



IAEA-NS-IRRS-2022/01
ORIGINAL: English

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

PORTUGAL

Lisbon, Portugal

21 February to 2 March 2022

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated
Regulatory
Review Service

IRRS



Integrated
Regulatory
Review Service
IRRS

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





Integrated
Regulatory
Review Service

IRRS

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

Mission dates:	21 February to 2 March 2022
Regulatory body visited:	Agência Portuguesa do Ambiente (APA) General Inspection of Agriculture, Sea, Environment, and Spatial Planning (IGAMAOT)
Location:	Lisbon, Portugal
Regulated facilities and activities in the mission scope:	Radiation Sources in Industrial and Medical Facilities, Waste Management Facilities, Decommissioning, Transport of radioactive material, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Monitoring
Organized by:	IAEA

IRRS REVIEW TEAM

MARKKANEN Mika	Team Leader (Finland)
BOAL Trevor	Reviewer (Australia)
DELGADO Maria Isabel Villanueva	Reviewer (Spain)
ECONOMIDES Sotiris	Reviewer (Greece)
GODET Jean-Luc	Reviewer (France)
JANŽEKOVIČ Helena	Reviewer (Slovenia)
KARINOU Eleftheria	Reviewer (Greece)
KRZ Petr	Reviewer (Czech Republic)
SMITH Veronica	Reviewer (Ireland)
TRIVELLONI Sandro	Reviewer (Italy)
PACHECO Ronald	IAEA Team Coordinator
TOMAS ZERQUERA Juan	IAEA Review Area Facilitator
SWOBODA Zumi	IAEA Administrative Assistant

February 2022

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

CONTENTS

EXECUTIVE SUMMARY	1
I. INTRODUCTION	3
II. OBJECTIVE AND SCOPE	4
III. BASIS FOR THE REVIEW	5
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	7
1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY	7
1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY	8
1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE.....	8
1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS	9
1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK	9
1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS	10
1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL	11
1.8. COMPETENCE FOR SAFETY	12
1.9. PROVISION OF TECHNICAL SERVICES.....	12
1.10. SUMMARY	13
2. THE GLOBAL SAFETY REGIME	14
2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION.....	14
2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE.	15
2.3. SUMMARY	16
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	17
3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES.....	17
3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS.....	19
3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY	19
3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS.....	21
3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES	22
3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL.....	22
3.7. SAFETY RELATED RECORDS.....	23
3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES.....	23
3.9. SUMMARY	24
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	25
4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY	25
4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM	26
4.3. THE MANAGEMENT SYSTEM.....	27

4.4.	MANAGEMENT OF RESOURCES.....	29
4.5.	MANAGEMENT OF PROCESSES AND ACTIVITIES.....	29
4.6.	CULTURE FOR SAFETY	30
4.7.	MEASUREMENT, ASSESSMENT AND IMPROVEMENT	31
4.8.	SUMMARY	31
5.	AUTHORIZATION	33
5.1.	GENERIC ISSUES.....	33
5.2.	AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES...	34
5.3.	AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES.	35
5.4.	AUTHORIZATION OF DECOMMISSIONING ACTIVITIES	36
5.5.	AUTHORIZATION OF TRANSPORT	36
5.6.	AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE.....	36
5.7.	AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE	37
5.8.	AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE	42
5.9.	SUMMARY	42
6.	REVIEW AND ASSESSMENT	44
6.1.	GENERIC ISSUES.....	44
6.2.	REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES	45
6.3.	REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES	45
6.4.	REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES	45
6.5.	REVIEW AND ASSESSMENT FOR TRANSPORT	45
6.6.	REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE	46
6.7.	REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE	46
6.8.	REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE	47
6.9.	SUMMARY	47
7.	INSPECTION	48
7.1.	GENERIC ISSUES.....	48
7.2.	INSPECTION OF WASTE MANAGEMENT FACILITIES	49
7.3.	INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES	49
7.4.	INSPECTION OF DECOMMISSIONING ACTIVITIES.....	49
7.5.	INSPECTION OF TRANSPORT	49
7.6.	INSPECTION OF OCCUPATIONAL EXPOSURE.....	50
7.7.	INSPECTION OF MEDICAL EXPOSURE.....	50
7.8.	INSPECTION OF PUBLIC EXPOSURE.....	50
7.9.	SUMMARY	51
8.	ENFORCEMENT.....	52
8.1.	ENFORCEMENT POLICY AND PROCESS	52
8.2.	ENFORCEMENT IMPLEMENTATIONS	53
8.3.	SUMMARY	54
9.	REGULATIONS AND GUIDES	55
9.1.	GENERIC ISSUES.....	55
9.2.	REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES	55

9.3.	REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES	56
9.4.	REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES.....	56
9.5.	REGULATIONS AND GUIDES FOR TRANSPORT	56
9.6.	REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE.....	56
9.7.	REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE.....	57
9.8.	REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE.....	57
9.9.	SUMMARY	57
10.	EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS....	58
10.1.	AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS	58
10.2.	REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS	59
10.3.	VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS	60
10.4.	ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY	61
10.5.	SUMMARY	62
11.	POLICY ISSUES.....	63
	APPENDIX I – LIST OF PARTICIPANTS.....	66
	APPENDIX II – MISSION PROGRAMME.....	68
	APPENDIX III – SITE VISITS.....	74
	APPENDIX IV – LIST OF COUNTERPARTS.....	75
	APPENDIX V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)	78
	APPENDIX VI – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW	83
	APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW.....	89
	APPENDIX VIII – ORGANIZATIONAL CHART	93

EXECUTIVE SUMMARY

At the request of the Government of Portugal, an international team of senior nuclear safety experts met with representatives of the Agência Portuguesa do Ambiente (APA) and the Inspeção-Geral da Agricultura, do Mar, do Ambiente e do Ordenamento do Território (IGAMAOT) as the Regulatory body in Portugal, from 21 February to 2 March 2022, to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of Portugal's national regulatory framework for nuclear, radiation, radioactive waste, and transport safety. The review compared Portugal's regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and Portuguese counterparts in areas covered by the IRRS.

The IRRS team consisted of 10 senior regulatory experts from 9 IAEA Member States, two IAEA staff members, an IAEA administrative assistant. The review covered the IRRS core modules 1 to 10, i.e., the responsibilities and functions of the government, the global safety regime, responsibilities and functions of the regulatory body, the management system of the regulatory body, the activities of the regulatory body including authorization, review and assessment, inspection and enforcement, regulations and guides, and emergency preparedness and response. Facilities, activities, and exposure situations covered included radiation source applications, waste management facilities, decommissioning, transport, occupational exposure, medical exposure, and public and existing exposure.

At the request of the regulatory body, the IRRS mission included 3 policy issues discussion during which members of the IRRS team and senior staff of APA and IGAMAOT shared views and regulatory experiences regarding the 3 policy issues:

- Graded approach to regulatory control;
- Management of Waste containing large amounts of NORM;
- Effects of the COVID-19 pandemic on the Regulatory Framework.

The review mission included a series of interviews and discussions with key personnel from APA and IGAMAOT.

The IRRS team also observed on-site inspections conducted by IGAMAOT at various facilities:

- Hospital Lusíadas;
- Industrial facility ISQ;
- Interim storage facility: Pavilhão de Resíduos Radioativos, Instituto Superior Técnico.

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

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

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

The government should:

- Establish a comprehensive national policy and corresponding strategies for safety to express its long-term commitment to safety.
- Ensure the establishment of a national policy and strategy for radioactive waste management.
- Ensure that the legislative framework for safety is further developed and maintained in a systematic way in order to keep it in compliance with the IAEA safety requirements.

The government should consider:

- Including in the national policy and strategy for radioactive waste management provisions for ensuring the establishment of technical and regulatory criteria for managing large amounts of NORM waste.

The regulatory body should:

- Establish a human resources plan, including a strategy to compensate for the departure of qualified staff.
- Establish, implement, and continuously improve an integrated management system in line with IAEA safety requirements.
- Establish and implement an enforcement policy that would be in line with IAEA requirements, while respecting the national legal framework.

The regulatory body should consider:

- Finalizing the formal agreement (MoU) between APA and IGAMAOT organizations to provide for effective coordination.
- Continuing to develop formal provisions for effective coordination with other relevant bodies of state administration.

The IRRS team believes that the recommendations and suggestions, if acted upon, will contribute to meeting these challenges and enhance nuclear and radiation safety in Portugal.

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

The IRRS team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of Portugal, an international team of senior safety experts met representatives from the Agência Portuguesa do Ambiente (APA) and the Inspeção-Geral da Agricultura, do Mar, do Ambiente e do Ordenamento do Território (IGAMAOT), from 21 February to 2 March 2022 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review Portugal's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Portugal on 18 May 2018. An IRRS information meeting and Self-Assessment workshop was held 20 to 21 February 2019 at APA Headquarters in Lisbon to introduce the IRRS process and to introduce the IAEA Self-Assessment methodology and SARIS tool. A preparatory meeting was conducted 16 to 17 January 2020 and a follow up preparatory meeting on 4 to 5 November 2021 at the APA's Headquarters in Lisbon with both authorities to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Portugal and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 10 senior regulatory experts from 9 IAEA Member States, 2 IAEA staff members plus 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection, and enforcement processes; development and content of regulations and guides; emergency preparedness and response. The scope of regulatory activities reviewed during the mission covered radiation sources facilities and activities, occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning.

In addition, policy issues were discussed, including Graded approach to regulatory control, Management of Waste containing large amounts of NORM, Effects of the COVID-19 pandemic in the regulatory framework.

The regulatory body 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 Portugal's advance reference material, conduct of interviews with management and staff from APA and IGAMAOT and direct observation of regulatory activities at regulated facilities.

All through the mission the IRRS team received excellent support and cooperation from APA and IGAMAOT.

II. OBJECTIVE AND SCOPE

The scope of the mission includes all regulatory functions and responsibilities that legally provide the scope of the national regulatory framework in Portugal excluding Azores and Madeira Autonomous Regions. These roles and responsibilities have been identified and confirmed in the IRRS preparatory meeting. It was agreed to include to the scope of the IRRS mission the core modules 1 to 10 defined in the IRRS guidelines for all facilities, activities. The interfaces with nuclear security will not be covered by the IRRS mission.

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

It is expected this IRRS mission will facilitate regulatory improvements in Portugal and other Member State, utilizing the knowledge gained and experiences shared between Portuguese counterparts and IRRS reviewers and the evaluation of the Portuguese regulatory framework for nuclear and radiation safety.

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

- a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
- c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- d) promoting the sharing of experience and exchange of lessons learned among senior regulators;
- e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;
- f) providing the host country with recommendations and suggestions for improvement;
- g) providing 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);
- h) contributing to the harmonization of regulatory approaches among states;
- i) promoting the application of IAEA safety requirements; and
- j) providing feedback on the use and application IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Portugal, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 16 to 17 January 2020 and a follow up preparatory meeting on 4 to 5 November 2021. The preparatory meeting was carried out by the appointed Team Leader Mr Mika Markkanen (STUK), the IAEA Coordinator Mr Ronald Pacheco, and APA and IGAMAOT representatives.

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

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

Mr João Oliveira Martins and Mr Marco Candeias made presentations on the national context, the current status of the national regulatory infrastructure and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Portugal in February 2022.

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

The Liaison Officer for the IRRS mission was confirmed as Mr Pedro Rosário.

Portugal provided IAEA with the advance reference material (ARM) for the review in December 2021. In preparation for the mission, the IRRS team members reviewed the Portugal advance reference material and provided their initial impressions to the IRRS Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 20 February, 2022 in Lisbon, directed by the IRRS Team Leader and the IAEA Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 21 February, 2022, with the participation of the Ministry of Environment and Climate Action, State Secretary for Environment, Ms Inês Santos Costa, Inspector-General Mr José Brito e Silva, President of the Executive Board of APA Mr Nuno Lacasta, Deputy Inspector-General Ms Paula Matias, Member of the Executive Board of APA Ms Ana Teresa Perez, and senior management and staff of APA and IGAMAOT. Opening remarks were made by Mr Nuno Lacasta, President of the Executive Board of APA, Inspector-General Mr José Brito e Silva and IRRS Team Leader Mr Mika Markkanen. Mr João Oliveira Martins Director of Emergencies and Radiation Protection (APA) and Mr Marco Candeias, Inspector Director (IGAMAOT) gave an overview of the Portugal 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 Portugal with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

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

The IRRS exit meeting was held on Wednesday 2 March 2022 where the IRRS Team Leader Mr Mika Markkanen presented the results of the IRRS mission highlighting the main findings. This was followed by a statement of Mr Peter Johnston, Director of the Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety and Security. Closing remarks were made by Inspector-General Mr José Brito e Silva and Mr Nuno Lacasta, President of the Executive Board of APA.

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

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Legislative and regulatory framework for safety in Portugal underwent significant changes in recent years. New legislation was adopted, new regulatory authorities established. Further developments are still on-going or under preparation.

Although different elements are embedded into the existing legislative and regulatory framework, a comprehensive national policy and strategy for safety expressing government long term commitment for safety has yet to be established. Some policy elements are missing, some are presented only in the general part of the national legislation, not adjusted to the specific area of safe use of nuclear technologies and ionizing radiation. Further developments in areas such as competence building (in relation with disposal facility for radioactive waste, decommissioning of research reactor, new technologies for medicine, etc.), formulation of research projects/programmes dedicated to radiation protection and nuclear safety, management of adequate human and financial resources or promotion of safety culture at operator/user organizations would benefit from such a comprehensive statement of Governments intent.

Missing single comprehensive national policy and corresponding strategy for safety was also indicated as a finding from the self-assessment prior the IRRS mission and represents dedicated item in the Initial Action Plan (A1). Missing implementing strategy/plan in area of competence building is discussed in section 1.6 of this report and relates to Initial Action Plan item A2 – development of a sustainable strategy/plan for the management of competences of all parties having responsibilities for safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Some elements of national policy and corresponding strategies for safety are missing, some are presented only in the general part of the national legislation, not adjusted to the specific area of safe use of nuclear technologies and ionizing radiation.

- | | |
|------------|--|
| (1) | <p>BASIS: GSR Part 1 Requirement 1 para. 2.3 states that <i>“National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government’s intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:</i></p> <ul style="list-style-type: none"><i>(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles;</i><i>(b) Binding international legal instruments, such as conventions and other relevant international instruments;</i><i>(c) The specification of the scope of the governmental, legal and regulatory framework for safety;</i><i>(d) The need and provision for human and financial resources;</i><i>(e) The provision and framework for research and development;</i><i>(f) Adequate mechanisms for taking account of social and economic developments;</i><i>(g) The promotion of leadership and management for safety, including safety culture.</i> |
|------------|--|

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R1	Recommendation: The Government should establish a comprehensive national policy and corresponding strategies for safety to express its long-term commitment to safety.
-----------	---

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Portuguese legal framework comprises of Laws enacted by the Parliament and Decree-Laws, Ministerial Orders and Dispatches in areas where the Constitution has entitled the Government with legislative power. Matters of radiation protection and nuclear safety, as well as radioactive waste management fall under the legislative purview of the Government and are therefore handled through Decree-Laws or Ministerial Orders.

The framework for safety was recently revised, with the entry into force of DL 108/2018 on radiation protection, which transposed EU Directive 2013/59/EURATOM. The framework covers all types of activities and facilities and exposure situations relevant for Portugal and allocates regulatory responsibility for safety related to the use of radiation sources, nuclear safety and the safe management of radioactive waste and spent fuel.

DL 108/2018, DL 156/2013 and DL 30/2012 (as amended by DL 135/2017) were developed independently, in different time periods and following the transposition of European Union Directives and cover different subjects. This approach led to some discrepancies that have identified and are being addressed.

The self-assessment results and the Initial Action Plan (items A8 and A10) indicate the need for review and update of different pieces of existing legislation for safety. For example, revision of DL 227/2008 and DL 156/2013 is in progress. Furthermore, the DL 24-B/2020 is not in line with the IAEA SSR-6 (Rev.1).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Different pieces of legislation for safety were developed or revised in different time periods. Additional revisions of legislation for safety are on-going or planned. Implementation of a systematic approach to maintenance of the legislative framework for safety is essential to eliminate gaps and overlaps and to ensure its compliance with IAEA safety standards.

(1)	BASIS: GSR Part 1 Requirement 2 states that <i>“The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.”</i>
R2	Recommendation: The Government should ensure that the legislative framework for safety is further developed and maintained in a systematic way in order to keep it in compliance with the IAEA safety requirements.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Under the new regulatory framework established with the entry into force of DL 108/2018, the Regulatory Body is comprised of the Portuguese Environment Agency (APA) and the General Inspection of Agriculture, Sea, Environment and Spatial Planning (IGAMAOT). In the regulatory body, IGAMAOT handles all inspection and enforcement duties as inspection authority, while APA is the competent authority for all other regulatory functions. Based on existing legal and regulatory framework, both APA and IGAMAOT have the legal authority to fulfil its statutory obligations.

APA is a public institute, part of the indirect administration of the State, with administrative and financial autonomy. Regarding IGAMAOT, it is a central service of the direct administration of the

Government, endowed also with administrative autonomy. Both bodies fall under the structure of Ministry of Environment and Climate Action. Through such arrangement the Government has ensured that the regulatory body is effectively independent and that it has functional separation from entities promoting or operating radiological and nuclear facilities or activities that could unduly influence its decision making.

There are different provisions, mainly in DL 108/2018, that create basis for adequate financing of the regulatory authorities. Provisions in article 12(3) of DL 108/2018 specify that the competent authority must have dedicated financial resources to carry out its regulatory duties. The legal standing of APA and IGAMAOT in the state administration and the rules valid for the public institutions in Portugal allows APA and IGAMAOT to request, in general, for adequate resources to cover their activities. For specific aspects of securing adequate resources for APA and IGAMAOT see chapter for Module 3 of this report.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The prime responsibility for safety for facilities and activities is settled in DLs 108/2018, 30/2012 and 156/2013.

DL 108/2018 states at article 8 on the principle of responsibility for radiological protection and safety that the responsibility for radiological protection and safety is up to the holder of a radiation source, complemented by article 24 about the duties of holders. Article 22 (3) also states that legal facts or acts that determine the transfer, modification or extinction of the practice or activity are subject to registration.

DL 156/2013 states in article 10 that the main responsibility for the safety of the facilities and for the management of spent fuel and radioactive waste lies with the operator and may not be delegated or transferred.

DL 30/2012 (as amended by DL 135/2017) states in article 12 that the holder of the license for a nuclear installation bears the primary responsibility for its safety, which may not be delegated or transferred.

The prime responsibility for safety lies with the authorized parties and cannot be transferred, delegated, outsourced, or contracted.

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

There are general rules for collaboration among bodies of the public administration in Portugal. Based on these general rules, the cooperation between APA and IGAMAOT is carried out through official pre-established procedures, including the regular sharing of regulatory information and access to databases and inspection reports. Specific Memorandum of Understanding (MoU) to support the coordination efforts is under development.

In addition, APA has concluded a set of MoUs with relevant authorities such as Republican National Guard or Foundation for Science and Technology. The IRRS team was informed, that more MoUs are planned to support coordination with other relevant authorities such as Authority for Working Condition (ACT), National Authority of Medicines and Health Products, transport authorities, customs, fire brigades, etc.

IRRS team observed that it is essential for APA and IGAMAOT to ensure proper coordination when interacting in regulatory activities, in particular regarding preparation of an inspection or regarding transfer of lessons learned from an inspection to other regulatory processes, including development of regulations and guides.

Missing MoU to support existing pre-established procedures for coordination of authorities with responsibilities for safety was also indicated as a finding from the self-assessment prior the IRRS mission and represents dedicated item A5 in the Initial Action Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: APA shares periodically with IGAMAOT information about authorized facilities and activities and at IGAMAOT’s request, while IGAMAOT shares all the inspection reports with APA through an electronic platform. The two organizations meet, when necessary, for coordination in planning their activities. There is no formal agreement such as MoU to complement pre-established procedures used for coordination between APA and IGAMAOT. APA and IGAMAOT plan to continue to conclude formal agreements for coordination with other relevant bodies of state administration such as ACT, customs, etc.

(1)	BASIS: GSR Part 1 Requirement 7 para 2.18 states that <i>“This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other’s experience.”</i>
S1	Suggestion: APA and IGAMAOT should consider finalizing the formal agreement (MoU) to provide for effective coordination.
S2	Suggestion: APA and IGAMAOT should consider continuing to develop formal provisions for effective coordination with other relevant bodies of state administration.

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

APA has identified two main existing exposure situations:

- Areas impacted by residual radioactive material of natural origin.
- Exposure to radon and thoron in workplaces, dwellings, and other buildings with any factor of public use.

Decree-Law 156/2013 establishes provisions for the management of residues containing radioactive materials. The management of residues containing radionuclides or natural origin (NORM) is included in the scope of this document with the exception of the residues from mining activities. APA is in the process of updating, to be submitted to the Government for approval, the Decree-Law 156/2013 to address, among others: the specification of the PRR as an interim storage facility, the provisions applicable to the closure and post-closure phases of nuclear facilities, the management of NORM waste, as well as updated provisions for inspection and enforcement. APA plans to include provisions for the management of these residues in an ongoing revision of this Decree-Law. The need of updating Decree-Law 156/2013 together with other regulatory documents is referred. **Recommendation R2 in Section 1.2 addresses this issue.**

In correspondence with Article 150 of Decree-Law 108/2018 APA, in collaboration with other relevant organizations, is developing a National Radon Action Plan to be presented to the Government for approval and further implementation. This plan is in compliance with relevant requirements in IAEA GSR Part 3. Due to relative abundance of thorium in several zones of the country, as part of this Plan APA foresees to assess the radiological impact of thoron in the Portuguese population to extend, where needed, protective actions against thoron.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: APA, in collaboration with other Portuguese organizations, is finalizing a National Radon Action Plan, which is in compliance with relevant requirements in GSR Part 3, to be presented to the Government for approval and further implementation.

(1)	BASIS: GSR Part 3 Requirement 50 states that <i>“The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors.”</i>
R3	Recommendation: The Government should ensure that Portugal has a National Radon Action Plan, adopted and implemented.

