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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

GREECE

Athens, Greece

20 to 30 May 2012

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

THE GOVERNMENT OF GREECE

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Mission date: 20 - 30 May 2012

Regulatory body: Greek Atomic Energy Commission (GAEC)

Location: Athens, Greece

Organized by: International Atomic Energy Agency (IAEA)

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EXECUTIVE SUMMARY

At the request of the Government of the Hellenic Republic, an international team of senior safety experts met representatives of the Greek Atomic Energy Commission (GAEC) from 20 to 30 May 2012 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at the headquarters of GAEC in Agia Paraskevi, Attica.

The purpose of this IRRS mission was to review the effectiveness of the Greek framework for safety within the competence of GAEC. The review compared the Greek regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used as an opportunity to exchange information and experience between the IRRS review team members and the GAEC counterparts in the areas covered by the IRRS.

The IRRS Review team consisted of nine senior regulatory experts from nine IAEA Member States, four IAEA staff members and an IAEA administrative assistant. The IRRS Review team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; transport, control of medical exposure, 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.

The IRRS mission also included the following regulatory policy issues for discussion: independence of the regulatory body, long term policy on waste management, clinical quality audits. The IRRS review addressed the facilities and activities regulated by GAEC which involve radiation sources in addition to the waste management facilities. The research reactor GRR-1 in the National Centre for Scientific Research (NCSR) “Demokritos” was out of the scope of this IRRS review, but will be included in the follow-up mission.

The mission included observations of regulatory activities and a series of interviews and discussions with GAEC staff and other organizations to help assess the effectiveness of the regulatory system. These activities included observations of inspections and/or surveillance visits to the Public Hospital “Attikon” (interventional radiology, nuclear medicine), NCSR waste facility, IFET industrial irradiator, BIOKOSMOS cyclotron facility, and Hospital “Hygeia” (radiotherapy).

The IRRS team members observed the working practices during inspections carried out by GAEC, including discussions with the licensee personnel and management. In addition the IRRS team observed an emergency exercise which was conducted with representatives from multiple organizations.

GAEC provided the IRRS review team with advanced reference material and documentation including the results of its self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS Review team was extended full cooperation in its review of regulatory, technical and policy issues by all parties. The staff of GAEC was very open and candid in their discussions and provided the fullest practicable assistance.

The IRRS review team identified a number of good practices and made recommendations and suggestions where improvements will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards. The IRRS Team recognized that the

action plan prepared by GAEC as a result of the self-assessment was broadly correlated with the IRRS findings.

The main observations of the IRRS Review team were the following:

- The IRRS Team has concluded that while the Greek Government's commitment to safety is being demonstrated through its actions, the development of a comprehensive national policy and strategy expressed in a consolidated statement would provide a valuable framework and guidance for future actions in terms of safety.
- GAEC has effective independence. The Greek government has ensured that GAEC is effectively independent in its safety related decision making and that it has functional separation from entities having responsibility or interests that could unduly influence its decision making.

Among the strengths/good practices identified by the IRRS review team were the following:

- Greece actively participates in the global safety regime including all relevant safety conventions;
- There is a real time monitoring of radioactivity levels at border posts in support of Customs and the detection of illicit trafficking and at various locations in the country by means of a network of telemetric stations, which contributes significantly to identifying the initial phase of a potential radiation emergency, due to events within or outside the country;
- GAEC exhibits a strong commitment to education and training in radiation protection.

The IRRS Review team identified issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system.

- The Radiation Protection Regulations require updating to bring them in line with the current IAEA Safety Requirements. Consideration should be given to the adoption of a more flexible hierarchy of safety regulations.
- The IRRS Team observed that the legal framework is dated, lacks the flexibility of a risk-based regulatory framework which provides for a graded approach to safety and has gaps particularly with respect to waste and decommissioning.
- The development and implementation of an integrated management system requires senior management commitment to allocate sufficient resources with the appropriate authority, and to actively involve all staff.
- The prime responsibility for safety, the responsibilities of employers and workers with respect to occupational exposure, and responsibilities with respect to emergency preparedness and response need to be explicitly assigned in the legal and regulatory framework for safety.

The IRRS Review team findings are summarized in Appendix V.

A press conference was conducted at the end of the mission, and press releases by IAEA and GAEC were issued.

I. INTRODUCTION

At the request of the Government of the Hellenic Republic, an international team of senior safety experts met representatives of the *Greek Atomic Energy Commission* (GAEC) from 20 to 30 May 2012, in order to conduct an Integrated Regulatory Review Service (IRRS) Mission. The mission took place at the headquarters of GAEC in Agia Paraskevi and included site visits.

The review mission was formally requested by GAEC in September 2009. A preparatory mission was conducted from 29 to 30 September 2011 at GAEC headquarters to discuss the objective, purpose and consequently the preparations of the review, as well as its scope in connection with the areas regulated by GAEC and selected safety aspects.

The IRRS Review team consisted of nine senior regulatory experts from nine IAEA Member States, four technical staff members from the IAEA and one IAEA administrative assistant. The IRRS Review team carried out the review of GAEC in the following areas: responsibilities and functions of the Government; global nuclear safety regime; responsibilities and functions of the regulatory body[1]; the management system of the regulatory body; the activities of the regulatory body for including the authorization, review and assessment, inspection and enforcement processes; regulations and guides; emergency preparedness and response. In addition, the IRRS Review team reviewed the following thematic areas: transport, control of medical exposure, 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.

In addition, the following policy issues were addressed: independence of the regulatory body, long term policy on waste management and clinical quality audits.

GAEC conducted a self-assessment in preparation for the mission. The results of its self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff from GAEC as well as external organizations, and performed direct observation of GAEC working practices during inspections. Meetings with other organizations involved in the national regulatory infrastructure for safety were also organized, including the General Secretariat of Research and Technology of the Ministry of Education, Lifelong Learning and Religious Affairs, the Ministry of Health, the General Secretariat of Civil Protection, the Prefecture of Attiki and the Customs Office at Piraeus Port.

All through the mission the IRRS team received excellent and open co-operation from GAEC, questions from the IRRS team members were fully answered, documents requested were presented and explained.

[1] The Term "Regulatory Body" is defined in the IAEA Safety Glossary as "*an authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety*".

II. OBJECTIVES AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Greek regulatory framework for safety for its effectiveness, and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all radiological facilities and activities regulated by GAEC including waste facilities.

During the preparatory meeting it was agreed not to include the regulatory functions relating to the research reactor of the NCSR "Demokritos" in this IRRS mission, since this research reactor has been shut down since 2004 and is under major refurbishment. There has been an international tender for the first phase of the refurbishment project, which has been almost completed. The highly enriched fuel has been exported. It was agreed to include the research reactor in the follow-up mission.

It is expected that the IRRS mission will facilitate regulatory improvements in Greece and other Member States from the knowledge gained and experiences shared by GAEC and the IRRS reviewers and through the evaluation of the effectiveness of the Greek regulatory framework and its good practices.

The key objectives of this mission were to enhance radiation safety and emergency preparedness and response by:

- Providing GAEC, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against IAEA safety standards;
- Providing Greece (GAEC) with a review of its regulatory programme and policy issues relating to radiation safety and emergency preparedness;
- Providing Greece (GAEC) with an objective evaluation of its radiation safety and emergency preparedness and response regulatory activities with respect to IAEA safety standards;
- Contributing to the harmonization of regulatory approaches among IAEA Member States;
- Promoting the sharing of experience and exchange of lessons learned;
- Providing reviewers from IAEA Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own fields;
- Providing key GAEC staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- Providing Greece (GAEC) with recommendations and suggestions for improvement;
- Providing other States with information regarding good practices identified in the course of the review.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of the Hellenic Republic, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 20 to 30 May 2012. The preparatory meeting was carried out by the appointed Team Leader Mr Tom Ryan, and the IRRS IAEA Team representatives, Mr Ahmad Al Khatibeh, Mr David Graves, and Mr Rodrigo Salinas.

The IRRS mission preparatory team conducted extensive discussions regarding the regulatory programme and policy issues with the senior management of GAEC represented by Mr Christos Housiadas, Chairman of GAEC, and other senior management and staff. The discussions resulted in agreement that the following areas were to be reviewed by the IRRS mission:

- The core modules 1 to 10 with the regulatory functions covering radiation sources and waste facilities;
- Transport;
- Control of medical exposure;
- Occupational radiation protection;
- Control of radioactive discharges and materials for clearance;
- Environmental monitoring associated with authorized practices for public radiation protection purposes;
- The control of chronic exposures and remediation; and
- Selected policy issues.

GAEC proposed in the preparatory meeting not to include the research reactor GRR-1 of the NCSR “Demokritos” in the mission at this stage. GAEC Chairman explained that at present the research reactor is shut down and under major refurbishment. The highly enriched fuel has been exported. There has been an international tender for the first phase of the refurbishment project, which has almost been completed. From the regulatory point of view, a review and update of the legislation and the documents of relevance for the license is being performed. The argument was accepted by the IRRS preparatory team and it was agreed to include the research reactor in the follow-up mission.

GAEC liaison officer, Mrs Vasiliki Kamenopoulou, made comprehensive presentations on the regulatory framework in Greece, and the progress in the self-assessment process to date. IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Greece in May 2012.

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

GAEC provided IAEA (and the review team) with the advance reference material for the review, including the self-assessment results, through an external webpage dedicated to IRRS

preparation. In advance of the mission, the IAEA review team members conducted a review of the advance reference material and provided their initial review comments to the IAEA Coordinator prior to the commencement of the IRRS mission.

The GAEC Liaison Officer for the preparatory meeting and the IRRS mission was Mrs Vasiliki Kamenopoulou and the dDeputy Liaison Officer was Mr Costas Hourdakis.

B) REFERENCE FOR THE REVIEW

The latest, most relevant IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as review criteria. A more complete list of IAEA publications used as the reference for this mission is given in Appendix VII.

C) CONDUCT OF THE REVIEW

An opening IRRS Review team meeting was conducted on Sunday, 20th May 2012 in Athens by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers.

The Liaison Officers were present at the opening IRRS Review team meeting, in accordance with the IRRS guidelines, and presented the agenda for the mission. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 21st May 2012, with the participation of GAEC senior management and staff. Opening remarks were given by GAEC Chairman, Mr Christos Housiadas, the General Secretary of Research and Technology of the Ministry of Education, Lifelong Learning and Religious Affairs, Mr Kostas Kokkinoplitis, and the IRRS Team Leader, Mr Tom Ryan, who made a brief presentation on the IRRS process and the expectation of this mission. GAEC Chairman gave an overview of GAEC status and activities, and the regulatory framework in Greece.

During the mission, a systematic review was conducted for all the review areas with the objective of providing GAEC with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national practices and activities.

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

The IRRS exit meeting was held on Wednesday 30th May 2012. The results of the mission were presented by the IRRS Team Leader, Mr Tom Ryan. Closing remarks were made by Mr Pil-Soo Hahn, IAEA, Director, Division of Radiation, Transport and Waste Safety, Mr Christos Housiadas, GAEC Chairman and Mr Kostas Kokkinoplitis, General Secretary of Research and Technology of the Ministry of Education, Lifelong Learning and Religious Affairs.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Greek government relies upon the explicit and implicit objectives of national legislative provisions and established safety infrastructure, including the remit and objectives of GAEC as the expression of its national policy and strategy for safety. In addition, the Greek government re-affirms its commitments and objectives in terms of safety through statements to the IAEA's General Conference and in meeting its obligations under relevant international conventions to which it is party including the Nuclear Safety Convention and the Joint Convention on the Safe Management of Spent Fuel and the Safe Management of Radioactive Waste. The Greek government points to its commitment to the safety principles established in the Fundamental Safety Principles as being implicitly expressed by meeting its obligations to those binding international conventions, in the provisions of human and financial resources to establishing and supporting the national regulatory infrastructure and in promoting safety through regulatory action and a commitment to education and training in the field of radiation protection.

However, the Greek government has not produced a standalone comprehensive national policy document outlining its commitment to the Fundamental Safety Principles and a strategy for their ongoing implementation including a commitment to the provisions of human and financial resources, the scope of legal provisions, and the promotion of leadership and management for safety, including safety culture. In addition, the Greek government relies upon detailed regulatory requirements to implement a graded approach in the absence of such a policy direction.

The IRRS Team has concluded that while the Greek Government's commitment to safety is being demonstrated through its actions, the development of a comprehensive national policy and strategy expressed in a consolidated statement would enhance its position and provide a valuable framework and guidance for future actions in terms of safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS:GSR Part 1 Requirement 1 states that: "*The Government shall provide a national policy and strategy for safety.*"
R1	**<u>Recommendation</u>: The Government should develop a consolidated statement that sets out the national policy and strategy for safety.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Greek framework for safety is set out primarily in a number of laws, decrees and common ministerial decisions. In particular:

- Legislative Decree 181/1974, 'Protection against Ionising Radiation' (L5)

- Law No. 1733/1987, 'Transfer of Technology, inventions, technological innovation and establishment of the Greek Atomic Energy Commission' (L7)
- Ministerial Decision No. 17176, 'Powers and competences of GAEC Board' (MD13)
- Presidential Decree 404/1993, 'Organisation of the Greek Atomic Energy Commission' (PD2)

These legislative measures provide for the initial establishment of an authorisation procedure for the use of ionising radiation in Greece, the issuance of regulatory decisions, compliance monitoring and penalties (L5). In addition, they provide for the establishment of the Greek Atomic Energy Commission (L7) as an autonomous legal entity within the public sector and for the powers and competencies of the GAEC Board (MD13).

Detailed regulations are set out in a suite of legislative measures based primarily on the transposition of EURATOM directives concerning radiation protection and nuclear safety including:

- Common Ministerial Decision 1014/2001, 'Approval of the Greek Radiation Protection Regulations (MD5)
- Ministerial Decision No. 9087 (FOR)1004/1996, 'Operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas' (MD3)
- Ministerial Decision No. 10828/(EFA)1897/2006, 'Control of high-activity sealed radioactive sources and orphan sources' (MD6)
- Presidential Decree No. 60/2012, "Establishing a national framework for the nuclear safety of nuclear installations" (transposition of the Council Directive 2009/71/ Euratom of 25 June 2009" (PD11)

In general the IRRS Team found that these legislative measures provide for a broad framework for safety within Greece setting out the safety objectives for protecting people, the types of facilities and activities within the scope of the framework, the establishment of a regulatory body, provision for the inspection of facilities and provision for response to a radiological emergency. Notable exceptions are in the areas of waste and decommissioning.

The IRRS Team found that the Radiation Protection Regulations (MD5) are often expressed in a passive form that does not assign responsibility for specific actions. Similarly, the IRRS Team observed that the regulatory framework does not provide for clear assignment of responsibilities to the employers and workers with respect to occupational exposure (see section 13), and also does not assign the responsibilities with respect to emergency preparedness and response (see section 10).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR-Part 1 Requirement 2 states that: "*The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.*"
R2	**<u>Recommendation</u>: The Government should ensure that the persons or entity with responsibilities for the implementation of regulatory requirements are explicitly specified.**

The IRRS Team has observed that in many areas the implementation of the regulatory framework is not fully in accordance with a graded approach. Details are given in sections 5, 7 and 8.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR-Part 1 Requirement 1states that: *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities"*
R3	**<u>Recommendation</u>: The Government should provide for a graded approach in the implementation of the regulatory framework.**

The government has established policy statements and elements of a waste management strategy in regulations. These have been reported in conjunction with the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. However, there is not a clear Government statement of waste management policy and strategy which would clearly indicate preferred options, responsibilities, interim targets, end states or decision making procedures for the management of all types of radioactive waste up to final disposal.

The Radiation Protection Regulations impose certain requirements as part of the authorisation process for waste management. The responsibility of waste management is assigned to the licensee in the case of on-site management or where export of sources for recycling is concerned. The financial liability in these situations is clear even if not specifically mentioned in the Radiation Protection Regulations.

The implementation of the HASS directive in Ministerial Decision (MD6) clearly provides that GAEC is responsible for the cost of recovering, managing and the disposal of orphan sources (Articles 9, 10).

The Ministerial Decision (MD6) also gives GAEC a mandate to require the licensee to provide for financial security as part of the authorisation of high activity sealed sources for their safe management should they become disused sources, including the case where the holder becomes insolvent or goes out of business. The Ministerial Decision (MD6) requires the applicant to have an agreement with the source supplier for their return to the country of origin when they are no longer required. GAEC also requires a written declaration from the applicant as part of an authorisation for the importation of radioactive material, that they cover all the costs of management of sources.

For other types of waste that may arise where government may have responsibility there are no clear financial liability mechanisms to cover costs for management and disposal. The current financial framework does not include clear provision for a funding mechanism to cover the costs of decommissioning of facilities, remediation and disposal of radioactive waste. The IRRS Team is of the view that this should be developed in line with a radioactive waste management policy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 5 Requirement 2 states that: *"To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established."*
	BASIS: GSR Part 1 para 2.33 states that: *"Appropriate financial provision shall be made for:* *(a) Decommissioning of facilities;* *(b) Management of radioactive waste, including its storage and disposal;* *(c) Management of disused radioactive sources and radiation generators"*
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.**

1.3. ESTABLISHMENT OF A REGULATORY BODY

The Greek Government has established the Greek Atomic Energy Commission (GAEC) as the primary regulatory body through Article 28 of Law No. 1733/1987 'Transfer of Technology, Inventions, Technological Innovation and establishment of the Greek Atomic Energy Commission' (L7). Specific regulatory roles are assigned to other authorities for certain facilities or activities such as in the medical and transport sectors.

The specific responsibilities of GAEC, inter alia, include:

- the measurement of radioactivity in the environment;
- the issuance of safety guidelines and the preparation of regulations for the operation of facilities and machinery that emit ionizing radiation
- postgraduate training of scientists and experts
- amending or revoking, upon justification, authorizations for the production, possession, disposal and use of radioactive substances (radioisotopes and labelled compounds) as well as of all kinds of radioactive sources, including fissile materials.
- representing Greece, where appropriate, in international organizations regarding issues of its competence
- issuing safety instructions for the securing, disposal, transport and storage of radioactive materials and making proposals to competent Ministers, as appropriate.

The detailed structure of GAEC is established in the Presidential Decree No 404/1993 (PD2). There are four divisions and the Presidential Decree sets out the detailed statutory responsibilities of each division.

For the regulation of medical facilities, the Ministry of Health as well as the Prefectures, have a role. The 9-member statutory committee under the auspices of the Ministry of Health has responsibility for overseeing health service provision policy and the justification of new medical practices involving ionising radiation, and deciding licensing periods in medical

facilities. Prefectures have an overarching role in relation to the licensing of medical facilities, where they require a certificate of compliance from GAEC to issue a licence.

For the regulation of transport of radioactive material, there are several transport competent authorities with different responsibilities and competencies as set out in section 11.2.

The IRRS Team is of the view that these authorities have been provided with sufficient legal authority to fulfil the statutory obligations for the regulatory control of all facilities and activities in Greece.

The IRRS Team has identified areas where GAEC's authority for enforcement could be strengthened. Additional enforcement powers would enhance the flexibility of GAEC's regulatory approach. It was noted that this weakness has been identified by GAEC and regulations have been drafted to address it, but that these regulations have not yet been enacted due to competing priorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1: Requirement 3 states that: *"The government, through the legal system, shall establish.....and shall confer on it the legal authority and provide it with the competence…"*
S1	**Suggestion: The Government should consider conferring legal authority to strengthen GAEC's powers of enforcement.**

GAEC is financially supported by two sources:

- The governmental budget. This contribution is included in the national budget approved by the Greek Parliament annually. This budget covers mainly the annual contribution to international organizations (IAEA), the salaries of the permanent staff and some operating expenses;
- The Special Account. These revenues come from fees, the provision of services and research grants. The special account covers the salaries of GAEC non-permanent staff and the majority of GAEC's operating expenses, including equipment purchase and travel expenses. Every requirement for expense has to be justified and is subject to prior approval. In case of equipment purchase, a special committee decides on its approval.

In 2010 the governmental budget and the special account contributed 43% and 57% of GAEC's budget, respectively. Of the governmental contribution more than half was used as the Greek contribution to the IAEA.

1.4. INDEPENDENCE OF THE REGULATORY BODY

GAEC is an autonomous public service under the auspices of the Ministry of Education, Lifelong Learning and Religious Affairs (Supervising Ministry) and is empowered to take regulatory decisions with regard to radiation safety independently (L7, PD2).

While the IRRS Team did not carry out a detailed staffing analysis, it observed that GAEC appears to have sufficient staffing currently to carry out its functions though it was noted that

there is an increasing reliance on fixed term contract staff, due to a recruitment embargo in the public sector. In addition, contract staff are funded from a statutorily based discretionary account, funded through the provision of services. There is an exceptionally high reliance on the special account for the funding of the regulatory function of the GAEC and effective independence may be vulnerable to erosion if those funds were to significantly decline. However, in a meeting with the General Secretary for Research and Technology (GSRT) within the supervising Ministry, the IRRS Team was re-assured of the priority that the Ministry attaches to GAEC and its funding within foreseeable budgetary constraints.

The IRRS Team observed that no responsibilities have been assigned to GAEC that might compromise it in exercising its regulatory responsibilities and that the staff have no direct or indirect interest in regulated facilities. In a meeting with the GSRT, the IRRS Team was informed that although several licensable facilities, including the research reactor at NCSR "Demokritos", are also under the GSRT supervision, GSRT has no role in GAEC decision making related to the regulation of these facilities. There are also no overlapping arrangements that would compromise GAEC's regulatory authority.

The IRRS Team noted that enforcement of regulatory requirements when not resolved through normal regulatory dialogue can be pursued through the judicial system. In this case GAEC has to refer the case to the State Prosecutor who prosecutes the case on behalf of the state and this observation is the subject of a suggestion in section 1.3. The IRRS Team noted that enhancing GAEC's powers in relation to its ability to initiate enforcement actions could strengthen its authority as regulator and by extension enhance its independence.

The IRRS Team, on the basis of its review of the reference material, interviews conducted with the counterparts and by direct observation has formed the view that the Greek government has ensured that GAEC is effectively independent in its safety related decision making and that it has functional separation from entities having responsibility or interests that could unduly influence its decision making.

1.5. PRIME RESPONSIBILITY FOR SAFETY

Greece has recently enacted a Presidential Decree No. 60, Issue A, Folio 111 of the 3rd May 2012 which transposes the Euratom directive concerning nuclear safety (PD11). The scope of the Presidential Decree covers only nuclear installations within the definition of the directive, but includes provisions explicitly assigning prime responsibility for safety of such nuclear installations to the license holder and provides that such responsibility cannot be delegated.

For all other facilities certain responsibilities for safety are assigned in legislation (MD5), in particular to the appointed radiation protection officer (RPO) and the named head of a department or principle clinician. Certificates of compliance issued by GAEC and subsequent licences issued by GAEC or the Prefecture are issued to the management of the facility and include the names of the RPO and Head of Department/Clinician as responsible individuals.

In discussion with GAEC's legal officer the IRRS team noted that prime responsibility for safety is not explicitly mentioned in the radiation safety legislation. The legal officer was of the view that the responsibility of management generally is derived from provisions of the Civil Code (Act 2783 of 1943 and as amended) Articles 71, 922 and Transitory Provisions 104 and 105 which describe owner responsibility, compensatory, criminal and penal considerations. The IRRS Team understood from interviews with GAEC's legal officer that if an enforcement action was pursued against a facility it could be taken against the management of the facility and/or the named responsible individuals.

The IRRS Team observed that from the limited history of enforcement actions pursued through the state prosecutor's office, the current legal construction in terms of primary responsibility has not given rise to any legal vulnerability or to a challenge to the authority of GAEC.

