

## INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

### **FOLLOW-UP MISSION**

то

GREECE

Athens, Greece

20 to 24 November 2017

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated Regulatory Review Service

IRRS



#### **REPORT OF THE**

## INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION

ТО

GREECE





Integrated Regulatory Review Service

#### **INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION FOLLOW-UP REPORT**

TO

#### **GREECE**

**Mission dates: Regulatory body** Location: **Organized by:** 

20 to 24 November2017 Greek Atomic Energy Commission (EEAE) Athens, Greece IAEA

#### **IRRS REVIEW TEAM**

**RYAN** Tom FRANZÉN Anna JOVA SED Luis PERRIN Marie Line **TRIVELLONI Sandro** AL KHATIBEH Ahmad SHADAD Ibrahim SWOBODA Zumi

Team Leader (Ireland) Reviewer (Sweden) Reviewer (Cuba) Reviewer (France) Reviewer (Italy) **IRRS** Coordinator (IAEA) **IRRS** Review Area Facilitator (IAEA) IRRS Administrative Assistant (IAEA)

EXE	CUTIVE S	UMMARY	1
I.	INTROD	UCTION	3
II.	OBJECT	IVE AND SCOPE	4
III.	BASIS F	OR THE REVIEW	5
1.	RESPON	SIBILITIES AND FUNCTIONS OF THE GOVERNMENT	7
	1.1.	NATIONAL POLICY AND STRATEGY FOR SAFETY	7
	1.2.	ESTABLISHMENT OF A FRAMEWORK FOR SAFETY	7
	1.3.	ESTABLISHMENT OF A REGULATORY BODY	10
	1.4.	INDEPENDENCE OF THE REGULATORY BODY	10
	1.5.	PRIME RESPONSIBILITY FOR SAFETY	10
	1.6.	COMPLIANCE AND RESPONSIBILITY FOR SAFETY	11
	1.7.	COORDINATION OF AUTHORITIES HAVING RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK	11
	1.8.	PROVISION FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND SPENT FUEL	11
	1.9.	COMPETENCE FOR SAFETY	
	1.10.	PROVISION OF TECHNICAL SERVICES	
2.	THE GLOBAL SAFETY REGIME13		
	2.1.	INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION	13
	2.2.	SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE	13
3.	RESPON	SIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	14
	3.1.	ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES	14
	3.2.	EFFECTIVE INDEPENDENCE DURING THE CONDUCT OF REGULATORY	14
	3.3.	STAFFING AND COMPETENCE OF THE REGULATORY BODY	
	3.4.	LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS	
	3.5.	LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES	15
	3.6.	STABILITY AND CONSISTENCY OF REGULATORY CONTROL	15
	3.7.	SAFETY RELATED RECORDS	15
	3.8.	COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES	16
4.	MANAG	EMENT SYSTEM OF THE REGULATORY BODY	17
	4.1.	QUALITY SYSTEM	17
	4.2.	INTEGRATED MANAGEMENT SYSTEM	17
	4.3.	SAFETY CULTURE	20
5.	AUTHO	RIZATION	22
6.	REVIEW	AND ASSESSMENT	27
7.	INSPEC	ΓΙΟΝ	28
	7.1.	INSPECTION PROGRAMME AND THE GRADED APPROACH	

#### CONTENTS

	7.2.	INSPECTION RESULTS	28
8.	ENFOR	CEMENT	30
9.	REGULA	ATIONS AND GUIDES	31
	9.1.	PROCESS FOR DEVELOPING REGULATIONS AND GUIDES	31
	9.2.	EXISTING REGULATIONS AND GUIDES	31
10.	EMERG	ENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	35
	10.1.	BASIC RESPONSIBILITIES	35
	10.2.	FUNCTIONAL REQUIREMENTS	36
11	TDANCI		
11.	1 KANSE 11 1	DECULATIONS AND THE CLODAL NUCLEAD SAFETY DECIME	
	11.1.	COMPETENT AUTHORITY	
	11.3.	RESPONSIBILITY FOR SAFETY	38
	11.4.	DELIVERY AND COORDINATION OF REGULATORY FUNCTIONS	39
	11.5.	OPERATIONAL ACTIVITIES AND COMPLIANCE ASSURANCE	39
12.	CONTRO	DL OF MEDICAL EXPOSURES	42
	12.1.	RESPONSIBILITIES	42
	12.2.	JUSTIFICATION OF MEDICAL EXPOSURES	43
	12.3.	OPTIMIZATION OF PROTECTION AND SAFETY	43
13.	OCCUPA	ATIONAL RADIATION PROTECTION	45
	13.1.	LEGAL / REGULATORY FRAMEWORK	45
	13.2.	GENERAL RESPONSIBILITIES OF REGISTRANTS, LICENSEES AND EMPLOYERS	45
	13.3.	GENERALRESPONSIBILITIES OF WORKERS	45
	13.4.	REQUIREMENTS FOR RADIATION PROTECTION PROGRAMMES	45
	13.5.	MONITORING PROGRAMME TECHNICAL SERVICES	45
14.	CONTRO	OL OF RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE	46
15.	ENVIRC	NMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR	. –
	PUBLIC	RADIATION PROTECTION PURPOSES	47
16.	CONTRO	OL OF CHRONIC EXPOSURES AND REMEDIATION	48
APPE	ENDIX I - I	LIST OF PARTICIPANTS	49
APPE	ENDIX II -	MISSION PROGRAMME	50
APPE	ENDIX III	- MISSION COUNTERPARTS	52
APPE	ENDIX IV THAT R	- RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE IRRS MISSION EMAIN OPEN	55
APPE	ENDIX V - FROM T	RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) HE 2017 IRRS FOLLOW-UP MISSION	55
APPE	ENDIX VI	- REFERENCE MATERIAL PROVIDED BY EEAE	56

APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW	69
APPENDIX VIII - EEAE ORGANIZATIONAL CHART	71

#### **EXECUTIVE SUMMARY**

At the request of the Government of Greece, an international team of five safety experts met representatives of the Greek Atomic Energy Commission (EEAE), formerly GAEC, from 20 to 24 November 2017 to conduct an Integrated Regulatory Review Service (IRRS) Follow-up mission. The purpose of the IRRS Follow-up mission was to review Greece's progress against the recommendations and suggestions identified in the initial IRRS mission (20 to 30 May 2012). The mission took place at the headquarters of EEAE in Athens, Greece.

The IRRS team consisted of five senior regulatory experts from five IAEA Member States, and three IAEA staff members.

The IRRS team carried out a review of the progress made on each recommendation and suggestion that is documented in the 2012 IRRS mission report. These recommendations and suggestions cover 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 authorization, review and assessment, inspection, and the development and content of regulations and guides; emergency preparedness and response, transport, occupational radiation protection, control of radioactive discharges and materials for clearance, environmental monitoring associated with authorized practices for public radiation protection purposes and the control of chronic exposures and remediation.

While it had been planned to include the research reactor in the follow-up mission, it was mutually agreed that, as there are no changes in the research reactor status since 2012 and it remains in extended shutdown mode, its inclusion in this follow-up mission is not warranted.

To assess progress, the IRRS team conducted a series of interviews and discussions with EEAE staff and reviewed the advance reference material provided by EEAE.

Overall, the IRRS team concluded that Greece, through EEAE, has been responsive to each recommendation and suggestion made in 2012, and continues to place appropriate focus on implementing a framework that provides for effective protection of public health and safety. 26 out of 28 recommendations and 9 out of 10 suggestions identified in 2012 have been closed.

Since 2012, EEAE has taken positive steps to:

- Update its legal and regulatory framework to bring into compliance with the latest IAEA safety standard;
- Develop and implement an integrated management system and foster safety culture;
- Develop and implement a graded approach throughout its regulatory oversight;
- Clearly assign responsibility for radiation safety including for the safe management of spent fuel and radioactive waste; and setting out the obligations and responsibilities of the license holder and the prime responsibility for safety;

- Develop its compliance assurance programme for transport of radioactive material and strengthen its capacity for review and approval of package design by validation of the original certificate;
- Monitor the justification of the diagnostic examinations and the optimisation and verification of the doses delivered both in diagnosis and therapy, in the context of a defragmented "one stop shop" authorization process, thus improving patient protection;
- Enhance the national regulatory framework for the management of radioactive waste and decommissioning.

The following new good practice was identified by the IRRS team:

• EEAE is implementing a research project on Radiation Protection and Clinical Audits in New Diagnostic and Therapeutic Technologies including topics on justification and referral criteria, the findings of which will improve the radiation protection of patients.

The IRRS team also offered 1 new recommendation for Government consideration:

• When amending the provisions for sanctions in the law, the Government should ensure that no facility or activity is allowed to operate once its licence expires and until it is renewed.

The specific findings of the follow-up mission are summarized in Appendix V.

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

Throughout the mission, the IRRS team received full cooperation from all parties involved. In particular, EEAE staff were very open in the discussions and provided the fullest practicable assistance.

#### I. INTRODUCTION

At the request of the Government of Greece, an international team of senior safety experts met representatives of the regulatory body of the host country Greek Atomic Energy Commission (EEAE)<sup>1</sup> from 20 to 24 November 2017 to conduct an Integrated Regulatory Review Service (IRRS) Follow-up mission.

The purpose of the follow-up mission is to review the implementation of the recommendations and suggestions given to the Government during the IRRS Mission in May 2012. The follow-up mission was formally requested by the Government of Greece in February 2016. A preparatory meeting was conducted from 1 to 2 March 2017 at EEAE Headquarters in Athens to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Greece and their related safety aspects.

The IRRS team consisted of five senior regulatory experts from five IAEA Member States, and three IAEA staff members. The IRRS team carried out the review in the areas covered by the main mission in May 2012.

Greece prepared a national follow-up report addressing the findings of the initial mission. While it had been planned to include the research reactor in the follow-up mission, it was mutually agreed that, as there are no changes in the research reactor status since 2012 and it remains in extended shutdown mode, its inclusion in this follow-up mission is not warranted.

The follow-up report and supporting documentation were provided to the IRRS team as advance reference material (ARM) for the mission. During the mission, the IRRS team performed a systematic review of all topics by reviewing the advance reference material, additional information, and by conducting interviews with management and staff of EEAE.

All through the mission, the IRRS team received excellent support and cooperation from EEAE.

<sup>&</sup>lt;sup>1</sup> At the time of the initial mission in 2012 the acronym GAEC was used, which is now replaced with EEAE.

#### **II. OBJECTIVE AND SCOPE**

The purpose of this IRRS follow-up mission was to conduct a review of the implementation of the recommendations and suggestions given to the Government of Greece during the IRRS Mission in May 2012 and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by EEAE. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in Greece and other Member States from the knowledge gained and experiences shared between EEAE and IRRS reviewers and through the evaluation of the effectiveness of the EEAE regulatory framework for nuclear and radiation safety.

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

- a) providing an opportunity for continuous improvement of the national regulatory body;
- b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory issues;
- c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of the progress in the development 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 Review Team members who have experience of other regulatory practices in the same field;
- f) providing the host country with recommendations and suggestions for improvement;
- g) providing other states with information regarding good practices identified in the course of the review;
- h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- i) contributing to the harmonization of regulatory approaches among states;
- j) promoting the application of IAEA Safety Requirements; and
- k) providing feedback on the use and application IAEA Safety Standards.

#### **III. BASIS FOR THE REVIEW**

#### A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Greece, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted at EEAE Headquarters in Athens, on 1 and 2 March 2017. The preparatory meeting was carried out by the appointed Team Leader, Mr. Tom Ryan, and IRRS IAEA Team representatives, Mr. Ahmad Al Khatibeh and Mr Geza Macsuga.

The IRRS Follow-up mission preparatory team had discussions regarding regulatory programmes with the senior management of EEAE represented by Mr. Christos Housiadas, Chairman of EEAE. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

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

Ms. Stavroula Vogiatzi made presentations on the national context, the current status of EEAE and the progress made by EEAE since the initial mission of May 2012.

IAEA staff presented the IRRS process and methodology of conducting a follow-up IRRS mission. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Greece in November 2017.

The proposed IRRS team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer, lodging and transport arrangements were also addressed.

The EEAE Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Ms. Stavroula Vogiatzi.

EEAE provided the IAEA (and the review team) with the advance reference material for the review in September 2017 and additional materials. In preparation for the mission, the IRRS team members conducted a review of the advance reference material and provided their initial review comments to the IRRS Team Coordinator and Team Leader prior to the follow-up mission.

#### **B) REFERENCES FOR THE REVIEW**

The relevant IAEA safety standards were used as review criteria. A list of IAEA publications used as the reference for this mission is given in Appendix VII.

#### C) CONDUCT OF THE REVIEW

An initial IRRS team meeting was conducted on Sunday 19 November 2017, with opening remarks by the IRRS Team Leader. The IAEA Team Coordinator made a presentation on the process and objectives of an IRRS Follow-up mission. The reviewers also reported their first impressions of the advance reference material. General approaches for mission conclusions drafting were agreed.

The Liaison Officer Ms. Stavroula Vogiatzi was present at the initial IRRS review team meeting on 19 November 2017, in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday 20 November 2017, with the participation of EEAE Chairman, senior management and staff. Opening remarks were made by the EEAE Chairman Mr. Christos Housiadas, IAEA Team Coordinator Mr. Ahmad Al Khatibeh and Team Leader Mr. Tom Ryan gave a presentation on the expectations of the IRRS Mission. Ms. Stavroula Vogiatzi gave an overview of EEAE activities and EEAE's response to the 2012 mission findings.