Regarding provisions for protection in situations related with the identification of orphan sources, according to Decree-Law 108/2018 these sources shall be received for storage by “the public entity responsible for the disposal of radioactive waste” (this responsibility, understood disposal as storage, is currently assigned to IST). The same Decree-Law establishes that, as a last resource, APA is responsible for planning the recovery and management of orphan sources and the costs associated with recovering the control over them may be covered by the Environmental Fund.

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

Decree-Law 156/2013 states the basis for the safe management and disposal of radioactive waste in Portugal. This document includes elements of a national policy and strategy as required in IAEA GSR Part 5. However, a national policy and a strategy for radioactive waste management, that serves as the basis for decision making with respect to the management of radioactive waste, has not been established in Portugal.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Although the national radioactive waste management programme includes several elements of a national policy and a strategy for radioactive waste management, a national policy and strategy for radioactive waste management has not been established yet in Portugal.

(1)	BASIS: GSR Part 5 Requirement 2 states that <i>“To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established. The policy and strategy shall be appropriate for the nature and the amount of the radioactive waste in the State, shall indicate the regulatory control required, and shall consider relevant societal factors. The policy and strategy shall be compatible with the fundamental safety principles and with international instruments, conventions and codes that have been ratified by the State. The national policy and strategy shall form the basis for decision making with respect to the management of radioactive waste.”</i>
R4	Recommendation: The Government should ensure the establishment of a national policy and strategy for radioactive waste management.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Technical and regulatory criteria for managing large amounts of NORM waste needs further enhancement.

(1) **BASIS: GSG-60 para. 3.4 states that** *“The policy and strategy for the management of NORM residues should also take into account the national policies and strategies for safety, for management of non-radioactive waste and for radioactive waste management. States may choose to integrate key elements of the strategy for NORM residue management into their national policy, legal framework and regulatory instruments. In such cases, a separate national strategy for NORM residue management might not be necessary.”*

S3 **Suggestion: The Government should consider including in the national policy and strategy for radioactive waste management provisions for ensuring the further development of technical and regulatory criteria for managing large amounts of NORM waste.**

Regarding decommissioning, Decree-Law 30/2012 (as amended by Decree-Law 135/2017) establishes that decommissioning of facilities is considered as a planned exposure situation and therefore is subject to the requirements applicable to this exposure situation.

1.8. COMPETENCE FOR SAFETY

DLs 108/2018, 156/2013 and 30/2012 (as amended by DL 135/2017) stipulate the need for the holders to build and maintain the competence of their workers. Also, DL 135/2017 (in article 8) states that competent authority should collaborate with the relevant competent entities in the preparation of the training plans of staff and other personnel that have responsibilities related to the nuclear safety of the nuclear installations, in order to obtain, preserve and develop qualifications and competences suited to the needs, in matters of nuclear safety and emergency preparedness in situ.

In addition to above mentioned provisions the DL 227/2008 defines the legal regime applicable to the professional qualification in radiological protection. In the time the IRRS mission took place, the DL 227/2008 is at final stages of revision. Final draft was sent for public consultation recently. For general recommendation on maintenance of the legislative framework for safety see the section 1.3 of this report.

Based on self-assessment results, the Initial Action Plan include item A2 on “developing a sustainable strategy/plan for the management of competences of all parties having responsibilities for safety” that should be developed and presented by APA and IGAMAOT to the Government for consideration. Such implementation policy would support extensively further development of national framework for safety. For general recommendation on development and implementation of national policy and corresponding strategies for safety see Section 1.1 of this report.

1.9. PROVISION OF TECHNICAL SERVICES

Articles 163 and following of the DL 108/2018 are used to regulate providers of services in the area of radiological protection. These companies are indispensable for prior control of the procedures and for maintaining the conditions of compliance with the legal requirements for all those who need to operate radiation sources. Following services are considered under art 163(2) of DL 108/2018:

- a) Study of conditions of radiological protection and safety of installations and equipment that produces or uses ionising radiation;
- b) Technical consultancy in the areas of activity of the installations;
- c) Individual and area dosimetry;
- d) Training in radiological protection and safety (according to DL 227/2008) and

- e) Verification of the radiological protection and safety conditions and of the compliance with the acceptance criteria for installations and equipment producing or using ionizing radiation.

The Government has made provision for technical services related to safety and has introduced process for authorization of technical services in the DL 108/2018.

1.10. SUMMARY

Legislative and regulatory framework for safety in Portugal underwent significant changes in recent years. As a result:

- Most of the existing legislation was upgraded, some new legislation was adopted.
- New regulatory authorities (APA and IGAMAOT) were established.

However, the areas for further improvement have been identified:

- Establishing a comprehensive national policy and corresponding strategy for safety to support further developments, mainly in areas such as competence building, R&D, management of resources, promotion of safety culture, etc.
- Update of the legislative framework for safety to be in compliance with the IAEA standards.
- Establishing formal provisions for coordination between APA and IGAMAOT and formal provisions for coordination with other relevant bodies of state administration.
- Adoption and implementation of the National Radon Action Plan.
- Establishing a national policy and strategy for radioactive waste, spent fuel and decommissioning.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Portugal has signed or is part of the most relevant international conventions and agreements for ensuring and enhancing radiation protection and nuclear safety as listed below:

- IAEA Member State since July 1957;
- Convention on the Physical Protection of Nuclear Material including its Amendment;
- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, where ANEPC is the counterpart with the support of APA;
- Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention
- Convention on Nuclear Safety;
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- Revised Supplementary Agreements Concerning the Provision of Technical Assistance by the IAEA (RSA);
- Code of Conduct on the Safety and Security of Radioactive Sources and the Guidance on the Import and Export of Radioactive Source and the Guidance of the Management of used Radioactive Sources.

APA represents Portugal or is the national counterpart in the vast majority of these conventions and agreements.

Portugal is also member of the following organizations and conventions:

- Organization for Economic Cooperation and Development/Nuclear Energy Agency (OECD/NEA) and their Committees and Working Groups;
- Heads of the European Radiological Protection Competent Authorities (HERCA) and their Working Groups;
- Convention on Environmental Impact Assessment in a Transboundary Context (Espoo Convention);
- The UNECE Convention on Access to Information, Public Participation in Decision making Access to Justice in Environmental Matters (Aarhus Convention); and
- The Convention for the Protection of the Marine Environment of the North East Atlantic (OSPAR Convention).

APA is also applying for the membership of the “FORO Iberoamericano de Organismos Reguladores Radiológicos y Nucleares” (Ibero-American Forum of Radiological and Nuclear Regulatory Bodies) having already been present in some meetings as an observer.

The obligations resulting from these agreements are fulfilled by having an active participation, by the implementation of the outcomes in national policies and procedures, by reporting the general status and development of specified areas of interest in accordance with agreed reporting cycles.

In a broad sense Portugal uses the outcomes of those agreements and the experience achieved to enhance its regulatory framework and the radiation and nuclear safety at the national and at the international level.

APA and several national laboratories and universities also have an active participation in IAEA R&D projects relating to radiation and nuclear safety on their different subjects, thus sharing the national knowledge and experience and gaining from the knowledge and experience from others.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Portugal has an active participation on the different *fora* previously mentioned, including the development of international standards for radiation and nuclear safety either as experts in the development itself or through the participation in the IAEA Safety Standards committees NUSSC, RASSC, WASSC, TRANSSC and EPreSC.

At bilateral level Portugal has a long history of collaboration with Spain in the field of radiation and nuclear safety. The oldest agreement has been since 1971 and the latest are the Technical Protocol for Cooperation in the Framework of Nuclear and Radiological Emergencies and Environmental Radiation Protection, signed by APA and ANEPC from the Portuguese part and CSN from the Spanish part in 2015, and a new MoU signed between APA and IGAMAOT from the Portuguese part and CSN from the Spanish part in September 2021. Due to the regulatory changes in Portugal and the covid pandemic the implementation of the Technical Protocol is still under development.

Portugal also provides experts for international training actions and peer review missions (namely IRRS and EPREV from the IAEA) and has hosted several workshops and training actions. Several Portuguese institutions and laboratories have received and are available to receive trainees and fellows from other countries, namely developing countries, in several areas of radiation safety and in particular on environmental monitoring and the medical area. Portugal promotes the participation of its experts in the relevant events such as workshops, conferences, training actions, exercises, or others. The INSARR mission took place in Portugal in 2016.

Although informal procedures exist to share nationally the outcomes of the international meetings, conferences and workshops, a formal procedure is still not available to ensure the practical dissemination of the information and guarantee its due implementation. As the IRRS team also noted during the interviews, IGAMAOT does not implement a formal procedure to use the results of the inspections as feedback information for the regulatory process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: Information and feedback of experiences collected (including internationally) by the regulatory body staff is shared on a case by case basis, but it is not systematically documented nor systematically shared with relevant stakeholders. No specific APA or IGAMAOT procedure or policy addresses this sharing and dissemination of such information.</p>	
(1)	<p>BASIS: GSG 12 para. 3.20 states that <i>“Information and knowledge are part of the corporate memory of the regulatory body and should be managed as a key resource that is embedded in the regulatory body’s processes, activities and functions (see Table A-19 in the Annex).... Effective management for safety will take into account the knowledge and information resulting from both positive and negative experiences (e.g. good practices and bad practices). Examples of information and knowledge relevant for regulatory bodies include the following:</i></p> <ul style="list-style-type: none"> - ... - <i>Feedback of experience from other authorities and national and international bodies;</i> - <i>Operating experience in authorized facilities and activities in the State and in other States.”</i>
S4	<p>Suggestion: The regulatory body should consider improving the processes for the dissemination of information and feedback of experiences for use by regulatory body, authorized parties, other authorities and stakeholders concerned.</p>

Portugal has agreed in a Technical Cooperation Project with the IAEA with the following title: Enhancing National Capabilities and Infrastructure in Nuclear and Radiation Safety (POR 9012).

2.3. SUMMARY

Portugal participates in the relevant international arrangements to enhance safety globally and fulfil its respective obligations. Portugal has signed, or is part of, the most relevant international conventions and agreements for ensuring and enhancing radiation protection and nuclear safety.

The regulatory body collects, analyses and disseminates operating and regulatory experience on a case by case basis, but it is not systematically documented nor systematically shared with relevant stakeholders. Outcomes of the experience gained in the several national and international interactions are evaluated internally and included in the national framework if believed relevant.

The area for improvement concerns the dissemination of information and feedback of experiences for use by the regulatory body, authorized parties, other authorities, and stakeholders concerned.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Considering the responsibilities and regulatory functions as well as the organizational structure of the regulatory body in Portugal the IRRS team reviewed APA's structure and resources for the authorization, review and assessment and development of regulation and guides process as well as, IGAMAOT's structure and resources regarding the inspection and enforcement process.

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

The current regulatory framework (DL 108/2018) provides that APA and IGAMAOT would have adequate resources (including both staff and the budget) reinforced by the government, based on the identified needs in carrying out their responsibilities and tasks.

APA's internal structure was reformulated through amendments in DL 56/2012, Ministerial Order 108/2013 and finally Ministerial Order 170/2019. The president of APA and the members of the Board are appointed after an open public procedure and their service is for a five-year period. The procedure is similar for the Directors and Unit Heads. The new department for Emergencies and Radiation Protection (DEPR) at APA includes the Division for Authorization and Nuclear Safety (DAN), the Division for Environmental Planning and Protection (DPA), as well as the Unit for Preparedness and Response to Emergencies (EPRE), at division level. Currently 19 out of a maximum of 20 people are employed in DEPR, including 1 Director and 3 Division Heads. APA general services provide the administrative, financial, legal, IT and logistics support to all APA departments, including DEPR.

This number of personnel employed in APA was reached by an initial assessment taking into account the type and number of practices carried out in Portugal as well as the experience gained within the previous regulatory framework where the various regulatory functions were scattered in different agencies. DEPR's personnel consists of civil servants employed in the previous authorities as well as new personnel that has been recruited. The procedure of recruiting new personnel includes a description of the job profile. Internal reallocation to staff responsibilities is possible based on the needs in specific regulatory areas. The IRRS team was informed that APA is lacking resources for the regulatory control of new practices, such as the proton therapy, or the decommissioning of the research reactor or the NORM practices. **Recommendation R6 in 3.3 addresses this issue.**

The responsibilities to staff personnel are assigned by the Unit Head, after the approval of the Director. The procedure of decision making starts with the employee who has been assigned with a specific responsibility then the Unit Head and the Director who approves the decision and finally the APA's manager who signs the administrative decision. For other responsibilities the procedure may be completed by the Unit Head or the Director.

Regarding APA's budget, a first draft of it is sent to the APA's Board and includes all the costs the DEPR may need within the next fiscal year. The final budget is approved on annual basis.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: When assigned its role as the regulatory body, APA structured its organization and managed its resources based on an initial assessment on its needs to fulfil its statutory obligations. However, considering the experience gained within the last years of operation, APA has not yet developed a formal procedure to assess its needs to fulfil its statutory obligations. APA has identified in its action plan the need to develop a formal procedure to assess the need to ensure the allocation of human and financial resources in accordance with a graded approach.

(1)

BASIS: GSR Part 1 para 4.5, states that *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. ..."*

(2)

BASIS: GSG-13 para 2.10, states that *"The application of the graded approach should be*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>reassessed as a better understanding is obtained of the radiation risks arising from the facility or activity.</i>
S5	Suggestion: APA should consider developing a formal procedure for the allocation of human and financial resources as to fulfil its statutory obligations effectively and in accordance with a graded approach.

IGAMAOT was restructured according to DL 108/2018 and now an inspection department for Ionizing Radiation (EM RAD) has been established. Currently, EM RAD has one inspector director, an inspector head of unit, one support technician, and 12 inspectors. The appointment of the director and the Unit Head and the recruitment of the inspectors follows the same procedure as for APA. The number of inspectors and the respective competences was reached after an initial assessment based on the number and type of practices in Portugal. IGAMAOT also has an annual budget to conduct of the inspections. In 2020 a series of equipment was purchased, and the respective calibration has been performed in order to enable inspectors perform safely their tasks.

The assignment of work in IGAMAOT is performed through the inspection plan which is prepared by the Director and approved by the board. All inspectors may inspect all different facilities and activities. The inspectors are not able to select the assigned authorized parties to be inspected. The inspection report is drafted by the group of two participating inspectors, then is approved by the Unit Head, the Director and finally signed by the IGAMAOT's manager.

Regarding the use of resources, IGAMAOT uses a matrix tool for the allocation of the respective manpower. Each inspection is always performed by two inspectors. The criteria for the establishment of the inspection plan are not based on risk evaluation only. Therefore, the whole inspection process (including the check lists, the inspection report, and the duration of the inspection) is not commensurate with the radiation risks from the facilities and activities to be inspected. The IRRS team observed that the annual inspection plans for 2020 and 2021 included several low-risk facilities. Furthermore, the IRRS team was informed that IGAMAOT decided to prioritize the inspection of facilities that were out of regulatory control, namely without authorization. Such facilities were mainly related to low-risk practices. The IRRS team was informed that the only waste storage facility (PRR) in the country was inspected for the first time under the current regulatory framework by the IGAMAOT during the mission (see site visits in Module 7).

Following the inspection, the notice with the non-compliances with the regulatory requirements is sent to the legal department of IGAMAOT for opening an administrative procedure. The enforcement process and the level of fines are classified according to the Law 50/2006 in mild, serious and very serious offenses with different values for the fines, according to a graded approach. A small percentage of the fines goes to both regulatory competent authorities and the rest to the State Treasury. For detail see text of Module 8.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Most of IGAMAOT human resources are allocated in 2020 and 2021 to planned inspections of low risk facilities. However, limited resources are allocated to inspections of high risk facilities such as the waste storage or external radiotherapy facilities.

(1)

BASIS: GSR Part 1 Requirement 16 para. 4.5 states that *“The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. ...”*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R5

Recommendation: IGAMAOT should locate its resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The independence of APA and IGAMAOT is provided in DL 108/2018. The general framework for all public servants, as provided in the Law No. 35/2014, is applied to the employees of both APA and IGAMAOT to manage potential conflicts of interest of staff. Based on this Law all civil servants (including the employees of the regulatory authorities) are not to be involved in other activities which are related with their regulatory tasks. However, they can be involved in other professional and scientific activities, if they are granted permission by the Board, provided there is no conflict of interest between the regulatory tasks and their parallel work.

When appointing the Board of APA and IGAMAOT, special procedures of impartiality are required regarding their relationship with the application and promotion of nuclear technologies.

Regarding the personnel coming from authorized parties to work at APA or IGAMAOT there are provisions to preserve their integrity as foreseen in Law No. 35/2014. In both authorities, the newly recruited staff (including the ones coming from authorized parties) do not have decision making rights before a given time period. Employees, when joining the civil service staff, are obliged to comply with general public administration rules that they must comply with.

The enforcement policy and criteria and instructions to implement the provisions are addressed in **Recommendation R17 and R 18 in Section 8.1.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

APA and IGAMAOT have recently been established and are in the phase of building capabilities to carry out their functions. An initial assessment for the number and the competence of staff needed to carry out the regulatory tasks was made by both organizations. The procedure that took place for the recruitment of the new staff members followed the general public administration rules based on pre-defined profiles. In this framework, APA and IGAMAOT could recruit the persons with the competence and skills defined at that time in the public offer. After the initial assessment of the human resources and within the last three-year period of operation a formal human resource plan to take into account the acquired experience and the existing facilities and activities as well as the foreseen ones has not yet been developed. Moreover, when a member of a staff is leaving from the regulatory body a recruitment process is initiated to fill the vacancy. However, due to the specific conditions in the procedures of recruiting personnel for Public Administration, this process can be long and is possible to create gaps during the transition period.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: APA and IGAMAOT have performed an initial assessment of the necessary staff and skills to exercise their regulatory functions. However, after this initial assessment, a formal process for the development of a human resource plan and a strategy to compensate for the departure of qualified staff are not in place.

(1)

BASIS: GSR Part 1 Requirement 16 states that *“The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.”*

(2)

BASIS: GSR Part 1 Requirement 18 para. 4.12 states that *“The human resources plan for the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff.”</i>
(3)	BASIS: GSR Part 2 Requirement 9 para. 4.12 states that <i>“Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them.”</i>
R6	Recommendation: The regulatory body should establish a human resources plan, including a strategy to compensate for the departure of qualified staff.

Regarding the training of new staff members includes mainly in house training on the legislative framework and the internal procedures of the regulatory body. Training on technical areas is performed also on the job and using the IAEA training courses and workshops and other training provided by other national and international entities (OECD, EC, namely).

For example, in IGAMAOT, the training of the staff members includes courses at IST and CIEMAT (Spain) in radiation protection as well as in IAEA training courses. The new inspectors are trained also on job by their participation in planned inspections and in thematic campaigns planned yearly, like for brachytherapy or industrial practices. However, in some inspections the team of inspectors are accompanied by the director inspector or the head of unit. Moreover, the technical performance of the inspectors is not evaluated in accordance with a documented procedure on a regular basis.

Both authorities have identified areas that need to gain experience, such as authorization of the decommissioning activities of the research reactor, NORM practices or the inspection of transport activities. Though these gaps have been identified no specific training programme based on systematic analysis at all hierarchy levels has been established yet.

Regarding the maintenance and development of knowledge both authorities arrange some internal meetings where they discuss and share the information and experience acquired in seminars or workshops. However, no systematic approach in developing and maintaining the acquired knowledge exists. This has been recognized in the ARM and is part of the action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team has identified that there are regulatory areas where APA and IGAMAOT staff need to be trained. However, no systematic analysis on the necessary competence and needs has been performed. Moreover, both APA and IGAMAOT have no process for the maintenance of the skills and competence that have already been developed.	
(1)	BASIS: GSR Part 1 Requirement 16 states that <i>“The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.”</i>
(2)	BASIS: GSR Part 1 Requirement 18 para. 4.13 states that <i>“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</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>inspecting facilities and activities, and for enforcing regulatory requirements.”</i>
(3)	BASIS: GSR Part 2 Requirement 9 para. 4.23 states that “ <i>Senior management shall ensure that competence requirements for individuals at all levels are specified and shall ensure that training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence. An evaluation shall be conducted of the effectiveness of the training and of the actions taken.</i> ”
R7	Recommendation: The regulatory body should establish a formal process for the knowledge management, including a specific training programme based on the analysis of the necessary competence and skills.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

APA may designate Technical Support Organizations (TSOs) or consult experts and advisory commissions based on the provisions of DL 108/2018. APA conducts periodic audits of their activity, proposes the necessary corrections and the deadline for their implementation and informing the members of Government responsible for the corresponding areas if corrections are not implemented. The potential for conflicts of interest is taken into account in the evaluation of proposals from candidate contractors in the establishment of framework arrangements. Up to now this kind of advisory or support is performed on the basis of collaboration protocols with universities and national laboratories for specific tasks (e.g., radon measurements, radon remediation, etc...).

In the field of environmental monitoring IST performs an environmental monitoring programme. Within the new regulatory system APA is responsible for this task. For this reason, APA has initiated a process to update this programme. The IRRS team was informed that the whole process is going to start in the near future waiting for the official authorization for the financial provisions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Portugal has operated for several years a national environmental radiological surveillance programme. The IRRS team was informed that APA has been working in the update of this programme.	
(1)	BASIS: GSR Part 3 Requirement 32 para. 3.135 states that “ <i>The regulatory body shall be responsible, as appropriate, for:</i> <i>(c) Making provision for an independent monitoring programme.</i>”
(2)	BASIS: GSR Part 3 Requirement 32 states that “ <i>The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available.</i> ”
(3)	BASIS: RS-G-1.8 para 5.5 states that “ <i>The setup of a monitoring programme is the result of an optimization process in which the availability of measurement resources, the relative importance of different exposure pathways, and the levels of activity and dose in relation to the regulatory constraints are taken into consideration. Once a monitoring programme has been implemented, it should be reviewed periodically to ensure that it continually fulfils the objectives.</i> ”

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S6

Suggestion: APA should consider concluding the update of the Environmental Monitoring Programme (PRAD).

Within the framework of advisory groups APA has also established an advisory board (ComissãoComissã de Acompanhamento Técnico, CAT), consisted of representatives of professional societies and other stakeholders from all relevant areas. CAT may advise APA on technical matters for implementing regulatory strategies and requirements. In this respect the establishment of CAT is also a way of high-level consultation of all stakeholders to review regulations and guides.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

APA communicates with authorized parties through official channels, mainly by official letters or emails. Moreover, the authorized parties may reach APA through scheduled meetings and phone calls. In the beginning of the implementation of the new regulatory framework meetings were organized to inform the authorized parties for the new requirements. The meetings were organized per specific thematic area according to practices like industrial companies or dentists. Moreover, APA organizes training courses during which they also interact with authorized parties.

