Information Exchange in Incidents and Emergencies (USIE) system. The test will be visible only to the IAEA and Austrian authorities.

Communication with the public in the event of an emergency at the Agency Seat in Seibersdorf is the responsibility of the Austrian authorities; they are also responsible for setting any emergency planning zones.

The IAEA does not use the International Nuclear Event Scale (INES) which is a voluntary tool for communicating the safety significance of nuclear and radiological events to the public.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IAEA does not currently assess events that occur at the Agency Seat against the International Nuclear Event Scale (INES).	
(1)	**BASIS: GSR Part 1 Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.*
(2)	**BASIS: GSR Part 7 Requirement 7 paragraph 5.16 states that** *"... The emergency classification system shall be established with the aim of allowing for the prompt initiation of an effective response in recognition of the uncertainty of the available information. It shall be ensured that any process for rating an event on the International Nuclear and Radiological Event Scale (INES) does not delay the emergency classification or emergency response actions.*
S12	**Suggestion: The DG and DDsG should consider assessing events at the Agency Seat against the INES and reporting any events Level 2 and above to share learning with Member States.**

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

The Regulations give prime responsibility for safety and security to the relevant DiCH for facilities at the Agency Seat. This includes EPR and sets out the DiCH's responsibilities with respect to EPR.

The Regulations require each DiCH to perform a hazard assessment based on a graded approach. The hazard assessment needs to include events that could affect the facility including events of very low probability and events not considered in the design. It also needs to include events that are a combination of a radiation emergency with a conventional emergency and take account of threat assessments for nuclear security. Depending on the potential for a radiological emergency based on the hazard assessment, emergency arrangements may be written as a separate emergency plan or as part of the Radiation Protection Programme (RPP).

The emergency plan reviewed by the IRRS team sets out the actions to be taken in the event of an emergency and identified emergency roles with a separate document detailing training requirements for each emergency role. The Emergency Controller is nominated as the on-site lead in the event of an emergency and will implement any necessary protective actions on site.

Emergency plans are revised to accommodate lessons learned from exercises, and if there are any changes in the facility or activity that affect the existing hazard assessment, a new or revised authorization will be required. This will include any necessary amendment of the emergency plan, and review by the Regulator as part of the authorization process. The authorization is valid for a period of five years after which a new application needs to be made, and this includes re-assessment of the emergency plan.

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

The adequacy of emergency plans is assessed by the Regulator before an authorization for a facility is granted. This assessment includes a review of the incident scenarios identified, the adequacy of response, how the incident will be reported and to whom, and the proposed frequency and nature of emergency

exercises. Depending on the outcome of the hazard assessment, the emergency plan may be a separate document or a section within the RPP for the facility.

The Regulations require exercising of emergency arrangements to be carried out at suitable intervals; the number and frequency of exercises are set out in the emergency plan or RPP. It was noted by the IRRS team that enforcement action has been taken against some facilities for their repeated lack of emergency exercises. The enforcement action was an escalation to the DDG-NA which resulted in suitable emergency exercises taking place, confirming that the Regulator has authority to enforce corrective actions.

The Regulator inspects EPR arrangements as part of its' wider regulation of a facility and requires annual reports on safety issues including emergency arrangements and exercises. Separate exercise reports are written for some larger emergency exercises and submitted to the Regulator for review; results of minor emergency exercises are reported in an annual report submitted to the Regulator. Sometimes, the Regulator observes an emergency exercise and makes internal notes of the observations. Once the Regulator receives the exercise report they will check that the report includes their observations and if not, they will require their observations to be included in the exercise report.

The Regulator reviews the lessons learned and checks that they have been implemented. This is done during inspections, by review of the annual report, and reviewed during renewal of the authorization every five years.

The emergency plans apply to radiological and security emergencies as the hazard assessment takes both into account. Exercises have taken place for radiological and security scenarios but no exercises that address both have been carried out.

10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

The Regulations and emergency plans require the Regulator to be promptly notified of all incidents and events including 'near-miss' events which had a potential for radiological consequences and require the Regulator to be ready to provide advice on safety and security to the response organizations if needed. The mechanism and form for doing this is set out in emergency plans; it is the DiCH's responsibility to ensure that the form is submitted, and this is usually done in conjunction with the Emergency Controller and RPO.

The IES is staffed by trained volunteers from the IAEA and one of the two members of regulatory staff is currently in the group of seven volunteer ERM in the IES. There is a potential conflict if there is an emergency at the Agency Seat and the Regulator is the ERM identified on the roster.

