INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION

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POLAND

Warsaw, Poland

4 to 15 September 2023

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated Regulatory Review Service

IRRS



NATIONAL ATOMIC ENERGY AGENCY



REPORT OF THE

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO POLAND





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INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION

ТО

POLAND

Mission dates:	4 to 15 September 2023
Regulatory body visited:	Państwowa Agencja Atomistyki (PAA)
Location:	Warsaw, Poland
Regulated facilities, activities, and exposure situations in the mission scope:	Research Reactor, Radiation Sources Facilities and Activities, Waste Management Facility, Transport, Decommissioning, Occupational, Medical and Public Exposure.
Organized by:	IAEA

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

CONTENTS

EXF	CUTIVE SUMMARY	1
I.	INTRODUCTION	4
II.	OBJECTIVE AND SCOPE	5
III.	BASIS FOR THE REVIEW	6
1.	RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	8
1.1	. NATIONAL POLICY AND STRATEGY FOR SAFETY	
1.2	2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY	
1.3	8. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE	9
PC	DLICY DISCUSSION ON MECHANISMS FOR FUNDING OF REGULATORY	
	BODY	
	. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS	11
1.5	5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR	10
1 /	SAFETY WITHIN THE REGULATORY FRAMEWORK	12
1.6	5 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS	13
1 7	7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE	13
1./	MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL	13
1.8	8. COMPETENCE FOR SAFETY	
	 PROVISION OF TECHNICAL SERVICES 	
	0. SUMMARY	
2.	THE GLOBAL SAFETY REGIME	
	INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR	1/
<i>4</i> .1	INTERNATIONAL COOPERATION	
2.2	2. SHARING OF OPERATING EXPERIENCE AND REGULATORY	
	EXPERIENCE	18
2.3	3. SUMMARY	19
3.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
3.1	. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND	
	ALLOCATION OF RESOURCES	20
3.2	2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY	
	FUNCTIONS	
	8. STAFFING AND COMPETENCE OF THE REGULATORY BODY	
	I. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS	22
3.5	5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED	•••
2.4	PARTIES	
	5. STABILITY AND CONSISTENCY OF REGULATORY CONTROL	
	7. SAFETY RELATED RECORDS	
	8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES	
). SUMMARY	
4.	MANAGEMENT SYSTEM OF THE REGULATORY BODY	
4.1	. RESPONSIBILITY AND LEADERSHIP FOR SAFETY	27

4.2	. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE	
	MANAGEMENT SYSTEM	
4.3	. THE MANAGEMENT SYSTEM	28
4.4	. MANAGEMENT OF RESOURCES	29
4.5	. MANAGEMENT OF PROCESSES AND ACTIVITIES	30
4.6		
4.7	. MEASUREMENT, ASSESSMENT AND IMPROVEMENT	31
4.8	. SUMMARY	32
5.	AUTHORIZATION	34
5.1	. GENERIC ISSUES	34
5.2	. AUTHORIZATION OF RESEARCH REACTORS	36
5.3	. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES	37
5.4	. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES	38
5.5	. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES	40
5.6	. AUTHORIZATION OF TRANSPORT	40
5.7	. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE	42
5.8	. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE	43
5.9	. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE	44
5.1	0. SUMMARY	47
6.	REVIEW AND ASSESSMENT	49
6.1	. GENERIC ISSUES	49
6.2	. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS	51
6.3	. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES	53
6.4	. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND	
	ACTIVITIES	53
6.5	. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES	54
6.6	. REVIEW AND ASSESSMENT FOR TRANSPORT	54
6.7	. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE	55
6.8	. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE	57
6.9	. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE	58
6.1	0. SUMMARY	58
7. IN	SPECTION	60
7.1	. GENERIC ISSUES	60
7.2	INSPECTION OF RESEARCH REACTORS	63
7.3	. INSPECTION OF WASTE MANAGEMENT FACILITIES	63
7.4	. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES	64
7.5	. INSPECTION OF DECOMMISSIONING ACTIVITIES	66
7.6	. INSPECTION OF TRANSPORT	67
7.7.	. INSPECTION OF OCCUPATIONAL EXPOSURE	68
7.8	. INSPECTION OF MEDICAL EXPOSURE	68
7.9	. INSPECTION OF PUBLIC EXPOSURE	69
7.1	0. SUMMARY	70
8. El	NFORCEMENT	71

8.1.	ENFORCEMENT POLICY AND PROCESS	71
8.2.	ENFORCEMENT IMPLEMENTATIONS	71
8.3.	SUMMARY	71
9. F	REGULATIONS AND GUIDES	72
9.1.	GENERIC ISSUES	72
9.2.	REGULATIONS AND GUIDES FOR RESEARCH REACTORS	73
9.3.	REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES	74
9.4.		
	ACTIVITIES	74
9.5.	REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES	74
9.6.	REGULATIONS AND GUIDES FOR TRANSPORT	
9.7.	REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE	
9.8.	REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE	
	REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE	
9.10	. SUMMARY	79
10. H	EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	80
10.1	. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF	
	OPERATING ORGANIZATIONS	80
10.2	. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING	
10.2	ORGANIZATIONS	80
10.3	. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS	Q1
10 /	. ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY	
	. SUMMARY	
	NTERFACE WITH NUCLEAR SECURITY	
	NTERFACE WITH NUCLEAR SECURITY	
	. REGULATORY OVERSIGHT ACTIVITIES	
	. INTERFACE AMONG AUTHORITIES	
	. INTERFACE AMONG AUTHORITIES	
	ALORED MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER	
	INTRODUCTION	
12.2		
12.2		
12.2		
12.2		
12.2. POI	.4 SSG-16 ELEMENT 04 REGULATORY FRAME WORK	91
rul	APPLICANTS FOR NEW AND ADVANCED POWER REACTORS	91
12.2		
12.2		
12.2		
,_	CONTRACTORS	93
12.2	.8 SSG-16 ELEMENT 08 LEADERSHIP AND MANAGEMENT FOR SAFETY	

12.2.9	SSG-16 ELEMENT 09 HUMAN RESOURCES DEVELOPMENT	94
12.2.10	SSG-16 ELEMENT 10 RESEARCH FOR SAFETY AND REGULATORY	
PU	RPOSES	
12.2.11	SSG-16 ELEMENT 11 RADIATION PROTECTION	96
12.2.12	SSG-16 ELEMENT 12 SAFETY ASSESSMENT	97
12.2.13	SSG-16 ELEMENT 13 SAFETY OF RADIOACTIVE WASTE, SPENT FUEL	
MA	NAGEMENT AND DECOMMISSIONING	97
12.2.14	SSG-16 ELEMENT 14 EMERGENCY PREPAREDNESS AND RESPONSE	
	EGULATORY ASPECTS)	
12.2.15	SSG-16 ELEMENT 15 OPERATING ORGANIZATION	
12.2.16	SSG-16 ELEMENT 16 SITE SURVEY, SITE SELECTION AND	
EV	ALUATION	
12.2.17	SSG-16 ELEMENT 17 DESIGN SAFETY	
12.2.18	SSG-16 ELEMENT 19 TRANSPORT SAFETY	100
12.2.19	SSG-16 ELEMENT 20 INTERFACES WITH NUCLEAR SECURITY	
	X I – LIST OF PARTICIPANTS	
APPENDI	X II – MISSION PROGRAMME	103
APPENDI	X III – SITE VISITS	105
APPENDI	X IV – LIST OF COUNTERPARTS	106
APPENDI	X V – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTIC	CES
(GP)		110
APPENDI	X VI – COUNTERPART'S REFERENCE MATERIAL USED FOR THE REVI	EW117
	X VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW	
APPENDI	X VIII – ORGANIZATIONAL CHART	127

EXECUTIVE SUMMARY

At the request of the Government of Poland, an international team formed by the International Atomic Energy Agency (IAEA) met representatives of Państwowa Agencja Atomistyki (PAA), the regulatory body of Poland, from 4 to 15 September 2023 to conduct an Integrated Regulatory Review Service (IRRS) mission. The IRRS team also met the Chief Sanitary Inspectorate (GIS), Regional State Sanitary Inspectorate (WSSE), the Civil Aviation Authority (ULC), the Military Preventive Medicine Centre (WOMP) of the Ministry of National Defence, the National Centre for Radiation Protection in Health Care (KCOR), Ministry of the Interior and Administration and Ministry of Climate and Environment.

Mr. Adam Guibourgé-Czetwertyński, Undersecretary of State, Ministry of Climate and Environment, welcomed the IRRS team and delivered opening remarks during the entrance meeting of the mission.

The IRRS team consisted of 15 senior regulatory experts from 14 IAEA Member States, three IAEA staff members, one IAEA administrative assistant, and one observer from the European Commission (EC).

The purpose of this mission was to review the Poland governmental, legal and regulatory framework for nuclear and radiation safety, against the IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources as international benchmarks for safety. The mission was also used to exchange information and experience between the IRRS team members and their Polish counterparts in the areas covered by the mission.

Poland conducted a self-assessment in preparation for the mission and prepared a preliminary action plan to address areas identified for improvement. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material prior to the mission.

The IRRS team reviewed the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes, and development and content of regulations and guides; emergency preparedness and response; research reactors; radiation sources facilities and activities; radioactive waste management facilities; decommissioning; transport of radioactive material; control of medical, occupational and public exposures; and interfaces with nuclear security. Moreover, as Poland is embarking on a nuclear power programme and is currently conducting preparatory work for the safety infrastructure development for the construction of a nuclear power plant, this was also reviewed by the IRRS team. . Given that other regulatory authorities were not involved in Poland's self-assessment in the areas of responsibilities and functions of the regulatory authority, and the management system, they were not included in the scope of the mission for those areas. However, some regulatory oversight activities of the GIS, the WSSE, the ULC and the WOMP were partially reviewed. Two policy issues were discussed in the course of the mission: Pre-licensing engagement with prospective applicants for new and advanced power reactors; and Mechanisms for funding of regulatory bodies.

The IRRS team conducted interviews and discussions with the PAA staff, in some cases involving staff of the above-mentioned national authorities. The IRRS team also observed regulatory oversight activities at a research reactor, a radioactive waste management facility, a radiotherapy facility and an industrial facility. These visits included discussions with management and staff of the facilities.

The IRRS team appreciated the outstanding efforts of PAA staff regarding their engagement in this extensive international peer review. Their active participation enabled the IRRS team to develop a broad understanding of Poland's regulatory infrastructure which resulted in the identification of 1 good practice and several areas of good performance. Continuing these activities, along with the consideration of several recommendations and suggestions offered by the IRRS team, should further enhance nuclear and radiation safety in the country.

The IRRS team concluded that Poland has a legal framework for nuclear and radiation safety generally in line with IAEA safety standards, covering the full range of facilities, activities and exposure situations. The PAA is a competent regulatory body whose staff are committed to deliver their regulatory statutory obligations effectively and to prepare to safely embark on a nuclear power programme.

The IRRS team identified a good practice of conducting a simulation of an NPP construction licence application assessment and issuance with international participation. This exercise, conducted in 2018 and 2019, resulted in improved understanding in the application review and assessment process. It enabled the PAA to enhance competences for the licensing of a nuclear power programme, to identify priorities for further developing the safety infrastructure and better prepare for several practical issues that may be encountered during licensing of the first NPP in Poland.

In addition, the IRRS team identified several areas of good performance, in relation to:

- The training of 300 Regional Sanitary Inspectorates staff on how to effectively inform the public on radon related issues;
- The communication strategy of the PAA to interact effectively with its interested parties, including information published on the PAA website in relation to the situation in Ukraine due to the armed conflict;
- The installation of thirty additional radiation monitoring stations close to its border to improve radioactivity detection capability;
- Guidance to reduce administrative burdens associated with the performance of emergency preparedness and response by the licensees of activities classified as hazard category III or IV;
- The proactivity of the PAA staff in issuing public communications in response to concerns in relation to radiation and nuclear safety issues; and
- The PAA's early, pro-active approach and continuous enhancement of technical and regulatory capabilities for the licensing of the first NPP through international cooperation.

In the spirit of continuous improvement, the IRRS mission report includes recommendations and suggestions intended to improve the Poland regulatory infrastructure and practices to oversee nuclear and radiation safety.

The IRRS team considers that the main challenge in Poland is to implement robust measures to ensure that the PAA is effectively independent and properly resourced.

Moreover, the IRRS team concluded that the following actions, if addressed by the government and the regulatory body, would further enhance the overall effectiveness of the regulatory system:

The Government should:

- ensure that the PAA is effectively independent;
- ensure timely availability of financial resources for decommissioning of nuclear facilities other than NPPs;
- improve coordination and cooperation between different authorities;
- further address the insufficient number of medical physicists; and
- provide the PAA with the authority to amend licensees for facilities and activities other than nuclear facilities and radioactive waste repositories on its own initiative without the required consent from the authorized party.

The PAA should:

- develop an integrated overarching human resource plan, including the identification of financial resources to implement it;
- establish an enforcement policy for implementing the comprehensive provisions for enforcing legal and regulatory requirements provided in the ALA;

The GIS and PAA should:

- enhance coordination of regulatory activities related to medical use of radiation sources;
- develop internal and external guidance for the authorization process; and
- enhance their capabilities to perform the review and assessment of the applications for all types of facilities and activities.

The IRRS team considered Poland's invitation to conduct a second cycle peer review to be a sign of its commitment to openness, transparency and continuous improvement for safety.

The IRRS team received the full support and cooperation of all parties in the regulatory, technical, and policy issue discussions which were conducted in a very open, transparent and frank manner throughout the mission.

The IAEA issued a press release upon conclusion of the mission.

I. INTRODUCTION

At the request of the Government of Poland, an international team of senior safety experts met representatives of Państwowa Agencja Atomistyki (PAA), the main regulatory body of Poland, from 4 to 15 September 2023 to conduct an Integrated Regulatory Review Service (IRRS) mission. The IRRS team also met representatives of the Chief Sanitary Inspectorate (GIS), Regional State Sanitary Inspectorate (WSSE), the Civil Aviation Authority (ULC), the Military Preventive Medicine Centre (WOMP) of the Ministry of National Defence, the National Centre for Radiation Protection in Health Care (KCOR), Ministry of the Interior and Administration and the Ministry of Climate and Environment.

The purpose of this peer review was to review the Polish governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Poland in October 2021. A preparatory meeting of the IRRS mission was organized in Warsaw, Poland, at premises of the PAA on the 1st and 2nd of March 2023 to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Poland and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 15 senior regulatory experts from 14 IAEA Member States, three IAEA staff members, an IAEA administrative assistant and an observer from the European Commission (EC). The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the PAA; the management system of the PAA; 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; research reactors; radiation sources facilities and activities; radioactive waste management facilities; decommissioning; transport of radioactive material; occupational radiation protection, control of medical exposure, public exposure control; and interfaces with nuclear security. As Poland is embarking on a nuclear power programme and is currently conducting preparatory work for the safety infrastructure development for the construction of a nuclear power plant, the IRRS mission also included Module 12, Tailored Module for countries embarking on nuclear power programme. Responsibilities and functions, and the management system of the other regulatory authorities were not included in the scope of the mission. However, some regulatory oversight activities of the GIS, the WSSE, the ULC and the WOMP were also partially reviewed. In addition, two policy issues were discussed: Pre-licensing engagement with prospective applicants for new and advanced power reactors; and Mechanisms for funding of the regulatory bodies.

Poland conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the Poland advance reference material, conduct of interviews with management and staff of the PAA and other national regulatory authorities. The IRRS team also conducted direct observations of regulatory activities at regulated facilities. A meeting with the Ministry of Climate and Environment was also conducted.

Throughout the mission the IRRS team received excellent support and cooperation from the PAA.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Poland's radiation and nuclear safety governmental, legal, and regulatory framework and activities against the relevant IAEA safety standards to report on the effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Poland and the preparatory works for the safety infrastructure development for the construction of a first nuclear power plant. It is expected this IRRS mission will facilitate regulatory improvements in Poland and other Member States, utilizing the knowledge gained and experiences shared between PAA and IRRS reviewers and the evaluation of the Poland regulatory framework for nuclear safety, including its good practices.

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

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IRRS TEAM

At the request of the Government of Poland, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted on the 1st and 2nd of March 2023. The preparatory meeting was carried out by the appointed Team Leader, Mr. Mike King, Deputy Team Leader, Mr. Mika Markkanen, and the IRRS IAEA Team representatives, Jean-René Jubin, IAEA Coordinator, and Manuel Recio, IAEA Deputy coordinator.

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

- Research Reactors;
- Waste management facilities;
- Radiation sources facilities and activities;
- Decommissioning;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Emergency preparedness and response;
- Waste management (policy and strategy, predisposal and disposal); and
- Selected policy issues.

In relation to the current preparatory work for the safety infrastructure development for the construction of a nuclear power plant conducted by Poland, it was also agreed that the IRRS mission will cover Module 12 – Tailored Module for countries embarking on a nuclear power programme.

Mr. Andrzej Głowacki delivered a presentation on the legal and regulatory framework in Poland and Mr. Michał Koc presented the organization set up by Poland to support the IRRS mission as well as the self-assessment process and the main results obtained 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 Poland in September 2023.

The proposed composition of the IRRS team was discussed along with key logistical issues such as meeting workplace needs, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements.

The Poland Liaison Officer for the IRRS mission was confirmed as Mr. Michał Koc, and Mr. Dariusz Janusz as Deputy Liaison Officer.

PAA provided IAEA with the advance reference material (ARM) for the review on 14 July 2023, In preparation for the mission, the IAEA team members reviewed the Poland advance reference material and provided their initial impressions to the IAEA Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on 3 September 2023 at PAA premises, directed by the IRRS Team Leader and the IAEA Coordinator. Discussions encompassed the scope and specific issues of the mission, the basis for the review and additional context and objectives of the IRRS programme. The methodology for review was reinforced and the agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on 4 September 2023, with the participation of PAA senior management and staff. Opening remarks were made by Mr. Adam Guibourgé-Czetwertyński, Undersecretary of State, Ministry of Climate and Environment, and Mr. Mike King, IRRS Team Leader. Mr. Andrzej Głowacki, PAA President, gave an overview of the Polish regulatory programme, PAA activities and the results 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 Poland and PAA with recommendations and suggestions for improvement and where appropriate, identifying good practices. 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 15 September 2023. The opening remarks at the exit meeting were presented by Mr. Andrzej Głowacki and were followed by the presentation of the results of the mission by the IRRS Team Leader, Mr. Mike King. Closing remarks were delivered by Ms. Kirsi Alm-Lytz, Head, Regulatory Activities Section, Division of Nuclear Installation Safety, IAEA.

An IAEA press release was issued.

1. **RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Council of Ministers approved a resolution on adopting the Policy and Strategy on the Development of Nuclear Safety and Radiation Protection of the Republic of Poland, submitted by the Minister of Climate and the Environment on 12 April 2022. The National Policy and Strategy expresses a long-term commitment for safety.

The following areas are addressed in the Strategy and Policy on the Development of Nuclear Safety and Radiation Protection of the Republic of Poland:

- The fundamental safety objectives and principles;
- The participation in and adherence to binding international conventions and relevant instruments;
- The need and provision for human and financial resources;
- Provisions for research and development;
- Consideration of social and economic development;
- Promotion of leadership and management for safety, and safety culture; and
- The basis for graded approach implementation.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legal framework for safety is in place. The system of nuclear safety, radiation protection, security and safeguards is regulated primarily by the provisions of the Atomic Law Act (ALA) and the implementing regulations issued on its basis. ALA has been amended several times in order to implement EU directives, IAEA standards and IRRS recommendations from the previous mission. Detailed requirements related to nuclear safety and radiation protection are included in the ALA and implementing regulations issued mainly by the Council of Ministers. All types of activities and facilities and exposure situations relevant for the country and the scope of the IRRS mission are covered by the legal framework. The responsibilities of each authority are clearly allocated by ALA. The framework for safety is maintained through internal and external review mechanisms. The President of the PAA shall, at least every 3 years, make assessment of PAA nuclear regulatory activities and perform an analysis of the current legal status in terms of its adequacy and suitability to nuclear safety, radiation protection, physical protection, accountancy of nuclear material and radioactive waste safeguards. The external assessment mechanism chosen by PAA is the IAEA IRRS.

The ALA is enacted by the Parliament and most of the regulations concerning radiation protection and nuclear safety are issued by the Council of Ministers and relevant ministers. The authority which is entitled to issue a regulation may not transfer its powers to another body. The President of PAA does not have the authority to issue binding legal acts and regulations, but the PAA develops the drafts of legal acts and regulations, and conducts the process of establishing their final form, according to the procedures established in the working rules for the Council of Ministers.

Drafts of the laws and regulations prepared by PAA need to be agreed to by the minister competent for climate matters, which is currently also the minister competent for energy matters, and can amend, modify or reject the drafts. The Minister of Climate and Environment proposes draft laws and regulations prepared by PAA to the Council of Ministers. The process to make and adjust laws and regulations takes around one year, which the IRRS team was informed has sometimes caused challenges to making timely updates to address regulatory issues.

The IRRS team noted that the definition of the management system in the Atomic Law is based on the IAEA standard GS-R-3 instead of on IAEA standard GSR Part 2, which superseded standard GS-R-3.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The President of the PAA is a central authority of government administration in charge of nuclear safety and radiation protection and a supreme nuclear regulatory authority. The PAA is a state budgetary unit and the President of PAA is the chief administrator of part 68 of the state budget. As such, it determines the appropriate resources necessary to perform its tasks.

The PAA employees are civil servants who cannot hold interests in the organizations they oversee. This results from general provisions of the civil service act. Members of the Council for the Nuclear and Radiation Safety (CNSRP), which give advice to the PAA's President shall recuse themselves from matters regarding facilities or activities in which they have any interest. The observations of the IRRS team regarding the CNSRP can be found in paragraph 3.4. The PAA does not promote or facilitate the use of radiation and nuclear energy. Responsibility for the promotion of nuclear power lies with the Ministry competent for energy matters and the Government Plenipotentiary for Strategic Energy Infrastructure. Currently, the Minister competent for energy matters is the Minister of Climate and Environment, who also supervises PAA.

There is a requirement in the Polish legislation addressing the independence of the President of the PAA. Pursuant to Article 64 of the ALA, the President of the PAA is designated as the supreme nuclear regulatory authority. The President of the PAA is appointed for a five-year term of office and may be reappointed only once. Upon expiry of his term of office, the PAA President remains in office until his successor is appointed. Pursuant to Article 109(2b) of the ALA, the President of the PAA may be dismissed by the Prime Minister before the expiry of the term of appointment only in the event of:

- 1. gross violation of the law;
- 2. conviction by a final sentence for an intentional offense or a fiscal offense;
- 3. a ban on occupying managerial positions or performing functions connected with special responsibility in state bodies;
- 4. an illness permanently preventing the performance of tasks;
- 5. submission of a resignation;
- 6. refusal of the Prime Minister to accept the annual report referred to in Article 110 item 13 of the Act ALA.

ALA gives power to the Prime Minister, for the appointment and dismissal of the President of the PAA.

Pursuant to the Act on the Government Administration Divisions, minister competent for the climate matters has an administrative supervision role over the President of PAA. Climate and Energy constitute two separate governmental divisions (among 37 divisions in total in Poland). The Prime Minister in accordance with art. 33 of the Act on the Council of Ministers, determines by regulation divisions over which the given Minister is in charge of. The Prime Minister on 6 October 2020 determined by regulation that the Minister of Climate and Environmental Matters manages the following divisions of government administration:

- 1. energy;
- 2. climate;
- 3. environment.

As a result, one minister is responsible for supervision of the President of PAA and for energy matters. The President of PAA reports directly to the Minister's Bureau. Department of Nuclear Energy is not involved in supervision of the PAA's President in any stage. Department of Nuclear Energy reports to the deputy Minister and the President of PAA is supervised by the Minister. The Minister of Climate does not supervise

investors on nuclear power. The Government Plenipotentiary for Strategic Energy Infrastructure exercises the powers of the State Treasury in relation to other entities in the energy infrastructure sector to the extent defined in separate regulations or in separately granted powers of attorney, including investors in NPP. Under the Polish constitution, all administrative bodies like the PAA must have supervision by a government ministry. The ministry receives an annual performance report from PAA. The PAA has the freedom to set its own goals, priorities and performance indicators regarding safety issues. The IRRS team reviewed the document: "Supervisory Activities of the Minister of Environment to the President of the National Atomic Energy Agency", issued in 2019, to review the independence of the President of the PAA in discharging his regulatory responsibilities.

No additional provisions were taken to ensure that the President of the PAA is effectively independent in its safety related decision making after the Minister of Climate and the Environment assumed the additional responsibility for the Energy department in 2020.

The following examples of challenges that have been identified with regards to independence of the regulator as described in documents provided:

- 1. All PAA proposed changes to laws and regulations require general authorization by the Minister;
- 2. Internal organizational structure change of the PAA at departmental level or higher require approval by the Minister;
- 3. The Minister appoints and dismisses the PAA vice President on the request of the PAA President;
- 4. The Minister supervises the President of the PAA including non-financial matters such as the PAA action plan and periodic reports of the President of the PAA; and
- 5. The Minister can utilize supervisory tools such as recommendations, orders, guidelines in response to periodic assessment of the performance of the President of the PAA or post-audit results.

In addition, the potential exists for the independence of the President of the PAA to be undermined due to the discretionary power specified in the ALA which enables the Prime Minister to dismiss the President of the PAA if the Prime Minister chooses not to accept the PAA President's annual report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Although the ALA designates the President of the PAA as the central nuclear regulatory authority, it is not effectively independent and free from undue influence in its safety related decision making, indeed:

- The PAA is supervised by the Minister of Climate and Environment who is also the leading authority for peaceful use of nuclear energy;
- Polish law does not prevent a situation in which supervision over the PAA President is exercised by a minister who is responsible not only for overseeing PAA but also for the energy matters;
- The PAA drafts safety related laws and regulations but the Ministry of Climate and Environment who has responsibility for energy matters can amend, modify or reject the drafts;
- The PAA President can be dismissed by discretionary power of the Prime Minister upon refusal to accept the annual report of the PAA.

	BASIS: GSR Part 1 (Rev.1) Requirement 4 states that "The government shall ensure that
(1)	the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making".

R1 Recommendation: The Government should review the governmental and legal framework to ensure that the President of the PAA is effectively independent in safety related decision making and has functional separation from entities having responsibilities or interests that could unduly influence decision making.

POLICY DISCUSSION ON MECHANISMS FOR FUNDING OF REGULATORY BODY

The President of PAA explained in his opening remarks that PAA's current funding approach is entirely based on State budget appropriations and no fees charged to licensees go to PAA budget. PAA is considering transition to a system in which the licensees will provide contributions to cover PAA's cost associated with discharging regulatory responsibilities. PAA hosted a policy discussion with IRRS Team members to share their country's financing approaches.

The IRRS team shared the experience of several countries, including benefits and challenges. Main topics that were discussed are:

- All the financing systems discussed use a fee-based financing system to recover a portion of the regulatory body's budget from the fees collected from authorized parties.
- In all cases, a portion of the regulatory body's budget is funded with a State budget appropriation. In most cases this State budget appropriation is intended to finance a diverse range of activities not directly related to regulatory duties over licensees, such as research activities, work done in response to State international obligations, and preparation for future regulatory programmes.
- The approach in determining the fees to charge the authorized parties was slightly different in each country. However, generally an average hourly cost of regulatory work was used combined with an estimate of the regulatory work required for various types of facilities in order to determine the applicable fees to recover for the estimated regulatory activities. In most cases this information is then used to determine the portion of the annual budget of the regulatory body that will be recovered from fees and the portion funded from the state budget.
- For nuclear facilities, most countries have a mechanism to reassess (mid-year or end-of-year) the amount collected from the licensees and apply corrections as needed, either to return the excess amount or to increase the fees. In some cases, fees collected from licensees which are not expended can be retained by the regulatory body to apply to the following year's budget and fees.
- For radiation sources facilities, most countries have fixed regulatory fees.
- All countries have a mechanism to adjust fees on an annual basis or when necessary. In most cases, budget appropriations are provided to the regulatory body by the financial authorities and fees collected are directly sent to the treasury. In one case, the fees collected are integrated into the regulatory body's finances.
- None of the countries collects or incorporates money from enforcement fines or penalties into their budget, they are collected and sent directly to the treasury.
- Challenges were reported related to funding work to prepare for new programmes or during periods of emergent heavy workloads, like work associated with commissioning new projects or decommissioning facilities. Different solutions were discussed to deal with these situations to avoid financial instabilities.

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

According to Article 7 Section 1 of the ALA, the responsibility for compliance with nuclear safety and radiation protection requirements rests with the head of the organizational entity authorized to perform an activity involving exposure to ionizing radiation. For nuclear facilities this responsibility covers all stages of the lifetime of a facility from construction to decommissioning. Specific for nuclear facilities, there is an additional article which gives the head of the entity the overall responsibility for safety. The Atomic Law Act only assigns overall responsibility for safety to the head of the organizations of nuclear facilities. The IRRS team noted that there is no equivalent provision for all other facilities or activities. In addition, the law does not address explicitly that compliance with regulations and requirements established or adopted

by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The Atomic Law Act only assigns overall responsibility for safety to the head of the organizations of nuclear facilities. There is no equivalent provision for all other facilities or activities. In addition, the law does not address explicitly that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 5 states that "The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance".
(2)	BASIS: GSR Part 1 (Rev.1) Requirement 6 states that "The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety".
R2	Recommendation: The Government should review the Atomic Law Act to ensure prime responsibility for safety for facilities and activities other than nuclear facilities is clearly assigned to the person or organization responsible for a facility or an activity and to explicitly stipulate that compliance with regulations and requirements does not relieve the person or organization responsible for any facilities or activities of its prime responsibility for safety.

The organizational entity holding a license cannot transfer the ionizing radiation source to another organization not holding a license valid for the facility or the activity. In case of anticipated organizational changes or termination of operation, the head of the organizational entity must inform and obtain written approval by the authority which has issued the license, including the rules for the management of authorized radioactive sources, nuclear materials or radioactive waste (Article 8a of the ALA), before such a change can take place.

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

According to ALA, the responsibility for issuing licenses or receiving notifications and conducting inspections concerning activities involving exposure to ionizing radiation is shared between different authorities. Detailed rules for the coordination and mutual cooperation of the different authorities are included in bilateral agreements (memoranda of understanding) agreed to by the PAA President with other authorities, e.g with the Chief Sanitary Inspector. Potential gaps and overlapping and conflicting requirements on authorization parties are avoided because the ALA clearly specifies the responsibilities of the authorities involved.

More detailed observations regarding coordination of authorities with responsibilities for safety within the regulatory framework on the medical use of the radiation sources, transport and the safety/security interface can be found in module 5-9 and 11.

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

Radiation risks arising from the most common types of exposure to natural radiation (radon in workplaces and homes, NORM industries, construction products, and cosmic radiation in aviation) are regulated in the ALA and in the Regulation of the Minister of Health.

In situations where unacceptable radiation risks may arise as a consequence of an accident or a discontinued practice, the President of PAA or nuclear regulatory inspectors may issue injunctions or interdictions. Other authorities like the regional governor will also be involved in the actions to be taken.

For activities involving exposure to naturally occurring radioactive substances, the head of the organizational entity conducting the activity can ask the authority for an opinion, within the scope of the potential application, of the measures to monitor the radiation situation and the intervention measures. The authority has the obligation to present the opinion within 30 days from the receipt of the application.

According to the ALA, when an abandoned radioactive substance has been found, including an orphan source, information is forwarded to the regional governor (voivode) of the region where the increased level of dose rate or radioactive contamination has been detected. The voivode undertakes intervention measures established in the regional emergency plan. The recovery and management of the radioactive materials or sources are carried out by the national radioactive waste operator ZUOP at the cost of the State. PAA attempts to identify the responsible party. The ZUOP has responsibilities for managing these materials. When orphan sources are discovered at the border, import is denied and responsible authorities in the neighbouring country are informed.

According to ALA, the President of PAA shall conduct a campaign for orphan source recovery at least once in every 10 years. Currently PAA conducts such a campaign in the form of an administrative search for the orphan sources. PAA compares the inventory of radioactive sources at the organizational entities with the records of these sources and the national register. Comparison is done using remote inspections. When an inconsistency is found, inspectors conduct a reactive physical inspection at the site and open an investigation and search for the missing source. The IRRS team has been provided with an example of such a reactive inspection. Passive physical search is required by law at scrap yards and borders. According to ALA, the head of the organizational entity, whose workers may come into contact with orphan sources during their work and heads of the organizations that employ first responders are responsible for the training of their employees in radiation protection issues. Additionally, in compliance with ALA, the heads of entities processing scrap metal shall immediately notify the competent region's governors about a meltdown of an orphan source or another metallurgic operation on such a source or a suspicion of occurrence of such an event. PAA does not verify the compliance with the above-mentioned requirements on the notification, monitoring and training. PAA maintains records of recovered orphan sources. No orphan sources were detected in 2023 and in 2022 there were 6 cases. Cases are reported to the IAEA Incident and Trafficking Data Base (ITDB). The PAA web-site contains safety information for members of the public who find suspicious materials or objects.