For IGAMAOT there is no liaison with the authorized parties other than the inspection itself.

For APA the official documents such as licenses and registrations are always based on facts and legal provisions. The whole process is performed through the document management system (Filedoc). The decision making in APA is initially performed by reviewing the information submitted. In most cases, a formal “invitation to improve” is sent to the applicant where any missing information is identified, the applicant is informed to submit it with the necessary clarifications and improvements. After the final submission of the relevant documentation the applicant is notified of the results for granting of an authorization, or not. In both cases, the applicant has a set period of time to reply to either option, after which the authorization is issued, or the application is formally denied. Prior to issuing a license, the draft license is sent to the applicant for review and may, if deemed appropriate by APA, be modified prior to formal issuance.

For IGAMAOT, regarding the non-compliances fixed in the inspection reports, these would result from the comparison of the information given by the authorized party against the conditions of the registration certificate or licence and the provisions in the legislation. The “notice” accompanied by the inspection report is transferred to the legal department of IGAMAOT for opening an administrative procedure. (See Module 8).

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

APA has developed application forms for registrations and licenses uploaded at its website. The use of these forms allows the authorized parties or applicants to submit the requested information as well as the staff of regulatory body to perform the analysis of submitted information in similar way. Each step of the analysis by individual staff members is sent for decision to its ranking officer, who then checks and decides whether adjustments are necessary. Higher ranking officials always validate proposed regulatory decisions and submit them to APA's manager, who takes the final decision. However, specific documented guidance, especially for some high-risk practices, does not exist. **Recommendation R20 in Section 9.1 addresses this issue.**

IGAMAOT has also developed check lists and templates of inspection reports. Though these tools are not part of the documentation of the management system, yet they allow the inspectors to analyse the inspection results in similar way. However, the whole inspection process is not integrated. **Recommendation R9 in Section 4.3 addresses this issue.**

When changes in the regulatory requirements are planned, APA can seek advice from CAT. Moreover, an official public consultation process through APA’s website (PARTICIPA portal) is also available. An example to this is the

current radon action plan which has been recently set to public consultation under a formal procedure of Environmental Assessment. However, a formal process for changing or updating regulatory requirements is not foreseen.

The IRRS team was informed that APA, in collaboration with Plan APP the “Competence Centre for Planning, Policy and Foresight in Public Administration”, has started a project on assessing the impact of the new legislation in the Portuguese economy. The project is expected to help APA set a methodology for a risk assessment combined with a cost benefit and consequence analysis for future changes in the regulatory system.

3.7. SAFETY RELATED RECORDS

APA has the responsibility to establish and keep updated the national register of radiation sources (including the transport data), the national inventory of authorized parties and the national dose register of exposed workers. The records of radioactive sources include the type of source, the radionuclide and the activity value indicated by the manufacture or estimated on a reference date. Additionally, all communication records from APA, including technical analyses, and safety-related decisions are archived in the Document Management System (Filedoc).

IGAMAOT keeps all the records of the inspection reports. In order to perform an inspection IGAMAOT has access to APA’s database and may extract all the information required. The same happens for APA who have access to IGAMAOT’s database system. However, the information kept by APA is in the form of spreadsheets, and, for this reason, APA decided to use a more robust system. The IRRS team was informed that RAIS database was selected, and the transition is planned to be integrated by the end of the year.

According to DL 108/2018, the authorized parties are responsible to maintain the inventories of the radiation sources under their responsibility as well as the records of occupational exposure. A copy of the inventory of radioactive sources is sent to APA by the authorized parties on a yearly basis, until the end of January next year. These records are under the scrutiny of IGAMAOT during the inspections.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The communication policy and strategy of the regulatory body is not integrated nor documented. Pieces of communication tools and means for transparency, openness and consultation exist in the recent DL 108/2018 according to which APA makes available information related to the justification of classes or types of practices, regulation of radiation sources and radiation protection for authorized parties, workers, members of the public, patients and other people subject to medical exposure, without prejudice to the provisions of the legislation on the personal data protection or on security matters. For nuclear facilities, there are also specific provisions for information to the public in DL 30/2018, as amended by DL 135/2017. For radon matters, a communication strategy exists.

APA’s website is an important tool for communication to the public and other interested parties and has been reorganized recently. The authorization administrative decisions of all the authorized facilities and activities are uploaded at the website. The list is updated regularly and includes only data relevant to public information taking into account security issues. In addition, APA publishes FAQs and briefings related to incident and accident in authorized parties. APA holds an account at YouTube channel where the interested parties can be briefed about significant events in the relevant fields.

The applicants can download the required information through APA’s site. The IRRS team was informed that DEPR is in the process of merging with a smart integrated tool for all APA services, with access from the website, which will guide applicants to various authorizations required.

APA also communicates with relevant ministries and other governmental authorities for issues of common interest.

APA summarizes the most important findings from authorizations as well as the common gaps at the submission of the documentation for authorization. Some of these are included in the FAQ list. IGAMAOT also summarizes the most important findings of the inspection reports into an annual report.

3.9. SUMMARY

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

- Application of graded approach in managing the regulatory body's resources.
- Establishment of human resource plan.
- Development of a formal process for the knowledge management and training programme.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The regulatory body prepared a very comprehensive Self-assessment Report and Summary Report for Module 4 where the activities of both APA and IGAMAOT were compared against the IAEA Safety Standard GSR Part 2, “Leadership and Management for Safety”.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

According to the IAEA Safety Standard GSR Part 2, leadership for safety can, amongst other things, be expressed through establishing a vision, mission, values, and behavioural expectations and fostering a strong safety culture.

APA’s mission is to ensure a high level of radiological protection and nuclear safety as well as the safe management of spent fuel and radioactive waste. APA has defined a vision that includes the development of a safety culture in the use of ionizing radiation. The APA mission and vision are included in the document *Plano Anual de Atividades*. Its mission and vision are publicly available on APA’s website. Additionally, in the document *Management system for safety* (DEPR_RS_01) APA’s mission and vision in radiological protection, nuclear safety and the safe management of radioactive wastes are defined. In the document DEPR_RS_01 the responsibilities of APA Officers are to:

- develop safety values by setting behavioural expectations for workers in order to shape a strong safety culture.
- encourage the acceptance of personal responsibility for safety among all workers.
- establish and communicate safety policies, strategy, plans and objectives with due regard to safety.
- ensure that responsibilities are aligned with safety policies so that safety requirements and goals are included in decision making at all levels.
- develop and maintain leadership skills at all levels.
- support and encourage a focus on safety and include it in the decision-making process.

However, it is not documented how APA applies the leadership for safety throughout the organization, for example in its statements, decisions, and actions.

IGAMAOT has defined its mission and values in the document *Manual de Acolhimento* and in the *Plano Anual de Atividades*. Its mission and functions are publicly available on IGAMAOT’s website. The *Manual de Acolhimento* also includes IGAMAOT’s code of ethics and code of conduct which includes the values of efficiency, effectiveness, quality, equity, impartiality, loyalty competence and responsibility but there is no clear evidence on how these values are implemented in a systematic way to demonstrate leadership and commitment to safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: IGAMAOT and APA have not formalized a systematic approach in demonstration of leadership for and commitment to safety. It is not documented how the leadership for safety is applied throughout the organization by means of explicit commitment with safety in its statements, decisions, and actions, developing questioning and learning attitudes and to correct acts or conditions that are adverse to safety.

(1)	BASIS: GSR Part 2 Requirement 2 states that <i>“The managers shall demonstrate leadership for safety and commitment to safety”</i>
(2)	BASIS GSR Part 2 Requeriment 2 para 3.1. states that <i>“The senior management of the organization shall demonstrate leadership for safety by:</i> <i>(a) Establishing, advocating and adhering to an organizational approach to safety that stipulates that, as an overriding priority, issues relating to protection and safety receive the attention warranted by their significance;</i> <i>(b) Acknowledging that safety encompasses interactions between people,</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>technology and the organization ”</i>
(3)	<p><i>BASIS GSR Part 2 Requirement 2 para. 3.2 states that “Managers at all levels in the organization, taking into account their duties, shall ensure that their leadership includes:</i></p> <ul style="list-style-type: none"> <i>(a) Setting goals for safety that are consistent with the organization’s policy for safety, actively seeking information on safety performance within their area of responsibility and demonstrating commitment to improving safety performance;</i> <i>(b) Development of individual and institutional values and expectations for safety throughout the organization by means of their decisions, statements and actions;</i> <i>(c) Ensuring that their actions serve to encourage the reporting of safety related problems, to develop questioning and learning attitudes, and to correct acts or conditions that are adverse to safety”</i>
R8	<p>Recommendation: The regulatory body should establish an organizational approach to assure goals for safety are set in accordance with a policy for safety. Organizational procedures should set goals for safety, seek information and commitment on improving safety performance.</p>

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

APA has identified the need to establish and develop a management system covering all activities developed within the scope of competences attributed to the Department of Emergencies and Radiation Protection, as defined in the document Quality Manual (DEPR_RQ_01) which expresses the commitment of APA’s Management Board to the establishment, implementation, evaluation, and continuous improvement of a quality management system. The Quality Manual includes a *Quality Policy*. This policy does not include elements of safety policy. Additionally, the IRRS team was informed that APA approved a separate Quality Policy in October 2020. This policy demonstrates the commitment of APA to the development of its functions, but it does not include any safety elements. The IRRS team observed that an integrated management policy which includes such things as a human resources policy and a safety policy is not in place. Regarding human resources there is a *Mapa de Pessoal for 2021* published on the APA web site which sets out the number of positions in APA in terms of function and position within the organization. This document does not include any arrangements for how APA will maintain the full range of competences and resources required to conduct its activities and to discharge its responsibilities for ensuring safety. Regarding APA’s interaction with interested parties, the IRRS team was informed that under article 15.1 of Decree-Law 108/2018, the competent authority may consult with experts or create technical advisory committees whenever it deems relevant and appropriate for the pursuit of its regulatory competences. The IRRS team noted that interested parties of the regulatory body are not identified in the strategy for the management system for safety. This strategy only includes the mechanism to disseminate information on APA’s regulatory activity to promote transparency and it does not include any mechanism to systematically interact with interested parties.

IGAMAOT does not have a safety policy, a human resources policy or a quality policy in place. Regarding the interaction with interested parties, IGAMAOT’s *Plano Anual de Atividades 2021* established, as part of its activities related to ionizing radiation, communication, and participation with other entities, mainly APA, in conducting thematic inspection campaigns and other joint activities. This plan also set out collaboration and cooperation with a significant number of national and international competent authorities in performing the ionizing radiation functions of IGAMAOT. The IRRS team was informed that IGAMAOT has no strategy or systematic approach defined on how to interact with interested parties. Some of those collaborations are carried out sporadically and others in a continuous manner, as in the case of APA, although this is not formally documented.

4.3. THE MANAGEMENT SYSTEM

APA and IGAMAOT have in place document management systems to record, track processes, and organize the documents and information associated with the performance of their functions and competences. APA has started the development of an integrated management system by drafting a strategy for a management system for safety as well as a quality manual.

An integrated management system that brings together in a coherent manner all the requirements for managing the organization aligned with GSR Part 2, to provide a single framework for the arrangements and processes necessary to address all the goals of the organization has not been developed. These goals include safety, health, environment, security, quality and economic elements and other considerations such as social responsibility. Neither APA nor IGAMAOT has started the development of a manual for the management system itself. Establishment of an integrated management system in accordance with IAEA requirements is a finding from the self-assessment prior to the IRRS mission and represents a dedicated item in the initial Action Plan (A26).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: APA and IGAMAOT has not yet established and implemented an integrated management system in line with IAEA safety requirements.	
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 19 states that <i>“The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.”</i>
(2)	BASIS: GSR Part 2 Requirement 6 states that <i>“The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised.”</i>
(3)	BASIS: GSR PART 2 Requirement 6 para 4.11 states that <i>“The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system.”</i>
(4)	BASIS: GSR Part 2 Requirement 13 states that <i>“The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety.”</i>
R9	Recommendation: The regulatory body should establish, implement, and continuously improve an integrated management system in line with IAEA safety requirements.

The IRRS team noted that for APA and IGAMAOT:

- The plan for establishing and implementing the management system does not yet exist;
- There is no team responsible for developing and implementing the integrated management system; and
- Training and information to the staff on the establishment, development and implementation of an integrated management system has not been provided.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: APA and IGAMAOT has not foreseen the preparation of a development and implementation plan for the integrated management system.

(1)	BASIS: GS-G-3.1 para 2.24 states that “Senior management should prepare a plan to achieve full implementation of the management system.”
S7	Suggestion: The regulatory body should consider developing a road map for planning the establishment and implementation of the integrated management system.

APA and IGAMAOT informed the IRRS team that a graded approach is used in licensing and inspection processes. However, the IRRS team observed that implementation of graded approach in regulatory functions has not fully implemented as e.g:

- Development of regulatory guides was prioritised by exposures situations for which a guide was not developed yet.
- An inspection programme was planned in 2021 which was not based only on risk evaluation criterio.
- Additionally, there are no criteria established for the development and application of the management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: APA and IGAMAOT have not developed a management system which takes into account a graded approach to all core regulatory processes.

(1)	BASIS: GSR Part 1 Requirement 16 states that “ <i>The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities</i> ”
(2)	BASIS: GSR Part 1 Requirement 16 para. 4.5 states that “ <i>The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. Thus, for the lowest associated radiation risks, it may be appropriate for the regulatory body to exempt a particular activity from some or all aspects of regulatory control; for the highest associated radiation risks, it may be appropriate for the regulatory body to carry out a detailed scrutiny in relation to any proposed facility or activity before it is authorized, and also subsequent to its authorization.</i> ”
(3)	BASIS: GSR PART 2 Requirement 7 para 4.15 states that “ <i>The criteria used to grade the development and application of the management system shall be documented in the management system.</i> <i>The following shall be taken into account:</i> <i>(a) The safety significance and complexity of the organization, operation of the facility or conduct of the activity;</i> <i>(b) The hazards and the magnitude of the potential impacts (risks) associated with the safety, health, environmental, security, quality and economic elements of each facility or activity [16, 24–26];</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>(c) The possible consequences for safety if a failure or an unanticipated event occurs or if an activity is inadequately planned or improperly carried out”</i>
R10	Recommendation: The regulatory body should develop and implement a management system considering a graded approach in all its regulatory processes.

4.4. MANAGEMENT OF RESOURCES

APA and IGAMAOT determines the competence of its staff in terms of the requirements that were included in the recruitment process for new posts and by evaluating educational qualifications, the curriculum vitae and previous experiences. APA and IGAMAOT staff are recruited in line with the process for civil servants.

APA and IGAMAOT currently perform knowledge management through the recording of all technical documents in an electronic system. APA’s system is called *Filedoc*. All staff of APA has access to *Filedoc* (the system content; application for authorization, authorization data, reports associated with the facility or activity, correspondence and, where required, the final Board decision). IGAMAOT refers to it as the Information Management system (*SGI - Sistema de Gestão de Informação*) and it is designed with different levels of access to the information and content depending on the responsibilities and functions of the individual and Departments.

Although the ARM prepared for the IRRS mission points out that APA has established in its strategy for a management system for safety, the training of its employees and managers based on an annual activity plan the IRRS team was informed that there is no systematic annual training programme in place. For newly recruited staff since 2021, there is an initial training programme of 203 hours which includes 5 modules on organization, values as civil servant, performance of public service, innovation, and public administration.

IGAMAOT drafted an annual training programme for all its staff which was approved by the Board.

APA and IGAMAOT as public entities must comply with dispositions included in Law 66-B/2007 establishing an integrated system for assessment performance in public administration (SIADAP). According to this Law all civil servants must go through an individual assessment performance process yearly. The objectives for each individual worker are reviewed every year and the performance assessment is carried out every two years.

APA carried out this process in accordance with the *Regulamento de Funcionamento do Conselho de Coordenação da Avaliação* (CCA). This document sets out the general competence objectives for APA departments and measurable key indicators. In this context APA has developed a document called *Competências definidas para o biênio 2019/20* with include the objectives and competences for staff according to their position in the organization.

However, the IRRS team observed there is not a systematic approach to knowledge management and training in place. The above-mentioned system for performance assessment applied by APA and IGAMAOT (so called SIADAP) does not include competences for leadership for safety at all management levels, competences for fostering and sustaining a strong safety culture and expertise to understand technical, human, and organizational aspects relating to the facility or the activity in order to ensure safety. **Recommendation R7 in Section 3.3 addresses this issue.**

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The core processes implemented by APA and IGAMAOT are established in Decree Law 108/2018.

The IRRS team observed that the APA and IGAMAOT processes are not yet formalized and documented in line with IAEA safety standards related to the integrated management systems. **Recommendation R9 in Section 4.3 addresses this issue.**

It was noted that:

- The process map identifying management, core and supporting processes is not defined;
- Management, core and supporting processes are not developed;
- Process owners are not formally assigned;
- Sequencing of the process is not formally defined; and
- The interactions between processes within the regulatory body and the interactions between processes conducted by the regulatory body and processes conducted by external parties are not specified.

4.6. CULTURE FOR SAFETY

The IRRS team was informed that APA has established a Policy for Management Risks, but it does not include safety culture.

The culture for safety of the regulatory body is not directly addressed in APA and IGAMAOT organizational documents. It is not documented how the regulatory body encourages a positive safety culture within the authorized parties.

There is no evidence demonstrating the existence of mechanisms in place to promote a common understanding of safety culture including awareness of radiation risks and hazards related to work and environment, or principles to encourage a questioning attitude at all levels underpinned by formal processes for raising concerns regardless of position in the organization.

There are no documents or existing mechanisms on how the regulatory body engages in ongoing dialogue with authorized parties to enhance the understanding of safety culture aspects and to seek licensees’ commitment to perform self-assessments and independent peer assessments of safety culture on a regular basis.

IRRS team observed that the management system developed by the regulatory body does not fully foster and sustain a culture for safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The safety culture is not explicitly documented in the APA and IGAMAOT organizational procedures and there is no evidence of existing mechanisms in place to promote a common understanding of safety culture including awareness of radiation risks and hazards relating to work and environment and a collective commitment to safety by teams and individuals.

(1)	<p>BASIS: GSR Part 2 Requirement 12 states that <i>“Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture.”</i></p>
(2)	<p>BASIS: GSR Part 2 Requirement 12 para 5.2 states that <i>“Senior managers and all other managers shall advocate and support the following: Senior managers and all other managers shall advocate and support the following:</i></p> <ul style="list-style-type: none"> <i>(a) A common understanding of safety and of safety culture, including: awareness of radiation risks and hazards relating to work and to the working environment; an understanding of the significance of radiation risks and hazards for safety; and a collective commitment to safety by teams and individuals;</i> <i>(b) Acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety;</i> <i>(c) An organizational culture that supports and encourages trust, collaboration, consultation and communication;</i> <i>(d) The reporting of problems relating to technical, human and organizational factors and reporting of</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p><i>any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement of, and reporting back of, actions taken;</i></p> <p><i>(e) Measures to encourage a questioning and learning attitude at all levels in the organization and to discourage complacency with regard to safety;</i></p> <p><i>(f) The means by which the organization seeks to enhance safety and to foster and sustain a strong safety culture, and using a systemic approach (i.e. an approach relating to the system as a whole in which the interactions between technical, human and organizational factors are duly considered);</i></p> <p><i>(g) Safety oriented decision making in all activities;</i></p> <p><i>(h) The exchange of ideas between, and the combination of, safety culture and security culture</i></p>
R11	<p>Recommendation: The regulatory body should develop a management system to promote by all mechanisms and instruments, a safety culture and provide structure and direction in a way that permits and promotes the development of such a culture.</p>

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

APA drafts an annual working plan which establishes the mission, vision, values, strategic missions, and strategic objectives. The annual working plan for 2020 includes 4 strategic objectives (SO). The SO related to the Department of Emergencies and Radiation Protection activities (number 2) is to increase the protection level of people and ensure good performance in crisis situations. For this SO, the annual working plan defines activities for ionising radiations (identified with code R9). To track the compliance with the established SO, APA has developed a document entitled *Evaluation and accountability framework* (QUAR) which defines for each SO different operational objectives (OO) to establish a measurable indicator. The OO are defined yearly, and the associated monitoring of results is also performed annually. To track the fulfilment of OO, intermediate verification is carried out periodically (eg. Every 4 months). The IRRS team was informed that in case that APA should consider this necessary they can review and update OO. IGAMAOT drafts an annual working plan establishing the mission, the vision, strategic objectives, and operational objectives. The annual working plan 2021 set out two strategic objectives (SO1 and SO4) to be achieved through three operational objectives (OO1, OO5 and OO6) in ionizing radiation. Every three months the multidisciplinary team on Ionising Radiation (EM RAD) of IGAMAOT drafts a Balance sheet report on the activities carried out in line with the annual working plan. The result of these periodic reports allows IGAMAOT to carry out corrective actions in order to comply with the annual working plan for the specific year. The IRRS team observed that measurement, assessment, and improvement processes are not documented and not regularly and systematically implemented. **Recommendation R10 in Section 4.3 addresses this issue.**

- Conducting internal assessments (internal audits);
- Conducting self-assessments of management system;
- Conducting self-assessments of safety culture;
- Conducting management system reviews.

4.8. SUMMARY

APA and IGAMAOT have in place document management systems associated with the performance of their functions and competences. However, the following areas for further improvement have been identified:

- Establishment and implementation of a management system of the regulatory body in line with the requirements of IAEA Safety Standard GSR Part 2, Leadership and Management for Safety.
- Development of a plan for the establishment and implementation of the integrated management system which have integrated among other elements a graded approach in all its regulatory processes.
- Fostering a safety culture and provide structure and direction in a way that permits and promotes the development of such a culture within the organization and the licensees.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Decree Law 108/2018 establishes the national legal regime for radiological protection and applies to all facilities and activities. Regulatory control is carried out by APA and IGAMAOT and concerns the whole life cycle of facilities with radiation sources. Transport of radioactive materials is a practice subject to authorization. The requirements for the transport of dangerous goods are applied to the transport of radioactive materials through the implementation of the international modal regulations. The transport of spent fuel and radioactive waste is addressed in Decree Law 156/2013.