10.5. SUMMARY

The Regulations include provisions for emergency preparedness and response for radiological incidents and emergencies at the Agency Seat and a regulator that has powers to implement and enforce the Regulations relating to EPR. Duties of the DiCHs for EPR are clearly set out in the Regulations and adopted through the authorization process which is assessed for compliance by the Regulator.

The IAEA has agreement with the Host Government on the reporting of events at the Agency Seat and the coordination of emergency responders who are provided with appropriate training and dosimetry.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

The legal framework for safety, security and the system for accounting and control of nuclear material is established in the Regulations. The Regulator is enforcing the regulatory requirements related to safety, and nuclear security, and the system for accounting and control of nuclear material, at the Agency Seat. The competent authority for nuclear security measures related to transport when IAEA is a consignor of radioactive material, is the competent authority in the country of origin of a shipment, e.g. the competent authority for transport in Austria. According to the Regulations, when IAEA activities are conducted outside the Agency Seat, the DiCH has responsibility to ensure, in cooperation with the host country, that the requirements of the safety standards and the recommendations of the IAEA nuclear security guidance that are relevant to the IAEA activity of concern, are met.

The Regulations empower the Regulator to conduct oversight activities and to take enforcement actions in relation to the security arrangements needed for maintaining nuclear and radiation safety. The Regulator might take advice on specific matters related to safety and security including their interface. The access to such advice provided by internal or external experts who provide expert opinion and advice is not managed through formal arrangements. The issue has been identified in the ARM, with regard to cybersecurity. *This issue has been addressed in S.2.*

As stated in the Regulations specific nuclear security measures apply for activities involving radioactive sources of category 1, 2 and 3 and nuclear material of category I, II and III. The Regulations also require that the only location where aforementioned radioactive sources and nuclear materials may be stored or used is on the site of the IAEA laboratories in Seibersdorf. The DiCH is responsible to assess and manage, as applicable, the interfaces between safety, nuclear security, and activities for nuclear material accounting and control to ensure that they do not adversely affect one another and remain mutually supportive.

The Regulations define a role for the Department of Management to ensure that services are available for nuclear security and for preparedness and response for radiation incidents and emergencies at the Agency Seat. For ensuring safety and nuclear security, the DiCH may obtain safety and nuclear security related services either from providers in the IAEA, or from external providers if the services cannot be provided internally in a timely manner as stated in the Regulations.

The Regulations specify a role of the CSC who shall make the results of the threat assessment available to the Regulator. The Regulator shall take steps to ensure that any change in the threat assessment is appropriately reflected in regulatory requirements and in the physical protection measures taken for IAEA facilities and activities.

The Regulations specify requirements related to nuclear security at the Seibersdorf site as a whole and on a facility level. The Regulations also address the management of contracted general security services.

The Regulations give responsibility to develop the Master Security Plan for the Agency Seat in Seibersdorf to MTGS. The Master Security Plan is prepared in cooperation with CSC and is approved by the Regulator. MTGS is required to establish a contingency plan to counter nuclear security events and to be coordinated with the overall emergency plans.

The Regulations require, that each DiCH shall assess and manage as applicable the interfaces between safety, nuclear security and activities for nuclear materials accounting and control, so that they do not adversely affect one another and they remain mutually supporting. Further, each DiCH is responsible for establishing a Security Plan for the facility or activity under their responsibility and for coordination of security measures at the Seibersdorf site. The coordination shall be verified by CSC. The security plans are part of the application for authorization. The DiCH is also responsible for classification of information and its sensitivity for nuclear security, assuring trustworthiness and management of access to such information

and shall ensure that computer-based systems used for physical protection, nuclear security, nuclear material accounting and control and radioactive sources inventory are protected against compromise consistent with the relevant threat assessment. The DiCH shall establish a contingency plan to counter nuclear security events and is coordinated with the overall emergency plans and is responsible for testing these plans.

The IAEA has specific role established in international treaties and conventions related to nuclear security and safeguards. However, as the IAEA is not a State, it cannot be a contracting party regarding obligations taken by a State. The issue was recognized in the ARM and was addressed in a policy discussion (see Module 2).

The Regulations do not explicitly address the main provisions of the CoC and supplementary guides.

11.2. REGULATORY OVERSIGHT ACTIVITIES

The Regulations require that the application for authorization should contain, among other things, a Security Plan and an Emergency Plan. There is no guidance issued by the Regulator for the DiCH on how to manage the safety and nuclear security interface or the form and content for an application. *This has been addressed in R.9.*

According to the Regulations, a DiCH shall also submit an annual report on safety and security performance including accounting and control of nuclear material to the Regulator and that is reviewed and assessed.