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

The Polish government made provisions for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel. The ALA, Article 38a and 38g, 57c and the Updated National Plan of Radioactive Waste and Spent Nuclear Fuel Management cover these aspects. The ALA, Article 119a covers unplanned situations. In the ALA, Article 38g requires a licence has the financial resources necessary to ensure nuclear safety, radiation protection, physical protection and nuclear material safeguards during the various stages of the operation of a nuclear facility until the completion of its decommissioning. However, in the ALA, there are no

provisions to specifically address the mechanism for funding decommissioning of nuclear facilities other than NPP.

The IRRS team observed that although, in the ALA there are provisions for the establishment of a decommissioning fund, it applies only to the radioactive waste and spent fuel generated by Nuclear Power Plants and as a result, other nuclear facilities are not covered. The IRRS team also observed that there are no established requirements and criteria for termination of the authorization for decommissioning and especially when facilities and /or sites are released with restrictions for their future use.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The ALA makes provision for the establishment of a decommissioning fund that applies only to the radioactive waste and spent fuel generated by Nuclear Power Plants.

(1)	BASIS: GSR Part 6 para. 3.3 states that " Establishing requirements for the licensee's financial assurance for decommissioning and requirements for a mechanism to ensure that adequate resources will be available when necessary for safe decommissioning, in the case where the government has delegated these responsibilities to the regulatory body"
R3	Recommendation: The Government should establish requirements for financial provisions for the decommissioning of nuclear facilities other than nuclear power plants.

The ALA, supporting regulation, and the Updated National Plan of Radioactive Waste and Spent Nuclear Fuel Management is the national legal and regulatory framework within which radioactive waste management activities can be planned and safely carried out. This includes clear and unequivocal allocation of responsibilities. The interdependencies in all steps in the predisposal management of radioactive waste have been covered in the Updated National Plan of Radioactive waste and Spent Nuclear Fuel Management. The responsibilities of the government for decommissioning are also covered by the ALA.

In the ALA, the Government has regulated all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. ALA includes the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste.

1.8. COMPETENCE FOR SAFETY

The Strategy and Policy for the Development of Nuclear Safety and Radiation Protection of the Republic of Poland provides allocation of responsibilities for the competence for safety among all respective parties. The Strategy divides responsibilities for building and maintaining the competence of a sufficient number of suitably qualified and experienced staff.

Moreover, the Polish Nuclear Power Programme (PNPP) describes the development of human resources for the purposes of nuclear power projects for all respective parties. This PNPP underlines the important role of technical support organizations as well.

The PAA has several different mechanisms for professional development of its staff. The Professional development program for workers of the PAA for the needs of the PNPP was adopted on April 2, 2023.

In Poland, there are several scientific institutes funded by the Ministry of Finance and under the control of the Ministry of Education and Science and Ministry of Climate and Environment. PAA can use these institutes as a TSO. The Strategy and Policy for the Development of Nuclear Safety and Radiation Protection of the Republic of Poland contains an action plan to turn these ongoing individual initiatives into a more integrated approach to obtaining the support needed from the various TSOs.

The Framework Plan for human resources development for the needs of the nuclear power programme in Poland was adopted by the Management of the Ministry of Climate and Environment on June 26, 2016. The main objective of the Framework Plan was the development of an adequate number of competent staff to meet the needs of all PNPP stakeholders. Observations by the IRRS team on the Framework Plan can be found in paragraph 12.2.9. The report on the implementation of the activities of the Framework Plan was approved by the Minister of Climate and Environment on May 11, 2021.

The organizational entities which conduct exposure-related activities are obliged to ensure the appropriate number of well qualified employees. Positions important from the viewpoint of nuclear safety and radiological protection in organizational entities may only be occupied exclusively by employees possessing an appropriate authorization issued by the PAA President. The candidate must pass an examination before a commission appointed by the PAA President. The PAA President issues such authorizations with 3 years periodicity for nuclear facilities, and 5 years periodicity for other entities.

1.9. **PROVISION OF TECHNICAL SERVICES**

According to the ALA, individual dose measurements and the measurements for the assessment of doses resulting from internal contamination have to be performed by the entities possessing appropriate accreditation. Accreditation is issued by the Polish Centre for Accreditation (PCA). The accreditation issued by PCA is also required for laboratories which conduct activity on:

- 1. indication of radioactive concentration of natural radioactive isotopes of potassium K-40, radium Ra-226 and thorium Th-232 in building materials;
- 2. measurement annual average activity concentration of radon in the air in the building, premises or room:
- 3. calibration of dosimetric equipment used for exposure control and assessment.

Entities performing calibrations need an accreditation issued by the PCA and an authorization of PAA if they use a radiation source to perform the calibration. Accreditations according to ISO/IEC standards, for individual monitoring and calibration services, are carried out by PCA. Moreover, PAA is part of an advisory group of the Polish Committee for Standardization that reviews new international standards before they are introduced in Poland. However, there are no requirements for PAA to authorize, approve, nor issue binding opinion on these services.

The regulation on the stations for early detection of radioactive contamination and on the units that conduct measurements, in paragraph 4.4. states that the station owner should conduct a systematic verification of the correct functioning of measuring equipment used for measurements. PAA, the meteorological services, and the Ministry of Defence are the only entities with these stations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES		
	Observation: Calibration and dosimetry services are available and accredited by Polish Centre for Accreditation. However, the PAA does not authorize these services, only the use of sources by these services.	
(1)	BASIS: GSR Part 1 (Rev.1) para. 2.41 states that "The government shall ensure that arrangements are in place for the provision of technical services relating to protection and safety, such as services for personal dosimetry, environmental monitoring and the calibration of monitoring and measuring equipment."	
(2)	BASIS: GSR Part 3 para. 3.73(c) states that <i>"The regulatory body shall authorize technical services that may have significance for safety, as appropriate."</i>	
S 1	Suggestion: The Government should consider providing the PAA with authority to authorize service providers for individual monitoring and calibration, as appropriate.	

Several areas which are addressed in the regulatory framework but are not within the competence of the regulatory bodies who participated in the mission were not reviewed in detail during the IRRS mission, i.e.:

- regulations related to the control radioactivity in building materials;
- regulatory control of residues from uranium mining activities from the past;
- regulatory regime of industry related to natural occurring radioactive material;
- management of newly identified existing exposure situations.

The IRRS team noted that the National Radon Action Plan prepared in 2021 has been gradually implemented. A radiological survey is ongoing. Responsibilities for implementing optimization of management of exposure due to radon are well established. The IRRS team noted that Regional Sanitary Inspectorates nominated about 300 regulatory staff members to be trained on how to effectively inform members of the public on radon related issues. This approach is recognized as a good performance.

1.10. SUMMARY

Although the ALA designates the President of the PAA as the central nuclear regulatory authority, it is not effectively independent and free from undue influence in its safety related decision making.

ALA only assigns overall responsibility for safety to the head of the entity of the nuclear facilities. There is no equivalent provision for all other facilities or activities. In addition, the law does not explicitly stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.

Calibration and dosimetry services are available and accredited by the Polish Centre for Accreditation. However, PAA does not authorize these services, only the use of sources by these services.

The IRRS team noted that Regional Sanitary Inspectorates nominated about 300 regulatory staff members to be trained on how to effectively inform members of the public on radon related issues. This approach is recognized as a good performance.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Poland is a signatory of various international conventions, treaties and agreements in the field of safety, nuclear security and safeguards. In the area of multilateral cooperation, Poland is a Contracting Party to all safety and nuclear security-relevant conventions, including the Convention on Nuclear Safety (CNS), the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention), the Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, the Convention on the Physical Protection of Nuclear Materials (CPPNM) and its Amendment (CPPNM/A). Poland has made the political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance on the Import and Export of Radioactive Sources, however, the IRRS team was informed that no political commitment has been made yet to the supplementary Guidance on the Management of Disused Radioactive Sources regarding the establishment of a national policy and strategy for the management of disused sources and on the implementation of management options such as recycling and reuse, long term storage pending disposal and return to a supplier.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: While Poland has made a political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance on the Import and Export of Radioactive Sources, it has not yet expressed its political commitment to the supplementary Guidance on the Management of Disused Radioactive Sources.

(1)	 BASIS: GSR Part 1 (Rev.1) para. 3.2 states that "The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally 3.2. The features of the global safety regime include: (b) Codes of conduct that promote the adoption of good practices in the relevant facilities and activities".
(2)	BASIS: Code of Conduct on Safety and Security of Radioactive Sources para. 31 states that <i>"Every State should, as appropriate, inform persons involved in the management of</i> <i>radioactive sources, such as industry, health professionals, and government bodies, and the</i> <i>public of the measures it has taken to implement this Code, and should take steps to</i> <i>disseminate that information."</i>
S2	Suggestion: The Government should consider expressing its political commitment to the supplementary Guidance on the Management of Disused Radioactive Sources.

The legal framework for the fulfilment of commitments of Poland arising from international agreements concerning nuclear safety, radiation protection, nuclear security and safeguards is addressed in the Atomic Law Act (ALA). The ALA assigns obligations resulting from international agreements on nuclear safety and radiation protection to the President of PAA who is also responsible for their implementation. The PAA's international activities are performed in close cooperation with the Ministry of Foreign Affairs, and Ministry of Climate and Environment.

In the area of bilateral cooperation, Poland has established bilateral agreements on cooperation in nuclear safety and on early notification of a nuclear or radiation emergency with all neighbouring countries. Poland has also developed and maintains cooperation arrangements with several foreign regulatory authorities which cover the exchange of information on safety regulations, operational and regulatory experiences, licensing, etc. In the context of the PNP programme and following the selection of technology for Poland's

first nuclear power plant, the PAA has intensified and strengthened cooperation with the vendor country, the scope of which is elaborated in more detail under Module 12.

Poland participates in all IAEA Safety Standards and Nuclear Security Guidance Committees and WENRA working groups. The ALA stipulates that the IAEA Safety Standards and WENRA reference levels shall be addressed when developing or amending national legislation and regulations.

Poland has been actively participating in international peer reviews such as the IRRS, ARTEMIS, INSARR, IPPAS, SEED and INIR. The PAA is legally required to host international review missions periodically and participate in the EU topical peer reviews.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The PAA analyzes and collects operational and regulatory experience feedback (OEF) from various international networks and sources and uses the same channels to disseminate its own. PAA participates in the Incident Reporting System for Nuclear facilities of the IAEA (IRS), the European Clearinghouse, the OECD/NEA ConEx database and has bilateral interactions with other regulatory bodies. The OEF for research reactors is being collected by the National Centre for Nuclear Research (NCBJ) which participates in the Incident reporting System for Research Reactors (IRS-RR) database. Mutual exchange of information regarding the OEF between the PAA and the NCBJ is ensured by the means of regular interactions, as needed.

As a part of its management system, the process for the use of the international OEF is described in PAA's procedure on collection of information on incidents and accidents from international databases. Quarterly reports documenting outcomes and lessons learned from OEF are prepared and qualified accordingly by a dedicated team within the Department of Nuclear Safety and Security (DBJ), and subsequently submitted for the approval of the PAA President and distributed to the DBJ staff. However, the IRRS team did not identify a similar systematic process to analyse the domestic and international operating experience for radiation facilities and activities.

Overall, the PAA has a well-established process for collecting OEF, including the dissemination of lessons learned within the PAA, other relevant authorities and authorized parties. However, the process of tracking the follow-up measures taken in response to the information and data collected from international databases has not yet been formalized. The DBJ is currently working on the development of a database to collect all the analysed events in nuclear facilities along with conclusions, and to track the follow-up measures.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	Ation: While the PAA has a documented process in place to analyse domestic and international operating latory experience for nuclear facilities, no such process is in place for radiation facilities and activities.
(1)	BASIS: GSR Part 1 (Rev.1) Requirement 15 states that "The regulatory body shall make arrangements for analysis to be carried out to identify lessons learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities".
S 3	Suggestion: The PAA should consider developing a documented process to identify lessons learned from domestic and international operating and regulatory experience for radiation facilities and activities.
	tion: The process of tracking follow-up measures taken in response to information and data collected rnational databases has not yet been formalized.

(1) **BASIS: GSR Part 1 (Rev. 1) para. 3.5 states that** *"To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response*

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	to information received via national and international knowledge and reporting networks. Such measures could comprise promulgation of new regulatory requirements or making safety enhancing modifications to operating practices or to equipment in authorized facilities and activities. Such feedback provided in response to information received via international networks also covers description of good practices that have been adopted to reduce radiation risks."
S 4	Suggestion: The PAA should consider establishing a documented mechanism for tracking feedback and follow-up measures taken in response to information received via national and international knowledge and reporting networks.

2.3. SUMMARY

Poland is active in cooperation at the international level, both bilaterally and multilaterally. Poland is a signatory to all nuclear safety-relevant conventions and consistently participates in various bilateral and multilateral international cooperation initiatives. The PAA contributes to the effort of Poland to fulfil its respective international obligations, has an established presence at international level and gains significant experience from this to manage and further enhance its regulatory functions and responsibilities.

The PAA has a process in its management system to collect, analyse and review domestic and international OEF, including reflection on the outcomes and lessons learned from the OEF review in its regulatory actions. A systematic process of collection of OEF exists for the nuclear facilities, however, no such process is currently in place for radiation facilities and activities. The OEF process does not include a documented mechanism for tracking feedback and follow up measures taken in response to information received via national and international knowledge and reporting networks.

Poland has established sound processes to fulfil its international obligations in line with international agreements and cooperation. The PAA's proactive approach demonstrates its full commitment to support international cooperation at all levels.

3. **RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**

The IRRS team noted that the self-assessment does not specifically address responsibilities and functions of national authorities other than the PAA, which also perform regulatory functions. As a result, they were not included in the scope of the mission for this module.

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

The PAA's organizational structure is established by a statute issued by the Minister of Climate and Environment. The detailed structure describing the units under the departments and the detailed scope of responsibility of the different units is set by the PAA President's Regulations. PAA's organization includes seven departments: the Department of Nuclear Safety and Security, for the authorization, assessment and inspection of nuclear facilities and radioactive waste repositories; the Department for Radiation Protection, for the same tasks as above in relation to other activities and facilities using ionizing radiation; the Radiation Emergency Centre, in charge of national radiation monitoring and emergency preparedness; and four support and management departments, namely the Legal Department, the Budget and Financial Department, the Policy and International Cooperation Bureau and the Director General Bureau. The total number of staff is currently at 140, with 34 in the Department of Nuclear Safety and Security, 23 in the Department for Radiation Protection and 26 working in the Radiation Emergency Centre. The supporting processes related to budgeting, human resources, legal representation, as well as the management system are under the purview of the PAA's Director General.

According to the Polish legal and administrative system, the Polish nuclear regulatory authority is the PAA President. In exercising the regulatory functions assigned by the Atomic Law Act (ALA) the PAA President is supported by the whole PAA organization, yet all PAA regulatory authorizations and decisions require the signature of the PAA President. According to the ALA and the Code of Administrative Proceedings (KPA), the PAA President may delegate his/her authority to qualified persons among PAA staff. Some tasks have been delegated to the PAA Vice President (a position which has been vacant since March 22, 2023) and, as an additional example, the authorization of personnel in radiation protection has been delegated to the Department for Radiation Protection. In view of an expected increase in the facilities and activities under PAA regulatory oversight, the IRRS team concluded that a renewed reflection on further delegation framework would foster leadership for safety in the organization and free up managerial resources for more strategic tasks and developments. The IRRS team encourages the PAA to consider expanding the delegation of regulatory tasks and decisions, as appropriate, in accordance with a graded approach.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The government established the President of the PAA as the central nuclear regulatory authority (refer to Module 1 for a Recommendation related to independence of the PAA) with the responsibility to discharge its authority in such a way as to preserve effective independence. Consistent with this responsibility the President of the PAA has established a detailed organizational structure with clearly defined responsibilities for the different units. As civil servants, the staff is expected to adhere to the rules of the civil service and the principles of the civil service code of ethics. Further, a specific PAA safety policy has been issued requiring impartiality and integrity of all staff in the execution of their functions. All new recruits (not coming from within the Polish civil service) are initially hired under a one-year contract, during which they are trained to conduct their work in accordance with well-defined processes in the PAA's Integrated Management System. During this training, the new recruits learn what is expected from them as civil servants and what it means to be part of the PAA.

authorized party, a waiting period is required before the employee is allowed to participate in regulatory activities and decisions related to that authorized party that may pose a conflict of interest. Individualized training programs are established for new staff by their managers, normally after six to twelve months of their employment, and are periodically updated, as necessary. Competence of staff is a crucial element in achieving effective independence in decision making, so special attention is given to providing new inspectors with extensive training programs ranging from minimum six months for safeguards inspectors to 15 months for inspectors of nuclear facilities. Additionally, on-the-job training is provided to inspectors who may have to enforce measures on the spot during their inspection of an authorized party to address significant radiation risks (for improvements please refer to Module 8). Training ends with an exam which trainees must pass in order to become authorized regulatory inspectors.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

Human capital and financial resources are allocated to the PAA through the state budget for execution of the full range of regulatory tasks. In order to support the development of the Polish Nuclear Power Programme (PNPP), the PAA associated budgetary allocations have been increasing - in 2021 amounted to PLN 20.7 million, in 2022 to PLN 30.7 million and further increase took place in 2023 at the level of PLN 52.3 million. Annual and three-year financial plans exist for the effective allocation of resources.

Planning of competence and staffing needs is done using different budget lines. For example, the competence and resources plan for the PNPP project covers budget needs for regulatory activities in relation to the first two Polish sites, but the small modular reactor (SMR) project is budgeted separately. The IRRS team noted that a similar level of rigor in the planning of competences and staff needs does not exist for other existing regulatory activities including forecasted expected developments. The integration of all separated plans in an overarching human resources plan would allow a strategic approach for managing needs and resources across the whole organization. The overarching human resources plan could also be used, inter alia, to cope with observed increases in departure of qualified staff and internal rotations while promoting a more cohesive organizational growth (e.g. in relation to salaries) and regulatory safety culture.

The PAA is responsible for regulating radiation source facilities and activities and transport of radioactive material, with 7761 activities from 4895 authorized parties. The regulatory oversight activities for transport safety in Poland, includes 500 organizations that transport radioactive material with approximately 71,000 packages in 30,000 shipments yearly, of which around 12,000 shipments were of Type A packages. The PAA currently has 23 staff members of the Radiation Protection Department, 11 of which are authorized regulatory inspectors, to conduct its required regulatory activities. The IRRS team noted that the PAA should review if the level of the current available staff is adequate to effectively discharge its regulatory responsibilities in the area of radiation source facilities and activities and transport as well. In particular, the IRRS team noted that the authorization of transport has only one full-time staff resource and one other staff member with part time involvement in the transport authorization process. The same PAA member staff also carries out the review and assessment, inspection and enforcement regulatory oversight of transport safety. The IRRS team considered this to be an insufficient level of resources which should be increased to provide resilience, particularly as the one PAA staff member is responsible for all regulatory activities in transport.

The IRRS team noted that the PAA has had difficulty achieving the identified hiring needs for new staff and have only had moderate success despite the commendable efforts by the PAA. In 2022, 33 new hires were successful, but at the same time 16 staff left the PAA. In 2023 up to the time of the IRRS mission, there were 24 successful hires while 18 staff left the PAA. Although the loss of PAA staff due to attrition is in line with the average attrition (15 to 20%) in the Polish administration, as revealed by a survey, it appears that the adopted measures to account for the departure of staff from the PAA organization as a whole are not very effective, which makes reaching the target of 170 employees by the end of 2023 a significant challenge. The PAA needs to grow and adapt as a whole in order to effectively discharge its regulatory duties for the current and future facilities and activities it oversees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA does not have an overarching human resources plan for monitoring staffing needs and ensuring strategic management of resources so as to discharge its responsibilities and perform its functions effectively for all facilities and activities.

(1)	BASIS: GSR Part 1 (Rev.1) para. 4.11 states that "The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."
(2)	BASIS: GSR Part 1 (Rev.1) para. 4.12 states that <i>"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."</i>
R4	Recommendation: The PAA should establish an overarching human resource plan for monitoring competence and staff needs across its whole organization, enabling strategic management of resources, including the formulation of regulatory body budget needs.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The ALA regulates the tasks and duties of the Council for Nuclear Safety and Radiation Protection as the advisory body to the President of the PAA. The Council's tasks include providing opinions on licenses for activities involving exposure to ionizing radiation during the construction, commissioning, operation and decommissioning of nuclear facilities, opinions on draft legal acts as well as PAA President's technical and organizational guides, as well as proposing initiatives to improve the supervision of PAA. A regulation issued by the Minister of Climate and Environment sets out the working rules and honorary compensation of the Council members. The regulation states that under certain conditions, in order to avoid conflicts of interest, a Council member shall not participate in the vote on a Council's resolution. There are, however, no internal procedures with effective arrangements on the implementation of said rules. The IRRS team noted, that in case of a conflict of interest, the simple prohibition of voting on a Council's resolution is not sufficient to avoid undue influence on a specific dossier or may lead to gaining an unfair competitive advantage through knowledge of internal discussions on applications and draft decisions. As a result, more stringent arrangements would be necessary to fully address conflicts of interest.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The Council for Nuclear Safety and Radiation Protection does not have sufficient arrangements for avoiding cases of conflicts of interest of its members.

(1)	BASIS: GSR Part 1 (Rev.1) para. 4.20 states that "Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services"
S 5	Suggestion: The Government should consider establishing more effective provisions to ensure there are no conflicts of interest in the Council for Nuclear Safety and Radiation Protection.

The PAA has not required support by any technical support organization (TSO) for the regulatory activities on existing facilities and practices. However, a network of TSOs is being established anticipating the support needed to PAA for the Polish Nuclear Power Programme. The ALA requires the President of the PAA to conduct activities related to the supervision of nuclear power plants using only authorized laboratories and expert organizations. Authorized laboratories and expert organizations can be tasked specifically with assessment of the application for a licence related to the operation of a nuclear power plant, carrying out inspections at a nuclear power plant, issuing a general opinion on the planned organizational and technical solutions by an applicant, and issuing an advance opinion regarding the siting of a nuclear power plant. In order to be prepared for the construction license application to be submitted for the first nuclear power plant, the PAA has authorized nine TSOs (published on the PAA's website), one of which is an international expert institute. The authorizations are time-limited to provide the ability to periodically assess the TSO's ability to provide the necessary expertise. The process includes clear criteria that need to be met by a TSO to be authorized with special emphasis on conditions for avoiding conflicts of interest. Once the PAA decides that external services and expert opinions for a specific topic and task are needed, a public procurement process is initiated in accordance with the principles set out in the Public Procurement Law. The procurement contract includes a prerequisite that the authorization of the President of PAA must be obtained.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

In response to an applicant's request for a license or other administrative decisions, communication with authorized parties takes place in a formal manner according to the rules set out in the KPA. In particular, the public administration body, i.e. the PAA, may summon persons to participate in the undertaken activities and to submit explanations or testimonies in person, by proxy, in writing, and if it is necessary to settle the case, or to perform official activities. When all the conditions for making an administrative decision are met, a decision is issued. Formal communication is supported by expert meetings aimed at reaching a common understanding on safety-related issues as well as at getting feedback for improving the regulatory processes. Periodic meetings with licensees of nuclear facilities to discuss plans for the coming months and challenges related to the operation of the facilities are also organized. Additional technical meetings can be held, as necessary, on specific technical issues to foster understanding among experts. After these meetings, an information note with the most important outcomes is drafted to record the discussions.

The PAA focuses on the development of communication with authorized parties building stable relations with such parties based on open dialogue in full respect of the different roles. Communication is maintained at both expert and management levels.

The IRRS team met representatives from different authorized parties. These meetings provided an opportunity to hear the views of authorized parties on their interactions with the PAA, including their feedback on PAA's activities and decisions. The meetings confirmed that there is a professional and constructive liaison between the PAA and the authorized parties which contributes to achieve their objectives in ensuring safety.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The PAA established the basic principles of regulatory control in its Mission, Vision and Safety Policy. The implementation of such principles is detailed in the core processes of the PAA's Integrated Management System (IMS). The PAA's internal procedures and instructions are based on legal requirements, its own experience and international good practices. The procedures and instructions are structured in a similar manner with reference to the requirements forming the basis for the document, responsibilities, means and rules of executing the process, control points, required records, as well as a list of related documents. Core processes include: Developing regulations and guides, including in relation to technical guides issued by the President of PAA and drafting and consulting on governmental regulations; Authorization; Safety Assessment and Review; Supervision and Inspection and Enforcement; Coordination of the national radiation monitoring system; and Preparedness and Response for radiological emergencies. The procedures and instructions supporting these processes ensure that the core processes are implemented

to prevent subjectivity in decision making by individual staff members: PAA's decisions go through a quality assurance process according to different levels in the hierarchy, up to the signature of the President of the PAA. During the preparation of a decision, the case is also reviewed by the Legal Department. Decisions to authorized parties are always provided with justifications that can be more or less detailed depending on the routine aspects of the application and in accordance with a graded approach. A regulatory decision issued in the first instance by the President of the PAA cannot be appealed to another administrative body. A party dissatisfied with a decision may apply to the President of the PAA for reconsideration of the case. In accordance with the KPA rules of procedure, the President of the PAA tasks a different staff member to perform an independent review of the appealed matter before issuing the final decision. Such a final decision can be then brought to the Administrative Court for further judicial review. All steps leading to the final decisions are traceable and recorded in the electronic document management system of the PAA.

The preparation process of regulations includes consideration of whether a change to the regulations is justified, soliciting internal comments as well as the opinion of the Council for Nuclear Safety and Radiation Protection. Draft government documents and normative acts as well as guides of the President of the PAA are published on the PAA's website for consultation with interested parties including authorized parties.

3.7. SAFETY RELATED RECORDS

The management of safety-related records is subject to requirements set up by the ALA complemented by licence conditions established by the PAA on the activities and facilities it regulates. Except the records on radiological devices managed by the Chief Sanitary Inspector in a national database, the PAA maintains all records specified in GSR Part 1 (Rev. 1). For this purpose, the PAA manages several document depositories and databases according to the type of records. Such records are used by the PAA for example to verify that individual doses received from occupational exposure and other exposure situations comply with the statutory limits, but also in support of PAA's regulatory functions as data for the planning of inspections or for enforcement actions.

The PAA is required to keep safety related records for a period of at least 25 years and afterwards to send them to the Polish Archives for further safe keeping. The PAA's electronic document management system is being developed further as the PAA is considering more integrated record keeping for the future in light of the PNPP. For nuclear facilities there are strict requirements in the regulations on redundancy and design of storage against fire and flooding hazards.

At the same time, the licence holders are required to maintain their own records necessary for the safe operation of facilities and conduct of activities in compliance with the conditions imposed in the authorizations. This includes maintaining an inventory of radiation sources, and inventories of radioactive waste and spent fuel as well as records of doses from occupational exposure. Record keeping by the authorized parties is subject to PAA's regulatory inspections.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The duty of the PAA is to inform and consult interested parties about radiation risks associated with facilities and activities, as well as, about its processes and decisions.

A new, detailed communication strategy for the PAA was adopted in 2023, which identifies the interested parties of the PAA, including managers and employees of the authorized organizations; institutional partners of the PAA; political decision-makers; but also non-governmental organizations (NGOs), experts and think tanks; scientific communities; students and scientific circles active at technical universities; young people as future decision makers; seniors as mentors in their families; the members of the public and the media.

The communication strategy further details the key messages of the PAA and the means to reach out to the intended interested parties, including communication channels and opportunities for focused interaction

with some interested parties (e.g., so-called universities of the third age). Crisis communication is also covered by this strategy.

The PAA website is highlighted as the central platform for disseminating information and making the PAA wider known among the public. In this respect, the website has been developed in order to be user-friendly, and it is used to raise awareness of the public on matters related to ionizing radiation and on the role of the PAA as the regulatory body for the nuclear safety and radiological protection in Poland.

The PAA also communicates through social media. To improve its recruitment process and the staff management for the Poland Nuclear Power Programme (PNPP), the PAA created a LinkedIn account in 2021. For several years, the PAA has been present on X (formerly Twitter) and on YouTube. Videos and social campaigns have been conducted successfully, such as the campaign "Meet the radon" (https://www.gov.pl/web/poznajradon).

In order to improve competences in social communication and to meet the expectations of media and the society, the PAA staff are trained in the field of crisis communication, contacts with journalists and public appearances.

The IRRS team was informed that in the context of the situation in Ukraine due to the armed conflict, the PAA has increased its public communication from the very first day. The PAA contributes to press conferences, gives interviews on TV, radio and on social networks. In addition, the PAA publishes regular notices with detailed explanations of events at or near Ukrainian nuclear installations and facilities. Due to the growing demands, the PAA reports more frequently on the current radiation situation in Poland. The information on the PAA website in relation to the situation in Ukraine is recognized internationally by foreign radiation protection authorities as being very relevant and up to date and the IRRS team considered this as an area of good performance.

According to the ALA, the PAA is required to consult the public in the process of issuing a construction licence for nuclear facility. After receiving the application, the President of the PAA publishes it in the local press and in the Public Information Bulletin together with an abbreviated safety analysis report and other relevant information. For transparency the PAA is required to provide information in the license justification on the public participation in the process and on how the public comments have been addressed in the decision making. For the new nuclear power plants, the PAA plans to be more proactive in engaging with the public during the authorization process and intends to organize a series of meetings with the citizens of the preferred NPP location and nearby towns.

Anyone can submit a request to the PAA for disclosure of public information on activities within PAA's competence. Deputies and senators may also submit requests for explanation to the PAA, which must reply within statutory deadlines.

The ALA requires the authorized parties to inform the public on the radiation risks (arising from operational states and accidents, including events with a very low probability of occurrence) associated with the operation of a facility or the conduct of an activity. The IRRS team was informed that the applicant for the new nuclear power plants has engaged with the members of the public and local authorities in information exchanges, including a dedicated website.

3.9. SUMMARY

The IRRS team reviewed the responsibilities and functions of the PAA. The IRRS team identified some areas of improvement related to the establishment of an overarching human resources plan and more effective provisions for avoiding conflicts of interest in the Council for Nuclear Safety and Radiation Protection.

The PAA was also commended by the IRRS team for the extensive, relevant and timely crisis communication on radiation and nuclear emergencies in relation to the war in Ukraine, among others through the PAA website.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The IRRS team noted that the self-assessment does not specifically address the management system of the regulatory body of national authorities other than the PAA, which also perform regulatory functions. As a result, they were not included in the scope of the mission for this module.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The senior management of PAA includes the top management (the President, Vice President, and the Director General) and the directors. The whole PAA management team also comprises heads of units and team leaders.

The role of leaders is performed primarily by members of the PAA management team which are expected to have a leading role with respect to the safety culture.

The management has defined the PAA Mission, Vision and Values which are documented in the Integrated Management System (IMS) Manual and published on PAA's intranet.

The IRRS team noted that the Vision does not express clearly what the PAA desires to achieve in the longterm time frame of five to ten years. The PAA staff are bound by Ordinance of the Prime Minister on the guidelines for compliance with the rules of the civil service and on the principles of the civil service code of ethics.

In addition to the Safety Policy, the PAA has also developed amongst others:

- Policy of Counteracting Corruption and Conflicts of Interest in the PAA; and
- Information Security Policy.

The PAA policies, values and principles of ethics identify expected behaviours and principles that staff should apply in all day-to-day decisions and actions.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The PAA top management is responsible for establishing, applying, sustaining and continually improving the management system to ensure safety. It has appointed an IMS coordinator who is responsible for coordination and implementation of the management system. It has also appointed a representative for the Information Security Management System (ISMS).

The PAA senior management is accountable for the fulfilment of the Safety Policy, accomplishment of the PAA goals and targets and managing the organization using the IMS. The responsibilities of the senior management are described in the Organizational Regulations, the IMS Manual and complementary internal regulations.

The PAA goals, strategies, plans and objectives are being developed in consistency with the mandate, mission, and the Safety Policy of the PAA. Each year the PAA develops the PAA Action Plan with key measurable goals connected with the core tasks of the PAA. These goals result also from the Polish Nuclear Power Program (PNPP). On the basis of the Action Plan, departmental plans are developed. All goals and objectives are being reviewed regularly on the level of senior management and are reported quarterly to the top management. They are also discussed at the management meetings every two weeks. At least once a month directors of the departments meet with all employees of the department to discuss current issues, tasks and work plans of the department. The execution of the Action Plan including the achievement of targets set in the PNPP are additionally reported quarterly to the Minister of Climate and Environment. The actions necessary to address any deviations from these plans are being agreed at the PAA organisational

level, if appropriate, or by directors at the level of departments. The results and actions are also discussed and reviewed during the management meetings.

The PAA cooperates with several parties (institutions, organizations, and groups of people). The relations with interested parties is properly addressed in the IMS Manual and in the Communication Strategy. This ensures that an appropriate interaction with the interested parties is implemented.

The system which ensures a systematic approach to communication with interested parties is considered as a good performance.

4.3. THE MANAGEMENT SYSTEM

The PAA has established and implemented a process-based management system which integrates all functions and activities implemented by the PAA, namely, regulatory functions as well as managerial and administrative functions. The IMS is based on the IAEA GSR Part 2 and also covers the ISMS based on the PN-EN ISO/IEC 27001 standard.

In the IMS Manual, it is stated that the top management of the PAA is responsible for implementation, maintenance, as well as, for the review and improvement of the management system to ensure safety.