During the mission, a review was conducted for all the mission scope areas with the objective of reviewing the Government and EEAE's response to the recommendations and suggestions identified during the initial mission. The review was conducted through meetings, interviews and discussions regarding all facilities and activities.

The IRRS team performed its activities based on the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday 24 November 2017 where the IRRS Team Leader Mr. Tom Ryan presented the results of the follow-up mission highlighting the main findings. This was followed by the statement by EEAE Chairman Mr. Christos Housiadas in response to the Team Leader's presentation as well as a statement by the General Secretary for Research and Technology, Ms. Matrona Kyprianidou. Closing remarks were made by Mr. Ahmad Al Khatibeh on behalf of the Director of the Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety and Security.

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

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

#### 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

# 2012 MISSION RECOMMENDATIONS, SUGGESTIONSR1Recommendation:<br/>sets out the national policy and strategy for safety.

#### Changes since the initial IRRS mission

**Recommendation 1**: The development of policies and strategies in relation to nuclear and radiation safety and associated technologies comes within the competency of the Ministry of Education, Research and Religious Affairs (Ministry) in conjunction with other Ministries as appropriate (L19) (See Appendix VI for details of these reference documents).

Priority has been given to the development of the legal framework for safety, including legislative initiatives in relation to spent fuel and radioactive waste management and radiation protection regulations. Once this legislative work is completed, Greece intends to develop a consolidated statement setting out the national policy and strategy for safety which will be progressed through a Ministerial Decision.

Nevertheless, progress has been made on establishing policies and strategies in a number of thematic areas that will set out the national policy and strategy for safety when it is developed. These are in the areas of education and training in radiation, transport and waste management safety at the national level; and a new national policy in relation to the management of spent fuel and radioactive waste.

A consolidated statement that sets out the national policy and strategy for safety is not yet in place.

#### Status of the finding in the initial mission

**Recommendation 1 is open.** A consolidated statement that sets out the national policy and strategy for safety is not yet in place.

#### **1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY**

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

R2 <u>Recommendation:</u> The Government should ensure that the persons or entity with responsibilities for the implementation of regulatory requirements are explicitly specified.

#### **Changes since the initial IRRS mission**

**Recommendation 2**: The clear allocation of responsibilities to persons or entities for the implementation of regulatory requirements has been one of the fundamental issues addressed in the revision of the Greek radiation safety legislative framework and associated regulatory documents including: the national framework for the management of spent fuel and radioactive waste (SF & RW) and the new Radiation Protection Regulations (RPR) including PD 14, PD 15, PD 17 and MD 17 (See Appendix VI).

Care has been taken in assigning responsibilities to persons and entities for the implementation of regulatory requirements to be specific and to avoid ambiguity. This is clearly demonstrated in the following examples from the legislation:

- the allocation of responsibilities for the safe management of SF & RW;
- the responsibility of stakeholders involved in the management of SF & RW to implement the national policy;
- the obligations and responsibilities of the licence holder;
- the responsibilities of EEAE and the Minister;
- the prime responsibility of the undertaking for safety and radiation protection issues;
- the responsibilities regarding medical exposures;
- the responsibility of the employer and the undertaking in the case of outside workers;
- the responsibility of the supplier and/or the manufacturer.

#### Status of the finding in the initial mission

**Recommendation 2 is closed.** The clear allocation of responsibilities to persons or entities for the implementation of regulatory requirements has been addressed in the revision of the Greek radiation safety legislative framework and associated regulatory documents.

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

**<u>Recommendation</u>**: The Government should provide for a graded approach in the implementation of the regulatory framework.

#### Changes since the initial IRRS mission

**Recommendation 3**: The graded approach to regulatory oversight has been comprehensively addressed in the revision of the national framework for safety including in provisions for the safe management of SF & RW and in the new radiation protection regulations. The 'graded approach' is clearly defined in MD 17 as 'a methodology which reflects, in a proportionate manner, the corresponding risk posed by an activity, practice or facility, which is assessed based on the type and complexity of the activity, practice or facility, the type, quantity and use of radioactive waste, as well the requirements as to the know-how and the human and other resources.' In addition, PD 15 provides for a graded approach to regulatory control, including authorization with provisions for notification, registration and licensing; for a graded approach to planning a

**R3** 

response to an emergency exposure situation as well as for the development of radiation protection strategies.

The graded approach is also provided for in L19, in relation to enforcement activities and corresponding offences. In particular, there are provisions for administrative penalties and fines, criminal sanctions and civil claims where the type and severity of the sanction is proportional to the nature of the offence.

#### Status of the finding in the initial mission

**Recommendation 3 is closed.** A graded approach to regulatory oversight has been comprehensively addressed in the revision of the national framework for safety and is provided in the implementation of the regulatory framework.

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

# R4 Recommendation: The Government should establish and maintain a national policy and strategy for radioactive waste management including provisions for the decommissioning of facilities, management of radioactive waste and related financial provisions.

#### Changes since the initial IRRS mission

**Recommendation 4:** Since 2012, a comprehensive revision of the national regulatory framework for the management of radioactive waste has been made. In addition, several regulatory documents and procedures complementing the national framework for the safe and responsible management of SF & RW have been endorsed and published in the Government Gazette.

The basic principles of the national policy on the management of SF & RW are provided in PD 14, while MD 17 specifies the national policy on the management of SF & RW. The national strategy on the management of SF & RW is provided in the PD 17 and in the national programme MD 20.

Provisions for the decommissioning of RW facilities are included in PD15 and PD 17. The legal provisions relating to the authorization for decommissioning are further specified in the MD 26 Joint Ministerial Decision (JMD) for the authorization of RW facilities. PD 17, which provides for the promulgation of MD 26, was published in the Government Gazette in September 2017 and therefore MD26 is in the process of being endorsed by the relevant Ministries.

Financial provisions pertaining to the management of SF & RW are included in PD 14 and in the national programme on the management of SF & RW MD 20. The National Committee for Radioactive Waste Management (EEDRA) is being established as provided for in PD 17. EEDRA has an advisory role to the Minister of Education, Research and Religious Affairs (The Minister) on the practical aspects for the implementation of the national policy and the national programme. In addition, EEDRA has responsibility for preparing and proposing the associated financial plan PD 17.

#### Status of the finding in the initial mission

**Recommendation 4 is closed.** In the revision of the national regulatory framework for the management of radioactive waste a national policy and strategy is established for radioactive waste management including provisions for the decommissioning of facilities, management of radioactive waste and related financial provisions.

#### 1.3. ESTABLISHMENT OF A REGULATORY BODY

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

**S1** 

**Suggestion:** The Government should consider conferring legal authority to strengthen GAEC's powers of enforcement.

#### Changes since the initial IRRS mission

**Suggestion 1:** In 2014, the Government of Greece re-established EEAE in the Act (L19) as a technological institution in the form of a public entity. This Act confers certain legal authority to EEAE and has strengthened its powers of enforcement.

In particular, EEAE can impose administrative penalties, fines, criminal sanctions and civil claims; fines can now be imposed at different levels depending on the seriousness of offence in line with a graded approach. A regulation specifying EEAE's role in conducting hearings in relation to infringements of the legislation has also been published in the Government Gazette (EDGG 11).

#### Status of the finding in the initial mission

**Suggestion 1 is closed.** Legal authority is conferred to strengthen EEAE's powers of enforcement within the Act of its re-establishment.

#### **1.4. INDEPENDENCE OF THE REGULATORY BODY**

There were no findings in this area in the initial IRRS mission.

#### **1.5. PRIME RESPONSIBILITY FOR SAFETY**

## 2012 MISSION RECOMMENDATIONS, SUGGESTIONS Recommendation: The Government should expressly assign the prime

#### Changes since the initial IRRS mission

**Recommendation 5:** The assignment of the prime responsibility for safety to a person or an organization has been comprehensively addressed in the revision of the regulatory framework.

This is evident in the national framework for the management of SF & RW, the new RPR including PD 14, PD 15, PD 17 and MD 22. This is clearly illustrated in the following examples:

- "License holder" is defined as the legal or natural person who has overall (i.e. prime) responsibility for any activity, practice or facility associated with the management of spent fuel or radioactive waste;
- the licensee has the prime responsibility for ensuring, maintaining and implementing at all stages of the facility's life, the basic nuclear safety principles;
- the producer of spent fuel (defined in terms of the license holder) has the prime responsibility for its management until it is finally returned to a country that supplies or produces fuel for nuclear research reactors;
- the producer of radioactive waste has the prime responsibility for its management;
- the undertaking is fully and exclusively responsible for safety and radiation protection issues.

The IRRS team noted that while PD 14 establishes that the prime responsibility for spent fuel and radioactive waste remains with their generators or, under specific circumstances, with a licence holder to whom this responsibility has been entrusted by competent bodies; PD 14 also provides that the Minister responsible for EEAE has 'ultimate responsibility' for the management of spent fuel and radioactive waste generated in Greece.

#### Status of the finding in the initial mission

**Recommendation 5 is closed.** The Government has assigned prime responsibility for safety to the person or organization responsible for a facility or activity within the legal framework for radiation safety.

#### **1.6. COMPLIANCE AND RESPONSIBILITY FOR SAFETY**

There were no findings in this area in the initial IRRS mission.

#### 1.7. COORDINATION OF AUTHORITIES HAVING RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

There were no findings in this area in the initial IRRS mission.

### **1.8. PROVISION FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND SPENT FUEL**

#### **1.9. COMPETENCE FOR SAFETY**

There were no findings in this area in the initial IRRS mission.

#### **1.10. PROVISION OF TECHNICAL SERVICES**

#### 2. THE GLOBAL SAFETY REGIME

## 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

There were no findings in this area in the initial IRRS mission.

#### 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

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

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

There were no findings in this area in the initial IRRS mission.

## **3.2. EFFECTIVE INDEPENDENCE DURING THE CONDUCT OF REGULATORY ACTIVITIES**

		2012 MISSION RECOMMENDATIONS, SUGGESTIONS
R6 <u>Recommendation</u> : GAEC should provide for a further operational separation R6 between technical services and the regulatory function to minimize the potentia for conflicts of interests.	R6	<u>Recommendation</u> : GAEC should provide for a further operational separation between technical services and the regulatory function to minimize the potential for conflicts of interests.

#### **Changes since the initial IRRS mission**

**Recommendation 6:** To address the potential for conflicts of interest identified in the main mission, an organizational restructuring has already taken place within EEAE and is in the process of been consolidated in the form of a Presidential Decree. This is currently being progressed by the Ministry in accordance with the applicable legal provisions (L 19). This new organization design assures the effective independence and separation of the technical services and the regulatory functions.

More specifically, the regulatory oversight functions are now conducted by the Division of Licensing and Regulatory Inspections; while the provision of technical services is the responsibility of the Division of Training, Regulatory Planning, Infrastructure and Research. There is no staff member involved simultaneously in both divisional activities.

#### Status of the finding in the initial mission

**Recommendation 6 is closed.** Operational separation is provided between EEAE technical services and the regulatory function.

#### **3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY**

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

R7 Recommendation: GAEC should implement a systematic training program on the basis of an analysis of the necessary competence and skills for the regulatory body.

#### Changes since the initial IRRS mission

**Recommendation 7:** The analysis of the necessary competence and skills for the regulatory body is now carried out annually and a systematic training programme is implemented based on the analysis. These processes have been incorporated into EEAE's revised Integrated Management System (IMS) and provide for:

- the heads of the relevant EEAE departments to draft staff training needs in Q4 each year which are discussed with and approved by the EEAE senior management;
- the approved annual training programmes being uploaded to the IMS fileserver and monitored by the manager responsible;
- the training courses attended by EEAE personnel in accordance with the approved annual training programme being monitored and evaluated;
- an On-the-Job-Training programme for new EEAE inspectors to be established and implemented within the framework of the IMS.

#### Status of the finding in the initial mission

**Recommendation 7 is closed.** EEAE implements a systematic training program based on the analysis of the necessary competence and skills.

#### 3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There were no findings in this area in the initial IRRS mission.

#### 3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

There were no findings in this area in the initial IRRS mission.

#### **3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL**

There were no findings in this area in the initial IRRS mission.

#### 3.7. SAFETY RELATED RECORDS

#### 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

#### 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

#### 4.1. QUALITY SYSTEM

There were no findings in this area in the initial IRRS mission.

4.1.1. Quality System for the Laboratories

There were no findings in this area in the initial IRRS mission.

4.1.2. Quality system for the Licensing and Inspections Department

There were no findings in this area in the initial IRRS mission.

#### 4.2. INTEGRATED MANAGEMENT SYSTEM

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

## **R8** <u>Recommendation:</u> When developing the integrated management system, GAEC should ensure that it is aligned with GS-R-3.

#### **Changes since the initial IRRS mission**

**Recommendation 8:** EEAE has developed and implemented an Integrated Management System (IMS) based on ISO 9001:2008. The new IMS covers all the processes of the regulatory body. EEAE successfully incorporated the management systems that were in operation in 2012 namely; ISO/IEC 17025:2005 standard (General requirements for the competence of testing and calibration laboratories); ISO/IEC 17020:2012 standard (Conformity assessment - Requirements for the operation of various types of bodies performing inspection) and ISO 29990:2010 standard (Learning services for non-formal education and training - Basic requirements for service providers) for EEAE activities.