The issues identified in authorization, review and assessment, inspection, and regulations and guides, also apply to the interface between safety and nuclear security and accounting and control of nuclear material. *These have been addressed in R.5, R.8, R.6, R.7 and S.5.*

The IAEA invited International Physical Protection Advisory Service (IPPAS) which was conducted in 2013. The results of the mission were used as an input for planning inspection and the IRRS team was informed that several inspections dedicated to security at the Agency Seats followed.

Management of records related to safety and security including management of sensitive information are addressed in Regulations. Division of Human Resources keeps records for all training offered and attended through LMS or sent for records by the offering divisions.

11.3. INTERFACE AMONG AUTHORITIES

The Regulator is enforcing the regulatory requirements for safety, nuclear security and the system of accounting for, and control of, nuclear material.

The IAEA is cooperating with relevant Austrian security authorities and Austrian competent authority responsible for emergency preparedness and response at the Agency Seat. Arrangements include transport of radioactive material in Austria. Austrian regulatory authorities are providing information to the IAEA on the existing threats in Austria. IAEA is taking this information into account as well as the threat assessments and incorporate safety and security measures as needed.

The IRRS team was informed that an Annual Safety Review in Seibersdorf is prepared by Austrian experts. The report documenting results of the safety review is signed by all parties involved including the Regulator. Observations made during this review are taken as an input for the Regulator to conduct its activities. The IRRS team encourages the Regulator to establish in the Regulator’s management system a process on its participation in Annual Safety Review including setting its role as an input in conducting of regulatory actions.

The Regulations require the DiCH to conduct formal investigation of abnormal conditions and events, radiation incidents and emergencies including nuclear security events and major malfunctions of equipment that could affect safety or security. Reporting to the Regulator is required. A specific guide has been developed addressing reporting of malfunctioning of security systems. DiCH is also obliged to keep records relating to abnormal conditions and events, including nuclear security events and radiation incidents and emergencies. The Regulator submits to the DG an annual report on performance of the regulatory system, i.e. on safety and nuclear security.

11.4. SUMMARY

The Regulator is enforcing the regulatory requirements for safety, nuclear security, and accounting and control of nuclear material. The Regulations require, that each DiCH shall assess and manage as appliable the interfaces between safety, nuclear security and activities for nuclear materials accounting and control, so that they do not adversely affect one another, and they remain mutually supporting.

The Regulations do not explicitly address the main provisions of the CoC and its supplementary guidelines.

The process to review and assess the interface between nuclear safety and security and accounting and control of nuclear material in an application for authorization should be documented in Regulator's management system and relevant guides to be used by the authorized parties should be developed.

APPENDIX I – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	GP1	Good Practice: The IAEA has demonstrated its commitment to the safety standards and made use of the peer review system designed for Member States for a review of its internal implementation of the safety standards, as mandated by the IAEA Statue. This goes beyond what is required, is unique, and is replicable for other bodies if relevant to their mandate; it is thus considered a Good Practice.
	R1	Recommendation: The DG and DDsG should develop a comprehensive policy and strategy for safety that is tailored to the IAEA specific situation with a level of attention that meets the strategic and operational ambitions of the IAEA; they should promulgate this policy and strategy across the IAEA and ensure its implementation in accordance with a graded approach.
	R2	Recommendation: The DG and DDsG should initiate a review of the resourcing at the IAEA-level with the aim of ensuring that the Regulator has sufficient human and financial resources for sustainable discharge of its assigned responsibilities, including the resources needed to continuously improve the regulatory framework and to enhance the competence of the regulatory staff.
	S1	Suggestion: The DDG-NS and the Regulator should consider formalising arrangements to ensure regulatory independence.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	S2	**Suggestion: The Regulator and relevant DDsG should consider adopting formal arrangements for the Regulator to acquire in-house expert opinion and advice from IAEA business units, for example, by entering into specific interservice agreements, that include measures to prevent conflict of interest.**
	S3	**Suggestion: The DG and DDsG should consider establishing requirements and developing a mechanism to ensure that adequate financial resources are guaranteed at the time of decommissioning.**
2. THE GLOBAL SAFETY REGIME	S4	**Suggestion: The Regulator should consider establishing a strategy to contribute and benefit from international cooperation amongst Member States and with other organizations that provides the means for sharing regulatory experience to enhance safety.**
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S5	**Suggestion: The Regulator should consider establishing a systematic programme for training and knowledge management in order for the Regulator to carry out its regulatory functions effectively.**
	S6	**Suggestion: The Regulator should consider making information related to authorized parties available to interested parties, as appropriate.**
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R3	**Recommendation: The Regulator should complete the documentation of the management system for formal adoption, and establish a mechanism for its regular independent review to ensure consistency and stability of control.**
	R4	**Recommendation: The Regulator should arrange for independent assessments at planned intervals to measure, evaluate and review its leadership for safety and safety culture, to improve the overall safety performance.**