The PAA IMS is well documented. The structure of IMS documentation is described in the IMS Manual and consists of:

- level 1 documents, including: The Safety Policy, the IMS Manual (which sets up the PAA Mission, Vision, and Values); the Organizational Regulations, the PAA Communication Strategy, The PAA Process List and other policy documents;
- level 2 documents: orders of the PAA President and Director General, process descriptions and procedures;
- level 3 documents: instructions, guidelines, job descriptions;
- other documentation and records required in the IMS.

The principles of management of IMS documents are set in the IMS Manual. The process of issuance of procedures and instructions is coordinated by the IMS Coordinator and is regulated by the Procedure for IMS documents control. The process of issuance of internal legal acts is coordinated by the Legal Department and is regulated by the relevant order of the President of the PAA.

The required records for processes and actions are specified in the relevant IMS documents. The mode and manner of handling and archiving the documentation (records) is specified in detail in the internal legal acts - Office Instruction, Archive Instruction and additional complementary orders of the Director General introducing the electronic management of documents.

The Uniform Subject File Index (JRWA) contains a classification of documentation, division into subject groups and archival categories indicating the retention times of the documentation.

Need for changes is regularly discussed by the management team and decisions on significant changes in the organisation are made after consultations with the members of the management team and all involved in the change. Changes including organizational changes are captured in the IMS Manual. However, a documented process for managing changes has not been developed, yet.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA has made some provision in the Management System Manual to identify and manage changes, including organizational changes. However, a comprehensive documented process for managing changes is not in place.

	(1)	BASIS: GSG 12 para. 4.60 states that " <i>The need for changes may arise unexpectedly, and the regulatory body should put a process in place for managing organizational changes. This process should be established in the very early stages of the establishment of the regulatory body since changes often take place during the initial growth of a regulatory body.</i> "
	(2)	BASIS: GSG 12 II 24 states that " The process should ensure that the potential impact of proposed changes on the effectiveness of the regulatory body is systematically assessed. Changes should not be implemented without adequate review and should be modified (e.g. by means of compensatory measures) if they impact negatively on the effectiveness with which the regulatory body discharges its mandate."
	S 6	Suggestion: The PAA should consider establishing a documented process for managing changes including organizational changes.

4.4. MANAGEMENT OF RESOURCES

The PAA senior management is responsible for ensuring all necessary resources are available. The PAA has implemented the rules and processes for analysing, planning and providing the resources necessary to carry out its activities. They are based on and compliant with the legal requirements.

PAA resources are identified in the IMS Manual:

- human resources;
- financial resources;
- infrastructure and working environment;
- specialized/measurement equipment;
- information and knowledge.

The IRRS team noted that training of PAA employees is systematic. Currently the competences specific for the regulatory body are being determined with use of following methods:

- Systematic Approach to Training (SAT), and the SARCoN methodology Systematic Assessment of Regulatory Competence Needs;
- benchmarking and analysis with support of the regulatory bodies with advanced Nuclear Power Programme (with significant input from the regulator of country providing the technology for the first Polish nuclear power plant);
- analysis conducted by directors when formulating plans and detailed job descriptions for recruitment purposes.

The IMS and safety culture were subject of many internal training and meetings organized at different levels in the organization. They were conducted with the aim of acquainting the employees with the PAA management system and safety culture.

The general plans and assumptions for provision and development of competences needed for the purposes of the PNPP have been included in the Professional Development Programme which constitutes the component of the Development of Human Resources for the Purposes of the PNPP.

On the basis of identified competence needs, annual training program for whole organisation is established - covering national and international training courses as well as other activities needed to develop and increase the competence of the PAA staff.

The documents / information kept for the knowledge management reasons are specified and managed at the level of the organisational units. The key data is being entered into data basis and registers, if applicable. The documents, their copies or electronic versions are kept accordingly in order to serve as a reference and source of information.

The IRRS team was informed that the PAA has been developing and improving the process and tools for keeping knowledge. A team was appointed to redesign the intranet including solutions for knowledge management development.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

The PAA processes implementing the PAA mission are defined in the IMS manual and described in related organisational procedures. The list of PAA processes is a standalone document within the IMS and is included in the IMS manual. General descriptions of the PAA processes are prepared in electronic version (in the dedicated application). The processes are managed in the line with the Procedure for Management of Processes and Procedure of Control of Integrated Management System Documents.

PAA identified 8 operational, 3 management and 3 administrative processes. Descriptions of the processes include process owners, general safety goals, objectives, key interested parties, main inputs, outputs, specific resources and risks, general rules/criteria for application of graded approach, links and interactions and rules of control. Sub-processes are additionally visualised with diagrams showing sequences of actions, inputs, outputs and records. Diagrams show relations to other processes and IMS documents. The process owners are by the rule the Directors of the Departments, who also nominate the owners of subprocesses. Achievement of goals within the processes is supervised by the Directors on ongoing basis and also periodically reviewed by the management.

In the framework of the process review the process owners consider: indicators, analysis of achieved results non-compliances, risks, resources, interfaces with other processes, external interfaces, good practices and managing changes. All these data are addressed in the document Summary of Measurement and Review of Processes. Main conclusions are also included in a final report for the IMS review. Furthermore, top level indicators defined in this document are also included in the PAA Annual Plan.

Some operational processes are under revision now in order to reflect the changing requirements, needs and conditions connected with the implementation of the PNPP. The IRRS team was informed that some of the processes, such as Supervision and Inspection Process have been already finalized.

4.6. CULTURE FOR SAFETY

The PAA management specifies and promotes appropriate principles, values, attitudes and behaviours in order to foster a strong safety culture in the PAA. The basic principles and expectations are described in key IMS documents:

- the PAA Safety Policy; and
- the IMS Manual.

Safety culture is based on providing a proper work environment, in which both the management and the employees follow and practice proper principles, values, attitudes, behaviours, and relations. A common understanding of safety and safety culture has been fostered through meetings on all levels, trainings and workshops – both with internal and with the external experts.

The PAA implements internal training programmes on safety culture. General internal trainings are performed for all employees, and specific training for selected groups i.e. PAA management, inspectors, etc. General training for all PAA employees is organized at least once a year.

In order to ensure a systematic approach to enhancing safety culture, the PAA developed and has been implementing the action plans approved by the President of the PAA. The first Action Plan on strengthening safety culture in the PAA was developed in 2015. The latest Plan for years 2022-2023 was developed in 2021. These plans cover actions to train and engage employees in fostering the safety culture.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The PAA measures, assesses and improves the effectiveness of the management system with the use of several methods, namely:

- monitoring, self-assessment and review of the processes;
- internal quality (IMS) audits;
- internal ISMS audits;
- internal audits under management control;
- self-assessments of management control;
- ISMS reviews;
- IMS reviews.

PAA conducts internal ISMS audits and reviews separately from IMS audits and reviews. PAA intends to further integrate ISMS into the IMS.

Internal IMS audits are conducted every three years for each process. They are conducted in line with the PAA Procedure on Internal Audits of IMS. The procedure does not clearly state who defines the deadlines for solving non-compliances identified during the audit. The audit procedure defines that at the end of the year the IMS coordinator prepares a report on the implementation of the annual schedule of the audits. However, there is no provision to include the review of the unsolved audit observations within the deadlines in the report.

As defined in the IMS Manual, the PAA management performs a comprehensive review of the IMS once per year in order to verify its constant adequacy, effectiveness and efficiency, and to plan the most important actions and possible changes to the IMS.

In 2020 - 2022, formal IMS reviews were not conducted due to the pandemic circumstances (causing the workforce shortages) and intensive works on organisational initiatives, changes and projects - including those related to the implementation of the PNPP and the ISMS. The IMS reviews in this period were based on the conclusions from the management control self-assessments, risk management reviews, reports on targets achievement and regular reporting of the IMS tasks and issues to the management. All these issues were discussed during biweekly management meetings.

In 2023 the management system review was again conducted, however, the IRRS team noted that the management system review programme did not foresee discussion on the feedback from operating and regulatory experience.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	Ation: The PAA Integrated Management System Manual does not address feedback from operating ce and regulatory experience during the management system review.
(1)	 BASIS: GSG 12 para. 5.48 states that "The integrated management system review should cover all significant sources of information on performance, including the following: Outputs from different forms of assessment, including self-assessments of senior management itself; Results delivered and objectives achieved by the regulatory body and its processes and activities; Non-conformances and the progress and effectiveness of corrective and preventive actions; Feedback from operating experience, including lessons learned and good practices from other organizations; Opportunities for improvement."
S7	Suggestion: The PAA should consider using feedback from operating experience and regulatory experience for the management system review.

Every year the PAA conducts self-assessment of the IMS through Management Control Self-Assessment according to the legal requirements. The self-assessment questionnaire covers all aspects of IMS as well as some aspects of leadership for safety and safety culture. The results of this assessment are published in the Intranet and discussed at the management meetings and at the meetings with employees.

The PAA started with some activities for performance of self-assessment of safety culture. However, the self-assessment has not been performed in a comprehensive way. IRRS team noted there is no requirement in the IMS Manual or procedure in IMS documentation for self-assessments of leadership for safety and of safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA does not have a documented process for systematically assessing leadership for safety and safety culture. The PAA has not conducted any systematic assessments.

(1)	BASIS: GSR Part 2 Requirement 14 states that <i>"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization."</i>
(2)	BASIS: GSG 12 para. 3.9 states that <i>"The regulatory body should establish and maintain a programme to develop, foster and evaluate its safety culture. Such a programme should include safety culture self-assessments, workshops and seminars for defining improvement programmes, as well as training and support."</i>
R5	Recommendation: The PAA should establish a documented process of conducting assessment of leadership of safety and of the safety culture in its management system, and should regularly conduct such assessments.

4.8. SUMMARY

The PAA management system is well established, documented and implemented based on a process approach which integrates all PAA functions and activities. A part of the IMS is also the ISMS. The IMS documentation is comprehensive, well organized and periodically reviewed. All management system documents are available on the Intranet. Some of the PAA processes are under revision in order to fulfil changing requirements, needs and conditions connected with the implementation of the PNPP.

The PAA has developed a Safety Policy which also includes provisions related to safety culture policy. Several activities have been conducted to promote a culture for safety at all levels in the organization. However, a comprehensive self-assessment on culture for safety was identified as an area for improvement of the PAA IMS.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Legal authority to issue authorizations and binding opinions and to exercise regulatory control over facilities and activities in Poland is given to the authorities indicated in the Atomic Law Act (ALA).

An authorization can only be granted when the applicant demonstrates the fulfilment of all the relevant requirements set forth in the ALA and associated regulations.

The ALA lists the facilities and activities and the specific stages that require authorization. Licenses are issued for an indefinite period unless the applicant specifically applies for a defined period. Modifications in the authorized activities require an application for a modified license, following the same process. Provisions to revoke a license are in place.

Roles and responsibilities of the authorities with regulatory responsibilities are assigned in the ALA. Regarding notification and authorization, they are described as follows:

- The National Atomic Energy Agency (PAA) President issues registrations and licenses, and receives notifications for all facilities and activities, with the exception of those authorized by other authorities (a detailed list is contained in the ALA).
- State Regional Sanitary Inspectorate (WSSE) issues licenses for:
 - commissioning and/or use of X-ray devices in a medical X-ray facility and commissioning of such laboratories;
 - commissioning and/or operation of X-ray devices for the purposes of diagnostic or interventional radiology practices, superficial radiotherapy or non-oncological radiotherapy outside an X-ray facility;

and receives notifications regarding activities that involve exposure to natural ionizing radiation in workplaces, not subject to supervision by mining supervisory authorities.

- Military Preventive Medicine Centre issues licenses for health care units supervised or established by the Minister of National Defence:
 - commissioning and/or use of X-ray devices in a medical X-ray facility and the commissioning of such laboratories,
 - commissioning and/or operation of X-ray devices for the purposes of diagnostic or interventional radiology practices, superficial radiotherapy or non-oncological radiotherapy outside an X-ray facility.
- Regional Mining Authority –receives notifications regarding activities that involve exposure to natural ionizing radiation in workplaces subject to supervision by mining supervisory authorities.

In addition to the provisions on cooperation set out in the ALA, there are a number of agreements for cooperation between the PAA and other entities participating in the authorization process.

In accordance with the graded approach, activities require different levels and types of authorizations to issue licences for various stages of a facility's life cycle. In the case of the PAA, authorizations are granted through registration and licensing. The other above-mentioned authorities use only licensing.

The use of registration and licensing by PAA ensures that a graded approach is used for authorization by specifying different requirements and documents to be submitted by the applicant in each case.

Activities of the PAA President and other authorities with regulatory responsibilities that are part of the public administration are regulated by the Code of Administrative Procedure (KPA). The Code determines

the method for proceedings, including regarding the participation of the involved parties and the access to collected information and documents. The KPA also provides mechanisms for ensuring adequacy and legality of the decisions made by such authorities. The obligations established by the provisions of the Code are taken into account in the PAA's internal procedures.

The ALA provides legal requirements for the content of a notification or an application for authorization. Additional requirements are provided in a regulation that provides a comprehensive list of documents required to submit an authorization request for activities that involve exposure to ionizing radiation or to report such activities for registration. No detailed guidance is given on the content of the documents to be submitted.

In the case of the PAA, the procedure for authorization requires a review of the application for completeness, then a review of the content of the documents supporting the application by a staff member assigned by a director of department at PAA. The IRRS team observed that the existing procedures at the PAA or GIS for evaluation of the application describe the administrative processes, but do not provide detailed acceptance criteria and do not grade the evaluation effort based on the type of facility or activity. This issue is further addressed in Recommendation R12 in Section 6.1.4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The GIS and PAA, within the scope of their responsibilities, have not issued guidance for the applicants for authorization of facilities and activities with radiation sources and transport of radioactive materials depending on the type of facility or activity that are specific to each practice.

(1)	BASIS: GSR Part 1 (Rev.1) para. 4.34 states that <i>"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization."</i>
(2)	BASIS: GSG-13 Functions and Processes of the Regulatory Body for Safety para. 3.141 states that "Essential documents to be prepared by the authorized party in the authorization process should be identified in the regulations and their content should be described in guides issued by the regulatory body. Additional documents may be requested as necessary, depending on the type of facility or activity concerned, and on the specific step of the authorization process."
(3)	BASIS: GSG-13 Functions and Processes of the Regulatory Body for Safety para. 3.93 states that "Principles for authorization should be established in the regulatory and legal framework. Examples of principles for authorization include the following:(f)A graded approach should be taken by the regulatory body when performing reviews, assessments or inspections throughout the authorization process."
R6	Recommendation: The PAA and GIS should, within the scope of their responsibilities, establish guidance for the applicants for the authorization processes of facilities and activities with radiation sources and transport of radioactive material, specific to the type of facility or activity in accordance with a graded approach.

The authorizations issued by the PAA generally are considered final and are not limited in time. There are provisions in place to revoke a licence, but the conditions of the licence cannot be modified unless there is consent by the authorized party. For nuclear facilities and radioactive waste repositories, ALA has a provision that allows PAA's President to change the conditions in a license, but such provision does not exist for facilities or activities only using radiation sources. Up to the time of the IRRS mission, the PAA has not used this kind of process before.

The IRRS team noted that the amendment to an authorization, such as a modification of its conditions may be needed for a number of circumstances, including, but not limited to, operating experience from the facility or activity or from other facilities, international operating and regulatory experience, technological changes, information of research and development relating to radiation safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA has no authority to amend issued licenses for facilities and **activities other than nuclear facilities and radioactive waste repositories** on its own initiative in the interest of safety without the documented consent from the authorized party.

	(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.36 states that "An authorization may have to be reconsidered and/or renewed in the different stages in the lifetime of the facility or the duration of the activity concerned (e.g. as a result of a change in the conditions under which the authorization was granted). This would have to lead to a new regulatory decision which may require the amendment, renewal, suspension or revocation of the authorization."
	(2)	BASIS: GSG-13 Functions and Processes of the Regulatory Body for Safety para. 3.142 states that " A request for an amendment may be initiated by the authorized party, or an amendment may be imposed by the regulatory body in the interest of safety"
	R7	Recommendation: The Government should revise legislation to provide the PAA with the authority to amend issued licenses for <i>facilities and</i> activities other than nuclear facilities and radioactive waste repositories on its own initiative without the documented consent from the authorized party.

5.2. AUTHORIZATION OF RESEARCH REACTORS

The authorizations of research reactors, which are categorized as nuclear facilities, are subject to the ALA, including the steps of the authorization process, i.e., construction, commissioning, operation and decommissioning.

According to the ALA, the Council of Ministers is responsible for establishing regulatory requirements for commissioning and operation of nuclear facilities, including research reactors. The ALA specifies the process and type of conditions that can be included in the different licences and gives authority to PAA to revoke the licenses and to amend the conditions attached to a licence.

When applying for authorization for any stage of the life of a nuclear facility, the ALA requires the applicant to submit supporting documents for the application. The scope and the way that the safety analyses are to be conducted in preparation of the application, as well as the scope and content of the preliminary safety analysis report, are defined by regulations.

Authorization for modification or modernization of research reactor structures or systems or components (SSCs) important for safety, as well as start-up of a research reactor after shutdown due to modification or modernization, require written consent from the PAA.

The IRRS team noted that there is no regulatory requirement for establishing a safety committee to advise the operating organization on all the safety aspects of the research reactor. However, MARIA research reactor has established such a committee. The IRRS team reviewed a report prepared by the licensee submitted to the PAA by MARIA's organization in support of the application for upgrading electrical components. The IRRS team noted that the report had been reviewed and approved by the safety committee.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *MARIA* research reactor has an independent safety committee; however, the establishment of a safety committee is not a regulatory requirement.

(1)	BASIS: SSR-3 Requirement 6 states that "A safety committee (or an advisory group) that is independent from the reactor manager shall be established to advise the operating organization on all the safety aspects of the research reactor."
S8	Suggestion: The Government should consider establishing a requirement for a safety committee for research reactors.

According to the ALA, the PAA has the duty to oversee the competence of employees responsible for ensuring nuclear safety and radiation protection. Under the ALA, the PAA president licenses positions important to safety in research reactors. Licences are issued after the applicants have successfully completed the required written and oral exams. The ALA establishes provisions to revoke these licences.

To support the conduct of licensing activities, the PAA has two internal procedures:

- 1. Procedure 001/DBJ for Issuing Licenses for Activities Related to Nuclear Facilities Nuclear Safety and Security Department;
- 2. Procedure P03/PO 1.1 for approving The Modernization or Modification of a Nuclear Facility and Approving the Reactor's Restart Following Modernization or Modification.

These procedures describe the administrative steps for authorization, including the preparation of the request for additional information and final decisions.

In 2015, the PAA granted to MARIA research reactor a ten-year operation license, to allow its operation up to 2025. Renewals of the operation license have to go through the same process which was used for the issuance of the first license as prescribed by the ALA. At the time of the IRRS mission, the operation license had been amended 8 times since 2015.

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The National Radioactive Waste Repository disposal facility Różan is the only disposal facility currently in operation in Poland. It is a near surface repository intended for disposal of short-lived, low and medium level radioactive waste with half-life of radionuclides shorter than 30 years. It is also used to store long-lived waste, mainly alpha-radioactive, as well as spent sealed radioactive sources waiting to be placed in a deep geological repository. Every year it receives about 35 m³ of solidified, compacted low and medium level radioactive waste.

The lifespan of the disposal facility is divided into four phases: the construction phase, operational phase, closure phase and post-closure monitoring phase (that should not last more than 300 years), and the release of the site from regulatory control.

ALA requires the development of a programme for closure of the repository facility before a license for its construction or operation of the radioactive waste repository is granted. An authorization will be needed for the closure. A plan for the institutional active control of the National Radioactive Waste Repository disposal facility over a maximum of 300 years will be required in the closure declaration. The transition period to a passive state will be defined in the authorization.

In Poland, radioactive waste is generated as a result of activities using radioactive sources in medicine, industry and research entities, as well as during the operation and decommissioning of the two research reactors. Most of the radioactive waste is categorized as low-level waste based on the radioactive concentration of radioactive isotopes contained in this waste. The receipt, transport, processing, storage and

disposal of radioactive waste produced in the country, as well as the storage of spent nuclear fuel, are handled by the ZUOP, which receives approx. 40m³ of solid waste and approx. 30m³ of liquid waste per year.

The authorization process for radioactive waste management facilities is similar for the authorization of nuclear facilities although different in terms of the additional technical requirements that must be fulfilled by waste management facilities as described in the regulation on radioactive waste and spent fuel. The IRRS team noted that there is specific regulation in terms of the contents of the documents related to the authorization process for radioactive waste management facilities. However, there is no prescribed format in the guidance.

Regarding the storage of spent nuclear fuel, there are two wet storage facilities (No. 19 and 19A) that were primarily for the needs of EWA and MARIA research reactors. Currently, the facility No.19A is used as a back-up in case there is a need to store spent fuel from MARIA research reactor while storage facility No.19 is used to store solid radioactive waste and high-level disused sealed radioactive sources.

The PAA has not approved which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA has not approved which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control.

(1)	BASIS: GSR Part 3 Requirement 8 states that " The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared form regulatory control.
(2)	BASIS: GRS Part 3, para 3.12 states that "using as the basis for such approval with the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of this criteria."
R8	Recommendation: The PAA should establish criteria for clearance for materials and objects, within notified practices or authorized practices that may be cleared from regulatory control.

5.4. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Under Polish legislation, authorization is required for the operation of radiation source facilities and the conduct of activities with radiation sources. A list of activities which are subject to license, either registration or notification, is set out in regulations depending on the risk and radiation doses involved, according to a graded approach.

An agreement has been established between the PAA and GIS to manage the coordination between them. This issue is further discussed in Suggestion S17 in section 7.4.

There are provisions in the regulations for the exemption from regulatory control of very low hazard sources. However, clearance criteria have to be clearly established. This issue is addressed in Recommendation R8 in Section 5.3.

ALA sets legal requirements for notification and for the application for an authorization. The regulations list the documents needed, but do not provide detailed requirements for their content. As discussed in Section 5.1 and addressed in Recommendation R6, PAA's authorization procedure requires to check the application's completeness, but does not provide detailed guidance and criteria to review and assess the content of the supporting documentation.

Modifications in the authorized activities require an application for a modified license. ALA states that in the case of the modification of a license the provisions of the issuance of a license shall apply accordingly to the scope of the modification. Since there is no further regulatory development of these provisions for facilities and activities that involve radiation sources, the modifications should follow the same process that was followed for the original licence. The applicant is typically required to send only the documentation needed according to the extent and impact of the modification. However, this is done on a case-by-case basis without a documented procedure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA does not have any guidance for the authorized person and no internal procedure on how to process amendments to authorization of facilities and activities that involve radiation sources.

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.37 states that "Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure, and shall make provision for the timely submission of applications for the renewal or amendment of the authorization."
S9	Suggestion: The PAA should consider establishing procedures and associated guidance for the amendment of authorizations of facilities and activities that involve radiation sources, and making provision for the timely submission of such applications.

Authorizations, unless otherwise requested by the applicant, have no time limit but they can be revoked by the PAA. The PAA cannot amend a license without the licensee's consent. This is addressed in Recommendation R7 in section 5.1.

As stated above, the legislation provides a detailed list of the documents needed for the submission of an application for authorization for an activity or facility that uses radiation sources. Although the list of documents covers most of the information needed to perform a safety assessment in line with GSR part 4, considering a graded approach, a comprehensive safety assessment is not clearly specified. Nonetheless, in the regulations nor in PAA's procedures for review and assessment of radiation source facilities and activities, there is no requirement to conduct a safety assessment. The regulations and PAA internal procedures do not regard the safety assessment as a critical element to determine the limits and conditions for operation throughout the lifetime of a facility or activity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Although the regulatory body reviews the applicants' documentation, there is no requirement for applicants for authorizations of radiation source facilities and activities to conduct and submit a comprehensive safety assessment. There is no regulatory process to conduct the review and assessment of the submitted safety assessment.

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.33 states that "Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."
(2)	BASIS: GSR Part 3 para. 3.29 states that <i>"The regulatory body shall establish requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct an appropriate safety assessment. Prior to the granting of an authorization, the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body."</i>
(3)	BASIS: GSR Part 4 para. 5.4 states that "The safety assessment provides one of the inputs

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	to the definition of the limits and conditions that are to be implemented by means of suitable procedures and controls. These procedures and controls shall include a means for monitoring to ensure that the limits and conditions are complied with at all times."
R9	Recommendation: The Government should establish a requirement for the applicants for authorization of radiation sources facilities and activities to submit a comprehensive safety assessment, and the PAA and GIS should establish a regulatory process to conduct its review and assessment.

5.5. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

The general regulatory requirements for the decommissioning of nuclear facilities are covered in the ALA and subsequent regulations, which include provisions for the head of the organizational entity performing exposure-related activities involving the decommissioning of a nuclear facility to prepare a nuclear facility decommissioning report to be submitted to the President of the PAA for approval by the deadline stated in the license for nuclear facility decommissioning.

Furthermore, ALA makes provisions for the nuclear facilities to ensure nuclear safety and radiation protection of workers and the public at the decommissioning stage and for the operators to prepare a decommissioning programme for the nuclear facility.

The authorization process for decommissioning of radioactive waste management facilities is similar to the authorization of nuclear facilities although different in terms of the additional technical requirements, as described in the regulations on radioactive waste and spent fuel.

The IRRS team noted that while there are provisions in the regulations for decommissioning in terms of the process, document and contents of the documents needed to support the authorization process for decommissioning of facilities, the regulations do not establish criteria for the termination of the authorization for decommissioning authorization, including radiological criteria.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: While there is a decision to remove the facilities from authorization after decommissioning, there is no specific requirement nor criteria established that is used to guide the process of termination of authorizations for decommissioning of nuclear facilities.

(1) **BASIS: GSR Part 6 para. 3.3 states that** "... The responsibilities of the regulatory body shall include establishing requirements and criteria for termination of the authorization for decommissioning and especially when facilities and /or sites are released with restrictions or their future use."

R10 Recommendation: The Government should include in regulations requirements and criteria for the termination of the authorization for decommissioning of nuclear facilities.

5.6. AUTHORIZATION OF TRANSPORT

As a member of the European Union, Poland is required to adopt the European Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods. In doing so, Poland has adopted the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for the transport of dangerous goods by road, European Agreement concerning the International Carriage of Dangerous Goods by Rail (RID) for the transport of dangerous goods by rail, and The European Agreement concerning the International Carriage of Dangerous Goods by rail, and The European Agreement concerning the International Carriage of Dangerous Goods by rail, and The European Agreement concerning the International Carriage of Dangerous Goods by rail, and The European Agreement concerning the International Carriage of Dangerous Goods by rail, and The European Agreement concerning the International Carriage of Dangerous Goods by rail, and The European Agreement concerning the International Carriage of Dangerous Goods by rail, and The European Agreement concerning the International Carriage of Dangerous Goods by rail, and The European Agreement concerning the International Carriage of Dangerous Goods by

Inland Waterways (ADN) for the transport of dangerous goods by inland waterway, which set out the requirements for the transport of radioactive material.

ADR, RID, and ADN are reviewed, revised, and published on a 2-year cycle and adopts the latest revision of the UN Model Regulations, which in turn adopt the latest published edition of IAEA SSR-6. Consequently, The UN Model regulations, ADR, RID, and ADN currently reflect IAEA SSR-6 (Rev.1).

The transport regulations for transport of radioactive material by air and sea modes are managed by the International Civil Aviation Organization (ICAO) and the International Maritime Organization (IMO) respectively, both organizations are Agencies of the UN. The transport regulations of ICAO and IMO are mandatory on a global basis.

The ICAO and IMO are reviewed, revised, and published on a 2-year cycle, each the latest revision of the UN Model Regulations, which in turn adopts the latest published edition of IAEA SSR-6. In addition, SSR-6 (Rev.1).

The PAA uses ADR, RID, ADN, ICAO, and IMO regulatory requirements to define the scope of requirements of the Authorization process for transport, which includes compliance with requirements for training, quality management, documentation, package design, placarding, marking, and labelling, consignments, and conveyance placarding.

The authorization of package designs is the responsibility of the Radiation Protection Department which uses the ALA Chapter 8 as a procedure. However, there are no PAA procedures for the package design authorization process. This issue is addressed by Recommendation R6 in Module 5.1.

The authorization process for transport safety reflects the number of licensees and transport activity in Poland in 2022, namely:

- Some 500 organizations that transport radioactive material;
- Approximately 71 000 packages in 30 000 shipments were completed, of which approximately 12000 shipments were of Type A packages;
- 111 transport facility inspections were completed, the employee responsible for package design authorization was included in the inspection team;
- The one staff resource for package design authorization is also involved in general authorization in industrial and research applications, and maintenance of the national registry of radioactive sealed sources.

The IRRS team considers this low level of resources should be increased to provide resilience in the areas of package design authorization, review and assessment, inspection of facilities with respect to transport, the assessment and inspection of the response of licensees to the enforcement notices, involvement in general authorization in industrial and research applications, and maintenance of the national registry of radioactive sealed sources. This issue is covered by Recommendation R4 in Module 3.3.

Records are kept by PAA concerning applications for transport authorization.

No guidance document has been issued to applicants regarding the authorization process for the transport of radioactive materials. This issue is covered by R6 in Module 5.1.

Poland has made the political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance on the Import and Export of Radioactive Sources. A Point of Contact to facilitate import and export of radioactive sources in compliance with the Guidance is assigned in the PAA. In particular, the Code of Conduct and its supplementary Guidance include provisions on the exchange of information between the States in the case of import and export of radioactive sources and IAEA developed forms for such information exchange.

There are no PAA internal procedures that fully implement provisions of the Guidance including the request for consent for the categories 1 and 2 radioactive sources when authorizing export. This issue is covered by Recommendation R6 in Module 5.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Sources.	tion: Poland has made the political commitment to the Guidance on the Import and Export of Radioactive There are no internal procedures that implement provisions of the Guidance such as request for the or the category 1 radioactive sources when authorizing the import and export of radioactive sources.
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 14 states that "The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally."
(2)	BASIS: Code of Conduct on the Safety and Security of Radioactive Sources states that <i>"23. Every State involved in the import or export of radioactive sources should take</i> <i>appropriate steps to ensure that transfers are undertaken in a manner consistent with the</i> <i>provisions of the Code and that transfers of radioactive sources in Categories 1 and 2 of Annex</i> <i>1 of this Code take place only with the prior notification by the exporting State and, as</i> <i>appropriate, consent by the importing State in accordance with their respective laws and</i> <i>regulations.</i>
S10	Suggestion: The PAA should consider establishing the internal procedure that implements provisions of the Guidance on the Import and Export of Radioactive Sources.

The IRRS team noted problems regarding the PAA ability to issue amendments to authorizations. This issue is covered by Recommendation R7 in Module 5.1.

5.7. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The ALA provides that activities involving exposure shall be performed such was as to ensure that the number of exposed workers and other workers (who are considered as members of the public) and the probability of their exposure are kept as low as reasonably achievable with reasonable consideration of economic and social factors as well as the current state of technical knowledge in accordance with the principle of optimization and in compliance with dose limits.

Registrants and licensees are required to carry out an assessment of the exposure of workers and to establish the corresponding dose constraints (usable dose limits). Dose constraints for occupational exposure proposed by the applicant for an authorization are reviewed by the authority that issues the authorization. Dose constraints may also be established by the relevant authority as conditions of the license.

Responsibility for categorization of exposed workers to categories A or B, in accordance with EU Directive definitions, is assigned to the registrants or the licensees. Workers may also be classified as members of the public. Registrants and licensees are also required to establish controlled and supervised areas, and for creating and maintaining a register of individual doses of workers. Doses received by category A workers are reported to the National Dose Registry (CRD) maintained by PAA.

Assessment of worker exposure is carried out through individual dose measurements and through workplace monitoring.

There are provisions for legal metrology of dosimetry instruments to be carried out with traceability to primary standards. Accreditations according to ISO/IEC standards, for individual monitoring and calibration services are carried out by the Polish Accreditation Centre (PCA). PAA is part of the Polish

Committee for Standardization (PKN)advisory group that reviews new international standards before they are introduced in Poland. However, there are no requirements for PAA involvement to authorize these services. This issue is addressed by Suggestion S1 in section 1.9.

Requirements for controlled and supervised areas are established in regulations, generally in line with provisions from GSR Part 3. However, these regulations do not require that persons under the age of 18 years can only be allowed to access controlled and supervised areas under supervision. This issue is addressed by Recommendation R18 in Section 9.1.

The dose limits for exposed workers, students and apprentices, as well as additional dose restrictions for a female worker who has notified pregnancy or is breast feeding, are consistent with IAEA standards. Provisions for protection of external workers are also in place.

In addition to the ALA, provisions concerning the rights and obligations of workers are complemented by those established in the Labour Code.

The role of the Radiation Protection Expert (designated in the legislation as Radiological Protection Inspector) of the licensee and his specific duties are established in the ALA.

The concept of safety culture is established in ALA regarding nuclear facilities. However, it does not apply to workers of radiation sources facilities and activities. This issue is addressed in Recommendation R15 in Section 7.1.

Provisions for health surveillance of exposed workers are established in the Labour Code. In order to initiate radiation work, a certificate of no contraindications issued by a physician with appropriate qualifications in occupational medicine is required. The necessary qualifications of the authorized physician in occupational medicine as well as the types and frequency of health examinations of exposed workers are specified in the corresponding provisions of the Labour Code.