A task, within the work plan to develop the IMS, was to take into consideration the differences between ISO 9001:2008 and GS-R-3. When developing the IMS, EEAE had an external consultant involved, but they continued to own the development of the IMS themselves. The consultant was instructed to use GS-R-3 as well as ISO 9001:2008. This resulted in the IMS getting implemented since November 2013 and certified in terms of ISO 9001:2008 standard (Quality management systems – Requirements) and developed according to IAEA GS-R-3.

The IRRS team was informed that the IMS was updated in December 2016 so that it fulfils the requirements of both the revised ISO 9001:2015 standard (Quality management systems – Requirements) and the IAEA Safety Standard GSR Part 2. The IRRS team was also informed that the revised IMS includes a risk analysis and maps of the applied processes, and, in general, it is more process oriented than the previous version and continues to have safety at its core.

#### Status of the finding in the initial mission

**Recommendation 8 is closed.** EEAE implements an integrated management system that is aligned with GS-R-3.

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

## S2 <u>Suggestion:</u> GAEC should consider preparing a plan for the development and implementation of the integrated management system.

#### Changes since the initial IRRS mission

**Suggestion 2:** EEAE senior management has appointed a working group to prepare a working plan and time schedule for the development and implementation of the IMS. After extensive consideration of the IAEA GS-R-3, the working group established a plan for the development of the IMS having as main milestones:

- the incorporation of the legislative and regulatory requirements, as well as requirements from other relevant organizations and standards adopted by EEAE;
- the development and implementation of a strong safety culture, setting safety as top priority in all EEAE activities;
- a graded approach in organizing the development and use of resources.

#### Status of the finding in the initial mission

**Suggestion 2 is closed.** A plan was prepared for the development and implementation of the EEAE integrated management system.

#### 4.2.1. Management commitment and staff involvement

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

**R9** Recommendation: GAEC should foster staff commitment to the quality systems and to the integrated management system.

#### Changes since the initial IRRS mission

**Recommendation 9:** When designing and developing the new IMS, fostering staff commitment to the system was one of the main objectives. The working group, assigned with this task, involved almost all EEAE staff in the design phase through several fruitful discussions.

The process maps, all procedures and all documentation of the IMS, are uploaded in a share point, so that all EEAE staff members can easily access them.

Regular staff meetings are organized at department and division levels so that all modifications to the IMS are communicated to the staff. These meetings also provide an opportunity for all staff members to express their views on the improvement of the IMS itself and its implementation. Further, internal communication events on specific subjects which have been

identified to be of interest for EEAE staff members are organized. Finally, the Chairman of EEAE holds two meetings on an annual basis with the staff. The continuous development and implementation of the IMS is one of the topics discussed during these meetings.

#### Status of the finding in the initial mission

**Recommendation 9 is closed.** EEAE initiated actions for ensuring that its staff is committed to the quality systems and to the integrated management system.

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

**R10 Recommendation:** GAEC should make sufficient resources with the appropriate authority available when developing and implementing the integrated management system.

#### Changes since the initial IRRS mission

**Recommendation 10:** After establishing the work plan and the time schedule for the development of the new management system, the IMS management team was appointed by the EEAE Chairman i.e. manager, deputy manager and secretarial support was provided. Currently, the three above mentioned staff members are responsible for the coordination of continuous improvement, further development and fostering the involvement of all personnel in the implementation of the IMS. The appropriate authority for the development and implementation of the IMS will be assigned to one of the two division heads when PD16 is promulgated.

EEAE senior management provided the working group developing the IMS with sufficient support including the assistance of external consultants and the necessary financial resources.

#### Status of the finding in the initial mission

**Recommendation 10 is closed.** Sufficient resources with the appropriate authority was available when developing and implementing the integrated management system.

#### 4.2.2. Organizational change

# 2012 MISSION RECOMMENDATIONS, SUGGESTIONSR11Recommendation:<br/>of organizational change in the integrated management system.

#### Changes since the initial IRRS mission

**Recommendation 11:** EEAE has a procedure for the management of organizational change.

Organizational change may relate to:

- the organizational structure of EEAE;
- the allocation of responsibilities within organizational units;

- restructuring of the performed activities/tasks;
- human resources (e.g. recruitment, retirement, education);
- financial resources.

The procedure for organizational change consists of the following steps:

- a) **Risk assessment.** In case of extensive organizational changes, the potential impact the change may have on the activities of EEAE will be assessed.
- b) **Analysis of results.** The impact of the organizational change on staff and stakeholders, to avoid problems with the safe use of radiation;
- c) **Management involvement.** EEAE management shall be updated on, monitor and approve all organizational changes inside the organization.
- d) **Communication with interested parties.** Any change to the existing situation shall be notified to the parties concerned both inside and outside the organization.

#### Status of the finding in the initial mission

**Recommendation 11 is closed.** A specific process for the management of organizational change is included in the integrated management system.

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

## <u>Suggestion:</u> The Government should consider establishing specific processes for the management of organisational change across all competent authorities dealing with radiation safety.

#### **Changes since the initial IRRS mission**

**Suggestion 3:** This suggestion is no longer relevant as according to L19, EEAE is now the only relevant competent authority involved in the authorization process of medical ionizing radiation facilities and activities.

#### Status of the finding in the initial mission

Suggestion 3 is closed. EEAE is now the only relevant competent authority.

#### 4.3. SAFETY CULTURE

# 2012 MISSION RECOMMENDATIONS, SUGGESTIONS R12 Recommendation: GAEC should explicitly address safety culture in the integrated management system.

**S**3

#### **Changes since the initial IRRS mission**

**Recommendation 12:** According to PD 16 EEAE is required to take measures to strengthen safety culture in Greece. One of the policy statements in the quality manual states that "*EEAE faithfully implement the IMS across its range of activities, to make safety a top priority and ensure constant quality of services*".

In the area of safety culture, EEAE has done the following:

- 1) a survey was conducted using an appropriate questionnaire for the assessment of EEAE personnel safety culture. The analysis of the questionnaire responses resulted in a series of recommendations which were accepted by the senior management and are currently in the process of being implemented. The main questions addressed were:
  - to emphasize the questioning attitude and spirit;
  - to investigate the effectiveness of communication between EEAE organizational units and among individual staff members;
  - to attend seminars focused on safety culture, especially for EEAE inspectors.

The majority of the questions raised have already been addressed. An internal code of conduct and a specific procedure for the internal communication have been drafted.

- 2) The majority of EEAE personnel have attended seminars about the IMS and safety culture, in plenary sessions or in smaller groups.
- 3) Safety culture training is included in the training programme for the staff.

Although a lot has been done with regard to safety culture, the concept is not explicitly reflected in the management system (quality manual) yet.

#### Status of the finding in the initial mission

**Recommendation 12 is closed, on the basis of progress made and confidence in effective completion**. Good progress is being made by EEAE in addressing safety culture in the management system and there is confidence that the concept will be explicitly reflected in the management system.

#### 5. AUTHORIZATION

Licensing of medical facilities

#### There were no findings in this area in the initial IRRS mission.

Licensing of industrial facilities

There were no findings in this area in the initial IRRS mission.

Licensing of research and education facilities

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

## **R13** R13 R13 R13 R13 R13

#### Changes since the initial IRRS mission

**Recommendation 13:** The current Radiation Protection Regulation (RPR) (MD 5) includes requirements for the authorization of facilities and activities involving exposure to ionizing radiation, taking into consideration the risks associated with the facilities or activities. MD5 will be replaced by the new regulations (PD 15) which also contain a number of provisions setting out requirements for licensing of radiation facilities and activities.

EEAE has developed a new web site which includes detailed guidance regarding the steps to be followed, as well as the type, the format and the content of the documentation that needs to be submitted by the applicants, in support of an application for authorization of facility or activity. It provides information on the documents that need to be submitted for the issuance of a new licence, renewal of licence and amendments of a licence for all types of facilities and activities in Greece.

In addition, EEAE has issued Review Assessment Guides (D 25) which provide detailed guidance to applicants on the information to be provided to review and assess the safety of the facility or the activity.

#### Status of the finding in the initial mission

**Recommendation 13 is closed.** EEAE developed guidance on the format and content of the documents to be submitted by the applicant in support of an application for licensing of facilities and activities.

#### 2012 MISION RECOMMENDATIONS, SUGGESTIONS

**S4** <u>Suggestion</u>: GAEC should consider improving the coordination with Prefectures

#### 2012 MISION RECOMMENDATIONS, SUGGESTIONS

to avoid delays in the licensing renewal process which can result in facilities operating without a valid license.

#### Changes since the initial IRRS mission:

**Suggestion 4:** According to L 19, EEAE is the only competent authority empowered to issue authorizations for facilities and activities involving ionising radiation. As a consequence, the Prefectures are no longer involved in the authorization system of medical facilities and activities.

#### Status of the finding in the initial mission

**Suggestion 4 is closed.** EEAE is the only competent authority empowered to issue authorizations for facilities and activities involving ionising radiation.

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

Suggestion: GAEC should consider revising its licensing approach in order to include conditions, limits and controls on licenses and or certificates of compliance.

#### **Changes since the initial IRRS mission:**

**Suggestion 5:** EEAE has revised its licensing approach, and includes specific conditions, limits and controls that are commensurate with the associated risk, in the licences and/or the certificates of compliance of facilities and activities. These conditions, limits and controls are either defined in the regulations (RPR, EEAE Decisions) or set as necessary requirements in the authorization to ensure safety.

The IRRS team reviewed several authorizations which contain conditions. According to MD 5, licensees are required to comply with these conditions within a predefined timeframe and to inform EEAE accordingly.

The draft JMD on Authorization and Regulatory Control clearly states that conditions in registrations, licences and certificates of compliance are legally binding for the authorized parties.

#### Status of the finding in the initial mission

**Suggestion 5 is closed.** Within the revision of the EEAE licensing approach are included conditions, limits and controls on licenses and certificates of compliance.

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

**R14 <u>Recommendation</u>: GAEC should improve the implementation of a graded approach in the authorization process.</u>** 

#### Changes since the initial IRRS mission:

**Recommendation 14:** Currently, EEAE issues authorizations called "Registration of Radioactive Material" which includes information on the type and the activity of the radioactive material in use. The IRRS team was informed that this type of authorization is a form of notification and covers mainly Smoke Detectors. Another type of authorization called "Licence for the use of Radioactive Sources with Low Activity" is issued by EEAE for low activity sources (eg. Ni-63 and XRF sources). These types of authorizations have no expiry date. In authorizing high risk facilities and activities, EEAE has included conditions, terms and controls in the licences and certificates of compliance, commensurate with the associated radiological risks.

The new draft regulations (PD 15) provide for different types of authorizations depending on the risk associated with the facility or the activity. These include authorization by notification, registration and licensing.

In preparation for implementing the new regulations, EEAE has established a categorization system for the facilities and activities that exist in Greece according to the risk associated with each. This system will assist EEAE to decide on the type of authorization to be issued in accordance with the graded approach.

#### Status of the finding in the initial mission

**Recommendation 14 is closed on the basis of progress made and confidence in effective completion.** Good progress is being made by EEAE in the implementation of a graded approach in the authorization process and there is confidence that further progress will be made.

#### Authorization of waste management facilities

# 2012 MISSION RECOMMENDATIONS, SUGGESTIONSR15Recommendation: GAEC should enforce the licensing requirements for all<br/>facilities at NCSR "Demokritos", including the interim storage facility.

#### Changes since the initial IRRS mission:

**Recommendation 15:** According to PD 14 "a licence or licence holders shall be required to demonstrate the safety of the facility and/or activity. This safety demonstration shall cover the development and operation of an activity and the development, operation and decommissioning of a facility or closure of a disposal facility as well as the complexity and size of the facility and/or activity. The licensing process shall contribute to and ensure safety in the facility or activity during normal operating conditions, anticipated operational occurrences and potential design basis accidents".

The IRRS team noted that despite an authorization for this facility being issued based on a safety report provided by the operator, important limits and conditions for the facility such as the maximum volume of radioactive waste or number of disused sealed sources that can be stored on site are still not established. The IRRS team was informed that this will be addressed when the

operator updates and submits the safety report in December 2017 for EEAE approval. The updated report is a condition of the facility's authorization.

#### Status of the finding in the initial mission

**Recommendation 15 is closed on the basis of progress made and confidence in effective completion.** EEAE has made progress in enforcing the licensing requirements for all facilities at NCSR "Demokritos", including the interim storage facility. Confidence is made that important limits and conditions for the interim storage facility will be considered by the end of 2017.

#### New observations from the follow-up mission

Although Article 90 (1) in L19 requires that no legal entity exercises any radiation activity without operation licence, Article 46 (14) (a) of the same Law states *that "Anyone who: continues to operate a radiation lab and omits to submit an application with a full file in order to renew its license within a period of three months after its expiration......shall be....."*.

Based on Article 46 (14) (a) radiation users may continue operating their radiation facilities for three months after the expiry of the operation licence. Article 27.2 of the current radiation protection regulation MD5 provides for the licensees to submit all necessary documents for the renewal of the operation licence three months before its expiry but it does not provide for when the renewal of licence should take place.

#### FU MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Article 46 (14) (a) of L19 provides for licensees to apply for the renewal of their licences within a period of three months after its expiration. This implies that users may continue to operate without a valid licence for three months.