The IRRS Team is of the view that primary responsibility for safety, other than in nuclear installations, is not expressly assigned.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR 1 Requirement 5 states that: "*The government shall expressly assign the prime responsibility for safety…*"
R5	**<u>Recommendation</u>: The Government should expressly assign the 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

As set out in Section 1.5, Presidential Decree No. 60, Issue A, Folio 111 of the 3rd May 2012 (PD11) and Common Ministerial Decision 1014/2001 'Approval of the Greek Radiation Protection Regulations (MD5) taken together with provisions of the Civil Code ensure that compliance with regulations does not relieve the person or organisation responsible for a facility or an activity of its prime responsibility for safety, despite the fact that the prime responsibility for safety is not expressly assigned in the radiation safety legislation as mentioned in section 1.5.

In addition, GAEC, as regulatory body, and as described elsewhere has the required powers to carryout inspections and assessments within its remit to satisfy itself that legal entities or responsible persons have the appropriate resources and processes in place to fulfil their regulatory obligations and have recourse to the judicial system through the state prosecutor to enforce those obligations.

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

For the licensing of medical facilities, the licensing process is described in Section 5.2.1. This involves a 9-member committee in the Ministry of Health which has a staff member of GAEC on the committee and is involved in the licensing at pre-feasibility and operational phases. Additionally, the licenses for medical facilities are issued by Prefectures upon the issuance of a certificate of compliance by GAEC amongst a range of other approvals required in licensing for the facility.

GAEC interacts with Customs in a range of ways including portal monitors at several border entry points including land, sea and air. GAEC maintains the equipment and is able to assess spectra online from its headquarters and respond in support of Customs as required. GAEC

also interacts with Customs in relation to import and export of radioactive materials (section 7 and 11.3)

Co-ordination with Emergency Response Organizations is well developed and is discussed in detail in Section 10.2.1.

Co-ordination between GAEC and other Transport Competent Authorities is complex and could be improved. The detail is given in Section 11.3.

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

The Greek legislative framework makes provision for some elements of the safe management of radioactive waste. However, the legislation or regulations do not define requirements concerning pre-disposal management, decommissioning of facilities or disposal of radioactive waste. International recommendations require, where appropriate, all facilities to develop a decommissioning plan at the design stage. For the research reactor (which is outside the scope of this review) GAEC has taken decommissioning into account as part of the draft Ministerial Decision for reactor licensing. The European Commission Directive for safe management of spent fuel and radioactive waste will also require similar requirements to be developed for waste management facilities. This issue is addressed in the Recommendation R4.

1.9. COMPETENCE FOR SAFETY

GAEC has a strong commitment to and a central role in education and training in both radiation protection and medical physics for Greece. This role involves direct contact with a significant fraction of those responsible for radiation protection in Greece and a national network of professional radiation protection personnel. This provides a direct means of communicating radiation protection issues throughout the country. Further, GAEC policy encourages staff involvement with research activities. The strong interaction with the medical physics community and involvement in national meetings in radiotherapy, diagnostic imaging and nuclear medicine as well as the radiation protection component of the medical physics training provide other excellent pathways for the dissemination of good and current radiation protection practice in Greece.

GAEC has a role in the training of First Responders in relation to Emergency Preparedness which is discussed in detail in Section 10.3.4.

Mandatory training required by the transport modal regulations is delivered by contractors to those organisations with assigned competence, as outlined in Section 11.

GAEC has a role in the training of Customs personnel, as well as border police and coast guards to assess initial alarms from portal monitors. Customs staff are trained to undertake preliminary surveys and to identify radionuclides encountered and are able to make an initial assessment and determine whether additional support is required from GAEC.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 paragraph 2.34 states that: *"As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available."*
GP1	**<u>Good Practice:</u> The team noted the strong commitment of GAEC to the training of medical physicists in radiation protection**

1.10. PROVISION OF TECHNICAL SERVICES

The Greek government has invested GAEC with the authority to both provide and to authorise the provision of technical services such as personnel dosimetry, environmental monitoring and the calibration of equipment. Currently GAEC is the only provider of dosimetric and calibration services in Greece.

The IRRS Team reviewed the provision of personnel dosimetry, environmental monitoring and calibration services by GAEC and was impressed that all of these services are accredited to the international standard ISO 17025.

The IRRS Team noted that GAEC's Licensing and Inspections Department and the Ionizing Radiation Calibration Laboratory are headed by the same individual. The Personal Dosimetry Department reports to the Head of the Division of Licensing and Inspections. These issues are further discussed in section 3.2.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONALOBLIGATIONS AND ARRANGEMENTS FOR COOPERATION

Greece is a contracting party to the following multi-lateral agreements related to safety:

- Convention on Nuclear Safety (1997)
- Convention on the Physical Protection of Nuclear Material (1991) and its amendment (2011)
- Convention on Early Notification of a Nuclear Accident (1991)
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1991)
- Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention (2001)
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (2001)

Greece has formally committed to the implementation of the Code of Conduct on the Safety and Security of Radioactive Sources and the Guidance on Import and Export of Radioactive Sources.

GAEC staff are familiar with IAEA safety standards and there are GAEC staff members who are corresponding members of the IAEA safety standards committees; RASSC, WASSC, TRANSSC and NUSSC. GAEC staff have participated in the development of IAEA safety standards through participation in the Safety Standards Committees, and participation in IAEA safety review missions where IAEA safety standards are used as the basis for the review. This includes recent participation in the IRRS Mission to Sweden.

Bilateral agreements have been signed with Bulgaria, Argentina, Romania, Cyprus, USA Department of Energy, USA NRC, IAEA Nuclear Security Department as well as a Long Term Agreement with IAEA in order to support GAEC as a regional training center in Europe.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

GAEC participates in many scientific networks, such as the European ALARA Network (and some sub-networks, such as EMAN and ERPAN), HERCA, EURADOS, EURAMET, EURDEP etc. These provide good opportunities for experience exchange and lessons learned and as a means for establishing strong international relationships and performing common projects.

GAEC surveys stakeholders and end users. This provides data on the extent of compliance with radiation protection standards and regulatory requirements.

Internally, GAEC uses oral briefings, report submission and formal briefing for communication, depending on the significance of the regulatory matter. The oral briefings are used for issues of minor interest and importance. Written reports are the most common method of communication about regulatory matters with the Chairman and the Heads of

Departments/Divisions being the recipients. Formal briefings sometimes follow written reports. These briefings are used for important topics requiring wide ranging discussion and to explore the opinions of other staff members. The outcome of all three levels of reporting may be the adoption of corrective actions, the introduction of new practices and the further investigation of the issue concerned.

Arrangements within GAEC to disseminate information include regular meetings (GAEC Board meetings, meetings of GAEC Chairman with Heads of Departments/Divisions, Departmental and Divisional meetings) and circulars to staff. Additionally, GAEC has provisions for the dissemination of information (lessons learned, good practices) to other parties, such as authorized bodies or national and international collaborating organizations.

Provisions are in place to provide the general public and the mass media with information related to radiation activities. The GAEC website is a useful tool for public information and includes: data from the telemetric monitoring stations; data on medical radiation laboratories and reports, such as annual activity reports, external evaluation reports, reports submitted to IAEA (CNS, Joint Convention). GAEC issues press releases from time to time as appropriate.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

GAEC was originally established in 1954, but was split into a Regulator and a separate Research Centre entity by Law No. 1514/1985 and Law No. 1733/1987. GAEC is a "decentralized public service". Its organizational scheme was established by the Presidential Decree No. 404/1993.

GAEC is governed by a 7-member Board, appointed by the supervisory Ministry for a three-year period. The Heads of Divisions are appointed by the Board for a five-year period.

GAEC is composed of 4 Divisions, 10 Departments and 2 independent Offices. The Board has authorised the creation of three additional units, as a result of the undertaking of further responsibilities, such as the inspection of non-ionizing radiation facilities and the operation of the SSDL.

The IRRS Team noted the formal structure is not always clearly aligned with the operational structure with some managers holding more than one position. GAEC have carried out an organisational review in 2009 on its own initiative, but was unable to get the required legislative changes enacted at the time. Subsequent to a downsizing initiative generally in the Greek public sector, GAEC revised its initial proposal in line with that initiative. The IRRS Team were concerned that the required organisational changes initially identified by GAEC in their needs assessment have not been addressed and may be compromised in the new horizontal public sector initiative.

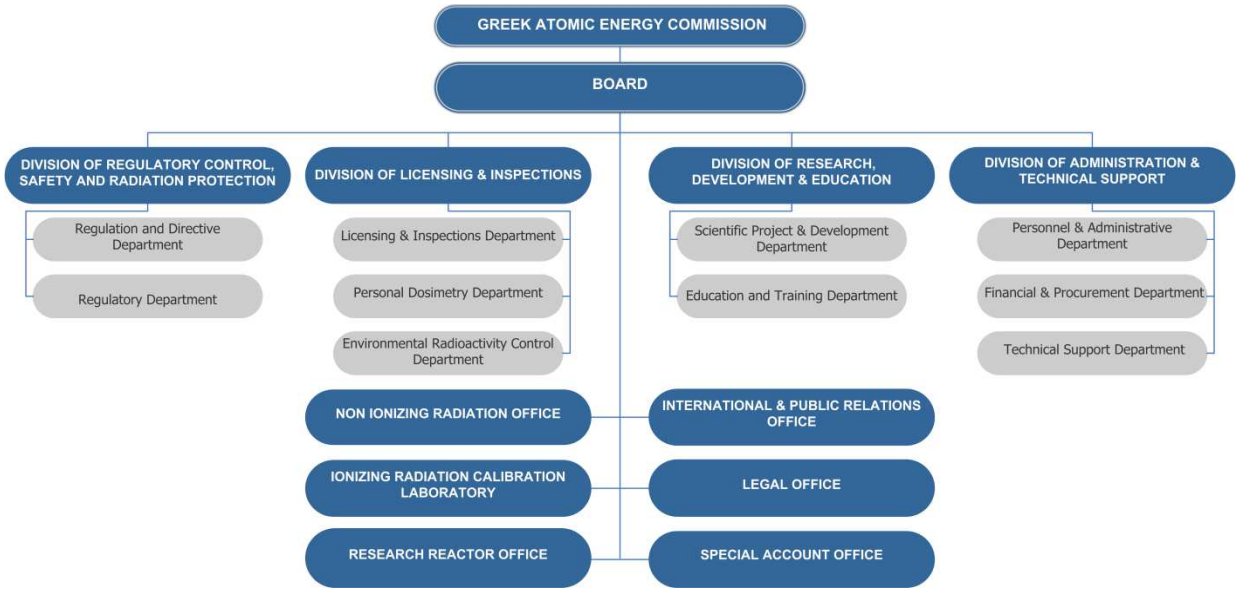

Figure 1.GAEC organizacional structure

A reform of the organizational scheme has been agreed internally and communicated to the supervisory bodies (GSRT, Ministry). For any structural change, a new Presidential Decree is required making reallocation of organizational units quite inflexible.

GAEC has resources deployed for each aspect of radiation regulation and service work required within its overall scope of operations. It is not clear that GAEC has undergone a detailed analysis of radiation risk for Greece and established priorities accordingly. The alignment of resource allocation with radiation risk has been undertaken by introducing changes in the period of licences and with some changes to inspection schedules but no systematic approach has been observed.

3.2. EFFECTIVE INDEPENDENCE DURING CONDUCT OF REGULATORY ACTIVITIES

GAEC has an ongoing unease about its effective independence. This arises from:

- its co-location with the NCSR "Demokritos" facility, housing GRR-1 and its historical association with the nuclear facilities of Greece;
- the fact that it comes under the same Ministry as several licence holders, including the NCSR "Demokritos" and research facilities operated by Universities, currently the Ministry of Education, Lifelong Learning and Religious Affairs;
- the lack of "independent regulatory authority" status or statements about independence in its legal basis, and
- queries raised during review meetings of international conventions.

The review notes the concerns, but has observed that there is no suggestion of interference in the decision-making independence of GAEC. The effective independence of GAEC is supported by the presence of the Board, the strong commitment demonstrated by the General Secretary of Research and Technology for independent regulation of the hazards of radiation and public interest in matters to do with radiation.

In terms of the independence of day to day activities, GAEC has sufficient resources to undertake its activities.

The obvious conflicts of interest regarding the delivery of technical services and the licensing and inspection functions mentioned in section 1.10 are of concern to the IRRS Team. The IRRS Team is of the view that a greater degree of functional separation between technical services and the regulatory function would be appropriate in order to minimise any potential conflicts of interest.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 para. 4.7 states that: "*The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework*"

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
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.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

GAEC employs 70 staff. The staff comprise 17% in the category of “Special scientific personnel”, 62% in “Scientific and technical personnel” and 21% in “Administrative personnel”. GAEC employees are employed either on permanent or fixed term contracts.

The number, qualifications and general competences of the permanent staff are given in the Presidential Decree No. 404/1993, defining the GAEC organizational structure, and additional fixed term staff can be appointed by Board decisions. The position descriptions for individual staff positions in the Licensing and Inspections Department include the qualifications and other requirements for recruitment of staff to those positions. These position descriptions are included in the Quality Management System for the Department.

For hiring personnel under permanent contracts: GAEC determines the qualifications needed and the selection is performed by the Supreme Personnel Selection Council, common for all public services (named ASEP). The only exception is the category of the Special Scientific Personnel (the relevant procedure is described in the Presidential Decree describing its organizational structure). For hiring personnel on fixed-term contracts: the heads of the departments propose to GAEC Chairman the qualifications required. For the selection of the staff, a selection committee is established (for each case) which proceeds to the analysis and evaluation of the certificates/CVs and then performs interviews. The committee submits its proposal to GAEC Chairman who takes the final decision.

The recruitment procedures are rigorous; 45 of the staff have higher degrees.

New staff receive on-the-job training and are supervised by a senior colleague for at least 6 months. All staff have individual learning plans for continuing development, however strategic plans for ongoing training for inspectors, for example, are not in evidence in the management system.Staff are encouraged to participate in scientific workshops, conferences and courses. Upon return, they are required to share the “know how” acquired and the lessons learned with the rest of the staff.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-R-1 paragraph 4.13 states that: *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
R7	**<u>Recommendation</u>: GAEC should implement a systematic training program on the basis of an analysis of the necessary competence and skills for the regulatory body.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

GAEC does not have standing advisory bodies. However, GAEC can obtain external technical or expert advice and has used the practice on several occasions in the past by establishing committees for specific regulatory activities. These committees are disbanded on completion of the task and none currently exist. There are practically no support organizations in Greece; however, GAEC seeks assistance from the IAEA if required and maintains a strong link with the Agency.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

GAEC has both formal and informal mechanisms of communication with authorized parties on all safety related issues. As a civil service, GAEC is obliged to follow official procedures of communication with all authorized parties and the general public (e.g. exchange of letters/faxes/e-mails duly signed and stamped).

Formal and informal mechanisms for communication include: correspondence by mail, fax, e-mail, oral communication, meetings, web-based information and public consultation as appropriate. Inspections are usually accompanied by routine exchanges of information of mutual benefit.

The IRRS Team was told that GAEC surveys authorized parties and takes the feedback received into consideration in future planning.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The regulatory framework has been established in law for many years and is stable. The requirements and criteria for authorization and licensing are clear and published as part of the national Radiation Protection Regulations. Regulatory decisions are supported by written justifications. There are formal procedures in place for the implementation of the basic

regulatory activities. The protocols to be followed, the requirements and the technical details have been issued and they are open and available to all interested parties. A number of them are included in the Quality Management System of the Licensing and Inspections Department.

Mitigation measures to minimize the risk of subjectivity need further development. The IRRS Team was told that inspection reports are systematically subject to review by a senior officer before being issued.

However, in some areas consistency of regulatory control is problematic. In some cases exempt material is under regulatory control. A medical facility with a valid certificate of compliance can become unlicensed as a result of a failure to meet criteria for licensing unrelated to radiation protection. The inflexibility of licensing without conditions has resulted in the failure to license two facilities at the NCSR "Demokritos". These are gaps in regulatory control arising from the inflexibility of the regulatory approach. More details are provided in section 5.

3.7. SAFETY RELATED RECORDS

GAEC maintains a National Radiation Protection Database which is regularly updated by the GAEC staff. The database includes:

- facilities and equipment
- licensing details
- inventory of radiation sources
- inspection results
- dose registry
- educational level of the occupationally exposed workers
- radioisotopes distribution/transport
- administrative and financial data

The database provides for an automatic notification prior to the expiry of licenses/or certificates of compliance. GAEC will inform the licensee accordingly to avoid the delays in the renewal of the license. The database does not include the inventory of: orphan sources identified and stored, disused sources and the radioactive sources stored in the interim storage facility of NCSR "Demokritos".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 requirement 36 states that: "*The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.*
	GS-G 1.5 para. 7.2 states that: "*The principal types of document that should be maintained by the regulatory body include:* *- All authorizations and notifications, which should include details of the radiation sources.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	- All communications between the regulatory staff and operators, starting with the submission of a notification or an application for authorization, issuing an authorization, and continuing through inspection findings, enforcement actions and, finally, the communications associated with the termination of an authorization. *- The regulatory body's review of any safety assessment submitted by the applicant or any other basis for granting an authorization.* *- Reports of inspections and investigations.* *- Operational data required to be submitted to the regulatory body by Operators"*
GP2	**<u>Good Practice</u>: The team acknowledges the excellence of the national database system for radiation protection maintained by GAEC.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

GAEC policy regarding information dissemination is based on the principles of transparency and openness both towards interested parties and the general public. GAEC International and Public Relations Office, among other responsibilities, has the role of disseminating information and informing the general public about the risks associated with radiation.

Public information activities are both proactive and reactive. GAEC prepares an Annual Report describing programs and research undertaken and its plans for the future. The team was impressed by the Annual Report which is produced while not being a governmental requirement. Reactive examples of public information include issues, such as the Fukushima Nuclear Accident and concerns about non-ionising radiation.

Information material is made available to the public and other interested parties. GAEC uses its website to provide information on existing radiation facilities, telemetric network measurements, radiation incidents/events, relevant legislation, etc.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-R-1 paragraph 4.67 states that: *"The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks.... and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities."*
GP3	**<u>Good Practice:</u> The team acknowledges the excellence of the Annual Report published by GAEC.**

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The requirements for a management system are stated in GSR Part 1 and are expressed as follows; “The regulatory body shall establish, implement, assess and improve a management system that is aligned with its safety goals and contributes to their achievements.” The management system of the regulatory body has three purposes:

- ensure that the responsibilities assigned are properly discharged;
- maintain and improve the performance by means of planning, control and supervision of its safety related activities;
- foster and support a safety culture through the development and reinforcement of leadership, as well as good attitudes and behaviour in relation to safety on the part of individuals and teams.

4.1. QUALITY SYSTEMS

GAEC has currently two quality systems independently accredited to ISO/IEC 17025:2005 (General requirements for the competence of testing and calibration laboratories) and 17020:1998 (Conformity assessment – Requirements for the operation of various types of bodies performing inspections). The quality systems for the laboratories were developed together with the staff more than ten years ago. The quality system for the Licensing and Inspections Department was developed during 2010, although the IRRS team was told that some additional procedures were developed before this time and do not currently form part of the management system following the advice of the certification body.

GAEC has translated its organisational objectives into the following mission for the organization “The protection of the public, the workers and the environment from ionising and artificially produced non-ionising radiation”. However, the mission is not stated within the management system.

It was not possible to ascertain if the other ministries and authorities with assigned competence operate their own management systems, although there would seem to be no interaction between GAEC’s management system arrangements and those of such other ministries and authorities.

4.1.1 Quality system for the laboratories

There is a common quality manual for the four laboratories (D4, dated 23 November 2011): office of non-ionizing radiation, dosimetry department, environmental radioactivity monitoring department and calibration laboratory for ionizing radiation instruments. The quality manual defines and justifies: the quality policy, the structure, responsibilities, and authorization related to the laboratories’ activities and the basic principles and operation regulations of the quality system with references, wherever necessary, to the written procedures of the quality system. The full documentation of the quality system comprises the quality manual, together with job descriptions, procedures, working instructions and quality records.

4.1.2 Quality system for the Licensing and Inspections Department

The quality manual (D3, dated 14 September 2010) for the Licensing and Inspections Department (LID) describes the department's policies for a number of areas. In each section various documents and procedures are referenced. In the quality manual the goals for LID are stated as to "Ensure the protection of the general population, patients, and workers against ionizing radiation, through the provision of high quality services and to officially recognize their technical proficiency and integrity at national and international level. The manual follows the same structure as the ISO 17020 standard, with the rationale that it will be easier to demonstrate compliance with the standard during recertification. The IRRS team was told that all LID personnel have a copy of the manual and relevant procedures in hard copy. A copy of the manual and all the related procedures are also kept on file in the quality manager's office. All the documentation is also saved on a server. When procedures and the manual are up-dated they are distributed as hard copies to the staff.

4.2. INTEGRATED MANAGEMENT SYSTEM

GAEC does not currently have an integrated management system that brings together in a coherent manner all the requirements for managing the organization. There is no formal document describing GAEC policies and strategies and safety is not stated in the documentation to being paramount and overriding all other demands.

The IRRS team recognised that the quality systems have elements in place that belong within an integrated management system but they are not well documented in all cases. Examples are management responsibility, resources management, measurement, assessments and improvement, control of documents, control of records. Some improvements are clearly needed, for example in terms of the documentation of policy statements and values for the organisation, administrative and legal support, decision making and the management of organisational change.

Since the ISO 17020 standard does not require that all relevant procedures for the Licensing and Inspections Department be included in the quality system, some procedures have been excluded from the scope of the management system; examples are procedures for licensing, review and assessment.

The quality systems of GAEC are not process oriented. In the organisation there are some processes although they are not documented. The proposed approach by the IRRS team for GAEC is to identify, develop and manage the processes in line with the IAEA Safety Standards. If using a top-down approach they should be hierarchically linked and when getting closer to the technical tasks they are better described in a procedure or instruction.

GAEC has decided to develop an integrated management system according to the ISO requirements of 9001:2008 and GS-R-3. GAEC may wish to consider undertaking a rigorous gap analysis to assist the development of a management system which fully complies with the relevant requirements of GS-R-3 and to allow GAEC to prioritise deployment of resources to develop interim solutions where necessary in order to minimise impacts arising from such gaps. There is currently no implementation plan but an initial gap analysis has been performed which, as the IRRS team understands has identified some of the procedures that need to be developed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 Requirement 19 states that: *"The regulatory body shall establish, implement, and assess and improve a management system that are aligned with its safety goals and contributes to their achievements."*
R8	**<u>Recommendation:</u> When developing the integrated management system, GAEC should ensure that it is aligned with GS-R-3.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-G-3.1 para 2.24 states that: *"Senior management should prepare a plan to achieve full implementation of the management system…"*
S2	**<u>Suggestion:</u> GAEC should consider preparing a plan for the development and implementation of the integrated management system.**

4.2.1 Management commitment and staff involvement

Management engagement and strong staff involvement are critical when developing, implementing and improving a management system. There was a lot of involvement from staff when developing the quality system for the laboratories, where there is evidence that the quality management system is implemented and understood by the staff. However, the quality system for LID does not cover all their activities. There is evidence that some staff consider the quality system as a matter for the quality manager.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-R-3 para 3.4 states that: *"Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system"*
	BASIS: GS-G-3.1 para 2.7 states that: *"The management system … should be implemented in such a way that it is known, understood and followed by all individuals"*
R9	**<u>Recommendation:</u> GAEC should foster staff commitment to the quality systems and to the integrated management system.**

At the moment there are five quality managers, one person for each laboratory and one person for LID. Recently one person has been appointed to be the coordinator for developing and implementing an integrated management system. During an interview with the quality managers, the IRRS team was told that approximately 50% of the quality managers' time is currently devoted to work on quality systems issues, which equates to approximately 2.5 full-time equivalent staff. It is therefore, believed that one person will have insufficient time to manage the development and deployment of an integrated management system at the same time as ensuring the current management system arrangements in their area of responsibility are maintained pending the development and implementation of the new system.