Decree Law 108/2018 specifies the types of regulatory control (Notification, Registration or Licensing) which apply to different facilities and activities and the related implementation procedures. Moreover, the legislation defines specific criteria for the exemption and clearance of justified practices with radiation sources.

APA is the competent authority for the authorization of facilities and activities. Five members of APA's staff are involved in the authorization procedures: one for import/export and transfer of sealed radioactive sources and four in the authorization of facilities and activities.

Registration certificates and licenses are valid for 5 years. A practice (facility or activity) may be initiated only after the granting of the authorization. Each registration certificate or licence may cover several practices. APA issued 529 registration certificates and 231 licences in 2021.

The IRRS team was informed that since 2019, 75% of the authorizations issued by APA address dental radiology practices, 11% medical radiology practices, 1% radiotherapy practices and 5% veterinary radiology practices, with a remainder of 15% for other practices involving sealed and non-sealed sources (including Nuclear Medicine and industrial practices).

Application forms for the authorization of different practices as well as information on the required submissions are available on APA's website. So far, applications for authorization are submitted electronically or in printed form and processed through APA's document management system. APA's intention is for the documents to be submitted electronically with the use of existing IT tools.

The evaluation of requests for the registration of practices is based only on the information provided in the submitted application forms. A safety assessment is required for facilities and activities which are subject to licensing. The safety assessment is developed by a Radiation Protection Expert or recognized technical service and includes estimated exposures of workers during normal operations, identification of potential exposures, the probability of occurrence of potential exposures, and an assessment of the quality and extent of protection and safety measures, including engineering aspects and administrative procedures. However, the scope and content of the safety assessment for different facilities and activities is not fully based on a graded approach. Furthermore, the existing guidance on safety assessment does not specify the cases in which an independent verification of the safety assessment is required before it is submitted to APA, to ensure it is commensurate with the risks associated with different facilities and activities.

Article 60 of DL 108/2018 defines industrial sectors involving natural radioactive material and Article 61 requires undertakings within these sectors to submit to the regulatory body a safety assessment for the facility or activity. The safety assessment considers the products, the byproducts, and also the resulting waste. Based on the assessment, APA determines whether the facility or activity constitutes a practice subject to notification, registration, or licensing.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The scope and content of the safety assessment for different facilities and activities is not fully based on a graded approach. The existing guidance on safety assessment does not specify the cases in which an

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

independent verification of the safety assessment is required before submitted to APA to ensure it is commensurate with the associated risks.

(1)	BASIS: GSR Part 4 (Rev.1) Requirement 2 states that <i>“A safety assessment shall be carried out for all applications of technology that give rise to radiation risks; that is, for all types of facilities and activities.”</i>
(2)	BASIS: GSR Part 4 (Rev.1) Requirement 21 para 4.68 states that <i>“The decisions made on the scope and level of detail of the independent verification shall be reviewed in the independent verification itself, to ensure that they are consistent with the graded approach and reflect the possible radiation risks associated with the facility or activity, and its maturity and complexity.”</i>
(3)	BASIS: GSR Part 4 (Rev.1) Requirement 21, para 4.66 states that <i>“The operating organization shall carry out an independent verification to increase the level of confidence in the safety assessment before it is used by the operating organization or submitted to the regulatory body.”</i>
R12	Recommendation: APA should ensure updating the guidance so that the safety assessment of facilities and activities is carried out and independently verified in accordance with a graded approach.

The legal framework includes provisions for notification of significant events, incident and accidents, and APA carries out the corresponding reviews. However, the IRRS team also observed a lack of guidance and a formal process concerning the reporting of incidents and accidents including unintended and accidental medical exposures to the regulatory body as well as for the analysis of the collected data and the dissemination of the lessons learned. **Recommendation 10 in Section 4.3 addresses this issue.**

Comprehensive guidance on the format and content of the required authorization submissions is still under preparation for some practices. So far, no specific processes and procedures for the authorization of facilities and activities have been established and implemented by APA. **Recommendation 10 in Section 4.3 addresses this issue.**

Furthermore, the IRRS team noted that APA has not established a formal training programme for personnel involved in the authorization process that is sustainable and commensurate with existing practices. **Recommendation R7 in Section 3.3 addresses this issue.**

APA shares information about authorized facilities and activities with IGAMAOT periodically and at IGAMAOT’s request, while IGAMAOT shares all the inspection reports with APA through an electronic platform. The authorities intend to sign a memorandum of understanding to facilitate their cooperation and the exchange of information in the regulatory control of facilities and activities. So far, there is no mechanism in place to ensure the effective coordination of their regulatory functions. **Suggestion S1 in Section 1.5 addresses this issue.**

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Decree-Law 156/2013 and 108/2018 establish requirements for licensing of radioactive waste management. This regime applies to all phases of the management of radioactive waste and spent fuel. All these phases (from siting to decommissioning) are subject of licensing to be granted by APA, except for authorized discharges, the storage of radioactive waste for a period not exceeding 30 days before disposal under the conditions set in the license for the practice, and radioactive waste management activities associated with actions in the context of radiological emergencies. Licensing application is made through a web based electronic platform (<https://residuos-radioativos.apambiente.pt/>).

Guidance on the application for authorization for such activities was published by the previous regulatory authority (COMRSIN) and now is in the process of being updated, together with other guidance documents, as referred in Section 9.

Pavilhão de Resíduos Radioativos (PRR) is the only interim waste storage facility in Portugal. It was licensed in 2016 by the previous regulatory authority COMRSIN. APA renewed this license in 2021 still under the provisions of the relevant regulations that are in place, and which are being updated.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The import/export of sealed radioactive sources with activities above the respective exemption levels, or of equipment incorporating sealed radioactive sources requires prior approval by APA. The related requirements in force have been approved by the APA's Management Board. Export of Category 1 or 2 radioactive sources requires the formal consent of the importing state in line with the related IAEA guidelines. Additionally, the sale, lease, granting or any other type of transmission of sealed radioactive sources or equipment incorporating them shall be notified to APA.

The authorized holders of sealed radioactive sources with activities above the exemption levels or of equipment that incorporates them shall notify APA within 10 days after receiving the source and request a confirmation. In this case, a financial security deposit must be paid to APA. The deposit is refunded to the authorized holders after a source has been returned to the supplier or transferred to another authorized party. For holding unsealed radioactive sources, some of the requirements of sealed radioactive sources are applicable, but they must be adapted, as appropriate, to the type of source and the associated risk. Guidance on the adaptation of the requirements is being drafted by APA, under the scope of its responsibilities.

Facilities that are subject to licensing and may have an impact on the environment and the public from radiation protection perspective, are also subject to a prior site approval by APA. In this respect, APA may request supplementary information from the applicants or perform a site visit if it is considered necessary for assessing compliance with safety requirements. In addition, APA may invite the applicants to attend an information meeting in which all aspects deemed necessary for a decision related to the authorization are addressed.

The disposal, recycling or reuse of radioactive materials that result from authorized practices is subject to licensing. According to the national programme for radioactive waste, disused sources shall be returned to their supplier. However, when this is not possible, if the authorized holder of radioactive sources applies through APA's platform for radioactive waste management within 10 days after the sources have been declared as disused, they are classified as waste and sent to the waste storage (PRR) facility.

According to the Decree Law 108/2018, orphan sources shall be received for storage by "the public entity responsible for the disposal of radioactive waste" (this responsibility, understood disposal as storage, is currently assigned to PRR operated by IST). APA is responsible for planning the recovery and management of orphan sources and the related costs are covered by the Environmental Fund. To this effect, 10% of all fees received by APA are transferred to this fund.

APA is responsible to organize annual campaigns to raise public awareness of the existence of orphan sources as well as to give guidance to people who suspect or are aware of the presence of an orphan source, on how to inform competent authority and what measures to adopt. Additionally, APA has to articulate with the entities responsible for the licensing of facilities where orphan sources are likely to be found (large scrap metal parks, large scrap metal recycling facilities and significant nodal transit points) so that systems are designed to detect sealed radioactive sources in places.

The introduction into the national territory of radiation generators or other equipment producing ionizing radiation with electricity, is subject to approval. Carrying out such activities constitutes a practice subjected to licensing; when granting such license, conditions may be set specifying the type and number of radiation generators that may be covered. This legal requirement is new and still under implementation.

As the national regulatory framework has been amended recently, the authorized parties are still not fully familiar with the new safety requirements and authorization procedures. The IRRS team was informed during a site visit that the authorized party expressed difficulty in understanding the new regulatory requirements and the need for detailed guides on their implementation as well as difficulty to communicate with the regulatory body on the implementation of the new safety requirements. **Suggestion S4 in Section 2.2 and Recommendation R20 in Section 9.1 address this issue.**

5.4. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

Decommissioning activities are not currently being conducted in Portugal. Therefore, no specific issues are reported.

5.5. AUTHORIZATION OF TRANSPORT

The Decree Law 24-B/2020 (Annex III) designates APA as the competent authority to issue approvals based on IAEA SSR-6 for road and rail transport. Moreover, it implements the IAEA Regulations SSR-6 2012 Edition for land transport of radioactive materials through the transposition of an EU directive. Air and sea transport regulations, ICAO TI and IMDG Code respectively implement the IAEA SSR-6 (Rev.1) 2018 edition. Therefore, there is a misalignment between the national regulations for land transport and air and sea transport. This potentially can affect the clear reference to the requirements and provisions applicable to the multimodal transport of radioactive materials that need to be based on the most recent edition of IAEA SSR-6 to ensure the harmonization between the different transport modes. **Recommendation R20 in Section 9.1 addresses this issue.**

APA is responsible for issuing approvals and the validation of the original certificates issued by the competent authority of the country of origin of the design or shipment in line with the IAEA SSR-6 (Rev.1). However, no guidance is available for those applying for an approval based on SSR-6 (Rev.1) considering the transport activities performed in the country. No manufacture or design of packages for radioactive materials requiring an approval is performed in Portugal. Should this change, guidance for applicants on how to apply for an approval should be established as part of the compliance assurance programme. Moreover, there is no procedure in place for such an approval process. **Recommendation R10 in Section 4.3 addresses this issue.**

5.6. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

APA carries out a review and assessment of the Radiation Protection Program appropriate to the practice. This programme includes measures for protection and safety of workers such as the classification of areas, monitoring procedures of workplaces and workers, and provisions to deal with accidents and incidents. Health surveillance of workers is based on Law 102/2009. Decree Law 108/2018 requires that the authorized party informs exposed workers of the radiation risks associated with their work, the importance of rapid declaration of a possible pregnancy, and the importance of announcing the intention to breast-feed.

Under Article 51 of the Law 102/2009, pregnant workers are forbidden to perform any activities in which they are or could be exposed to ionizing radiation. Similarly, in Article 54, a breast-feeding worker is prohibited from performing any activity involving exposure to ionizing radiation. The Directorate-General of Health, under the Ministry of Health, responsible for occupational health, has issued Technical Guide 1 to clarify the meaning of Articles 51 and 54. Technical Guide 1 states that “forbidden to perform any activities in which they are or could be exposed to ionizing radiation” and “prohibited from performing any activity involving exposure to ionizing radiation” means that the exposure of the unborn child or the breast-fed infant is below the public dose limit. In accordance with Article 69(1) of Decree Law 108/2018, on protection of pregnant, postpartum and breastfeeding workers, the protection granted to the unborn child and to the breast-fed child shall be equivalent to that provided to any member of the public.

Article 6 of DL108/2018 requires optimization of protection and safety of occupational exposures. Dose constraints are used as part of the optimization process. Article 71 of DL108/2018 establishes that the authorized party must establish dose constraints for occupational exposure, that can go up to 30% of the dose limit.

Decree Law 227/2008 defines professional qualification levels in radiation protection, the minimum qualifications to access training, the training requirements, and the training programmes. There are three levels for the training of workers involved with radiation sources. Training is provided by training providers approved by APA. Level 3 is the basic level of training and is intended for all workers dealing with radiation sources. Radiation Protection Officers require 100 hours of training (Level 2). Radiation Protection Experts (Level 1) undergo 300 hours of training and a mandatory on the job internship. For all three levels, there are two streams of training: one for workers in medical facilities and the other for non-medical workers. APA has identified deficiencies in Decree Law 227/2008 and proposes to expand the training content for Level 2 experts and to update the minimum qualifications for entry, particularly to Level 1 training. The training providers require recognition by APA, and the content of each training course is also approved by APA.

Dosimetry service providers require recognition by APA. There are four service providers for external radiation measurements. They are required to report doses of workers to the Central Dose Register. There is one recognized ionizing radiation metrology facility in Portugal that provides the legal metrological verification of radiation monitoring equipment. There are currently around 30,000 workers monitored in Portugal. There are also service providers for providing radon dosimeters for measuring radon levels in workplaces, that is part of the National Radon Action Plan. These providers should also be approved by APA.

APA has approved remediation plans for areas contaminated with residual radioactive material. The occupational exposure of workers in the remediation process includes the determination of external exposure through wearing individual dosimeters on site, and of internal exposure through high volume air sampling of dust on the remediation site. The sum of the external and internal dose is reported to the Central Dose Register.

A reference level of 300 Bq/m³ has been established for radon in workplaces in DL 108/2018. If the activity concentration level exceeds 300 Bq/m³, APA requires a dose assessment to be carried out by the employer. If the calculated dose is less than 6 mSv, requires the employer to keep exposures under observation. If the calculated dose exceeds 6 mSv, employers are required to apply for an authorization. The guidance to report dose values resulting from radon exposure includes the dose conversion factor to be used to the calculation of the effective dose from the measured radon activity concentration levels.

The IRRS team was informed that the civil aviation companies are required to assess exposure of air crew. APA has approved the methodology that is used by the companies. A reference level for aircraft crew of 10 mSv in a year has been established in DL108/2018. Doses received by air crew are reported to Central Dose Register. Female air crew are also required to be informed of the requirements relating to pregnant workers.

The occupational exposure arising from industries involving NORM is assessed as part of a safety assessment to be submitted to APA. The assessment considers the pathways of internal and external exposure, as well as, those arising from the resulting products, by products and waste. The provisions for occupational exposure for practices will be applicable if APA determines that the facility or activity constitutes a practice.

Article 128 of DL108/2018 establishes reference levels for emergency workers. Emergency exposure should preferably be kept below the dose limit for occupational exposure. Where this is not possible the effective dose should not exceed 100 mSv. In exceptional circumstances, namely, to save lives, to prevent serious health effects, and to prevent or minimize the occurrence of catastrophes, an effective dose of 100 mSv may be exceeded but should not exceed 500 mSv.

5.7. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

Based on the graded approach, the regime of authorization for medical exposures is commensurate with the risk for the patient and identifies the activities or practices submitted for registration and those submitted for licensing. The sharing of responsibilities between the authorized party, the person responsible of medical exposures (“a doctor, dentist or any other qualified health professional) and other medical doctors or medical physicists seems to be well addressed and verified by APA during the authorization procedure.

APA has adopted a specific licensing form to be used for the authorization of medical exposures. The form defines which requirements for radiological protection specific to practices involving medical exposures should be fulfilled.

The data to be submitted to APA during the authorization procedure are clearly listed in DL108/2018, subsection III).

Training and competences of health professionals

The responsibilities, training, and competences of health professionals (medical practitioners, medical physicist, technologists, etc.) involved in medical exposures are defined in Decree Law 108/2018. Clinical responsibility requirements are outside the scope of radiation protection; therefore, they are regulated by the Ministry of Health and the Portuguese Medical Society. Education and training of doctors and other professionals involved in the practical aspects of medical radiological procedures ensure the necessary theoretical and practical knowledge for radiological practices.

The basic tuition programmes in schools of medicine, and dentistry include a course on radiological protection, with contents prepared in collaboration with the competent authority. APA collaborates with other competent entities (Ministries of Health and of Education) in the preparation of appropriate curricula and in the recognition of corresponding diplomas, certificates, or professional qualifications.

Regarding on-going training, health professionals must continue to receive training after becoming qualified, particularly in the clinical use of new medical techniques. The IRRS team was informed that APA recognizes the need to articulate with the relevant authorities for the preparation of appropriate curricula, for on-going radiation protection training for specialists using X-rays to perform fluoroscopically guided interventions in operating rooms (cardiologists, rheumatologists, surgeons, neurosurgeons, etc.).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: APA recognises the need to collaborate with the relevant authorities and medical societies for the preparation of appropriate curricula, that should pay special attention to on-going training in radiation protection of specialists using X-rays to perform radio-guided interventions in operating rooms (cardiologists, rheumatologists, surgeons, neurosurgeons).	
(1)	BASIS: GSR Part 1 Requirement 35 states that <i>“that the regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfill the requirements for education, training and competence in the relevant specialty.”</i>
(2)	BASIS: GSR Part 3 para 3.150 states that <i>“The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they: (a) Are specialized in the appropriate area; (b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32; c) Are named in a list maintained up to date by the registrant or licensee.”</i>
(3)	BASIS: GSG-46 para 2.121 states that <i>“The competence of a person is normally assessed by the State through a formal mechanism for registration, accreditation or certification of the particular specialized health professional. States that have yet to develop such a mechanism should assess the education, training and competence of an individual proposed by a licensee to act as a specialized health professional and to decide, on the basis either of international standards or standards of a State where such a system exists, whether the individual can be considered competent.”</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(4)	BASIS: GSG-46 para 2.124 states that “ <i>The regulatory body and the relevant professional body should periodically review the radiation protection and safety aspects of the education and training to ensure that it is still up to date and relevant.....</i> ”
S8	Suggestion: APA should consider collaborating with the relevant authorities and medical societies about the on-going training needs in radiation protection of specialist using X-ray to perform radio-guided interventions in operating rooms.

Medical physicists

The duties of medical physicists (optimisation, quality assurance, acceptance testing of equipment, etc.) are clearly defined in the Decree Law 108/2018. Medical physicists must be recognized by the Central Administration of the Health System, which is a public institute. The training programme for these experts was established by ministerial order 254/2021. For authorization purposes, the licensee must submit to APA a prior assessment of radiological safety including an assessment of the necessary human resources, including the radiological protection specialists, medical physicists, etc. The calculation of the required number of medical physicists in a facility is based on the RP 174 publication. As the IRRS team was informed, the number of medical physicists is low and focused on the areas of nuclear medicine and radiotherapy, and there is an increased need for recognized medical physicists in Portugal for the optimisation of patient doses.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are not enough recognized medical physicists in Portugal, to cover the needs of medical practices.	
(1)	BASIS: GSR Part 3 Requirement 4 para. 2.41 (d) states that “ <i>Other parties shall have specified responsibilities in relation to protection and safety. These other parties include:</i> <i>(d)Medical physicists</i> ”
(2)	BASIS: GSR Part 1 Requirement 11 para. 2.34 states that “ <i>As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available.</i> ”
(3)	BASIS: GSR Part 1 Requirement 11 para. 2.36 states that “ <i>The government:</i> <i>(c) Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties.</i> ”
(4)	BASIS: GSR Part 3 Requirement 36 para. 3.154 (b) and (c) states that “ <i>Registrant and licensees shall ensure that:</i> <i>(b) Radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in relation to protection and safety for patients in a given radiological procedure are specialized in the appropriate area;</i> <i>c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority...</i> ”

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R13	Recommendation: The Government should establish provisions to foster an increase in the number of medical physicists.
------------	--

Diagnostic Reference Levels (DRLs)

According to the Decree Law 108/2018, APA is responsible for establishing the national Diagnostic Reference Levels (DRLs). As, the related procedure has not been completed yet (see action identified in the Initial Action Plan), registrants and licensees are using the European DRLs instead. Under its competencies APA may establish the DRLs for medical imaging and image guided interventional procedures, and periodically review and, if necessary, revise their values.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Article 97(2) of DL 108/2018 provides for APA to establish and review the national diagnostic reference levels. However, Diagnostic Reference Levels are not yet established.	
(1)	BASIS: GSR Part 3 Requirement 34 para 3.148 states that <i>“The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.”</i>
R14	Recommendation: APA, in consultation with the health authorities and relevant professional bodies, should ensure that a set of national diagnostic reference levels is established and implemented.

Management system (MS) and quality assurance (QA) programme

According to Decree Law 108/2018, the authorized party must implement a management system (MS) including protection and safety procedures and measures subject to periodic review and update based on the lessons learned in past exercises and events. The MS should address all types of exposures, including medical exposure. However, it is not trivial for medical exposures that the quality assurance (QA) programme, as defined in Decree Law 108/2108, should be part of the MS, and furthermore APA is currently working on guidelines to define its content. Consequently, the scope and the minimum content of a QA programme for medical exposures is not yet defined.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: It is not trivial that, for medical exposures, the Quality Assurance Program (QAP), as referred in the article 100 of DL108/2018, should be part of the management system. Furthermore, APA is currently working on guidelines to clarify this issue, defining the content of the QAP in relation to medical exposures.	
(1)	BASIS: GSR Part 3 Requirement 5 and 38, para 3.170 and 371 states that <i>“Requirement 5 (Management for protection and safety) - The principal parties shall ensure that protection and safety are effectively integrated into the overall management system of the</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p><i>organizations for which they are responsible.</i></p> <p><i>3.170. Registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate. Principles established by the World Health Organization, the Pan American Health Organization and relevant professional bodies shall be taken into account.</i></p> <p><i>3.171. Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility: (a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist ...: (b) Implementation of corrective actions if measured values of the physical parameters mentioned in (a) above are outside established tolerance limits; (c) Verification of the appropriate physical and clinical factors used in radiological procedures; (d) Maintaining records of relevant procedures and results (e) Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.”</i></p>
R15	<p>Recommendation: APA should complete the guidance for the scope and content of the quality assurance programme for medical exposure, in cooperation with the health authorities and relevant professional bodies.</p>

Justification

The requirements in Decree Law 108/2018 for justification are in line with the IAEA safety requirements. APA verifies the compliance with the corresponding requirements during the authorization of medical facilities and activities.

For the registration or licensing of a practice involving medical exposure, the applicant must submit an appraisal of the general justification to APA. This general justification must briefly analyse the risks and benefits of the medical exposure in the practice and access whether the risks are considered acceptable.