(1)	<b>BASIS: GSR Part 1 Requirement 23 states that</b> "Authorization of facilities and activities by the regulatory body: Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."
(2)	<b>BASIS: GSR Part 3 General requirement Para 3.5 states that</b> "No person or organization shall adopt, introduce, conduct, discontinue or cease a practice, or shall, as applicable, mine, extract, process, design, manufacture, construct, assemble, install, acquire, import, export, supply, provide, distribute, loan, hire, receive, site, locate, commission, possess, use"
(3)	<ul> <li>BASIS: GSR Part 3 Requirement 8 Para 3.9 "Any person or organization applying for authorization:</li> <li>(b) Shall refrain from carrying out any of the actions specified in para. 3.5 until the registration or the licence has been issued"</li> </ul>
RF1	<b>Recommendation:</b> When amending the provisions for sanctions in the law, the

FU MI	SSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
	Government should ensure that no facility or activity is allowed to operate once its licence expires and until it is renewed.

#### 6. REVIEW AND ASSESSMENT

2012 MISSION RECOMMENDATIONS, SUGGESTIONS		
R16	<u>Recommendation</u> : GAEC should document the procedure to review and assess the safety assessment reports that demonstrate the safe operation of the facilities and activities.	

#### Changes since the initial IRRS mission:

**Recommendation 16:** EEAE has developed Review and Assessment Guides (D25) which provide detailed guidance to the staff of EEAE on the information to be provided, reviewed and assessed to ensure the safety of the facility or the activity. It also includes procedures for the review and assessment of the safety assessment reports provided by applicants. The guides include detailed guidance for the application process for practices including:

- Diagnostic radiology;
- Radiotherapy;
- Industrial radiography;
- Research and education;
- Nuclear medicine;
- Veterinary; and
- Radioactive Waste Management and Storage Facility.

#### Status of the finding in the initial mission

**Recommendation 16 is closed.** The procedure to review and assess the safety assessment reports that demonstrate the safe operation of the facilities and activities is now documented.

#### 7. INSPECTION

#### 7.1. INSPECTION PROGRAMME AND THE GRADED APPROACH

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

### S6 <u>Suggestion</u>: GAEC should consider reducing the influence of the license renewal process on the inspection programme.

#### Changes since the initial IRRS mission

**Suggestion S6:** EEAE has established criteria for determining the activities to be inspected during 2017 which uses a graded approach. The IRRS team was informed that EEAE will develop the inspection programme on an annual basis using these criteria.

EEAE presented the annual inspection programme for 2017 to the IRRS team. The programme includes the number of facilities and activities to be inspected by EEAE independently of their licence renewal process. The IRRS team was informed that EEAE takes into consideration the allocation of resources for conducting inspections in the public and private sector facilities and activities using the graded approach.

The licence renewal for low and some medium risk facilities and activities (related to the categorization criteria under development) is mainly based on the outcome of the review and assessment of the documentation submitted by the applicant. This enables EEAE to consider the graded approach to plan and perform inspections corresponding to the associated risk.

#### Status of the finding in the initial mission

**Suggestion S6 is closed.** The influence of the license renewal process on the EEAE inspection programme is reduced.

#### 7.2. INSPECTION RESULTS

	2012 MISSION RECOMMENDATIONS, SUGGESTIONS
R17	<u>Recommendation</u> : GAEC should provide inspection results officially to the operator of the NCSR "Demokritos" waste storage facility, and ensure that the inspection findings are addressed.

#### Changes since the initial IRRS mission

**Recommendation 17:** The IRRS team was informed that EEAE inspections to the NCSR "Demokritos" interim storage facility (EDRY) have been enhanced, both in frequency and extent, during the last years. The IRRS team had the opportunity to review inspection reports of this facility, which were officially provided to the operator, and noted that inspection findings, in terms of compliances and non-compliances, and the analysis of the radiation measurements conducted during the inspection, are described in the relevant sections of the inspection report.

Recommendations and suggestions, as well as timeframes for the implementation of specific corrective or optimization actions are also included in the report relevant sections.

The IRRS team was informed that inspection findings are also included in the review and assessment reports that are uploaded to EEAE website, in the public accessible area. EEAE ensures that the inspection findings are addressed by the operator during follow-up inspections.

#### Status of the finding in the initial mission

**Recommendation 17 is closed.** EEAE provides officially the inspection results to the operator of the NCSR "Demokritos" waste storage facility.

#### 8. ENFORCEMENT

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

## **R18 Recommendation:** GAEC should formalize its enforcement policy in line with a graded approach and incorporate it into the integrated management system.

#### Changes since the initial IRRS mission

**Recommendation 18:** According to L 19, EEAE is empowered to impose administrative sanctions, penalties and fines for any violation of the provisions concerning radiation protection regulations and applicable legislation on nuclear safety and radioactive waste management or any of the regulatory acts issued under the Law, upon a hearing of the parties involved.

EEAE has developed a hearing regulation which was published in the Government Gazette in April 2017. The regulations set out the procedures governing the hearings in the case of non-compliance by a licensee. The regulation does not provide for a policy to be developed or used for enforcement actions.

The IRRS team was informed that EEAE is in the phase of developing a table of fines with regard to specific non-compliances, taking into account their severity and frequency of occurrence.

Within the IMS procedures, EEAE has included few elements on enforcement policy. EEAE has not developed a written enforcement policy incorporating a graded approach.

#### Status of the finding in the initial mission

**Recommendation 18 remains open.** EEAE has not formalized yet its enforcement policy in line with a graded approach and has incorporated only a few elements of it into the integrated management system.
#### 9. REGULATIONS AND GUIDES

## 9.1. PROCESS FOR DEVELOPING REGULATIONS AND GUIDES

There were no findings in this area in the initial IRRS mission.

#### 9.2. EXISTING REGULATIONS AND GUIDES

#### 9.2.1. The use of radiation in medical facilities, industry, education and research

2012 MISSION RECOMMENDATIONS, SUGGESTIONS			
R19	<b><u>Recommendation:</u></b> GAEC should prepare updated Radiation Protection Regulations to bring them in line with the current IAEA Safety Requirements for submission to the Government.		
<b>S7</b>	<u>Suggestion</u> : The Government should consider adopting a more flexible hierarchy of Radiation Protection Regulations.		

#### **Changes since the initial IRRS mission**

**Recommendation 19:** Following the transposition requirement of the Council Directive 2013/59/EURATOM to the national legislative framework, EEAE prepared new radiation protection regulations (PD 15). PD 15, which is in line with the IAEA Basic Safety Standards (GSR Part 3), was submitted to the Government in July 2017 for approval. The IRRS team was informed that PD 15 is expected to be approved before February 2018.

The secondary legislation, regulatory and guidance documents that will complement the national framework are under preparation. The IRRS team was informed that the Joint Ministerial Decisions (JMD) are scheduled to be published in the Government Gazette in the six month period after the entry into force of PD 15 and include:

- Joint Ministerial Decision (JMD) on regulatory control;
- Joint Ministerial Decision (JMD) on radon action plan;
- Joint Ministerial Decision (JMD) on the implementation of strategies for the management of existing exposure situations.

PD 15 confers the required authority on EEAE to perform its regulatory oversight functions.

#### Status of the finding in the initial mission

**Recommendation 19 is closed on the basis of progress made and confidence in effective completion.** EEAE prepared new radiation protection regulation, which is in line with the IAEA Basic Safety Standards (GSR Part 3). This regulation was submitted to the Government in July 2017 for approval and is expected to be approved by February 2018.

#### Changes since the initial IRRS mission

**Suggestion 7:** L19 provides the hierarchy of the legislative/regulatory regime and for the issuance of:

- Presidential Decrees for the transposition of European Council Directives;
- Joint Ministerial Decisions for several specific radiation safety issues;
- EEAE decisions to be published in the Government Gazette;
- EEAE guidance documents.

The hierarchy of radiation protection regulations, as indicated above, is presented in the following figure.



Regarding the approval of each type of the regulations in the above hierarchy:

- PD 15 is approved by the President of the Republic after the examination of the Council of State;
- detailed statutory issues are approved by the competent Ministers (JMDs);
- regulatory radiation safety provisions are approved by the Board of EEAE and published in the Government Gazette;
- practical details and technical issues to be covered in guidance documents issued by EEAE and uploaded to its website.

In the above hierarchy, the regulations issued under level 1, 2 and 3 are legally binding, while level 4 is guidance for licensees and are not legally binding.

This approach enables the efficient and timely revision of the regulatory radiation safety provisions and the guidance documents in light of new scientific knowledge, technical developments and information.

The IRRS team was informed that in levels 1 and 2, consultation with interested parties is conducted prior to the submission of the final drafts for endorsement by the Government. A presentation of this hierarchic scheme for the national framework is also available in EEAE website.

#### Status of the finding in the initial mission

Suggestion 7 is closed. A more flexible hierarchy of Radiation Protection Regulations is now adopted.

#### 9.2.2. Waste management and waste management facilities

2012 MISSION RECOMMENDATIONS, SUGGESTIONS		
R20	<b><u>Recommendation</u></b> : GAEC should establish safety requirements for decommissioning of facilities and pre-disposal management of radioactive waste.	
<b>S</b> 8	Suggestion: GAEC should consider incorporating a waste classification scheme into its regulatory system.	

#### Changes since the initial IRRS mission

Recommendation 20: PD 17 amends and complements PD 14 and includes:

- safety requirements for the management of RW, including the decommissioning phase of RW facilities;
- safety requirements for the disposal of RW; and
- authorization provisions for RW management facilities.

The establishment of the National Committee for the management of SF & RW (EEDRA) is also provided in PD 17. It has a consultative, advisory and supportive role to the competent Minister for EEAE on the practical aspects for the implementation of the national policy and the national programme. Interested parties at the national level, involved in the RW management, will be represented on EEDRA. It is noted that EEDRA members are expected to be designated and discharge their duties in due time according to MD 20.

In addition, PD 17 establishes the main safety requirements on:

- predisposal management of RW, including obligations and responsibilities of the licensee and the competent authorities; conduct of safety assessments and safety verification, verification of design, construction, operation, maintenance and decommissioning of RW management facilities, including minimization, transport, conditioning and clearance;
- disposal of RW, including passive safety measures, physical limitations and isolation from the biosphere and the closure of disposal facilities;
- nuclear security, quality assurance, emergency preparedness and response;

- authorization and compliance inspections to RW management activities; and
- information dissemination and public participation.

The IRRS team noted that significant progress was made by EEAE to enhance the legal and regulatory framework on safety of predisposal management of radioactive waste and decommissioning of facilities. The IRRS team was informed that plans are in place for the elaboration and approval of regulations and guides to complement the recently approved legal instruments on RW management and decommissioning in accordance with the IAEA safety standards.

#### Status of the finding in the initial mission

**Recommendation 20 is closed on the basis of progress made and confidence in effective completion.** EEAE made significant progress to enhance the legal and regulatory framework on safety of predisposal management of radioactive waste and decommissioning of facilities. Confidence is made that the elaboration and approval of regulations and guides to complement the recently approved legal instruments on radioactive waste management and decommissioning in accordance with the IAEA safety standards will be completed.

#### **Changes since the initial IRRS mission**

**Suggestion 8:** According to the national program (MD 20), EEAE will establish and publish the RW classification scheme in the 2 year period following the establishment of EEDRA and the publication of PD 17 in the Government Gazette.

The IRRS team noted that the IAEA classification scheme is generally applied in regulatory oversight despite not being incorporated in the regulatory system. The IRRS team was informed that this classification scheme will be applied in the near future.

#### Status of the finding in the initial mission

**Suggestion 8 is open**. Even if the IAEA classification scheme is generally applied in regulatory oversight, EEAE has not incorporated it into its regulatory system.

#### 10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

#### **10.1. BASIC RESPONSIBILITIES**

#### There were no findings in this area in the initial IRRS mission.

#### **10.1.1.** Assessment of threats

# 2012 MISSION RECOMMENDATIONS, SUGGESTIONSR21Recommendation: GAEC should liaise with relevant organizations, to conduct the assessment of hazards at the national level in accordance with GS-R-2.

#### **Changes since the initial IRRS mission**

**Recommendation 21:** The development of the emergency management system is based on the requirements of the Council Directive 2013/59/EURATOM and on the IAEA Safety Standards (GSR-Part 7). The emergency management system provides for the implementation of the concept of reference levels and optimized protection strategies which are to be established as part of hazard assessments and emergency plans development.

In the new legislative framework, EEAE has received a clear mandate for developing emergency plans in cases of nuclear or radiation incidents or threats with nuclear or radioactive material, which will be approved by decisions of the relevant competent Ministers (L 19). PD 15 assigned the responsibility to perform the hazard assessment to EEAE, in cooperation with other concerned parties. PD 15 also allocates responsibilities among various authorities, organizations and stakeholders for the emergency preparedness and response (EPR) phases.

EEAE collaborates with other competent authorities as defined in the General Civil Protection Plan "Xenokratis".

According to PD 15, EEAE is also responsible, in collaboration with other competent authorities, for the development of the associated National Emergency Plans using GSR Part 7 as guidance. In this framework, all involved local authorities are also required to amend, as necessary, their own plans according to the National Plans. Specific provisions are made for public consultation regarding the National Plans, at local and national levels.

The IRRS team was informed that EEAE has already organized two meetings with national stakeholders involved in EPR, namely General Secretariat for Civil protection, Fire Brigade and Ministries. As a result, it was decided that EEAE will assume the responsibility of carrying out the radiological hazard assessment and that the national stakeholders will offer their collaboration and expertise within their area of responsibility. A comprehensive hazard assessment draft has been prepared and is in the process of being approved.

#### Status of the finding in the initial mission

**Recommendation 21 is closed on the basis of progress made and confidence in effective completion.** EEAE has liaised with relevant organizations, to conduct the assessment of hazards at the national level. Confidence is made that the already prepared comprehensive hazard assessment will be approved.