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
5. AUTHORIZATION	R5	Recommendation: The Regulator should finalize and formally adopt procedures for authorization taking into account a graded approach.
	S7	Suggestion: The DG and DDsG should consider ensuring that requirements are established for the formal recognition of qualified experts
	S8	Suggestion: The Regulator should consider, in cooperation with the VIC Medical Service, reviewing and updating the health surveillance guide as required to include all Occupationally Exposed Workers.
	S9	Suggestion: DDG-NS in collaboration with the Regulator should consider expediting the finalization of a central dose register at the RSTSU with the integration of doses from external providers into their existing records.
6. REVIEW AND ASSESSMENT		
7. INSPECTION	R6	Recommendation: The Regulator should develop an inspection programme and plan in accordance with a graded approach.
	S10	Suggestion: The Regulator should consider formally adopting procedures for inspections.
8. ENFORCEMENT	S11	Suggestion: The Regulator should consider establishing, formalizing and implementing a comprehensive enforcement policy that clarifies and expands the criteria for initiating and determining the level of the enforcement action.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
9. REGULATIONS AND GUIDES	R7	Recommendation: The Regulator should formally adopt a process for establishing, regulations and regulatory guides, including the frequency for reviewing the regulatory guides and a system to ensure that the development and implementation of regulations and guides is based on a graded approach.
	R8	Recommendation: The Regulator should issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for authorization.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	S12	Suggestion: The DG and DDsG should consider assessing events at the Agency Seat against the INES and reporting any events Level 2 and above to share learning with Member States.
11. INTERFACE WITH NUCLEAR SECURITY		

APPENDIX II – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
LARSSON Carl-Magnus	Norwegian Radiation and Nuclear Safety Authority (DSA) NORWAY	carl-magnus.larsson@dsa.no
KRS Petr	State Office for Nuclear Safety (SÚJB) - CZECH REPUBLIC	Pet.Kr@seznam.cz
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CHIPURU Justice	Radiation Protection Authority - ZIMBABWE	jchipuru@rpaz.co.zw
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SMITH George	Nuclear Regulatory Commission (NRC) - USA	george.smith@nrc.gov
WRIGHT Angela	Office for Nuclear Regulation (ONR) - UK	angela.wright@onr.gov.uk
JANZEKOVIC Helena	Slovenian Nuclear Safety Administration - SLOVENIA	helena.janzekovic@gov.si
FISCHER Helmut (Observer)	Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology - AUSTRIA	helmut.fischer@bmk.gv.at
IAEA STAFF		
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LIAISON OFFICER		
SUMAN Hazem		h.suman@iaea.org

GROUP PHOTO

APPENDIX III – LIST OF IRRS REVIEWERS AND COUNTERPARTS

	IRRS EXPERTS	LEAD COUNTERPART	SUPPORT STAFF
1.	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**		
	Petr Krs	Hazem Suman, Lydie Evrard, Mike Finnerty	Judith Sylie Michael Appiateng
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Petr Krs	Hazem Suman	
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Aayda	Hazem Suman	
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Justice	Hazem Suman	
5.	**AUTHORIZATION**		
	Lee Casterson	Marcin Zagrajek	David Tissington, SGAS-RPO Andy Bugg, NA-RPO Giselle Ruiz de Neumayr, NA Labs Coordinator
6.	**REVIEW AND ASSESSMENT**		
	Hassan Kharita	Marcin Zagrajek	Miroslav Pinak, SH-RSM Rodolfo Cruz Suarez, UH-RSTSU Marta Bavio, RSTSU Associate Quality Management Officer
7.	**INSPECTION**		
	Camilaa Salata	Marcin Zagrajek	Dongxin Feng, Dir-NAFA Rui Cardoso Pereira, SH-IPC Polychronis Rempoulakis, LH-IPCL Andy Bugg, NA-RPO Hanano Yamada, IPCL-ARPO
8.	**ENFORCEMENT**		
	Petr Krs	Hazem Suman	
9.	**REGULATIONS AND GUIDES**		
	George Smith	Hazem Suman	David Tissington, SGAS-RPO