For existing exposure situations, the ALA establishes that work in workplaces in which, despite actions taken in accordance with the principle of optimisation, the indoor radon concentration exceeds the reference levels is subject to notification. Work in underground workplaces in which, despite actions taken in accordance with the principle of optimisation, the level of potential alpha energy concentration of short-lived decay products of radon indicates a potential for the worker to receive an effective dose of more than 1 mSv (millisievert) per year is also subject to notification.

5.8. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

Authorizations for medical use of x-ray generators are issued by the State Regional Sanitary Inspector (WSSE). The elements required for such authorization include:

- technical documentation, the user manual and information on exposure, proper use, testing and maintenance,
- information on patient risk assessment and available clinical evaluation elements of the equipment,
- quality assurance program,
- number of appropriately qualified staff,
- training program in the field of radiation protection for exposed workers,
- the instructions should contain detailed rules of conduct in the field of radiological protection of employees and patients,
- acceptance tests and basic and specialized tests of radiological and auxiliary equipment.

After ensuring that the content of the documents submitted by the applicant is sufficient to verify that the safety requirements have been met, an inspection may be carried out. Afterwards, WSSE issues an administrative decision authorizing the practice.

Medical physicists are responsible for the optimization of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels; the definition of quality assurance criteria of the medical radiological equipment; the preparation of technical specifications for medical radiological equipment; the selection of equipment required to perform radiation protection measurements and the analysis of events involving, or potentially involving, accidental or unintended medical exposures.

The IRRS team was informed that the number of medical physicists in the country is insufficient to fulfil the updated requirements of ALA, especially in the areas of nuclear medicine and diagnostic radiology.

During the site visit to a radiotherapy department of Maria Sklodowska-Curie National Research Institute of Oncology, the IRRS Team was informed by the hospital representatives that one factor to explain the low number of medical physicists is the high cost of the training programme that is borne directly by the students. The hospital representatives also highlighted challenges for recruitment staff to fulfill other competences. This has forced the hospital to train the staff in-house.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The number of medical physicists in diagnostic radiology and nuclear medicine is not sufficient for the needs of the country.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 11 states that <i>"The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."</i>
(2)	BASIS: GSR Part 3 para. 2.41(d) states that "Other parties shall have specified responsibilities in relation to protection and safety. These other parties include: (d) Medical physicists;"
S11	Suggestion: The Government should consider further developing the strategy for ensuring that the number of medical physicists covers the country's needs.

5.9. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

Polish legislation requires optimisation of public exposure to be subject to regulatory control. Dose limits and dose constraints in planned exposure situations and reference levels in emergency and existing exposure situations for members of the public are set in legislation. The application for authorization of facilities and activities to be submitted to the regulatory body should comprise the assessment of doses of the members of the public. However, there is no provision in the legislation requesting the person or organization responsible for a facility or activity that gives rise to radiation risks to conduct a comprehensive safety assessment of radiation sources facilities and activities to support the application for authorization. This issue is addressed in Recommendation R9 in Section 5.4. Moreover, there is no guidance for applicants regarding the form and content of the safety assessment as a part of an application for authorization.

Dose constraints of members of the public are set in the authorization process of the PAA. The President of PAA can impose dose constraints for the public exposure which are different from those proposed by the applicants. The regulations do not provide criteria to be used for defining dose constraints for public exposure by the President of the PAA in the authorization process. The IRRS team also noted that shared responsibilities for authorization of radiation sources facilities and activities among different competent authorities require cooperation in order to assure that members of the public subject to exposure from

facilities and activities authorized by different competent authorities do not exceed dose limits and their radiation protection is optimized.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	ion: Regulations do not include complete set of criteria to be taken into account when establishing dose s for public exposure in authorization process or any subsequent updates.
(1)	 BASIS: GSR Part 3 para. 3.120 states that "The government or the regulatory body shall establish or approve constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public. When establishing or approving constraints in respect of a source within a practice, the government or the regulatory body shall take into account, as appropriate: a) The characteristics of the source and of the practice that are of relevance for public exposure; b) Good practice in the operation of similar sources; c) Dose contributions from other authorized practices or from possible future authorized practices, estimated at the design and planning stage, so that the total dose to members of the public is not expected to exceed the dose limit at any time after the start of operation of the source; d) The views of interested parties."
R11	Recommendation: The Government should develop a complete set of criteria to establish dose constraint for public exposure in authorization process or any subsequent updates.

An authorization of discharges from facilities to the environment are issued by the PAA. The lack of guidance regarding the use of clearance levels to release radioactive materials from regulatory control is addressed in Recommendation R8 in Section 5.3.

The source monitoring and environmental monitoring conducted by registrants and licensees are subject to authorization. The scope of the monitoring programmes is given in regulations and registrants and licensees are obliged to develop and implement those programmes. The PAA is developing technical guidance to be used by registrants and licensees on performing monitoring programmes in order to assure adequacy and quality of monitoring programmes since regulations do not specify conditions for conducting such monitoring.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: There is no guidance for specific conditions related to source monitoring and environmental monitoring to be addressed in quality assurance programme of registrants and licensees.	
(1)	BASIS: GSG-9 para. 5.82 states that "The operating organization should establish an appropriate quality assurance programme covering the control of discharges and the monitoring programme. The programme should set out the corrective actions that should be taken in the event that deficiencies in control and monitoring are identified. It should cover both sample collection and measurement."
(2)	 BASIS: GSG-9 para. 5.83 states that "Measures to satisfy the following specific conditions should be incorporated into the quality assurance programmes, as relevant: a) Requirements relating to source monitoring and environmental monitoring and to the collection of representative samples, including the identification of the environmental media and the associated sampling frequency; b) Requirements relating to the accreditation or qualification of analytical

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	laboratories;20
	c) Procedures for the calibration and performance testing of measurement equipment;
	d) A programme for the intercomparison of measurements;
	e) A record keeping system;
	f) A reporting procedure that is in compliance with requirements of the regulatory body."
S12	Suggestion: The PAA should consider finalizing guidance on specific conditions to be incorporated into the quality assurance programmes of registrants and licensees addressing source monitoring and environmental monitoring.

The IRRS team was informed that pre-operational studies were performed in order to assure that environmental impact assessment (EIA) conducted by the future applicants for the operation of nuclear power plants is in line with the legislation. The General Directorate of Environmental Protection in cooperation with the PAA and other competent authorities in Poland, regulates the environmental process of new power plants. The IRRS team observed that PAA does not have a documented process addressing the review of the above-mentioned pre-operational studies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA as a competent authority which in cooperation with the General Directorate of Environmental Protection and other competent authorities in Poland regulates siting of nuclear facilities does not have a procedure to assess the pre-operational studies conducted by future applicant for nuclear facilities to ensure that pre-operational studies establish 'baseline' environmental radiation levels and activity concentrations for the purpose of subsequently determining the impacts of the source.

purpose o	subsequently determining the impacts of the source.
(1)	BASIS: RS-G-1.8 para. 5.11 states that "Pre-operational studies should be performed for practices to establish 'baseline' environmental radiation levels and activity concentrations for the purpose of subsequently determining the impacts of the source. Preoperational assessments should also be made of the expected inventories of radionuclides during operation of a facility, the possible discharge pathways and the likely amounts that will be discharged to the environment, with due consideration of the effluent treatment systems that will be installed. The preoperational studies should also be such as to provide basic environmental data for use in the prediction of doses to the public and discharges to the environment. The first authorized limits on discharges and conditions of discharge to the environment should be established and the monitoring programme designed on the basis of these pre-operational studies such areas."
(2)	 BASIS: RS-G-1.8 para. 5.12 states that "For this purpose it is necessary to determine: a) The expected activity inventory and radiation characteristics of the source; b) The types and activities of radionuclides that will be discharged, their physical and chemical forms, the methods and routes of discharge and the rates of discharge; c) The mechanisms for the transfer of radionuclides through environmental media, including dispersion and reconcentration mechanisms, and their seasonal variation; d) The natural and artificial features of the environment that will affect this transfer (e.g. geological, hydrological and meteorological conditions, vegetation or the presence of reservoirs or harbours); e) The ecological characteristics of the water body planned to receive liquid discharges (e.g. its fauna and flora, annual variability, state of eutrophication and expected changes in ecosystems);

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	 f) The utilization of the environment for agriculture, the supply of water and food, industry, habitation and recreation; g) The density of population, its distribution according to age and to dietary, occupational, domestic and recreational habits; h) Possible critical groups; i) Existing levels of radionuclides in the environment and their variability; j) The existence of any physical or chemical pollutants that may affect the transfer of radionuclides."
S13	Suggestion: The PAA should consider developing a procedure to assess the pre- operational studies conducted by future applicant for nuclear facilities in order to ensure that pre-operational studies establish 'baseline' environmental radiation levels and activity concentrations for the purpose of subsequently determining the impacts of the source.

The regulations also address consumer products. As noted in PAA's action plan, the regulatory regime for consumer products, including the authorization process, needs to be improved. This issue is addressed in Recommendation R21 in Section 9.9.

Smoke detectors are not regarded as consumer products in Poland. The authorization process also addresses the control of smoke detectors with radiation sources, which were widely installed in the past. Their use is successfully controlled by the regulatory regime containing authorization of companies installing and dismantling the products and annual oversight conducted by these companies. PAA's well-established regulatory control of so widely used products prevents from losing these products and allows them to be managed as disused sources or radioactive waste.

The requirements related to existing exposure situations are set in the regulations. Activities related to enhanced levels of materials with enhanced concentration of natural radioactive materials are controlled as planned exposure situations.

The IRRS team was unable to review management of NORM industry, and in particular issues for residues from uranium mining and building materials. In case that new existing exposure situations are identified, the governmental units on the site where such a situation exists would be responsible for the development of a strategy to manage the situation, including justification and optimization of the protection of members of the public. Cooperation with other competent authorities is also foreseen. The IRRS team noted that the regulatory regime in Poland considers every situation at the moment of identification of contamination as an emergency situation. Once initial monitoring is finished, a situation is managed as an existing exposure situation as appropriate.

5.10. SUMMARY

Poland has a well-established system for authorization. However, the assignment of responsibilities to several different authorities, results in a complex system that requires a high level of coordination to ensure the absence of gaps or overlaps.

The concept of comprehensive safety assessment in relation to facilities and activities that involve radiation sources is not clearly specified in the regulations and, in consequence, there is no formalized regulatory process to conduct its regular review and assessment.

IRRS team encourages the development of additional guidance for the applicants and procedures for the authorities with regulatory responsibilities.

The improvement actions identified will further enhance the already well-established regulatory framework for the authorization of facilities and activities in Poland.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The PAA is the main organization entrusted with reviewing and assessing safety information to ensure that facilities, activities, and exposure situations comply with the regulatory requirements and authorization conditions. For certain activities related to medical uses of X-rays, the organizations responsible for review and assessment are the State Regional Sanitary Inspector (WSSE) or the Military Sanitary Inspector.

The national legal framework stipulates the responsibilities and requirements for PAA review and assessment. The review and assessment activities are generally conducted using a graded approach. PAA performs review and assessment for nuclear facilities and activities throughout their lifetime or duration and verifies that licensees conduct periodic safety reviews as established, manage deviations and events, periodic reporting, and observed deficiencies; and report principal modifications, as required. For radiation sources facilities and activities, the review only occurs at the time of application for authorization and is complemented by inspection during the lifetime of the facility.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

Review and assessment for the research reactor MARIA falls under the responsibility of the Nuclear Safety and Security Department. Periodic Safety Review (PSR) of the safety of MARIA, in accordance with the ALA, is carried out at least every 10 years.

Review and assessment of the waste management facilities is performed by the Radioactive Waste and Siting Division of the Nuclear Safety and Security Department. In this case, the Periodic safety review (PSR) of the safety of radioactive waste disposal facility is carried out, in accordance with the ALA, at least every 15 years.

The IRRS team was informed that facilities and activities related to the use of radioactive sources, devices generating ionizing radiation, and other sources of ionizing radiation are in excess of 7700 and growing each year.

The number of inspectors in the Department of Radiation Protection (DOR) of PAA is 11. They are responsible for licensing, review and assessment, and inspection of facilities and activities using sources, and also the transport of radioactive materials. New inspectors have to go through an extended period of training as interns, that includes mentoring by existing inspectors and internships at one or more regulated facilities. They have to take an examination to be awarded an inspector position. This process guarantees an adequate level of competence and training, which is later maintained through an individualized personal training program. The ALA includes provisions for PAA to make use of external expertise if needed.

The IRRS team observed that the resources of the DOR, are not commensurate with the actual workload, including the efforts needed to implement the IRRS team recommendations, and noted that there is a clear risk that this trend will continue in the future.

This issue of proper and balanced staffing is addressed by Recommendation R4 in Section 3.3.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Review and assessment is based primarily on the review of the information submitted by the applicants in accordance with the requirements of ALA and the regulations on the documents required when submitting an application for the issuance of a license to perform an activity related to exposure to ionizing radiation.

Periodic safety reviews are requested for certain facilities, including radioactive waste disposal facilities and nuclear facilities.

PAA has not issued to date guides on how to comply with the requirements of the regulation on the documents required for the applications of the different types of facilities and activities for the conduct and periodic review of the safety assessment of facilities and activities other than nuclear facilities. These issues are addressed by recommendations in Section 5.4.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

For any authorization, the type of facility or activity determines how the documentation is checked for completeness and quality by the regulatory body. The first step of the authorization process always involves a formal check for completeness to make sure all the documents identified in the law and regulations are submitted. The second step is to examine the quality and detail of the documents. If something is missing, wrong, or unclear, the applicant is requested to supplement or clarify the information. An inspection can be considered as part of the review and assessment process, and in certain cases, it is also possible to perform inspections during the initial licensing of the facility or activity.

This review and assessment of radiation sources facilities and activities, for decommissioning activities and for transport of radioactive materials is performed by PAA staff primarily based on their expertise and using established practices, but they do not have a comprehensive set of procedures in place establishing criteria and describing the activities to be performed for the review and assessment.

The review and assessment process results in a proposal regarding the validity of the application for the consideration of the PAA's President However, in the case of radiation sources facilities and activities, as well as for decommissioning activities, the basis for the licensing decision, the analysis performed and the conclusions of the review process are not documented and kept as records. The IRRS team observed that such a documented process with its corresponding procedures is also missing at the GIS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA and GIS, within the scope of their responsibilities, do not have a documented process for review and assessment of applications for authorization of radiation sources facilities and activities, for transport and for decommissioning activities, nor for periodic review and assessment of the documentation and performance of the authorized activities and facilities.

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(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 25 states that "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. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization."
(2)	BASIS: GSR Part 1 (Rev. 1) para. 4.40 states that <i>"The regulatory body shall review and assess the particular facility or activity in accordance with the stage in the regulatory process … The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."</i>
(3)	BASIS: GSG-13 para 3.161 states that "In order to provide assurance that all topics significant to safety will be covered consistently with submissions for similar facilities or activities, review and assessment should be carried out by means of a systematic and formalized process implemented through specific procedures."
(4)	BASIS: GSG-13 para. 3.209 states that <i>"Review and assessment should result in a decision on the acceptability of the safety of the facility or activity, which may be connected to a step in the authorization process. The basis for the decision should be recorded and documented in</i>

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	an appropriate form. This documentation should summarize the review and assessment performed and should present a clear conclusion about the safety of the authorized facility or activity. Typically, the following topics should be covered:
	a) Reference to the documentation submitted by the authorized party;
	b) The basis for the evaluation;
	c) The evaluation performed;
	d) Comparison with regulatory requirements, regulations and guides;
	e) Comparison with another similar (reference) facility or activity, where appropriate;
	f) Independent analysis performed by the regulatory body's staff, or by consultants or dedicated support organizations on its behalf;
	g) Conclusions with respect to safety;
	h) Additional requirements to be met by the authorized party"
R12	Recommendation: The PAA and GIS, within the scope of their responsibilities, should develop a comprehensive documented process to enhance the implementation of review and assessment for radiation sources facilities and activities, for transport and for decommissioning activities, that ensures the preservation of records in accordance with a graded approach.

6.2. REVIEW AND ASSESSMENT FOR RESEARCH REACTORS

The review and assessment activities of research reactors are conducted following the authorization steps of a nuclear facility as defined by the ALA, which prescribes the content of the application for license and the list of documents to support the application for every phase of the life of the research reactor. The documents to be provided should include among others: location report (site report); design of a nuclear facility; safety analysis report; safety classification for structures, systems and components; integrated management system; commissioning programme; plan and report for the performance of a periodic safety assessment; and decommissioning programme. As stated by the ALA, the documents required for applying for a license aim to confirm conformity with nuclear safety and radiation protection requirements, taking into account the speciality of the performed activity, with the aim to ensure evaluation whether the nuclear safety and radiation protection requirements have been met, and taking into account the potential hazards associated with the performance of a given activity. The ALA also addresses the needed steps to be taken by the PAA to review and assess the safety demonstration, including by performing an inspection, by requesting studies and analysis, and by requesting additional information when needed.

The review and assessment process for research reactor is implemented in accordance to:

- 1. Regulation on documents required when submitting an application for the issuance of a license to perform an activity related to exposure to ionizing radiation; and
- 2. Regulation on scope and methodology for performance of safety analyses and scope of the preliminary safety report for a nuclear facility.

The latter regulation is not completely specific to research reactors. The IRRS team observed that the references in the document are outdated.

The key nuclear safety-related requirements to be fulfilled are established by the regulations on nuclear safety and radiological protection requirements which must be fulfilled by a nuclear facility design. However, the IRRS team was informed that these regulatory requirements are only applicable for new nuclear power reactors and research reactors, therefore they are not applicable for MARIA research reactor.

For MARIA research reactor, the PAA focuses on the commissioning and operation phases alongside modifications and modernizations requirements since this reactor was built in the 70's. Only two reactors of this kind were built worldwide. The other one is now decommissioned, whereas MARIA is still in operation.

In addition to the requirements of the regulation on requirements for the commissioning and operation of nuclear facilities, the PAA has two procedures to support the conduct of review and assessment:

- 1. 001_DBJ Issuing licenses for activities related to nuclear facilities; and
- 2. Modernisation procedure.

Both procedures are administrative oriented with forms but without technical guidance. In order to overcome this absence of technical guidance, the PAA has set up an internal guide "W01/P03/PO1.1 Guideline for the assessment of substantive modification and modernization of systems, structures and components in nuclear facilities". The IRRS team considered it may be necessary to enhance those procedures and guidance by including technical provisions with acceptance criteria and provisions for applying graded approach, to support a comprehensive review and assessment of research reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA does not have established acceptance criteria for review and assessment of the safety of research reactors. Moreover, there is no formal process to conduct review and assessment according to a graded approach.

(1)	BASIS: SSR-3 para. 3.12. states that "Each State shall develop its own approach to acceptance criteria depending upon its particular legal and regulatory infrastructure. Acceptance criteria based on principles for safe design and operation shall be made available to the operating organizations".
(2)	BASIS: GSG-3 para. 3.27 states that <i>"The government or the regulatory body should ensure that the following technical, administrative and procedural topics and requirements are included in the regulations, if appropriate, depending on the State's legal system and practices:</i>
	<i>(j)</i> Acceptance criteria and performance criteria for any manufactured or constructed source, device, equipment or facility that when in use has implications for safety; "
(3)	BASIS: GSR Part 1 (Rev. 1) para. 4.33 states that "Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."
(4)	BASIS: GSR Part 1 (Rev. 1) Requirement 26 states that <i>"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."</i>
S14	Suggestion: The PAA should consider establishing acceptance criteria as a basis for conducting review and assessment for research reactors. The PAA should consider enhancing provisions to conduct such a review and assessment in accordance with a graded approach.

For MARIA research reactor, Periodic Safety Reviews (PSR) are legally required to be conducted at least every 10 years. The review and assessment of PSR by the PAA comprises first an evaluation of the PSR plan, and then the PSR report. The latest PSR was submitted in 2019 The PAA issued a safety evaluation report and approved it in 2020. The PAA held technical meetings and issued 295 requests for additional information to MARIA research reactor. The PAA review team consisted of 18 staff members without any external support. The PAA included in the safety evaluation report the corrective actions to be implemented by MARIA research reactor, in addition to the corrective actions, the report presented ten internal recommendations to be considered by the PAA for the next PSR review and assessment.

The IRRS team was informed that in practice the PAA conducts review and assessment in accordance with a graded approach by taking into account the complexity of the case and considering previous regulatory experience. However, this is made at the discretion of the person responsible for the task, as there is no formal procedure for applying graded approach.

MARIA research reactor was in shut down state for nearly 1 year at the time of the mission to implement, six modifications and modernizations are currently conducting.

6.3. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

A radioactive waste storage facilities directly related to the nuclear facility and located within the site of a nuclear facility are regulated as nuclear facilities. The PAA and the operators of all nuclear facilities are required to review and assess the safety of these facilities systematically and regularly. Radioactive waste repository is not considered as nuclear facility in the law. The operational spent fuel pools placed at the research reactor sites are regulated through the research reactor's licensing process.

The ALA and the implementing regulations on the PSR of a radioactive waste repository include provisions for the PSR of a radioactive waste repository to be performed every 15 years and for its review by the PAA.

The IRRS team observed that PAA is complying with the requirements for regulatory review and assessment of waste management facilities.

6.4. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Authorization applications of radiation sources facilities and activities are reviewed by the PAA Department of Radiation Protection (DOR), prior to the granting of the authorization, following the procedure P01/PO3.2. This review is conducted by inspectors and prospective inspectors (under inspectors' supervision) of DOR. The process comprises two steps: a review for completeness of the documentation submitted, and a substantive review in accordance with the requirements of ALA and relevant regulations for the particular type of activity or facility. If documents are considered inadequate, DOR requires the applicant to correct them. Upon successful review of the documents, the assigned inspector prepares the licence or registration to be signed by the PAA President. The licence proposal includes the conditions imposed for operation and is also signed by the inspector in charge of the review.

The above-mentioned procedure used to perform the review focuses on administrative aspects but does not provide any guidance or criteria on how to conduct the review. The IRRS team was informed that DOR has a so-called "best practices" document with informal criteria shared by all inspectors to perform the review. There are also internal lists of conditions to be included in the license for each type of facility or activity, and additional conditions can be added after internal discussion within DOR.

Inspectors do not document the review process, therefore no record of the activities could be provided to the IRRS team other than examples of letters sent to applicants requiring corrections to the applications. The basis for the decisions to grant licenses are not recorded and documented in an appropriate form summarizing the review and assessment performed and presenting a clear conclusion about the safety of the facility or activity.

Neither regulations nor conditions of the licence require submission of periodic reports on safety performance, which is the consequence of not applying the concept of safety assessment for radiation sources facilities and activities. This is discussed in Recommendation R9 in Section 5.4. The licences for

these facilities and activities are final. There are no requirements for licence renewal or for the submission of further safety analysis. Thus, the PAA does not conduct any periodic review and assessment of the documents and performance of the facilities, other than that the reviews performed during inspections.

The lack of an established review and assessment process for all types of facilities and activities is addressed in Recommendation R12 in section 6.1.4.

6.5. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

The ALA and supporting regulations require the operator to prepare a decommissioning programme prior to the application for a license for construction, commissioning, or operation of a nuclear facility. The IRRS team observed that review and assessment of the decommissioning programme is carried out, as well as for the phased and final decommissioning reports.

The IRRS team observed that while the process of review and assessment of the decommissioning activities is done in practice, the PAA does not have an internal process that guides the review process. This issue is addressed in Recommendation R12 under section 6.1.4.

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT

The review and assessment of transport package designs is the responsibility of the Radiation Protection Department which uses inspection of facilities in the context of transport as an important mechanism in the review and assessment process for package designs for the transport of radioactive material.

There are two requirements that are not taken into consideration by PAA in the scope of assessment of package designs: ageing mechanisms and transitional arrangements.

Regarding the ageing mechanisms, for packages intended for repeated use, the effects of ageing mechanisms should be evaluated during the design phase and included in the package design safety report that defines the package design and demonstrates its compliance with the appropriate SRR6 (Rev.1) requirements.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The review and assessment of package designs for the transport of radioactive material, does not include ageing mechanisms of package designs operating in Poland.	
(1)	BASIS: SSR-6 (Rev. 1) para. 613A states that <i>"The design of the package shall take into account ageing mechanisms."</i>	
(2)	BASIS: SSG-26 (Rev. 1) para. 613A (3) states that <i>"For packagings intended for repeated use, the effects of ageing mechanisms on the package should be evaluated during the design phase in the demonstration of compliance with the Transport Regulations. Based on this evaluation, an inspection and maintenance programme should be developed demonstration of compliance of the package are confirmed to be valid through the lifetime of the packaging "</i>	
(3)	BASIS: SSG-26 (Rev. 1) para. 613A (4) states that "In the design of packages intended to be used for shipment after storage, consideration of ageing mechanisms is important due to the long period between loading and the end of shipment after storage, the conditions of storage (even though the Transport Regulations do not apply to the storage of the package), for the identification and assessment of ageing effects should be recognized".	
R13	Recommendation: The PAA should ensure ageing mechanisms of package designs are included in the review and assessment of package designs for the transport of radioactive material.	

Transitional arrangements are stated in paras 819 to 823 of SSR-6 (Rev. 1). The IRRS team noted that as SSR-6 is revised the transitional arrangements stated therein will change to remove from the scope of SSR-6 designs packages and special form radioactive material for sealed sources, that were designed to comply with earlier editions of SSR-6.

Therefore, the PAA should consider transitional arrangements in the review and assessment process for package designs and special form radioactive material transported within or through Poland.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The review and assessment process for the transport of radioactive material, the PAA does not take into consideration the transitional arrangements for package designs and special form radioactive material, transported within or through Poland.

	BASIS: SSR-6 (Rev. 1) paras. 819 – 823 state that "
	- Packages not requiring competent authority approval of design under the 1985, 1985 (As Amended 1990), 1996 Edition, 1996 Edition (Revised), 1996 (As Amended 2003), 2005, 2009 and 2012 Editions of these Regulations.
(1)	- Package designs approved under the 1985, 1985 (As Amended 1990), 1996 Edition, 1996 Edition (Revised), 1996 (As Amended 2003), 2005, 2009 and 2012 Editions of these Regulations,
	- Packages excepted from the requirements for fissile material under the 2009 Edition of these Regulations,
	- Special form radioactive material approved under the 1985, 1985 (As Amended 1990), 1996 Edition, 1996 Edition (Revised), 1996 (As Amended 2003), 2005, 2009 and 2012 Editions of these Regulations".
	Recommendation: The PAA should ensure the transitional arrangements are included in
R14	the review and assessment process for package designs and special form radioactive material transported within or through Poland.

The IRRS team observed that while the process of review and assessment of transport activities is done in practice, the PAA does not have an internal documented process. This issue is addressed in Recommendation R12 under section 6.1.4.

The IRRS team considered the low level of resources should be increased to provide resilience in the review and assessment process, particularly as the same PAA staff member is responsible for the transport authorization, and enforcement activities. This issue is addressed by Recommendation R4 in Section 3.3.

6.7. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

PAA procedures for reviewing an application with regard to occupational exposure are focused on ensuring that the total radiation exposure of both workers from the use of radiation sources is kept as low as reasonably achievable (ALARA) and in compliance with the dose limits. These provisions also ensure protection for workers that may be classified as members of the public.

The applicant for a licence is required to propose dose constraints for occupational exposure and to present documentation to demonstrate that it has established protection measures to ensure compliance. This documentation shall include the opinion of a Radiation Protection Expert. This documentation is focused on demonstration of compliance with regulations, including:

- Plans to manage radiation safety deviations and implementation of emergency preparedness measures.
- Classification of areas and requirements for access control, warning lights and signs, markings.

- Classification of exposed workers and methodology for individual monitoring.
- Health surveillance and qualifications of the health service that carries it out.
- Availability of personal protective equipment for exposed workers.
- Shielding requirements.

(1)

• Training of exposed workers.

However, not all the expected elements of a safety assessment according to GSR Part 4 are considered in PAA's review and assessment process (e.g. identification of the possible radiation risks resulting from normal operation, anticipated operational occurrences or accident conditions, identification and assessment of a comprehensive set of safety functions, assessment of human factor related aspects of the design and operation of the facility or the planning and conduct of the activity, etc). This issue is addressed by Recommendation R9 in Section 5.4.

The IRRS team observed that the applicant for an authorization is required to describe how the information will be recorded (e.g. ensuring that the templates of tables that will be filled out are in accordance with applicable regulations). The accuracy of the records kept by the applicant is then verified by PAA inspectors through inspections.

Exposed workers that are classified in category A, which corresponds to those that may receive, over one year, an effective dose higher than 6 mSv, or an equivalent dose in excess of 15 mSv for the lens of the eye, or of 150 mSv for the skin or extremities. These workers are required to have their exposure assessed on the basis of systematic individual dose measurements. If these workers may be exposed to internal contamination, internal contamination measurements are required as well.

Exposed workers who are not likely to exceed the above mentioned doses are classified in category B. For these workers, the dose assessment is carried out through workplace monitoring. However, the registrant or licensee may decide to carry out systematic individual dose measurements. PAA may also include conditions in the license of a facility or activity requesting category B workers to be monitored through systematic individual dose measurements.

Registrants and licensees are required to maintain exposure records of exposed workers and to submit the records with the results of the monitoring carried out for Category A workers yearly to the National Dose Register (CRD) maintained by PAA.

The IRRS team was informed that currently there are around 7700 exposed workers registered in the CRD. The PAA carries out regular reviews of exposed workers in the CDR. However, since the CRD only contains information of category A workers, the PAA does not perform systematic review of the exposures of all the exposed workers subject to systematic individual dose measurements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The National Dose Register (CRD) only contains information on doses received by exposed workers classified as Category A, but not on all exposed workers for whom personal monitoring is required.

BASIS: GSG-7 para. 7.265 states that "Consideration should be given to the establishment of a national dose registry as a central point for the collection and maintenance of dose records. The storage of information at the national dose registry should be such as to allow workers, during and after their working life, to retrieve information on the doses they received while occupationally exposed. Long term storage of such information in a national dose registry also serves the following purposes:

a) It prevents the loss of data on individual doses in the event that the registrant or licensee ceases its activities in the State concerned.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	b) It allows periodic analysis of all data on exposures collected in order to characterize the situation at the national level with regard to occupational exposure."	
S15	Suggestion: The PAA should consider expanding the National Dose Register to include information on doses received by exposed workers for whom personal monitoring is required.	

6.8. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

For facilities and activities that carry out medical exposures, the PAA and the Chief Sanitary Inspectorate (GIS) share responsibilities with regard to the review and assessment of the applications. In the case of facilities and activities authorized by PAA, the review and assessment is carried out in a similar way as described in previous section, and it focuses on occupational and public exposures.

Review of patient protection aspects is carried out by GIS at the authorization phase and during inspections thereof. During the authorization phase, GIS reviews the information submitted by applicant, such as:

- Quality assurance programme.
- Allocation of responsibilities and tasks.
- Requirements for the operation, and maintenance of radiation sources and their associated equipment.
- Security measures for radioactive sources.
- Emergency management system.
- Processes for minimizing unintended medical exposures and recording and analysing significant events.

Another tool used in the review of patient protection are clinical audits, either internal or external. Internal clinical audits are requested to be conducted at least once a year and whenever incidents lead to skin damage on the patient as a result of interventional radiology treatment.

There are requirements for medical exposure to be justified, taking into account the expected diagnostic or therapeutic benefits, considering the direct benefits to the health of a person and the benefits to society against the health detriment that the exposure might cause in persons or their descendants. The justification requirements take into account the benefits and the types of risks associated with the use of alternative methods employed for the same purpose.

In the case of medical exposures of carers and comforters, the justification also takes into account their expected benefits and harm.

Justification is assumed for standard radiological procedures that are in accordance with referral guidelines that are available free of charge for all medical staff. Referral guidelines have been established and their application is verified through internal and external clinical audits carried out regularly in healthcare facilities. However, the IRRS team observed that the GIS does not verify through the inspection process whether licensees have established internal procedures for carrying out this justification at the third level for each individual patient, for procedures other than standard radiological procedures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Verification of compliance with requirements for justification of individual exposures is based on checking the correctness of referrals carried out through clinical audits. However, the GIS does not verify during inspection that the authorized party has established internal procedures for carrying out justification for each individual patient, for procedures other than standard radiological procedures.

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.52 states that <i>"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections."</i>
(2)	BASIS: GSG-46 para. 2.11 states that <i>"The application of the justification principle to medical exposure requires a special approach, using three levels (the three-level approach) For the final level of justification (level 3), the application of the radiological procedure to a given individual patient should be considered."</i>
S16	Suggestion: The GIS should consider including in their processes for inspection the verification that licensees have established internal procedures for carrying out justification of individual exposures.

6.9. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

Review and assessment of documents sent by an applicant for authorization includes review of arrangements related to public exposure. Regulations include well established criteria to be used when assessing some of the pathways related to exposure to members of the public, e.g. external exposure. In such cases, calculations are verified by the regulatory body staff. For radiation sources facilities and activities a set of information related to public exposure is provided in an application, however a complete safety assessment is not required to be conducted by the registrant and licensee. This issue is addressed in detail in Recommendation R9 in Module 5. Confirmatory inspections as part of review and assessment before issuing an authorization are also in place.