GAEC will also need to ensure that those responsible for the development and the deployment of the integrated management system are fully supported by the GAEC Board and have the necessary authority and access to resources in order to realise the benefits that an integrated management system will bring.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-R-3 para 3.1 states that: *"Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities."*
R10	**<u>Recommendation:</u> GAEC should make sufficient resources with the appropriate authority available when developing and implementing the integrated management system.**

4.2.2 Organizational change

The Board of GAEC has authority to redeploy some resources within the organization, but major structural changes require the amendment of the Presidential Decree No. 404/1993 establishing the organization. There is no information in either of GAEC's quality systems that addresses organisational change. On a broader level, the IRRS Team identified change management gaps in terms of all other competent authorities dealing with radiation safety issues in Greece including the transport sector, the Prefectures, Customs and Health. Since the management of organisational change for radiation safety authorities entails specific considerations, the IRRS team recommends that the Government and GAEC develop and implement a process to manage organisational change across the regulatory body.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-R-3 para 5.28 states that: *"Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified."*
	BASIS: GS-R-3 para 5.29 states that: *"The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised."*
R11	**<u>Recommendation:</u> GAEC should include a specific process for the management of organizational change in the integrated management system.**
S3	**<u>Suggestion:</u> The Government should consider establishing specific processes for the management of organisational change across all competent authorities dealing with radiation safety.**

4.3. SAFETY CULTURE

The IRRS team was told that safety culture is perceived by GAEC staff as being the underlying principle in daily work. In addition, it was stated that it is discussed in meetings at all levels. However, the IRRS Team noted that safety culture is not explicitly addressed in the quality systems. The IAEA Safety Standards require that safety culture should be explicitly addressed to ensure that all staff give appropriate attention to safety culture in their roles and tasks. While there is evidence that radiation protection and fire protection are given the proper attention, sufficient priority is not always evident in procedures, communication activities and decision making processes in other safety related areas.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 para 4.15 states that: *"The management system of the regulatory body has three purposes:* … *(3) The third purpose is to foster and support a safety culture in the regulatory body through the development and reinforcement of leadership, as well as good attitudes and behaviour in relation to safety on the part of individuals and teams."*
R12	**<u>Recommendation:</u> GAEC should explicitly address safety culture in the integrated management system.**

5. AUTHORIZATION

The major applications of ionising radiation in Greece are medical, industrial and research, and include the following facilities:

- 58 radiotherapy (including brachytherapy)
- 180 nuclear medicine
- 1190 diagnostic/interventional radiology
- 13000 dental laboratories
- 160 veterinary laboratories
- 223 research facilities
- 240 industrial facilities

In addition, Greece has one research reactor in the NCSR "Demokritos" (shut down under major refurbishment in 2005, and is outside of the scope of this mission), two sub-critical assemblies (one in the National Technical University of Athens which is fully decommissioned, and the other is in the Aristotle University of Thessaloniki) and one interim storage facility for radioactive waste in NCSR "Demokritos" (for solid radioactive waste and sealed sources).

According to Article 4 of the Legislative Decree No. 181 "Protection Against Ionising Radiation" and the Radiation Protection Regulations issued by the Ministerial Decision No. 1014/2001; "A natural or legal person must obtain a special license to carry out any activity involving ionising radiation. This license shall be issued when the direct and indirect radiation protection requirements are met".

Law No. 1733 of 1987 has established the Greek Atomic Energy Commission (GAEC), as a competent authority in the field of radiation protection and nuclear safety. Article 28 of this Law provides for the main responsibilities of GAEC and its designation as a Regulatory Authority having the responsibilities of licensing all facilities and activities involving ionising radiation.

According to the Decree No. 181, authorization (or licensing) is a prerequisite for facilities and activities not explicitly exempted from regulatory control. Exemptions are prescribed in Article 1.1.6 of the Radiation Protection Regulations. The authorization of all practices is done by licensing only.The Radiation Protection Regulations provide the requirements and processes for licensing of five types of ionizing radiation facilities:

a) Medical Facilities: the license is issued by the Prefectures, following the opinion of a 9-Member Committee and is based on the certificate of compliance issued by GAEC; for the renewal the opinion of the 9-member Committee is not required.

b) Industrial Facilities: the first operational license is issued by GAEC supervisory Ministry (Ministry of Education, Lifelong Learning and Religious Affairs) and the renewal of the license is done by GAEC;

c) Research and Education facilities: the license is issued by GAEC

d) Radioactive Waste: the license is issued by GAEC

e) Import, export, possession and use and transport of radioactive sources: the license is issued by GAEC.

Articles: 1.1.4, 2, 7, 8 and 9 of the Radiation Protection Regulations describes the requirements for the licensing of medical, industrial and research facilities. The procedure for granting an operation license for each application may involve other organisations or committees in addition to GAEC.

Licensing of medical facilities

According to the Radiation Protection Regulations, the operational licenses for medical facilities are granted by the Prefectures. The validity of the license depends on the type of medical practice (5 years for radiology and radiotherapy facilities and 3 years for nuclear medicine facilities). Three steps are involved for the operation license to be granted:

- Feasibility license: issued by the prefecture upon the agreement of the 9-Member Committee of the Ministry of Health and Welfare.
- Pre-construction license: issued by the prefecture upon written approval for the construction of the facility provided by GAEC
- Operational license: granted by the Prefecture upon the agreement of the 9-Member Committee of Ministry of Health and Welfare in addition to Certificate of Compliance issued by GAEC.

The renewal of the license is granted by the Prefectures subject to the issuance of a certificate of compliance by GAEC. The Prefecture has the right to revoke or suspend any operational license for a medical facility without consulting GAEC for reasons other than radiation protection.

Licensing of industrial facilities

The operational license for the industrial facilities is granted by the Ministry of Education, Lifelong Learning and Religious Affairs with a validity of two years. It requires a certificate of compliance from GAEC to the applicant. The renewal of license for industrial facilities is granted by GAEC directly.

Licensing of research and education facilities

All other activities including research, education, transport, interim storage facilities, export and import of radioactive sources are licensed by GAEC.

Articles 8.2, 9.7 and 10.7 in the Radiation Protection Regulations empower GAEC to renew, amend or revoke licenses/or certificates of compliances.

The IRRS team was informed that two laboratories belonging to NCSR “Demokritos” function without licenses. The IRRS team was informed that GAEC has conducted inspections to these laboratories. Corrective actions that need to be addressed by the laboratories were communicated to the laboratories for the completion of the license process.

The application procedures for a license/or certificate of compliance for the different types of facilities are available on the GAEC web page. The Radiation Protection Regulations provide requirements for licensing of facilities and activities, taking into consideration the risks associated with the equipment or sources used. However, detailed guidance on licensing procedures for the applicants is not available.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 para 4.34 states that: *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization"*
R13	**<u>Recommendation</u>: GAEC should further develop 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.**

The licensing process for the medical facilities has to go through three steps which involve three different authorities including the Prefectures, GAEC and the 9-Member Committee of the Ministry of Health. Cooperation and coordination between the three authorities in order to facilitate the efficient operation of the licensing process should be improved.

The Radiation Protection Regulations specify that licence renewals must be applied for 3 months before its expiry. During the sites visits, the IRRS Team was informed that the time needed for the renewal of a license, especially in the case of medical applications, can exceed the period available. The renewal of licenses, in case of medical facilities, need to be coordinated with Prefectures to avoid the possibility of a facility operating without license.

The national radiation protection database is used to trace the applications for licenses in the medical field in collaboration with the Prefectures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 para 2.18 states that: *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned. This coordination and liaison can be achieved by means of memoranda of understanding"*
	BASIS: GS.G-1.5 para 5.10 states that: *"….the regulatory body should identify areas where co-ordination and co-operation with other local, national and international organizations are needed to fulfil its mandate. When such needs are identified, the regulatory body, together with the other organizations involved at the local and national levels, should establish specific arrangements for co-ordination and co-operation".*
S4	**<u>Suggestion</u>: GAEC should consider improving the coordination with Prefectures to avoid delays in the licensing renewal process which can result in facilities operating without a valid license.**

Although the legislation empowers GAEC to include conditions in the license/or the certificate of compliance, all licenses and/or certificates of compliance issued by GAEC do not include conditions to be considered by the licensees during the operation of the facility. In the licensing process, all non-compliance issues identified by GAEC are communicated to the applicants and actions taken by applicants have to be reported to GAEC prior to the issuance

of the license/or certificate of compliance. GAEC will only issue a license/or certificate of compliance if all safety requirements are fulfilled by the applicant. A common alternative approach would be to consider issuing a licence with conditions, limits or controls attached to it. In fact, the IRRS Team observed a few examples, such as the waste management facility and other laboratories in the NCSR "Demokritos", where GAEC accept that facilities continue operating without a license when certain safety requirements are not met.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 para 4.31 states that: *"In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party's subsequent activities..."*
S5	**<u>Suggestion</u>: GAEC should consider revising its licensing approach in order to include conditions, limits and controls on licenses and or certificates of compliance.**

The Radiation Protection Regulations do not provide for registration of some of the activities or facilities. GAEC has to license all facilities or activities in the country irrespective of the risk associated with them.

The Radiation Protection Regulations for licensing/or issuing certificate of compliance provide different requirements for different practices taking into consideration the risk associated with them. Clear guidelines for the implementation of the graded approach in terms of authorisation are not in place.

The IRRS team was informed that, some of radioactive sources recorded by GAEC have activities below the exemption limits. Article 1.1.6 of the Radiation Protection Regulations state clearly that GAEC can exempt some activities or facilities from regulatory control.

In licensing the import of a radioactive source, GAEC has a separate application form for this purpose. All source information and its transportation to the user premises have to be provided by the applicant prior to the issuance of the import license. GAEC has arrangements in place with Customs to deal with the imported or exported sources. Points of entry do not have in-transit storage facilities except at Athens airport. Direct delivery requirements are applied in order for the licensee to transport the source immediately after its arrival at the point of entry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 requirement 24 para 4.33 states that: "*The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
	BASIS: GSR Part 1 para 4.3 states that: *"…The performance of regulatory functions shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach.."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R14	**<u>Recommendation</u>: GAEC should improve the implementation of a graded approach in the authorization process.**

Authorisation of waste management facilities

The only waste management facility in Greece, according to GAEC, is the interim storage at NCSR "Demokritos" site. This facility is used for the storage of disused and orphan sources, other radioactive material declared as radioactive waste, operational waste from research reactor GRR-1 (outside the scope of the mission) and other legacy operational waste from the NCSR "Demokritos" research institutes.

The Radiation Protection Regulations require all activities involving ionising radiation to be authorised. However, the NCSR "Demokritos" interim storage facility is in operation, but has not yet been licensed. GAEC does not envisage being in a position to issue the operational licence for some time, since the NCSR "Demokritos" storage facility does not comply fully with the Radiation Protection Regulations or draft safety requirements. The uninterrupted operation of an unauthorised facility is not in accordance with IAEA Safety Standards or Greek Radiation Protection Regulations.

According to GAEC the licence procedure for the storage facility is under preparation. To promote safety enhancements and to ensure facility radiation safety GAEC has performs unofficial reviews of the operator's reports, prepares draft material and performs regular inspections.

In relation to a Recommendation made under Section 5.2.3 concerning guidance on format and content of application documents, GAEC should consider developing guidance for the development of the safety assessment and safety case of the interim storage facility in NCSR "Demokritos".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 Requirement 23*:* *"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"*
R15	**<u>Recommendation</u>: GAEC should enforce the licensing requirements for all facilities at NCSR "Demokritos", including the interim storage facility.**

6. REVIEW AND ASSESSMENT

GAEC performs review and assessment mainly during authorisation of facilities and activities, which are connected to pre-construction, operational and renewal of licensing. Review and assessment is connected to inspection, as in most cases GAEC performs a thorough inspection before authorisation or issuing a certificate of compliance. The requirements for information to be submitted to GAEC are described in Radiation Protection Regulations Part 2-10. GAEC has issued protocols or guidance related to most of the types of facilities and activities (e.g. radiology, radiotherapy). These together with RPR requirements form the criteria against what GAEC personnel perform review and assessment.

Prior to granting an authorisation/or a certificate of compliance, GAEC requires a safety report of the safe operation of a facility or conduct of an activity. This report forms part of the documents to be provided by the applicant to demonstrate the safety of the facility. GAEC reviews the report to ensure the safe operation of the facility as part of the licensing process.

During the interviews the Team was informed that review and assessment is done according to GAEC quality management system. The GAEC quality manual for Licensing and Inspection Department forms the basis only for inspection activities, and does not give guidance for performing review and assessment. There are no documented procedures used by GAEC in order to assess the safety reports of the different practices and activities in accordance to the associated risk.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 para 4.33 states that: "*Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures…..*"
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.**

The use of a graded approach in review and assessment is mainly based on the requirements in the RPR depending on the licensing period and type of facility or activity in question. In practice GAEC allocates more time and resources for reviewing more complex facilities. GAEC's review and assessment process contains elements of risk based graded approach, but it is not obvious that GAEC follows a comprehensively graded approach in review and assessment and there is no guidance in quality management system to explain implementation of the approach. Development of review and assessment guidance should enhance the transparency of regulatory review and assessment and decision making process. This should be considered as part of actions related to Recommendation R13. Criteria for review and assessment are detailed within RPR.

The results and decisions of reviews and assessments for each facility are registered in the Licensing and Inspections Department archives, as well as in the National Radiation Protection Database kept by GAEC.

7. INSPECTION

Articles 2.9, 9.10 and 10.8 in the Radiation Protection Regulations empower GAEC to conduct inspections to the facilities and of activities to verify compliance with the safety requirements.

GAEC conducts inspections of facilities and activities prior to the issuance of a certificate of compliance or the license, the renewal of licenses as well as for other reasons determined by GAEC. GAEC has written procedures in place for conducting inspections which have been included in the Quality Manual issued in Sept. 2010 as part of the accreditation of the Licensing and Inspections Department (LID) of GAEC (ISO 17020). Specific check lists for inspecting different types of facilities and activities are being used by GAEC's inspectors during inspections. Effective use of these checklists was noted during the site visits conducted.

Articles 2.9, 9.10, and 10.8 in the Radiation Protection Regulations describe the inspections to be conducted to each type of facilities.

7.1. INSPECTION PROGRAMME AND THE GRADED APPROACH

GAEC uses annual inspection programme to plan for the inspections. The programme is updated on a two weeks basis. The development and updating of the inspection programme by GAEC is based mainly on the renewal of licenses or the certificate of compliance in case of medical facilities. Other factors used by GAEC to develop and update the inspection programme are:

- new facilities to be licensed;
- facilities with a license to expire in the next two months;
- facilities, where radiation protection issues are pending and compliance with the regulations must be verified;
- information about possible violation of regulations;
- geographic spread.

GAEC carries out announced and unannounced inspections. The performance of unannounced inspections usually occurs randomly, but suspicions of bad practice, complaints by third parties, and unavailability of licensees to arrange an inspection are reasons for unannounced inspections. The IRRS Team was informed that the number of unannounced inspections in 2011 was 93 out of a total number of 434. Inspections not related to the licence renewal process can be either an announced or unannounced. The IRRS team was informed that GAEC would like to increase the number of unannounced inspections.

The inspection programme contains elements of a graded approach as those facilities of higher risk are more likely to be inspected between the renewal of a licence. For example, the industrial irradiator is inspected each year while its licence is renewed every two years; nuclear medicine facilities are licensed for 3 years and are inspected about once every two years, and radiotherapy departments are inspected once every two years whereas license duration is five years; GAEC plans to perform inspections every year for industrial radiography whereas the license duration is two years.

GAEC uses checklists during the performance of inspections, based on the requirements in the Radiation Protection Regulations. As part of the inspections for licensing being conducted,

GAEC assesses the competence of the staff of the applicant's organizations as it empowered to do so according to the Article 2 of the Radiation Protection Regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 Requirement 29 states that: *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach"*
S6	**Suggestion: GAEC should consider reducing the influence of the license renewal process on the inspection programme.**

7.2. INSPECTION RESULTS

The results of inspections are reported and kept as hard copies at LID as well as being stored in the Radiation Protection Database. In case of the inspection of medical facilities copies of the inspection findings or certificates of compliance are sent to the Prefectures. If during the inspection a serious violation is identified, GAEC may ask the public prosecutor to take further action, as provided for in the Radiation Protection Regulations.

Since the NCSR "Demokritos" storage facility has not been licensed, GAEC's strategy has been to perform intensive inspections to ensure radiation safety and step-wisely promote safety improvements in the facility.

GAEC performs these inspections with the same procedure as described in the quality manual for the LID. GAEC has also developed specific inspection check list that they follow during inspections of the interim storage facility. These inspection results have been provided to the operator orally, but results have not been officially submitted to the operator and GAEC has not taken any official enforcement actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 para 4.51 states that: *"The regulatory body shall record the results of inspections and shall take appropriate action (including enforcement actions as necessary). Results of inspections shall be used as feedback information for the regulatory process and shall be provided to the authorized party."*
	BASIS: GSR Part 5 Requirement 3 states that: *"...The regulatory body shall provide for the issuing, amending, suspension or revoking of licences, subject to any necessary conditions. The regulatory body shall carry out activities to verify that the operator meets these conditions. Enforcement actions shall be taken as necessary by the regulatory body in the event of deviations from, or non compliance with, requirements and conditions."*
R17	**Recommendation: GAEC should provide inspection results officially to the operator of the NCSR "Demokritos" waste storage facility, and ensure that the inspection findings are addressed.**

8. ENFORCEMENT

The Law provides GAEC with the authority to carry out enforcement actions in relation to non-compliance with the Law or regulations in relation to radiation safety.

The Legislative Decree 181/1974 (Article 8) contains penal provisions for persons who use radiation while not holding an authorization, who intentionally infringe the terms of an authorization, or who intentionally create a risk for life, health or property.

The Law 1733/1987 (Article (2) (c) and (2) (g)) provides GAEC with the authority to propose to competent bodies on the taking of corrective actions where the regulations and guidelines have been infringed. This Law also provides GAEC with the authority to amend or revoke authorizations for the production, possession, disposal and use of radioactive sources.

Subject to a reasoned report by GAEC, the Radiation Protection Regulations (2001) require that the responsible administrative authority amend or revoke, in whole or in part, any license issued under the regulations if it is found that the conditions under which it was issued are no longer complied with or serious violations of the radiation protection rules have occurred.

Enforcement actions are implemented by GAEC as a result of inspections carried out during the authorization process, or as the result of unannounced inspections of authorised facilities and activities. The following enforcement actions are used:

- Verbal notification of non-compliances requiring corrective actions at the conclusion of the inspection;
- Written notification of non-compliances requiring corrective actions in the report of the inspection. The time period allowed for the implementation of the corrective action is related to the magnitude of the risk associated with the non-compliance. Follow-up inspections are carried out to ensure that the corrective actions have been made by the licensee;
- For severe non-compliances, written notification is sent prior to the report of the inspection;
- If the licensee has not corrected the non-compliances, as observed through follow-up inspections, then the enforcement of regulatory requirements can be pursued through the judicial system. This requires GAEC to issue a judicial summons through the Prosecutor's office, to initiate action in both the Administrative Court and the Criminal Court;
- Where the authorized party repeatedly violates safety requirements in the regulations, GAEC can petition the Prosecutor's Office for permission to suspend or cancel the license.

GAEC inspectors prepare reports of inspections that include verbal or written notification on non-compliances to licensees. The inspectors also carry out follow-up inspections to determine that the non-compliances have been corrected. The GAEC lawyer issues the judicial summons through the Prosecutor's office. While the process is understood by the inspectors, GAEC has not developed a written enforcement policy setting out the procedures for inclusion in its Management System.

As an example of enforcement actions taken by GAEC, the IRRS team was informed that GAEC has suspended the licence of an industrial radiography company for 6 months

following the theft of an industrial radiography source that was left unattended at an outside radiography site.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS:GSR Part 1 Requirement 30 states that: "*The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.*"
R18	**<u>Recommendation</u>: GAEC should formalize its enforcement policy in line with a graded approach and incorporate it into the integrated management system.**

9. REGULATIONS AND GUIDES

The legal basis for developing the Radiation Protection Regulations is in the following Laws:

- article 28, par. 2(c), of the Law 1733/87 (G.G. A 171) “Transfer of technology, inventions, technological innovation and establishment of the Atomic Energy Commission”;
- article 5, par. 3, Legislative Decree 181/1974 (G.G. A 347) “Protection against Ionizing Radiation”.

The Radiation Protection Regulations (2001) also give GAEC with the authority to issue guidance documents or protocols on issues in to relation radiation protection and management of radioactive waste.

9.1. PROCESS FOR DEVELOPING REGULATIONS AND GUIDES

GAEC develops regulations, guidance material, protocols and circulars. Regulations, guidance material and protocols are approved by either the supervising Minister or by GAEC, depending on the status of the document. Circulars are developed for use within GAEC and approved by the Board.

The procedure followed by GAEC for the development of regulations is:

- a committee is established by GAEC, consisting of staff of GAEC and external experts, to prepare a first draft of the regulations and guides. The drafting committee includes the legal officer at GAEC;
- a draft of the regulations is circulated to interested parties, such as professional associations (e.g. medical physics, nuclear medicine physicians, radiologists), Ministries, workers in radiation facilities and activities for comment. The draft is also made available to the public for comment;
- the comments are reviewed by the committee established by GAEC, and a revised draft is prepared;
- the draft is approved by GAEC Board;
- the draft is submitted to the supervisory Ministry for comment;
- for those regulations implementing EC Directives, the revised draft is submitted to the EC for comment and approval;
- the revised draft is submitted to the supervisory Ministry for acceptance;
- the final text is signed by the involved Ministers (such as Health, Economy);
- the Ministerial Decision is then published.

The Radiation Protection Regulations require the approval of four Ministers before they can be approved.

The process for the development of guidance material and protocols is similar. The process for developing guidance material and protocols is:

- a committee is established by GAEC, consisting of staff of GAEC and external experts, to prepare a first draft of the regulations and guides. The drafting committee includes the legal officer at GAEC;
- a draft of the guidance material and protocols is circulated to interested parties, such as professional associations (e.g. medical physics, nuclear medicine physicians, radiologists), Ministries, workers in radiation facilities and activities for comment. The draft is also made available to the public for comment;
- the comments are reviewed by the committee established by GAEC, and a revised draft is prepared;
- the draft is approved by GAEC Board;
- the Guidance material or Protocol is then published as a Ministerial Decision or published by GAEC.

Interested parties are able to download all relevant Laws, Regulations, Guidance material and Protocols from the GAEC web site.

GAEC also develops Circulars. They are developed by GAEC staff to provide guidance to GAEC staff, licensees and other interested parties on the interpretation of the Law on how to implement the Law. Circulars are approved by the Board of GAEC.

While GAEC follow the above procedures for developing regulations and guides, these procedures are not documented in its management system.