Justification of new radiological procedures (including new technologies and techniques) is performed by health authorities and professional societies in collaboration with APA. However, for new techniques or procedures, the data to be provided for the risk-benefit analysis, and the responsibilities regarding justification are not yet specified.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<p>Observation: The process for carrying out justification for new radiological procedures is yet to be established.</p>	
(1)	<p>BASIS: GSR Part 3 Requirement 37 states that <i>“relevant parties shall ensure that medical exposures are justified.</i></p> <p><i>3.156. Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments.”</i></p>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S9

Suggestion: APA should consider coordinating with health authorities and medical societies to establish the mechanism for the justification of new radiological procedures.

5.8. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

The safety assessment submitted by the applicant is required to include an estimation of doses received by members of the public during both normal operation and some potential abnormal scenarios. The fulfilment of public radiation protection should be demonstrated, using as reference the established dose constraint for public exposure (30% of 1 mSv/year dose limit).

For the case of discharges of radioactive substances to the environment, APA has established dose constraint values specific for different exposure routes: 0.03 mSv/year for the intake component (committed effective dose) and 0.3 mSv/year for all other components of the effective dose. Applicants for a discharge authorization should demonstrate compliance with these values and present the monitoring plan to be carried out to ensure that these conditions are met and maintained during the whole operational life of the facility or activity.

For protection of the public against radon, an air concentration reference level of 300 Bq/m³ has been established and the full implementation of related provisions are in development as part of the national Radon Action Plan (refer Section 1.6).

Regarding provisions for the authorization of use of consumer products refer Section 9.8.

As result of the operation during years of different industries generating NORM residues, Portugal faces the challenge of managing large amounts of these residues, for which solutions need to be defined based on the specific of each residue (concentration, volume, physical characteristics, chemical composition, etc.). Provisions specific for the authorization of NORM residues management activities are pending this definition.

The public exposure arising from industries involving natural radiation is assessed as part of a safety assessment to be submitted to APA. The assessment considers the pathways of internal and external exposure, as well as, those arising from the resulting waste. The provisions for public exposure for practices will be applicable if APA determines that the facility or activity constitutes a practice.

Article 153 of DL 108/2018 defines a reference level of 1 mSv/a for building materials and Annex III establishes an activity concentration index as the criteria for informing APA, and to estimate the doses involved. Whenever building materials are likely to produce doses higher than the reference level, APA determines the appropriate measures to be adopted, which may include specific requirements in the relevant construction standards or restrictions on the intended uses of such materials.

5.9. SUMMARY

Portugal has an authorization system in place which covers all facilities and activities. However, the following areas for further improvement have been identified:

- Ensuring that the safety assessment of all facilities and activities is carried out and independently verified, in accordance with a graded approach.
- Fostering the increase in the number of medical physicists in the country.

- Establishing and implementing National Diagnostic Reference Levels.
- Preparing guidelines on the scope and content of quality assurance programmes for medical exposure.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

The following sub-sections apply to facilities and activities regulated by APA, as set out in Article 2 of DL 108/2018.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

Decree Law 108/2018 establishes the legal framework for radiation protection and the safety of radiation sources, including provisions for radiological evaluation of facilities and activities.

The amount of information required to be submitted by the applicant depends on the type of regulatory control e.g., registration or licence, for the radiation source or the facility or activity. The amount of documentation required to be submitted by applicants for registration includes a radiation protection program, design characteristics of the facility and radiation sources, and radiation dosimetry arrangements for workers. In addition to the documentation submitted by applicants for registration, applicants for licensing are also required to submit a safety assessment. The safety assessment has to be prepared by a radiation protection expert or recognized technical service. Authorized parties are required to be covered by quality control programs and are required to prepare an internal emergency plan.

There are occasional reviews and assessments if an authorized party requests an alteration to a licence or registration.

APA conducts review and assessment over the lifetime of the facility or the duration of the activity. The review and assessment are carried out on information submitted as a part of the authorization process. APA has developed several check lists to be used by authorization staff to review and assess the documentation such as check list related to internal emergency plan, radiation protection program and safety assessment. However, the complete process on review and assessment to be applied for all practices, focusing on specifics of a particular practice, is yet to be formally established. APA is planning to update the process so that the reviewer of application documentation is able to verify all aspects of each type of practice as required in regulatory provisions, and to ensure a uniform review and evaluation methodology. This has been already noted in the Initial Action Plan.

The IRRS noted that APA and IGAMAOT are challenged by assuring staff competencies related to review and assessment. **Recommendation R7 in Section 3.3 addresses this issue.** The recent changes in regulatory requirements for radiation protection and safety and some gaps in the requirements and guidance makes review and assessment particular challenging tasks.

APA reviews and analyses the safety assessment that is submitted as part of the documentation for an application for a license. IRRS team noted that independent assessment of safety assessment has not been included in the related guidance. **Recommendation R12 in Section 5.1 addresses this issue.**

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The review and assessment of applications for authorization are carried out by Division of Authorization and Nuclear Safety, Department of Emergencies and Radiation Protection. Seven people work in this Division. Whenever additional resources are required to conduct review and assessment, staff of other units in the Department may be used, taking into consideration the staff members' skills and competencies.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The applications for authorization are developed according to the provisions of the DL 30/2012, DL 262/2012 (both as amended by DL 135/2017) for nuclear installations, DL 156/2013 for radioactive waste management activities, and DL 108/2018 for all other facilities and activities.

The bases for review and assessment are the Decree Laws mentioned in the previous paragraph, EC RP162, EC RP174, NCRP 147 and 151 in relation to shielding, and IAEA Safety Standard GSR Part 4.

Additional guidance and regulations are being drafted by APA, taking into account a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: APA's processes related to review of an applicant documentation are not yet complete as noted in Initial Action Plan.	
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 25 states that <i>“The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization ..”</i>
R16	Recommendation: APA should complete the development of the review and assessment process to cover all practices and all relevant information.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The documentation submitted by the applicant is reviewed by APA to ensure that it is complete. If any aspect of the documentation, or any aspect of the safety assessment is missing or considered insufficient, the applicant is sent a formal notification to present the missing documentation or to revise the documentation.

Authorization is only granted after all changes required by APA have been made and implemented.

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The procedures for review of licensing applications for radioactive waste management do not yet include specifications of waste acceptance criteria. APA is planning to update these procedures as part of the process of updating national regulatory documents, as set out in the Initial Action Plan. **Recommendation R10 in Section 4.3 addresses this issue.**

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

APA conducts review and assessment over the lifetime of the facility or the duration of the activity in connection with modifying the authorization due to change in the practice and through periodical renewal of the authorizations.

6.4. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Decommissioning activities are not currently being conducted in Portugal. Therefore, no specific issues are reported.

6.5. REVIEW AND ASSESSMENT FOR TRANSPORT

An implementation of a management system with protection and safety measures is requested by Decree Law 108/2018 for any practices, including transport, for which a licence is requested.

In the review and assessment of an application of a licence for transport of radioactive material based on the Decree Law 108/2018 the management system of the applicant is not evaluated. The approvals based on IAEA Regulations SSR-6 (Rev.1), require a specification of the applicable management system based on international, national, or other standards acceptable to the competent authority. There is, however, no guidance on what to be considered an acceptable management system of the applicant [SSR-6 (Rev.1) para 306]. There is a need to develop guidance on the structure and contents of a management system for the applicant. **Recommendation R20 in Section 9.1 addresses this issue.**

6.6. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

Occupational exposure issues, including classification of areas, arrangements for individual dosimetry, personal protective equipment are addressed in the radiation protection program and in the safety assessments that must be submitted with the application for an authorization. The IRRS team was informed that APA uses checklists for the review of the radiation protection program and the safety assessment submitted by the applicant.

The IRRS team was informed that the Central Dose Register held by APA reviews the dose reports received from the dosimetry service providers for measuring external radiation exposure of workers. An investigation level of 2 mSv/wearing period has been established by APA for $H_p(10)$ and of 10 mSv/wearing period for $H_p(0.07)$. The wearing periods are 1 month for category A workers and up to 3 months for category B workers. There have been 369 notifications of doses exceeding the investigation level since April 2019. The authorized party is required to investigate the event that led to the dose exceeding the investigation level, and to inform the provider of the health surveillance service for the worker and report the findings to APA.

6.7. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

Clinical audit

For medical exposures, DL 108/2018 (article 102) states that the authorized party shall promote, with adequate frequency, the performance of clinical audits, whether internal or external (the definition of clinical audit is clearly defined). More detailed guidance on clinical audits is given in IAEA Safety Standard SSG-46.

For licensing purposes, the applicant must submit to the regulatory authority the licensing form where they must declare the type of clinical audit they are planning to conduct, the expected frequency of these audits and submit the plan foreseen for carrying them out, and a description of their scope. The methodology and the organization of clinical audits are described at the national level, by the Directorate-General of Health. However, such provisions do not yet include specific requirements for clinical audits for medical exposures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The methodology and the organization of clinical audits are described at the national level, by the Directorate-General of Health. However, such provisions do not yet include specific requirements for clinical audits for medical exposures.

(1)

BASIS: GSR Part 3 para 2.50 states that *“The principal parties shall be able to demonstrate the effective fulfilment of the requirements for protection and safety in the management system.”*

(2)

BASIS: SSG-46 para. 2.148 states that *“The management system should include a review cycle. The general principles for audits and reviews are well established (see GS-G-3.1 [25] and GSR Part 2 [47]). For a medical radiation facility, a possible tool for this is the clinical audit. Clinical audits can be considered as a systematic and critical analysis of the quality of clinical care, including the procedures used for diagnosis and treatment, the associated use of resources and the effect of care on the outcome and quality of life for the patient. A clinical audit looks beyond a strict radiation protection and safety focus and seeks to assess the quality and efficacy of the medical practice*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>offered in the facility, ultimately the patient health outcome. This should include the radiation protection and safety aspects of medical uses of ionizing radiation and, importantly, should keep these aspects in the context of medical practice, ensuring a common goal.”</i>
S10	Suggestion: APA should consider cooperating with the health authorities and relevant medical societies for the establishment of guidance on the requirements for clinical audits concerning safety aspects of medical uses of ionizing radiation, as part of the management system in medical facilities.

6.8. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Provisions to be implemented by authorized parties for the protection of members of the public are verified during the review of licensing documentation, specifically of the safety assessment. Requirements establish the obligation of authorized facilities and activities that may release radioactive material to the environment of conducting a monitoring of these releases and report periodically to APA to demonstrate compliance with limits and conditions imposed in the authorization, with the intent of protecting the public and the environment against these releases.

6.9. SUMMARY

APA carries out review and assessment of applications for authorization and of authorized parties to determine compliance with the regulatory requirements.

Review and assessment are carried out over the lifetime of the facility or activity in connection with modifying the authorization due to change in the practice and through periodical renewal of the authorizations.

APA has developed several check lists to be used by authorization staff to review and assess the documentation such as check list related to internal emergency plan, radiation protection program and safety assessment.

However, the following areas for future improvement have been identified:

- Completing the development of the review and assessment process to cover all practices and all relevant information.
- Cooperation of regulatory body with the relevant health authorities and medical societies for the performance of clinical audits as part of the management system in medical facilities.

7. INSPECTION

7.1. GENERIC ISSUES

According to DL 108/2018, IGAMAOT is the competent authority designated to plan and perform inspections for facilities and activities using radiation sources. Additionally, IGAMAOT:

- may order corrective actions, including the suspension or revocation of authorizations, the temporary or permanent closure of facilities, if deemed necessary for the protection of workers, the public and the environment.
- apply the necessary administrative offenses in case of non-compliances with the legislative requirements.
- verify the proper implementation of recommended corrective actions.

A Multi-disciplinary Ionizing Radiation Team (EM RAD) was created within IGAMAOT in 2019. The team consists of 2 Multidisciplinary Team Leaders (Inspector Director and Inspector Head of Unit) who are designated by the General Inspector annually, 12 inspectors and 1 technician. The IGAMAOT inspectors were hired in 2020 and have different academic background (biology, physics, chemistry, radiology, etc.), and are undergoing training.

IGAMAOT organizes and conducts planned and reactive inspections, as well as thematic campaigns. The inspections can also be announced or unannounced. Thematic campaigns concern the investigation of safety issues in high-risk facilities and activities such as industrial radiography and brachytherapy.

IGAMAOT has developed a risk analysis (2020) to determine the inspection priorities and frequencies for the different types of radiation practices and sources associated with the different operators, which will be in use from 2021 onwards.

IGAMAOT's Activity Plans for 2020 and 2021 established a set of objectives and targets to be achieved by EM RAD. These had to be adapted as a result of restrictions imposed by the Government, as a result of the COVID-19 pandemic. It was necessary for the EM RAD team to adapt to other virtual forms of communication between the elements of the EM RAD team, namely, through the Skype and Zoom tools. Nevertheless, it was still possible to carry out inspection activities in-situ in installations using radiation sources, as well as in person training for inspectors.

The inspection plan in 2020 were still very limited taking into account the recent creation of EM RAD, the need to train inspectors and the COVID-19 pandemic. In the year 2020, it is reported "the inspections to be selected will not take into account the risk associated to the operator, because the new inspectors need to be trained". For the first inspections programme, the inspections to be carried out had a lower level of difficulty such as the dental radiography, veterinary radiography, diagnostic radiology and industrial radiography. In 2020, IGAMAOT performed six reactive inspections in response to complaints/reports (two to industrial and four to medical practices respectively) and 46 planned inspections.

The number of inspections increased significantly in 2021, including thematic inspection campaigns (more than 400 inspections): an enforcement campaign for practices potentially beyond regulatory control (284), a follow-up campaign on non-conformities subject to mandatory reporting (297), a brachytherapy campaign (transfer, import, export, storage and use of sealed radioactive sources) (22) and a campaign for inspection and control of shipments of radioactive waste and detection of orphan sources (68). In 2021, 269 notices for non-compliances were issued. In 2022, 329 inspections are planned the average number of inspections to 2022 is 180 and 149 for medical activities and non-medical activities respectively.

Since 2019, IGAMAOT has developed some documents concerning the conduct of the on-site inspections. Moreover, it has developed a "Support guide for radiological protection inspection" where all the inspection steps and the techniques are described in detail to facilitate the inspectors in their work. Check lists have been prepared

and used in the inspections of different practices; however, they do not cover the whole range of practices authorized by APA.

The inspections conducted by IGAMAOT have three distinct phases: a) preparation of the inspection, b) conduct of inspection (physical verification, documentation check and shielding verification), and c) preparation of the inspection report. However, the IRRS team noted that IGAMAOT has not established documented procedures although there is a support guide for radiation protection inspections.

After the conduct of an inspection IGAMAOT staff orally informs the inspected parties about the findings and should notify them in writing to request for any documents that need to be provided for further investigation.

The inspection report includes inspection findings and associated recommendations. In case of compliance with safety requirements the signed inspection report is directly sent to the inspected party. If non-compliances have been observed, IGAMAOT inspectors prepare an informative notice, which is sent with the report to the IGAMAOT's legal services for consideration and further actions. For severe non-compliances, IGAMAOT inspectors send an order to the inspected party with the related corrective actions. IGAMAOT may conduct follow-up inspections to investigate the implementation of the corrective actions.

As the IRRS team noted during the discussions with the counterparts, IGAMAOT provides the inspection reports to APA. IGAMAOT does not implement a procedure to use the results of the inspections as feedback information to improve the regulatory process. **Suggestion S4 in Section 2.2 addresses this issue.**

Regarding the competence of inspectors, the IRRS team noted that although the 12 inspectors were recruited recently and have different backgrounds. IGAMAOT has not established a process to develop and maintain their necessary competence and skills. Moreover, the performance of the inspectors is not evaluated in accordance with a documented procedure on a regular basis **Recommendation R7 in Section 3.3 addresses this issue.**

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

Inspection by IGAMAOT to waste management facilities is conducted using a check list which was adapted from the one prepared for industrial facilities to consider specific requirements like inventory and nature of stored waste, controls of radiation levels inside and around the facility, the functioning of alarms and specific signalization, as well as specific conditions imposed by APA in the license.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

IGAMAOT has organized a campaign called "Industrial Sealed Radioactive Sources - Annual Inventory Obligation" to verify the compliance of the holders of sealed radioactive sources for industrial and non-medical applications with the requirement to submit their sources inventory to APA on an annual basis. The selected holders were requested to send proof of compliance to IGAMAOT and to APA. In this framework, 48 on-site inspections were conducted of source holders who did not prove compliance with the related requirement or did not respond to the IGAMAOT's request.

7.4. INSPECTION OF DECOMMISSIONING ACTIVITIES

Decommissioning activities are not currently being conducted in Portugal. Therefore, no specific issues are reported.

7.5. INSPECTION OF TRANSPORT

Transport activities are subject to authorization by APA and can be inspected by IGAMAOT. IGAMAOT has the responsibility to inspect the transport arrangements and enforce actions of the operating organizations. The inspections performed are still quite limited in the scope and do not cover all the phases of the transport due to the lack of specific knowledge of the responsibilities of the different operators (consignor, carrier, and consignee) involved in the transport of radioactive material. IGAMAOT is in the phase of capacity building due to recruitment of personnel having limited experience in inspections and specific training on transport of radioactive material that

is necessary to conduct complete inspections of the management system, the radiation protection programme, the compliance of packages not requiring competent authority approval and the maintenance of packages. The need for training of the personnel **Recommendation R7 in Section 3.3 addresses this issue.**

Besides the two authorities that form the regulatory body, APA and IGAMAOT, other authorities have authority to perform the inspections during transport of dangerous goods including radioactive materials namely the National Civil Police (PSP) and the National Guard (GNR). The need for coordination between these authorities is essential to avoid overlap that could create conflict in requirements being placed on the authorized parties. **Suggestion S2 in Section 1.5 addresses this issue.**

7.6. INSPECTION OF OCCUPATIONAL EXPOSURE

IGAMAOT carries out inspections of the facilities and activities of authorized parties. The inspection procedures include requesting the authorized holder to provide information on the number of workers in the facility, on the doses received by workers in the facility, on the provision of personal protective equipment, on the training of workers, on the information provided to female workers, of the classification of work areas and the warnings signs on such areas, and on the records of accidents and incidents. There was also a check of which service provider provides individual dosimeters for the workers, and of the calibration date of the survey meter and other radiation monitoring equipment. The observations made during the inspection in relation to occupational radiation protection are included in the inspection report that is provided to the authorized party.

There are no procedures for inspection of compliance with requirements for workers in existing exposure situations such as radon in work places. The IRRS team was informed that IGAMAOT was planning on the developing such procedures in the next 2-3 years. IGAMAOT has given priority to developing plans for inspection of authorized facilities over existing exposure situations. Provisions for inspection of radon in workplaces are included in DL 108/2018.

7.7. INSPECTION OF MEDICAL EXPOSURE

For the control of medical activities, guides made available to inspectors and issues in the inspection reports in 2021 show that the inspections focused mainly on the control on site of the documentation held by the authorized party, the human resources available (including the training), the rules in relation to occupational exposure (see 7.6.), and the controls carried out on these equipment's (covered by a quality assurance programme). A specific attention is given to the modification of equipment needed to comply with the new requirement related to patient doses measurements in radiology.

Inspections intended to control the management system in place and to verify the robustness of the internal organization and the associated processes, for instance in brachytherapy, in external radiotherapy and in nuclear medicine, are not yet performed. This issue is considered by IGAMAOT as a second step, requiring an increase in the competence of inspectors, before it can be addressed. The same finding is also applicable for the development of on-the-spot control of the effective implementation of optimisation procedures during CT examination, interventional radiology and during radio guided acts in operating rooms.

7.8. INSPECTION OF PUBLIC EXPOSURE

During the inspection of facilities and activities by IGAMAOT, the report template and checklist used by the inspector address topics that relate to protection of the public such as: verification of shielding design; access to controlled areas; control of sealed and unsealed radioactive sources; management of radioactive waste; procedure for carrying out discharges; monitoring of discharges; and internal emergency plan.

Site Visits:

The IRRS team observed the inspections performed by IGAMAOT to three different facilities: an industrial facility, a medical institution, and a waste management facility. All inspections observed were announced inspections.

In all the cases the inspections were well prepared, based on the authorization documents provided by APA. The inspections were performed according to the plan and conducted with professionalism. A short description of activities conducted follows.

ISQ company

ISQ company conducts industrial radiography (location Lisbon) with a use of radioactive sources, i.e., Se-75, Cs-137, Ir-192 and x-ray generators. The company also used hand-held devices for performing x-ray fluorescence. Three ISQ staff members were involved in the inspection. In conducting the inspection, a detailed IGAMAOT checklist for industrial radiography facilities and activities was used. Moreover, the inspectors performed the necessary radiation safety measurements using IGAMAOT's measuring instrumentation. At the end of the inspection the leading inspector presented orally the findings to the ISQ representatives.

IGAMAOT's inspectors performed at high standards despite the lack of experience in inspections of industrial radiography practices. After the inspection, the IRRS team interviewed the ISQ representatives who stressed out the difficulty in understanding the new regulatory requirements and the need for detailed guides on their implementation.

Lusíadas Hospital

The scope of the inspection to Lusíadas Hospital in Lisbon addressed occupational and medical exposures for practices that are carried out in radiology and in nuclear medicine departments. The head of the medical physicist's unit represented the authorized party.

The leading inspector conducted the inspection using the report template as a check list. In the entrance meeting the findings of the previous inspection were checked and the authorized party's documentation was investigated. Some documentation has directly been sent to IGAMAOT by email, to be registered. During the visit to inspected areas the inspector's collected information on the workers and patient safety, the equipment performance and the applied radiation protection measures. Issues like the process for patient identification or the optimization of patients' exposures (for CT scan and interventional procedures) were not addressed with the operators.

At the end of the inspection, the leading inspector presented orally the findings to the authorized party representative. After the inspection, the IRRS team members interviewed the hospital representative who underlined the useful interaction with the inspectors.

Waste storage facility at IST

The inspected waste storage facility is located in the Technologic and Nuclear Campus of Instituto Superior Técnico (IST). Two IGAMAOT inspectors conducted the inspection. During the inspection the verification of formal institutional documentation and safety related registers was made, followed by the performance by inspectors of gamma dose rate measurements in different sections of the facility and around the premises. Visual and sound alarms were also verified. The inspection ended with a discussion on license documentation and compliance with license conditions. During the interview with IST representatives the need of more precise requirements related to documentation to be prepared in support of authorization applications was stressed out.