#### **10.2. FUNCTIONAL REQUIREMENTS**

#### 10.2.1. Emergency management and operations

There were no findings in this area in the initial IRRS mission.

**10.2.2.** Identifying, notifying and activating

There were no findings in this area in the initial IRRS mission.

10.2.3. Taking mitigatory action

There were no findings in this area in the initial IRRS mission.

10.2.4. Taking urgent protective action

There were no findings in this area in the initial IRRS mission.

**10.2.5.** Protecting emergency workers

There were no findings in this area in the initial IRRS mission.

**10.2.6.** Assessing the initial phase

There were no findings in this area in the initial IRRS mission.

**10.2.7.** Managing the medical response

There were no findings in this area in the initial IRRS mission.

10.2.8. Keeping the public informed

There were no findings in this area in the initial IRRS mission.

**10.2.9.** Taking long-term protective action

#### **10.3. REQUIREMENTS FOR INFRASTRUCTURE**

10.3.1. Organization

There were no findings in this area in the initial IRRS mission.

10.3.2. Plans and procedures

There were no findings in this area in the initial IRRS mission.

10.3.3. Logistical support and facilities

There were no findings in this area in the initial IRRS mission.

10.3.4. Training, drills and exercises

#### 11. TRANSPORT OF RADIOACTIVE MATERIAL

# 11.1. REGULATIONS AND THE GLOBAL NUCLEAR SAFETY REGIME

#### There were no findings in this area in the initial IRRS mission.

#### **11.2.** Competent Authority

There were no findings in this area in the initial IRRS mission.

## **11.3. RESPONSIBILITY FOR SAFETY**

# 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

S9 Suggestion: The Government should consider revising its regulatory framework for the transport of radioactive materials to provide for a contemporary set of requirements which are fully consistent with the international regulatory framework.

#### Changes since the initial IRRS mission

**Suggestion S9:** In 2012, the IRRS team noted that the existing regulations (MD 5) only partially incorporated IAEA Regulations TSR-1 and contained an error in the definition of "Quality Assurance". It was noted that in Greece, the review and revision cycle for radiation protection regulations differs significantly from that for IAEA Regulations SSR-6 (former TSR-1). In addition, the transposition of the revised UN Recommendations on the Transport of Dangerous Goods (that incorporate the SSR-6 revised requirements) involves other competent authorities and legislative considerations beyond the field of radiation safety.

In developing the new Radiation Protection Regulations (RPR) and specifically the Joint Ministerial Decision (JMD) on regulatory control, reference is made to the pertinent legislation for the transport of Class 7 material by any transport mode. By adopting this approach, definitions and requirements are not duplicated in the regulations.

In this context, the national regulatory framework for the transport of radioactive material (TRAM) provides for a contemporary set of requirements which are fully consistent with the international regulatory framework.

Moreover, TRAM is considered a practice that falls within radiation protection regulatory oversight (PD 15). Provisions for notification, registration and authorization of carriers and shipments, validation of package design approval certificates, assignment of responsibilities and accident reporting are included in the draft JMD on regulatory control.

JMD provides the legislative link between the new RPR and other relevant transport legislation. When it comes into force, the complete legislative framework for transport of radioactive

material will be consistent with the international regulatory framework and will facilitate synchronising the revision cycle with the IAEA Regulations revision cycle.

#### Status of the finding in the initial mission

**Suggestion S9 is closed on the basis of progress made and confidence in effective completion.** The revised national regulatory framework for the transport of radioactive material (TRAM) provides for a contemporary set of requirements which are fully consistent with the international regulatory framework. Confidence is made that the legislative document will be approved by February 2018 and the secondary legislation and guidance 6 months thereafter.

# 11.4. Delivery and coordination of regulatory functions

# 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

R22 Recommendation: GAEC should collaborate and coordinate with other Greek authorities with assigned competence for the transport of radioactive material to: facilitate the timely and effective exchange of information; and enable effective coordination of regulatory functions.

## Changes since the initial IRRS mission

**Recommendations R22:** The IRRS team noted that while there is no formalised national process in place, in practice EEAE co-operates and collaborates efficiently and effectively with other national authorities with assigned competence for TRAM. Consequently, EEAE complies with the relevant IAEA requirements.

#### Status of the finding in the initial mission

**Recommendations R22 is closed.** EEAE co-operates and collaborates efficiently and effectively with other national authorities with assigned competence for TRAM.

# 11.5. Operational Activities and Compliance Assurance

	2012 MISSION RECOMMENDATIONS, SUGGESTIONS
R23	<b><u>Recommendation</u></b> : GAEC should review, develop and strengthen its capacity for review and approval of package and material designs.

# Changes since the initial IRRS mission

**Recommendations R23:** The IRRS team noted that package and material designs that require Competent Authority approval are not designed, tested or manufactured in Greece. The IRRS team were informed that in the past fifteen years, only one application for the multilateral approval of a Type B (M) package was submitted to EEAE. The lack of capacity in this field was initially addressed by EEAE by joining the European Association of Competent Authorities (EACA) in 2014. EEAE intends to rely on the existing experience among EACA members and Competent Authorities for technical assistance in future, should the need arise.

Furthermore, EEAE participates in the Mediterranean Network for the safe transport of radioactive materials (MedNet) serving as the Chair since 2015. MedNet members, including EEAE, requested and received relevant training from IAEA in 2016. Arising from this training, EEAE developed and incorporated a number of guides and templates into its IMS including:

- internal guide for package design certificate validation according to ADR/RID;
- internal guide for package design certificate validation according to IAEA SSR-6;
- template for Validation Certificate of Package Design for the Transport of Radioactive Material.

In addition, EEAE's review and assessment for the validation of packaging and material design is conducted against the European PDSR Guide, issue 3, 2014 published by EACA.

The strategy and the actions put in place by EEAE, joining the EACA and participating in the activities of MedNet have developed and strengthened its capacity for the review and approval of package and material designs.

#### Status of the finding in the initial mission

**Recommendations R23 is closed.** EEAE capacity for review and approval of package and material designs is strengthened.

# 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

**R24 <u>Recommendation</u>: GAEC and other transport competent authorities should implement appropriate, co-ordinated, compliance assurance programmes.</u>** 

**S10** Suggestion: GAEC and other transport competent authorities should consider using IAEA TS-G-1.5 in developing their compliance assurance programme(s).

#### Changes since the initial IRRS mission

**Recommendations R24 and Suggestion S10:** In the context of its participation in MedNet, EEAE conducted a review of its compliance management system against the IAEA Safety Guide TS-G-1.5. Moreover, the Strengths Weaknesses Opportunities Threats (SWOT) analyses was performed by EEAE. These compliance management system reviews triggered the development of the EEAE internal guides for the review and assessment of package designs and the use of the EACA inspection check lists.

The IRRS team noted that while there is no formalised national process in place, in practice, EEAE co-operates and collaborates efficiently and effectively with other national authorities

with assigned competence for TRAM, including in relation to compliance assurance programmes.

#### Status of the finding in the initial mission

**Recommendations R24 and Suggestion 10 are closed.** EEAE implements co-ordinated compliance assurance programmes. The other transport competent authorities were not involved in the review during the initial or follow up missions.

#### 12. CONTROL OF MEDICAL EXPOSURES

#### **12.1. RESPONSIBILITIES**

2012 MISSION RECOMMENDATIONS, SUGGESTIONS			
R25	<u>Recommendation</u> : GAEC should ensure that all health professionals with specific duties in relation to the radiation protection of patients have adequate education, training and competence in radiation protection.		

#### Changes since the initial IRRS mission

**Recommendations R25:** EEAE established and approved a National Programme for education and training in Radiation, Transport and Waste Safety in 2013 (EDGG 7, EDGG 8), within the framework of the national strategy for education and training. The training programmes are designed in collaboration with universities and the health professionals' societies involved in medical exposures of patients.

Training programmes on radiation protection for veterinary radiologists, interventional radiologists and interventional vascular surgeons have been designed and delivered, leading to a certificate of competency in radiation protection signed by EEAE Chairman. This certificate is required by the regulations to practice. Training programmes for interventional neurosurgeons and orthopaedics are under development.

To allow EEAE to improve the process, the participants and the lecturers are asked to evaluate the training course upon completion. All the procedures of this process are included in EEAE's IMS.

#### Status of the finding in the initial mission

**Recommendation 25 is closed.** EEAE ensures that all health professionals have adequate education, training and competence in radiation protection.

#### 2012 MISSION RECOMMENDATIONS, SUGGESTIONS

R26Recommendation:GAEC should verify that no person incurs a medical<br/>exposure unless there has been an appropriate referral.

#### Changes since the initial IRRS mission

**Recommendation 26:** EEAE initiated an investigation concerning the justification process during on-site inspections of medical facilities to verify whether licensees ensure that each medical procedure/exposure is prescribed by a medical practitioner. An appropriate field was added in the inspection check list for diagnostic radiology facilities including a check on the existence of appropriate referrals for each medical exposure. This continues to be part of the routine inspection procedure.

#### Status of the finding in the initial mission

**Recommendation R26 is closed.** EEAE verify that no person incurs a medical exposure unless there has been an appropriate referral.

#### **12.2.** Justification of medical exposures

#### There were no findings in this area in the initial IRRS mission.

#### New observations from the follow-up mission

EEAE is implementing a research project on radiation protection and clinical audits in new diagnostic and therapeutic technologies. Topics on justification and referral criteria have been included in the project. Moreover, EEAE monitors the justification of the diagnostic examinations, the optimisation and verification of the doses delivered both in diagnosis and therapy, in the context of a defragmented "one stop shop" authorization process, thus improving patient protection.

#### FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** EEAE is implementing a research project on radiation protection and clinical audits in new diagnostic and therapeutic technologies to enhance patient protection.

(1)	<b>BASIS: GSR Part 3 Paragraph 3.156 states that</b> "Generic justification of radiological procedure shall be carried out by the health authority in conjunctio with appropriate professional bodies, and shall be reviewed from time to time with account taken of advances in knowledge and technological developments."			
GPF1	<b><u>Good Practice</u></b> : EEAE is implementing a research project on radiation protection and clinical audits in new diagnostic and therapeutic technologies including topics on justification and referral criteria the findings of which will enhance patient protection.			

#### **12.3.** Optimization of protection and safety

2012 MISSION RECOMMENDATIONS, SUGGESTIONS			
R27	<u>Recommendation</u> : GAEC, in collaboration with the Ministry of Health and the relevant professional bodies, should complete the process for the determination of national DRLs for all diagnostic procedures.		

#### Changes since the initial IRRS mission

**Recommendations R27:** After consultation with the Ministry of Health and the relevant professional societies, EEAE has completed the process for the determination of national DRLs

for all diagnostic procedures. The DRLs values determined for radiographic and computed tomography examinations, as well as for interventional cardiology procedures were published in the Government Gazette in 2014 (MD 21).

The IRRS team was informed that EEAE checks the use of DRLs during on-site inspections. Additionally, typical patient doses for diagnostic and interventional radiology procedures and typical administered radiopharmaceutical activities for nuclear medicine procedures are systematically measured and monitored by the inspectors. These collected data are used to advise the licensee if the DRLs are exceeded.

The data gathered during inspections combined with the data electronically submitted by the licensees, as required by the regulations, will allow EEAE to revise the national DRLs in the future, as appropriate.

#### Status of the finding in the initial mission

**Recommendations R27 is closed.** EEAE has completed the process for the determination of national DRLs for all diagnostic procedures.

#### 13. OCCUPATIONAL RADIATION PROTECTION

#### 13.1. LEGAL / REGULATORY FRAMEWORK

There were no findings in this area in the initial IRRS mission.

#### 13.2. GENERAL RESPONSIBILITIES OF REGISTRANTS, LICENSEES AND EMPLOYERS

There were no findings in this area in the initial IRRS mission.

#### **13.3. GENERALRESPONSIBILITIES OF WORKERS**

There were no findings in this area in the initial IRRS mission.

#### **13.4. REQUIREMENTS FOR RADIATION PROTECTION PROGRAMMES**

There were no findings in this area in the initial IRRS mission.

#### **13.5. MONITORING PROGRAMME TECHNICAL SERVICES**

# 14. CONTROL OF RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE

# 15. ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES

#### 16. CONTROL OF CHRONIC EXPOSURES AND REMEDIATION

#### NORM

There were no findings in this area in the initial IRRS mission.

**Remedial actions** 

There were no findings in this area in the initial IRRS mission.

Radon

There were no findings in this area in the initial IRRS mission.

**Drinking water** 

There were no findings in this area in the initial IRRS mission.

#### Spring water

2012 MISSION RECOMMENDATIONS, SUGGESTIONS			
R28	<u>Recommendation</u> : GAEC should ensure clear separation of its regulatory functions from any advisory actions given to the operator for existing exposure situations and remedial actions.		

#### **Changes since the initial IRRS mission**

**Recommendations R28:** According to L19 and the new organizational structure of EEAE, a clear separation between regulatory functions and technical services provided by EEAE is assured. The regulatory oversight functions are conducted by the Division of Licensing and Regulatory Inspections while technical services are provided exclusively by the Division of Training, Regulatory Planning, Infrastructure and Research.

The IRRS team also noted that in the new RPR (PD 15), provisions related to existing exposure situations, including remediation actions, NORM activities, radon concentrations in public and working environment are established.

#### Status of the finding in the initial mission

**Recommendations R28 is closed.** A clear separation between regulatory functions and technical services provided by EEAE is ensured.