9.2. EXISTING REGULATIONS AND GUIDES

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

The regulations relating to radiation safety issued in Greece include:

- Common Ministerial Decision 1014/2001, 'Approval of the Greek Radiation Protection Regulations'
- Ministerial Decision No. 9087 (FOR)1004, 'Operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas'
- Ministerial Decision No. 10828/(EFA)1897, 'Control of high-activity sealed radioactive sources and orphan sources'
- Ministerial Decision No. 11592(FOR)1125, 'Mandatory installation and use of equipment for the detection of radioactive materials in scrap metals and for their illicit import'

The Radiation Protection Regulations (2001) are based on the European 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" and European Directive 97/43/Euratom of 30 June 1997 on "Health protection of individuals against the dangers of ionizing radiation in relation to medical exposures".

The Radiation Protection Regulations provide basic conditions and requirements that are applicable to all types of facilities and activities. The regulations include both general licensing and safety requirements. There are also criteria for the following activities and facilities: diagnostic radiology, nuclear medicine, radiotherapy, management and disposal of

radioactive waste, research and education, industrial radiography, sealed source irradiators, particle accelerators, and the transport of radioactive material. The detailed criteria for these facilities and activities might be more suitable to be issued as GAEC binding guidance.

GAEC has planned revision of the Radiation Protection Regulation to bring them in line with the IAEA Safety Requirements that have been developed since the Radiation Protection Regulations (2001) were published. These IAEA Safety Requirement publications include Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (GSR Part 3) (2011) and the forthcoming EC BSS; GS-R-2 on Preparedness and Response to Nuclear and Radiological Emergencies (2002); and the Transport Regulations for the Transport of Radioactive Material (2009). Some of the issues that require revision or inclusion in the Radiation Protection Regulations include:

- in the area of occupational exposure control: Responsibility of employers, responsibility of workers, and the new dose limit to the lens of the eye (see section 13);
- in the area of emergency plans and procedures: the need for the emergency plan to be in place before the license is issued, and for guidelines on the content of emergency plan to be issued by GAEC (see section 10);
- transport of radioactive material (see section 11);
- discharges (see section 14);
- environmental monitoring (see section 15);
- existing exposure situations (see section 16).

GAEC also needs to ensure that terminology used across regulations, guidance material, protocols and other documents is consistent.

The regulations on the Control of high-activity sealed radioactive sources and orphan sources are based on the European Council Directive 2003/122/Euratom of 22 December 2003 on the "Control of high-activity sealed radioactive sources and orphan sources". The purpose of these regulations is to prevent exposure of workers and the public to ionizing radiation arising from inadequate control of high-activity sealed radioactive sources and orphan sources and to define specific requirements for the controls that should be implemented, in order to ensure that each such source is kept under control. These regulations state that GAEC is the competent authority for the recovery of orphan sources and for the dealing with radiological emergencies due to orphan sources as well as for the drawing up of appropriate response plans and measures.

For those facilities and activities that GAEC has not developed regulations or guidance material, GAEC uses IAEA standards or EU directives or guidance documents.

GAEC is considering developing a hierarchical regulatory system that would include regulations covering general safety provision encompassing all facilities and activities, and issuing guidance documents that contain more prescriptive requirements that could undergo more frequent and timely revision.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 Requirement 33 states that: *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
R19	**Recommendation: GAEC should prepare updated Radiation Protection Regulations to bring them in line with the current IAEA Safety Requirements for submission to the Government.**
S7	**Suggestion: The Government should consider adopting a more flexible hierarchy of Radiation Protection Regulations.**

9.2.2 Waste management and waste management facilities

Concerning waste management the Radiation Protection Regulations defines requirements for management of radioactive waste for some activities, requirements for small storages for short lived waste and procedures for release of radioactive material from regulatory control. However, the requirements concerning waste management are scattered in regulation and do not form coherent set of requirements. The part 6 of the RPR defining requirements on waste management and disposal mainly concentrates on short term storage, clearance and discharge of medical and laboratory waste. The Radiation Protection Regulations do not define requirements concerning pre-disposal radioactive waste management and decommissioning of facilities as part of authorisation in accordance with IAEA safety Standards. GAEC has not issued regulations concerning waste management facilities (e.g. interim storages) or authorisation procedure for them. GAEC has prepared draft authorisation requirements, which has also been communicated to facilities concerned.

Internationally accepted recommendations require that radioactive waste shall be characterised and classified according to regulatory requirements in various steps of pre-disposal management. At present GAEC has not introduced waste classification in its regulations except for exemption and clearance levels. The development and adaptation of waste classification requirements may assist in further development of waste management policy and strategy. An example of waste classification from disposal perspective is described in IAEA SSR-5 Disposal of Radioactive Waste (Annex) and in GSG-1 Radioactive waste classification.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 5 Requirement 3 states that: *"The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process..."*.
R20	**Recommendation: GAEC should establish safety requirements for decommissioning of facilities and pre-disposal management of radioactive waste.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 5 Requirement 9 states that: *"At various steps in the predisposal management of radioactive waste, the radioactive waste shall be characterized and classified in accordance with requirements established or approved by the regulatory body."*
S8	**Suggestion: GAEC should consider incorporating a waste classification scheme into its regulatory system.**

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. BASIC RESPONSIBILITIES

The legislative and statutory framework established at the national level with regard to preparedness and response to a nuclear or radiological emergency is based on various legal instruments as detailed below:

- Government Gazette, Law No. 1733, issued on September 22, 1987, "Transfer of technology, inventions, technological innovation and establishment of the Greek Atomic Energy Commission": This Law establishes under its Article 28, paragraph 2b, "It [GAEC] shall propose to the Minister of Industry, Energy and Technology and any other competent Minister, on the plan(s) for the handling of risks and needs arising from increased radiation activity."
- Government Gazette, Ministerial Decision 2739/94 March 15 1994, "Regulation for public information in the event of a radiological emergency": This decree defines the role of GAEC in disseminating information to the public about radiation safety.
- GAEC's plan (1998) covering nuclear technological accidents for the response to a radiological or nuclear emergency occurring within the national borders or beyond.
- Government Gazette, Ministerial Decision No 1014 issued on March 6 2001, "Approval of Radiation Protection Regulations": Under this decision, GAEC is required to provide training in radiation protection to the staff of special groups. It is required to establish dose constraints (refer to 10.2.5) for exposure of emergency workers, individual monitoring in case of emergency situations, considerations on emergency intervention plans, emergency measures, requires emergency plans for most of the relevant practices.
- Government Gazette, Law 3013, May 1, 2002, "Upgrade of the civil protection and other issues": This law establishes that the General Secretary of the Civil Protection is responsible for: studying, planning, organizing and coordinating national policy, concerning issues of public awareness, prevention and management of natural or man-made or other disasters.
- Government Gazette, Ministerial Decision No 1299, April 10, 2003, "General Civil Protection Plan Xenokratis": This decision establishes that a national coordination body would handle all major hazards in the country and this is in line with the all hazard approach. GAEC's plan (1998) was modified and included in this national plan as Annex R.
- GAEC Internal Emergency Plan for Dealing with Radiological Incidents or Chemical, Biological and Radio-Nuclear (CBRN) Threats: This Plan includes written procedures, analytical tools and computer Programs, for the support of GAEC's participation in the above mentioned plans. This is also partially incorporated in NRBC emergency plan.
- Decision of the General Secretary for Civil Protection "National Plan on CBRN threats", November 2011: This CBRN Plan refers to the management of chemical, radiological, biological or nuclear agents arising from acts of terrorism and applies after the completion of the antiterrorism tasks performed by the Hellenic Police.

The following figure represents the legal infrastructure in relation to emergency preparedness and response:

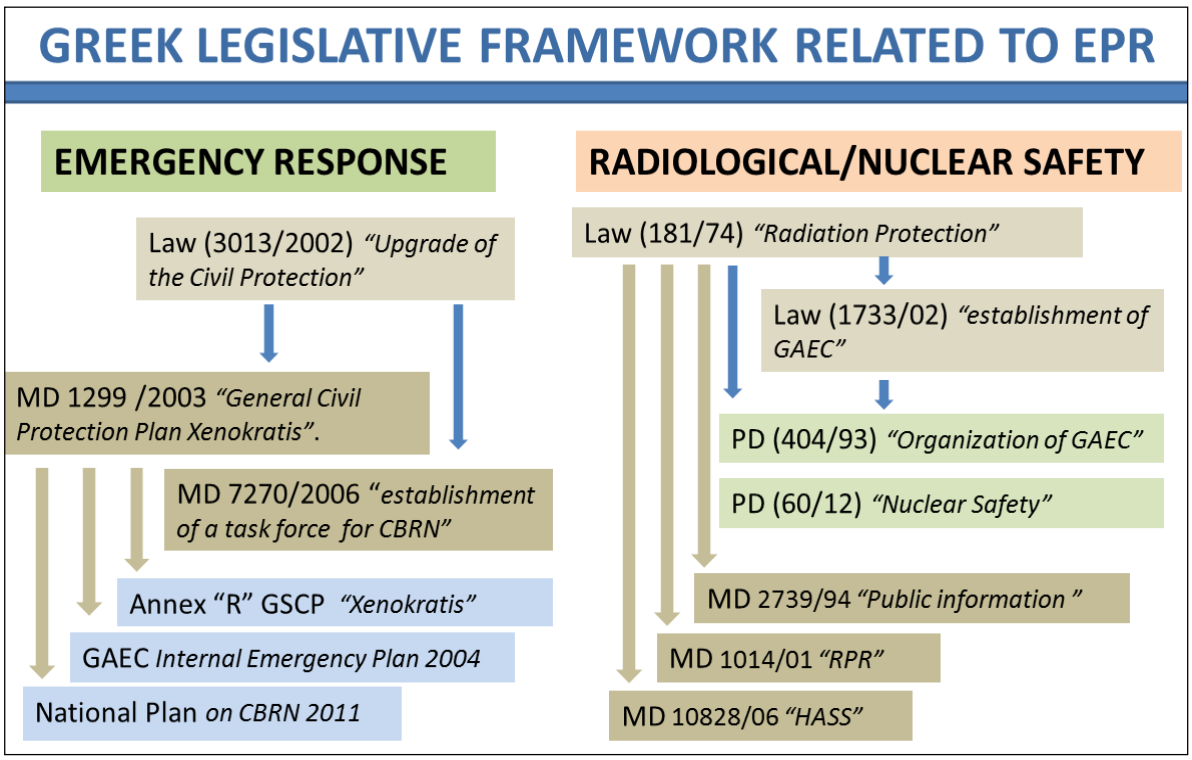

Figure 2. Greek legislative framework related to EPR

The legal infrastructure establishes the General Secretariat of Civil Protection as the governmental body to act as a national coordinating authority whose functions, among others, is to co-ordinate the assessment of the threats within the State, and also to resolve issues between various response organizations. In planning for, and in the event of a nuclear or radiological emergency, the GAEC acts as an adviser to the government (Minister of Interior) and General Secretary of Civil Protection in respect of nuclear safety and radiation protection. The General Secretary of Civil Protection and the response organizations ensure that the arrangements for response to a nuclear or radiological emergency are coordinated with the arrangements for response to conventional emergencies. During an emergency situation involving radiation, GAEC is responsible for assessing the situation, recommending activation of the relevant radiation emergency response plan and proposing countermeasures.

10.1.1 Assessment of threats

Greece does not have any power reactor and its one research reactor is under shutdown. A threat categorization compatible with the threat categories established in the Table 1 of GS-R-2 has not been conducted. Instead, it has identified the risk categories based on the nature of sources or radiation applications.

It has also not made assessment of threats based on the IAEA categorization of threats (Table I of GS-R-2).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-R-2 para. 3.15 states that: *"The nature and extent of emergency arrangements [for preparedness and response] shall be commensurate with the potential magnitude and nature of the [threat]… associated with the facility or activity." The full range of postulated events shall be considered in the threat assessment…. The threat assessment shall be so conducted as to provide a basis for establishing detailed requirements for arrangements for preparedness and response by categorizing facilities and practices consistent with the five threat categories shown in Table I."*
R21	**<u>Recommendation:</u> GAEC should liaise with relevant organizations, to conduct the assessment of hazards at the national level in accordance with GS-R-2.**

10.2. FUNCTIONAL REQUIREMENTS

10.2.1 Emergency management and operations

In accordance with Annex R of the General Emergency Plan, GAEC is responsible for the assessment of the situation, activation (up to level B) and taking the emergency response measures, assisted by competent government entities, universities and research centres. GAEC is also the competent body for responding to individual cases of radioactive contamination in Greece.

The General Secretary of Civil Protection directs and coordinates the associated institutions and is responsible for the implementation of the necessary response measures for widespread or severe radioactive contamination in Greece due to nuclear accidents inside or outside the country, nuclear war, sabotage, irregular activity, etc.

The coordination at various levels amongst various agencies is supported by a Task Force (which is a scientific supporting team) for the Management of Chemical, Biological, Radiological and Nuclear Threats and Incidents, under the General Secretariat for Civil Protection. The functions of the Task Force include the provision of specialized know-how and scientific information on the management of chemical, biological, radiological and nuclear incidents, either caused by accidents or terrorist acts or even for a potential threat scenario.

The overall role of GAEC with regard to radiation emergency is shown schematically in the below figure 3.

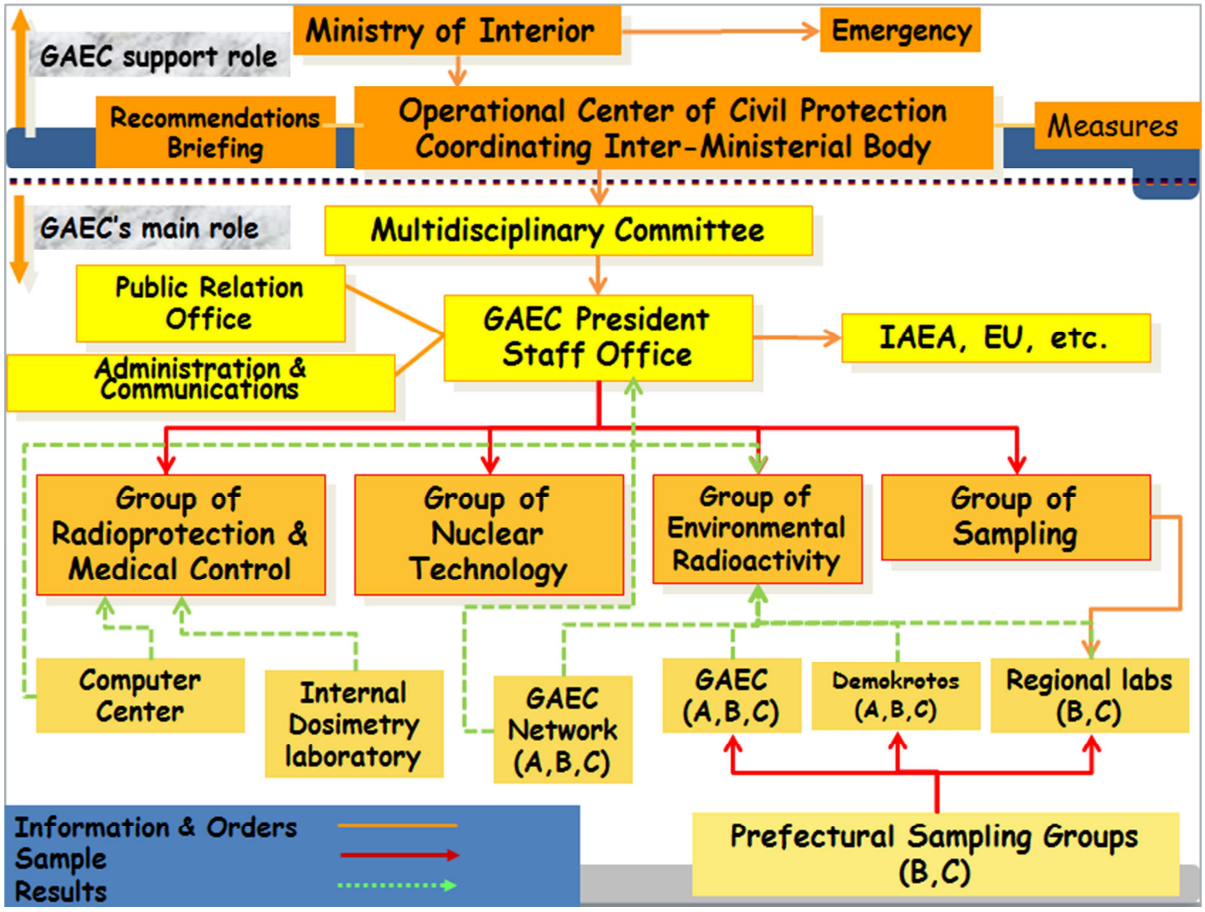

Figure 3. Role of GAEC during radiation emergencies

10.2.2 Identifying, notifying and activating

For the purpose of activation, three levels have been defined: Level A indicating normal circumstances, Level B indicating "Alert" and Level C indicating a radiation emergency in which the other agencies get involved into the response.

Level B of emergency would be declared by GAEC and Level C of emergency would be declared by Civil Protection. The response involves various public authorities handled by the Civil Protection Department.

GAEC is also the National Contact Point on a 24/7 basis, for receiving and sending emergency notifications of an actual or potential nuclear or radiological emergency. The agencies with which it interacts in this regard include IAEA, other international organizations and countries with which Greece has entered into bilateral agreements for such purposes. Similarly, GAEC has the role as Competent Authority at the national level and National Competent Authority for abroad purposes under the conventions on Early Notification and Assistance.

Within the country, GAEC informs the concerned Ministers, and also the General Secretary of Civil Protection, who is responsible for the preparedness and activation of the Coordinating Inter-ministerial Body.

In case of an emergency at radiological facilities, the licensee and the person responsible for radiation protection (qualified expert, medical physicist, safety source officer etc.) would be responsible to notify the accident to the GAEC and cope with the response. Under all

scenarios, GAEC's internal response plan gets activated and it is in a position to deploy all its available resources to respond to the emergency, including not only its own personnel but also others in educational and research institutions.

A variety of communication channels are used for conveying and receiving information. These include telephone, telefax, internet and dedicated lines.

To serve the objective of detecting illicit trafficking and thereby also pre-empting any emergency scenario, GAEC has installed nine radiation detection monitors at various locations to control inbound / outbound traffic at ports, airports and boundary entry points and also makes arrangements for maintaining them. Similar equipment has also been installed at locations seeing movement of scrap. A visit was made by IRRS team members to the Piraeus Port Authority to witness the functioning of this system. In the event of an alarm, the Custom officials have been trained to take necessary actions for carrying out secondary checks and if there is a need GAEC can be notified for additional help. The data from this monitoring system are available to GAEC in real time (see GP8).

10.2.3 Taking mitigatory action

With regard to taking mitigatory actions, GAEC has the legal responsibility to provide expertise in radiation protection to local officials and first responders in the event of a radiation emergency.

Arrangements have been put in place by GAEC to provide expertise and services in radiation protection to local officials and first responders responding to actual or potential emergencies. Among others, these include on-call advice and provisions to dispatch an emergency team with radiation specialists to the scene. Intervention teams for mitigating the consequences of an emergency are also available to carry out mitigatory actions at the facility. Arrangements are also in place to initiate a prompt search and to issue a warning to the public in the event of a dangerous source being lost or illicitly removed and possibly being in the public domain.

While responsibilities have been assigned to the radiation safety officer or the radiation protection officer, there are no provisions which make it mandatory on the part of the facility operator to take mitigatory actions to prevent an escalation of the threat, for returning the facility or activity to a safe and stable state, and to reduce the potential and consequences of radioactive material releases or exposures. This issue should be considered when implementing the general recommendation indicated in the point 1.2 in relation to the allocation for responsibilities.

10.2.4 Taking urgent protective action

GAEC is formally responsible for developing and adopting national intervention levels for taking urgent protective actions. The principles adopted for taking these actions include the principle of justification, indicating that the sale of food is subject to EU regulations and conditions and all efforts would be made to avoid serious exposure of individual members of the population through the implementation of appropriate measures so that the dose received by these persons does not exceed the corresponding levels.

Based on field measurements, GAEC would propose suitable protective actions relating to sheltering, iodine prophylaxis and evacuation.

GAEC also has the responsibility for adopting emergency planning zones for various facilities. These are described in the Radiation Protection Regulations and the procedures are included in GAEC's internal emergency plan. In accordance with these, GAEC has defined

three zones – the cold zone, the warm zone and the hot zone (based on relevant IAEA's TECDOC series). The GAEC internal plan explains how these can be organized and the tasks to be performed by GAEC's Intervention Teams.

It needs to be mentioned that there are no GAEC guidelines requiring the facilities to draw up formal procedures to mitigate the consequences of a radiological emergency.

10.2.5 Protecting emergency workers

Under Ministerial Decision No. 1014, dose constraints for exposure of emergency workers have been established. The responsibility for defining, implementing and managing dose levels for emergency workers, for different types of response activities, lies with GAEC. In accordance with this decision, GAEC shall determine dose constraints or committed doses during the exposure of volunteers who participate in emergencies as the case may be and may exceed the double annual dose limits, but they cannot exceed five times the annual dose limits for the worker's life span. This concept should be reviewed so as to be in line with the new safety standards. The general recommendation indicated in the point 9.2.1 includes the need to update the relevant regulations.

In addition it has been stated in the Annex R of the national response plan, that the maximum level for emergency workers could go up to 500 mSv under life saving conditions.

10.2.6 Assessing the initial phase

Assistance and support to local officials and first responders during the initial phase of a radiation emergency is provided by the GAEC and the nature of these is described under the responsibilities of the supporting team in its internal plan. This includes assessment of the incident (identification of radioisotopes and type of radiation, assessment of dose rate), recommendations for cold / warm zone limits, sampling and measurements, instrumentation and equipment. Procedures have been laid down in the internal plan of GAEC regarding the composition of its Intervention Teams (IT), the equipment it would carry and the actions it would take.

In this regard, GAEC has a radiation monitoring network which includes 24 stations complemented with 3 additional aerosol stations. This system is operated and maintained effectively by GAEC. The inputs provided by these stations are used by GAEC to check for any abnormal increase in background levels, so that they can assess a possible radiation emergency situation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(6)	**BASIS: GS-R-2 para. 4.67 states that: "***Radiation monitoring and environmental sampling and assessment shall be carried out in order to identify new hazards promptly and to refine the strategy for response."*
GP4	**Good practice: GAEC's real time monitoring of radioactivity levels at various locations in the country by means of a network of telemetric stations contributes significantly to identifying the initial phase of a potential radiation emergency due to events within or outside the country.**

10.2.7 Managing the medical response

The response plans at the national level include medical response by way of inclusion of the health department in the plans. GAEC has encouraged the medical community in the country to include the radiation protection discipline in the academic curriculum for medical doctors and medical technicians, this element will help in recognizing a potentially emergency scenario.

While the initial treatment of radiation injuries is expected to be carried out within the country, it is understood that under extreme circumstances, the Assistance Convention of the IAEA could be invoked for medical treatment.

No formal procedure or guideline with regard to medical specialized treatment has been drawn. Nonetheless, during previous major public events (2004) medical guidelines were issued and distributed to reference hospitals in local language (using as a basis material from IAEA).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(7)	**BASIS: GS-R-2 para. 4.77 states that:** *"Arrangements shall be made for medical personnel, both general practitioners and emergency staff, to be made aware of the medical symptoms of radiation exposure and of the appropriate notification procedures and other immediate actions warranted if a nuclear or radiological emergency is suspected."*
(8)	**BASIS: GS-R-2 para. 4.18 states that: "***Arrangements shall be made to ensure that first responders are aware of: the indicators of the presence of radiation or radioactive material…; the symptoms that would indicate a need to conduct an assessment to determine whether there may be an emergency… if an emergency is suspected."*
GP5	**Good practice: GAEC has successfully advocated the inclusion of the radiation protection course, which covers the recognition of radiation injuries, into the basic curricula for medical doctors.**

10.2.8 Keeping the public informed

GAEC has a major responsibility to provide useful, timely, credible, consistent and appropriate information through appropriate channels to the public during a radiation emergency.