7.9. SUMMARY

Since its creation in 2019, IGAMAOT has been gradually building up its structure by recruiting new inspectors, training them and starting its first inspections in 2020. Following, the annual inspection programme is gradually increasing and starting to be planned on the basis of risk analysis survey carried out in 2021.

IGAMAOT is continuing to provide the inspectors with the necessary tools and procedures. However, it has not established a process to develop and maintain their necessary competence and skills.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

DL 108/2018 provides enforcement powers to IGAMAOT to conduct inspections in nuclear and radiation safety and to enforce regulatory provisions. Inspection and enforcement activities are conducted in line with the general Law, i.e., Law 50/2006, DL 276/2007 and Dispatch no. 10466/2017. Law 276/2007 empowers IGAMAOT to act in case of environmental crime, reporting to the Public Prosecutor's Office as appropriate.

DL 108/2018 provides a set of enforcement actions to be applied, e.g., ordering corrective measures, setting operating procedures as well as the temporary or permanent closure of a facility. DL 108/2018 also addresses authorization amendments and revocations which are conducted by APA. IGAMAOT inspectors are according to DL 108/2018 also empowered to:

- adopt precautionary measures, “whenever a situation of serious danger to the environment or to human health is detected”; and
- exercise precautionary seizure of assets and documents.

The IRRS team noted that inspection procedures as well as enforcement procedures are under development reflecting the fact that IGAMAOT has recently been established. When non-compliances are identified, in addition to the inspection report, a “notice” is elaborated by inspectors containing a description of any non-compliances, corrective actions and offences identified. In line with DL 276/2007 the report might also contain “technical recommendations” to improve safety.

IGAMAOT conducts additional enforcement procedures related to administrative offences set out in DL 108/2018. IGAMAOT sends an official letter i.e., “notice”, to the operator presenting the offence and the penalty if the offence is not addressed. The operator is given the opportunity to provide additional information related to the offence. Based on this additional information, the procedure might be closed by IGAMAOT or alternatively the operator is required to pay the fine in line with DL 108/2018. This decision can be challenged in court by the operator.

Grading of non-compliances is performed in accordance with DL 108/2018. Offences are classified as mild, serious, and very serious. The IRRS team observed that there is no enforcement policy to address the factors that are to be taken into account by IGAMAOT in deciding which type of enforcement action is appropriate. IAEA GSG -13, para. 3.308. provides information on the contents of an enforcement policy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: IGAMAOT has not established and implemented an enforcement policy for responding to non-compliances by authorized parties with regulatory requirements or with any conditions specified in the authorization, that would be both in line with the general Law of Portugal and with the IAEA requirements. Formal instructions that would guide inspectors in implementing an enforcement policy have not yet been developed.

(1)	BASIS: GSR Part 1 (Rev 1) Requirement 30 states that <i>“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.”</i>
(2)	BASIS: GSR Part 1 (Rev 1) Requirement 31 para. 4.58. states that <i>“The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary. On-site inspectors, if any, shall be authorized to take</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>corrective action if there is an imminent likelihood of safety significant events.”</i>
R17	Recommendation: The regulatory body should establish and implement an enforcement policy that is in line with IAEA requirements, while respecting the national legal framework.
R18	Recommendation: The regulatory body should develop enforcement criteria and specific instructions on how to implement them to allow for consistent implementation of the enforcement policy.

8.2. ENFORCEMENT IMPLEMENTATIONS

IGAMAOT identifies non-compliances mainly through on-site inspections. The IRRS team noted that IGAMAOT has recently been challenged with the training of new staff and the constraints due to COVID-19 pandemic which did not allow full scope inspection and enforcement activities e.g., inspections in hospitals were not allowed. The IRRS team was informed that in 2021 among 440 inspections conducted, 269 were related to administrative offences. Corrective actions were required from three inspections. IGAMAOT developed a document entitled *Support Guide for Radiological Protection Inspections* focusing mainly on inspections. Enforcement activities are not completely described in this document.

Although the *Support Guide for Radiological Protection Inspections* addresses some components of the enforcement process including legal services to be involved, the complete procedure to be followed in enforcement actions is incomplete. Items missing from this support guide include the setting of corrective actions on-site and in the inspection report and checking that corrective actions have been implemented by operators. As already noted in the ARM Initial National Action Plan (A46 and A47), IGAMAOT needs to develop a procedure to ensure that the authorized party effectively implements corrective actions.

The IRRS team was informed that no amendment or revocation of a licence or a registration has been exercised to date and no precautionary measures, seizures or sealing of equipment implemented. The experiences in the implementation of the enforcement processes are limited. The IRRS team noted a lack of training of IGAMAOT inspectors in this respect. This lack of training was included in ARM Initial National Action Plan (A48). **Recommendation R7 in Section 3.3 addresses this issue.**

The cooperation between IGAMAOT and APA is already addressed in DL 108/2018. However, the IRRS team noted that effective cooperation among regulatory authorities is needed to implement lessons from enforcement activities in other regulatory processes. **Suggestion S2 in Section 1.5 and Suggestion S4 in Section 2.2 address this issue.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: IGAMAOT has not developed a written procedure to confirm that the authorized party has effectively implemented any necessary corrective actions.
(1)	BASIS: GSR Part 1 (Rev 1) Requirement 31, para. 4.60. states that <i>“Finally, the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions.”</i>
R19	Recommendation: IGAMAOT should establish a written procedure to confirm that the authorized party has effectively implemented any necessary corrective actions.

8.3. SUMMARY

National legislative framework empowers IGAMAOT to perform inspections and enforcement activities. However, the IRRS team observed some areas which might benefit from further improvements, i.e.:

- an enforcement policy prepared in line with IAEA requirements;
- enforcement criteria and specific instructions on how to implement them to allow for consistent implementation of the enforcement policy; and
- IGAMAOT written procedure to confirm that the authorized party has effectively implemented any necessary corrective actions.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

In 2018 the Portuguese legislation related to nuclear and radiation safety changed significantly. Based on the provisions of DL 108/2018, APA is responsible for issuing regulations and guides. APA already published guidance on authorization, recognition of expert and services, radioactive waste, general requirements for practices, requirements for practices within veterinary medicine as well as guidance documents related to radon and a guide on the safety assessment of groundwater facilities. Several other guidance documents are also being drafted. Comprehensive guidance on the format and content of the required submission for authorization is still under preparation, with preliminary guidance already published on APA’s website. It should be noted that guidance published before DL 108/2018 is still considered to be valid e.g., guidance on industrial radiography, but APA plans to update this guidance in order to be in line with the new requirements. The IRRS team was informed that IAEA guidance is used as a reference when there is yet no Portuguese regulations or guidance.

Guides specific to certain areas i.e., radioactive waste management facilities, facilities and activities with radiation sources, decommissioning activities, transport, occupational, medical, and public exposure as well as in emergency preparedness and response are yet to be published. The issue was also highlighted by authorized parties during the discussions that took place during the inspection of an industrial facility that was witnessed by the IRRS team. An appropriate system of regulations and guides could help authorized parties to comply with the transition to the new regulatory provisions in DL 108/2018. The development of the current set of guidance was not fully based on the graded approach. The Initial National Action Plan has addressed the need for various guidelines.

APA has established a Technical Advisory Committee (Comissão de Acompanhamento Técnico - CAT), that includes representatives of stakeholders, and that is consulted in the preparation of regulations and guidance. Regular review and revision as necessary to keep regulations and guides up to date is not yet planned. In addition, there is yet no systematic approach to implementing relevant international safety standards and technical standards and to make use of relevant experiences gained. The IRRS team noted that there is no formal process for developing regulations and guides, but APA has started the development of such a process. **Recommendation 10 in Section 4.3 addresses this issue.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: APA has developed a limited number of regulations and guides to support implementation of safety measures for specific practices and, existing and emergency exposure situations to be used by authorized parties and other stakeholders with a role in safety.</p>	
(1)	<p>BASIS: GSR Part 1 (Rev. 1) Requirement 32 states that <i>“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.”</i></p>
R20	<p>Recommendation: APA should complete the development of regulations and guides relevant to support the implementation of safety measures specifying the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.</p>

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

Portugal is in the process of updating DL156/2013. APA plans to include the specification of the PRR as an interim storage facility, the provisions applicable to the closure and post-closure phases of nuclear facilities, the management of NORM waste as well as updated provisions for inspection and enforcement in the new legislation, as described in the Initial Action Plan. In the revision process, requirements to demonstrate the radiological, mechanical, physical, chemical, and biological characteristics that are required for some key wastes and packages,

and how these ensure the safety case requirements are met have yet to be developed. **Recommendation R2 in Section 1.2 and Suggestion S3 in Section 1.7 address this issue.**

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

APA has published only limited number of guides related to radiation sources and activities based on DL 108/2018 e.g., *General guidance for authorized parties* and *Guidance for practices in veterinary medicine*. The guides are published on the APA website. There is a lack of guidance on:

- operation industrial irradiator;
- radiotherapy facility;
- nuclear medicine facility;
- industrial radiography;
- well logging;
- nuclear gauges;
- X-ray generators and other radiation sources used for inspection purposes and for non-medical human imaging;
- X-ray generators used in laboratories; and
- open source used in research.

It should be noted that for some of these areas, as stated above, guidance published before DL 108/2018 is still considered to be valid e.g., guidance on industrial radiography, but APA plans to update this guidance in order to be in line with the new requirements.

While essential regulatory provisions concerning radiation safety for facilities and activities with radiation sources are in place, providing a comprehensive set of guidance documents remains a priority and is requiring a substantial effort. **Recommendation R20 in Section 9.1. addresses this issue.**

9.4. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

As part of the process for updating national regulations and guides APA plans to develop guidance on decommissioning of facilities, including specific provisions aimed at the decommissioning of the RPI. **Recommendation R20 in Section 9.1 addresses this issue.**

9.5. REGULATIONS AND GUIDES FOR TRANSPORT

The IAEA safety requirements for transport of radioactive material are implemented in the national legal framework by the international regulations for all modes of transport. However, further guidance based on SSR-6 (Rev.1) and its supplementary guides, such as on radiation protection programmes, management systems and for the designer and/or user of packages in demonstrating compliance with the provisions of SSR-6 (Rev.1) would be beneficial. There is no detailed guidance on applying for or issuing approvals based on the SSR-6 (Rev.1), such as package design approvals, transport under special arrangements. It was noted that such approvals are rare. The need for detailed guides is evident. **Recommendation R20 in Section 9.1 address this issue.**

9.6. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The IRRS team was informed that APA has identified several gaps in DL108/2018 with regard to occupational exposure. APA is therefore proposing to develop additional regulations and guides that will cover the following topics:

- investigation of accidental and unintended medical exposures;

- the records relating to radiation safety that need to be maintained by authorized parties, including information and training provided to workers;
- information to be provided by authorized parties to employers of external workers;
- the storage of contaminated personal protective equipment;
- the provision of instruction to workers on the proper use of respiratory protective equipment, including testing for good fit; and
- authorized parties cannot offer benefits as substitutes for measures for protection and safety.

These topics are identified in the Initial National Action Plan. **Recommendation R20 in Section 9.1 addresses this issue.**

The IRRS team was informed that there are some practice specific guidance documents prepared under the previous regulatory system that require review against current international safety standards are described in Section 9.3. There are some practices where no national guidance is available. APA indicated that IAEA safety guides are used as a reference when necessary.

9.7. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

IRRS team observed that APA already published some regulations and guides related to medical exposure. However, several are still missing e.g., guides on:

- establishment of national diagnostic reference level **Recommendation R14 in Section 5.7 addresses this issue.**
- quality assurance programmes **Recommendation R15 in Section 5.7 addresses this issue;**
- dosimetry of patients;
- measurements of physical parameters;
- the release of patients after radionuclide therapy;
- identification, technical criteria for reporting, investigation, analysis and remedial actions of unintended or accidental exposures in line with IAEA GSR Part 3, Requirement 41 para 3.180.

APA already identified a need to provide several guides in the Initial National Action Plan. **Recommendation R20 in Section 9.1. addresses this issue**

9.8. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

Portuguese regulations include requirements for the control of consumer products to be supplied to members of the public. Article 151 of DL 108/2018 establishes a reference level for consumer products of 1 mSv in one year. However, complementary guidance and procedure to implement them have not yet been developed. This guidance and procedures are expected to be developed as part of the ongoing process of complementary regulatory guides and procedures. In addition, APA plans to publish standard guidance on the operational limits and conditions for public exposure including authorized limits for discharges. **Recommendation R20 in Section 9.1 addresses this issue.**

9.9. SUMMARY

APA has already developed regulations and guides to support implementation of safety measures for specific practices and, in existing and emergency exposure situations. However, there is still a lack of necessary regulations and guides, and APA is encouraged to continue preparing them.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

Under DL 108/2018, APA is the competent authority for identifying the practices and associated facilities that may give rise to radiological emergency situations for the purposes of emergency preparedness and response (EPR).

Portugal has completed a national hazard assessment which assesses all the key risks facing the State including the risk from a nuclear accident abroad and the risk of an emergency involving a nuclear-powered submarine in Lisbon port. However, as identified in the Initial National Action Plan (A72), a hazard assessment that identifies the hazards and potential consequences associated with the whole range of facilities and activities in Portugal has not been completed. This hazard assessment will provide the basis for APA to identify the practices and associated facilities that may give rise to radiological emergencies so that a graded approach can be applied in preparedness and response for a nuclear or radiological emergency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A hazard assessment that identifies the hazards and potential consequences associated with the whole range of facilities and activities in Portugal is not available.	
(1)	BASIS: GSR Part 7 requirement 4 states that <i>“The government shall ensure that a hazard assessment is performed to provide a basis for a graded approach in preparedness and response for a nuclear or radiological emergency.”</i>
(2)	BASIS: GSR Part 7 para. 4.23 states that <i>“The government shall ensure that for facilities and activities, a hazard assessment on the basis of a graded approach is performed. The hazard assessment shall include consideration of:</i> <ul style="list-style-type: none"> <i>a) Events that could affect the facility or activity, including events of very low probability and events not considered in the design;</i> <i>b) Events involving a combination of a nuclear or radiological emergency with a conventional emergency such as an emergency following an earthquake, a volcanic eruption, a tropical cyclone, severe weather, a tsunami, an aircraft crash or civil disturbances that could affect wide areas and/or could impair capabilities to provide support in the emergency response;</i> <i>c) Events that could affect several facilities and activities concurrently, as well as consideration of the interactions between the facilities and activities affected;</i> <i>d) Events at facilities in other States or events involving activities in other States.</i>
R21	Recommendation: The Government should ensure that a hazard assessment that identifies the hazards and the potential consequences associated with the whole range of facilities and activities in Portugal is completed.

For practices subject to licensing, the applicant’s Internal Emergency Plan must be approved by APA before the licence is issued. When a licence application is received, the Authorization and Nuclear Safety unit (DAN) in APA makes a preliminary assessment of the content of the Internal Emergency Plan against a check list of requirements (DAN_RQ_04) which is based on Annex VI of DL 108/2018. The Internal Emergency Plan is then sent to APA’s emergency preparedness and response experts in the Emergency Planning and Response unit (EPRE) for review.

The IRRS team considers this a good performance.

The level of detail required by APA in the plan is decided on a case by case basis using a graded approach. As noted in the ARM, the EPRE unit is developing a procedure for the evaluation of Internal Emergency Plans to ensure a consistent approach is used. The EPRE unit reports their findings on the Internal Emergency Plan to the DAN unit. The DAN unit then responds to the applicant requesting that they address any findings on the Internal Emergency Plan and the licence application. Examples of this process were provided to the IRRS team by EPRE. In some cases, where there are minor issues with an Internal Emergency Plan, a licence may be issued with a condition attached requiring amendments to the plan by a specific date.

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

The IRRS team noted that there is a lack of guidance available for operating organizations on the requirements for on-site EPR including the information that should be included in an Internal Emergency Plan and guidelines on preparing, conducting, and evaluating emergency exercises. In the Initial National Action Plan (A73), APA identified several guides that must be developed to support operating organizations with developing and maintaining on-site EPR including:

- Guidelines on developing on-site emergency plans and procedures;
- Guidelines for relevant practices on performing a hazard assessment;
- Guidelines on complying with the requirements for on-site EPR including Internal Emergency Plans; and
- Guidelines for operating organisations on classifying and declaring an emergency and taking mitigatory actions.

It was also noted in the ARM that APA will develop guidelines and criteria for staff evaluating Internal Emergency Plans and the effectiveness of operating organisations’ on-site emergency exercises. Some of these guidelines for operating organizations and APA staff are in the process of development and many are expected to be published in 2022. **Recommendation R20 in Section 9.1 addresses this issue.**

While DL 108/2018 includes provisions for emergency workers with defined functions in an emergency and who may be exposed to ionising radiation during the emergency response, the IRRS team noted that there are no arrangements to ensure that helpers and emergency workers not designated in advance are protected in a nuclear or radiological emergency. In the Initial National Action Plan (A71), it was noted that a Ministerial Order to address this is currently under discussion between the Ministries of Environment, Internal Administration and Health.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Arrangements for the protection of helpers and emergency workers not designated in advance in a nuclear or radiological emergency are absent from current regulations.	
(1)	BASIS: GSR Part 7 requirement 11 states that <i>“The government shall ensure that arrangements are in place to protect emergency workers and to protect helpers in a nuclear or radiological emergency.”</i>
(2)	BASIS: GSR Part 7 para. 5.50 states that <i>“Arrangements shall be made to register and to integrate into operations in an emergency response those emergency workers who were not designated as such in advance of a nuclear or radiological emergency and helpers in an emergency. This shall include designation of the response organization(s) responsible for ensuring protection of emergency workers and protection of helpers in an emergency.”</i>
R22	Recommendation: The Government should ensure appropriate arrangements are put in place to protect helpers and emergency workers not designated in advance in a nuclear or radiological emergency.

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

IGAMAOT is the inspection authority responsible for inspecting the compliance of operating organizations with DL 108/2018. IGAMAOT inspectors include EPR arrangements in their site inspections. IGAMAOT confirmed that during inspections they check that

- on-site incidents have been reported to APA;
- actions identified in exercise reports and incident reports have been implemented;
- staff are aware of the Internal Emergency Plan; and
- training records exist to show that staff have received training in the plan.

Decree Law 108/2018 requires that some aspects of the operating organization’s Internal Emergency Plan are tested annually and that the plan is fully tested at least once every three years. APA must be notified by the licence holder 10 days in advance of an emergency exercise. Staff from EPRE and DAN observe some of these exercises but, as recognized in the ARM and in Section 10.2, there are no criteria in place for APA to evaluate the effectiveness of these exercises.

The National Civil Protection and Emergency Authority (ANEPC) has responsibility for preparing the off-site or external emergency plan, or if appropriate requests the territorially competent civil authority to do so, following their assessment of the Internal Emergency Plan. APA has observed some exercises where arrangements in Internal Emergency Plans for contacting off-site emergency services have been tested.

EPR arrangements and Internal Emergency Plans are reviewed at the authorization stage and as part of the licence renewal process (every five years) or modification (whenever changes to the practice or activity are introduced). If an incident occurs or an emergency exercise is held at a licensed facility, the actions identified may or may not require updates to the Internal Emergency Plan, and its implementation can be checked during verification visits performed by APA. During site inspections IGAMAOT checks that these actions are implemented. However, there is no other mechanism in place to promote, in a timely manner, communication with licensees when new information is available that might affect existing EPR arrangements. Examples of such new information is given in GSR Part 7 and includes information on projected flooding and on storms or other meteorological hazards. It was noted in the ARM that APA plans to implement a mechanism for communicating with licensees when new information is available that might affect existing EPR arrangements to ensure that the licensees review and identify changes to their EPR arrangements, including their Internal Emergency Plans, in a timely manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The existing mechanisms to ensure that operating organizations review and update their EPR arrangements include evaluation during licence renewal or modification, verification visits and site inspections. However, there is no other mechanism in place to promote, in a timely manner, communication with licensees when new information is available that might affect existing EPR arrangements.	
(1)	BASIS: GSR Part 7 para. 4.26 states that <i>“The government through the regulatory body shall ensure that operating organizations review appropriately and, as necessary, revise the emergency arrangements (a) prior to any changes in the facility or activity that affect the existing hazard assessment and (b) when new information becomes available that provides insights into the adequacy of the existing arrangements.”</i>
R23	Recommendation: APA should ensure that a mechanism is established to promote, in a timely manner, the dissemination of new information that may affect existing EPR arrangements of the operating organizations.

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

APA has been assigned several roles in response to nuclear and radiological emergencies in DL 108/2018. These include

- maintaining a continuous monitoring network (RADNET) to detect abnormal increases in radioactivity in the environment;
- proposing protective actions to protect the environment and public in a nuclear or radiological emergency;
- maintaining an operational centre for emergency response; and
- collaboration with civil protection authorities in the preparation and testing of external emergency plans.

APA is the National Warning Point and the designated Competent Authority under the IAEA Early Notification Convention. ANEPC is the competent authority under the IAEA Assistance Convention with APA support. APA has in place a Duty Officer system operated by seven staff members. When on call, the Duty Officer is available to respond within 30 minutes to an emergency notification received through USIE or ECURIE, the National Civil Protection and Emergency Authority (ANEPC), holders or other entities and any alarm from RADNET. A procedures manual to support Duty Officers in responding to these notifications was developed in May 2020 but it has not been submitted to the APA Management Board for approval.

APA has developed a new emergency response plan called the ‘*Operational Procedure for Radiological Emergencies Response*’ to provide practical guidance on the response to different types of radiological and nuclear emergencies. This plan has not yet been submitted to the APA Management Board for approval. Within the plan, several emergency response roles for individual staff and teams as well as four different ‘Modes of Operation’ to clarify what teams are required to respond depending on the severity of the emergency are described. Selected staff have been assigned to teams in Annex 1 of the plan. Another document called the ‘*Management Manual*’ has also been developed and it contains procedures for training staff, management of equipment, checking communication channels and decontamination as well as sample press releases for use in an emergency. While the procedures in this manual reflect current practice, it also has not yet been submitted to the APA Management Board for approval.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The new emergency response manuals have not been submitted to the APA Management Board for approval.	
(1)	BASIS: GSR Part 7 para. 6.17 states that “Each response organization shall prepare an emergency plan or plans for coordinating and performing their assigned functions as specified in Section 5 and in accordance with the hazard assessment and the protection strategy.”
R24	Recommendation: APA should approve the new emergency response manuals.