	IRRS EXPERTS	LEAD COUNTERPART	SUPPORT STAFF
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		
	Angela Wright	Hazem Suman	Carlos Torres, DIR -IEC Florian Baciu, IEC Victor Varychenko, SH-SLSS Ewald Keller, Security Coordination Officer David Tissington, SGAS-RPO
11.	**INTERFACE WITH NUCLEAR SECURITY**		
	Helena Janžekovič	Hazem Suman	Tepani Hack, MAFA-NSNS Heather Looney, SH-MAFA, NSNS Nilgun Gerseker, MAFA-NSNS Victor Varychenko, SH-SLSS Ewald Keller, Security Coordination Officer David Tissington, SGAS-RPO

APPENDIX IV – MISSION PROGRAMME

Abbreviations

ARM	Advanced Reference Material
DGO	Director General's Office
IEC	Incident and Emergency Centre
IPCL	Insect Pest Control laboratory
LO	Liaison Officer
MPB	Multipurpose Building, Seibersdorf
NA	IAEA Department of Nuclear Sciences and Applications
NALC	Laboratory Coordinator and Outreach Officer of the NA department
NA-RPO	Radiation Protection Officer of the NA department
NSNS	Division of Nuclear Security
RSTSU	Radiation Safety Technical Services Unit
SCO	Security Coordination Officer
SGAS	Safeguards Analytical Services
SLSS	Seibersdorf Laboratories Services Section
TC	IRRS Team Coordinator
TL	IRRS Team Leader
VIC	Vienna International Centre

Meeting rooms

CR5	VIC, C-Building, 7th floor	Entrance & Exit meeting
M0E58	VIC, M-Building, ground floor	Interviews
M0E59	VIC, M-Building, ground floor	Interviews
M0E05	VIC, M-Building, ground floor	IRRS Team discussions (30 Sep – 4 Oct)
M0E12	VIC, M-Building, ground floor	IRRS Team discussions (7 – 9 Oct)
GF05	MPB, Seibersdorf	IRRS discussions and interviews (2 Oct)
Arcotel	Arcotel's Meeting Room	Initial Team Meeting; Daily Team Meetings

IRRS IAEA MISSION PROGRAMME		
Sunday 29 September 2024		
IRRS Initial IRRS Review Team Meeting		
13:30 - 17:30	▪ *Opening remarks by the IRRS TL* ▪ *Introduction by TC* ▪ *Self-introduction of all attendees* ▪ *IRRS Process (TC)* ▪ *Report writing (TC)*	**Venue:** Arcotel **Participants:** IRRS Team + LO

IRRS IAEA MISSION PROGRAMME		
	▪ *Schedule (TL, TC, LO)* ▪ *First impression from experts arising from the ARM (All Experts)* ▪ *Administrative arrangements (LO, TC): Detailed Mission Programme*	
Monday 30 September 2024		
IRRS Entrance Meeting		
09:30 – 10:30	▪ *DG – Welcoming Address* ▪ *TC – The IRRS programme* ▪ *TL – Expectations for the Mission* ▪ *Introduction of the IRRS Team* ▪ *Introduction of the Counterparts*	**Venue:** CR5 **Participants:** – *IAEA management and concerned staff* – *Regulatory Team* – *IRRS Team*
10:30 – 10:45	Group photo	
10:45 – 12:00	Presentation by the LO: Regulatory overview, Self-assessment results (strength, challenges, action plan)	**Venue:** CR5
12:00 – 13:00	Lunch	
Daily Discussions / Interviews		
	Room M0E58 (H. Suman)	**Room M0E59 (M. Zagrajek)**
13:00 – 16:30	▪ *Modules 1 (main topic of this session)* ▪ *Modules 2 (main topic of this session)* ▪ *Modules 3* ▪ *Modules 4* ▪ *Module 11* <u>Related meetings for module 1 and 2:</u> ▪ *13:00 – 14:30 Meeting with DDG-NS & DGO* ▪ *15:00 – 16:00 Meeting with OLA*	▪ *Modules 5 – 9* – *Occupational exposure* – *Sources & public exposure (main topic of this session)* – *Waste & decommissioning* – *Transport* ▪ *Module 10*
17:00 – 18:00	Daily IRRS Review Team meeting	**Venue:** Arcotel **Participants:** IRRS Team + LO
18:30 –	Report writing	