This would cover right from the reporting of the event to the termination of the emergency. Under normal circumstances, the External Affairs Office of the GAEC functions as the Press Office. Under emergency levels B and C, the Press Office would also be staffed through detachment of predetermined, suitable manpower from the Ministry of Development and the Ministry of Press, and shall be at the disposal of the National Committee for Information. The Press Office is required to notify the population through the Mass Media concerning the extension, causes, forecast, possible impact of the radioactive pollution, the radiation protection measures taken and anything else related to the Emergency. Depending on the demand for information from the public, GAEC adopts a range of tools to ensure transparency. These include press releases and individual responses to media (through email, fax, telephone, etc.), press conferences and individual interviews.

10.2.9 Taking long-term protective action

In accordance with the national plan, GAEC is formally involved in formulating recommendations for long term protective actions. GAEC adopts EU and IAEA guidelines in this regard with respect to commercial food distribution, environmental protection, etc. It supports the local and/or national officials with actions in the long term phase of a radiation emergency, through the special committees established under the national plan by providing radioactivity measurements with the support of the collaborating laboratories and assessing the relevant risk.

Whenever GAEC has ascertained that a situation may lead to long-term exposure as a result of an emergency situation or due to a past practice, depending on the extent and the severity of the hazard, it would delimit the area, determine and supervise the mechanisms for monitoring exposure and take appropriate action and regulate the procedures for accessing the area and possible activities therein. This would include prescription and implementation of dose limits to workers who would participate in the recovery operations. Similar provisions are in place with respect to CBRN events which would also incorporate decontamination procedures and disposal of radioactive waste arising from the recovery operations. Under these circumstances, GAEC also has the responsibility of adopting Operational Intervention Levels (OILs) for long term protective actions.

10.3. REQUIREMENTS FOR INFRASTRUCTURE

10.3.1 Organization

At the national level, a Task Force supports the competent civil protection forces and organs at the tactical, operational and political level. The functions of this Task Force include the provision of specialized know-how and scientific information on the management of chemical, biological, radiological and nuclear incidents, either caused by accidents or terrorist acts or being threatened incidents or terrorist threats and may provoke emergency situations. The same mechanism is expected to be available during other radiation emergency scenarios in the public domain. It is staffed by personnel from various ministries such as the General Secretary for Civil Protection, the Ministry of Health and Social Solidarity, the Ministry of Environment, Planning and Public Works, the Ministry of Rural Development and Food, the General Chemical State Laboratory, the Greek Atomic Energy Commission, the Hellenic National Meteorological Service, the Fire Brigade, the Hellenic Police Force, the Hellenic Coast Guard and the National Defense General Staff.

GAEC has its own Internal Emergency Plan which is integrated into the national response plan. GAEC Chairman is the head of the internal emergency organization and has a supporting staff office. He/she has the power to deploy Intervention and Support Teams (IT and ST) during an emergency situation and these include groups for: radiation protection nuclear technology, environmental radioactivity measurement and analytical procedures and sampling. The functions of these teams have been formally laid out in the internal plan of GAEC. In addition, analytical laboratories of GAEC along with a group of ten collaborating laboratories support the above teams. The names and designations of concerned personnel are periodically updated.

10.3.2 Plans and procedures

As the national regulatory authority, GAEC has incorporated in its regulatory and licensing system, the requirements for having appropriate emergency plans in place for most of the

practices handling radiation sources. This requirement has not been specifically stated for industrial radiography and transport practices. In this regard, GAEC should clearly assign responsibilities to all relevant licensees.

As mentioned earlier GAEC has its own internal emergency plan, which is interlinked to the national response plan. There is an ongoing process to make them in accordance with international standards, especially those laid out under IAEA's guidelines. A considerable amount of effort was made for drawing up a special safety plan during the 2004 Olympic Games to deal with CBRN threats and efforts are on maintain and improve on these. GAEC has drawn up a range of procedures and work sheets to carry out response functions during a radiological emergency. It also has tools to carry out various analytical and computational functions.

The terminology used in the Annex R is not fully compatible with the terminology and concepts of the GAEC internal Plan and CBRN, due to the fact that they were issued at different times.

The issues indicated in previous paragraphs, related to the availability of a plan before issuing the certificate of compliance, its minimum content and the need for ensuring consistency in the terminology amongst different plans; should be considered when implementing the general recommendation indicated in the point 9.2.1.

10.3.3 Logistical support and facilities

GAEC has set up its own Emergency Response Center within its premises. The facilities available to it include support from the GAEC Central Secretariat, an Equipment Storage Room, Support Team Room (with dispersion models and infrastructure), Vehicles (mobile laboratory) and General Support (telecommunication, UPS, etc.). The support is based on the needs envisaged under the internal response plan of GAEC. The facilities supporting this center include the External and Internal Dosimetry Laboratory, the Environmental Radioactivity Laboratory, and the automated Environmental Radioactivity Monitoring Systems (telemetric). Support is also provided by the personnel and the infrastructure of the Collaborating Research Laboratories, involved in the Emergency Plans. A range of tools, instruments, and equipment are available to the IT and ST. Appropriate communications systems have also been provided to the response teams. A formal maintenance infrastructure has also been put in place to ensure high availability of equipment during an emergency. The communication system used by GAEC is not compatible with those used by other response agencies and this could be a weak link in the response plan.

10.3.4 Training, drills and exercises

GAEC is required to provide radiation protection training for ancillary, technological, technical and scientific staff employed in various fields of nuclear science. It also provides continuing training in radiation protection to the staff of special groups for emergency situations.

GAEC also has the responsibility of providing expertise through various committees and to the Task Force including professional teams who would respond to an emergency situation, such as medical doctors, paramedical staff, firemen, law enforcement etc.

GAEC has put in place mechanism for on-going initial and refresher training to ensure that personnel assigned to positions in the emergency organization undergo specific training with regard to the response to a radiation emergency. This includes periodic training on basics of radiation safety, continuing education and training of first responders (Law Enforcement, Army, Fire brigade, etc.) and seminars for organizations involved in emergency planning and

response for CBRN scenarios. GAEC's own personnel are trained in a periodic manner by way of scheduled programs.

A range of exercises are conducted to test out the various response plans. These include exercises for GAEC's own staff. In addition, regular exercises are conducted in coordination with first responders, such as police and fire brigade personnel. These include presentations, table top exercises and exercises in the field. Exercises are also conducted with the national coordinating body with regard to radiation emergencies. As the national competent authority under the notification and assistance conventions, GAEC participates in the international exercises of the IAEA.

The IRRS team had the opportunity to observe a table top exercise in coordination with various national emergencies simulating a potential CBRN threat scenario. The participating organizations were General Secretariat of Civil Protection, Hellenic Police including the bomb squad, Fire Brigade, Ministry of Health and GAEC. It was evident from this exercise that the various agencies were aware about the roles that they would have to carry out in a radiation emergency scenario and the relevance of GAEC into it. In addition, a visit has been organized to the headquarters of Civil Protection Emergency Centre to get an overall view of the national emergency response system. This centre is well equipped with various facilities to get real time information on emergencies developing not only within the country but also in the EU area and has systems for offering and requesting for assistance and for directing actions at the site of emergencies. The relevant agencies –like GAEC- are expected to be represented at this centre in the event of a radiation emergency.

11. TRANSPORT OF RADIOACTIVE MATERIAL

11.1. REGULATIONS AND THE GLOBAL NUCLEAR SAFETY REGIME

The transport safety requirements of the IAEA (currently known as TS-R-1) are revised periodically and are incorporated into Greek law in a rather fragmented way. The detail is primarily dependent upon the mode of transport, although GAEC has some responsibility for all modes of transport through the Radiation Protection Regulations (RPRs).

Internationally, revisions to TS-R-1 are used to inform the update of the United Nations Recommendations on the Transport of Dangerous Goods from time to time (the UN recommendations being updated biennially). These updates are subsequently transposed into specific regulations and codes for all modes of transport (augmented by mode specific requirements) by international organizations thus:

- for road transport, the United Nations Economic Commission for Europe (UNECE) through the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);
- for air transport, ICAO (International Civil Aviation Organization) through the Technical Instructions for the Safe Transport of Dangerous Goods by Air;
- for sea transport, the International Maritime Organization (IMO) through the International Maritime Dangerous Goods (IMDG) Code;
- for rail transport, the Intergovernmental Organisation for International Carriage by Rail (OTIF) via the Convention concerning International Carriage by Rail (COTIF) Appendix C – Regulations concerning the International Carriage of Dangerous (RID)

Greece has implemented laws which give effect to relevant European Directives and International Conventions and Treaties. It has therefore implemented the above modal regulations and codes through a variety of domestic legislation, specifically:

Road transport

- Government Gazette, Ministerial Decision No. 52167/4683 Folio No. 37B, 20 January 2012: Transposition of European Commission Directive 2010/61/EU in relation to Annexes A and B to the ADR as applicable with effect from 1 January 2011

Air transport

- Government Gazette, Decision No. ΥΠΑ/Δ2/11894/3631, Folio No.549, second issue, 18 April 2007: “Adoption of Annex 18, 3rd Edition, amendment 8 of the International Civil Aviation Organization on the safe air transport of dangerous goods, according to the Chicago Convention”
- The Commander of the Hellenic Civil Aviation Authority has the right to sign as Minister, orders, decisions, documents or other administrative acts under Ministerial Decision No. Δ10/Α/50277/2655 Folio No.2539/15 December 2008.
- The Commander of the Hellenic Civil Aviation Authority has the competency of policy making for safety / security and protection in aviation and to approve integrated quality and safety systems under Ministerial Decision No.Δ10/Α/14966/946 Folio No.1587/10 May 2012

- Hellenic Civil Aviation Authority Operations Procedures Manual, Chapter 2, 31 March 2010 (GAEC explained that this document is issued as an internal HCAA document in order to maintain flexibility, as it needs to be updated on a regular basis, often following ECAC review and updates)

Sea transport

- Government Gazette, Ministerial Decision No. 1218.74/1/95, Folio No. 531, second issue, 20 June 1995: "Adaptation of the International Maritime Dangerous Goods Code of the International Maritime Organization (IMDG-IMO-CODE)" (as revised from time to time)

Rail transport

- Government Gazette, Ministerial Decision No. 52167/4683 Folio No. 37B, 20 January 2012: Transposition of European Commission Directive 2010/61/EU in relation to Annex to the RID, appearing in Appendix C to the COTIF, as applicable with effect from 1 January 2011.

Greece has also implemented the Universal Postal Union (UPU) regulations.

Post

- Government Gazette, Ministerial Decision No. 504/145, Folio No. 46, second issue, 19 January 2009: "Regulation for general licensing of postal services" (as revised from time to time)

Although radioactive material is not currently transported by rail or by post in Greece, the regulatory framework exists for it to be so transported if required. Radioactive material is not transported by inland waterway in Greece.

GAEC actively participates in IAEA committees, such as the Transport Safety Standards Committee (TRANSSC), as well as a variety of international meetings and peer reviews to review and improve the transport regulations (and supporting guidance) and thereby improve the global safety regime.

In practice, GAEC's work in relation to radioactive materials transport is governed by the RPRs, with some requirements of the IAEA Regulations for the Safe Transport of Radioactive Material (actually ST-1: 1996 Edition, rather than TS-R-1: 2009 Edition) being set forth explicitly in those regulations; whilst other aspects of TS-R-1 have been (in part) addressed by the statement in 11.5 of the RPRs: *"As regards matters which have not been addressed in this Regulation ... the rules set out in the "Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. ST-1, 1996 edition", or any future revision thereof, shall apply"*. Although the intention of this statement is clear, in practice it does not allow for the situation where TS-R-1 is, or has been, revised such that its requirements conflict with the provisions set forth explicitly in the RPRs.

The RPRs also introduce supplementary requirements, such as the Greek transport licensing regime, where there is little obvious application of a graded approach and which does not fully align with IAEA or international modal requirements. For example, RPR require the licensing of all carriers of radioactive material, including carriers of Type A packages.

There is also an error, which has been recognized by GAEC, in the definition of Quality Assurance in the RPRs, whereby Quality Assurance is defined as *"a systematic program of supervisions and controls prepared and **executed by GAEC** aimed at the provision of sufficient assurance that all safety standards, as specified herein, have been practically implemented" there in;* and as *"a systematic programme of controls and inspections **applied***

by any organization or body *which is aimed at providing adequate confidence that the standard of safety prescribed in these Regulations is achieved in practice"* in TS-R-1.

11.2. COMPETENT AUTHORITY

GAEC is the Competent Authority for the safe transport of radioactive material in Greece through Government Gazette, Law No 1733, Folio No. 171, first issue, 22 September 1987: "Transfer of technology, inventions, technological innovation and establishment of the Greek Atomic Energy Commission", Article 2, paragraph (i), which states that "for the attainment of its objectives, GAEC shall have the following competences: ... it issues safety instructions for the securing, disposal, transport and storage of radioactive materials and makes proposals to competent ministers, as appropriate, for the rendering of ministerial decisions to govern the related control procedures and the observance thereof."

The RPRs also state in 1.1.3 that the GAEC is the competent authority for matters concerning radiation protection in respect of hazards arising from ionizing and non-ionizing radiation. Its responsibilities include the implementation of the Radiation Protection Regulations (which, as noted above, form the basis for the implementation of TS-R-1 requirements (other than through the modal texts)). As noted elsewhere in this report, the structure of GAEC is defined in law and hence there are significant inflexibilities associated with amending its structure.

Notwithstanding GAEC's role as competent authority, a number of other officials and official bodies have some assigned competence in relation to the transport of radioactive material, including for:

Road and rail transport

- the Minister of Economic Affairs, the Minister of Infrastructure, Transport and Networks and other competent ministers are responsible for the transposition of EC Directives into Greek domestic legislation (it is noted that GAEC were not asked for advice by the competent ministry in relation to the transposition of EC Directive 2010/61/EU)

Air transport

- the Hellenic Civil Aviation Authority (HCAA) is responsible for the ratification / transposition of conventions and regulations concerning air transport; the licensing of air carriers; and the issue of approvals for the air transport of dangerous goods

Sea transport

- the Ministry of Development, Competitiveness and Shipping has the competency for preparing legislation concerning merchant marine issues, including technical issues; inspection of cargo; and handling issues concerning the safe transport of packaged dangerous goods.

Post

- the Hellenic Telecommunications and Post Commission issues the regulations for Postal Services Licensing and has the competency of performing inspections in order to supervise and monitor postal services.

The main law providing for the protection of persons from hazards associated with ionizing radiations is Legislative Decree No. 181, Folio No. 347, first issue, 20 November 1974: "Protection against Ionizing Radiation", which also provides for penalties. The decree

provides, through Article 4 for the requirement of, and mechanism to issue, administrative authorizations; through Article 5 for the issue of regulatory decisions associated with the transport of radioactive material; and through Article 8 for penalties to be levied on "any person who intentionally releases radioactive substances conducive of risks to humans or directly or indirectly exposing humans to ionizing radiation in a way that could create risk for the life, health or property thereof."

11.3. RESPONSIBILITY FOR SAFETY

TS-R-1 places the prime responsibility for safety in the transport of radioactive material on consignors, although carriers and consignees also have some duties. The modal regulations which are given effect in Greek law also place the prime responsibility for safety in the transport of radioactive material on consignors, although 'other participants' are also assigned certain duties.

There are few consignors of radioactive material in Greece and hence the RPRs tend to focus on the carrier in relation to transport. Although consignors of radioactive material in Greece are understood to be considered by GAEC as part of facility and / or export licensing activities, it is not clear how either GAEC or other regulatory bodies with assigned competence for the modal transport regulations stipulate that compliance with regulations and requirements established by the regulatory bodies does not relieve consignors (as the person or organization responsible for transport (as an activity)) of their prime responsibility for safety. It was also noted that the RPRs do not require the consideration of emergency response arrangements as part of an application for a transport licence. The IRRS Team was told that GAEC requests the submission of emergency response plans from licensees prior to the issue of any transport license.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 Requirement 33 states that: *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained"*
	BASIS: TS-G-1.1 para 103.1 states that: *"When making national or international shipments it is necessary to consult the regulations for the particular mode of transport to be used for the countries where the shipment will be made. While most of the major modal requirements are in agreement with the Transport Regulations, there can be differences with respect to the assignment of responsibilities for carrying out specific actions"*
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.**

11.4. DELIVERY AND COORDINATION OF REGULATORY FUNCTIONS

GAEC's transport regulatory functions are performed within the Licensing and Inspections Department (LID) by a person who is suitably qualified and competent for the regulatory functions that GAEC currently provides. Some transport regulatory functions, such as multilateral approval of transport package designs; and special form radioactive material design approvals which are within GAEC's assigned competence, could not currently be performed directly by GAEC and there appears to be little resilience or defence in depth provided by the current arrangements, with no explicit succession arrangements being shared with the IRRS reviewer.

Resources available to other ministries and authorities with assigned competence for radioactive material transport were not independently verified as part of this IRRS mission. Although there are some formal communications between GAEC and their counterparts in such organizations (e.g. whereby GAEC will make proposals to relevant competent ministers if GAEC decide that an issue needs wider consideration), some communications are less formal, with a basis in personal relationships rather than process. The demarcation of responsibilities, and coordination, between different authorities would benefit from clarification and the adoption of a more systematic and inclusive approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 Requirement 7 states that: *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties"*
R22	**<u>Recommendation</u>: 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.**

11.5. OPERATIONAL ACTIVITIES AND COMPLIANCE ASSURANCE

GAEC stated that there are currently no designers of radioactive material transport packages; or of special form radioactive material in Greece. The majority of radioactive material is imported, some of which is subsequently exported. Nevertheless, some radioactive material is consigned from facilities in Greece and issues relating to the authorization and inspection regime in that regard were noted (see 'visit to cyclotron facility' in Appendix III of this report). It was also noted that a request has been made by an overseas organization for GAEC to consider how a Type B(M) package may be granted a multilateral approval in Greece.

Three types of transport licenses are issued by GAEC and are described in the RPRs, namely:

1. General licence (validity period of one year)
2. Specific licence (validity period as specified)
3. Individual licence (validity period as specified)

TS-R-1 (and the modal transport regulations) advocates a graded approach to safety via application of contents limits for packages and conveyances and to performance standards applied to package designs, depending upon the hazard of the radioactive contents; requirements on the design and operation of packages and on the maintenance of packaging, including consideration of the nature of the radioactive contents; and by requiring administrative controls, including, where appropriate, approval by competent authorities. TS-R-1 para 802 requires that competent authority approval shall be required for the following:

(a) Designs for:

(i) Special form radioactive material;

(ii) Low dispersible radioactive material;

(iii) Packages containing 0.1 kg or more of uranium hexafluoride;

(iv) Packages containing fissile material (unless otherwise excepted);

(v) Type B(U) packages and Type B(M) packages;

(vi) Type C packages

(b) Special arrangements;

(c) Certain shipments;

(d) Radiation protection programme for special use vessels;

(e) Calculation of radionuclide values that are not listed in TS-R-1 Table 2

Competent authority approval is not required for other types of packages and materials, which form the vast majority of packages transported in Greece. The Greek licensing system, however, currently requires that all such packages be authorized for carriage (via a shipment licence) by GAEC.

The relationship between the RPRs and the requirements of IAEA TS-R-1 was explored in some detail and, although there is no direct correlation between the two frameworks, there are some areas of overlap. Although it is understood that consignors of radioactive material in Greece are captured under site and / or import / export licensing, it is unclear how TS-R-1 (and modal regulation) consignor requirements are considered as part of that process, particularly within the GAEC management system. Likewise, it is unclear how failure in the duties of an overseas consignor could be remedied under Greek law.

Under the current arrangements, package approval certificates issued by the competent authority of the country of origin of a package design are evaluated by GAEC, but only in terms of expiry date; mode(s) of transport; radioisotopes; maximum radioactivity etc. This evaluation is a prerequisite for the issue of shipment license under the RPRs by GAEC, which also includes the acceptance of the package approval certificate (it should be noted that this does not extend to shipment approvals issued under TS-R-1 para 820). It is believed that such an approach brings inherent risks, as the GAEC (as the competent authority granting approval) is not able to independently verify compliance with all transport regulatory requirements.

It would therefore appear that the current arrangements (which do not fully implement IAEA requirements) are not sustainable.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: TS-R-1 para 801 states that: *"For package designs where it is not required that a competent authority issue an approval certificate, the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all the applicable requirements"*
	BASIS: TS-R-1 para 802 states that: *"Competent authority approval shall be required for the following:* *(a) Designs for...* *(i) Special form radioactive material;* *(ii) Low dispersible radioactive material;* *(iii) Packages containing 0.1 kg or more of uranium hexafluoride;* *(iv) Packages containing fissile material (unless otherwise excepted);* *(v) Type B(U) packages and Type B(M) packages;* *(vi) Type C packages* *(b) Special arrangements;* *(c) Certain shipments;* *(d) Radiation protection programme for special use vessels;* *(e) Calculation of radionuclide values that are not listed in TS-R-1 Table 2"*
R23	**<u>Recommendation</u>: GAEC should review, develop and strengthen its capacity for review and approval of package and material designs**

Examination of documents supporting licensing decision making revealed no issues concerning regulatory independence. An inspection at a cyclotron facility was observed by IRRS team members on 24 May 2012, where the relationship between regulator and operator appeared cordial but professional and effective and no inappropriate behaviours were observed.

GAEC presented the IRRS reviewer with several files of documents which provided objective evidence of their written interactions with authorized parties (carriers). The interactions appeared to be appropriate, with clear communications and written justifications for decisions available, together with explanations of the basis of decisions.

Due to lack of English translations of certain documents, it was not possible for the IRRS Team to verify the content of key local procedures relating to radioactive material transport inspection activities, although the content of the procedures were described to the IRRS reviewer. It was noted that procedures for the transport functions relating to assessment and licensing do not currently exist.

Although no evidence was found of inconsistent decision making in relation to radioactive material transport, stability and consistency of regulatory control appear to be achieved more by reference to the same individual doing the job in the same way, than by reference to published processes and procedures.

GAEC does not currently obtain technical or other expert professional advice or services from other bodies in support of its radioactive material transport regulatory functions.

GAEC does not publish an enforcement policy statement (see section 8 of this report) which presents difficulties in terms of the regulatory body being able to justify its enforcement decision making as consistent and proportionate. Enforcement policy established by other

ministries and agencies with assigned competence in relation to radioactive material transport was not determined.

Nevertheless, the reviewer established that GAEC deal with:

- serious non-compliances by informing their manager; the Licensing and Inspections Director; and involve the GAEC lawyers
- less serious non-compliances by writing to the authorized party explaining the circumstances of the non-compliance and requiring certain corrective actions to be implemented within a specified time period.

There are currently five approved road carriers of radioactive material in Greece. These organisations are inspected periodically as part of GAEC's carrier licensing process.

The inspection of radioactive material during transport by road falls under the competence of the Joint Inspection Groups (JIGs), of which GAEC is now a member by virtue of Article 15.1 of Government Gazette, Law No. 3710, Folio No. 216, first issue, 23 October 2008: "Regulations for transport issues and other topics", which amends Government Gazette, Law No. 2801, Folio No. 46, first issue, 3 March 2000: "Regulations regarding responsibilities of the Ministry of transport and Communications".