Once an authorization is issued, review and assessment is not only conducted through the inspection process but also through the review and assessment of the documentation required by the regulations or the authorization conditions to be sent by registrant or licensee to the regulatory authority, e.g. periodic reports on discharges and annual reports on environmental monitoring and assessment of public exposure. The documentation required to be sent for a review and assessment depends on the characteristics of a facility or activity. The IRRS team noted that the PAA does not have a documented procedure to carry on the review and assessment process. This issue is addressed in the Recommendation R12 in Section 6.1.4.

The PAA is responsible for the assessment of total public doses. The results of monitoring programmes conducted in order to provide needed data and total public doses are published in its annual reports.

The IRRS team noted that the PAA recently installed thirty additional radiation monitoring stations close to the border in less than twelve months due to the situation in Ukraine caused by the armed conflict, in order to improve radioactivity detection capability. This is considered to be a good performance.

6.10. SUMMARY

The IRRS team evaluated the review and assessment processes in place at PAA for a wide range of types of nuclear and radiological facilities and activities, and partially GIS processes related to medical exposures. The IRRS team has concluded that PAA has established a process for conducting reviews and assessment of the applications for facilities and activities generally in line with IAEA Safety Standards.

However, the review and assessment of the applications of some of the facilities and activities lack documented procedures. This could compromise the quality and consistency of the review and assessment

of these facilities. Therefore, the establishment of comprehensive processes and procedures for review and assessment of all facilities and activities, including the review and assessment of planned and existing exposure situations, has been identified as the main area for further improvement.

Other areas for improvement were identified regarding the review and assessment of activities performed by PAA and GIS:

- Establishment of acceptance criteria for review and assessment of research reactors.
- Inclusion of the transitional arrangements in the review and assessment process for package designs for transport of radioactive materials, and consideration of ageing mechanisms of package designs.
- Expansion of the National Dose Register.
- Provisions for regulatory verification of the justification of individual exposures by PAA and GIS.

The IRRS team identified as a good performance the installation of thirty additional radiation monitoring stations to detect radioactivity in the air in response to the situation in Ukraine due to the armed conflict.

7. INSPECTION

7.1. GENERIC ISSUES

The legal framework for safety includes provisions on inspections of facilities and activities. Provisions for the inspections conducted by the PAA are established in the ALA. The IRRS team was informed that inspection provisions are also established for State Regional Sanitary Inspectors (WSSE) in chapters 3 and 4 of the Act of Parliament on State Sanitary Inspection, for the Regional Mining Authority in chapter 4 of the Geological and Mining Law and for Civil Aviation authority in chapter 3 of the act of the Parliament establishing the Aviation Law.

The facility or activity is inspected by the state body that authorizes this facility or activity. According to the ALA, inspection activities cover all facilities and activities that are under regulatory control. Inspection activities also cover the premises where nuclear material, radioactive material, radioactive substances, radioactive sources, devices containing radioactive sources, radioactive waste or spent nuclear fuel may be found, in particular as a result of past activities.

The inspection process followed by the above-mentioned authorities include programmed inspections and reactive inspections, both announced and unannounced. Namely, according to the ALA, there are three kinds of regulatory inspections:

- periodical inspections planned,
- ad-hoc inspections unplanned including reactive inspections (whenever circumstances arise which may have a substantial impact on the nuclear safety and radiological protection at the organizational entity),
- continuous inspection only for NPPs.

The IRRS team did not make any observations that indicate that regulatory inspections substitute for the control, supervision and verification activities conducted under the responsibility of the authorized party.

The PAA and WSSE regularly develop and implement a programme of inspection of facilities and activities aimed to confirm compliance with regulatory requirements and with any condition specified in the authorization.

The PAA develops a general inspection programme for facilities and activities on a yearly basis. This general programme assigns frequencies of inspection for the different categories of facilities and activities. The inspection frequency depends on the radiation risk ranging from once per year for research reactors, radioactive waste management facilities, teletherapy and 1st class laboratories to once every 10 years for low activity radiation sources and certain types of x-ray devices. Inspection findings are taken as feedback into the inspection programme, allowing for increased frequency for practices where higher numbers of non-compliances have been identified. On the basis of the general programme, the PAA inspectors prepare a plan of inspection for the following year. This plan contains details about scope, topics, number of inspections and name of inspected entities.

The inspection programme of the WSSE establishes a minimum inspection frequency of at least once every four years. However, the concept of graded approach is not consistently applied. This is addressed in Suggestion S19 in Section 7.8.

Authorization and inspection of facilities or activities are performed by the same departments of the PAA and the WSSE, respectively. This facilitates the exchange of inspection feedback involved in authorization and inspection activities. During the authorization process, when it is needed, staff in charge of authorization and review and assessment can conduct inspections to verify that the applicant fulfils nuclear safety, radiological protection, security or safeguards requirements.

The PAA inspections are carried out in compliance with procedures for inspection DBJ P01/PO 4.1 and DOR 001/002/DOR. The procedures cover the four areas of inspections: radiation protection (activities and installations other than nuclear facilities), radiation protection and nuclear safety (nuclear facility), security (nuclear material, nuclear facility) and safeguards (nuclear material).

The PAA nuclear inspectors (note: all the PAA nuclear regulatory inspectors, not only those who inspect nuclear facilities are called "nuclear inspectors") and the WSSE sanitary inspectors record the results of inspections and issue an inspection report. Based on the inspection report, corrective actions can be requested for implementation within a specific period of time when necessary. Inspectors can also take enforcement actions (this is discussed in Section 8). The inspection report of inspections is provided in writing to the authorized party. The authorized party is held accountable for remedying the non-compliances identified in the inspection report. In the case of a direct nuclear or radiological threat being identified during an inspection, the nuclear inspector in charge of the inspection can issue an order of prohibition to immediately remove the threat. The IRRS team was informed that sanitary inspectors also have legal authority to request immediate enforcement actions when necessary.

In accordance with the ALA provisions and Act of Parliament on State Sanitary Inspection, inspectors shall be granted free access to the facilities and activities at any time to perform inspection. The PAA inspectors and WSSE sanitary inspectors can request access to facilities and activities on the basis of the notice for inspection issued by the head of their organization. The inspectors are provided with inspection credentials to request access to the facilities and activities intended to be inspected. Inspectors are authorized to bring all the necessary equipment and vehicles to conduct independent technical and dosimetry measurements at the sites.

In conducting inspections, the PAA considers all safety aspects, including but not limited to: structures, systems and components and materials important to safety; management systems; operational activities and procedures; records of operational activities and results of monitoring; liaison with contractors and other service providers; competence of staff. The oversight of safety culture is not covered in the inspection programme of facilities and activities. This issue is outlined in this Section and addressed in Recommendation R15 in Section 7.1.

In accordance with the ALA, the inspectors can use appropriate inspection methods, such as verification, collection of information, interviews, collection of samples, visual inspections, recording.

PAA and WSSE inspectors may conduct joint inspections to medical facilities in accordance with an agreement made by these authorities. However, joint inspections are not conducted regularly. This is addressed in Suggestion S17 in section 7.4.

During the site visit to the medical facility The Maria Sklodowska-Curie National Research Institute of Oncology, the IRRS team observed that although the joint inspections are not regularly conducted, the inspectors of both authorities established effective dialogue for coordinating their questions and requests to the licensee.

The IRRS team was informed that in some areas like fire protection, safeguards or pressure equipment, inspections usually are conducted together with third parties like the fire brigade, EURATOM and IAEA safeguards inspectors or the Office of Technical Inspection (UDT).

In accordance with the ALA, anybody who prevents or obstructs inspection activities or fails to provide information or provides false information or conceals the truth in the field of nuclear safety and radiological protection, shall be subject to a fine.

The PAA has 23 inspectors classified in 3 types. Level I inspectors are authorized to perform inspections in organizational units performing exposure activities like waste management facilities, radiation sources facilities, transport, occupation exposure, public exposure. Level II inspectors are authorized to perform

inspections in organizational units performing exposure activities mentioned for Level I and nuclear facility, fuel cycle facility, radioactive waste repository.

Inspectors for safeguards – authorized to carry out inspections only in the scope of control of nuclear technologies and safeguards. The ALA established the requirements and qualifications for a PAA staff member to be certified as inspector.

The WSSEs have 140 inspectors who are authorized to carry out inspections. The WSSEs inspectors are internally trained. The scope and duration of this training depends on the trainee's education and professional experience. After appropriate training, the state provincial sanitary inspector issues an authorization to the employee to carry out radiation hygiene inspections. Common WSSEs practice is to perform inspections by at least two authorized inspectors.

The IRRS team was informed that during inspections, the inspectors could assess limited aspects of the licensee's safety culture, but this is done on a case-by-case basis and not supported by written procedures. Additionally, there is no legal requirement for facilities and activities other than nuclear power plants and nuclear waste management sites regarding the establishment and maintenance of an adequate safety culture.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Requirements governing the authorization of facilities and activities do not include provisions for the establishment and development of an adequate safety culture by the authorised party of non-nuclear facilities in line with IAEA requirements.

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.53 states that "In conducting inspections, the regulatory body shall consider a number of aspects, including Safety culture;"
(2)	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>
(3)	 BASIS: GSR Part 3 para. 2.48 states that "The principal parties shall ensure that the management system is designed and applied to enhance protection and safety by: e) Promoting safety culture"
R15	Recommendation: The Government should expand the requirement for establishing an adequate safety culture to facilities and activities other than nuclear facilities.

Observation: *PAA* inspectors address limited aspects of the authorised persons safety culture during authorisation and inspection, however, there is neither internal guidance regarding the scope of these assessments nor established criteria.

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.53 states that "In conducting inspections, the regulatory body shall consider a number of aspects, including Safety culture;"
(2)	 BASIS: Code of Conduct on the Safety and Security of Radioactive Sources para. 7 states that "Every State should, in order to protect individuals, society and the environment, take the appropriate measures necessary to ensure: b) the promotion of safety culture and of security culture with respect to radioactive sources."
(3)	BASIS: GSG-13 Functions and Processes of the Regulatory Body for Safety para. 3.161 states that <i>"In order to provide assurance that all topics significant to safety will be covered</i> <i>consistently with submissions for similar facilities or activities, review and assessment should</i> <i>be carried out by means of a systematic and formalized process implemented through specific</i> <i>procedures."</i>

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Recommendation: The PAA should develop a process, comprising procedures and criteria, to assess and promote authorized parties' safety culture for radiation source facilities and activities.

7.2. INSPECTION OF RESEARCH REACTORS

The inspection activities of the MARIA research reactor are scheduled in the annual inspection plan. The inspection plan is prepared according to a wider 6-year inspection plan which has been established to ensure that all research reactor safety-related areas (e.g., SSCs, maintenance, operation, ageing management, radiation protection) are covered within a 6-year period in accordance with a graded approach. The overall inspection process for research reactors is appropriately documented. For instance, the preparation of the 6-year plan is carried out in accordance with the procedure P01/PO 4.1 providing detailed instructions for preparation of a 6-year plan of inspections to nuclear facilities.

The inspection report is prepared by the staff who carried out the inspection and endorsed by the lead inspector before sending the inspection report to the inspected facility for review and endorsement. There is a process to cover the situation where the licensee disagrees with some of the inspector's conclusions. The final inspection report is sent to the licensee by the Nuclear Safety and Security Department.

In 2022, the PAA performed eight inspections to the MARIA research reactor. The inspections were conducted by inspectors of the Inspection and Non-Proliferation Division. Seven of them were announced inspections and one unannounced. Two of them were reactive inspections regarding spent fuel and modifications. Typically, one-day inspections are conducted by a team consisting, on average, of 3 or4 inspectors.

The scope of 2022 inspections were as follows: core, instrumentation & control systems, electrical system, start-up, fresh and spent fuel, radiation protection inspection, reactor dosimetric system, cooling system, ventilation, modifications and fire protection.

Site visit at the MARIA Research Reactor

The IRRS team observed an inspection conducted by the PAA inspectors to the MARIA research reactor. Three inspectors participated in the inspection. The inspection team conducted the inspection according to the inspection program prepared by the lead inspector. The inspection programme was approved by both the division head and the department head. The PAA informed the operators of the MARIA research reactor about the inspection several days in advance by phone. As usual, the inspection scope and date were announced on the PAA website as part of the annual inspection plan (this practice is applied for announced inspections).

During the inspection, the inspectors conducted interviews, document checks, and took a walkdown in the facility. At the end of the inspection, the inspectors had an internal meeting to discuss the findings and finalize the inspection outcomes before presenting and discussing their conclusions with the operators and the facility director.

7.3. INSPECTION OF WASTE MANAGEMENT FACILITIES

The inspection of radioactive waste management facilities is done in accordance with the Inspection recommendation 8 which is a PAA internal guide specific on storage of radioactive waste that provides guidance for the inspection of radioactive waste facilities. The purpose of recommendation 8 to ensure that the inspection of the radioactive waste storage facility is in line with the PAA internal procedures, regulations, requirements, and licence conditions.

There are two waste management facilities subject to inspection, namely, the Radioactive Waste Management Plant (ZUOP) and the National Waste Repository in Rozan. Currently, the spent nuclear fuel from MARIA research reactor is stored in the reactor pool. The two storage facilities dedicated for spent nuclear fuel storage are currently empty. The PAA inspectors perform inspections on radioactive waste facilities in accordance with their respective field of expertise.

7.4. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Inspections of radiation sources facilities and activities are done as described in the Section 7.1. There are 11 certified nuclear inspectors in the PAA that are authorized to perform inspections for radiation sources facilities and activities. The number of registered organizational entities conducting activities (one or more) involving exposure to ionizing radiation subject to supervision of the PAA is 4895. The total number of registered activities involving exposure to ionizing radiation is 7761. In 2022 PAA conducted 615 inspections. In 2022, the WSSEs inspectors carried out inspections that covered, in total, 5356 radiological equipment in medical facilities providing services in all areas of healthcare. The largest number of inspected radiological equipment were dental intraoral x-ray generators (2550).

Inspections of radiation sources facilities and activities are commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach. The graded approach is established in the internal inspection procedure and in the PAA regulatory activities information system SIDOR. SIDOR includes the general check-list that is complemented with specific check-lists to be used for the different activities and facilities and practices, such as check-lists for radioactive sources, brachytherapy, transport, etc.

The IRRS team identified that no national retraining or other training courses in the area of radiation sources facilities and activities are offered in Poland. However, inspectors of the Radiation Protection Department use international training opportunities (mainly IAEA training activities), national events (such as schools of nuclear medicine, national non-destructive testing conferences, etc.) and pass certification as Radiation Protection Experts on their own initiative.

The IRRS team was informed that the Chief Sanitary Inspector collects and analyzes data on noncompliances and, based on the analysis of non-compliances, develops and updates recommendations and guidelines for the conduct of state regional sanitary inspections related to medical ionizing radiation exposure.

The Agreement between the Chief Sanitary Inspector and the President of the PAA on the cooperation on the implementation of radiation protection tasks was revised in 2017. This agreement covers the medical use of the radiation sources. The new agreement contains provisions for the exchange of inspection plans, inspection reports, and information on the non-compliances revealed during inspection. The agreement includes the possibility of planning and conducting joint inspectors. The PAA according to the internal procedure on inspections yearly sends to the Chief Sanitary Inspector the inspection plan and monthly sends the inspection reports that include non-compliances revealed during the PAA inspections. The IRRS team reviewed one example of the information shared by the PAA on the inspections from Mazowiecki State Voivodship Sanitary Inspector to PAA. On the other hand, the Sanitary Inspectors do not systematically inform the PAA about their inspection activities and provide full scope information about them.

Currently, the outcomes of the inspections carried out by both organizations are not systematically analyzed and no reactive actions are taken based on these information exchanges. The IRRS team considers that regulatory activities of the PAA and the Sanitary Inspectors would benefit from enhanced cooperation between them, including systematic exchange of the regulatory plans, feedback and experience, regular communication including meetings and joint inspections. The PAA monitoring and assessing the effectiveness of the established coordination arrangements would also be useful.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: According to the Agreement with the Chief Sanitary Inspector, the PAA regularly sends the inspection plans and reports on the medical use of radiation sources but rarely received them. There are no joint meetings to discuss and exchange regulatory feedback and experience, information on the non-compliances revealed during inspections and no joint inspections are conducted.

(1)	BASIS: GSR Part 1 (Rev. 1) para. 2.19 states that "If responsibilities and functions do overlap, this could create conflicts between different authorities and lead to conflicting requirements being placed on authorized parties or on applicants. This, in turn, could undermine the authority of the regulatory body and cause confusion on the part of the authorized party or the applicant."
(2)	BASIS: SSG-44 Action 32 para. 4-126 states that <i>"The arrangements for coordination should comprehensively cover the identified interfaces, including consistency of requirements, procedures for implementation, communication and flow of information."</i>
(3)	BASIS: SSG-44 Action 32 para. 4-127 states that <i>"The arrangements for coordination may include regular meetings of representatives of relevant designated bodies and/or interested parties, which could take place bilaterally or could involve several designated bodies"</i> .
(4)	BASIS: SSG-44 Action 32 para. 4-128 states that <i>"The designated body should monitor and assess the effectiveness of the established coordination arrangements and, when necessary, should undertake actions to improve coordination."</i>
S17	Suggestion: The GIS and PAA should consider enhancing the coordination of their regulatory activities in the area of the medical use of radiation sources by means of systematic exchange of the regulatory plans, feedback and experience, regular communication and joint inspections.

The IRRS team observed the conduct of two inspections planned by the PAA to an industrial facility and jointly scheduled by the PAA and the GIS to a medical facility.

Visit to GEXAM NDT to observe PAA inspection

Two members of the IRRS team observed an inspection conducted by two PAA inspectors at GEXAM NDT in Plock which performs industrial radiography on client sites including transport of radioactive sources. The company has seven workers who are occupationally exposed and performed industrial radiography mainly at the refinery nearby. As a rule, PAA conducts inspections of the licensee every two years. Two owners (one of them is the radiation protection expert) of GEXAM NDT participated in the inspection.

The inspection started with a short entrance meeting followed by a review of documentation, inspection of the storage bunker, and inspection of two of the company vehicles. One PAA inspector requested to see various documents whilst the second inspector recorded the findings via a laptop linked to PAA inspection report software operating on the PAA server in Warsaw. The checklist in the PAA software included a selected set of legal requirements, for example on protection of workers, procedures to be applied in emergency exposure situations, documentation related to leakage tests, etc. The inspection of the storage facility for disused radiation sources included dose rate measurements which were conducted by the PAA inspectors in an efficient manner. PAA inspectors carried their own equipment and personal protective equipment, including personal dosimeters. PAA inspectors performed measurements independently. Equipment within two licensee cars used for the transport of radioactive sources was performed in order to verify compliance with ADR.

Open questions regarding implementation of legal requirements were resolved during the inspection using access to the PAA documentation by the inspector using his laptop. All inspection observations were given

orally to the operator. In parallel they were noted in the inspection report, which was prepared during inspection. Two copies of the inspection report were printed, using a PAA mobile printer, and both copies were signed by both inspectors and both owners of the company. A signed copy of the inspection report was retained by the PAA lead inspector and the director of the company.

The IRRS team observed good interaction between licensee and inspectors as well as between both inspectors.

In a discussion with the IRRS team, the operator underlined the prompt response of the PAA regarding the authorization and inspection processes as well as the professional attitude of the PAA inspectors. It was also noted that the operator appreciated the PAA giving comprehensive information regarding implementation of regulations related to industrial radiography.

<u>Visit to The Maria Sklodowska-Curie National Research Institute of Oncology to observe PAA and WSSE inspection</u>

The IRRS team observed two simultaneous inspections performed by the PAA and the WSSE to the radiotherapy department of the hospital The Maria Sklodowska-Curie National Research Institute of Oncology, that is authorized by the PAA and the WSSE to carry out diagnostic radiology, radiotherapy and nuclear medicine. There were two announced and planned inspections based on the related authorization documents running simultaneously, but they were not prepared as a joint inspection. The IRRS Team was informed that normally such inspections are carried out separately.

During the initial meeting, the Hospital representatives were informed about the scope of the inspection. The management of the hospital was present at the initial meeting, and staff members with relevant responsibilities were involved in the inspection.

The inspections were carried out according to the PAA and WSSE's respective inspection protocols. The inspectors in both authorities conducted themselves very professionally and openly discussed issues with the hospital representatives. The inspectors established an effective dialogue for coordinating their questions and requests.

PAA inspectors carried their own equipment and personal protective equipment, including personal dosimeters, and performed measurements independently.

At the end of the inspection PAA and WSSE inspectors prepared their written reports and presented them to the Hospital representatives in draft form for review of correctness of information, before the final reports were issued. The inspection reports were presented orally to Hospital heads at the exit meeting and signed. At the exit meeting the Vice-director of the hospital was present.

After the inspection, the IRRS team interviewed the Hospital representatives who stated that they had good cooperation with both authorities. They highlighted some difficulties in having access to medical physics specialists to fulfil the requirements of the updated ALA.

While it was considered that some authorizations took too much time, and that there was some overlap with inspections, the hospital representatives reported that both authorities openly and readily replied to any queries and had a constructive impact.

7.5. INSPECTION OF DECOMMISSIONING ACTIVITIES

The inspection of technical conditions of the EWA research reactor under decommissioning is done in accordance with the Inspection Recommendation 9, which is a PAA internal guide specific on inspection of decommissioning. The purpose of this document is to check that the inspection of decommissioning of the facilities is in line with PAA internal procedures, regulations, requirements and license conditions.

The PAA inspectors perform inspections on decommissioning facilities in their respective field of expertise.

Visit to EWA Research Reactor Facility at the ZUOP site to observe PAA inspection.

Two members of the IRRS team observed an inspection conducted by the PAA to EWA research reactor at ZUOP (Radioactive Waste Management Plant) site. The EWA research reactor is under decommissioning.

The inspection started with an entrance meeting with the Director of the ZUOP and the other representatives of the facility. PAA inspectors explained the inspection scope, objectives and programme which included checking of maintenance records in the logbook and performing independent workplace radiation measurements.

After the review of maintenance records, the inspectors visited the facility checking the ventilation systems as well as performing radiation measurements in the building. After the walk down, the inspectors compiled their findings and presented them to the facility team during the exit meeting.

After the exit meeting, the IRRS Team had an opportunity to discuss in private with the Director of the facility. He indicated that there is in general a good working relationship with PAA in that there had been an opportunity to also comment on the recent revision of the ALA. He further indicated that the relationship with the PAA supports the prioritization of safety related activities.

The members of the IRRS team were of the view that the inspection was conducted in a professional manner and in accordance with set procedures.

7.6. INSPECTION OF TRANSPORT

Inspection of licensees is applied using the graded approach with the periodicity ranging from 2 to 5 years. The supervision and control, requirements are cited in chapter 9 of the Atomic Law Act (ALA) and the process of inspection is documented by the PAA.

The extent of transport activity in the transport of radioactive material sector in 2022 was as follows:

- Some 500 organizations that transport radioactive material,
- Approximately 71 000 packages in 30 000 shipments were completed, of which 12 000 shipments were of Type A packages,
- 111 transport inspections were completed,

The IRRS team considers this low level of resources should be increased to provide resilience to the inspection process for facilities in relation to the transport of radioactive material, particularly as the same PAA staff member is responsible for the review, assessment, and authorisation processes for package designs related to transport safety regulatory oversight activities. This issue is addressed by Recommendation R4 in Section 3.3.

The IRRS team noted that for the transport of radioactive material, the Main Inspectorate of Road Transport is responsible for ADR roadside compliance inspection of vehicles carrying radioactive material. The PAA does not receive information for any enforcement notices issued relating to vehicles carrying radioactive material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: In the regulatory inspection of activities related to the transport of radioactive material, the PAA does not exchange information regarding enforcement actions with the Chief Inspectorate of Road Transport that is responsible for ADR, roadside compliance inspections.

(1)

BASIS: GSR Part 1 (Rev. 1) Requirement 7 states that "Coordination of different authorities with responsibilities for safety within the regulatory framework for safety, Where several authorities have responsibilities for safety within the regulatory framework for

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."	
S18	Suggestion: The PAA should consider seeking agreement with the Chief Inspectorate of Road Transport to develop a process for the timely exchange of information regarding enforcement actions relating to the transport of radioactive material.	

7.7. INSPECTION OF OCCUPATIONAL EXPOSURE

Inspections concerning occupational exposure are carried out by the PAA according to procedures outlined in previous sections. The inspection programme is aimed at verifying that registrants and licensees have implemented the requirements for:

- Classification of exposed workers.
- Classification of areas.
- Individual and workplace monitoring.
- Health surveillance of exposed workers.
- Radiation detection systems and protective equipment.
- Application of the optimization principle in working methods.
- Records of occupational exposure results.
- Procedures to address and correct the situation if exposure exceeds the predicted level.
- Training of exposed workers.

During inspections, PAA inspectors carry out independent measurements to verify compliance with the dose constraints for the public and for exposed workers that have been proposed by the registrant or licensee and that dose limits are not exceeded.

The inspection programme implemented by the PAA with regards to occupational exposure is established according to a graded approach, with frequencies ranging from 1 to 10 years.

PAA inspectors are heavily dependent on the implementation and the comprehensiveness of the inspection programme in occupational protection as no review and assessment of the issue is done during the authorization process. This issue is addressed in Recommendation R12 in section 6.1.4.

The WSSE also carries inspection in matters relating to inspection of occupational exposure in healthcare facilities, although the main focus of such inspections is patient protection. The IRRS observed, during WSSE inspections, that workers' dose records kept by the operator are reviewed by the inspectors, as well as workers' qualifications. The process for WSSE inspections is detailed further in section 7.8. The fact that there are some overlaps with the scope of inspections carried out by both authorities highlights the need for further enhancing cooperation between both organizations. This issue is addressed by Suggestion S17 in Section 7.4).

7.8. INSPECTION OF MEDICAL EXPOSURE

The PAA conducts inspections for the facilities and activities that carry out medical exposures that are under its regulatory oversight (e.g. radiotherapy, nuclear medicine) according to the same procedures described in previous sections. These inspections are focused on aspects of occupational and public exposure.

Inspection of aspects relating to patient protection in all healthcare units are carried out by the WSSE

Regulations for inspection of healthcare facilities by the WSSE determine that inspections should be carried out at least once every four years. The WSSE has established an inspection plan.

The number of inspections outlined in section 7.4 indicates that the WSSE carried inspections in around 20% of the facilities with authorized medical radiological equipment, regardless of the type. Thus, it can be inferred that the frequency of inspection for the different types of equipment considered in the inspection plan does not take into account a graded approach, using instead the same criteria for all types of equipment despite the different risks.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The regulations establish a minimum frequency of inspections carried out by GIS, but the inspection plan for medical facilities uses does not differentiate between the different practices involved to take into account a graded approach.

(1)	BASIS: GSR Part 1 para. 4.50 states that "The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."
S19	Suggestion: The Government should consider assigning the GIS with the authority to establish the frequencies of inspections to be implemented in accordance with a graded

7.9. INSPECTION OF PUBLIC EXPOSURE

approach.

Provisions for inspection of the arrangements related to public exposure are included in the inspection programme of the facilities and activities regulated by the corresponding competent authorities, i.e. When needed, specific inspections related to public exposure can be conducted, e.g. related to unusual discharges from a facility. In such cases continuous monitoring including inspections of operator's activities is carried out by the PAA.

Competent authorities use checklists at inspections in order to assess compliance with regulatory requirements. The IRRS team was informed that the PAA has recently developed nine new inspection protocols which are applicable for inspections of facilities and activities with radiation sources. The protocols do not specifically address the control of visitors in controlled areas. This issue is addressed in Recommendation R21 in Section 9.9.

As a general practice, the inspectors review documents related to public exposure, e.g. calibration of instruments and use of signs and labels, followed by independent measurements to verify shielding of the facility as appropriate. The measurements are recorded. The inspector observations related to public exposure are documented in an inspection report which is given to the operator.

7.10. SUMMARY

The PAA and WSSE inspection processes are defined by the legal framework and generally are in line with the IAEA safety standards. Suggestions for improvements are given in the areas of: enhancing coordination of PAA and WSSE inspection activities, assessing and promoting the safety culture, using in inspection process the exchange of information regarding enforcement actions relating to the transport of radioactive material and establishing the frequency of inspections conducted by sanitary inspectors in accordance with a graded approach.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The ALA provides a basis for the PAA to initiate and exercise enforcement actions for non-compliance with applicable legal provisions and conditions in the authorizations. These articles of the ALA set the process and the elements that enable the PAA to enforce its regulatory requirements and conditions of the authorizations. The PAA inspectors can also take immediate enforcement actions, including suspending the activities, if imminent threat to safety is observed.

The IRRS team acknowledged that the PAA implements enforcement actions when necessary for responding to non-compliance by authorized parties with regulatory requirements or conditions specified in the authorization of facilities and activities. The IRRS team was informed that the PAA is in the process of completing an enforcement procedure. but concluded that the PAA does not have an enforcement policy establishing internal governance and guidance for enforcement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The ALA has comprehensive provisions for enforcing legal and regulatory requirements and the PAA applies these legal provisions in the enforcement process. However, the PAA has not yet developed its own enforcement policy establishing internal governance and guidance for enforcement.

(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: GSG-13 para. 3.312 states that "The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions, which should be documented in internal guidance. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures."
R17	Recommendation: The PAA should establish and implement an enforcement policy to establish internal governance and guidance for enforcement.

8.2. ENFORCEMENT IMPLEMENTATIONS

Enforcement is included in the scope of the training programme of PAA inspectors and attention is given to the applying a graded approach as is used in the ALA which defines different financial penalties for non-compliances.

Other authorities have appointed inspectors and there is a room to improve coordination between the authorities to ensure the training programmes and appointment process provides a consistent approach to implementing enforcement in a harmonized and consistent way. The establishment of an enforcement policy would assist in this issue.

8.3. SUMMARY

The ALA provides appropriate means for enforcing regulatory requirements. The PAA addressed the need for an enforcement procedure in the action plan. The PAA has not established an enforcement policy to ensure that PAA uses enforcement actions for responding to non-compliances to ensure proper implementation of the legal provisions in accordance with a graded approach.

9. **REGULATIONS AND GUIDES**

9.1. GENERIC ISSUES

The Government has issued a comprehensive set of regulations covering requirements for authorized facilities and activities and all other exposure situations. The PAA President is the leading authority in Poland regarding the ALA, i.e. the PAA is drafting the law as well as all its amendments. In addition to the ALA, regulations and guides are issued. The guides are not legally binding. Regulations, i.e. 61 in total, are drafted by PAA or other competent authorities as stated in the ALA. At present 12 regulations are planned. Regulations are adopted by the Council of Ministries or by appropriate minister in line with the ALA.

The PAA has a well-established process to draft the regulations which includes several steps before approval of a regulation by the Council of Ministers. The initial draft prepared by the appropriate organizational unit of the PAA is also presented to the Council for the Nuclear and Radiation Safety (CNSRP) in the process of preparing regulations. One of the steps includes consultation with the public, i.e. a draft is published on the web for public consultation. The cooperation with other ministries is assured. The regulations issued by the respective minister follow a similar approach. The public is asked to give the comments also on the drafts of the regulations to be approved by the respective ministry. All regulations are published in Official Journal and on the web.

The PAA procedure to prepare and publish a guide is less complex than a procedure used for preparing law or regulations. Guides are approved by the President of the PAA. At present five guides exist and six are planned. The PAA quarterly reviews its plan for preparation of guides.

Although the list of regulations available is comprehensive, the IRRS team noted some missing regulatory requirements. Protection of visitors of controlled and supervised areas is addressed in regulations but there is no regulatory provision requiring that a person under the age of 18 years are allowed access to controlled areas only under supervision and that visitors have to be accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The legal requirements for access to controlled areas do not ensure that persons under the age of 18 years are allowed access only under supervision and that visitors are accompanied by a person who knows the measures for protection and safety for the controlled area.

(1)	BASIS: GSR Part 3 para. 3.116 states that "Employers, registrants and licensees shall ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment in which they are or could be subject to occupational exposure or for the purpose of studies in which sources are used."
	BASIS: GSR Part 3 para. 3.128 states that <i>"Registrants and licensees, in cooperation with employers where appropriate:</i>
	a) Shall apply the relevant requirements of these Standards in respect of public exposure for visitors to a controlled area or a supervised area;
(2)	b) Shall ensure that visitors are accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area;
	c) Shall provide adequate information and instructions to visitors before they enter a controlled area or a supervised area, so as to provide for protection and safety for visitors and for other individuals who could be affected by their actions;
	d) Shall ensure that adequate control is maintained over the entry of visitors to a controlled area or a supervised area, including the use of signs for such areas."

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Recommendation: The Government should update regulatory requirements for access to controlled areas assuring that persons under the age of 18 years are allowed access only under supervision and only for training or studying purposes and that visitors are accompanied by a person who knows the measures for protection and safety for the controlled area.

Regarding occupational exposure, the current set of legislations and regulations on radiation protection are generally applicable to a nuclear power programme. Furthermore, there are mechanisms for the regulatory body to establish dose limits and requirements for constraints for planned exposure situations.