# **APPENDIX I - LIST OF PARTICIPANTS**

INTERNATIONAL EXPERTS				
1.	RYAN Tom	Environmental Protection Agency IRELAND	t.ryan@epa.ie	
2.	FRANZÉN Anna	Swedish Radiation Safety Authority SWEDEN	anna.franzen@ssm.se	
3.	JOVA SED Luis	Senior Expert CUBA	jovaluis@gmail.com	
4.	PERRIN Marie Line	Senior Expert FRANCE	marie-line.perrin@wanadoo.fr	
5.	TRIVELLONI Sandro	Institute for Environmental Protection and Research ITALY	sandro.trivelloni@isprambiente.it	
		IAEA STAFF MEMBERS		
1.	AL KHATIBEH Ahmad	Division of Radiation Transport and Waste Safety	A-Alkhatibeh@iaea.org	
2.	SHADAD Ibrahim	Division of Radiation Transport and Waste Safety	I.Shadad@iaea.org	
3.	SWOBODA Zumi	Division of Radiation Transport and Waste Safety	Z.Swoboda@iaea.org	
LIAISON OFFICER				
1.	VOGIATZI Stavroula	Greek Atomic Energy Commission (EEAE)	stavroula.vogiatzi@eeae.gr	

# **APPENDIX II - MISSION PROGRAMME**

#### IRRS FOLLOW-UP MISSION TO GREECE 19 – 24 November 2017 AGENDA

Time	Contents	Notes		
Sunday 19.11.2017				
13:30 –17:30	<ul> <li>IRRS Team Initial Team Meeting:</li> <li>Opening remarks (TL)</li> <li>IRRS Process (TC)</li> <li>First Impressions (IRRS team)</li> <li>Mission logistics (EEAE LO)</li> </ul>	Location: Alexandros Hotel, Millenium Conference Room <i>Participation:</i> - IRRS team - EEAE LO		
Monday 20.11.20	17			
09.00 – 10:30	<ul> <li>Entrance Meeting: <ul> <li>Opening remarks from EEAE</li> <li>Opening remarks from IAEA</li> <li>Team Coordinator</li> <li>Presentation: first impressions and general expectation of the mission IRRS Team Leader</li> <li>EEAE Presentation <ul> <li>(Overview of current situation, highlighting what has changed since 2012 mission)</li> </ul> </li> <li>Introductions (IRRS review team; EEAE management team, liaison officer &amp; counterparts, observers)</li> </ul></li></ul>	<ul> <li>Location: EEAE</li> <li><i>Participation:</i> <ul> <li>EEAE senior management &amp; team</li> </ul> </li> <li>Officials from other Ministries/organizations</li> <li>IRRS Team Leader, Deputy Team Leader, IAEA Coordinators &amp; support staff</li> </ul>		
10:30 - 10:45	Coffee Break			
10:45 - 12:00	Interviews and Discussions with Counterparts EEAE (parallel discussions)	Location: EEAE <i>Participation:</i> EEAE/IRRS team		
12:00 – 13:00 Lunch				
13:00 - 17:00	Interviews and Discussions with Counterparts EEAE (parallel discussions)	Location: EEAE <i>Participation</i> : EEAE/IRRS team		
17:00 - 18:00	Daily IRRS Review Team Meeting	Location: EEAE <i>Participation</i> : IRRS team & EEAE Liaison officer		

Tuesday 21.11.2017			
08:30 - 1200	30 - 1200Interviews and discussions with counterparts EEAE (parallel discussions)Location: EEAE Participation: EEAE/IRRS		
12:00 - 13:00	Lunch		
13:00 - 17:00	Interviews and discussions with counterparts EEAE (parallel discussions)	Location: EEAE <i>Participation</i> : EEAE/IRRS team	
	Daily IRRS Review Team Meeting	Location: EEAE	
17:00 - 18:00	Report preparation: finalize decisions on Rs and Ss	<i>Participation</i> : IRRS Team & LO	
Wednesday 22.11	.2017		
08:00 - 12:00	Interviews and discussions with counterparts EEAE (parallel	Location: EEAE	
	discussions) if needed	<i>Participation</i> : EEAE/IRRS team	
12:00 – 13:00 Lunch			
13:00 - 16:30	Report finalization: Modules 1-4	<b>Location</b> : EEAE & later Alexandros Hotel, Millenium Conference Room	
17:00 - 21:00		LO	
Thursday 23.11.2	017		
08:00 - 12:00	Report finalization: Modules 5-10.	<b>Location</b> : Alexandros Hotel, Millenium Conference Room <i>Participation</i> : IRRS team + LO	
12:00 -	Draft report to EEAE for comments	TC	
12:00 - 13:00	Lunch		
12:00 - 15:00	EEAE reviews the report		
15:00 - 16:30	Final discussion of draft report	Location: EEAE <i>Participation</i> : all	
Friday 24.11.2017			
09:00 - 11:00	Exit Meeting Official handover of mission report - Presentation of findings by IRRS Team Leader - EEAE Remarks - Closing remarks: IAEA	Location: EEAE <i>Participation</i> : EEAE senior management & staff Officials from other Ministries/organization IRRS team.	

# **APPENDIX III - MISSION COUNTERPARTS**

IRRS EXPERTS	EEAE Lead Counterparts	EEAE Support Counterparts	
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT			
Tom Ryan Ahmad Al Khatibeh	Christos Housiadas, Stavroula Vogiatzi, Costas Hourdakis, Adamantia Metaxaki	Konstantinos Karfopoulos	
2. GLOBAL NUCLEAR SAFETY	REGIME	•	
Tom Ryan Ahmad Al Khatibeh	Christos Housiadas, Stavroula Vogiatzi, Costas Hourdakis, Adamantia Metaxaki		
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY			
Tom Ryan	Christos Housiadas, Eleftheria Carinou, Costas Hourdakis, Konstantinos Karfopoulos		
4. MANAGEMENT SYSTEM OF	THE REGULATORY	BODY	
Anna Franzen	Eleftheria Carinou, Konstantinos Karfopoulos	Argiro Boziari, Sotiris Economides, Maria Kolovou, Eleni Papadomarkaki	
5. AUTHORIZATION	-		
Ibrahim Shadad Marie Line Perrin	Sotiris Economides, Maria Kalathaki	Panagiotis Tritakis, Kyveli Zourari	
Luis Jova Sed	Costas Hourdakis Panagiotis Tritakis	Dimitris Mitrakos, Costas Potiriadis	
6. REVIEW AND ASSESSMENT			
Ibrahim Shadad Marie Line Perrin	Maria Kalathaki, Sotiris Economides	Antonis Maltezos, Maria Nikolaki	

IRRS EXPERTS	EEAE Lead Counterparts	EEAE Support Counterparts	
Luis Jova Sed	Costas Hourdakis Panagiotis Tritakis	Dimitris Mitrakos, Costas Potiriadis	
7. INSPECTION			
Ibrahim Shadad Marie Line Perrin	Sotiris Economides, Maria Kalathaki	George Simantirakis	
Luis Jova Sed	Costas Hourdakis, Panagiotis Tritakis	Dimitris Mitrakos, Costas Potiriadis	
8. ENFORCEMENT	•	•	
Ibrahim Shadad Marie Line Perrin	Adamantia Metaxaki, Sotiris Economides	Panagiotis Tritakis	
Luis Jova Sed	Costas Hourdakis, Panagiotis Tritakis		
9. REGULATIONS AND GUIDE	S		
Ibrahim Shadad Marie Line Perrin	Costas Hourdakis, Sotiris Economides, Maria Kalathaki	Eleftheria Carinou	
Luis Jova Sed	Costas Hourdakis, Panagiotis Tritakis	Dimitris Mitrakos, Costas Potiriadis	
10. EMERGENCY PREPAREDN	ESS AND RESPONSE		
Ahmad Al-Khatibeh	Costas Potiriadis, Dimitris Mitrakos, Antonis Maltezos	Argiro Boziari, Maria Nikolaki	
11. TRANSPORT OF RADIOAC	TIVE MATERIAL		
Sandro Trivelloni	Stavroula Vogiatzi	Alexandros Liossis, Adamantia Metaxaki	
12. CONTROL OF MEDICAL EXPOSURE			
Marie Line Perrin	Maria Kalathaki, Konstantinos Karfopoulos, Sotiris Economides	Costas Hourdakis	
13. OCCUPATIONAL RADIATION PROTECTION			
Marie Line Perrin	Eleftheria Carinou		

IRRS EXPERTS	EEAE Lead Counterparts	EEAE Support Counterparts	
14. CONTROL OF RADIOACTI FOR CLEARANCE	VE DISCHARGES AN	D MATERIALS	
Luis Jova Sed	Costas Potiriadis, Dimitris Mitrakos	Konstantina Kehagia, Maria Kolovou	
15. ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES			
Luis Jova Sed	Costas Potiriadis, Dimitris Mitrakos	Konstantina Kehagia, Maria Kolovou	
16. CONTROL OF CHRONIC EXPOSURES AND REMEDIATION			
Luis Jova Sed	Costas Potiriadis, Dimitris Mitrakos	Konstantina Kehagia, Maria Kolovou	
EEAE ADMINISTRATIVE & SE	CRETARIAL SUPPO	RT	
Anna Dalles, Kyriaki Irodiadou, Vasiliki Tafili			
EEAE IT & TECHNICAL SUPPORT			
Stavroula Serfa, Athanasios Papathanasiou			

# APPENDIX IV - RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE IRRS MISSION THAT REMAIN OPEN

Section	Module	R/S	<b>Recommendations/Suggestions</b>
1.1	Module 1	R1	The Government should develop a consolidated statement that sets out the national policy and strategy for safety.
8	Module 8	R18	GAEC should formalize its enforcement policy in line with a graded approach and incorporate it into the integrated management system.
9.2.2	Module 9	<b>S</b> 8	GAEC should consider incorporating a waste classification scheme into its regulatory system.

# APPENDIX V - RECOMMENDATIONS (RF), SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2017 IRRS FOLLOW-UP MISSION

Section	Module	RF/SF/GPF	<b>Recommendations, Suggestions or Good Practices</b>
	Module 5	RF1	When amending the provisions for sanctions in the law, the Government should ensure that no facility or activity is allowed to operate once its licence expires and until it is renewed.
12.2	Module 12	GPF1	EEAE is implementing a research project on radiation protection and clinical audits in new diagnostic and therapeutic technologies including topics on justification and referral criteria the findings of which will enhance patient protection.

# **APPENDIX VI - REFERENCE MATERIAL PROVIDED BY EEAE**

# **LEGISLATIVE FRAMEWORK – REFERENCES**

# LAWS – REFERENCE: L1 – L20

1.	Government Gazette, Law No. 211, Folio No. 35, First issue, February 28, 1947, <i>"Ratification of the International Civil Aviation Convention of December 7, 1944"</i>
2.	Government Gazette, Decree No. 1287, Folio No. 294, First issue, October 31, 1949, "Ratification of the International Convention on Intergovernmental Maritime Consultative Organization signed in Geneva on March 6, 1948"
3.	Government Gazette, Decree No. 330, Folio No. 89, First issue, June 11, 1963 "Approval of regulation concerning the transport of dangerous goods by vessels"
4.	Government Gazette, Act No. 854, Folio No. 54, First Issue, March 18, 1971, "On the terms regarding the establishment and operation of nuclear facilities" (translated)
5.	Government Gazette, Legislative Decree 181, Folio No: 347, First issue, November 20, 1974, " <i>Protection against ionizing radiation</i> " (translated). Partially not in force any more please see L19
6.	Government Gazette, Law No. 1146, Folio No. 109, First issue, April 23, 1981, "Ratification of the amendments of the International Convention on Intergovernmental Maritime Consultative Organization made on November 14, 1975, November 17, 1977 and November 15, 1979"
7.	Government Gazette, Law No. 1741, Folio No: 225, First issue, December 21, 1987, <i>"Ratification of the European Agreement on the International Carriage of Dangerous Goods by Road (ADR) signed in Geneva on September 30, 1957</i>
8.	Government Gazette, Law No. 2805, Folio No. 50, First Issue, March 3, 2000, "Ratification of the Additional Protocol"
9.	Government Gazette, Law No. 2824, Folio No. 90, First Issue, March 16, 2000, "Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management"
10.	Government Gazette, Law No. 3787, Folio No. 140, First Issue, August 7, 2009, "Ratification of the Protocol amending the Convention on Third Party Liability in the field of nuclear energy of 29 July 1960, as amended by the additional protocol of 28 January 1964 and by the Protocol of 16 November 1982"
11.	Government Gazette, Law No. 3013, Folio No. 102, First issue, May 1, 2002, "Upgrade of the civil protection and other issues" (partially translated)
12.	Government Gazette, Law No. 3710 Folio No: 216, First issue, October 23, 2008, "Regulations for transport issues and other topics"
13.	Government Gazette, Law No. 3868, Folio No. 129, First issue, August 3, 2010, "Upgrade of the National Health System and other issues"

14.	Government Gazette, Law No. 3990, Folio No. 159, First issue, July 13, 2011, "Amendment of the Convention of Physical Protection of Nuclear Materials"
15.	Government Gazette, Law No. 2801, Folio No. 46, First issue, March 3, 2000, "Regulations regarding responsibilities of the Ministry of Transport and Communications"
16.	Government Gazette, Law No. 2480, Folio No. 70, First Issue, May 14, 1997, "Convention on Nuclear Safety".
17.	Government Gazette, Law No. 4085, Folio No. 194, First Issue, October 12, 2012, "Ratification of the Long-Term Agreement between the IAEA and the Government of the Hellenic Republic to support EEAE as a Regional Training Center in Europe for radiation, transport and waste safety issues" (translated).
18.	Government Gazette, Law No. 4310, Folio No. 258, First Issue, August 12, 2014, "Research, Technological Development and Innovation and other provisions (in particular Chapter E - Nuclear Energy, Technology and Radiation Protection - Greek Atomic Energy Commission (EEAE), Articles 39-46 and Article 90)" (Articles 39-46, 50
	and 90 translated).
19.	and 90 translated). Government Gazette, Law No. 2690, Folio No. 45, First Issue, March 08, 1999, "Ratification of the Administrative Procedure Code and other provisions" (Chapter E) (translated).