The constitution of a JIG is constrained by law, and comprises:

- 2 members from the Transport Directorate of the relevant Prefecture;
- 1 member from the Traffic Police or the Coastguard;
- 1 member from another Directorate of the relevant Prefecture (if deemed necessary);
- 1 member from GAEC (if deemed necessary)

In the case of the transport of radioactive material by road, whether by a licensed carrier or otherwise, one member of GAEC participate in a JIG if it is deemed necessary by the leader of the JIG. As the leader of the JIG is likely to be from the Transport Directorate of the relevant Prefecture, it is unclear how GAEC may participate in the JIGs, other than at their instigation. No programme for such participation currently exists, and GAEC has not as yet participated in JIGs. This appears to be a gap in GAEC's inspection arrangements.

The Hellenic Civil Aviation Authority (HCAA) inspects air carriers as part of its role. GAEC provide radiation protection advice to the HCAA, but do not participate in airside inspections. Air carrier licensing is required and inspections are performed by HCAA Aviation Safety Inspectors and Aviation Security Inspectors. Greece is also one of 42 European states engaged in the Safety Assessment of Foreign Aircraft (EC SAFA) programme.

GAEC are not routinely involved in the inspection of the transport of radioactive material by sea (of which it is understood that there are very few trans-shipments and no imports).In the few cases of trans-shipments through Greece, it is understood that GAEC co-operates with the Ministry of Development, Competitiveness and Shipping in terms of licensing, monitoring and re-assuring physical protection of the shipments. There is currently no transport of radioactive material by rail in Greece; and radioactive material is not currently sent by post in Greece. Hence no inspections in relation to rail or post are performed.

GAEC's various inspection programmes are largely driven by the expiry of licenses and authorisations. Although there appears to be some opportunity and willingness to introduce reactive inspections into the programme, it is unclear on what basis such inspections are selected and executed; and that, in relation to transport, it was noted that no such inspections were performed during 2011.

During an inspection of a cyclotron facility observed by IRRS team members during the mission, several instances of non-compliance with transport regulatory requirements by the consignor were noted, including:

- Package inspected was incorrectly marked and labelled
- No consignment documents are produced by the consignor
- Package was approved against a superseded version of the IAEA transport regulations

These (or similar) non-compliances are believed to have persisted for some time without regulatory intervention. Furthermore, GAEC did not inspect the consignor's management system arrangements for adequacy; nor seek clarity of, and check compliance with, maintenance requirements for the reusable packaging being used by the consignor.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: TS-R-1 para 307 states that: *"The competent authority is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, special form radioactive material and low dispersible radioactive material, and the preparation, documentation, handling and stowage of packages by consignors and carriers, to provide evidence that the provisions of these Regulations are being met in practice."*
R24	**Recommendation: GAEC and other transport competent authorities should implement appropriate, co-ordinated, compliance assurance programmes.**
S10	**Suggestion: GAEC and other transport competent authorities should consider using IAEA TS-G-1.5 in developing their compliance assurance programme(s).**

12. CONTROL OF MEDICAL EXPOSURES

Medical Facilities are licensed by Prefectures following certification by GAEC based on Chapter 1 of the Radiation Protection Regulations (MD5, 2001). The 9-member Special Committee, within the Ministry for Health and Welfare has a role in pre-feasibility and operational licensing of Facilities (Section 5) as well in regard to justification and referral guidelines. The role of the Prefecture is to issue licences when all requirements for the establishment of a medical facility including general safety issues are satisfied including the certificate of compliance issued by GAEC.

General principles of radiation protection applied to medical exposures include justification, optimization and reference levels. GAEC issues circulars in order to inform licence holders about expectations in terms of inspections and new equipment.

The inspection group in GAEC responsible for medical exposure control is comprised of 10 medical physicists and 3 medical technologists (2 holding Masters degrees in medical physics). The staff are divided mainly in the following areas: 8 inspectors in radiology, 3 inspectors in nuclear medicine and 2 inspectors in radiotherapy.

In 2011, there were 180 nuclear medicine, 1200 radiology, and 13000 dental facilities. For radiotherapy, there were 36 linear accelerators, as well as 9 Co teletherapy and 10 brachytherapy equipment. As well as responsibility for authorization, inspections and licensing, GAEC plays an important role in continuing education, training, certification of personnel and accreditation of courses in radiation protection.

12.1. RESPONSIBILITIES

In MD5, the definition of “radiological medical practitioner” (MD5 1.1.7 (e) and 1.1.7.1.3) includes radiologists, nuclear medicine physicians, radiation oncologists and dentists. There is no training program in radiation protection established for cardiologists, orthopaedics surgeons and other specialties other than radiologists who conduct radiological procedures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR part 3 para 2.32 states that: “*The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety.*”.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR part 3 para 3.149 states that: "*The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals". with specific duties in relation to the radiation protection of patients) to take on the responsibilities specified in these Standards only if they:* *(a) are specialized in the appropriate area;* *(b) meet the respective requirements for education, training and competence in radiation protection, in accordance with para. 2.32;* *(c) are named in a list maintained up to date by the registrant or licensee."*
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.**

According to the regulations (MD5 1.1.4.3), registrants and licensees should ensure each medical exposure is prescribed by a medical practitioner. Currently, the regulatory body has no means to verify whether a licensee fulfils this requirement.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR part 3 Requirement 36states that: "*Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks*"
R26	**<u>Recommendation</u>: GAEC should verify that no person incurs a medical exposure unless there has been an appropriate referral**

The actual classification expressed in Radiation Protection Regulations for the facilities and practices does not include new technologies. Consequently, the application of regulatory requirements is not commensurate with the radiation risk associated with the exposure situation. In radiology, multi-slice CT scanners, digital radiology systems, cone beam CT, and other new equipment are not included in the classification system in the RPRs. Furthermore, specific requirements concerning the type and the characteristics of the equipment used in diagnostic radiology are given in par. 3.6 of the Radiation Protection Regulations. The inflexibility of the regulations causes a regulatory gap in regard to new technologies. Recommendation R19 in Section 9 also applies to this situation.

12.2. JUSTIFICATION OF MEDICAL EXPOSURES

The Radiation Protection Regulations require the justification of medical exposures. Best practice in the justification of medical exposures involves the use of referral guidelines or criteria established by the collaboration of professional bodies, health authorities and regulators. In 2011, detailed referral guidelines for radiological procedures were developed by a collaboration involving the Hellenic Radiological Society, the Ministry of Health and GAEC. These guidelines have been published by the Hellenic Radiological Society.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR part 3 para 3.157 states that: "*Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure*".
GP6	**<u>Good Practice</u>: In 2011, referral criteria were published by the Hellenic Radiological Society based on European Guidance.**

12.3. OPTIMIZATION OF PROTECTION AND SAFETY

The Radiation Protection Regulations require the optimization of protection for medical exposures. National DRLs are established by GAEC for mammography and nuclear medicine. GAEC is carrying out surveys of all imaging procedures and establishing national DRLs values. Facilities are required to generate local DRLs; however, the use of DRLs for the optimization of radiology practices is not widespread in Greece.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR PART 3 para 3.147 states that: "*The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures….*"
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.**

The National Radiation Protection Database developed by GAEC is an excellent tool for the evaluation of patient doses and DRLs. The utility of the database has been discussed in other sections of the report and is mentioned as a good practice in section 3.

13. OCCUPATIONAL RADIATION PROTECTION

13.1. LEGAL / REGULATORY FRAMEWORK

A legislative and regulatory framework is established to provide for Occupational Radiation Protection through:

- Legislative decree 181, Folio N°347, article 5-3-a “Issuance of regulatory decisions”, which mentions “protection of radiation workers during their work”.
- Government Gazette, Legislative Decree 181, Folio N°347, First issue, November 20, 1974, “Protection against ionizing radiation” ;
- Government Gazette, Joint Ministerial Decision n° 1014 (FOR) 94, Second issue, Folio N° 216, March 6, 2001, “Approval of Radiation Protection Regulations” ;
- Government Gazette, Ministerial Decision n° 9087 (FOR) 1004, Folio N°849, Second issue, September 13, 1996 “Operational protection of outside workers exposed to the risk of ionizing radiation protection during their activities in controlled areas”.

The Joint Ministerial Decision n° 1014 (FOR) 94 (FOR) 94 is organised in 12 parts. Parts 1 and 2 provide general radiation protection principles (justification, optimisation and limitation) and general requirements for licensing respectively. Parts 3 to 12 provide detailed specific requirements relative to a specific practice.

Effective and equivalent dose limits for exposed workers, for apprentices and students are described in the paragraphs 1.2 and 1.3 of the Joint Ministerial decision n° 1014. Requirements are given for any single year and for 5 year period and in practice, the doses are checked against the last twelve running months through the national dose register.

Dose limits are consistent with GSR Part 3, except for the annual equivalent dose limit for the lens of the eye (20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and 50 mSv in any single year) which has not yet been implemented.

Article 1.1.3.b of the Joint Ministerial Decision n° 1014 (FOR) 94 states that GAEC shall lay down dose constraints for the workers.

Article 1.4.1 of the Joint Ministerial Decision n° 1014 (FOR) 94 states that the values of annual external exposure for each practice in any single year is recommended not to exceed 5/10 of the dose limits laid down in paragraphs 1.2.1, 1.2.2 and 1.3.2.

Article 1.4.2 of the Joint Ministerial Decision n° 1014 (FOR) 94 states that the values of annual intake by inhalation or ingestion in any single year for each practice or intervention is recommended not to exceed three-tenths of the dose limits laid down in paragraphs 1.2.1, 1.2.2 and 1.3.2.

GAEC uses the data registered in the National Dose Registry and the third quartile method to assess dose constraints for each category of medical exposed workers. These values are then part of the discussions on optimisation performed with the licensees during inspections, within a pilot study.

Article 1.2.a of the Joint Ministerial Decision n° 1014 (FOR) 94 requires that no person under the age of 18 years may be assigned to work which would result in becoming exposed workers. The regulations do not require that no person under the age of 18 years shall be allowed to work in a controlled area unless supervised and then only for the purpose of

training. However, article 1.2.3.1 of the Joint Ministerial Decision n° 1014 (FOR) 94 fixes dose limits for such persons.

Article 1.2.3 of the Joint Ministerial Decision n° 1014 (FOR) 94 provides requirements for specially authorized exposures. GAEC can determine dose constraints or committed doses, case by case. The dose may exceed the double of the annual dose limit (40 mSv) and cannot exceed five times the annual dose limit (100 mSv) in the lifetime.

Article 1.2.4 of the Joint Ministerial Decision n° 1014 (FOR) 94 provides guidance for limitation of exposures of workers undertaking intervention in emergency situations. GAEC may determine dose constraints or committed doses, case by case. The dose may exceed the double of the annual dose limit (40 mSv) and cannot exceed five times the annual dose limit (100 mSv) in the lifetime.

The Joint Ministerial Decision n° 1014 (FOR) 94 requires an emergency plan for radiotherapy laboratories (article 5.8.3), sealed source irradiators (article 9.6.2.g) and particle accelerators installations (article 10.5.3.e).

For implementing the regulations, article 2.2.3 of the Joint Ministerial Decision n° 1014 (FOR) 94 requires the presence of different “qualified experts”, depending on the practice: specialist radiation protection adviser, radiation protection programme officer, radiation protection officer for non-medical applications, medical physics expert for medical applications. All must be recognised by GAEC.

However, the regulations do not specify who designates these qualified experts.

13.2. GENERAL RESPONSIBILITIES OF REGISTRANTS, LICENSEES AND EMPLOYERS

Only licenses are issued, there is no registration process in place.

There is no clear statement in the regulations about:

- assigning the prime responsibility to the licensee
- the responsibilities of the employer of the exposed workers
- assigning the responsibility to the licensee or to the employer to ensure that optimisation is in place
- assigning the responsibility to the licensee or to the employer to ensure that the dose limits for the workers are not exceeded.

According to the regulations, the Radiation Protection Officer (RPO) for non-medical applications and medical physics experts (as RPO) for medical applications share the responsibility of the radiological protection of the workers with the licensee, when submitting to GAEC a file to be licensed.

Only concerning the radiation protection of the outside workers, the Ministerial Decision n°9087 (FOR) clearly states the responsibilities of the “operator” (licensee) and the “outside undertaking” (employer of the outside worker).

There is no clear statement in the regulations requiring employers to make every reasonable effort to provide workers with suitable alternative employment in circumstances where it has been determined, either by the Regulatory Authority or in the framework of a health

surveillance programme, that the worker, for health reasons, may no longer continue in employment involving occupational exposure.

13.3. GENERALRESPONSIBILITIES OF WORKERS

Article 1.1.7.1 of the Joint Ministerial Decision n° 1014 (FOR) 94 states that, in addition to the specialists in radiation protection such as the RPO, any of the following shall have direct responsibility for implementing the regulations: radiologist, radiotherapist, practitioner of nuclear medicine, dentist, technical service officer, radiographer, technologist-radiologist, operator developer, operator-assistant and radiography assistant.

Article 1.5.3.2 of the Joint Ministerial Decision n° 1014 (FOR) 94 states that exposed workers, apprentices and students shall comply with the technical, medical and administrative requirements.

There is no general statement in the regulations requiring workers to use properly the monitoring devices and the protective equipment and clothing provided by the employer, registrant or licensee.

Some parts of the Joint Ministerial Decision n° 1014 (FOR) 94 concerning specific activities, require workers to make proper use of the monitoring devices and the protective equipment and clothing (paragraph 3.7.2 for radiological procedures, paragraph 3.8.9 for fluoroscopy, paragraph 3.9.3 for radiography, as examples).

There is no clear statement in the regulations requiring workers:

- to cooperate with the employer, registrant or licensee with respect to protection and safety and the operation of radiological health surveillance and dose assessment programmes;
- to refrain from any wilful action that could put themselves or others in situations that contravene the requirements of the regulations
- to accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the regulations.
- to report to the employer, registrant or licensee if, for any reason, they are able to identify circumstances that could adversely affect compliance with the regulations. In practice, workers sometimes report on such circumstances to GAEC who then investigates the subject with both employees and employers.

13.4. REQUIREMENTS FOR RADIATION PROTECTION PROGRAMMES

Requirements for radiation programmes are provided in the Joint Ministerial Decision n° 1014 (FOR) 94:

- controlled areas (paragraph 1.5.2.1) and supervised areas (paragraph 1.5.2.2) shall be assessed under the responsibility of RPO and submitted to GAEC by “official channel” and, if approved by GAEC, implemented under the responsibility of the undertaking in collaboration with the RPO and medical practitioner. The means by which the controlled areas shall be managed are specified;

- classification of exposed workers, apprentices and students (paragraph 1.5.3) in category A and category B shall be made. There is no requirement on the responsibility of this classification;
- information and training (article 1.5.3.2) are provided to exposed workers, apprentices and students by the RPO and the authorized medical practitioners, under the responsibility of the licensee holder, and are recognised by GAEC.

Women must be informed of the need for early declaration of pregnancy in view of the risks of exposure for the child to be born and the risk of contaminating the nursing infant in case of bodily radioactive contamination.

The regulations do not require employers, in co-operation with registrants and licensees, to keep records of the training provided to individual workers.

However, the training programme of the personnel is investigated during the regular and unscheduled inspections of GAEC.

Those workers who could be affected by an emergency plan (article 1.2.4) shall be volunteers and provided with appropriate information, instruction and training by the RPO and the authorized medical practitioner.

Assessment and implementation of arrangements and equipment controls (protective equipment and measuring instruments for radiation fields and contamination) shall be under the responsibility of the RPO (article 1.5.3.2)

Monitoring of workplaces including external dose rates, air activity concentration and surface activity concentration shall be under the responsibility of the RPO (article 1.6.2).

The nature and the frequency of assessment of exposure of workplaces shall be determined by the RPO (article 1.6.1).

The records of the workplace monitoring shall be kept in a special log book which shall be certified by the license holder and shall be open to the scrutiny of GAEC (article 1.6.1).

Individual monitoring shall be systematic for category A workers (article 1.6.3.2) and monitoring for category B workers shall be at least sufficient to demonstrate that their categorisation is correct.

GAEC may require individual monitoring for category B workers. In practice, almost all category B workers are individually monitored.

In cases where individual monitoring for any worker is inappropriate, inadequate or not feasible, the individual monitoring shall be based on an estimate from either individual measurements made on other exposed workers or from the results of surveillance of the workplace provided (article 1.6.3.2).

Article 1.6.3.2 requires any worker liable to receive significant contamination to be provided with appropriate medical monitoring.

The occupational exposure records shall be retained by GAEC until the individual has or would have attained the age of 75 years, but in any case for a period of at least 30 years from the termination of the work involving exposure to ionizing radiation.

GAEC sends the individual dosimetry results to the employer and to the workers. The employer keeps these records in a special log book which must be accessible upon request to any worker and to his occupational physician.

In any case where the effective dose received by a worker exceeds 6 mSv per year, the RPO shall investigate the reasons and, where necessary, propose that suitable measures be adopted and submit a written report through the official channels to GAEC.

In protocols issued by GAEC (CD1 and CD7) there are investigation levels for the instantaneous dose rates.

Medical surveillance (article 1.7) shall be based on the general principles of occupational medicine and on the special principles arising from the requirements of radiation protection.

The regulations do not require employers to make every reasonable effort to provide workers with suitable alternative employment in circumstances where it has been determined, either by the Regulatory Authority or in the framework of a health surveillance programme, that the worker, for health reasons, may no longer continue in employment involving occupational exposure.

Recording of the following results shall be kept by the RPO in a special log book checked by the license holder and open to the scrutiny of GAEC: collective monitoring measurements, monitoring in workplaces and all data available related to the assessment of individual doses, equipment controls, effectiveness of protective devices, individual dosimetry results, medical surveillance of the worker.

13.5. MONITORING PROGRAMME TECHNICAL SERVICES

Article 1.6.3.1 of the Joint Ministerial Decision n° 1014 (FOR) 94 states that GAEC is the competent body to coordinate the individual dose monitoring of exposed workers. Such monitoring shall be conducted by the Personal Dosimetry Department of GAEC or by suitable laboratories of other bodies which have been authorized by GAEC.

In practice only GAEC performs the individual monitoring of all occupationally exposed workers in Greece, for external dosimetry and internal dosimetry (whole body counting, thyroid intake and bioassays on urines and faeces). The dosimetry service is operated by the Personal Dosimetry Department of GAEC. The service is accredited by the Hellenic Accreditation Council according to ISO/IEC 17025 to perform measurements of Hp(10) and Hp(0.07) in photon beams using whole body and extremity dosemeters.

Also biological dosimetry can be performed at the Institute of Nuclear Technology and Radiation Protection located at Demokritos Center.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: RS-G-1.1 para 7.18 states that: *"Only at doses much higher than the dose limits (i.e. 0.2–0.5 Sv or higher) will special dose investigations involving biological dosimetry… be necessary"*
GP7	**<u>Good Practice:</u> Greece has developed the technical capability to perform biological dosimetry in case of overexposures.**

Article 1.6.4.2 of the Joint Ministerial Decision n° 1014 (FOR) 94 states that GAEC shall keep the national dose registry of all the occupationally exposed workers in Greece. This national dose registry is kept by GAEC since 1963 and on an electronic form since 1989.

GAEC uses this national dose register to set up trigger levels to check the exceeding dose limits, to issue dose passbooks for outside workers in compliance with the Joint Ministerial decision n° 849 and to provide the life dose to the exposed worker on request. This supports the excellence of the national radiation protection database as mentioned in section 3.7.

Article 1.6.2 of the Joint Ministerial Decision n° 1014 (FOR) 94 states that measurements at workplaces shall be carried out by the RPO who is recognised by GAEC.

Article 1.2.5.8 of the Joint Ministerial Decision n° 1014 (FOR) 94 requires that radon measurements at workplaces be performed by GAEC or by a natural or legal person duly authorized by GAEC.

Article 1.5.3.2 of the Joint Ministerial Decision n° 1014 (FOR) 94 requires information and personnel training be provided under the responsibility of the licensee by the RPO recognised by GAEC and the authorised medical practitioners. GAEC provides training and seminars as well, in cooperation with education providers who are certified and approved by GAEC.

14. CONTROL OF RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE

The Radiation Protection Regulations (MD5, 2001) establish specific requirements (conditions and criteria) in Chapter 6 for the control of radioactive discharges. These specific requirements are provided for radioactive discharges for various types of radioactive waste.

Dose constraints for discharges were established at the same level as for exemption and clearance of about 10 μSv/a, while in the case of external exposure of the whole body or of a substantial fraction of the body, the value of annual external exposure for each practice in any single year is recommended not to exceed 50% of the public dose limits and, in the case of internal exposure, the values of annual intake by inhalation or ingestion in any single year for each practice or intervention is recommended not to exceed 30% of the public dose limits.

Prescriptive limits with respect to radioactive discharges have been adopted. The operator is allowed to discharge a daily fixed amount of liquid radioactive materials accordingly. In addition, it is established (Radiation Protection Regulations) that liquid waste may be released from a washbasin or other suitable container designated for this purpose to the public sewage system together with a considerable quantity of running water and on the further condition that the waste is dispersed or immediately dissolved in the water. Daily limits for discharges together with the possibility of legally diluting liquid radioactive materials for discharge complicate the optimization process of discharge controls.

Although there are provisions in the legislation providing the maximum acceptable activities that may be released daily, there is no clearly established requirement for registrants and licensees, before initiating the discharge of any solid, liquid or gaseous radioactive substance from sources under their responsibility to the environment to determine the characteristics and activities of the materials to be discharged; the potential locations and methods of discharge; the determination by an appropriate pre-operational study of all significant exposure pathways by which discharged radionuclides can deliver public exposure; the assessment of doses to the critical groups due to the planned discharges; and to submit this information to the Regulatory Body as an input to establish and review of the authorized discharge limits and the conditions for their implementation.

The Radiation Protection Regulations (MD5, 2001) require licensees to report to the Regulatory Body any significant increase in contamination that could be attributed to the radiation or radioactive discharges emitted by sources under their responsibility only if the event of the dose constraints is being systematically exceeded. Nevertheless, the IAEA Safety Requirements require licensees to promptly report to the Regulatory Body any discharges exceeding the authorized discharge limits in accordance with reporting criteria established by the Regulatory Body.

There is no requirement for applicants or licensees for when a source within a practice, which could cause public exposure outside Greek territory, to perform an assessment of the radiological impacts, including those impacts outside the territory or other area under the jurisdiction or control of Greece; and to establish to the extent possible, how discharges are to be controlled.

For reasons mentioned above, it was discussed with the GAEC specialists that the Radiation Protection Regulations in force are not totally in line with IAEA Basic Safety Standards (BSS 115 and GSR Part 3 (interim)) and, in reviewing the MD5 Radiation Protection Regulations, GAEC will need to take into account the latest international recommendations for the regulation and control of radioactive discharges (See Recommendation R19 in section 9).

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

The Radiation Protection Regulations do not require licensees to have monitoring programmes covering the whole lifecycle of facilities in place whenever they are needed. Such requirements are, however, explicitly provided for in the regulations for nuclear safety and the licensing procedure for the Greek research reactor. Since the time the self assessment tool phase of the IRRS mission was completed, a Presidential Decree for the transposition of the EC Directive for nuclear safety has been issued. The requirement for a monitoring program for the research reactor is explicitly provided in the draft Ministerial Decision (sixth point of the Article 15) to be issued under the above Presidential Decree.