9.2. REGULATIONS AND GUIDES FOR RESEARCH REACTORS

The scope and methods of safety analysis, and the scope of preliminary safety analysis reports are prescribed by regulations. Requirements were reportedly prepared for all nuclear facilities. However, a number of requirements are only applicable to nuclear power plants. The specificities of research reactors are not sufficiently taken into consideration and several requirements are irrelevant for them, e.g., those related to the format and content of the safety analysis report. Moreover, utilization of research reactors as experiment facilities, irradiation equipment and hot cells are not covered by this regulation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The document "Reg 31.08.2012 on scope on methodology to perform safety analyses and scope of preliminary safety report for a nuclear facility" does not clearly establish the provisions on the content of SAR for RRs, in accordance with a graded approach. There is no guide to address the format of SAR for RRs.

(1)	BASIS: GSR Part 1 (Rev.1) para 4.34 states that "The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."
(2)	BASIS: GSR Part 1 (Rev.1) Requirement 32 states that "The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based".
S20	Suggestion: The PAA should consider establishing regulatory provisions and guides on the format and content of the SAR for research reactors.

The ALA sets up legal provisions requiring the establishment of an integrated management system for nuclear facilities. However, there are no legal provisions for assessment and continuous improvement of such management systems throughout the lifetime of nuclear facilities, including research reactors. Only provisions related to radiological protection are required to be assessed and improved.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There are no regulatory provisions requiring the assessment and continuous improvement of the integrated management system during the construction and decommissioning of nuclear facilities. The current provisions are only to assess the correctness of implementation of integrated management system in the scope of radiological protection during commissioning and operation of nuclear facilities.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: SSR-3 Requirement 4 states that "The operating organization for a research reactor facility shall establish, implement, assess and continuously improve an integrated management system."	
S21	Suggestion: The Government should consider establishing regulations to require the assessment and continuous improvement of the integrated management system of research reactors.	

9.3. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The ALA and supporting regulations have well-established requirements on radioactive waste and spent nuclear fuel. The updated National Plan of radioactive and spent nuclear fuel management is aimed at ensuring development and implementation of national, consistent, integrated, and sustainable management system comprising all categories of radioactive waste generated in the country. Actions, provided for in the National Plan, shall ensure appropriate, safe, and sustainable management of radioactive waste and spent nuclear fuel.

9.4. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Safety requirements for the facilities and activities of the radiation sources are established in the ALA and regulations of the Council of Ministers. The IRRS team was provided with 9 regulations of the Council of Ministers for the safety of radiation facilities and activities.

Until now, only one safety guide concerning radiation sources applications has been published: "Technical and organizational recommendations of the President of the National Atomic Energy Agency on the use of x-ray machines for purposes veterinary in x-ray and commissioning laboratories of such laboratories and concerning the use of apparatus for veterinary purposes outside the laboratory".

To regulate patient protection and the use of x-ray generators for medical purposes for humans, a number of regulations of the Minister of Health are applied.

9.5. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

There is no specific observation in this area. The ALA and supporting regulations have well-established regulations on nuclear safety and radiological protection requirements for the stage of decommissioning of the nuclear facilities and the contents of report on a decommissioning facility.

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

Poland has adopted the ADR Agreement for the transport of dangerous goods by road, RID Agreement for the transport of dangerous goods by rail, and ADN Agreement for the transport of dangerous goods by inland waterway, which set out the requirements for the transport of radioactive material. ADR, RID, and ADN have adopted the requirements set out in SSR-6 (Rev.1). SSR-6 (Rev.1) requirements are also adopted by:

- 1. The International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) which augment the broad principles governing the international transport of hazardous materials by air contained in Annex 18 to the Convention on International Civil Aviation; and
- 2. The International Convention for the Safety of Life at Sea, 1974 (SOLAS), as amended, deals with the various aspects of maritime safety, and contains in chapter VII the mandatory provisions

governing the carriage of dangerous goods in packaged form. The carriage of dangerous goods in packaged form shall comply with the relevant provisions of the International Maritime Dangerous Goods (IMDG) Code which is considered an extension to the provisions of SOLAS chapter VII.

The national regulatory requirements regarding transport safety are already in place and are successfully implemented for various radiation sources including High Activity Sealed Sources (HASS).

9.7. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

Provisions for protection of workers and the responsibilities of all parties involved are mainly established in the ALA, including dose limits for occupational exposure for workers and apprentices.

Requirements for controlled and supervised areas are established in regulations, generally in line with provisions from GSR Part 3. However, these regulations do not ensure that persons under the age of 18 years are allowed access to such controlled areas only under supervision. This issue was identified in the Action Plan and is addressed in Recommendation R18 in section 9.1.

Provisions in the Labour Code require workers to comply with all the principles of health and safety at work, ensuring requirements for radiation protection and safety are met. While the ALA does not explicitly state that an employer cannot provide benefits to employees as a substitute for the necessary protective measures, the general provisions of the Labour Code in place limit such a possibility.

Requirements for occupational exposure in existing exposure situations are established in the ALA and Regulations.

Provisions in the law assign responsibility for radiation protection of aircrews to the aircraft operators. If the dose received by aircrews are likely to exceed 1 mSv per year, the aircraft operator is required to ensure the assessment of worker doses and to take that into account when planning flights. The IRRS team was informed that these assessments are regularly carried out by a laboratory in a neighbouring country that is accredited according to the ISO/IEC 17025 standard. The results of the assessments are submitted regularly by aircraft operators to the Civil Aviation Authority. However, the authority did not define the methodology used to carry out these assessments.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *No methodology has been established to carry out the assessment of doses received by individual aircrews.*

(1)	BASIS: GSR Part 3 para. 5.31 states that <i>"Where such assessment is deemed to be warranted, the regulatory body or other relevant authority shall establish a framework which shall include a reference level of dose and a methodology for the assessment and recording of doses received by aircrew from occupational exposure to cosmic radiation."</i>
(2)	 BASIS: GSR Part 3 para. 5.32 (a) states that "Where the doses of aircrew are likely to exceed the reference level, employers of aircrew: i. Shall assess and keep records of doses; ii. Shall make records of doses available to aircrew."
S22	Suggestion: The Government should consider defining the methodology for the assessment of doses received by aircrews.

9.8. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

In addition to the ALA and regulations prepared by the PAA, there are comprehensive regulations established by the Ministry of Health, namely for acceptance and constancy testing defined for medical radiological equipment. These regulations specify the parameters to be verified before clinical use and for

evaluation of equipment performance. However, these do not include a requirement that medical physicists should perform independent verifications of the calibration of radiation therapy units.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Regulations do not include requirements for calibration of radiation therapy units to undergo independent verification prior to clinical use.

(1)

(1)

BASIS: GSR Part 3 para. 3.167(c) states that "... the medical physicist shall ensure that: ...

c) Calibrations of radiation therapy units are subject to independent verification* prior to clinical use.

*Independent verification' ideally means verification by a different, independent medical physicist using different dosimetry equipment. However, other options, such as verification by a second medical physicist or verification using a second set of equipment, or even using a form of verification by postal thermoluminescence dosimetry, could be acceptable."

R19 Recommendation: The Government should establish provisions in the regulations to ensure independent verification of calibration of radiation therapy units.

There are provisions for legal metrology of dosimetry instruments to be carried out with traceability to primary standards. Accreditation according to ISO/IEC standards is carried out by the Polish Accreditation Centre (PCA). The PAA is part of the Polish Committee for Standardization (PKN) advisory group that reviews new international standards before being introduced in Poland.

There are requirements for medical exposure to be justified, taking into account the expected diagnostic or therapeutic benefits, including the direct benefits to health of a person and the benefits to society, against the health detriment that the exposure might cause in persons or their descendants. The justification requirements take into account the benefits and types of risks associated with the use of alternative methods employed for the same purpose.

Regulations are in force regarding training and authorization of relevant parties with duties in relation to protection and safety for individuals undergoing medical exposures.

Diagnostic reference levels have been established in regulations and are reviewed every 5 years. They were established through a process of national surveys and through a review of relevant literature.

Regulations from the Ministry of Health establish guidelines for the release of patients that have undergone therapeutic radiological procedures with sealed or unsealed sources. These guidelines determine that such patients must not be released from healthcare facilities unless the activity remaining in the body is lower than 800 MBq. However, these guidelines do not describe the methodology to be used for assessing this activity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The guidelines for release of patients that have undergone therapeutic radiological procedures with sealed or unsealed sources do not include the methodology for assessing the activity of radionuclides remaining in the patient and the doses that may be received by members of the public and family members.

BASIS: GSR Part 3 para. 3.178 states that "The radiological medical practitioner shall ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source or an unsealed source is discharged from a medical radiation facility until it has been established by either a medical physicist or the facility's radiation protection officer that:

(a) The activity of radionuclides in the patient is such that doses that could be received by members of the public and family members would be in compliance with the requirements set

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	by the relevant authorities;"	
R20	Recommendation: The Government should include the methodology for assessment of activity remaining in the patient in the regulation covering the release of patients that have undergone therapeutic radiological procedures with sealed or unsealed sources.	

9.9. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The regulations address public exposure from authorized facilities and activities, existing and emergency exposure situations, including radioactivity in commodities.

Regarding consumer products, the regulations do not address several obligations of designers, manufacturers and other providers of consumer products as required by GSR Part 3. The regulations do not require that providers of consumer products shall plan for appropriate arrangements for the servicing, maintenance, recycling or disposal of consumer products. Nor do they address the responsibilities of designers, manufacturers and other providers of consumer products are accompanied by appropriate information and instructions for safe handling including storage and transport. The issue in relation to the regulatory control related to consumer products was addressed in the Action plan developed by Poland.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
consumer	tion: Regulations do not address all obligations of designers, manufacturers and other providers of products regarding servicing, maintenance, design of consumer products, information to be provided on il packaging and each consumer product and information on transport and storage to be provided to
	BASIS: GSR Part 3 para. 3.140 states that "Providers of consumer products:
(1)	<i>a)</i> Shall comply with the conditions of the authorization to provide consumer products to the public;
(1)	b) Shall ensure that consumer products comply with the requirements of these Standards;
	<i>c)</i> Shall plan for appropriate arrangements for the servicing, maintenance, recycling or disposal of consumer products."
	BASIS: GSR Part 3 para. 3.141 states that "The design and manufacture of consumer products, with regard to features that could affect exposure during normal handling, transport and use, as well as in the event of mishandling, misuse, accident or disposal, shall be subject to the optimization of protection and safety. In this regard, designers, manufacturers and other providers of consumer products shall take into account the following:
	a) The various radionuclides that could be used in consumer products and their radiation types, energies, activities and half-lives;
(2)	b) The chemical and physical forms of the radionuclides that could be used in consumer products and their significance for protection and safety in normal conditions and abnormal conditions;
	c) The containment and shielding of radioactive substances in consumer products and access to these radioactive substances in normal conditions and abnormal conditions;
	<i>d)</i> The need for servicing or repair of consumer products and ways in which this could be done;
	e) Relevant experience with similar consumer products."

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 3 para. 3.142 states that "Providers of consumer products shall ensure that:	
	a) Where practicable, a legible label is firmly affixed to a visible surface of each consumer product that:	
(3)	<i>i.States that the consumer product contains radioactive substances and identifies the radionuclides and their activities;</i>	
	<i>ii.States that the provision of the consumer product to the public has been authorized by the regulatory body;</i>	
	iii.Provides information on required or recommended options for recycling or disposal.	
	<i>b)</i> The information specified in (a) above is also printed legibly on the retail packaging of the consumer product."	
	BASIS: GSR Part 3 para. 3.143 states that <i>"Providers of consumer products shall provide clear and appropriate information and instructions with each consumer product on:</i>	
	1. Correct installation, use and maintenance of the consumer product;	
(4)	2. Servicing and repair;	
	3. The radionuclides and their activities at a specified date;	
	4. Dose rates in normal operation and during servicing and repair;	
	5. Required or recommended options for recycling or disposal."	
	BASIS: GSR Part 3 para. 3.144 states that "Providers of consumer products shall provide	
(5)	the consumer product retailers with appropriate information on safety and instructions on their transport and storage."	
	Recommendation: The Government should revise the regulations in order to address all	
R21	the obligations of the designers, manufacturers and other providers of consumer products.	

Monitoring programmes conducted by registrants and licenses to control public exposure include control of external exposure, discharges and radioactivity in the environment. The results are reported to the PAA which is obliged to keep the data on discharges, monitoring programmes and assessment of public exposure. On the other hand, there is no requirement for registrants and licensees to maintain records of source monitoring, environmental monitoring and estimated doses to members of the public.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Regulations require authorized parties to record the results of programmes for source monitoring, environmental monitoring and estimated doses to members of the public, but maintenance of the records is not addressed.

(1)	 BASIS: GSR Part 3 para. 3.117 states that "Registrants and licensees shall, as appropriate: b) Maintain appropriate records of the results of the monitoring programmes and estimated doses to members of the public.
R22	Recommendation: The Government should revise regulations to require authorized parties to maintain appropriate records of the results of the source and environmental monitoring programmes and estimated doses to members of the public.

9.10. SUMMARY

The IRRS team concluded that the present set of regulations and guides in general sufficiently address nuclear and radiation safety. Improvements are needed in several areas, namely:

- the updating of regulatory requirements for access to controlled areas;
- establishing regulatory provisions and guides on the format and content of the SAR for research reactors;
- establishing regulations to require the assessment and continuous improvement of the integrated management system of research reactor;
- defining the methodology for the assessment of doses received by aircrews;
- establishing provisions in the regulations to ensure independent verification of calibration of radiation therapy units;
- including the methodology for assessment of activity remaining in the patient in the guidelines for release of patients that have undergone therapeutic radiological procedures with sealed or unsealed sources;
- revision of the regulations in order to address all the obligations of the designers, manufacturers and other providers of consumer products; and
- revision of regulations to require registrants and licensees to maintain appropriate records of the results of the source and environmental monitoring programmes and estimated doses to members of the public.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

This module of the report deals with the PAA and does not specifically address the other regulatory authorities (the State Provincial Sanitary Inspectors and the Military Sanitary Inspector) unless it is deemed relevant.

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

The roles and responsibilities for regulating on-site EPR of operating organizations have been assigned to the appropriate regulatory bodies, namely, the PAA, State Regional Sanitary Inspectors and Military Sanitary Inspector, through Article 5 of the ALA.

The Radiation Emergency Centre of the PAA has demonstrated that they have the necessary human, financial and other resources to regulate on-site EPR arrangements of relevant facilities in accordance with a graded approach. These arrangements are primarily dealt with through the licensing and inspection procedures and processes established by PAA.

For the licensing of facilities, PAA procedures make provisions for the inclusion of suitably qualified staff from relevant departments of the organization to review licence applications. According to the ALA, licence applications must include information on the Emergency Management System for the facility, i.e. information on hazard assessments, on-site emergency plans, communication plans, notification measures and criteria for transition from an emergency exposure situation to a planned or existing exposure situation. Staff from the Radiation Emergency Centre review the Emergency Management System for on-site EPR arrangements submitted as part of the licensing process for relevant (Emergency Preparedness) Category II facilities.

In addition, the PAA have procedures for both the preparation and carrying out of periodic and ad-hoc inspections that also include provisions for relevant PAA employees to take part in inspections as experts or specialists. Staff from the Radiation Emergency Centre can and do participate in inspections to review on-site EPR arrangements for Category II facilities.

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

Requirements for on-site EPR arrangements are outlined in Article 86d of the ALA and have been supplemented further in the following Regulations:

- Regulation on emergency plans in the event of radiation emergencies (2021);
- Regulation on the scope of a hazard assessment resulting from an activity involving exposure to ionizing radiation (2021);
- Regulation on the types of protective actions introduced in an external zone, and the operational intervention levels constituting a basis for the introduction of these actions in the external zone (2020);
- Regulation on the scope of an environmental radiation monitoring program developed and implemented by organizational entities included in category I or II of hazards (2022); and
- Regulation on intervention levels for various intervention measures and criteria for cancelling intervention measures (2004).

PAA has produced guidance for operating organizations for on-site EPR arrangements to assist them in the fulfilment of their obligations under these regulations. For Category I and Category II facilities, the PAA has produced guidance for licensees on the Determination of emergency planning zones and emergency planning distances around Category I or Category II facilities. At the request of the Radiation Protection

Department of the PAA, the Radiation Emergency Centre produced guidance for licensees performing activities classified as hazard category III or IV, which has reduced the administrative burden for operating organizations and the PAA when licensing these facilities. The IRRS team considered this guidance as a good performance.

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

As outlined in Section 10.1 above, PAA procedures for the preparation and carrying out of both periodic and ad-hoc inspections include provisions for staff from the Radiation Emergency Centre to take part in inspections as an expert or specialist to review on-site EPR arrangements. Prior to such inspections, an inspection plan is drafted by the inspector and relevant experts. If Radiation Emergency Centre staff are in attendance, the inspection plan would include a review of the Emergency Management System and outcomes from exercises conducted by the operating organization. The regulations address monitoring to be conducted by the licensee of Category I or Category II hazard activities during an emergency in the event of unexpected increases in radiation levels or in concentrations of radionuclides in the environment resulting from an accident or from other unusual events attributed to the authorized source or facility. However, there is a lack of formal criteria to be used by PAA when assessing the licensee's capabilities to conduct such monitoring. However, there is no PAA internal guidance addressing registrant or licensee capabilities to conduct monitoring in an emergency exposure situation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: There is no PAA internal guidance addressing registrant or licensee capabilities to conduct monitoring in an emergency exposure situation.

(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.45 (10) states that "In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as: (10) Arrangements for preparedness for, and response to, emergencies;"
(2)	BASIS: GSG-13 para. 4.45 states that "In order to ensure a systematic and consistent approach, the regulatory body should develop internal guidance on the processes and procedures to be followed to carry out the regulatory functions in an effective and efficient manner as well as on the safety objectives to be met"
(3)	BASIS: GSR Part 3 para. 3.135 (f) states that <i>"The regulatory body shall be responsible, as appropriate, for: …</i> Verification of compliance of an authorized practice with the requirements of these Standards for the control of public exposure".
(4)	 BASIS: GSR Part 3 para. 3.137 (f) states that "Registrants and licensees shall, as appropriate: (f) Establish and maintain a capability to conduct monitoring in an emergency in the event of unexpected increases in radiation levels or in concentrations of radionuclides in the environment due to an accident or other unusual event attributed to the authorized source or facility.
S23	Suggestion: The PAA should consider developing internal guidance to review applicants and authorised parties, as appropriate, capabilities to conduct monitoring in an emergency exposure situation.

Emergency Exercises for Categories I, II, III and IV facilities are performed routinely, the frequency of which are outlined in Article 96 (6) of the ALA.

These exercises are evaluated against pre-established criteria and can also be witnessed by PAA. Radiation Emergency Centre Staff members can attend an on-site inspection, as specialists, to observe on-site emergency exercises at Category II facilities. However, only one on-site exercise has been observed in the past four years which may not be sufficient to evaluate the level of readiness of Category II facilities to respond to a nuclear or radiological emergency situation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES Observation: The PAA have only observed one on-site exercise at a Category II facility in the past four years.	
(2)	 BASIS: GSR Part 1 (Rev. 1) para. 4.3 states that "The objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. The regulatory process shall provide a high degree of confidence, until the release of facilities and activities from regulatory control, that e) Facilities are operated and activities are conducted within the limits and conditions specified in the safety assessment and established in the authorization, and operations
S24	 are carried out safely under a proper management system [9, 10]." Suggestion: The PAA should consider observing on-site EPR exercises at category II facilities more frequently to provide a high degree of confidence that EPR arrangements are effective, as part of its overall evaluation.

Exercises conducted by operating organizations are evaluated against pre-established criteria and include verification of all emergency scenarios specified in the on-site emergency plan, which includes co-operation with external emergency teams. On-site emergency procedures and plans are required to be updated taking into account lessons learned from emergency exercises. According to Article 96 section 7 of the ALA, outcomes from these exercises are forwarded to the regulatory body and, where appropriate, Regional Governors within 30 days of the exercises and are stored for a period of five years. Outcomes from these exercises can be reviewed by the PAA at any time and also during inspections. The PAA may issue an action plan to take corrective actions that may include updating the Emergency Management System or on-site EPR arrangements and the operating organization must address such corrective actions within an agreed timeframe.

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

The authority and responsibility for making decisions for on-site, regional and national response actions and communications are set out in the Article 84 of the ALA and in the Regulation on emergency plans in the event of radiation emergencies. For category I or II facilities, the licensee has responsibility for emergency preparedness and response in coordination with the regional governor, the regional chief of the State Fire Service and the regional police chief. In case of an emergency at a regional level, emergency preparedness and response is the responsibility of the Regional Governor in cooperation with the regional sanitary inspector.

The Minister of the Interior is responsible for emergency preparedness and response at the national level.

These roles and responsibilities for the coordination of response arrangements between operating organizations, and authorities at an on-site, regional and national level are set out in the ALA and in the National Nuclear Emergency Plan. The National Nuclear Emergency Plan is coordinated with other emergency plans through the 2007 Act on Crisis Management. The most recent national hazard assessment was conducted in 2021. The National Nuclear Emergency Plan was published in 2015 and was updated in 2019. Due to the transposition of the BSS Directive to ALA in 2019, the Minister of Interior is obligated to prepare completely new National Nuclear Emergency Plan and publish it before the end of 2023. Responsibilities for communication with the public following a nuclear or radiological emergency are set out in Article 92a of the ALA.

The Radiation Emergency Centre of PAA has developed appropriate procedures to enable the staff of the Radiation Emergency Centre, including Duty Officers, to respond appropriately to all stages of a nuclear and radiological emergency. The Radiation Emergency Centre has also developed internal EPR arrangements for all staff of the organization to enable them to prepare and respond to a nuclear and radiological emergency and provide relevant training to PAA staff on their roles and responsibilities during a nuclear or radiological emergency.

The Radiation Emergency Centre has analytical software that enables Radiation Emergency Centre staff to perform assessments of contaminations and doses. Sufficient supplies of monitoring equipment are available and maintained on a routine basis so that staff can respond to on-site emergencies and other radiological incidents where necessary.

The PAA operates and maintains a 24/7 National Contact Point for Radiation Emergency that enables them to respond to any nuclear or radiological emergency. This centre can be contacted by all operating organizations, national and regional government bodies, agencies, response organizations and members of the public concerning matters related to EPR for nuclear and radiological emergencies and incidents. The National Contact Point also acts as the designated national warning point and national competent authority for the IAEA early notification and assistance conventions. The National Contact Point is operated by a Duty Officer system and all Duty Officers undergo relevant specialist training to ensure they can respond effectively in the event of a nuclear or radiological emergency and provide the relevant advice to decision makers.

Response to a nuclear or radiological emergency is routinely tested through internal, national (e.g. PATROL exercises) and international nuclear exercises (e.g. ConvEx, ECUREX and INEX). The IRRS team witnessed an IAEA ConvEx 2b exercise during the mission.

International Nuclear exercises, such as Convex and ECUREX, are typically conducted by the PAA and coordination of response with other response organizations at a national level is not routinely tested. For example, PAA could invite the Ministry of Internal Affairs to participate in Convex-2 types and Convex-3 exercises.

	RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The PAA does not routinely involve other response organisations in international nuclear exercises.	
(1)	BASIS: GSR Part 7 para. 6.12 states that "Arrangements shall be developed, as appropriate, for the coordination of emergency preparedness and response and of protocols for operational interfaces between operating organizations and authorities at the local, regional and national levels, including those organizations and authorities responsible for the response to conventional emergencies and to nuclear security events (see paras 4.3, 4.10, 6.3)

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	and Requirement 6). The arrangements shall be clearly documented and the documentation shall be made available to all relevant parties. Arrangements shall be put in place to ensure effective working relationships among these organizations, both at the preparedness stage and in an emergency."
S25	Suggestion: The PAA should consider increasing the involvement of the authorities responsible for response to emergencies in international nuclear exercises on a routine basis to ensure effective working relationships amongst all organizations.

The PAA has the responsibility to assess contamination and doses in a nuclear or radiological emergency and to provide these assessments to the responsible authority to ensure they and other relevant stakeholders have the appropriate technical information prior to taking any protective actions. The PAA uses technical tools such as RASCAL and RODOS to assess contamination and doses and these tools are routinely tested during emergency exercises.

Poland maintains bilateral agreements with ten neighbouring countries: Austria, Belarus, Czechia, Denmark, Lithuania, Germany, Norway, Russian Federation, Slovakia and Ukraine. These agreements include mechanisms for exchange of information from an EPR perspective. The PAA has made significant use of these information exchange mechanisms in their bilateral agreement with Ukraine in the past 18 months.

The Radiation Emergency Centre staff are also building capacity to respond to radiological emergencies through the training of staff in the measurement and detection of radioactivity using the appropriate radiation measurement equipment. Training has been provided to the Regional Fire Services, WSSE and Border Guards. Radiation Emergency Centre staff are also very proactive in issuing public communications in response to concerns in relation to radiation and nuclear safety issues.

10.5. SUMMARY

The IRRS team identified a good performance in the area of EPR:

• The PAA has produced guidance for licensees performing activities classified as hazard category III or IV, which has reduced the administrative burden for Operating Organisations and PAA when licensing these facilities.

The IRRS team have made three suggestions to improve regulatory aspects of EPR:

- The PAA should consider developing internal guidance to review applicants and authorised parties, as appropriate, capabilities to conduct monitoring in an emergency exposure situation.
- The PAA should consider observing on-site EPR exercises at category II facilities more frequently to provide a high degree of confidence that EPR arrangements are effective.
- The PAA should consider involving, where relevant, the authorities responsible for response to emergencies in international nuclear exercises on a routine basis to ensure effective working relationships amongst all organizations. For example, PAA could invite the Ministry of Internal Affairs to participate in Convex-2 type and Convex-3 exercises.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

(1)

The legal framework for nuclear safety, radiation protection, security and safeguards of Poland is established under one comprehensive nuclear law – the ALA, covering all aspects of activities involving ionizing radiation, thereby having common provisions for licensing, oversight and enforcement. The ALA provides for the basis of the regulatory framework for safety, nuclear security and safeguards.

In the Polish legislation, provisions to protect people and the environment from harmful effects of ionizing radiation encompass nuclear security measures. The President of the PAA is the main authority responsible for safety and radiation protection, security, and safeguards for nuclear and radioactive materials. The roles and responsibilities of the PAA are provided in the ALA which mandates the PAA to oversee activities and to take enforcement actions in case of non-compliances related to safety, nuclear security, and the system of accounting for and control of nuclear material.

There are other authorities that are also responsible for different aspects of nuclear safety and nuclear security. For physical protection, the ALA assigns roles and oversight responsibilities to the President of the PAA and the Head of the Internal Security Agency (ABW), while roles and specific responsibilities for oversight and enforcement of other competent authorities derive from dedicated legislation and regulations.

The responsibility for developing and implementing a physical protection system for nuclear facilities or plan for the security of radioactive sources is assigned, respectively, to the head of an organizational entity authorized for a facility or an activity. The President of PAA is required to approve the physical protection system which has to be submitted – same as the plan for the security of radioactive sources - as part of the application for authorization, thus verifying the integrated design of safety measures and nuclear security measures.

In the case of nuclear facilities, the PAA is required to consult the Head of the ABW and can approve the physical protection system- and thus issue a license - only after obtaining its positive opinion.

Overall, the IRRS team found that the provisions and infrastructural arrangements for interfaces of safety, nuclear security and the system of accounting for, and, control of, nuclear material, are generally well established within the Polish governmental and legal framework. The IRRS team was informed that further efforts and areas of improvement with regard to nuclear security and consequently the interface between safety and nuclear security measures were identified following a gap analysis conducted by the PAA and clear proposals for revision have been formulated. In particular, issues concerning the emergency response arrangements and exercise to account for adequate response to both safety-related and nuclear security-related incidents. The IRRS team was informed that a comprehensive revision of the ALA and some of the regulation for physical protection is currently underway to improve the interfaces between nuclear safety and nuclear security aspects. The amendments are expected to be carried out in an overarching manner along with proposals related to the area of nuclear safety and radiation protection.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Gaps have been identified by the PAA in legal basis with regard to further integration between safety and physical protection of nuclear material and nuclear facilities and security of radioactive sources.

BASIS: GSR Part 1 (Rev. 1) para. 2.40 states that *"Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise nuclear safety and safety measures do not compromise nuclear security."*

develop a measures integratio	tion: The ALA mandates the head of the organizational entities of relevant facilities and activities to system for the management of radiation emergency situations. That system should be consistent with the for preparedness and response to nuclear security events, where needed. While there is some degree of m between safety measures in relevant facilities or activities at the response phase, this has not yet been cted in the legal and regulatory framework.
(1)	BASIS: GSR Part 1 (Rev. 1) para. 2.40 states that <i>"Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise nuclear safety and safety measures do not compromise nuclear safety and safety measures do not compromise nuclear security."</i>
(2)	 BASIS: GSR Part 1 (Rev. 1) para. 2.39 states that "Specific responsibilities within the governmental and legal framework shall include: (d) Integration of emergency arrangements for safety related and nuclear security related incidents."
S27	Suggestion: The Government should consider revising the existing legal and regulatory framework to request relevant facilities and activities to integrate safety and nuclear security measures in their emergency arrangements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Suggestion: The Government should consider finalizing the revision of the ALA and

relevant regulations to account for the identified gaps related to further integration

11.2. REGULATORY OVERSIGHT ACTIVITIES

between safety and nuclear security.

S26

The ALA assigns responsibility to the PAA to regulate the interface with nuclear security and to the Internal Security Agency (ABW) which is responsible for the internal security of Poland. ABW is also directly involved in the oversight of nuclear security through execution of its statutory tasks, namely with respect to counter-terrorism, nuclear proliferation prevention and other nuclear-security specific tasks (e.g. ICT systems and networks accreditation, physical protection system assessment, etc.).

The PAA oversees the fulfilment of the legislation with respect to the interface through authorizations activities concentrated around the assessment of the physical protection system of nuclear facilities or plan for the security of radioactive sources in case of activities involving radioactive material, and through decisions related to licensee's organization, procedures and facility design.

Within the PAA, authorization, oversight and enforcement for nuclear facilities are carried out by the Nuclear Safety and Security Department (DBJ) and for radioactive sources and associated facilities by the Radiation Protection Department (DOR). For both, having nuclear safety and nuclear security responsibilities institutionally structured under a joint Department ensures adequate coordination and safety-security interface as appropriate. Further, the interface between accounting for, and control of, nuclear material and the implementation of safeguards and nuclear security is handled by the DBJ's Division of Inspection and Non-Proliferation.

The PAA's oversight function includes inspections conducted by the DBJ (for nuclear material and nuclear facilities) and DOR (for radioactive sources and associated facilities), whereby PAA's inspectors have the authority to perform inspections in both nuclear safety and nuclear security, and some also in safeguards. The ALA also contains enforcement-related provisions allowing PAA's President to, inter alia, revoke a license if nuclear safety and/or nuclear security requirements are not fulfilled. The Police also conducts periodic inspections at nuclear facilities to review the implementation of the protection plan which is,

according to the Polish law, required for nuclear facilities as facilities important to national security and public infrastructure.

As part of regulatory inspection activities and oversight of licensee's performance, the licensee is required to report operating feedback to the President of the PAA which may include security events.

Both safety and nuclear security requirements are addressed in the Polish legislation and reflected in the PAA's management system, but they are often described individually for nuclear facilities and radiation sources and without referring to the interface between them. As part of its integrated management system, the PAA has a process and procedure for development of regulations on safety and nuclear security which require consultation with relevant Departments/Sections/Units during the drafting of a PAA regulation. However, without explicit recognition of the interface between safety and nuclear security, potential interference between them might be overlooked. The PAA acknowledges the need to further address the interface between safety and nuclear security in an integrated manner, in particular in the context of the Polish Nuclear Power Programme, and is working on a revision of the legal and regulatory framework to improve it. In this context, the PAA has identified the need to enhance the awareness, competencies and skills of its staff to ensure that they effectively manage the safety and nuclear security interface.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: Currently, the PAA has limited competences to adequately assess the effective management of the safety and nuclear security interface of facilities and activities. The need to raise awareness of the interface among staff has been identified.

-	(1)	BASIS: GSR Part 1 (Rev. 1) para. 4.13 states that " <i>A process shall be established to develop</i> <i>and maintain the necessary competence and skills of staff of the regulatory body, as an element</i> <i>of knowledge management. This process shall include the development of a specific training</i> <i>programme on the basis of an analysis of the necessary competence and skills. The training</i> <i>programme shall cover principles, concepts and technological aspects, as well as the</i> <i>procedures followed by the regulatory body for assessing applications for authorization, for</i> <i>inspecting facilities and activities, and for enforcing regulatory requirements</i> ".
	S28	Suggestion: The PAA should consider developing an internal training programme to raise awareness and ensure that the PAA staff are adequately competent to manage the safety and security interface.

11.3. INTERFACE AMONG AUTHORITIES

The ALA contains provisions establishing a system of comprehensive coordination of control and supervision of nuclear facility operations (i.e. "coordination system") between the PAA and other competent authorities, including the Internal Security Agency. According to the existing legal framework, the cooperation system is scoped around nuclear facilities and does not contain explicit reference to a similar mechanism with respect to radiation facilities.