# PRESIDENTIAL DECREES – REFERENCE: PD1-PD17

1.	Government Gazette, Presidential Decree No.610, Folio No. 130, First issue, August 23, 1978 "Conditions and procedures for licensing on nuclear installation of the Public Electricity Corporation ( $\Delta EH$ )"
2.	Government Gazette, Presidential Decree No. 404, Folio No. 173, First issue, October 5, 1993 "Organization of the Greek Atomic Energy Commission" (translated)
3.	Government Gazette, Presidential Decree No. 83, Folio No. 147, First Issue, September 3, 2010, "Transposition of Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel into the Greek legislative framework" (translated)
4.	Government Gazette, Presidential Decree No. 49, Folio No. 66, First Issue, March 11, 2005, "Transposition of Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system"
5.	Government Gazette, Presidential Decree No. 56, Folio No. 28, First Issue, February 1, 1989, "Organization of the Civil Aviation Authority"

6.	Government Gazette, Presidential Decree No. 242, Folio No.201, First Issue, September 30, 1999, "Organization of the Ministry of Merchant Marine"
7.	Government Gazette, Presidential Decree No. 96, Folio No. 170, First Issue, September 28, 2010, "Establishment of the Ministry of Maritime Affairs, Islands and Fisheries and redistribution of Ministerial responsibilities"
8.	Government Gazette, Presidential Decree No. 73, Folio No. 178, First Issue, August 11, 2011, "Renaming of General Secretariat of Communication and General Secretariat of Information and redistribution of their supervised authorities, transfer of authorities and competencies from Ministry of Culture and Tourism to the Prime Minister, establishment of General Secretariat of Maritime Affairs in the Ministry of Development, Competitiveness and Shipping, and regulation of other relevant issues"
9.	Government Gazette, Presidential Decree No. 147, Folio No. 200, First Issue, August 17, 2005, "Inspectors for flying means and HCCA Aviation Safety Inspectors standards"
10.	Government Gazette, Presidential Decree No. 165, Folio No. 219, First Issue, September 1, 2005, "HCAA aviation security Inspectors for Safety Standards against unlawful actions and electronically supported means"
11.	Government Gazette, Presidential Decree No. 60, Folio No. 111, First Issue, May 3, 2012, "Establishing a National framework for the nuclear safety of nuclear installations" (transposition of the Council Directive 2009/71/ Euratom of 25 June 2009"
12.	Government Gazette, Presidential Decree No. 123, Folio No. 208, First Issue, November 4, 2016, "Reorganization and renaming of the Ministry of Administrative Reform and e-Government, reorganization of the Ministry of Tourism, establishment of the Ministry of Migration Policy and Ministry of Digital Policy, Telecommunications and Information, renaming of Ministries of Interior and Administrative Reconstruction, Economy, Development and Tourism and Infrastructure, Transport and Networks"
13.	Government Gazette Presidential Decree No. 125, Folio No. 210, First Issue, November 5, 2016, "Appointment of Ministers, Deputy Ministers and Assistant Ministers"
14.	Government Gazette, Presidential Decree No. 122, Folio No. 177, First Issue, August 12, 2013, "Transposition in the Greek legislation of the Council Directive 2011/70 / Euratom of 19 July 2011 establishing a community framework for the responsible and safe management of spent fuel and radioactive waste" (translated)
15.	Radiation Protection Regulations Presidential Decree Bill submitted to the Government in July 2017 ( <b>translated</b> )
16.	Presidential Decree Bill on Organizational Chart of EEAE (translated)

17.	Government Gazette, Presidential Decree No. 91, Folio No. 130, First Issue, September
	1, 2017, "Legislative, regulatory and organizational framework for the responsible
	and safe management of spent fuel and radioactive waste and amendment of the
	Presidential Decree No. 122/2013" (translated)

# MINISTERIAL DECISIONS- REFERENCE: MD1-MD25

1.	Government Gazette, Ministerial Decision 2739/94, Folio No.165, Second issue, March 15, 1994, "Regulation for public information in the event of a radiological emergency"
2.	Government Gazette, Ministerial Decision No. 1218.74/1/95, Folio No. 531, Second issue, June 20, 1995, "Adaptation of the International Maritime Dangerous Goods Code of the International Maritime Organization (IMDG-IMO-CODE)"
3.	Government Gazette, Ministerial Decision No. 9087(FOR)1004, Folio No: 849, Second issue, September 13, 1996 "Operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas" (translated)
4.	Government Gazette, Ministerial Decision No EEAE/1/829, Folio No.924, Second issue, December 28, 1988, "Transfer of signature rights "Upon Ministerial Authorization" to the Chairman of EEAE Administration Board, the Director and Heads of Departments of EEAE Administration Directorate" (translated)
5.	Government Gazette, Joint Ministerial Decision No. 1014 (FOR) 94, Second Issue, Folio No. 216, March 6, 2001, "Approval of Radiation Protection Regulations" (translated)
6.	Government Gazette, Ministerial Decision No. 10828/(EFA)1897, Folio No. 859, Second Issue, July 10, 2006, "Control of high-activity sealed radioactive sources and orphan sources" (translated)
7.	Government Gazette, Decision No. YIIA/ $\Delta 2/11894/3631$ , Folio No. 549, Second issue, April 18, 2007, "Adoption of Annex 18, 3 <sup>rd</sup> edition, amendment 8 of the International Civil Aviation Organization on the safe air transport of dangerous goods, according to Chicago Convention"
8.	Government Gazette, Decision No. $\Delta Y \Gamma 2/92027$ , Folio No: 2345, Second issue, December 11, 2007, "Determination of Diagnostic Reference Levels for mammography and Guidance Levels for nuclear medicine diagnostic examinations"
9.	Government Gazette, Ministerial Decision No. A $\Sigma$ 4.1/OIK.45573/3719, Folio No. 1874, Second issue, September 12, 2008, "Amendment of the Ministerial Decision No. $\Phi$ 4.2/18960/1446/19.06.2001"
10.	Government Gazette, Ministerial Decision No. 504/145, Folio No. 46, Second issue, January 19, 2009, "Regulation for general licensing of postal services"

	Government Gazette, Ministerial Decision No. 35043/2524, Folio No. 1385, Second
11	issue, September 2, 2010, "Adjustment of the Greek legislation to the regulations of the
11.	Directive 2008/68/EK concerning the inland transport of dangerous goods". Not in
	force any more please see MD25
	Government Gazette, Ministerial Decision No. 154949, Folio No. 1918, Second issue,
12.	December 10, 2010, "Conditions, requirements, bodies and procedure for issuing
	feasibility license and operation license for ionizing and non-ionizing systems"
13	Government Gazette, Ministerial Decision No 1/1/6, Folio No.832, Second issue,
15.	November 15, 1988, "Powers and competences of EEAE Administration Board
	(translated)
	Government Gazette, Ministerial Decision No 11592(FOR)1125, Folio No.1633,
14.	Second issue, August 18, 1999, "Mandatory installation and use of equipment for the
	detection of radioactive materials in scrap metals and for their illicit import"
	(translated)
1.5	Government Gazette, Ministerial Decision No 1299, Folio No. 423, Second Issue,
15.	April 10, 2003, "General Civil Protection Plan Xenokratis" (partially translated)
10	Government Gazette, Ministerial Decision, Folio No. 892, Second issue, July 11, 2001,
16.	"Quality of water intended for human consumption"
	Covernment Cazette Ministerial Decision Folio No. 1858 Second issue August 27
17	2015 "National policy on the management of spant fuel and radioactive waste"
17.	(translated)
18.	Government Gazette, Ministerial Decision, Folio No. 3610, Second issue, November 4,
	2016, "Determining the order of the Ministries"
	Government Gazette, Ministerial Decision No II/112/1057/2016, Folio No. 241,
	Second issue, February 9, 2016, "Establishment of requirements for the protection of
19.	the health of the general public with regard to radioactive substances in water
	intended for human consumption, in compliance with the Council Directive
	2013/51/EURATOM of 22th of October 2013" (translated)
	Government Gazette, Ministerial Decision No. Δ.ΥΓ2/οικ.98941, Folio No. 2941,
20.	Second issue, December 31, 2015, "NATIONAL PROGRAM "for the management of
	spent fuel and radioactive waste" (translated)
	Government Gazette Ministerial Decision Folio No. 3176 Second issue November
	26. 2014. "Establishment of Diagnostic Reference Levels for radiographic
21.	examinations CT scan interventional cardiology procedures and dental x-ray
	examinations" (translated).
	Contemport Constant Ministerial Decision No. 11/112/205, Ealia No. 2977, Second
22.	Government Gazette, Ministerial Decision No. 11/112/305, Folio No. 28//, Second
	1 issue, October 20, 2012, "Basic Requirements - Principles for Nuclear Safety and

	Regulatory Control of Research Reactors" (translated)
23.	Government Gazette, Ministerial Decision No. 95553, Folio No. 2182, Second issue, June 27, 2017, "Adjustment of the lower limit of the fine under Article 46, paragraph 3, subsection b of Law 4310/1414 (A 258)" (translated)
24.	Government Gazette, Ministerial Decision No 91175, Folio No. 1991, Second issue, June 9, 2017, "Amendment of Decision No P/112/305/2012 (B 2877/26.10.2012) 'Basic requirements - principles of nuclear safety and regulatory control of nuclear research reactors' to incorporate Council Directive 2014/87/Euratom 8 July 2014 amending Council Directive 2009/71 /Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations (L219/25.7.2014)" (translated)
25.	Government Gazette, Ministerial Decision No. Γ5/22039/2825 Folio No. 2915B, 24 August 2017 "Transposition of Directive 2008/68/EU of the European Parliament and Council, inland transport of dangerous goods, in relation to the annexes as per the Directives 2010/61/EU, 2012/45/EU, 2014/103/EU and (EU) 2016/2309 of the Commission"
26.	Draft Joint Ministerial Decision "Procedures and requirements for the authorisation of radioactive waste management facilities", endorsed by the EEAE Board and communicated to the EC according to article 33 of the Euratom Treaty in 2015. (translated)

# **EC DIRECTIVES – REFERENCE: ECD1-ECD15**

1.	Council decision on 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency
2.	Council Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel
3.	Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations
4.	Council Directive 2011/70/EURATOM of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste
5.	Council Directive 2011/70/EURATOM of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste
6.	Council Directive 2002/59/EC of 27 June 2002 establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC

7.	Commission Regulation (EC) No 859/2008 of 20 August 2008 amending Council Regulation (EEC) No 3922/91 as regards common technical requirements and administrative procedures applicable to commercial transportation by aeroplane
8.	Council Directive 2008/68/EC of 24 September 2008 on the inland transport of dangerous goods
9.	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
10	Commission Recommendation of 21 February 1990 on the protection of the public against indoor exposure to radon (90/143/Euratom)
11.	Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom
12.	Council Directive 2013/51/EURATOM of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption
13.	Council Directive 90/641/EURATOM of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas. Not in force any more please see ECD13
14.	Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. Not in force any more please see ECD13
15.	Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/ Euratom. Not in force any more please see ECD13

# EEAE DECISIONS PUBLISHED IN THE GOVERNMENT GAZETTE – REFERENCE: EDGG1-EDGG11

1.	Government Gazette, Folio No. 1074, Second issue, April 15, 2016, "Transfer of responsibilities and rights of signature of the Board of Directors of the Greek Atomic Energy Commission (EEAE) to the President, heads of organizational units and members of the staff of EEAE" (translated)
2.	Government Gazette, Folio No. 947, Second issue, May 26, 2015, "Special requirements for issuing a special license for the operation of blood derivative irradiators" (translated)

3.	Government Gazette, Folio No. 947, Second issue, May 26, 2015, "Clarifications on the provisions of Part 6 of the Radiation Protection Regulations for the management and disposal of radioactive waste from nuclear medicine laboratories" (translated)
4.	Government Gazette, Folio No. 947, Second issue, May 26, 2015, "Determination of additional requirements for the issue of a special license to operate mobile radiographic systems for home radiographic imaging" (translated)
5.	Government Gazette, Folio No. 947, Second issue, May 26, 2015, "Use of new- technology mammography systems with a tungsten lamp (W) and / or Rhodium (Rh) anode" (translated)
6.	Government Gazette, Folio No. 1958, Second issue, July 18, 2014, "Determination of the procedures for releasing / receiving radioactive waste and radioactive waste generated by medical applications" (translated)
7.	Government Gazette, Folio No. 588, Second issue, March 14, 2013, "Provision of knowledge and training on radiation protection of graduates of the Department of the TEI of Athens" (translated)
8.	Government Gazette, Folio No. 588, Second issue, March 14, 2013, "Provision of knowledge and training on radiation protection of IEK graduates of the specialties of 'Medical Imaging Devices' and 'Medical Radiotherapy Devices" (translated)
9.	Government Gazette, Folio No. 2182, Second issue, July 23, 2012, "Laboratory Authorization Criteria for Measurement of Radiological Characterization of Healing Natural Resources" (translated)
10.	Government Gazette, Folio No. 2182, Second issue, July 23, 2012, "Determination of the billing prices for the services rendered by the UPEA to third parties" (translated)
11.	Government Gazette, Folio No. 1405, Second issue, April 25, 2017, "Hearing Regulation of the Greek Atomic Energy Commission" (translated)