IRRS IAEA MISSION PROGRAMME		
Tuesday 1 October 2024		
Daily Discussions / Interviews		
	Room M0E58 (H. Suman)	**Room M0E59 (M. Zagrajek)**
09:00 – 12:00	▪ *Modules 1* ▪ *Modules 2* ▪ *Modules 3 (main topic of this session)* ▪ *Modules 4 (main topic of this session)* ▪ *Module 11*	▪ *Modules 5 – 9* – *Occupational exposure (main topic of this session)* – *Sources & public exposure* – *Waste & decommissioning* – *Transport* ▪ *Module 10* <u>Related meetings (for occupational):</u> ▪ *11:00 – 12:00 meeting with RSTSU*
12:00 – 13:00	Lunch	
	Room M0E58 (H. Suman)	**Room M0E59 (M. Zagrajek)**
13:00 – 16:30	▪ *Module 1* ▪ *Module 2* ▪ *Module 10 (main topic of this session)* ▪ *Module 11 (main topic of this session)* <u>Related meetings for modules 10 and 11:</u> ▪ *13:00 – 14:00 meeting with IEC* ▪ *16:00 – 16:30 meeting with NSNS*	▪ *Module 3* ▪ *Module 4* ▪ *Modules 5 – 9* – *Occupational exposure* – *Sources & public exposure* – *Waste & decommissioning (main topic of this session)* – *Transport*
17:00 – 18:00	Daily IRRS Review Team meeting	**Venue:** Arcotel **Participants:** IRRS Team + LO
18:30 –	Report writing	

IRRS IAEA MISSION PROGRAMME		
Wednesday 2 October 2024		
Site visit and Daily Discussions / Interviews (in Seibersdorf)		
08:00	Departure to Seibersdorf; arrival ~ 08:45	
	Room GF05 (H. Suman)	**IPCL (M. Zagrajek)**
09:00 – 12:00	• *ll team members who are not observing the inspection are welcome to join the discussion and interview in this session.* ▪ *Module 4* ▪ *Modules 5 – 9* – *Waste & decommissioning* – *Transport (main topic of this session)* ▪ *Module 10*	Inspection at the IPCL • *To be continued from 13:00 to 14:00, if needed)* • • *RRS Team decides which experts would observe the inspection.*
12:00 – 13:00	Lunch	
	Room GF05 (H. Suman)	**Room GF05 (M. Zagrajek)**
13:00 – 16:15	▪ *Modules 5 – 9* – *Waste & decommissioning* – *Transport* ▪ *Module 10 (main topic of this session)* ▪ *Module 11 (main topic of this session)* <u>Related meetings for these four modules:</u> ▪ *13:00 – 14:00 meeting with SGAS, SLSS and SCO* ▪ *15:00 – 16:00 Meeting with NALC and NA-RPO (optional)*	(*Interviews start after the inspection*) ▪ *Module 3* ▪ *Modules 5 – 9* – *Occupational exposure* – *Sources & public exposure*
16:30	Departure back to the hotel, arrival ~ 17:15	
17:30 – 18:30	▪ *Quick briefing on the site visit* ▪ *Daily IRRS Review Team meeting* ▪ *First draft of Rs, Ss and GPs*	**Venue:** Arcotel **Participants:** IRRS Team + LO
18:30 –	Report writing	

IRRS IAEA MISSION PROGRAMME		
Thursday 3 October 2024		
09:00 – 10:00	**Room M0E58 (H. Suman)** Follow-up Interviews and Discussions (*if needed*)	**Room M0E59 (M. Zagrajek)** Follow-up Interviews and Discussions (*if needed*)
09:00 – 12:00	Finalization of Rs, Ss and GPs	**Venue:** M0E05 **Participants:** IRRS Team
12:00 – 13:00	Lunch	
13:00 – 14:30	Policy issue discussion: ▪ *Participations on legal and non-legal binding international instruments and globalization of the nuclear community* ▪ *Human Resources and knowledge management*	**Venue:** Room M0E05 **Participants:** IRRS Team and counterparts
14:30 – 17:00	Report writing	**Venue:** M0E05
17:00 – 18:00	▪ *Daily IRRS Review Team Meeting* ▪ *Finalization of the first draft report*	**Venue:** Arcotel **Participants:** IRRS Team + LO
Friday 4 October 2024		
09:00 – 12:00	Cross reading of the report	IRRS Team
12:00 – 13:00	Lunch	
15:00 – 17:00	Individual review of full report	**Venue:** Room M0E05 **Participants:** IRRS Team
18:00 –	Individual review of full report continues	**Venue:** Arcotel **Participants:** IRRS Team
Saturday 5 October 2024		
09:00 – 17:00	Team finalizes the report together	**Venue:** Arcotel **Participants:** IRRS Team
18:00 – 22:00	TL and TC review the draft report	
22:00	Submission of the draft report to the RB for comments	
Sunday 6 October 2024		
	▪ *Free day for the IRRS Team* ▪ *Review and commenting on the draft report by RB*	