Cooperation with other competent authorities, including law enforcement agencies, is stipulated in the legal framework for a number of matters, such as the approval of physical protection systems, development of the design basis threat and inspections. However, on an operational level, the cooperation on aspects related to safety and nuclear security interface occurs mostly on the basis of informal working level exchanges and existing needs, rather than on formal practical arrangements. Consideration could therefore be given to further formalizing the means of cooperation as well as extending the scope of the coordination system to encompass all types of facilities and authorities performing regulatory supervision and control, including the safety and nuclear security interface.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The coordination and cooperation between the different authorities having responsibility for safety and nuclear security, in particular with the Internal Security Agency (ABW) and the Ministry of the Interior and Administration, is in practice not always based on formal agreements, and relies on informal working-level arrangements and exchanges based on the existing needs.

(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 12 states that "The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material."
(2)	BASIS: GSR Part 1 (Rev. 1) para. 2.39 states that "Specific responsibilities within the governmental and legal framework shall include: (c) Liaison with law enforcement agencies, as appropriate."
(3)	BASIS: SSG-16 Action 194, para 3.124 states that "A single regulatory body may be responsible for both safety and nuclear security or the regulatory body may consist of separate competent authorities covering the areas of safety and nuclear security. A consultation and coordination mechanism is required between these authorities to ensure that any potential conflicts in implementing different regulatory requirements are avoided."
S29	Suggestion: The Government should consider enhancing the means for effective coordination and cooperation between the different authorities, which may include the development of formal working agreements, to enable for effective interfaces between safety and nuclear security.

11.4. SUMMARY

The ALA establishes the overall roles and responsibilities with regard to safety and nuclear security with a number of other legislative acts and regulations covering more specific responsibilities of other competent authorities for oversight and enforcement in nuclear security The PAA is the main authority responsible for the regulation of safety, nuclear security and safeguards.

The Polish legal framework contains provisions to enable for cooperation and coordination among the authorities having responsibilities for safety and nuclear security. However, this is often, in practice, limited to informal working-level arrangements and exchanges based on the existing needs rather than formalized process of mutual interactions. For further facilitation of effective communication and coordination regarding the interface between safety and nuclear security, consideration could be given to addressing the improvement of this coordination.

Both safety and nuclear security requirements are reflected in the PAA's management system and the PAA ensures that these are considered during regulatory activities. In doing this, the PAA should consider ensuring that the interface between safety and nuclear security is well addressed and documented in its management system, thus enabling early identification of potential conflicts and warranting that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.

With respect to competence, the PAA involves staff with both competences to ensure that the interface between safety and security is effectively addressed and accounted for, nevertheless further efforts within the PAA are needed to increase the awareness of safety and nuclear security interface as well as to sustain adequate capacities and strengthen culture in this regard.

12. TAILORED MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER

12.1 INTRODUCTION

Poland requested the inclusion of Module 12, the tailored module for countries embarking on a nuclear power programme, in the scope of the IRRS initial mission, to be carried out as a Phase 2 country. This tailored module comprises a review against actions set out in IAEA Safety Guide SSG-16 (Rev 1) Establishing the Safety Infrastructure for a Nuclear Power Programme.

SSG-16 (Rev 1) addresses the roles of the government, regulatory body, and operating organization. It should be noted that only the SSG-16 (Rev 1) actions that are to be taken by the government and the regulatory body are addressed in the mission. In addition, four actions from phase 1, namely actions 12, 49, 85 and 93, are considered relevant and were included in this review process.

Some of the actions described in SSG-16 (Rev 1) overlap with the scope of other IRRS Modules. When a suggestion made in Module 12 coincides with a finding made in another module, the relevance of the observation was used as the criteria to determine which module will host the recommendation or suggestion. In such cases, the observation is included in the text by limiting the discussion in the tailored module to the supplemental information in relation to the nuclear power programme and the reference is given to the recommendations and suggestions made in the other module.

The objective of the Polish Nuclear Power Programme (PNP Programme), which was last updated in 2020, is the construction and commissioning of a total of 6-9 GWe large-scale Generation III (+) pressurized water reactors of proven technology.

Polskie Elektrownie Jądrowe (PEJ), the prospective licensee of the nuclear reactors, has chosen a candidate design AP1000 to be located in Lubiatowo-Kopalino to become the first Polish NPP. The Environmental Impact Assessment report for this investment has been prepared by the applicant and assessed by the General Director of Environmental Protection. The Government issued a Decision in Principle for the investment and the site evaluation report is under preparation. PEJ is yet to decide on the location and the design of the second reactor to achieve the 6-9 GWe target of the PNP Programme.

The IRRS team has been informed that another NPP, an APR1400 design, has been planned to be built by the PGE PAK Energia Jądrowa S.A. located possibly in Konin/Pątnów, near the existing coal-fired power plant in the central part of Poland. While the PGE is partially government owned, the PAK is a private enterprise. At the time of the IRRS mission, no further steps were taken regarding this investment.

The Government has also taken some steps towards building Small Modular Reactors (SMRs), despite the fact that the PNP Programme states an explicit preference for large scale reactors. Within the scope of SMRs, two different partially government owned companies have shown interest in two different SMR designs. Orlen Synthos Green Energy (OSGE) has chosen the BWRX-300 design and applied for the decision of the General Director of Environmental Protection on the scope of the Environmental Impact Assessment report for three potential sites. On the other hand, KGHM Polska Miedź S.A. (KGHM) has chosen the VOYGR reactor designed by NuScale Power, but the location has not been selected.

Taking these initiatives into consideration, the state of preparedness of the PAA and the Government regarding Phase 2 activities was reviewed by the IRRS team.

12.2. CONSIDERATION OF ELEMENTS OF SSG-16

12.2.1 SSG-16 Element 01 National Policy and Strategy

The Government of Poland established a national policy and strategy for nuclear safety and radiation protection in "The Strategy and Policy for the Development of Nuclear Safety and Radiation Protection of the Republic of Poland" in April 2022. The Strategy Document covers the fundamental safety objectives

and principles, and provides directions to achieve these objectives. One of the four main objectives described in the Strategy Document is to strengthen the national competences in the areas of nuclear safety and radiation protection, through international information exchange and collaboration with regulatory bodies in other countries. The long-term PNP Programme, which was updated in October 2020, also addresses some safety issues.

The ALA states the main roles and responsibilities of the relevant organizations involved in the national nuclear power programme. The Strategy Document and the PNP Programme further detail the responsibilities of these organizations at different stages of the programme.

Organizations identified in the Strategy Document and the PNP Programme have already been established and development of other elements such as national industry infrastructure is underway. The Department of Nuclear Energy under the Ministry of Climate and Environment is the responsible body for development of other elements of the infrastructure needed for the nuclear power programme.

Further detailed discussion of national policy and strategy can be found on Section 1.1.

12.2.2 SSG-16 Element 02 Global nuclear safety regime

Poland is party to all necessary conventions and agreements regarding nuclear safety, security, and safeguards, and signed bilateral agreements with various States for collaboration and information exchange. Poland is a member of the IAEA safety standards committees such as NUSSC, RASSC, TRANSSC, WASSC, EPReSC, etc., and, as an EU Member State, a member of ENSREG. Poland is active in ENSREG working groups, IAEA technical cooperation projects and attends relevant Nuclear Energy Agency working groups. Poland applied to WENRA to update its status from observer to a member State, and it is expected that this application will be on the agenda of the next WENRA plenary meeting.

Operating organization PEJ has initiated collaborations with international and industrial organizations regarding operation of NPPs and is participating in international meetings in accordance with the PNP programme. PEJ is a member of WNA, associate member of Nuclear Europe and in close relations with IAEA and OECD/NEA. PEJ is also considering applying for membership of WANO.

There is close cooperation supported by agreements at governmental level with various countries such as France, South Korea, USA, Canada, etc., covering various activities to ensure information exchange on nuclear safety. Additionally, PAA has concluded cooperation agreements with foreign regulatory bodies. Active cooperation continues with the US NRC from the United States, CNSC from Canada, ASN from France, NSSC from South Korea and others.

PAA's early, proactive approach and continuous enhancement of technical and regulatory capabilities through increased, comprehensive and structured cooperation with national regulatory authorities in countries with established nuclear power programme and the IAEA's Regulatory Cooperation Forum is recognized as a good performance allowing for a gradual and timely capacity building of the PAA, especially in view of the first nuclear power plant in Poland.

Further information on participation of the Government on the global safety regime can be found in Section 2.

12.2.3 SSG-16 Element 03 Legal framework

The ALA, which was comprehensively amended, addresses all issues, including main safety principles, facilities and activities that need authorizations, types of authorizations, etc. The ALA is supported by a set of regulations issued to provide further detailed provisions.

Further detailed review of the legal framework can be found under Section 1.2.

12.2.4 SSG-16 Element 04 Regulatory framework

The role and responsibilities of the PAA and the President of PAA have been established in the ALA. According to the ALA, the PAA President reports to the minister competent for climate who is also currently responsible for energy in Poland. The Minister of Climate and Environment can amend, modify or reject the draft regulations prepared by the PAA. This arrangement weakens the independence of PAA. Further discussion on the independence of the PAA President is given in Section 1.3 of this report, including a recommendation to the Government for enhancing its independence.

The budget of the PAA comes directly from the state. Although applicants and licensees are charged for the costs of regulatory oversight, including the review and assessment of the NPP licence application, these costs are remitted to the state, not to the PAA. When the Government approved the last revision of the PNP programme in 2020, the annual financial contribution to the PAA was envisaged for various purposes until 2033, adding to the PAA budget. This budget can only be used for activities within the scope of the PNP programme, including hiring and training new staff. A third source was added in 2023 in light of a governmental decision to pursue possibilities of building SMRs. This third source of funding can only be used for activities relating to SMRs.

Currently 140 staff are working in the PAA. The PNP programme enables the PAA to gradually hire new staff to increase the number of dedicated staff to the PNP programme to around 110 until 2033 but most of the new staff will be hired by 2025. To regulate SMRs, the PAA deems that an additional 59 staff would be needed.

The PAA has prepared national regulations, in accordance with the procedure laid out for developing normative documents, at the principles level using the IAEA safety requirements as the main reference documents. Some of the safety regulations, particularly the ones on safety principles for nuclear facilities, may need to be updated as they are based on previous versions of IAEA safety standards. In this regard, a suggestion has been formulated to the PAA under section 12.2.17 on Design Safety.

The PAA has already established relations with the potential operating organization, and national and international organizations to be better prepared for the authorization of the first NPP in Poland. Further information on participation in international activities can be found in Section 12.2.2.

Policy Issue: Pre-licensing engagement with prospective applicants for new and advanced power reactors

Poland expressed interest in having a focused policy discussion on the pre-licensing approach for new and advanced power reactors and to gain insights from the IRRS team. Specifically, PAA requested a discussion on national practices on issues such as expectations from pre-licensing for a country embarking in a nuclear power programme, the limits of pre-licensing engagement, pre-licensing documentation, and the use of pre-licensing outcomes in the licensing process itself.

Poland anticipates construction of 6-9 giga-watts of electrical generation capacity from large pressurized water reactors and the potential future construction of Small Modular Reactors (SMR). The ALA provides an opportunity for the prospective applicants to apply for a general opinion from the PAA President of the planned organizational and technical solutions and draft versions of documents intended for a future application for a construction licence or siting of a nuclear facility.

The policy discussion highlighted the following key items:

• Pre-licensing is usually a voluntary tool to be used by prospective applicants. In some countries, there is a legal basis for requiring the prospective applicant to get a preliminary opinion from the regulatory body;

- Pre-licensing is recognized to be a useful tool to provide the regulatory body early insights about a future project and for providing prospective applicants preliminary feedback. This preliminary interaction is a key opportunity to convey and clarify the expectations of the regulatory body for the licensing process. It also provides an opportunity for early identification of key technical or policy issues that would need to be addressed by the prospective applicants in the application;
- Pre-licensing activities provide regulatory bodies of embarking nations an opportunity to train regulatory staff through the review and evaluation of the preliminary information provided by the prospective applicant;
- Pre-licensing does not guarantee the applicant a future successful outcome in the licensing process;
- Siting and design information provided during pre-licensing helps the regulatory body identify the resources and technical expertise that will be needed to complete the licensing review, and
- The regulatory body may need to prioritize multiple requests for pre-licensing activities based on the level of the maturity of prospective projects or other factors.

12.2.5 SSG-16 Element 05 Transparency and openness

Regarding the nuclear power programme, the Department of Nuclear Energy in the Ministry of Climate and Environment is responsible to inform the public and other interested parties about the developments of the PNP programme. The Department effectively uses mass and social media to disseminate the information about nuclear power and developments in the PNP Programme. The IRRS team has been informed that the majority of public opinion in Poland is in favour of nuclear power.

Regarding safety implications of the decisions made during the implementation of the PNP Programme, which is the responsibility of the PAA, pursuant to ALA Article 110, the PAA has started to inform the public and interested parties about the safety aspects of the PNP programme through social media, including the measurements taken by the national radiation monitoring system in Poland. Additionally, the PAA answers specific questions raised by the mass media. In 2022, the PAA established a detailed communication strategy, and the intention is to implement this strategy effectively in the upcoming year.

The ALA requires the licensee to provide information to the public and individuals about safety and radiological performance of the facility. Moreover, the PNP programme has an action plan regarding public communication and providing information concerning nuclear power to be carried out by different contributors of the programme.

12.2.6 SSG-16 Element 06 Funding and financing

The applicant is required by Article 38g of the ALA to demonstrate financial capability to the authorities to ensure nuclear safety, radiation protection, physical protection, and safeguards, until the completion of decommissioning. Additionally, there are provisions for the decommissioning fund to finance the decommissioning. While the contribution to this fund is monitored by the minister responsible for energy, the fund may be placed on term deposits or earmarked for the purchase of long-term bonds issued by the minister responsible for public finance.

The PNP Programme has a scheduled budget projected until 2033 for the activities of the programme. It plans additional human resources of the PAA and the education and training for both the PAA and the operator to support the safe operation of an NPP. Meanwhile, the PNP Programme does not address the financial support for other national infrastructures necessary for safe operation, such as emergency response arrangements. Their financial support is provided through relevant Ministries, such as financing of the research activities on nuclear safety, carried out by the National Centre for Nuclear Research, through the Ministry of Education and Science. No specific problems regarding the financing of such activities have been observed.

The PAA is funded directly from the state budget. The PNP Programme estimated the annual funding to the PAA until 2033, for performing its regulatory task for the programme. The cost of external support that PAA would need to perform its activities is to be covered by the organizational entity in accordance with the ALA and additionally through funding secured by PNP Programme.

The mechanism for ensuring financial needs of the decommissioning is in place for NPPs. This decommissioning fund (Article 38d of ALA) will be also used for:

- The storage of the spent nuclear fuel for the entire period of the nuclear power plant operation;
- The storage of low-, intermediate-, and high-level radioactive waste, produced in the nuclear power plant from the entire period of its operation, including spent nuclear fuel storage facilities operating for the nuclear power plant needs;
- The decommissioning of the nuclear power plant, of radioactive waste storage facilities, and the spent nuclear fuel storage facilities, operating for the nuclear power plant needs; and
- The management of radioactive waste generated during the nuclear power plant decommissioning, of radioactive waste storage facilities and spent nuclear fuel storage facilities operating for the nuclear power plant needs.

According to the National Plan of Radioactive Waste and Spent Nuclear Fuel Management, which was updated in 2022, there are plans to establish a clear division of funds between the safe management and disposal of radioactive waste and spent fuel, and decommissioning activities.

12.2.7 SSG-16 Element 07 External support organizations and contractors

The PNP programme plans for supporting national industry to actively participate in the nuclear power programme. Pursuant to this objective, the Minister of climate and environment approved a Programme of Support to Domestic Industry for Cooperation with Atomic Energy by the end of 2021. This programme includes identification of potential areas of participation of local industry and solutions for developing them to participate in the supply chain of the NPP. Envisaged support covers financial contribution to the local industry in order to meet the nuclear supplier qualifications, such as quality management certificates required by the PAA or the operator, training of its staff, and improving conditions for technology transfer.

The PAA does not have a dedicated technical support organization but has authority to procure technical or other expert professional advice or services as necessary in support of its regulatory functions, particularly for review and assessment of applications for authorization. The cost of such services will be recovered from the applicant according to the Article 37 of the ALA. As preparation for the procurement for such support, the PAA has established a system for authorizing such support organizations.

The IRRS team did not identify any planned arrangements for overseeing the activities of the technical support organization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA has no arrangements for overseeing the activities and performance of its potential external support organizations.	
(1)	BASIS: SSG-16 (Rev.1) Action 66 states that <i>"The regulatory body and the operating organization should plan arrangements for overseeing the activities performed by their respective external support organizations and contractors".</i>
S30	Suggestion: The PAA should consider planning arrangements for overseeing the activities performed by its external support organizations.

12.2.8 SSG-16 Element 08 Leadership and management for safety

Leadership and management of safety is the third principle out of ten in the Strategy and Policy for the Development of Nuclear Safety and Radiation Protection of the Republic of Poland. Fostering a strong safety culture is included in this principle. To implement it, the Strategy document describes the promotion of safety culture as one of its directions to move forward.

To implement the Strategy document, main elements and the Information Security aspect (ISO 27001) were added to the PAA's integrated management system (IMS) in 2021. Additionally, the PAA has its own safety policy addressing safety and culture for safety. The IMS manual of the PAA establishes the organizational values regarding safety and safety culture. Regarding safety culture, IAEA missions (SCCIP) were implemented both in the PAA and the operator. However, the PAA does not have an established process for the regulatory oversight of safety culture of the operating organization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA has not developed a process for the regulatory oversight of safety culture of the operating organization.

(1)	BASIS: SSG-16 (Rev.1) Action 75 states that <i>"The regulatory body and the operating organization should start developing and implementing effective integrated management systems in their respective organizations and should foster a strong safety culture."</i>
(2)	BASIS: SSG-16 (Rev.1) para. 2.187 states that <i>"The regulatory body should also implement a process of regulatory oversight of the culture for safety in the operating organization."</i>
S 31	Suggestion: The PAA should consider developing a process for regulatory oversight of the safety culture of the operating organization.

The PAA has experience in managing growth of the organization and changes necessary to address the internal and external needs and challenges. The PAA has developed separate human resource plans for different new nuclear power plant options. The basic rules for change management are indicated in the IMS Manual. Detailed discussions and findings relevant to the PAA integrated management system is provided in Section 4 of this report.

As a part of its IMS, the PAA has set up a system for measurement, self and independent assessment, continuous improvement, and performs necessary activities.

12.2.9 SSG-16 Element 09 Human resources development

The Government has identified the necessary human resources required for the nuclear power projects and has provided the necessary funding to the PAA for recruiting and retaining the experts required for the PNP Programme. This programme was last updated in 2020.

The updated PNP Programme secures the financial resources for development of the competencies needed by all parties until 2033, including the resources necessary for the PAA to hire new staff and conduct necessary training to support the licensing and construction of the first NPP.

The PAA has initiated hiring and training activities utilizing the resources allocated to them in the budget in accordance with the PNP Programme. However, the IRRS team was informed that PAA is experiencing difficulties in recruiting new staff, which has caused them to fail to meet hiring targets identified in the PNP Programme. These difficulties include the inability to compete with the higher salaries being offered in the private sector, a lack of interest in a nuclear career or government service among the new graduates, and increased competition for suitable candidates due to the ambitious hiring campaigns of future operators and local industry. One of the challenges the IRRS team also identified, is that the portion of the human resources budget to support hiring for the PNP programme was fixed in 2020 based on assumptions, such as starting salary, which are outdated and no longer valid. As a result, the PNP Program budget does not provide the necessary financial resources to hire the number of staff needed to achieve the PNP Programme targets. The IRRS team was informed that the PAA will not be able to fill up positions vacant for 2023 with the remaining budget if it is necessary to offer the maximum allowable salary in order to be able to recruit. The IRRS team was informed that significant increases to the budget would require Prime Minister approval under exceptional conditions only.

In the opinion of the IRRS team, the Government should provide PAA with additional means for attracting and retaining qualified staff needed for the PNP Programme and the ability to adjust the resources if the assumptions used in developing the budgeted resources change.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA has been unable to recruit the number of experts in accordance with the milestones established in the PNP Programme.

(1)	BASIS: SSG-16 (Rev.1) para. 2.205 states that " In light of the experience of developing States, a strategy to attract and retain high quality staff within the State should be developed. This strategy could include measures such as adequate return arrangements for trainees sent to other States, sufficient salaries, and good working conditions and career positions. Furthermore, all national organizations with safety related functions, especially the regulatory body, should be provided with the means to attract and retain high quality staff, in potential competition with recruitment by the operating organization and industrial organizations."
(2)	BASIS: SSG-16 (Rev.1) Action 53 states that "The government should decide on the mechanism for sustainable funding of the regulatory body."
S32	Suggestion: The Government should consider providing the PAA with additional means of attracting and retaining an adequate number of experts, particularly financial provisions to effectively recruit.

The PAA actively recruits new staff in accordance with the PNP Programme, which is expected to continue until 2025 and then gradually decrease until 2033, with ambitions to ultimately reach 110 experts dedicated to the PNP Programme. In 2023, the PAA was provided with an additional budget, dedicated to SMR activities for ensuring availability of the necessary human resources at the time of application. A human resource development plan has been prepared, specifically for SMRs, in addition to the plan used for NPPs within the scope of PNP Programme. The PNP programme is expected to be updated to include SMRs in the upcoming year.

For providing safety related training to their staff, the PAA and the operator are cooperating with academic institutions and foreign partners. Safety related international trainings have been conducted for over 10 years. An On-the-Job Training Programme in foreign nuclear regulatory authorities has been launched in 2015, training over 40 PAA staff. PAA specialists also extensively participate in international training activities and workshops.

The PAA coordinated an innovative "Advanced Licensing Exercise Project" which proved to be an effective way to leverage international experience and expertise with NPP construction to better prepare for NPP licensing activities in Poland. Between 2018 and 2019, the PAA coordinated with IAEA and US NRC experts in a simulation of an AP-1000 NPP construction license application assessment and issuance. This exercise resulted in improved understanding and competency in the application review and assessment process and enabled PAA to identify and better prepare for several practical issues that may be encountered during licensing of the first NPP in Poland. The exercise enabled PAA to identify areas in existing

regulations that needed to be improved, specific competency and human resource needs, areas where external technical support would be needed, areas where internal guidance for review and assessment of safety analyses was needed, etc.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The PAA conducted an innovative national "Advanced Licensing Exercise Project" with IAEA and US NRC assistance between 2018 and 2019 which proved to be an effective way to leverage experience and expertise with NPP construction to better prepare for NPP licensing activities in Poland.

(1)	BASIS: SSG-16 (Rev.1) Action 14 states that <i>"All relevant organizations should participate in the global nuclear safety regime."</i>
(2)	BASIS: SSG-16 (Rev.1) Action 16 states that <i>"All relevant organizations should strengthen their cooperation on safety related matters with States that have advanced nuclear power programmes."</i>
GP1	Good Practice: The PAA coordinated and conducted a simulation of an NPP construction license application assessment and issuance with international participation to enable PAA to identify and better prepare for several practical issues that may be encountered during licensing of the first NPP in Poland.

The PAA continues the implementation of cooperation with academic institutions and tailored training programs for PAA staff at regulatory bodies abroad. The cooperation plan with the US NRC in relation to AP1000, which is selected as the first NPP, has been finalized in May 2023 which includes among others an on-the-job training (OJT) programme for PAA staff at US NRC during 2023 / 2024.

12.2.10 SSG-16 Element 10 Research for safety and regulatory purposes

The ministry of education and science coordinates and funds the research activities in general in Poland, which includes nuclear research mainly carried out by the National Centre for Nuclear Research and the Institute of Nuclear Physics is active in nuclear physics research. In addition, a number of universities are involved in research projects in nuclear safety and technology. These organizations and other scientific and academic organizations participate in national research programmes and international projects which are usually financed by the government, European organizations, OECD or IAEA.

The PAA may request a specific safety subject to be considered as a research project from the ministry of education and science through the ministry of climate and environment. Additionally, if a nuclear research project is safety related, the PAA is requested to provide opinion of the proposal. However, there is no legal or regulatory provision asking the PAA's opinion on safety-related projects.

The PAA participates in research activities carried out under the auspices of OECD NEA, ENSREG and WENRA working groups. The IRRS team encouraged the PAA and the operating organization to be more active in initiating and implementing research for safety and for regulatory purposes.

12.2.11 SSG-16 Element 11 Radiation protection

The ALA addresses radiation protection issues in occupational and public exposure. Additionally, there are various articles addressing the dose limitations in emergency situations and other specific cases. The provisions of ALA are supported with the regulations regarding nuclear facilities, particularly:

- On nuclear safety and radiological protection requirements to be taken into account in the design of a nuclear facility;
- On the scope and manner of conducting safety analyses prior to applying for a license to build a nuclear facility, and the scope of the initial safety report for a nuclear facility;

- On the requirements for commissioning and operation of nuclear facilities; and
- On nuclear safety and radiological protection requirements for the stage of decommissioning of nuclear facilities and the content of the report on the decommissioning of a nuclear facility.

There are several other regulations addressing the radiological protection of public, workers and environment in general, such as:

- Regulation on the basic requirements for controlled and supervised areas; and
- Regulation on the protection against ionizing radiation of external workers exposed while working in a controlled or supervised area.

The ALA specifies the radiological criteria concerning the public, workers, and the environment for both normal operation and emergency conditions of a nuclear power plant. These criteria are mentioned in Chapter 3, 4 and 11 and Annex 4 of the ALA. In addition, the PAA may determine dose constraints within the scope of license conditions.

The general responsibility of carrying out the environmental impact assessment process lies with the General Directorate of Environmental Protection. However, in case of a nuclear installation, the opinion of the PAA on the radiological impact of the facility on the environment is required for final decision. Therefore, the PAA reviews and assesses the information provided on the radiological environmental impact of a facility or activity. In this respect, the PAA has participated in the EIA process of the first NPP to be built in Poland, which has not been yet finalized.

Further detailed discussion and findings on radiation protection can be found in various sub-Sections of 5 to 9.

12.2.12 SSG-16 Element 12 Safety assessment

The Department of Nuclear Safety and Security currently employs 34 staff, most of them are involved in the NPP project. The PAA is actively recruiting new staff to develop its human resources which will be dedicated to the regulatory oversight of future NPP in accordance with the PNP programme. The target is to double the dedicated human resources available for this purpose by 2025 with recruitment continuing until 2033. The PAA also started to authorize potential external support organizations which may participate in the safety assessment.

As part of the preparation of the PAA for regulatory oversight of nuclear power plants, the PAA arranged a staff demand matrix necessary for licensing and supervision in 2018 which was established as a basis for the PNP programme. The document indicates what specific positions will be needed, whether the PAA has employees with the necessary qualifications, the positions for which employees will need to be recruited, detailed job definitions, and the initial competency requirements. This plan is updated in accordance with the needs and experience gained (e.g. resulting from consultations with other nuclear regulators and training) and is used for current employment decisions. A similar matrix has been prepared for the SMR project in 2023.

Additionally, the PAA implemented a project on "Advanced Licensing Exercise Project" which is described in Section 12.2.9, to prepare its experts for the upcoming licensing activities. The IRRS team recognized the efforts given into these preparatory activities.

12.2.13 SSG-16 Element 13 Safety of radioactive waste, spent fuel management and decommissioning

Articles 47 through 55 of the ALA set up legal requirements for the radioactive waste and facilities or activities for the safe management of such waste. Article 47 states that spent fuels intended for disposal are

considered high-level radioactive waste. Additionally, the ALA addresses the general requirements concerning decommissioning.

The national strategy document extensively addresses the safety of radioactive waste, spent fuel management, and decommissioning. Strengthening the safety of radioactive waste repositories together with nuclear facilities is listed as the first step to move forward.

Based on this strategy, the National Plan of Radioactive Waste and Spent Nuclear Fuel Management was adopted in 2015 and updated in 2020. The National Plan specifies actions and determines tasks to enable the assumptions of the state policy in the field of radioactive waste and spent nuclear fuel management to be accomplished. The national plan also envisages the establishment of a new spent fuel repository.

The PAA established the national regulatory requirements on safe management of radioactive waste and spent fuel and safety of decommissioning in the Council of Ministers regulations:

- On radioactive waste and spent nuclear fuel;
- On nuclear safety and radiological protection requirements for the decommissioning stage of nuclear facilities and the content of the nuclear facility decommissioning report;
- On the periodic safety assessment of a radioactive waste repository; and
- On the documents required when submitting an application for a licence to conduct activities related to exposure to ionizing radiation or when reporting such activities.

The findings identified by the IRRS team on the overall approach to the management of radioactive waste, spent fuel management, and decommissioning can be found in Sections 1 and 5 through 9 of this report.

12.2.14 SSG-16 Element 14 Emergency preparedness and response (regulatory aspects)

The findings in relation to the emergency preparedness and response (EPR) in Poland can be found in Section 10 of this report. The IRRS team observed that necessary measures for the nuclear power plants are addressed by the existing EPR arrangements.

The national response organizations with responsibilities for EPR have been identified. These organizations are currently enhancing their infrastructure and capabilities, in accordance with the established classification of emergency situations. The potential emergencies originating from the nuclear power plants are also considered in this classification.

The IRRS team encouraged the PAA to continue with the arrangements of improving its emergency response centre.

12.2.15 SSG-16 Element 15 Operating Organization

While the ALA stipulates the compliance of the operating organization with the regulations and requirements of the regulatory body and holds the operating organization responsible for safety, security and safeguards, the prime responsibility has not been explicitly given to the operating organization. This finding has been discussed and is subject to Recommendation R2 in Section 1.4 of this report.

12.2.16 SSG-16 Element 16 Site survey, site selection and evaluation

The main requirements for sites of nuclear facilities, particularly for NPPs, have been established in the ALA, requiring the investor (applicant) to perform an assessment of the site suitability, based on site investigations. Environmental Impact Assessment is carried out by the General Directorate of Environmental Protection. Nevertheless this process does not cover engineering site approval (Location report review) what is processed by the PAA during the review and assessment of the application for the construction license of a nuclear facility. While the PAA has no specific authorization to deliver regarding

the site of an NPP, the Regional Governors decision requires the preliminary opinion of the PAA President concerning the planned site of the nuclear power plant and environmental protection. This opinion is given based on the Preliminary Location Report, which includes the results of preliminary site survey activities.

The detailed scope of a site survey for a future nuclear facility is regulated in Regulation of Council of Ministers on Detailed Scope of Assessment with Regard to Land Intended for the Location of a Nuclear Facility, Cases Excluding Land to be Considered Eligible for the Location of a Nuclear Facility and on Requirements Concerning Location Report for a Nuclear Facility. This regulation includes site conditions which make the location inappropriate and conditions for effective implementation of emergency measures in response to any radiation emergency, as well as requirements for the location report, whilst ensuring the nuclear safety, radiological protection and physical protection during commissioning, operation, and decommissioning of the facility.

The Location Report is submitted to the PAA with the application for authorization of the construction to assess the suitability of the site and its characteristics. The operating organization of the first NPP has not submitted the Location Report to the PAA for preliminary opinion.

The PAA has sent staff to South Africa for an OJT as regard the review and assessment of a site.

12.2.17 SSG-16 Element 17 Design safety

After the decision was made on the vendor, both the PAA and the PEJ made necessary arrangements with respective bodies to increase the understanding of their staff of the potential design to be built in Poland. The PAA is collaborating with US NRC to train its staff for review and assessment of the safety of the design, including OJT of its staff. The "Advanced Licensing Exercise Project" carried out by the PAA was an important effort to increase understanding of experts on the design of the first NPP. Similar efforts continued within the scope of cooperation with regulatory bodies from other countries, IAEA and external advisors. The PEJ also collaborates with vendor Westinghouse and Bechtel for further understanding of the design.

The main principles on safety of nuclear facilities are laid out in Article 36 of the ALA. Regulatory requirements on the design of a nuclear facility are laid out in the Regulation of the Council of Ministers of 2012 on Nuclear Safety and Radiological Protection Requirements which must be Fulfilled by a Nuclear Facility Design. This regulation has been supplemented with the regulations of the Council of Ministers:

- On Activities Important for Nuclear Safety and Radiological Protection in an Organizational Unit Conducting Activity Which Consists in Commissioning, Operations or Decommissioning of a Nuclear Power Plant;
- On Requirements for the Commissioning and Operation of Nuclear Facilities;
- On the Scope and Method of Conducting Safety Analyses Prior to Applying for a License to Build a Nuclear Facility, and the Scope of the Preliminary Safety Analysis Report for a Nuclear Facility; and
- On Requirements for the Decommissioning of Nuclear Facilities.

The IRRS team observed that the regulation regarding safety of nuclear power plant design is based on superseded revisions of IAEA safety standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: The regulations regarding safety of nuclear power plant design are based on superseded revisions of the IAEA safety requirements.

(1) **BASIS: SSG-16 Action 174 states that** *"The regulatory body should prepare and enact"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	national safety regulations on design that are necessary for bid specification or contract negotiations."
S33	Suggestion: The Government should consider revising national regulations on safety of nuclear power plants to be in line with the latest IAEA safety standards.

12.2.18 SSG-16 Element 19 Transport Safety

As a member of the European Union, Poland has adopted the European Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods. In doing so, Poland has adopted the ADR Agreement for the transport of dangerous goods by road, RID Agreement for the transport of dangerous goods by rail, and ADN Agreement for the transport of dangerous goods by inland waterway, which set out the requirements for the transport of radioactive material. ADR, RID, and ADN have adopted the requirements set out in SSR-6 (Rev.1).