The IRRS team was informed that a Ministerial Decision No. 11592 (FOR) 1125 on "Mandatory installation and use of equipment for the detection of radioactive materials in scrap metals and for their illicit import" has established a compulsory monitoring programme for scrap metal recycling industries using portal and handheld detectors, in order to reduce the risk for a radioactive source melting and giving rise to radioactive contamination. The establishment of such a monitoring programme is also mandatory within the customs controls of the country whereby equipment with special measuring devices is used for the detection of any illicit import of radioactive materials. According to this Ministerial Decision, the Greek Atomic Energy Commission (GAEC) shall determine, for each industry and custom, the number and the specifications of the required detection devices, the necessary personnel for their use and the related control procedures.

The IRRS team was also informed that, in medical applications and taking into account the quantity of imported radionuclides, GAEC has concluded that operators are not obliged to establish routine monitoring programmes. Instead, GAEC performs these environmental impact studies. In the case of Athens two main scenarios have been considered: a) workers in the sewage system in the vicinity of hospitals and b) workers in the central waste treatment plant in Psitalia. The key factors are: in the first case the radionuclide released from the hospitals or the medical laboratories and in the second case the total amount of radionuclide releases from all the medical applications in Athens region.

In NORM applications, a routine environmental monitoring programme is performed by GAEC for operating phosphogypsum stacks. Samples of underground water and soil samples are taken and measured. Additionally, contaminated materials from inside the factory (e.g. metal and plastic tubes) are inspected by GAEC.

GAEC has established and implements a detailed licensing process to ensure the avoidance of radioactive discharges above the limits. Article 6.10 of the Radiation Protection Regulations requires licensees to keep records of all released radioactive materials.

The IRRS team was informed that a national environmental surveillance network has been established in the country which includes:

a. the operation of a network of telemetric stations installed across the country consisting of:
    - 24 stations monitoring the total gamma dose rate in air; and
    - 3 aerosol monitoring stations.
b. air filter measurements, which are performed by GAEC and a network of collaborating laboratories.

It should be noticed that GSR Part 3 (interim) clearly expresses that the regulatory body shall be responsible, as appropriate, for:

(a) Review and approval of monitoring programmes of registrants and licensees, which shall be sufficient for: verifying compliance with the requirements of these Standards in respect of public exposure in planned exposure situations; assessing doses from public exposure;

(b) Review of periodic reports on public exposure (including results of monitoring programmes and dose assessments) submitted by registrants and licensees;

(c) Making provision for an independent monitoring programme;

(d) Assessment of the total public exposure from authorized sources and practices in the State on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments;

(e) Making provision for maintaining records of discharges, results of monitoring programmes and results of assessments of public exposure; and

(f) Verification of compliance of an authorized practice with the requirements of the standards for the control of public exposure;

while licensees shall, as appropriate, establish and implement monitoring programmes.

When reviewing the MD5 Radiation Protection Regulations, GAEC should take into account the latest IAEA recommendations for the environmental monitoring covered in GSR Part 3 (interim).

It should be noted that the Radiation Protection Regulations in force are not totally aligned with IAEA Basic Safety Standards (BSS 115 and GSR Part 3 (interim)) regarding environmental monitoring associated with authorized practices for public radiation protection purposes and in reviewing the MD5 Radiation Protection Regulations GAEC will also need to take into account the latest IAEA recommendations for the regulation and control of radioactive discharges covered in GSR Part 3 (interim) (See Recommendation R19 in section 9).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: The IAEA Code of Conduct on the Safety and Security of Radioactive Sources, para 9 states that: "*Every State should ensure that appropriate facilities and services for radiation protection, safety and security are available to, and used by, the persons who are authorized to manage radioactive sources. Such facilities and services should include, but are not limited to, those needed for:* *(a) searching for missing sources and securing found sources; ...."*
GP8	**<u>Good Practice:</u> GAEC requires the scrap metal industry and the customs authorities to establish portal monitoring.**

16. CONTROL OF CHRONIC EXPOSURES AND REMEDIATION

GAEC is the responsible regulatory body, from a radiation protection point of view, for any activity or practice that involves radioactivity. This includes radon, NORM, drinking water and remediation activities. Nevertheless the Radiation Protection Regulations in section 1.2.5 establish requirements only for the regulation of "Occupational exposure with significant increase due to natural radiation sources". In addition to the clearance levels established in the Radiation Protection Regulations, GAEC has issued a circular (CD3, "Clearance levels of Naturally Occurring Radioactive Materials") which adopts the European standards for the clearance of NORM.

A detailed review of the Radiation Protection Regulations in force against BSS 115 and the latest international recommendations, GSR Part 3 (interim) showed that the RPRs do not conform with all the recommended requirements for existing exposure situations (before "chronic exposure") (Recommendation R19 in section 9 also applies to this situation). For example: provisions for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting appropriate strategies in place for radioactive waste management are addressed in the RPRs. It is not required that a strategy for radioactive waste management is put in place to deal with any waste arising from remedial actions, nor that provision for such a strategy be made in the framework for protection and safety.

The requirements that persons or organizations responsible for the planning, implementation and verification of remedial actions shall, as appropriate, ensure that a remedial action plan, supported by a safety assessment, is prepared and is submitted to the regulatory body or other relevant authority for approval are not set down in the RPRs, and those regulations do not require the person or organization responsible for post-remediation control measures to establish and maintain (for as long as required by the regulatory body or other relevant authority) an appropriate programme, including any necessary provisions for monitoring and surveillance, to verify the long term effectiveness of the completed remedial actions for areas in which controls are required after remediation has been completed. The legal framework does not provide for specific restrictions that may be placed upon the use of or access to an area before, during and, if necessary, after remediation. Such restrictions are defined by GAEC on an ad hoc basis, taking into account societal factors.

The reference levels established in the Radiation Protection Regulations for the exposure due to radon in workplaces need to be reviewed in accordance with the latest recommendations (GSR Part 3 (interim), para 5.27) which requires that the reference level for ^{222}Rn shall be set at a value that does not exceed an annual average activity concentration of ^{222}Rn of 1000 Bq/m^3, taking account of prevailing social and economic circumstances. The IRRS team was instead informed about special provisions for different activities performed by GAEC.

NORM

The main activities performed by GAEC concerning NORM are the following:

- inspections inside NORM industries for occupational exposure control purposes;
- assessment of environmental impact of NORM depositions;
- management (control or clearance) of materials contaminated with NORM;
- decommissioning of NORM industrial activities after cessation of operations; and
- regulation of NORM in building construction materials or in agricultural applications.

The IRRS team noted that the management of affected areas is controlled by the local authorities and the operator under the guidance of GAEC, through the review of relevant hazard reports and remediation plans. The responsibility to investigate and designate contaminated areas that require remediation is assigned to GAEC.

Remedial actions

The IRRS team was informed that remediation and decontamination activities are made on an ad-hoc basis under the general requirements (dose limits and constraints, clearance levels, radiation protection of workers and the public etc), described in the Radiation Protection Regulations for planned exposure situations. The most extensive project of remedial actions has been performed in an abandoned fertilizer industry in the Drapetsona area, near the port of Piraeus. The owner signed an agreement with a private company which specializes in the decontamination of chemical waste. The private company submitted alternative techniques for the decontamination of the area to GAEC, who subsequently approved and supervised the final strategy and performed all required measurements (surveys of surface dose rates and laboratory measurements of samples). For the unconditional release of the land, GAEC also performed extensive surveys which confirmed that the dose rate and the radium concentration were within the levels of the area's background.

Although a stricter legal assignment of responsibilities between GAEC, operators and the local authorities is needed, the remedial actions that have been undertaken were completed successfully and the cooperation between the relevant parties was satisfactory.

Radon

The RPRs provide the legislative framework for the protection of workers from exposure to radon. For indoor radon concentrations, GAEC performs measurements and incorporates the measurements performed by the collaborating university laboratories into the national radon map. The measurements are performed for two purposes: (i) to respond to requests from individual persons or companies and (ii) to create the Greek radon map. The concentration limits in force are those provided in the EC Recommendation "on the protection of the public against indoor exposure to radon" (90/143/EURATOM) dated 21 February 1990. About 600 measurements have been performed annually since 2009 using passive radon detectors. In cases where the limits are exceeded, users must perform remedial actions and bear the cost of such remediation. When needed, GAEC assesses the risk and informs the owners and the public. In a few cases (e.g. increased radon concentration above limits in a public school) sequential measurements have been performed by GAEC, free of charge, and remedial actions have been taken by external providers.

The construction of the Greek radon map is in progress (half of Greece has been covered). The map is expected to be completed within the next three years.

Drinking water

GAEC performs radioactivity measurements in drinking water according to EC Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. The limit for the total indicative dose (TID) is 0.1 mSv/a. The verification of the TID is performed by GAEC determining the total α/β radioactivity and the uranium isotopes concentration. GAEC then issues certificates of compliance (from a radiation protection point of view) for drinking water, as part of the whole licensing process coordinated by the Ministry of Health (MD16). The IRRS team was informed that a new EU Directive is in preparation which will

specify detailed radionuclide concentration limits. We were told that Greece will follow this Directive as soon as it is issued.

Spring water

Concerning spring water from spas, GAEC is responsible for the accreditation of the laboratories that perform measurements of Ra-226 and Rn-222, as part of the licensing procedure of the spas coordinated by the Greek Tourism Organization. In practice, GAEC laboratory is the only laboratory in Greece which can perform radium-226 and uranium isotopes measurements in water and issues the appropriate certificate of compliance from a radiation protection point of view.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GSR Part 1 para 4.6 states that: *"Requirements 3 and 4 in Section 2 stipulate that the government establish and maintain a regulatory body that is effectively independent in its decision making and that has functional separation from entities having responsibilities or interests that could unduly influence its decision making. This imposes an obligation on the regulatory body to discharge its responsibilities in such a way as to preserve its effective independence"....*
	BASIS: GSR Part 3 para 5.12 states that: *"The persons or organizations responsible for the planning, implementation and verification of remedial actions shall, as appropriate, ensure that:* *(a) A remedial action plan, supported by a safety assessment, is prepared and is submitted to the regulatory body or other relevant authority for approval..."*
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.**

17. POLICY ISSUES DISCUSSIONS

The policy discussions were held during a 3 hour session on Tuesday 28 May 2012. Mr. Peter Johnston, Deputy Team Leader, chaired the discussions.

17.1. INDEPENDENCE OF THE REGULATORY BODY

Mrs. V. Kamenopoulou introduced the discussion, by emphasizing the issue of independence of the regulatory bodies in countries that do not have nuclear power, where the size of the regulatory body is much smaller. The purpose of the discussion was to identify areas for GAEC to further improve its effective independence, and to consolidate arguments towards the establishment of an independent regulatory body in Greece.

Mr. P. Johnston made a short presentation on a number of issues relating to independence of GAEC. He noted that GAEC is located on the same site as a major user of radiation sources; that it has the same reporting lines as a number of license holders, and that the independence of GAEC has been raised at international meetings e.g. Joint Convention.

It was important to acknowledge the threat of lack of independence, but to do the regulatory tasks thoroughly. An evaluation of the independence of the regulatory body should be based on its performance. The importance of moral authority (e.g. setting of standards, discussing issues with funding organizations) was considered as being as important as the legal authority.

It was noted that all regulatory bodies receive funding from Governments, and were required to report to a Government. The importance of reporting to a Minister with technical responsibilities over non-technical was highlighted. It was important to assess how being placed in the alternative Ministries would also affect the independence of the regulatory body. There were issues relating to conflicts of interest if located in the Ministry for Health; over low political profile if located in a Ministry of Environment; and of being a small cog in a large Ministry if located in the Ministry for Industry. Experts on the review team provided examples of the funding and reporting lines of the regulatory bodies in their countries.

A number of issues were discussed that may threaten the independence of the regulatory body. It was considered that not enforcing the law and regulations, and allowing some facilities to operate without a license creates a negative impression. Where the regulator provides technical services, providing a technical service badly will affect its moral authority. It is important that there is functional separation of the regulatory activities from the provision of technical services in the structural organization of the regulatory body. Experts shared views that it was particularly important for the persons involved in the provision of technical services were not carrying out regulatory review and assessment of reports from licensees and from applicants for licenses.

17.2. LONG TERM POLICY ON MANAGEMENT OF RADIOACTIVE WASTE

Mr. C. Potiriadis noted that Greece was a non-nuclear country with a research reactor. He added that the spent fuel from the research reactor would be returned to the USA. He said that there was an interim radioactive waste storage facility in Greece that was unlicensed, but was inspected by GAEC. A safety case and waste acceptance criteria needed to be developed for the facility. The necessary financial and human technical resources for the management of

radioactive waste also needed to be developed in Greece. A disposal option for the waste also needed to be developed over time. It was necessary for GAEC to specify priorities for the licensing procedures and the steps to be followed in developing the disposal policy.

Mr. J. Heinonen said that it was the responsibility of each State to be responsible of management of its own radioactive waste; to establish and maintain national policies and frameworks; and to assure the needed resources and transparency. He added that it was the prime responsibility of the license holder for the safety of the management of radioactive waste. There is also the need for a competent and independent regulatory body for the regulatory control of the waste. He recommended the IAEA publication: Policies and Strategies for Radioactive Waste Management (NW-G-1.1).

A typical policy should include the following elements: defined safety and security objectives, arrangements for providing resources for radioactive waste management, preferred approaches for the management of the each category of radioactive waste, and provisions for public information and participation. In addition, the policy should define national roles and responsibilities for radioactive waste management. However in many cases a national radioactive waste management organization is responsible for development of long-term plans and implementing them.

The strategy reflects and elaborates the goals and requirements set out in the policy statement and how they will be implemented within available resources. For its formulation, detailed information is needed on the current situation in the country (organizational, technical and legislative), and on the amounts of radioactive waste to be generated in the future. The strategy should set out the technical procedures proposed for the waste types in the country that should be politically, technically and economically feasible. The steps in formulating and implementing the strategy include selecting the technological procedures, allocating the responsibility for their implementation, establishing supervisory mechanisms and developing implementation plans.

Mr Heinonen described as an example the observations made during the mission about the current approach in Greece to managing different types of waste:

- Short lived radioactive waste – decay and discharge
- Disused/Orphan sources – return/recycling abroad, short term storage
- Spent fuel from GRR-1 - return the spent fuel into the country of origin
- GRR-1 operational waste – policy at the moment is for interim storage
- Legacy waste at NCSR “Demokritos” – policy at the moment is for interim storage
- Sources and waste that cannot be exported – policy at the moment is for interim storage
- Decommissioning waste – no clear policy or strategy
- NORM – decisions are made case by case
- Disposal – interest for international co-operation

Radioactive waste having no back-end solution is currently stored in the interim storage facility at NSCR “Demokritos”. As discussed during the Mission, this facility should undergo a stepwise authorization. There was a discussion on the stepwise approach to the authorization of the facility:

- an agreement between GAEC and the operator of the facility of a process, including time-lines, for the licensing of the radioactive waste management facility. This agreement would require the operator to produce a concrete action plan, with time schedule, for safety enhancements of the facility that is agreed with regulatory body;

- an agreement between GAEC and the operator of the facility of an appropriate international standard to be used as a reference to ensure the safety of the radioactive waste management facility. (e.g. GSR part 5 Predisposal Management of Radioactive Waste and WS-G-6.1 Storage of Radioactive Waste);
- the development of radioactive waste acceptance criteria as one key element for assessing storage design criteria, waste packaging, acceptable volumes that storage can encompass, etc. (Further guidance e.g. GSR Part 5, Requirement 12);
- GAEC to license the interim storage facility in a stepwise manner, using license conditions that include the agreed safety enhancements;
- GAEC to formalise existing inspection activities, and to issue inspection reports;
- GAEC to take enforcement actions to ensure that operator complies with the license conditions.

The development of regional or national disposal facility was mentioned during the discussions, but was not addressed deeply since for example implementation of disposal is a long project and has several aspects to be considered.

17.3. CLINICAL AUDIT

Mr. C. Hourdakis introduced the discussion on clinical audit. He said that clinical audits are related to the implementation of justification and optimization principles. He asked how the clinical audit outcome could be used for the improvement of medical practices in the country and in the individual clinics, and what is the involvement of authorities such as the regulator for radiation protection and the Ministry of Health in clinical audit.

Ms. S. Kodlulovich provided a presentation on clinical audit. The definition of the European Commission for clinical audit as “a systematic examination or review of medical radiological procedures which seeks *to improve the quality and the outcome of patient care* through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary.”

The objective of the clinical audit is to: improve the quality of patient care; promote the effective use of resources; enhance the provision and organization of clinical services; and to further professional education and training.

Several elements to evaluate during the clinical audit were described. There are different levels of audit: level I, level II, etc. The complexity of the audit increases with each level.

The focus of the work on clinical audit to date has been towards radiotherapy facilities. An example was provided of a level I audit for radiotherapy of “postal surveys of dose”. Examples of such national surveys were shared by experts in the IRRS. An example was provided of the technical expertise that would be needed to carry out an audit of a radiotherapy centre: oncology, medical physics, radiation therapist, and as appropriate, engineer and radiation protection. Aspects of the audit programme were discussed, including the “infrastructure” of the radiotherapy facility, procedures for the treatment of the patient (from identification through to treatment planning, treatment delivery and follow-up), quality assurance for the equipment, and competence of the staff.

It was noted that the clinical audit went into greater detail and beyond a regulatory inspection.

The importance of developing the objectives of clinical audit, procedures and clinical indicators was stressed. The collaboration with professional societies and other government ministries is considered essential.

APPENDIX I LIST OF PARTICIPANTS

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APPENDIX II MISSION PROGRAMME

DATE AND TIME	ACTIVITY	TEAM MEMBERS
Sunday 20 May 2012		
15:00 – 19:00	Initial IRRS Review team meeting: - Opening remarks (T. Ryan) - Self-Introduction of liaison officer - Self-introduction of the IRRS Team members - Presentation of the logistical arrangements of the mission (V. Kamenopoulou) - Presentation of the IRRS process and guidance for report preparation (H. Suman) - Review of mission schedule - Report of initial assessment of the Advance Reference Material (all)	All
Monday 21 May 2012		
10:00 – 13:00	Entrance meeting: - Welcome statement (C. Housiadas) - Welcome statement by the General Secretary for Research and Technology (K. Kokkinoplitis) - Opening remarks and presentation by IRRS Team Leader (T. Ryan) - Self introduction of team members and counterparts - Presentation of Greece regulatory framework (C. Housiadas)	All
14:00 – 17:00	Module Discussion/Interviews	All
17:00 – 18:30	Team meeting	All
Tuesday 22 May 2012		
09:00 – 11:00	Meeting with the Chairman and the Ministry representative of the 9-Member committee of Ionizing and non-Ionizing Radiation of the Ministry of Health and Social Solidarity	T. Boal, S. Kodlulovich
09:00 – 17:00	Module Discussion/Interviews	All
17:00 – 18:30	Team meeting	All
Wednesday 23 May 2012		
11:00 – 12:00	Meeting with the General Secretary for Research and Technology	T. Ryan P. Johnston H. Suman

09:00 – 15:00	Emergency response exercise at GAEC	M. Krishnamachari R. Salinas
15:45 – 17:00	Visit at the Civil Protection Emergency Centre	M. Krishnamachari R. Salinas
09:00 – 13:00	Site visit to the waste facility of NCSR "Demokritos"	J. Heinonen L. Jova Sed
09:00 – 17:00	Site visit to the public hospital "Attikon" (radiology and nuclear medicine)	T. Boal I. Shadad S. Kodlulovich M. L. Perrin L.J. Sed (afternoon)
09:00 – 17:00	Module Discussion/Interviews	All
18:00 – 19:30	Team meeting	All
Thursday 24 May 2012		
09:00 – 17:00	Site visit to "Hygeia" hospital (radiotherapy)	S. Kodlulovich
09:00 – 14:00	Site visit to the IFET industrial irradiator	T. Boal I. Shadad
09:00 – 17:00	Site visit to the cyclotron facility "BIOKOSMOS"	L. Jova Sed M.L. Perrin I. Barlow
14:00 – 17:00	Site visit to the customs in Piraeus Port	T. Boal I. Shadad M. Krishnamachari R. Salinas
09:00 – 17:00	Module Discussion/Interviews/report drafting	All
18:00 – 19:30	Team meeting	All
Friday 25 May 2012		
11:00 – 12:00	Meeting with the General Secretary of Civil Protection	P. Johnston M. Krishnamachari R. Salinas
11:00 – 12:00	Meeting with representative from Prefecture of Attica	T. Ryan H. Suman
09:00 – 17:00	Module Discussion/Interviews/report drafting	All
18:00 – 19:30	Team meeting	All
Saturday 26 May 2012		
09:00 – 12:00	Team meeting	All
12:00 –	Report drafting	All
Sunday 27 May 2012		

09:00 – 16:00	Report drafting / reviewing	T. Ryan P. Johnston T. Boal H. Suman
16:00 – 22:00	Social event	All
Monday 28 May 2012		
09:00 – 12:00	Module Discussion	All
14:00 – 17:00	Policy discussions	All
18:00 –	Team review of final draft report	T. Ryan P. Johnston H. Suman
Tuesday 29 May 2012		
09:00	Initial Draft Report forwarded to GAEC	H. Suman
09:00 – 18:00	GAEC review of IRRS draft report	
15:30 – 16:00	Meeting with the Director of D1 Division of the Ministry of Foreign Affairs	Pil-Soo Hahn T. Ryan P. Johnston H. Suman
18:00 – 21:00	Discussion of GAEC report review	All
Wednesday 30 May 2012		
09:00 – 12:00	Plenary review of draft report with GAEC Management and counterparts	All
13:00	Submission of final IRRS Mission Report to GAEC	H. Suman
13:00 – 14:00	Exit meeting	All
14:30 –	Press conference	Pil-Soo Hahn T. Ryan

APPENDIX III SITE VISITS

SITE VISITS	
Wednesday 23 May 2012	
1.	Public Hospital “Attikon” Interventional radiology, Nuclear medicine
2.	Waste facility “NCSR” Demokritos
3.	Civil Protection Emergency Centre
Thursday 24 May 2012	
4.	IFET - Industrial irradiator
5.	BIOKOSMOS -Cyclotron facility and “transport”
6.	Hospital “Hygeia”: Radiotherapy
7.	Customs Office (Piraeus port)

The IRRS team visited three facilities, two medical and one industrial, to observe GAEC staff conduct inspections.

Inspection of Radiology Department of Attikon Hospital

The inspection was conducted by two inspectors from the Licensing and Inspections Department of GAEC. The inspection included areas such as radiation protection organization and competence, QA program, safety systems, monitoring, laboratory practices, and categorization of workers and workplaces. The inspection also included QC check of the Angiographic system (GE Advant X). The inspection started by a round table discussion/interview with the radiation protection officer of the facility and relevant staff. All radiation safety records were checked by the inspectors. The inspectors then proceeded to the control room inside the Angiography System facility to conduct practical observation and assessment of how the staff in the hospital conducts their activities. They also performed QC measurements to inspect the safety of the machine. The inspectors of GAEC conducted the inspection in a professional manner and had a cooperative attitude with the radiation protection officer and concerned staff of the radiology department.

Following the observation, an exit briefing has been conducted with the radiation protection officer and the head of the department and relevant staff of the radiology department and findings of the inspection were presented and discussed at the exit meeting.

The inspectors used their own radiation measuring instrumentation for performing any independent verifying measurements.

Inspection of the Nuclear Medicine Department of Attikon Hospital

The inspection was conducted by two inspectors from the Licensing and Inspection Department of GAEC. The inspection included areas such as radiation protection organization and competence, safety systems, monitoring, laboratory practices, and categorization of workers and workplaces. The inspection started by a round table discussion/interview with the radiation protection officer of the Department and relevant staff. All radiation safety records

were checked by the inspectors. The most critical areas were monitored to check for contamination, like the Hot Lab. The inspectors of GAEC conducted the inspection in a professional manner and had a cooperative attitude with the radiation protection officer of the Nuclear Medicine department.