Staff development in the EPRE Unit is achieved through in-house training and attendance at international training courses, workshops, and conferences. Staff who attend these international events are encouraged to deliver a presentation to their colleagues on their return to describe their key learnings. In addition, a training plan outlined in the *Management Manual* covers general radiation and radiation protection material and some specific elements of nuclear and radiological EPR which should be provided to new staff as well as refresher training at least once per year for existing staff. However, this training plan does not explicitly include training on APA’s emergency response arrangements and the requirements of individuals and team roles and coordination arrangements in emergency response, although it is part of the training effectively provided to the EPRE team members and duty officers. The systematic training of the individuals from other units with a role in APA’s emergency response arrangements is not yet implemented. **Recommendation R7 in Section 3.3 addresses this issue.**

APA maintains the national radiation monitoring network, RADNET, and all staff in EPRE can access and manage the network remotely. When radiation levels at any station exceed pre-defined thresholds, an alarm is activated at APA and Duty Officers are simultaneously notified. Monitoring stations on the network have recently been upgraded and APA is preparing a short video and other public communication materials, namely flyers, to inform the public about the network.

APA has established an Emergency Response Centre (CRER) in its offices in Lisbon. Staff with emergency response roles will be based there in the event of a nuclear or radiological emergency and the centre is used in emergency exercises. APA has a comprehensive set of radiation measurement instruments, personal protective equipment, VHF communication systems in case conventional communications channels are unavailable, computers and facilities that can be used in emergency response. In addition, several staff in the EPRE unit have knowledge and expertise in decision support systems, including atmospheric dispersion modelling and assessment and prognosis, that is required in the event of an emergency in a nuclear facility abroad or any radiological facility or site.

APA regularly participates in emergency response exercises such as the IAEA ConvEx and ECUREX exercises to test their emergency response capabilities. Staff from APA help to organize and also participate in national exercises promoted by the National Commission for Radiological Emergencies (CNER), APA and other entities. APA also participates in the development of the Radiological Emergencies Course which involve all entities involved in the civil protection activities, approximately every two years. Staff from APA participate also in the in-house training of other entities such as first responders, the safety and security forces, armed forces, customs, and others. Staff from APA also help to organize and participate in annual CBRN exercises organized by the army.

10.5. SUMMARY

APA is the competent authority in Portugal for identifying the practices and associated facilities that may give rise to radiological emergency situations for the purposes of EPR. APA has also been assigned several roles in response to nuclear and radiological emergencies in DL108/2018. The EPRE unit in APA is very well resourced with good facilities, excellent technical expertise and a comprehensive suite of tools and equipment.

Internal emergency plans are required as part of all license application to APA. In addition, inspection of EPR is performed by IGAMAOT and some exercises at licensees' facilities are observed by APA. The IRRS team considered it a good performance that all Internal Emergency Plans are reviewed by APA's emergency preparedness and response experts in the EPRE unit. Inspection of EPR is performed by IGAMAOT and some exercises at licensees' facilities are observed by APA.

However, some areas of further improvement have been identified:

- Completing a hazard assessment that identifies the hazards and potential consequences associated with the range of facilities and activities in Portugal.
- Ensuring that appropriate arrangements are in place to protect helpers and emergency workers not designated in advance in a nuclear or radiological emergency.
- Establishing a mechanism to promote, in a timely manner, the dissemination of new information that may affect existing EPR arrangements of the operating organizations.
- Ensuring that all staff with emergency response roles are trained in APA's emergency response arrangements and that the comprehensive in-house emergency response procedures are submitted to the APA Management Board for approval.

11. POLICY ISSUES

The policy issue discussions took place on 25 February 2022. Representatives of APA and IGAMAOT and the IRRS team participated in the discussions. The host counterpart wished to collect the international experience and views of the IRRS team regarding the topics of 1) the application of graded approach on the regulatory activities, 2) the management of large amounts of NORM waste and 3) the effects of the COVID-19 pandemic on regulatory activities. Background information in the three topics was attached to ARM material. Closing remarks were provided by Ms Ana Teresa Perez, Member of the Executive Board.

1. Application of Graded approach on the regulatory activities

In Portugal a graded approach is defined in DL 108/2018. APA and IGAMAOT identified four main issues related to implementation of the graded approach in Portugal, namely, how to use graded approach in authorization, i.e., which practices shall be subject to registration or licensing; applying criteria to be used for type approval of equipment; conduct of inspections with an emphasis on determining the frequency of inspections; enhancing risk perception and safety culture by authorized parties.

The experts shared their regulatory experiences by providing the following information:

- In many countries a similar distinction between notification, registration and licensing is being applied as in Portugal. However, it was emphasised that making this distinction is not sufficient as a further application of the graded approach is needed especially in licensing because it covers a wide range of different types of practices with varying risks.
- Various examples were given on practices subject to notification (only), registration and licensing. In all cases high-risk practices are subject to licensing.
- The example was given where the regulatory body used the graded approach to analyse the processes for authorization and inspection, as a whole, and decided which safety-related areas can be controlled on-site and which in the office (i.e; interventional radiology). Based on that analysis, in some countries, many practices previously subject to licensing, for example conventional radiology, are now subject to registration.
- The example was given where the regulatory body focuses not only on the risk associated with the practice but also analyses the impact that the regulatory control might have on a practice to decide if it should be subject to licensing or registration.
- It was emphasized that all regulatory activities should be graded, for example the process for regulating the modifications to a practice.
- A use of digital means might help the regulatory body to conduct efficient oversight of a performance of authorized parties.
- In transport activities, a graded approach is applied in the process of approving packages.
- Examples of inspection programmes were given; mostly the inspection programmes are focused on high-risk practices, i.e., those practices which are subject to licensing while the registered practices are inspected rarely. Additional examples were given in targeting inspections based on experiences gained from earlier inspection findings and incidents and accidents; this could be based on specific practices or through the analysis of data related to certain types of practices.
- Close contact with licensees was also emphasised to ensure complete understanding of the nature of the implemented practices and the licensee's activities e.g., modifications which need a special attention of inspectors.
- Training of Radiation Protection Officers is one of the key components to enhance safety culture. An example was given where the regulatory body conducted a survey on risk perception.

- Regulatory body reinforced communication with radiation protection societies, media and other stakeholders using workshops. Advisory committee on communication has been established.
- IAEA has recently issued TECDOC 1974 Application of a Graded Approach in Regulating the Safety of Radiation Sources to help Regulatory Bodies to implement graded approach.

2. Management of large amounts of NORM

The Regulatory body introduced the discussion by stating that Portugal has a number of legacy sites that were not regulated under the former radiation protection framework, e.g., fertiliser plants, that have undergone dismantling. There are very significant volumes of residues that contain naturally occurring radioactive material (NORM). There is one radioactive waste management facility in Portugal, and it has limited capacity. Portugal is investigating alternative management paths, such as promoting the reuse of the material as a raw material for other industries, provided safety can be guaranteed. APA also identified industries which generates NORM, and is developing NORM waste characterisation, identification of facilities generating NORM waste and an analysis of the rate of generation.

The experts shared their regulatory experiences by providing the following information:

- That large volumes of mining and millings tailings are managed under the legislative framework for environment and general waste management. Often this framework excludes radioactive waste. For cases where such tailings happen to include NORM this might pose a legislative challenge. An example was given where legislation was developed so that it recognizes the case where such waste continues to be managed as normal tailings, but some additional requirements may be set as to ensure optimization of radiological protection.
- An example was given by one of the experts where about 30t of NORM material from production of TiO₂ was sent to the USA to a waste disposal facility.
- Identification of national competent authorities at local, regional and Governmental level involved in NORM waste managements is an issue identified by some countries. Collaboration and coordination among different competent authorities should be a key point.
- For the recycle of residues from NORM in building materials, the question of public acceptability should have to be examined upstream, with an open discussion between the authorities, the experts and the representatives of civil society.
- Another example addressed the registration (authorized) given to an enterprise to manage NORM waste. However, only small quantities of NORM waste were identified, so that the problem is manageable.
- It is important to characterise the NORM residues. The NORM residues may contain heavy metals and hazardous chemicals. NORM waste that has not been treated with chemicals can often be diluted with other mine materials prior to disposal. Tailings resulting from chemical treatment of NORM cannot be treated in that way. NORM residues include tailings and waste rock require rehabilitation after the mine or facility has closed. The levels of NORM in residues from the oil and gas industry can range from less than 1 Bq/g (non-radioactive) to over 1000 Bq/g. Higher level NORM waste may require packaging and disposal at a radioactive waste management facility.
- The IAEA has recently published (August 2021) the Safety Guide SSG-60: Management of NORM Residues containing Naturally Occurring Radioactive Material from the Uranium Production and Other Activities. This Safety Guide includes guidance on reuse and recycling of NORM waste, such as their use in road construction

3. Effects of the COVID-19 pandemic on regulatory activities

Regulatory bodies and competent authorities initiated a number of measures to maintain the delivery of their statutory regulatory functions and to contribute to the safe operation of facilities and conduct of activities, during the COVID-19 pandemic. To contribute to the experience sharing and exchange of lessons learned between the IRRS Team and regulatory body, APA and IGAMAOT, a policy discussion was held on the effects of the Covid-19 pandemic. The discussions focussed on prioritizing resources and fulfilling safety requirements during a pandemic.

The experts share their regulatory experiences by providing the following information:

- Several countries highlighted those functions related to authorization process were not affected. In specific cases concerning medical facilities the authorization process was prioritized by the regulatory body. Due to the increased need to use X-ray generators for examining patients the regulatory body adapted their procedures to respond to an urgent need for authorization from applicants.
- The implementation of a graded approach to adjust the annual inspection plan in such a manner that safety will not be compromised.
- The regulatory body had to adjust their inspection process and have conducted several inspections remotely or according to a hybrid format, i.e., inspections conducted in the presence of inspectors, usually resident or on-site inspectors, with remote participation of other inspectors or regulatory experts.
- Regulatory bodies have revisited their inspection procedures to adapt them to the specificity of remote inspections. This action has been identified as an opportunity to learn and gain experience. However, legal advice is needed to see if the evidence collected remotely, can be used for enforcement actions.
- The system and capabilities of regulatory bodies for providing a full response in case of an emergency have been maintained. The major challenges for emergency preparedness have been to perform drills with other competent authorities and training activities involving exercising and the participation of different organizations.
- Communication activities with authorized parties has been strengthened because regulatory bodies had to respond to large numbers of questions, particularly at the beginning of the pandemic.
- Reference was made on the IAEA survey about the impact of COVID 19 on the Regulatory Body functions. The survey was answered by 123 States and highlighted the challenges and lessons learned during the time of the pandemic.
- A challenge needing attention is the financial failure of the users to ensure safety and security of the radiation sources, including disused radioactive sources; lack of medical staff for the medical use of radiation sources; unjustified exposures and the lack of technical services provision.
- The pandemic situation already raises questions of a systemic nature, which could arise, in the same terms, in the event of a nuclear crisis. This is the case in particular for the relationship of trust between citizens and scientific expertise and the authorities, and for the conditions of acceptability of restrictive measures to protect the population.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
MARKKANEN Mika	Radiation and Nuclear Safety Authority (STUK)	mika.markkanen@stuk.fi
BOAL Trevor	Senior Expert	tboal@hotmail.com
DELGADO Maria Isabel Villanueva	Consejo de Seguridad Nuclear (CSN)	ivd@csn.es
ECONOMIDES Sotiris	Greek Atomic Energy Commission (EEAE)	sotiris.economides@eeae.gr
GODET Jean-Luc	Senior Expert	jeanlucgodet75@gmail.com
JANŽEKOVIČ Helena	Slovenian Nuclear Safety Administration	helena.janzekovic@gov.si
KARINOU Eleftheria	Greek Atomic Energy Commission (EEAE)	eleftheria.carinou@eeae.gr
KRZ Petr	Senior Expert	Pet.Kr@seznam.cz
SMITH Veronica	Environmental Protection Agency	V.Smith@epa.ie
TRIVELLONI Sandro	Senior Expert	sandro.trivelloni@alice.it
IAEA STAFF		
PACHECO Ronald	Division of Radiation, Transport and Waste Safety	r.pacheco.jimenez@iaea.org
TOMAS ZERQUERA Juan	Division of Radiation, Transport and Waste Safety	J.Tomas-Zerquera@iaea.org
SWOBODA Zumi	Division of Radiation, Transport and Waste Safety	Z.Swoboda@iaea.org
LIAISON OFFICER		
Pedro Rosario	Agência Portuguesa do Ambiente (APA)	pedro.rosario@apambiente.pt

GROUP PHOTO



APPENDIX II – MISSION PROGRAMME

IRRS MISSION TO PORTUGAL

20 February to 2 March 2022

MISSION PROGRAMME

Sunday 20 February 2022		
IRRS Initial Team Meeting		
13:30 - 18:00	Opening remarks by the IRRS Team Leader Introduction by IAEA Coordinator Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA) Administrative arrangements (host country Liaison Officer, IAEA): Detailed Mission Programme First impression from IRRS Team members arising from the Advance Reference Material (all team members): Presentations and preliminary findings	Venue: Hotel Participants : IRRS Team + Liaison Officer (LO)
19:30 – 21:00	IRRS Team dinner	Venue: Hotel IRRS Team, LO

Monday 21 February 2022

IRRS Entrance Meeting		
09:30 – 11:30	09:30 Arrival, registration, 9:45 Welcoming Address – <i>(officials from the host country)</i> 10:15 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team 10:30 IRRS Team members’ and Counterparts’ self-presentation 10:45 Host Institution presentation – Regulatory Overview, SARIS results (strengths, challenges, action plan) (APA+IGAMAOT) 12:00 Group Photo	Venue: APA Participants: High level government officials (TBC), RB, management and staff, officials from relevant organizations, IRRS Team, LO
12:00 -13:00	Lunch	
13:00 - 17:00	Interviews and discussions with counterparts (parallel discussions)	Venue: APA offices (per Module) Counterparts and IRRS team
17:00 - 18:00	Daily IRRS Team meeting (Reporting on interviews; preliminary findings)	Venue: APA Participants: IRRS Team + LO
	Writing the report	Hotel

Tuesday 22 February 2022

Daily Discussions / Interviews		
09:00 - 12:00	Interviews and discussions with counterparts (parallel discussions) and/or Site visits	Venue: APA offices (per Module) Counterparts and IRRS team
09:00 – 16:00	Site-visits	(With IGAMAOT) Medical facility: Hospital Lusíadas Industrial facility: ISQ

12:00 - 13:00	Lunch	
13:00–17:00	Interviews and discussions with counterparts (parallel discussions) and/or site visits	Venue: APA offices (per Module) Counterparts and IRRS team
17:00 - 18:00	Daily IRRS Team meeting (quick briefing on interviews and/or site visits, draft of preliminary findings)	Venue: APA Participants: IRRS Team + LO
	Writing the report	Hotel
Wednesday 23 February 2022		
09:00 - 16:00	Interviews and discussions with counterparts (parallel discussions) and/or site visits	Venue: APA offices (per Module) Counterparts and IRRS team
	Site-visits	(With IGAMAOT) <i>Waste management facility:</i> PRR
12:00 - 13:00	Lunch	
17:00-18:00	Daily IRRS Team meeting (quick briefing on interviews and/or site visits, draft of preliminary findings)	Venue: APA Participants: IRRS Team + LO
	Draft of preliminary findings - finalization	Hotel
Thursday 24 February 2022		
Daily Discussions / Interviews		
09:00 - 10:30	Follow-up Interviews and discussions with counterparts, if necessary (parallel discussions) Individual discussion with counterparts on the preliminary findings	Venue : APA Participants : IRRS Team and Counterpart
10:30 – 12:00	IRRS Team finalize recommendations, suggestions and good practices	Venue : APA

		Participants: IRRS Team + LO
12:00 - 13:00	Lunch	
13:00 – 17:00	Report writing	Venue: APA Participants : IRRS Team
17:00 - 18:00 extend as needed	Daily IRRS Team Meeting (Quick review any difficulties regarding the report)	Venue: APA Participants: IRRS Team + the LO
	Finalization of first draft of the report (without compilation)	Hotel
Friday 25 February 2022		
09:00 - 12:00	Cross reading	Venue: APA Participants : IRRS Team
12:00	Draft report individual contributions after cross reading to administrative assistant – Compilation	
12:00 - 13:00	Lunch	
13:00 - 15:00	Policy Discussion	Venue: APA Participants: IRRS Team + the LO
15:00 – 18:00	Individual review of the full report	Venue: APA Participants: IRRS Team + the LO
	Individual review of the full report	Hotel
Saturday 26 February 2022		
09:00 - 18:00	Finalization of the draft report by the entire IRRS Team	Venue : hotel Participants : IRRS Team
20:00 – 22:00	IRRS Team Lead and IAEA Coordinator edit draft report	Venue: hotel

		Participants : IRRS Team
	Draft Report submitted to counterparts	
Sunday 27 February 2022		
IRRS Team cultural event and rest day		
Monday 28 February 2022		
09:00 - 12:00	IRRS TL and TC draft the Executive Summary, the Press Release and the TL Presentation	Venue: Hotel Participants: TL and TC
12:00 - 13:00	Lunch	
13:00 - 15:00	Host review of the draft report and submit written comments to the IRRS Team	
15:00 -	IRRS Team reviews Host's comments and finalizes draft report.	Venue: Hotel Participants: IRRS Team
	IRRS Team Lead and IAEA Coordinator finalize draft report editing	Venue: Hotel Participants: TL and TC
Tuesday 1 March 2022		
09:00 - 12:00	Team meeting for report finalization based on discussions with the Hosts	Venue: APA Participants: IRRS Team and Host counterparts
12:00 - 13:00	Lunch	
13:00 - 16:00	Team meeting for report finalization based on discussions with the Hosts IRRS Team Lead and IAEA Coordinator finalize draft report editing	Venue: APA Participants: IRRS Team and Host counterparts
16:00	Submission of the Final Draft Report to the Hosts	
16:00 - 17:00	Press release finalization	Venue: APA IRRS Team Lead and IAEA Coordinator

19:00 – 21:00	Farewell dinner	Venue: TBD Participants: IRRS Team and Counterparts
Wednesday 2 March 2022		
10:00 - 11:00	IRRS Exit meeting	Venue: APA
	Main findings of the IRRS mission (Team Leader)	Participants: Government Officials (TBC), Management and staff, the IRRS Team + the Liaison Officer
	Remarks by the Host Institution in response to the mission findings. (APA+IGAMAOT)	
	IAEA Official: Closing	

APPENDIX III – SITE VISITS

1. Medical facility: Lusiadas, S.A.
2. Industrial facility: ISQ – Instituto da Soldadura e Qualidade
3. Waste facility: Pavilhão de Resíduos Radioativos, Instituto Superior Técnico

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS	Lead Counterpart	Support Staff
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES			
	Petr Krs	Mr. Nuno Lacasta Ms. Ana Teresa Perez Ms. Paula Matias	Mr. João Oliveira Martins Mr. Marco Candeias
2. GLOBAL NUCLEAR SAFETY REGIME			
	Petr Krs	Mr. Nuno Lacasta Ms. Ana Teresa Perez	Mr. João Oliveira Martins Mr. Marco Candeias
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY			
	Eleftheria Karinou	Mr. João Oliveira Martins Mr. Marco Candeias Mr. Pedro Rosário	Ms. Graça Bravo
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY			
	Maria Isabel Villanueva Delgado	Mr. Miguel Pereira Ms. Paula Santos Mr. Marco Candeias	Ms. Catarina Antunes Ms. Graça Bravo
AUTHORIZATION			

	IRRS EXPERTS	Lead Counterpart	Support Staff
5.	Sotiris Economides	Mr. Miguel Pereira Ms. Inês Krull	
6.	REVIEW AND ASSESSMENT		
	Helena Janžekovič	Mr. Pedro Rosário Ms. Margarida Malta	
7.	INSPECTION		
	Sotiris Economides	Mr. Marco Candeias Ms. Graça Bravo	
8.	ENFORCEMENT		
	Helena Janžekovič	Mr. Marco Candeias Ms. Graça Bravo	
9.	REGULATIONS AND GUIDES		
	Helena Janžekovič	Mr. Guilherme Cardoso Ms. Margarida Malta Mr. Luis Portugal Mr. Pedro Rosário	
5-9	WASTE MANAGEMENT AND DECOMMISSIONING		
	Juan Tomas Zerquera	Ms. Patrícia Santos Ms. Margarida Malta Mr. Pedro Rosário	
5-9	PUBLIC EXPOSURE AND EXISTING EXPOSURE SITUATIONS		

	IRRS EXPERTS	Lead Counterpart	Support Staff
	Juan Tomas Zerquera	Margarida Malta Heloísa Fonseca	
5-9	MEDICAL EXPOSURE		
	Jean-Luc Godet	Paula Santos Pedro Rosário	
5-9	OCCUPATIONAL EXPOSURE		
	Trevor Boal	Miguel Pereira Helena Moreira	
5-9	TRANSPORT		
	Sandro Trivelloni	Joana Pereira Luis Portugal	
10.	EMERGENCY PREPAREDNESS AND RESPONSE		
	Veronica Smith	Luis Portugal Paulo Nunes	

APPENDIX V – 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	R1	The Government should establish a comprehensive national policy and corresponding strategies for safety to express its long-term commitment to safety.
	R2	The Government should ensure that the legislative framework for safety is further developed and maintained in a systematic way in order to keep it in compliance with the IAEA safety requirements.
	S1	APA and IGAMAOT should consider finalizing the formal agreement (MoU) to provide for effective coordination.
	S2	APA and IGAMAOT should consider continuing to develop formal provisions for effective coordination with other relevant bodies of state administration.
	R3	The Government should ensure that Portugal has a National Radon Action Plan, adopted and implemented.
	R4	The Government should ensure the establishment of a national policy and strategy for radioactive waste management.
	S3	The Government should consider including in the national policy and strategy for radioactive waste management provisions for ensuring the further development of technical and regulatory criteria for managing large amounts of NORM waste.