In addition, Poland has adopted ICAO Technical Instructions (ICAO-TI) for the Safe Transport of Dangerous Goods by Air and Annex 18 to the Convention on International Civil Aviation, and the International Maritime Dangerous Goods Code, 2018 Edition Amendment 39-18 (IMDG Code). The requirements set out in the latest editions of ICAO-TI, Annex 18, and the IMDG Code have adopted the requirements set out in SSR-6 (Rev.1).

The duties of the PAA associated with the transport of radioactive material in Poland are set out in the ALA and the Act on the transport of dangerous goods. According to Article 9 of the Act on the Transport of Dangerous Goods, administrative activities, such as approval of relevant types of packages and designs of packages for fissile material and designs of radioactive materials in special form, in matters of road transport conditions, railway and inland navigation of radioactive materials is performed by the President of the PAA.

According to the ALA, the transport of nuclear materials, radioactive materials, radioactive sources or radioactive waste requires a licence, registration, notification or notification in the field of nuclear safety and radiological protection. Therefore, the national regulatory requirements regarding transport safety are already in place and are successfully implemented for various radiation sources including High-Activity Sealed Sources (HASS).

Employees of the PAA participate in work related to the transport of radioactive materials in:

- The IAEA Transport Safety Standard Committee (TRANSSC); and
- The European Association of Competent Authorities (EACA).

Further details on IRRS team findings on transport safety can be found on Sections 5.6, 6.6, 7.6 and 9.6 of this report.

12.2.19 SSG-16 Element 20 Interfaces with nuclear security

The safety and security interface and the IRRS team findings were discussed in Module 11 of this report. There is no finding on this subject specific to Module 12.

APPENDIX I – LIST OF PARTICIPANTS

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GROUP PHOTO



APPENDIX II – MISSION PROGRAMME

Sunday		Monday	Tuesday			Thurs	,		Saturday	Sunday	
3 September	Entra	eptember Ince Meeting Dup Photos Meeting with PAA Council of RadProt and NucSafety	5 September	6 Septemb	Inspections - RR Maria - Medical - Industrial	7 Septer Interviews Meeting with Ministry of Climate and Environment	DTC writes introductory parts	TEAM wr TL and D introduc Draft tex	ite report TL review tory part t to TL for review	9 September	10 September 9:30-15:30
12:00-13:00 Lunch	12	2:00-13:00 Lunch	12:00-13:00 Lunch	12:00-13:0 Lunch	00	12:00-1 Lunc		12:00-13:00 Lunch		12:00-13:00 Lunch	Social Tour and Lunch
13:00-18:00 Initial Team Entrance - Welcome - Self-intro - Rrefresher training - Mission logistics - Discussion of first	Ir	nterviews	Interviews	Interviews Written preliminary findings delivered	Inspections - RR Maria - Medical - Industrial	TEAM write report Group discussions/ interviews if necessary	Inspection ZUOP	Policy dia Scrt edits report if needed	Team cross reading	Secretariat edits draft report Finalisation of draft report (focus on observation	-
impressions - Closing		17:00-18:00 Daily Team Meeti	ng	Daily Team Meeting:	17:00-18:00 aily Team Meeting: Discussion of findings		17:00-18:00 Daily Team Meeting		boxes only)	Free day	
18:00-20:00 IRRS team Dinner	-	8:00-20:00 Dinner	18:00-20:00 Dinner	18:00-20: Dinner	00	18:00-20:00 Dinner		18:00-20:00 18:00-20:00 Dinner Dinner		Dinner	Cross-reading of the Report
		Writing of the rep	ort	, ,	Daily Team Meeting: Discussion of findings		ne report	-	ads draft oort	Secretariat edits the report	

Mor 11 Sept		Tuesday 12 September			Wednesday .3 Septembe			Thursday September	Friday 15 September		
Discussion of Ob GP) with counte		Cross-reading TL, DTL, TC every Finaliz	, DTC read thing	Review and finalisation of the Report by the IRRS team Submission of the Draft Report to the Host		Report by the IRRS team		Report by the IRRS team Submission of the Draft Report to		TEAm discuss the Mission and provides IAEA with feedback	Submission of the Preliminary Report Exit Meeting
12:00-13:	00 Lunch	12:00-13:	00 Lunch	12:	00-13:00 Lur	nch		D-13:00 Lunch Ints provided by the HOST	12:00-13:00 Lunch		
If necessary - discussions of	Finalization of		TC, DTC	TL finalizes HOST reads Summary TC drafts		HOST reads Executive TC drafts		•	discuss and resolve Host Comments		
observations (cont'd)	the Report by the IRRS team	Discussion of the report by the TEAM	prepare Executive Summary and exit	Report Press	Draft and Exit	and Exit Pressentat	to discuss <u>pend</u>	y (TEAM+HOST) ling Host comments and ize the report			
17:00- Daily Tear (to endorses o observatio	n Meeting nly changes in		presentation	Discussion	17:00-18:00 Discussion of Executive Summary and delivery to the Host		Briefing of IAEA Director Finalisation of the press release and of the Preliminary Report		Departure		
18:00-20:00 Dinner		1:	8:00-20:00								
Secretariat up	odates Report	Secretariat up	odates Report	Host reads Draft Rport		Far	ewell Dinner				

APPENDIX III – SITE VISITS

- 1. Industry facility: Gexam NDT s.c.
- 2. Medical facility: The Maria Sklodowska-Curie National Research Institute of Oncology
- 3. Waste facility: Radioactive Waste Management Plant (ZUOP)
- 4. Research reactor: National Centre for Nuclear Research Research Reactor MARIA

APPENDIX IV – LIST OF COUNTERPARTS

	IRRS EXPERTS Lead Counterpart		Support Staff			
1.	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES					
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2.	GLOBAL NUCLEAR SAFETY REGI	ME				
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3.	RESPONSIBILITIES AND FUNCTIO	NS OF THE REGULATORY BODY				
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4.	MANAGEMENT SYSTEM OF THE I	REGULATORY BODY				
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	Kevin KELLEHER	Bartosz Dzikowski	Karol Łyskawiński Dawid Frencel Michał Zuba Monika Skotniczna
11.	INTERFACE WITH NUCLEAR SEC	URITY	
	Natalia SUBRTOVA	Paulina Giżowska	Karol Dulny
12.	TAILORED MODULE FOR COUNT	RIES EMBARKING ON NUCLEAR POW	ER
	Serhat ALTEN Ugur BEZDEGUEMELI	Marcin Dąbrowski	Ernest Staroń Łukasz Żmijewski Agnieszka Modrzejewska Paweł Domitr Mateusz Włostowski Michał Koc Paweł Smoliński Aleksandra Kowalska Andrzej Chwas

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

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<u>R1</u>	The Government should review the governmental and legal framework to ensure that the President of the PAA is effectively independent in safety related decision making and has functional separation from entities having responsibilities or interests that could unduly influence decision making.
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	<u>R2</u>	The Government should review the Atomic Law Act to ensure prime responsibility for safety for facilities and activities other than nuclear facilities is clearly assigned to the person or organization responsible for a facility or an activity and to explicitly stipulate that compliance with regulations and requirements does not relieve the person or organization responsible for any facilities or activities of its prime responsibility for safety.
	<u>R3</u>	The Government should establish requirements for financial provisions for the decommissioning of nuclear facilities other than nuclear power plants.
	<u>S1</u>	The Government should consider providing the PAA with authority to authorize service providers for individual monitoring and calibration, as appropriate.
2. THE GLOBAL SAFETY REGIME	<u>S2</u>	The Government should consider expressing its political commitment to the supplementary Guidance on the Management of Disused Radioactive Sources.
	<u>\$3</u>	The PAA should consider developing a documented process to identify lessons learned from domestic and international operating and regulatory experience for radiation facilities and activities.

AREA R: Recommenda S: Suggestion G: Good Pract		Recommendations, Suggestions or Good Practices
	<u>84</u>	The PAA should consider establishing a documented mechanism for tracking feedback and follow-up measures taken in response to information received via national and international knowledge and reporting networks.
3. RESPONSIBILITIES AND FUNCTIONS OF THE	<u>R4</u>	The PAA should establish an overarching human resource plan for monitoring competence and staff needs across its whole organization, enabling strategic management of resources, including the formulation of regulatory body budget needs.
REGULATORY BODY	<u>85</u>	The Government should consider establishing more effective provisions to ensure there are no conflicts of interest in the Council for Nuclear Safety and Radiation Protection.
	<u>86</u>	The PAA should consider establishing a documented process for managing changes including organizational changes.
4. MANAGEMENT SYSTEM OF THE REGULATORY	<u>87</u>	The PAA should consider using feedback from operating experience and regulatory experience for the management system review.
BODY	<u>R5</u>	The PAA should establish a documented process of conducting assessment of leadership of safety and of the safety culture in its management system, and should regularly conduct such assessments.
	<u>R6</u>	The PAA and GIS should, within the scope of their responsibilities, establish guidance for the applicants for the authorization processes of facilities and activities with radiation sources and transport of radioactive material, specific to the type of facility or activity in accordance with a graded approach.
5. AUTHORIZATION	<u>R7</u>	The Government should revise legislation to provide the PAA with the authority to amend issued licenses for facilities and activities other than nuclear facilities and radioactive waste repositories on its own initiative without the documented consent from the authorized party.
	<u>88</u>	The Government should consider establishing a requirement for a safety committee for research reactors.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<u>R8</u>	The PAA should establish criteria for clearance for materials and objects, within notified practices or authorized practices that may be cleared from regulatory control.
	<u>89</u>	The PAA should consider establishing procedures and associated guidance for the amendment of authorizations of facilities and activities that involve radiation sources, and making provision for the timely submission of such applications.
	<u>R9</u>	The Government should establish a requirement for the applicants for authorization of radiation sources facilities and activities to submit a comprehensive safety assessment, and the PAA and GIS should establish a regulatory process to conduct its review and assessment.
	<u>R10</u>	The Government should include in regulations requirements and criteria for the termination of the authorization for decommissioning of nuclear facilities.
	<u>S10</u>	The PAA should consider establishing the internal procedure that implements provisions of the Guidance on the Import and Export of Radioactive Sources.
	<u>811</u>	The Government should consider further developing the strategy for ensuring that the number of medical physicists covers the country's needs.
	<u>R11</u>	The Government should develop a complete set of criteria to establish dose constraint for public exposure in authorization process or any subsequent updates.
	<u>S12</u>	The PAA should consider finalizing guidance on specific conditions to be incorporated into the quality assurance programmes of registrants and licensees addressing source monitoring and environmental monitoring.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<u>813</u>	The PAA should consider developing a procedure to assess the pre- operational studies conducted by future applicant for nuclear facilities in order to ensure that pre-operational studies establish 'baseline' environmental radiation levels and activity concentrations for the purpose of subsequently determining the impacts of the source.
	<u>R12</u>	The PAA and GIS, within the scope of their responsibilities, should develop a comprehensive documented process to enhance the implementation of review and assessment for radiation sources facilities and activities, for transport and for decommissioning activities, that ensures the preservation of records in accordance with a graded approach.
	<u>S14</u>	The PAA should consider establishing acceptance criteria as a basis for conducting review and assessment for research reactors. The PAA should consider enhancing provisions to conduct such a review and assessment in accordance with a graded approach.
6. REVIEW AND ASSESSMENT	<u>R13</u>	The PAA should ensure ageing mechanisms of package designs are included in the review and assessment of package designs for the transport of radioactive material.
	<u>R14</u>	The PAA should ensure the transitional arrangements are included in the review and assessment process for package designs and special form radioactive material transported within or through Poland.
	<u>815</u>	The PAA should consider expanding the National Dose Register to include information on doses received by exposed workers for whom personal monitoring is required.
	<u>S16</u>	The GIS should consider including in their processes for inspection the verification that licensees have established internal procedures for carrying out justification of individual exposures.
7. INSPECTION	<u>R15</u>	The Government should expand the requirement for establishing an adequate safety culture to facilities and activities other than nuclear facilities.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<u>R16</u>	The PAA should develop a process, comprising procedures and criteria, to assess and promote authorized parties' safety culture for radiation source facilities and activities.
	<u>817</u>	The GIS and PAA should consider enhancing the coordination of their regulatory activities in the area of the medical use of radiation sources by means of systematic exchange of the regulatory plans, feedback and experience, regular communication and joint inspections.
	<u>S18</u>	The PAA should consider seeking agreement with the Chief Inspectorate of Road Transport to develop a process for the timely exchange of information regarding enforcement actions relating to the transport of radioactive material.
	<u>S19</u>	The Government should consider assigning the GIS with the authority to establish the frequencies of inspections to be implemented in accordance with a graded approach.
8. ENFORCEMENT	<u>R17</u>	The PAA should establish and implement an enforcement policy to establish internal governance and guidance for enforcement.
	<u>R18</u>	The Government should update regulatory requirements for access to controlled areas assuring that persons under the age of 18 years are allowed access only under supervision and only for training or studying purposes and that visitors are accompanied by a person who knows the measures for protection and safety for the controlled area.
9. REGULATIONS AND GUIDES	<u>S20</u>	The PAA should consider establishing regulatory provisions and guides on the format and content of the SAR for research reactors.
	<u>S21</u>	The Government should consider establishing regulations to require the assessment and continuous improvement of the integrated management system of research reactors.
	<u>822</u>	The Government should consider defining the methodology for the assessment of doses received by aircrews.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<u>R19</u>	The Government should establish provisions in the regulations to ensure independent verification of calibration of radiation therapy units.
	<u>R20</u>	The Government should include the methodology for assessment of activity remaining in the patient in the regulation covering the release of patients that have undergone therapeutic radiological procedures with sealed or unsealed sources.
	<u>R21</u>	The Government should revise the regulations in order to address all the obligations of the designers, manufacturers and other providers of consumer products.
	<u>R22</u>	The Government should revise regulations to require authorized parties to maintain appropriate records of the results of the source and environmental monitoring programmes and estimated doses to members of the public.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	<u>823</u>	The PAA should consider developing internal guidance to review applicants and authorised parties, as appropriate, capabilities to conduct monitoring in an emergency exposure situation.
	<u>824</u>	The PAA should consider observing on-site EPR exercises at category II facilities more frequently to provide a high degree of confidence that EPR arrangements are effective, as part of its overall evaluation.
	<u>825</u>	The PAA should consider increasing the involvement of the authorities responsible for response to emergencies in international nuclear exercises on a routine basis to ensure effective working relationships amongst all organizations.
11. INTERFACE WITH NUCLEAR SECURITY	<u>826</u>	The Government should consider finalizing the revision of the ALA and relevant regulations to account for the identified gaps related to further integration between safety and nuclear security.

AREA	R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	<u>S27</u>	The Government should consider revising the existing legal and regulatory framework to request relevant facilities and activities to integrate safety and nuclear security measures in their emergency arrangements.
	<u>S28</u>	The PAA should consider developing an internal training programme to raise awareness and ensure that the PAA staff are adequately competent to manage the safety and security interface.
	<u>S29</u>	The Government should consider enhancing the means for effective coordination and cooperation between the different authorities, which may include the development of formal working agreements, to enable for effective interfaces between safety and nuclear security.
12. TAILORED MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER	<u>S30</u>	The PAA should consider planning arrangements for overseeing the activities performed by its external support organizations.
	<u>S31</u>	The PAA should consider developing a process for regulatory oversight of the safety culture of the operating organization.
	<u>832</u>	The Government should consider providing the PAA with additional means of attracting and retaining an adequate number of experts, particularly financial provisions to effectively recruit.
	<u>GP1</u>	The PAA coordinated and conducted a simulation of an NPP construction license application assessment and issuance with international participation to enable PAA to identify and better prepare for several practical issues that may be encountered during licensing of the first NPP in Poland.
	<u>833</u>	The Government should consider revising national regulations on safety of nuclear power plants to be in line with the latest IAEA safety standards.

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

Laws

- Atomic Law Act
- Act on Preparation and Carrying out Investments in Nuclear Power Facilities and Accompanying Investments
- Act on Civil Service
- Labour Code
- Environment Protection Law
- Public Procurement Law
- The Code of Administrative Proceedings
- The Criminal Code
- Building Law
- Act on Technical Inspection
- Act on Crisis Management
- Act on the Provision of Information on the Environment and its Protection
- Act on Transport of Dangerous Goods by Air
- Civil Service Principles and on Ethics of Civil Service

Executive Regulations to Atomic Law Act

- Ordinance No. 4 of the Minister of Internal Affairs and Administration of 26.03.2002 on the manner of exercising the provision of Act - Atomic Law in the Police, the State Fire Service, the Border Guard and organizational entities subordinate to the Minister of Internal Affairs
- Regulation of the Council of Ministers of 17.12.2002 on the stations for early detection of radioactive contamination and on the units that conduct measurements of radioactive contamination
- Regulation of the Council of Ministers of 23.12.2002 on requirements for dosimetric equipment
- Ordinance No 51 of the Minister of National Defence of 17.08.2003 on the manner of exercising the provisions of the Act – Atomic Law in organizational entities subordinate to the Minister of National Defence
- Regulation of the Council of Ministers 27.04.2004 on intervention levels for various intervention measures and criteria for cancelling intervention measures
- Regulation of the Minister of Health 27.04.2004 on entities competent to inspect max permitted levels of rad contamination of food stuffs and feeding stuffs
- Regulation of the Minister of Health 12.12.2022 on operational tests of radiological equipment and auxiliary devices Part 1
- Regulation of the Minister of Health 12.12.2022 on operational tests of radiological equipment and auxiliary devices Part 2
- Regulation of the Council of Ministers 27.04.2004 on prior information to the members of the public in the event of a radiation emergency
- Regulation of the Council of Ministers 12.07.2006 r. on detailed conditions for safe work with ionising radiation sources

- Regulation of the Minister of Health 21.08.2006 on detailed conditions of safe use of radiological equipment
- Regulation of the Minister of Health 22.12.2006 on supervision and control of compliance with conditions of radiation protection in organisational units using X-ray equipment for medical diagnostics, interventional radiology, surface radiotherapy and radiotherapy of non-oncological diseases
- Regulation of the Council of Ministers 20.02.2007 on basic requirements for controlled and supervised areas
- Regulation of the Council of Ministers 21.10.2008 on granting license and permit to import into the territory of the Republic of Poland, export from the territory of the Republic of Poland and transit through this territory radioactive waste and spent nuclear fuel
- Regulation of the Council of Ministers 04.11.2008 on physical protection of nuclear material and nuclear facilities
- Regulation of the Prime Minister 08.01.2010 on method of carrying out supervision and inspection in ISA, FIA and CAB by the nuclear regulatory authority
- Regulation of the Minister of Health 11.01.2023 on the conditions for the safe use of ionizing radiation for all types of medical exposures
- Regulation of the Minister of Interior on 13.04.2011 on the list of border crossings across which nuclear material, radioactive sources, installations containing such sources, radioactive waste and spent nuclear fuel can be imported into and exported from the territory of the Republic of Poland
- Regulation of the Minister of Finance 14.09.2011 on guaranteed minimum amount of the compulsory civil liability insurance of the nuclear facility's operator
- Regulation of the Minister of Health 29.09.2011 on psychiatric and psychological tests of employees
 performing activities important for nuclear safety and radiological protection at the organizational unit
 conducting activities related to exposure which consist in commissioning, operation or
 decommissioning or a nuclear power plant
- Regulation of the Minister of Environment 18.11.2011 on the Council for Nuclear Safety and Radiological Protection
- Regulation of the Council of Ministers 27.12.2011 r. template of the quarterly report on the amount of the payment made to decommissioning fund
- Regulation of the Council of Ministers 26.03.2012 r. on the subsidy granted for ensuring nuclear safety and radiological protection of the country in ionizing radiation applications
- Regulation amending the Regulation on subsidy granted for ensuring nuclear safety and radiological protection of the country in ionising radiation applications
- Regulation of the Council of Ministers 27.12.2011 on periodical safety assessment of a nuclear facility
- Regulation of the Minister of Economy 23.07.2012 on detailed rules for the establishment and operation of Local Information Committees and cooperation on nuclear power facilities
- Regulation of the Council of Ministers 10.08.2012 on activities important for nuclear safety and radiological protection in an organizational unit conducting activity which consists in commissioning, operations or decommissioning of a nuclear power plan

- Regulation of the Council of Ministers 10.08.2012 on detailed scope of assessment regard land intended for location of a nuclear facility, cases excluding land to be considered eligible for the location of a nuclear facility and on requirements concerning location report for a nuclear facility
- Regulation of the Council of Ministers 31.08.2012 on scope and method for performance of safety analyses prior to the submission of an application requesting the issue of a license for the construction of a nuclear facility and the scope of the preliminary safety report for a nuclear facility
- Regulation of the Council of Ministers 31.08.2012 on nuclear safety and radiological protection requirements which must be fulfilled by a nuclear facility design
- Regulation of the Council of Ministers 10.10.2012 on the amount of the contribution to cover the costs of the final management of spent fuel and radioactive waste and to cover the costs of decommissioning a nuclear power plant by an organizational entity which has been issued a licence to operate a nuclear power plant
- Regulation of the Council of Ministers 11.02.2013 on nuclear safety and radiological protection requirements for the decommissioning of nuclear facilities and the content of a report on decommissioning of a nuclear facility
- Regulation of the Council of Ministers 11.02.2013 on requirements for the of commissioning and operation of nuclear facilities
- Ordinance of the Minister of Energy 01.03.2017 on enacting the statue of to the state-owned public utility of company named "Radioactive Waste Management Plant" (ZUOP)
- Regulation of The Council Of Ministers of December 14th, 2015 on radioactive waste and spent nuclear fuel
- Notice of the Prime Minister 15.01.2016 on the correction of errors
- Regulation amending the regulation on radioactive waste and spent nuclear fuel
- Regulation of the Council of Ministers 14.12.2015 on the periodic safety review of a radioactive waste repository
- Regulation of the Minister of Health 6.03.2020 on trainings in radiation protection of patients
- Regulation of the Minister of Climate 22.06.2020 on enacting the statute of the National Atomic Energy Agency (PAA)
- Regulation of the Minister of Climate 27.08.2020 on the template of an official identity card of a nuclear regulatory inspector
- Regulation of the Minister of Health 27.08.2020 on an order to perform non-medical exposures related to employment or insurance
- Regulation of the Minister of Climate 18.09.2020 on allocated and special-purpose subsidy the fees and the content of an annual financial and material plan of the 'Radioactive Waste Management Plant'
 state-owned public utility company
- Regulation of the Council of Ministers 30.11.2020 types of protective actions introduced in an external zone, and the operational intervention levels constituting a basis for the introduction of these actions in the external zones
- Regulation of the Council of Ministers 30.11.2020 providing for itinerant workers exposed during work in a controlled or supervised area
- Regulation of the Council of Ministers 17.12.2020 on building materials which require determining the activity concentration of radioactive potassium K-40, radium Ra-226 and thorium Th-232

isotopes, requirements to be fulfilled by these determinations, and the value of the activity concentration index which, once exceeded, requires informing proper authorities 2

- Regulation of the Council of Ministers 10.03.2021 on cases in which the performance of exposurerelated activity involving ionising radiation originating from natural radioactive isotopes does not require a notification
- Regulation of the Council of Ministers 05.03.2021 on radiation protection officers
- Regulation of the Council of Ministers 05.03.2021 on the position of major importance for ensuring nuclear safety and radiation protection
- Regulation of the Council of Ministers 10.03.2021 on cases in which activities involving exposure to ionising radiation do not require a license, registration or notification and cases in which they may be performed on the basis of a registration or notification
- Regulation of the Minister of Interior and Administration 22.04.2021 on the scope of information covered by the order for non-medical exposures using radiological equipment for the purpose of immigration, age assessment of persons and identification of objects hidden in the human body
- Regulation of the Minister of Health 08.06.2020 on the scope of information contained in the Central Database for Medical Exposures
 - Regulation of the Council of Ministers 25.05.2021 requirements for the registration of individual dose
- Regulation of the Council of Ministers 25.05.2021 the scope of a hazard assessment resulting from an activity involving exposure to ionising radiation, and the form of presenting conclusions from the hazard assessment
- Regulation of the Council of Ministers 25.05.2021 on emergency plans in the event of radiation emergencies
- Regulation of the Council of Ministers 11.08.2021 on nuclear regulatory inspectors
- Regulation of the Council of Ministers 11.08.2021 on indicators enabling the determination of ionizing radiation doses used when assessing exposure to ionizing radiation
- Regulation of the Council of Ministers 30.08.2021 on documents required when submitting an application for the issuance of a license to perform an activity related to exposure to ionizing radiation
- Regulation of the Minister of Health 13.09.2021 on the minimum requirements for health care units conducting medical exposure activities involving the provision of X-ray diagnostics, interventional radiology or diagnostics involving the administration of radiopharmaceutical products to patients Xray diagnostics
- Regulation of the Minister of Health 14.10.2021 on radiation protection officer authorization to exercise internal supervision over compliance with radiation protection requirements in health care units
- Regulation of the Minister of Health 19.10.2021 on the minimum requirements for health care units conducting activity involving exposure for medical purposes
- Regulation of the Minister of Health 18.10.2021 on the form and detailed scope of reference medical radiological procedures for standard medical exposures and specific medical radiological procedures
- Regulation of the Council of Ministers 01.10.2021 on the security of radioactive sources
- Regulation of the Minister of Health 19.10.2021 on the information contained in the National Database of Radiological Equipment

- Regulation of the Council of Ministers 09.08.2022 on scope of environmental radiation monitoring
 program developed and implemented by organizational entities included in category I or II of hazards
- Regulation of the Minister of Health 06.12.2022 on diagnostic reference levels
- Regulation of the Minister of Health 06.12.2022 on the detailed scope of internal and external clinical audits and the template of their reports
- Regulation of the Minister of Health 13.12.2022 on the categories and eligibility criteria for unintended and accidental exposures, actions to be taken at the health care unit after their occurrence, and the scope of information covered by the Central Database of Unintended and Accidental Exposures
- Draft Regulation of the Minister of Health on special protection of some categories of persons in relation to medical exposure in diagnostic tests, procedures and treatment
- Notice of the Minister of Health 22.12.2014 on the announcement of the list of reference radiological procedures in nuclear medicine
- Regulation of the Minister of Health 02.02.2023 on bioethics committee and the Bioethics Appeal Committee
- Regulation of the Minister of Health 22.12.2006 on supervision and control of compliance with the conditions of radiation protection in organizational units using X-Ray equipment for medical diagnostics, interventional radiology, surface radiotherapy and radiotherapy of non-oncological diseases
- Regulation of the Council of Ministers 17.12.2013 on the types of technical equipment subject to technical inspection in an NPP
- Regulation of the Minister of Development 24.06.2016 on technical requirements of technical inspection for technical equipment subject to technical inspection in an NPP

PAA Internal documents

- Statute of PAA 2019
- Organizational Regulations of PAA
- PAA Safety Policy 2023
- IMS Manual 2023
- List of processes PAA 2023
- Communication Strategy of PAA 2022
- Information Security Policy
- Policy of counteracting corruption and conflicts of interest in PAA
- Rules on counteracting corruption within processes Appendix 2 to the Policy
- Procedure of control of IMS documents
- Procedure for management of processes
- Procedure of the IMS internal audit
- Procedure of internal audit of information security
- Procedure of Information Security Management System review
- Procedure for nuclear safety inspections
- Procedure of issuing licenses for activities related to nuclear facilities

- Procedure for approving the modernization or modification of a nuclear facility and approving the reactors restart following modernization or modification
- Procedure for development and submission of periodic reports on events in NPPs
- Procedure for conducting regulatory inspection by nuclear regulatory inspectors of the Radiation Protection Department
- Manual for conducting inspections in the field of radiation protection by nuclear regulatory inspectors of the Radiation Protection Department
- PAA Action Plan for 2023
- Report on the IMS strategic goal under PAA Action Plan (2016-2021)
- PAA Action Plan on strengthening of safety culture 2022-2023
- PAA Action Plan on strengthening of safety culture 2017-2019
- PAA Action Plan on strengthening of safety culture 2015-2016
- Management control self-assessment questionnaire for employees 2022
- Rules of organization and financing of professional development of the employees
- Professional development program for workers of PAA for PNPP
- App. 1. Competency Profiles 2023 PAA
- List of Competencies PAA 2014
- PAA Workforce Needs Matrix
- PAA TSO Needs Matrix
- List of TSO authorization topics preferred by the President of PAA
- Agreement on cooperation between PAA President and Government Security Office 2013
- Agreement on cooperation between PAA President and Armed Forces General Command2017
- Agreement on cooperation between PAA President and Polish Border Guard HQ 2005
- Agreement on cooperation between PAA President and Office of Technical Inspection 2022
- Agreement on cooperation between PAA President and Chief Sanitary Inspectorate 2017
- Agreement on cooperation between PAA President and Ministry of Finance 2008
- Technical recommendations of the PAA President determination of emergency planning zones and emergency planning distances

National plans, strategies and reports

- Strategy and Policy for the Development of Nuclear Safety and Radiation Protection of the Republic of Poland
- Polish Nuclear Power Programme (PPEJ) 2020 update
- Polish Nuclear Power Programme 2014
- Updated National Plan of Radioactive Waste and Spent Nuclear Fuel Management 2020
- Programme of Support to Domestic Industry for Cooperation with atomic energy as executive document to PNPP
- Annual Report of the President of PAA 2021
- National action plan for long-term risks related to the exposure to radon in buildings designed for human occupancy and in workplaces (National Radon Action Plan 2021)
- Report on the implementation of the Polish Nuclear Power Programme for 2020-2021

- Report on the implementation of the National Spent Nuclear Fuel and Radioactive Waste Management Plan for 2020-2021
- Report on the execution of Framework Human Resource Development Plan for Nuclear Power in 2020
- Framework Plan of Human Resource Development for Nuclear Power 2016

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

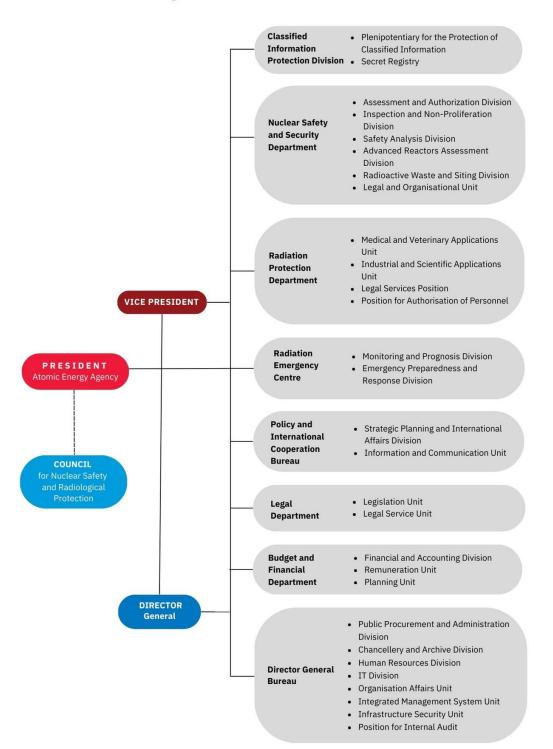
1.	INTERNATIONAL ATOMIC ENERGY AGENCY - Fundamental Safety Principles, No SF-
	1, IAEA, Vienna (2006)
2.	INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory
	Framework for Safety, General Safety Requirements Part 1, No GSR Part 1 (Rev. 1), IAEA,
	Vienna (2016)
3.	INTERNATIONAL ATOMIC 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.	1 0
7	Radioactive Waste, General Safety Requirements Part 5, No GSR Part 5, IAEA, Vienna (2009)
/.	INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Facilities, General Safety Requirements No GSR Part 6, IAEA, Vienna (2014)
0	INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for Nuclear
0.	or Radiological Emergency, General Safety Requirements No GSR Part 7, IAEA, Vienna (2015)
0	INTERNATIONAL ATOMIC ENERGY AGENCY - Site Evaluation for Nuclear
<i>.</i>	Installations, Specific Safety Requirements No SSR-1, IAEA, Vienna (2003)
10	INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Power Plants:
10	Design, Specific Safety Requirements 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 No SSR-2/2 (Rev. 1), IAEA,
	Vienna (2016)
12	. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Research Reactors, Specific
	Safety Requirements No SSR-3, IAEA, Vienna (2016)
13	5. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Nuclear Fuel Cycle Facilities,
	Specific Safety Requirements No SSR-4, IAEA, Vienna (2017)
14	INTEDNATIONAL ATOMIC ENERCY ACENCY Disposed of Dedicative Wester
	. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste,
	Specific Safety Requirements No SSR-5, IAEA, Vienna (2011)
15	Specific Safety Requirements No SSR-5, IAEA, Vienna (2011) INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of
15	Specific Safety Requirements No SSR-5, IAEA, Vienna (2011) 5. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements No SSR-6 (Rev. 1), IAEA,
	 Specific Safety Requirements No SSR-5, IAEA, Vienna (2011) INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements No SSR-6 (Rev. 1), IAEA, Vienna (2018)
	 Specific Safety Requirements No SSR-5, IAEA, Vienna (2011) INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements No SSR-6 (Rev. 1), IAEA, Vienna (2018) INTERNATIONAL ATOMIC ENERGY AGENCY - Classification of Radioactive Waste,
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APPENDIX VIII – ORGANIZATIONAL CHART



Organizational structure of the PAA