IRRS IAEA MISSION PROGRAMME		
Monday 7 October 2024		
09:00 – 12:00	RB reviews draft report	
12:00 – 13:00	Lunch	
13:00 – 15:00	RB submits comments to IRRS team	
15:00 – 18:00	IRRS Team reviews RB comments and finalize the report	**Venue:** M0E12 **Participants:** IRRS Team
18:00 –	TL & TC finalize draft report editing	**Venue:** Arcotel **Participants:** TL and TC
Tuesday 8 October 2024		
09:00 – 12:00	Team meeting for finalization of draft report	**Venue:** M0E12 **Participants:** – *IRRS Team* – *Regulatory Team*
12:00 – 13:00	Lunch	
13:00 – 15:00	Team meeting for finalization of draft report	**Venue:** M0E12 **Participants:** – *IRRS Team* – *Regulatory Team*
15:00 –	Report Submission and finalization of press release	**Venue:** M0E12 **Participants:** – *IRRS Team* – *Regulatory Team*
18:30	Farewell Dinner	**Venue:** The View restaurant
Wednesday 9 October 2024		
IRRS Exit Meeting		
10:00 – 11:00	▪ *Main findings of the IRRS mission (Team Leader)* ▪ *Remarks by the Regulator in response to the mission findings* ▪ *Closing Remarks by DDG-NS* ▪ *Press release*	**Venue:** CR5 **Participants:** – *IAEA management and concerned staff* – *Regulatory team* – *IRRS Team*

APPENDIX V – SITE VISITS

Regulatory inspection at the Insect Pest Control Laboratory (IPCL)

Inspected facility: IPCL

Inspection date: 2 October 2024

Type of inspection: announced; planned (inspection during IRRS mission in the Agency)

Inspection team: Mr. Marcin Zagrajek

Representatives of inspected facility:

1. *Ms. Dongxin Feng, Dir-NAFA (separate meeting)*
2. *Mr. Rui Cardoso Pereira (SH-IPC)*
3. *Mr. Polychronis Rempoulakis, LH-IPCL*
4. *Mr. Andy Bugg, NA-RPO*
5. *Ms. Hanano Yamada, IPCL-ARPO*

APPENDIX VI –REFERENCE MATERIAL OF THE IAEA USED FOR THIS REVIEW

[1] The Statute of the International Atomic Energy Agency.

[2] IAEA Radiation Safety and Nuclear Security Regulations, Administrative Manual, Part X, 20 June 2017.

[3] Occupational Health and Safety Policy, Administrative Manual Part II, section 17, Appendix H (AM.II/17, H)

[4] The Agency's Headquarters Agreement with Austria and Related Matters, INFCIRC/15/Rev.1, 31 October 1975.

[5] The Agreement Of 16 May 1986 Between the Government of Monaco and the Agency Concerning the International Laboratory of Marine Radioactivity and the Privileges and Immunities of the Agency within the Principality, INFCIRC/337, March 1987.

[6] Agreement Between the International Atomic Energy Agency and the Federal Government of the Republic of Austria Regarding the Laboratories at Seibersdorf, INFCIRC/15/Rev.1/Add.2, July 1990.

[7] Technical Agreement Between the Federal Ministry for Agriculture, Forestry, Environment and Water Management and the International Atomic Energy Agency Regarding the Seibersdorf Laboratories, entered into Force on 1 February 2018.

[8] Establishment of Recording Levels for Individual Monitoring, RGS-RSNSR-2020-02, 18 December 2020.

[9] Application of the Regulatory Requirements in Cross-Divisional Activities, RGS-RSNSR-2021-01, 2 September 2021.