# EEAE Circulars – Decisions – REFERENCE: CD1-CD9

1.	EEAE Interpreting Circular of 18.10.2006, "Quality control protocols for radiology laboratories"
2.	EEAE Circular Ref. No. P/105/241 / 03.08.2006, "Clearance levels of Naturally Occurring Radioactive Materials" (translated)
3.	EEAE Circular Ref. No. P/105/241 / 03.08.2006, "Clearance levels of Naturally Occurring Radioactive Materials" ( <b>translated</b> )
4.	EEAE Interpreting Circular, $\Pi/405/325$ / 14.10.2009, "Clarifications on the

	determination of criteria for awarding competence in radiation protection to non medical health professionals who participate in radiation procedures" ( <b>translated</b> )
5.	CORRIGENDUM* EEAE Decision Ref. No: П/199/153 (May 28th, 2009), October 13, 2009, "Decision on the determination of criteria for awarding competence in radiation protection to non medical health professionals who participate in radiation procedures" (translated)
6.	EEAE Interpreting Circular, Π/105/412 / 09.12.2009, " <i>Clarifications regarding the training of holders and non holders of qualifications related to ionizing radiation</i> " (translated).
7.	EEAE Decision Ref. No: Π/199/239/19.07.2010, "Quality control protocols for radiotherapy departments".
8.	EEAE Interpreting Circular, Π/105/371 / 09.11.2010, " <i>Clarifications regarding non</i> holders of qualifications related to activities involving ionizing radiation" (translated)
9.	EEAE Circular Ref. No. P/105/388 / 30.11.2006, "Patients' excreta release after nuclear medicine treatments (therapies)" (translated) Published please see EDGG3

# **EEAE Documents – REFERENCE: D1-D25**

	Reports to IAEA:
1.	• National Report of Greece under the Convention on Nuclear Safety: 2004, 2007, 2010, 2012, 2013, 2016
	• National Report of Greece under the Joint Convention on the safety of spent fuel and on the safety of radioactive waste management: 2005, 2008, 2011, 2014
	• National report on the implementation of the Code of Conduct for the safety and the security of radioactive sources and its Supplementary Guidance on the import and export of radiation sources, July 2013
2.	EEAE, Licensing and Inspections Department, Quality Manual for accreditation as per ISO/IEC 17020:1998 (translated)
	EEAE, Quality Manual as per ISO 17025:2005 for:
	i. Office of non-ionizing radiation (translated);
3.	ii. Dosimetry Department (translated);
	iii. Radiation & Environment Control Department ( <b>translated</b> );
	iv. Calibration Laboratory for Ionizing Radiation Instruments ( <b>translated</b> )
	EEAE Internal Emergency Plan for Dealing with Radiological Incidents or Chemical,
4.	Biological and Radio-Nuclear (CBRN) Threats, 2004 (translated)
5.	EEAE Internal Emergency Plan for Dealing with Radiological Incidents or Chemical,

	Biological and Radio-Nuclear (CBRN) Threats, 2004 (translated)
6.	EEAE Internal Emergency Plan for Dealing with Radiological Incidents or Chemical, Biological and Radio-Nuclear (CBRN) Threats, 2004 ( <b>translated</b> )
	NCCP "Demakritas" Deerd Desision of 21.02.1096 meeting on "Iumout installation
7.	and commerce of radioactive rods"
8.	EEAE Board Decision (26 <sup>th</sup> meeting, 02.04.90), "Radiation sources inspection"
9.	EEAE Board Decision (37 <sup>th</sup> meeting, 07.09.90), "Disused radioactive sources"
10.	EEAE Board Decision (87 <sup>th</sup> meeting, 06.09.93), "License for radioactive sources import"
	EEAE Board Decision (218 <sup>th</sup> meeting, 12.07.13), "EEAE education and training
11.	radiation" (translated)
12.	IMS - Quality Manual (translated)
13.	IMS – OE EEAE 12-01: Management of Organization issues (translated)
14.	IMS – OE EEAE 04-01: Training and evaluation of inspectors (translated)
15.	IMS – EEAE $\triangle 04$ : Staff evaluation & training ( <b>translated</b> )
16.	IMS – EEAE $\Delta 12$ : Procedure for the management & approval of modifications (translated)
17.	Education and Training Appraisal, EduTA mission report: 2008, 2015
18.	Integrated Regulatory Review Service, IRRS mission report: 2012
19.	EEAE Board Decision (223rd meeting, 09.10.15), "EEAE strategy for education and training"
	Reports to EC: a. Greece Report as required under Article 9.1 of Council Directive
	2009/71/EURATOM of 25 June 2009 "Establishing a Community framework for the nuclear safety of nuclear installations". July 2014
20.	b. National Report of Greece on compliance with the Council Directive
	2011//0/EURATOM of 19 July 2011 "Establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste", November 2015.
21.	IMS – ΕΓΧ TAE-01 Operation Manual

22.	IMS –E EEAE 04-01 Assessment of training needs
23.	IMS –E EEAE 04-02 Annual training plan
24.	IMS –E EEAE 04-09 Inspectors' Evaluation
25.	IMS – OE TAE 04-010 Application documentation content – Review Assessment Guide

# **OTHER DOCUMENTS – REFERENCE: OD1-OD22**

1.	Government Gazette, Number 7270, Folio No: 102, Issue on information concerning special positioned public employees and administration tools for the enlarged public sector, December 7, 2006, " <i>Establishment of a Task Force for the Management of Chemical, Biological, Radiological and Nuclear Threats and Incidents under the General Secretariat for Civil Protection</i> " (translated)
2.	Decision of the General Secretary for Civil Protection "National Plan on CBRN threats", November 2011 (translated)
3.	Operations Procedures Manual, Civil Aviation Authority, 31.03.2010 (Internal Document)
4.	Statement regarding the Implementation of the "Guidance on the Import and Export of Radioactive Sources" in Greece, 2006
5.	Annex "R" of the General Civil Protection Plan "Xenokratis" (translated)
6.	Non paper: Defining the conditions and terms for the licensing of the existing radioactive waste interim storage facility of the NCSR Demokritos, 3 July 2006
7.	Bilateral agreement with Bulgaria on early notification in case of nuclear accident and on information exchange about nuclear installations. This agreement has been ratified by the Greek Parliament (Decision No.F.0544/3/AS192/L.3989, Folio 66/A/06.05.1991). Updated please see OD21
8.	Bilateral agreement with Romania on early notification in case of nuclear accident and on information exchange about nuclear installations. This agreement has been ratified by the Greek Parliament (Law No. 2382, Folio 39/A/07 .03.1996)
9.	Bilateral agreement with Argentina on co-operation in the field of peaceful applications of nuclear energy (Law No. 2596, Folio 64/A/24.03.1998)
10.	Arrangement between EEAE and the United States Nuclear Regulatory Commission (U.S.N.R.C.) for the exchange of technical information and cooperation in nuclear safety matters, September 1998
11.	Arrangement between the Greek Atomic Energy Commission (EEAE) and the United States Nuclear Regulatory Commission (U.S.N.R.C.) for the exchange of technical information and cooperation in nuclear safety matters, September 16, 2003. Updated please see OD20
-----	--
12.	Declaration of intent between the Department of Energy of the USA and the Directorate General of Customs and Excise of the Ministry of Economy and Finance of the Hellenic Republic and the EEAE concerning cooperation to prevent the illicit trafficking in nuclear and other radioactive material, October 30, 2003
13.	Nuclear Security Cooperation and Support Arrangement between IAEA and EEAE, March 10, 2004
14.	Practical arrangements between EEAE and IAEA in order to enhance cooperation and exchange of experience and information and in order to promote nuclear security as well as programs and research relating thereto, September 21, 2010
15.	Practical arrangements between EEAE and IAEA in order to enhance cooperation and exchange of experience and information and in order to promote nuclear security as well as programs and research relating thereto, September 21, 2010
16.	Memorandum of understanding No. 31883 between European Union and the National EURDEP Data Provider of Greece EEAE on the participation to the EURDEP system during routine and emergency conditions, 2010
17.	Update of the Agreement between the Greek Atomic Energy Commission (EEAE) and the United States Nuclear Regulatory Commission (NRC) for the exchange of technical information and cooperation in nuclear safety matters, 17 September 2013
18.	Update of the Agreement between the Greek Atomic Energy Commission (EEAE) and the Bulgarian Nuclear Regulatory Agency (BNRA) for early notification of a nuclear accident and exchange of information on nuclear facilities, 28 September 2016
19.	Draft of Presidential Decree "Establishing a National framework for the nuclear safety of nuclear installations" (transposition of the Council Directive 2009/71/ Euratom of 25 June 2009) (translated). Published please see PD11 & MD24
20.	Draft of Presidential Decree "Establishing a National framework for the nuclear safety of nuclear installations" (transposition of the Council Directive 2009/71/ Euratom of 25 June 2009) (translated). Published please see PD11 & MD24
21.	Long Term Agreement between the IAEA and the Government of the Hellenic Republic in order to support EEAE as a regional training centre in Europe for radiation, transport and waste safety, July 11 2011. <b>Published please see L18</b>

22.	Draft of Ministerial Decision defining the conditions and terms for the licensing of the
	research reactor Published please see MD22

## APPENDIX VII - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- 1. No. SF-1 Fundamental Safety Principles
- 2. INTERNATIONAL ATOMIC ENERGY AGENCY Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1(Rev 1) (Vienna2016)
- 3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety Requirement GSR Part 2 IAEA, Vienna (2016)
- INTERNATIONAL ATOMIC ENERGY AGENCY Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, (2014)
- 5. INTERNATIONAL ATOMIC ENERGY AGENCY Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
- 6. INTERNATIONAL ATOMIC ENERGY AGENCY Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
- 7. INTERNATIONAL ATOMIC ENERGY AGENCY Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
- INTERNATIONAL ATOMIC ENERGY AGENCY Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirement Part 7, No. GSR Part 7, IAEA, Vienna (2015)
- 9. INTERNATIONAL ATOMIC ENERGY AGENCY Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 6, No. SSR 6, IAEA, Vienna (2012)8.
- INTERNATIONAL ATOMIC ENERGY AGENCY Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
- 11. INTERNATIONAL ATOMIC ENERGY AGENCY Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
- 12. INTERNATIONAL ATOMIC ENERGY AGENCY Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
- 13. INTERNATIONAL ATOMIC ENERGY AGENCY Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
- 14. INTERNATIONAL ATOMIC ENERGY AGENCY- Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
- 15. INTERNATIONAL ATOMIC ENERGY AGENCY Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)

- 16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
- 17. INTERNATIONAL ATOMIC ENERGY AGENCY Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
- 18. INTERNATIONAL ATOMIC ENERGY AGENCY Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)
- 19. INTERNATIONAL ATOMIC ENERGY AGENCY Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
- 20. INTERNATIONAL ATOMIC ENERGY AGENCY Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
- 21. INTERNATIONAL ATOMIC ENERGY AGENCY Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)
- 22. INTERNATIONAL ATOMIC ENERGY AGENCY Establishing the Safety Infrastructure for a Nuclear Power Programme Specific Safety Guide No SSG-16, IAEA, Vienna (2011)
- 23. INTERNATIONAL ATOMIC ENERGY AGENCY Disposal of Radioactive Waste Specific Safety Requirements 5, No. SSR 5, IAEA, Vienna (2011)
- 24. INTERNATIONAL ATOMIC ENERGY AGENCY Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
- 25. INTERNATIONAL ATOMIC ENERGY AGENCY Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
- 26. INTERNATIONAL ATOMIC ENERGY AGENCY Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
- 27. INTERNATIONAL ATOMIC ENERGY AGENCY Safety of Nuclear Power Plants: Design, Specific Safety Requirement Series SSR-2/1 IAEA, Vienna (2012)
- 28. INTERNATIONAL ATOMIC ENERGY AGENCY Safety of Nuclear Power Plants: Operation, Safety Requirement Series No. NS-R-2, IAEA, Vienna (2000)
- 29. INTERNATIONAL ATOMIC ENERGY AGENCY Safety of Research Reactors, Safety Requirement Series No. NS-R-4, IAEA, Vienna (2005.)
- 30. INTERNATIONAL ATOMIC ENERGY AGENCY Periodic Safety Review of Nuclear Power Plants Specific Safety Guide SSG-25, IAEA, Vienna (2013)
- 31. INTERNATIONAL ATOMIC ENERGY AGENCY A System for the Feedback of Experience from Events in Nuclear Installations Safety Guide No. NS-G-2.11, IAEA, Vienna (2006)

## APPENDIX VIII - EEAE ORGANIZATIONAL CHART

## BOARD CHAIRMAN

DIVISION OF L REGULATORY	ICENSING AND	DIVISION OF TRAIN REGULATORY PLAN INFRASTRUCTURE	DIVISION OF TRAINING, REGULATORY PLANNING, INFRASTRUCTURE AND RE-		DEPARTMENT OF FINANCE, HUMAN RE- SOURCES AND SPECIAL ACCOUNT MAN- AGEMENT	
lonizing Radiation Department	Non-Ionizing Radiation Department	SEARCH Dosimetry and Calibration Department	r Environmental Radioactivity Department		Information Technology Department	
		LEGAL AFFAIRS DE- PARTMENT	PUBL DEPA	IC RELATIONS RTMENT		