Following the observation, an exit briefing has been conducted with the radiation protection officer and the head of the department and the relevant staff of the nuclear medicine department and findings of the inspection were presented and discussed at the exit meeting.

In a separate discussion, the licensee representatives highlighted the problem of delaying the renewal of license by the Prefectures. They also mentioned that a good contact is established with GAEC.

Inspection of the I.F.E.T Sterilization Unit

The inspection was conducted by two inspectors from the Licensing and Inspections Department of GAEC. The facility is equipped with Co-60 of activity 165 kCi. The inspection included areas such as radiation protection organization and competence, QA program, safety systems, monitoring and workplaces. The inspection started by a round table discussion/interview with the radiation protection officer and the Management of the facility and the relevant staff. All radiation safety records were checked by the inspectors. The inspectors then proceeded to the control room of the irradiator to conduct practical observation and assessment of how the staff in the facility conducts their activities. The inspectors carried a thorough check to the interlocks and the safety systems of the irradiator. The inspectors of GAEC conducted the inspection in a professional manner and had a cooperative attitude with the radiation protection officer and management of the irradiator.

Following the observation, an exit briefing has been conducted with the management and relevant staff of the irradiator facility and findings of the inspection were presented and discussed at the exit meeting.

In a separate discussion, the licensee representatives highlighted the good contact they established with GAEC.

Site visits related to waste management

As part of IRRS mission Team observed an inspection to NCSR “Demokritos” interim storage. The inspection was organised in accordance to GAEC quality manual and followed their inspection form (checklist).

The interim storage consists of two buildings that are at the NCSR “Demokritos” campus area under security surveillance. The IRRS team member observations during the inspection were that the newer building appeared to be in better condition and waste was mostly in proper order. The older building/shed contains legacy waste that should go through characterisation, classification and arrangement for storage. In general the interim storage infrastructure needs improvements in organising of waste packages, housekeeping, and maintenance of the storage as well as some security improvements.

The Team had also the opportunity to participate in some inspections to facilities where radioactive waste is produced and stored. During the inspections it was noticed that in such facilities it was common to store radioactive waste together with non-radioactive materials. This is related recommendation that GAEC should issue regulations of pre-disposal management in accordance with IAEA Standards.

Visit to cyclotron facility

IRRS observation of GAEC inspection at 'ΒΙΟΚΟΣΜΟΣ', Lavrio, Attica. 24 May 2012

An opening meeting was held between GAEC and the Radiation Protection Officer (RPO), where the purpose of meeting was explained. It was noted that the licence holder (CEO) was not present, having been called to a meeting in Athens. GAEC clarified to the RPO that the IRRS team were not inspecting the facility, and that this was a supplementary inspection (the last being to support the re-issue of the facility licence in March 2012).

The relationship between regulator and operator appeared cordial but professional and effective. No inappropriate behaviours were observed.

The GAEC inspector confirmed that there had been no significant changes to arrangements or personnel since the last inspection and then went on to check and /or discuss:-

- Staff records
- Pharmaceutical licence issues
- Procedures
- External workers
- Process waste issues (ensuring that the cycle is effectively closed and does not allow for discharges, as on-site decay storage (>35 T½) is deployed prior to disposal of any process waste products).

Preventative maintenance of the cyclotron; the shielded cells; and the synthesis area was discussed. GAEC do not specify maintenance criteria or guidelines for equipment. If they have 'a feeling' that things are not being done, they raise their concerns with the operator. It was not possible to establish how GAEC satisfied themselves that what was being done in terms of maintenance was adequate, or matched the safety case assessed as part of the license submission.

There were some minor configuration control issues observed with the operator's management system documents. The IRRS reviewers were told that GAEC do not look at the 'ISO aspects' of operations (other bodies looking at such matters) and focus on the radiation protection aspects. Given the requirements for QA in the RPRs, it is unclear how GAEC satisfy themselves that operators' management system arrangements meet regulatory requirements.

Discussions were also held with the operator about potential future exports of radioactive material.

The office based review and discussion was followed by a brief facility inspection covering:

- Cyclotron
- Shielded cells
- Synthesis area
- Decommissioning plans: A discussion took place on the (lack of a) decommissioning plan for the facility. The company is considering building another facility in the North of Greece (currently on hold due to the economic climate). As part of the licensing system of the second (and potentially third) cyclotron, decommissioning plans must be drawn up – including a plan for the Lavrio facility – prior to licensing. It was noted

that the facility has an expected working life of 30 years, having opened 8 years ago. Items to be considered include activated concrete and steel.

- Transport concerns identified by IRRS reviewer:
    - No inspection of management system arrangements for adequacy
    - No clarity of maintenance requirements for reusable packaging
    - Package inspected was incorrectly marked and labelled
    - No consignment documents are produced by the consignor
    - Package was approved against a superseded version of the IAEA transport regulations

Inspection of Radiotherapy Department of HYGEIA Clinic, Athens

The inspection was conducted by two inspectors from the Licensing and Inspections Department of GAEC. The inspection started with a round table discussion/interview with the radiation protection officer of the radiotherapy department and relevant staff. An inspection checklist was followed. All radiation safety records were checked by the inspectors. The inspection included areas such as radiation protection organization and competence, QA program, safety systems, monitoring, laboratory practices, and categorization of workers and workplaces.

The inspection included a QC check of the Linear Accelerator (ELEKTA 18MV), measurements for the verification of patient dosimetry, and the basic mechanical and radiation performance of the linac. The inspectors used GAEC radiation measuring instrumentation for performing the measurements.

The inspectors of GAEC conducted the inspection in a professional manner and a cooperative attitude to the radiation protection officer and other staff of the radiotherapy department.

The inspection concluded with an exit briefing with the radiation protection officer, the head of the radiotherapy department and relevant staff of the department where the findings of the inspection were presented and discussed.

APPENDIX IV LIST OF MISSION COUNTERPARTS

IRRS EXPERTS	GAEC Lead Counterparts	GAEC Support Counterparts
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT		
Tom Ryan Peter Johnston Hazem Suman	Christos Housiadas Vasiliki Kamenopoulou Lena Metaxaki	
2. GLOBAL NUCLEAR SAFETY REGIME		
Tom Ryan Peter Johnston Hazem Suman	Christos Housiadas Vasiliki Kamenopoulou	
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY		
Tom Ryan Peter Johnston Hazem Suman	Christos Housiadas Vasiliki Kamenopoulou	Georgia Karatzia
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY		
Anna Franzen	Eleftheria Carinou	Ch. Housiadas K. Kehagia Th.Karabetsos C. J. Hourdakis S. Economides C. Potiriadis E. Papadomarkaki
5. AUTHORIZATION		
Jussi Heinonen Trevor Boal Ibrahim Shadad	Vasiliki Kamenopoulou Costas J. Hourdakis Lena Metaxaki	C. Potiriadis D. Mitrakos
6. REVIEW AND ASSESSMENT		
Jussi Heinonen Trevor Boal Ibrahim Shadad	Vasiliki Kamenopoulou Costas J. Hourdakis	
7. INSPECTION		
Jussi Heinonen Trevor Boal Ibrahim Shadad	Vasiliki Kamenopoulou Costas J. Hourdakis	S. Economides Ch. Pafilis G. Simantirakis S. Vogiatzi Al. Liossis A. Boziari P. Tritakis M. Kalathaki D. Mitrakos C. Potiriadis S. Papadopoulos A. Maltezos

IRRS EXPERTS	GAEC Lead Counterparts	GAEC Support Counterparts
8. ENFORCEMENT		
Jussi Heinonen Trevor Boal Ibrahim Shadad	Vasiliki Kamenopoulou Costas J. Hourdakis Lena Metaxaki	
9. REGULATIONS AND GUIDES		
Jussi Heinonen Trevor Boal Ibrahim Shadad	Costas J. Hourdakis Lena Metaxaki	C. Potiriadis D. Mitrakos
10. EMERGENCY PREPAREDNESS AND RESPONSE		
Rodrigo Salinas Muralidhar Krishnamachari	Antonis Maltezos Panagiotis Dimitriou Argiro Boziari	M. Kalathaki P. Askounis G. Takoudis M. Nikolaki G. Manousaridis P. Tritakis
11. TRANSPORT OF RADIOACTIVE MATERIAL		
Ian Barlow	Stavroula Vogiatzi	
12. CONTROL OF MEDICAL EXPOSURE		
Simone Kodlulovich	Sotirios Economides	A. Boziari C. J. Hourdakis S. Vogiatzi
13. OCCUPATIONAL RADIATION PROTECTION		
Marie Line Perrin	Eleftheria Carinou Argiro Boziari	
14. CONTROL OF RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE		
Luis Jova Sed	Costas Potiriadis Konstantina Kehagia Dimitris Mitrakos	S. Vogiatzi P. Dimitriou
15. ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES		
Luis Jova Sed	Costas Potiriadis Konstantina Kehagia Dimitris Mitrakos	S. Vogiatzi
16. CONTROL OF CHRONIC EXPOSURES AND REMEDIATION		
Luis Jova Sed	Costas Potiriadis Konstantina Kehagia Dimitris Mitrakos	

SUPPORTING GAEC STAFF	Anna Dalles, Kyriaki Irodiadou, Vasiliki Tafili

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	AREAS	R: Recommendation S: Suggestion GP: Good Practice	RECOMMENDATIONS, SUGGESTION AND GOOD PRACTICES
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**	**R1**	The Government should develop a consolidated statement that sets out the national policy and strategy for safety.
		R2	The Government should ensure that the persons or entity with responsibilities for the implementation of regulatory requirements are explicitly specified.
		R3	The Government should provide for a graded approach in the implementation of the regulatory framework.
		R4	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.
		R5	The Government should expressly assign the prime responsibility for safety to the person or organization responsible for a facility or activity within the legal framework for radiation safety.
		S1	The Government should consider conferring legal authority to strengthen GAEC's powers of enforcement.
		GP1	The team noted the strong commitment of GAEC to the training of medical physicists in radiation protection.
2.	**GLOBAL NUCLEAR SAFETY REGIME**		

	AREAS	R: Recommendation S: Suggestion GP: Good Practice	RECOMMENDATIONS, SUGGESTION AND GOOD PRACTICES
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	**R6**	GAEC should provide for a further operational separation between technical services and the regulatory function to minimize the potential for conflicts of interests.
		R7	GAEC should implement a systematic training program on the basis of an analysis of the necessary competence and skills for the regulatory body.
		GP2	The team acknowledges the excellence of the national database system for radiation protection maintained by GAEC.
		GP3	The team acknowledges the excellence of the Annual Report published by GAEC.
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	**R8**	When developing the integrated management system, GAEC should ensure that it is aligned with GS-R-3.
		R9	GAEC should foster staff commitment to the quality systems and to the integrated management system.
		R10	GAEC should make sufficient resources with the appropriate authority available when developing and implementing the integrated management system.
		R11	GAEC should include a specific process for the management of organizational change in the integrated management system.
		R12	GAEC should explicitly address safety culture in the integrated management system.
		S2	GAEC should consider preparing a plan for the development and implementation of the integrated management system.
		S3	The Government should consider establishing specific processes for the management of organisational change across all competent authorities dealing with radiation safety.

	AREAS	R: Recommendation S: Suggestion GP: Good Practice	RECOMMENDATIONS, SUGGESTION AND GOOD PRACTICES
5.	**AUTHORIZATION**	**R13**	GAEC should further develop 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.
		R14	GAEC should improve the implementation of a graded approach in the authorization process.
		R15	GAEC should enforce the licensing requirements for all facilities at NCSR "Demokritos", including the interim storage facility.
		S4	GAEC should consider improving the coordination with Prefectures to avoid delays in the licensing renewal process which can result in facilities operating without a valid license.
		S5	GAEC should consider revising its licensing approach in order to include conditions, limits and controls on licenses and or certificates of compliance.
6.	**REVIEW AND ASSESSMENT**	**R16**	GAEC should document the procedure to review and assess the safety assessment reports that demonstrate the safe operation of the facilities and activities.
7.	**INSPECTION**	**R17**	GAEC should provide inspection results officially to the operator of the NCSR "Demokritos" waste storage facility, and ensure that the inspection findings are addressed.
		S6	GAEC should consider reducing the influence of the license renewal process on the inspection programme.
8.	**ENFORCEMENT**	**R18**	GAEC should formalize its enforcement policy in line with a graded approach and incorporate it into the integrated management system.

	AREAS	R: Recommendation S: Suggestion GP: Good Practice	RECOMMENDATIONS, SUGGESTION AND GOOD PRACTICES
9.	**REGULATIONS AND GUIDES**	**R19**	GAEC should prepare updated Radiation Protection Regulations to bring them in line with the current IAEA Safety Requirements for submission to the Government.
		R20	GAEC should establish safety requirements for decommissioning of facilities and pre-disposal management of radioactive waste.
		S7	The Government should consider adopting a more flexible hierarchy of Radiation Protection Regulations.
		S8	GAEC should consider incorporating a waste classification scheme into its regulatory system.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	**R21**	GAEC should liaise with relevant organizations, to conduct the assessment of hazards at the national level in accordance with GS-R-2.
		GP4	GAEC's real time monitoring of radioactivity levels at various locations in the country by means of a network of telemetric stations contributes significantly to identifying the initial phase of a potential radiation emergency due to events within or outside the country.
		GP5	GAEC has successfully advocated the inclusion of the radiation protection course, which covers the recognition of radiation injuries, into the basic curricula for medical doctors.
11.	**TRANSPORT**	**R22**	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.
		R23	GAEC should review, develop and strengthen its capacity for review and approval of package and material designs

	AREAS	R: Recommendation S: Suggestion GP: Good Practice	RECOMMENDATIONS, SUGGESTION AND GOOD PRACTICES
		R24	GAEC and other transport competent authorities should implement appropriate, coordinated, compliance assurance programmes.
		S9	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.
		S10	GAEC and other transport competent authorities should consider using IAEA TS-G-1.5 in developing their compliance assurance programme(s).
12.	**CONTROL OF MEDICAL EXPOSURE**	**R25**	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.
		R26	GAEC should verify that no person incurs a medical exposure unless there has been an appropriate referral.
		R27	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.
		GP6	In 2011, referral criteria were published by the Hellenic Radiological Society based on European Guidance.
13.	**OCCUPATIONAL RADIATION PROTECTION**	**GP7**	Greece has developed the technical capability to perform biological dosimetry in case of overexposures.

	AREAS	R: Recommendation S: Suggestion GP: Good Practice	RECOMMENDATIONS, SUGGESTION AND GOOD PRACTICES
14.	**CONTROL OF RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE**		
15.	**ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES**	**GP8**	GAEC requires the scrap metal industry and the customs authorities to establish portal monitoring.
16.	**CONTROL OF CHRONIC EXPOSURES AND REMEDIATION**	**R28**	GAEC should ensure clear separation of its regulatory functions from any advisory actions given to the operator for existing exposure situations and remedial actions.

APPENDIX VI GAEC REFERENCE MATERIAL USED FOR THE REVIEW

DOCUMENT
LAWS
1. Government Gazette, Law No. 211, Folio No. 35, First issue, February 28, 1947, "Ratification of the International Civil Aviation Convention of December 7, 1944"
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, "Protection against ionizing radiation" (translated).
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. 1733, Folio No: 171, First issue, September 22, 1987, "Transfer of Technology, inventions, technological innovation and establishment of the Greek Atomic Energy Commission" (translated).
8. Government Gazette, Law No. 1741, Folio No: 225, First issue, December 21, 1987, "Ratification of the European Agreement on the International Carriage of Dangerous Goods by Road (ADR) signed in Geneva on September 30, 1957
9. Government Gazette, Law No. 2805, Folio No. 50, First Issue, March 3, 2000, "Ratification of the Additional Protocol"
10. 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"
11. 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"
12. Government Gazette, Law No. 3013, Folio No. 102, First issue, May 1, 2002, "Upgrade of the civil protection and other issues" (partially translated).
13. Government Gazette, Law No. 3710 Folio No: 216, First issue, October 23, 2008, "Regulations for transport issues and other topics"

14. Government Gazette, Law No. 3868, Folio No. 129, First issue, August 3, 2010, "Upgrade of the National Health System and other issues"
15. Government Gazette, Law No. 3990, Folio No. 159, First issue, July 13, 2011, "Amendment of the Convention of Physical Protection of Nuclear Materials"
16. Government Gazette, Law No. 2801, Folio No. 46, First issue, March 3, 2000, "Regulations regarding responsibilities of the Ministry of Transport and Communications".
17. Government Gazette, Law No. 2480, Folio No. 70, First Issue, May 14, 1997, "Convention on Nuclear Safety"
PRESIDENTIAL DECREES
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 (ΔΕΗ)".
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”.
MINISTERIAL DECISIONS
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 GAEC Administration Board, the Director and Heads of Departments of GAEC 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. ΥΠΑ/Δ2/11894/3631, Folio No. 549, Second issue, April 18, 2007, “Adoption of Annex 18, 3rd 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. ΔΥΓ2/92027, 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. ΑΣ4.1/ΟΙΚ.45573/3719, Folio No. 1874, Second issue, September 12, 2008, “Amendment of the Ministerial Decision No. Φ4.2/18960/1446/19.06.2001”.
10. Government Gazette, Ministerial Decision No. 35043/2524, Folio No. 1385, Second issue, September 2, 2010, “Adjustment of the Greek legislation to the regulations of the Directive 2008/68/ΕΚ concerning the inland transport of dangerous goods”.
11. Government Gazette, Ministerial Decision No. 504/145, Folio No. 46, Second issue, January 19, 2009, “Regulation for general licensing of postal services”.

12. Government Gazette, Ministerial Decision No. 154949, Folio No. 1918, Second issue, 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 17176, Folio No.832, Second issue, November 15, 1988, “Powers and competences of GAEC Board” (translated).
14. Government Gazette, Ministerial Decision No 11592(FOR)1125, Folio No.1633, 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).
15. Government Gazette, Ministerial Decision No 1299, Folio No. 423, Second Issue, April 10, 2003, “General Civil Protection Plan Xenokratis” (partially translated).
16. Government Gazette, Ministerial Decision, Folio No. 892, Second issue, July 11, 2001, “Quality of water intended for human consumption”.
GAEC CIRCULARS – DECISIONS
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2. GAEC Circular Ref. No. P/105/388 / 30.11.2006, “Patients' excreta release after nuclear medicine treatments (therapies)” (translated).
3. GAEC Circular Ref. No. P/105/241 / 03.08.2006, “Clearance levels of Naturally Occurring Radioactive Materials” (translated).
4. GAEC Interpreting Circular, Π/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” (translated)
5. *CORRIGENDUM* GAEC Decision Ref. No: Π/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. GAEC Interpreting Circular, Π/105/412 / 09.12.2009, “Clarifications regarding the training of holders and non holders of qualifications related to ionizing radiation” (translated).
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8. GAEC Interpreting Circular, Π/105/371 / 09.11.2010, “Clarifications regarding non holders of qualifications related to activities involving ionizing radiation” (translated).
GAEC DOCUMENTS
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2. 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 (in English).
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4. GAEC, Quality Manual as per ISO 17025:2005 for: i. Office of non-ionizing radiation (translated); ii. Dosimetry Department (translated); iii. Radiation & Environment Control Department (translated); iv. Calibration Laboratory for Ionizing Radiation Instruments (translated).
5. GAEC Internal Emergency Plan for Dealing with Radiological Incidents or Chemical, Biological and Radio-Nuclear (CBRN) Threats, 2004 (translated)
6. GAEC Annual Activity Report: 2008, 2009, 2010 (in English)
7. GAEC Board Decision (204th meeting, 14.01.11) “Procedures of authorization (in terms of radiation protection) of outside undertakings”
8. NCSR “Demokritos” Board Decision of 21.03.1986 meeting on “Import, installation and commerce of radioactive rods”
9. GAEC Board Decision (26th meeting, 02.04.90),“Radiation sources inspection”
10. GAEC Board Decision (37th meeting, 07.09.90),“Disused radioactive sources”
11. GAEC Board Decision (87th meeting, 06.09.93), “License for radioactive sources import”
OTHERS DOCUMENTS
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, “Establishment of a Task Force for the Management of Chemical, Biological, Radiological and Nuclear Threats and Incidents under the General Secretariat for Civil Protection” (translated).
2. 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).
3. Long Term Agreement between the IAEA and the Government of the Hellenic Republic in order to support GAEC as a regional training centre in Europe for radiation, transport and waste safety, July 11 2011 (in English).
4. Decision of the General Secretary for Civil Protection “National Plan on CBRN threats”, November 2011 (translated).
5. Operations Procedures Manual, Civil Aviation Authority, 31.03.2010 (Internal Document) (in English).
6. Statement regarding the Implementation of the “Guidance on the Import and Export of Radioactive Sources” in Greece, 2006.
7. Annex “R” of the General Civil Protection Plan “Xenokratis” (translated).
8. Draft of Ministerial Decision defining the conditions and terms for the licensing of the research reactor.

9. 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.
10. 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).
11. 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).
12. 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).
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15. 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 GAEC concerning cooperation to prevent the illicit trafficking in nuclear and other radioactive material, October 30, 2003 (in English).
16. Nuclear Security Cooperation and Support Arrangement between IAEA and GAEC, March 10, 2004 (in English).
17. Bilateral agreement for scientific and technical cooperation in the fields of radiation protection and nuclear security with the Department of Labour Inspection of the Ministry of Labor and Social Insurance of the Republic of Cyprus, December 13, 2008.
18. Practical arrangements between GAEC 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 (in English).
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APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

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2. IAEA SAFETY STANDARDS SERIES No. GSR PART 1 “Governmental, Legal and Regulatory Framework for Safety”

3. IAEA SAFETY STANDARDS SERIES No. GSR PART 3 (Interim) “Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards”

4. IAEA SAFETY STANDARDS SERIES No. GS-R-2 “Preparedness and Response for a Nuclear or Radiological Emergency”

5. IAEA SAFETY STANDARDS SERIES No. GS-R-3 “The Management System for Facilities and Activities”

6. IAEA SAFETY STANDARDS SERIES No. GS-G-1.1 “Organization and Staffing of the Regulatory Body for Nuclear Facilities”

7. IAEA SAFETY STANDARDS SERIES No. GSG-2“Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency

8. IAEA SAFETY STANDARDS SERIES No. GS-G-2.1 - Arrangements for Preparedness for a Nuclear or Radiological Emergency

9. IAEA SAFETY STANDARDS SERIES No. GS-G-3.1 “Application of the Management System for Facilities and Activities”

10. IAEA SAFETY STANDARDS SERIES No. GS-G-3.2 “The Management System for Technical Services in Radiation Safety”

11. IAEA SAFETY STANDARDS SERIES No. RS-G-1.3 “Assessment of Occupational Exposure Due to External Sources of Radiation”

12. IAEA SAFETY STANDARDS SERIES No. RS-G-1.4 “Building Competence in Radiation Protection and the Safe Use of Radiation Sources”

13. INTERNATIONAL ATOMIC ENERGY AGENCY “Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency”, Legal Series No. 14, Vienna (1987).

14. IAEA SAFETY STANDARDS SERIES No. TS-R-1 2009 Edition “Regulations for the Safe Transport of Radioactive Material”

15. IAEA SAFETY STANDARDS SERIES No. TS-G-1.1 “Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material”

16. IAEA SAFETY STANDARDS SERIES No. TS-G-1.4 “The Management System for the Safe Transport of Radioactive Material”

17. IAEA SAFETY STANDARDS SERIES No. TS-G-1.5 “Compliance Assurance for the Safe Transport of Radioactive Material”