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. INTERNATIONAL ATOMIC ENERGY IAEA - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2. INTERNATIONAL ATOMIC ENERGY IAEA - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3. INTERNATIONAL ATOMIC ENERGY IAEA – Leadership and Management for Safety, General Safety Requirements Part 2, No GSR Part 2, IAEA, Vienna (2016)
4. INTERNATIONAL ATOMIC ENERGY IAEA - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No GSR Part 3, IAEA, Vienna (2014).
5. INTERNATIONAL ATOMIC ENERGY IAEA - Safety assessment for facilities and activities, General Safety Requirements Part 4, No GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY IAEA - Predisposal Management of Radioactive Waste, General Safety Requirements Part 5, No GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY IAEA - Decommissioning of Facilities, General Safety Requirements No GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY IAEA - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirements No GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY IAEA - Safety of Research Reactors, Specific Safety Requirements No SSR-3, IAEA, Vienna (2016)
10. INTERNATIONAL ATOMIC ENERGY IAEA - Disposal of Radioactive Waste, Specific Safety Requirements No SSR-5, IAEA, Vienna (2011)
11. INTERNATIONAL ATOMIC ENERGY IAEA - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements No SSR-6 (Rev. 1), IAEA, Vienna (2018)
12. INTERNATIONAL ATOMIC ENERGY IAEA - Classification of Radioactive Waste, General Safety Guide No GSG-1, IAEA, Vienna (2009)
13. INTERNATIONAL ATOMIC ENERGY IAEA - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide No GSG-2, IAEA, Vienna 2011)
14. INTERNATIONAL ATOMIC ENERGY IAEA - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide No GSG-6, IAEA, Vienna (2017)
15. INTERNATIONAL ATOMIC ENERGY IAEA - Occupational Radiation Protection, Safety Guide No GSG-7, IAEA, Vienna (2018)
16. INTERNATIONAL ATOMIC ENERGY IAEA - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide No GSG-9, IAEA, Vienna (2018)
17. INTERNATIONAL ATOMIC ENERGY IAEA - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide No GSG-12, IAEA, Vienna (2018)
18. INTERNATIONAL ATOMIC ENERGY IAEA - Functions and Processes of the Regulatory Body for Safety, General Safety Guide No GSG-13, IAEA, Vienna (2018)
19. INTERNATIONAL ATOMIC ENERGY IAEA Leadership, Management and Culture for Safety in Radioactive Waste Management, Safety Guide No GSG-16, IAEA, Vienna (2022)
20. INTERNATIONAL ATOMIC ENERGY IAEA - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide No GS-G-2.1, IAEA, Vienna (2007)

21. INTERNATIONAL ATOMIC ENERGY IAEA - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide No NS-G-2.8, IAEA, Vienna (2002)
22. INTERNATIONAL ATOMIC ENERGY IAEA - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide No RS-G-1.8, IAEA, Vienna (2005)
23. INTERNATIONAL ATOMIC ENERGY IAEA - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide No RS-G-1.10, IAEA, Vienna (2008)
24. INTERNATIONAL ATOMIC ENERGY IAEA - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide No SSG-14, IAEA, Vienna (2011)
25. INTERNATIONAL ATOMIC ENERGY IAEA - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material Specific Safety Guide (2018 Edition) No SSG-26 (Rev.1), IAEA, Vienna (2022)
26. INTERNATIONAL ATOMIC ENERGY IAEA - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide No SSG-40, IAEA, Vienna (2016)
27. INTERNATIONAL ATOMIC ENERGY IAEA - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide No SSG-45, IAEA, Vienna (2019)
28. INTERNATIONAL ATOMIC ENERGY IAEA - Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Safety Guide No SSG-46, IAEA, Vienna (2018)
29. INTERNATIONAL ATOMIC ENERGY IAEA –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide No SSG-49, IAEA, Vienna (2019)
30. INTERNATIONAL ATOMIC ENERGY IAEA - Preparedness and Response for a Nuclear or Radiological Emergency Involving the Transport of Radioactive Material, Safety Guide No SSG-65, IAEA, Vienna (2022)
31. INTERNATIONAL ATOMIC ENERGY IAEA - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
32. INTERNATIONAL ATOMIC ENERGY IAEA - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna (2008)
33. INTERNATIONAL ATOMIC ENERGY IAEA - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna (2009)
34. INTERNATIONAL ATOMIC ENERGY IAEA - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition), Specific Safety Guide No SSG-33 (Rev.1) IAEA, Vienna (2021)
35. INTERNATIONAL ATOMIC ENERGY IAEA - Storage of Radioactive Waste, Safety Guide No WS-G-6.1, IAEA, Vienna (2006)
36. INTERNATIONAL ATOMIC ENERGY IAEA - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide NoWS-G-5.2, IAEA, Vienna (2009)
37. INTERNATIONAL ATOMIC ENERGY IAEA - Storage of Radioactive Waste, Safety Guide No WS-G-6.1, IAEA, Vienna (2006)

APPENDIX VIII – ORGANIZATIONAL CHART OF IAEA