AREA	R: Recommendations	Recommendations, Suggestions or Good Practices
	S: Suggestions	
	G: Good Practices	
2. THE GLOBAL SAFETY REGIME	S4	The regulatory body should consider improving the processes for the dissemination of information and feedback of experiences for use by regulatory body, authorized parties, other authorities and stakeholders concerned.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S5	APA should consider developing a formal procedure for the allocation of human and financial resources as to fulfil its statutory obligations effectively and in accordance with a graded approach.
	R5	IGAMAOT should locate its resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.
	R6	The regulatory body should establish a human resources plan, including a strategy to compensate for the departure of qualified staff.
	R7	The regulatory body should establish a formal process for the knowledge management, including a specific training programme based on the analysis of the necessary competence and skills.
	S6	APA should consider concluding the update of the Environmental Monitoring Programme (PRAD).
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	R8	The regulatory body should establish an organizational approach to assure goals for safety are set in accordance with a policy for safety. Organizational procedures should set goals for safety, seek information and commitment on improving safety performance.

AREA	R: Recommendations	Recommendations, Suggestions or Good Practices
	S: Suggestions	
	G: Good Practices	
	R9	The regulatory body should establish, implement and continuously improve an integrated management system in line with IAEA safety requirements.
	S7	The regulatory body should consider developing a road map for planning the establishment and implementation of the integrated management system.
	R10	The regulatory body should develop and implement a management system considering a graded approach in all its regulatory processes.
	R11	The regulatory body should develop a management system to promote by all mechanisms and instruments, a safety culture and provide structure and direction in a way that permits and promotes the development of such a culture.
5. AUTHORIZATION	R12	APA should ensure updating the guidance so that the safety assessment of facilities and activities is carried out and independently verified in accordance with a graded approach.
	S8	APA should consider collaborating with the relevant authorities and medical societies about the on-going training needs in radiation protection of specialist using X-ray to perform radio-guided interventions in operating rooms.
	R13	The Government should establish provisions to foster an increase in the number of medical physicists.
	R14	APA, in consultation with the health authorities and relevant professional bodies, should ensure that a set of national diagnostic reference levels is established and implemented.

AREA	R: Recommendations	Recommendations, Suggestions or Good Practices
	S: Suggestions	
	G: Good Practices	
	R15	APA should complete the guidance for the scope and content of the quality assurance programme for medical exposure, in cooperation with the health authorities and relevant professional bodies.
	S9	APA should consider coordinating with health authorities and medical societies to establish the mechanism for the justification of new radiological procedures.
6. REVIEW AND ASSESSMENT	R16	APA should complete the development of the review and assessment process to cover all practices and all relevant information.
	S10	APA should consider cooperating with the health authorities and relevant medical societies for the establishment of guidance on the requirements for clinical audits concerning safety aspects of medical uses of ionizing radiation, as part of the management system in medical facilities.
7. INSPECTION	NA	NA
8. ENFORCEMENT	R17	The regulatory body should establish and implement an enforcement policy that is in line with IAEA requirements, while respecting the national legal framework.
	R18	The regulatory body should develop enforcement criteria and specific instructions on how to implement them to allow for consistent implementation of the enforcement policy.

AREA	R: Recommendations	Recommendations, Suggestions or Good Practices
	S: Suggestions	
	G: Good Practices	
	R19	IGAMAOT should establish a written procedure to confirm that the authorized party has effectively implemented any necessary corrective actions.
9. REGULATIONS AND GUIDES	R20	APA should complete the development of regulations and guides relevant to support the implementation of safety measures specifying the principles, requirements, and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	R21	The Government should ensure that a hazard assessment that identifies the hazards and the potential consequences associated with the whole range of facilities and activities in Portugal is completed.
	R22	The Government should ensure appropriate arrangements are put in place to protect helpers and emergency workers not designated in advance in a nuclear or radiological emergency.
	R23	APA should ensure that a mechanism is established to promote, in a timely manner, the dissemination of new information that may affect existing EPR arrangements of the operating organizations.
	R24	APA should approve the new emergency response manuals.

APPENDIX VI – COUNTERPART’S REFERENCE MATERIAL USED FOR THE REVIEW

1.	SARIS
2.	Self-Assessment
3.	Executive Summary
4.	Action Plan
5.	Terms of Reference
6.	Legal documents
	Decree-Law 19/1979
	Approves the ratification of the safeguards agreement
	Decree-law 375/90
	Sets out the rules relating to the physical protection of nuclear materials
	Ministerial Order 1456-A/95 Establishes rules for safety signage
	Ministerial Order 247/2000 Rules for archiving of documents
	Decree-Law 319/2003
	Approves the ratification of the Additional Protocol
	Law 2/2004
	Approves the status of public managers
	Law 50/2006
	Framework-law for environmental fees.
	Decree-Law 276/2007
	Establishes the framework inspection within direct and indirect State administration
	Decree-Law 227/2008
	Establishes the framework for qualified experts and technicians
	Decree-Law 145/2009
	Sets out rules relating, <i>inter alia</i> , to radiological protection in medical devices and accessories, transposing Directive 2007/47/EC
	Decree-Law 198/2009
	Sets out rules relating to transfers of spent fuel and radioactive waste, transposing Directive 2006/117/Euratom
	Law 7/2009
	General regime for labour
	Law 102/2009

	General regime for security and safety in the workplace, including provisions concerning radiological protection of workers
	Decree-Law 10/2010
	Legal framework for the management of waste, including radioactive waste, resulting from mining operations, transposing Directive 2006/21/EC
	Decree-Law 41-A/2010
	Sets out the rules applicable, <i>inter alia</i> , to radiological protection during transport of radioactive materials by land, transposing Directives 2006/90/EC and 2008/68/EC. The last revision transposed Directive 2012/45/EU
	Decree-Law 23/2012
	Establishes the internal structure of IGAMAOT.
	Decree-Law 30/2012
	Established the framework for nuclear safety and regulated the functioning of the regulatory body
	Decree-Law 56/2012
	Regulates the functioning and competencies of APA
	Decree-Law 262/2012
	Regulates the obligations of operators of nuclear facilities, in furtherance of the regime set out in Decree-Law 30/2012
	Decree-Law 79/2013
	Rules restricting the use of certain dangerous substances in electronic and electrical equipment, including ionizing radiation and establishment of certain exemptions
	Ministerial Order 108/2013 Establishes the statutes of APA
	Decree-Law 151-B/2013
	Rules for environmental impact assessment, including for nuclear facilities, transposing Directive 2011/92/EU
	Decree-Law 156/2013
	Establishes the legal and regulatory framework for the safe management of spent fuel and radioactive waste, transposing Directive 2011/70/Euratom
	Law 19/2014
	Defines the fundamental basis of environmental policy, including obligations to assess risk of radioactive environmental contamination
	Law 35/2014
	General Law of Civil Service
	Decree-Law 4/2015

	Establishes the Code of Administrative Procedures.
	Decree-Law 153/2015
	Updates the internal structure of IGAMAOT
	Decree-Law 42-A/2016
	Establishes the Environmental Fund
	Law 114/2017
	Establishes the State Budget for 2018
	Resolution from the Council of Ministers 122/2017
	Approves the National Programme for Spent Fuel and Radioactive Waste Management
	Decree-Law 135/2017
	Alters Decree-Law 30/2012 and Decree-Law 262/2012 to ensure compliance with the updated Nuclear Safety Directive
	Decree-Law 80/2018
	Establishes the rules for Ethics Commissions
	Decree-Law 108/2018
	Establishes the regulatory framework for radiation protection and defines the new regulatory body
	Ministerial Order 247/2018
	Approves the Regulation of Metrological Control of Instruments for Measuring Ionizing Radiation
	Law 25/2019
	Alters the framework-law for environmental fees.
	Law 58/2019
	Applies Regulation EU 2016/679, on data protection
	Ministerial Order 136/2019
	Establishes the rules for the central dose registry
	Ministerial Order 138/2019
	Establishes exemption and clearance criteria
	Ministerial Order 170/2019
	Alters the statutes of APA
	Dispatch 3310/2020
	Establishes the Laboratory of Metrology of Ionizing Radiations (LMRI) of IST as metrological verification body of ionizing radiation measuring instruments
	Ministerial Order 254/2021

	Establishes the regulations for recognition of Medical Physics Experts
7.	Other documents of the regulatory body
	<ul style="list-style-type: none"> • APA Guidance DAN_O1 – General guidance for authorized parties
	<ul style="list-style-type: none"> • APA Guidance DAN_O2 – Guidance for practices in veterinary medicine
	<ul style="list-style-type: none"> • APA Guidance on SF and RW Management (draft update of previous RB document)
	<ul style="list-style-type: none"> • APA Guide on Safety Assessment for industrial practices involving NORM
	<ul style="list-style-type: none"> • APA Guide on prevention measures for radon in new buildings
	<ul style="list-style-type: none"> • APA Guide on mitigation measures for radon in new buildings
	<ul style="list-style-type: none"> • APA Guide for the provision of services in radon measurement in buildings with passive radon detector.
	<ul style="list-style-type: none"> • APA Guide for employers for managing radon exposure in the workplace
	<ul style="list-style-type: none"> • APA Guide for reporting dose values resulting from radon exposure in the workplace
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_01 – Application form for registration
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_02 – Application form for licensing (practices with medical exposures)
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_03 – Application form for licensing (practices without medical exposures)
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_04 – Application form for licensing (other practices)
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_05 – Application form for non-sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_06_rev1 – Application form for importing x-ray generators
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_07_rev1 – Application for importing sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_08 – Application form for exporting sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_09_rev1 – Notification of receipt of sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_10 – Normalized Record Sheet for sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_11 – Template 1 for cautionary fee for sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_12 – Template 2 for cautionary fee for sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_13 – Template 3 for cautionary fee for sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_14 – Template normalized EURATOM document for sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_15 – Template for document for holding sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_16_rev1 – Acceptance of export document
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_17_rev2 – Acceptance of import document
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_18_rev1 – Acceptance of transfer document (outgoing)
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_19_rev1 – Acceptance of transfer document
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_20 – Document for transmission of sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_21 – Registration for transport of sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_22 – License for transport of sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_23 – Radiation passport template
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_24 – Procedure for review and assessment of notification applications
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_25 – Procedure for review and assessment of registration applications

	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_26 – Procedure for review and assessment of licensing applications (practices without medical exposures)
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_27 – Procedure for review and assessment of Internal Emergency Plans
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_28 – Procedure for review and assessment of Radiation Protection Programmes
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_29 – Procedure for review and assessment of Prior Safety Assessment Documents submitted by applicants
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_30_rev1 – Procedure for review and assessment applications for sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_31 – License
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_32 – Registration
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_33 – Application form for radiation passport
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_34 – Application form for release of cautionary fee for sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_35_rev1 – Applicant statement for liability insurance
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_36 – Notification of receipt of sealed sources (I-135 implants)
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_37 – Acceptance of import of equipment without sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_38 – Template for inventory of sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DAN_IM_39 – Procedure for review and assessment of licensing applications (practices with medical exposures)
	<ul style="list-style-type: none"> • APA Internal Document DAN_PG_01 – procedure for registrations
	<ul style="list-style-type: none"> • APA Internal Document DAN_PG_02 – procedure for notification of doses above investigation level
	<ul style="list-style-type: none"> • APA Internal Document DAN_PG_03 – procedure for collection of fees
	<ul style="list-style-type: none"> • APA Internal Document DAN_PG_04 – procedures for sealed sources
	<ul style="list-style-type: none"> • APA Internal Document DEPR_RQ01 – Internal Quality manual (draft)
	<ul style="list-style-type: none"> • APA Internal Document DEPR_RS01 – Management system for safety (draft)
	<ul style="list-style-type: none"> • APA Internal Document – Application form for RW management licenses
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Datasheet SG3
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Datasheet VP1
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Inspection report brachytherapy
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Inspection report entities outside regulatory control
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Inspection report (general)
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Inspection report nuclear medicine
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Inspection report radiotherapy
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Inspection report industrial
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Inspection report medical radiology
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Inspection report veterinary radiology
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Welcoming manual for staff

	<ul style="list-style-type: none"> • IGAMAOT Internal document – Manual for handling denunciations
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Environmental measurements for shielding verification
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Notification – in person, generic
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Notification – in person, brachytherapy
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Activity Plan
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Technical procedures and performance sheets
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Procedures for data entry SAR
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Risk analysis
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Internal management system
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Support Guide for EM RAD
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Simplified report for publication
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Supporting document for industrial inspection reports
	<ul style="list-style-type: none"> • IGAMAOT Internal document – MTR Infographic
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Report on transport of waste
	<ul style="list-style-type: none"> • IGAMAOT Internal document – Activity report for 2020

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

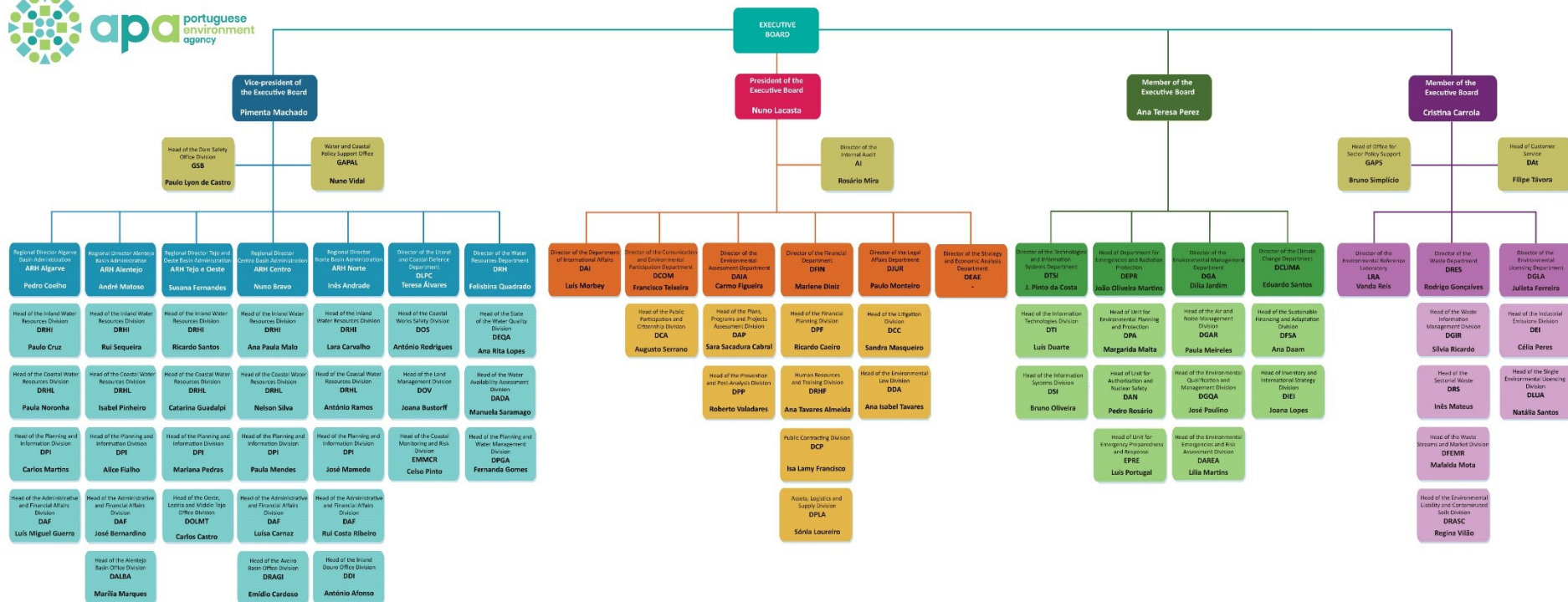
1.	INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2.	INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3.	INTERNATIONAL ATOMIC ENERGY AGENCY – Leadership and Management for Safety, General Safety Requirements Part 2, No. GSR Part 2, IAEA, Vienna (2016)
4.	INTERNATIONAL ATOMIC ENERGY AGENCY - 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 AGENCY - Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste, General Safety Requirement Series Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Facilities, General Safety Requirement Series No. GSR Part 6, IAEA, Vienna (2014)
8.	INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirement Series No. GSR Part 7, IAEA, Vienna (2015)
9.	INTERNATIONAL ATOMIC ENERGY AGENCY - Site Evaluation for Nuclear Installations, Specific Safety Requirement Series No. SSR-1, IAEA, Vienna (2003)
10.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Design, Specific Safety Requirements Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Specific Safety Requirements Series No. SSR-3, IAEA, Vienna (2016)
13.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements Series No. SSR-4, IAEA, Vienna (2017)
14.	INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste, Specific Safety Requirements Series No. SSR-5, IAEA, Vienna (2011)
15.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018)
16.	INTERNATIONAL ATOMIC ENERGY AGENCY - Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
17.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, Safety Guide Series No GSG-2, IAEA, Vienna (2012)

18.	INTERNATIONAL ATOMIC ENERGY AGENCY - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide Series No. GSG-6, IAEA, Vienna (2017).
19.	INTERNATIONAL ATOMIC ENERGY AGENCY - Occupational Radiation Protection, Safety Guide Series No. GSG-7 , IAEA, Vienna (2018)
20.	INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide Series No GSG-9, IAEA, Vienna (2018)
21.	INTERNATIONAL ATOMIC ENERGY AGENCY - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide Series No. GSG-12, IAEA, Vienna (2018).
22.	INTERNATIONAL ATOMIC ENERGY AGENCY - Functions and Processes of the Regulatory Body for Safety, General Safety Guide Series No. GSG-13, IAEA, Vienna (2018).
23.	INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
24.	INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Disposal of Radioactive Waste, Safety Guide Series No GS-G-3.4, IAEA, Vienna (2008)
25.	INTERNATIONAL ATOMIC ENERGY AGENCY - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna 2011)
26.	INTERNATIONAL ATOMIC ENERGY AGENCY - A System for the Feedback of Experience from Events in Nuclear Installations, Safety Guide Series No. NS-G-2.11, IAEA, Vienna (2006)
27.	INTERNATIONAL ATOMIC ENERGY AGENCY - Modifications to Nuclear Power Plants, Safety Guide Series No NS-G-2.3, IAEA, Vienna (2001)
28.	INTERNATIONAL ATOMIC ENERGY AGENCY - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide Series No NS-G-2.8, IAEA, Vienna (2002)
29.	INTERNATIONAL ATOMIC ENERGY AGENCY - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide Series No. RS-G-1.8, IAEA, Vienna (2005)
30.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide Series No. RS-G-1.10, IAEA, Vienna (2008)
31.	INTERNATIONAL ATOMIC ENERGY AGENCY - Borehole Disposal Facilities for Radioactive Waste, Safety Guide Series No SSG-1, IAEA, Vienna (2009)
32.	INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides Series No. SSG-2, IAEA, Vienna (2010)
33.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-3, IAEA, Vienna (2010)
34.	INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide Series No. SSG-4, IAEA, Vienna (2010)
35.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide Series No. SSG-5, IAEA, Vienna (2010)
36.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide Series No. SSG-6, IAEA, Vienna (2010)

37.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide Series No. SSG-7, IAEA, Vienna (2010)
38.	INTERNATIONAL ATOMIC ENERGY AGENCY - Licensing Process for Nuclear Installations, Specific Safety Guide Series No. SSG-12, IAEA, Vienna (2010)
39.	INTERNATIONAL ATOMIC ENERGY AGENCY - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide Series No. SSG-14, IAEA, Vienna (2011)
40.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Spent Nuclear Fuel, Safety Guide Series No SSG-15 (Rev. 1), IAEA, Vienna (2020)
41.	INTERNATIONAL ATOMIC ENERGY AGENCY - Periodic Safety Review for Nuclear Power Plants, Safety Guide Series No SSG-25, IAEA, Vienna (2013)
42.	INTERNATIONAL ATOMIC ENERGY AGENCY - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Specific Safety Guide No SSG-26, IAEA, Vienna, (2014)
43.	INTERNATIONAL ATOMIC ENERGY AGENCY - Commissioning for Nuclear Power Plants, Safety Guide Series No. SSG-28, IAEA, Vienna (2014)
44.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide Series No SSG-40, IAEA, Vienna (2016)
45.	INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-41, IAEA, Vienna (2016)
46.	INTERNATIONAL ATOMIC ENERGY AGENCY - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide Series No SSG-45, IAEA, Vienna (2019)
47.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Safety Guide Series No SSG-46, IAEA, Vienna (2018)
48.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide Series No SSG-47, IAEA, Vienna (2018)
49.	INTERNATIONAL ATOMIC ENERGY AGENCY – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide Series No SSG-48, IAEA, Vienna (2018)
50.	INTERNATIONAL ATOMIC ENERGY AGENCY –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide Series No SSG-49, IAEA, Vienna (2019)
51.	INTERNATIONAL ATOMIC ENERGY AGENCY – Operating Experience Feedback for Nuclear Installations, Safety Guide Series No SSG-50, IAEA, Vienna (2019)
52.	INTERNATIONAL ATOMIC ENERGY AGENCY - Accident Management Programmes for Nuclear Power Plants, Safety Guide Series No SSG-54, IAEA, Vienna (2019)
53.	INTERNATIONAL ATOMIC ENERGY AGENCY - Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material, Safety Guide No TS-G-1.2 (2002)
54.	INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
55.	INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna, (2008)

56.	INTERNATIONAL ATOMIC ENERGY AGENCY - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna, (2009)
57.	INTERNATIONAL ATOMIC ENERGY AGENCY - 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)
58.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No WS-G-6.1, IAEA, Vienna (2006)
59.	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No.WS-G-5.2, IAEA, Vienna (2009)
60.	INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide Series No. WS-G-6.1, IAEA, Vienna (2006)

APPENDIX VIII – ORGANIZATIONAL CHART



FEBRUARY 2022

General inspector + Deputy General Inspector

Management board

José Brito e Silva / Paula Matias

Inspection board

Departments

*Administrative
and Financial
Audits*

Anabela Adónis

*Environmental
Inspections*

**Rodrigo Ferreira
Andrea Santos
Maria J. Rodrigues
Pedro Santana
Susana Araújo**

*Spatial Planning
and Nature
Conservation
Inspections*

**Cristina Branco
Fernando Salvado**

*Legal Issues,
Administrative
Procedures and
Criminal
Investigation*

Cristina Canheto

*Regulation
Systems and
Food Safety
Systems
Audits*

Paula Almeida

*National and
European Funds
Systems Audits*

**Isabel Costa
Ana Arraia
Ana Ferreira**

*Human and
Financial
Resources and IT*

**Cássia Silva
Cláudia Loureiro
Laudelino Ribeiro**

*Institutional
Cooperation and
International
Affairs*

Ana Garcia

*Ionising
Radiations*

**Marco Candeias
Graça Bravo**