

**INTEGRATED REGULATORY  
REVIEW SERVICE (IRRS)  
MISSION  
TO  
THE REPUBLIC OF CYPRUS**

LEFKOSIA (NICOSIA), CYPRUS

*13 to 22 February 2017*

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



Integrated  
Regulatory  
Review Service

**IRRS**



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**REPORT OF THE  
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Regulatory  
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**IRRS**

## **REPORT OF THE INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO THE REPUBLIC OF CYPRUS**

<b>Mission dates:</b>	<i>13 February to 22 February 2017</i>
<b>Regulatory body visited:</b>	<i>Radiation Inspection and Control Service of the Department of Labour Inspection</i>
<b>Location:</b>	<i>Lefkosia (Nicosia), Cyprus</i>
<b>Regulated facilities and activities in the mission scope:</b>	<i>Radiation Sources in Industrial and Medical Facilities, Waste Management Facilities, Decommissioning, Transport, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Monitoring</i>
<b>Organized by:</b>	<i>IAEA</i>

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IAEA February 2017

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

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## EXECUTIVE SUMMARY

At the request of the Government of Cyprus, an international team of senior safety experts visited the Ministry of Labour, Welfare and Social Insurance from 13 to 22 February 2017 to conduct an Integrated Regulatory Review Service (IRRS) Mission. The purpose of the IRRS mission was to perform a peer review of Cyprus's regulatory framework for radiation safety.

The IRRS mission covered all civilian facilities and activities in Cyprus. The review compared Cyprus's regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Cypriot counterparts in the areas covered by the IRRS.

The IRRS team consisted of ten senior regulatory experts from nine IAEA Member States, one IAEA staff member, one IAEA administrative assistant and one observer. The IRRS team conducted a review of the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection, enforcement and development and content of regulations and guides; emergency preparedness and response; control of medical exposure; occupational radiation protection; control of radioactive discharges and materials for clearance; environmental monitoring; control of chronic exposures; transport of radioactive materials; waste management and decommissioning. The IRRS mission included discussions on policy issues regarding justification in medical exposure practices, including the justification in "medico-legal" exposure; establishing an appropriate education and training system on radiation protection and safety, in accordance with IAEA safety standards; and management and final disposal of legacy disused sealed radioactive sources (DSRS).

The mission included observations of regulatory activities, interviews and discussions with management and staff of the Radiation Inspection and Control Service (RICS) of the Department of Labour Inspection (DLI) of the Ministry of Labour, Welfare and Social Insurance (MLWSI), as well as high level management of DLI and MLWSI. Activities included visits to Bank of Cyprus Oncology Centre, Nicosia, Nortest (Cyprus) Industrial Radiography facility, and Nicosia General Hospital. The IRRS team observed regulated activities and performance of inspection activities, including discussions with the licensee personnel and management.

In preparation for the IRRS mission, Cyprus conducted a self-assessment and prepared a preliminary action plan to address weaknesses that were identified. The results of the self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics presented in the advance reference material. Throughout the mission, the IRRS review team was extended full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

The Minister for Labour, Welfare and Social Insurance is the regulatory authority for regulatory oversight of radiation safety of facilities and activities in Cyprus, and exercises its regulatory responsibilities through the Radiation Inspection and Control Service (RICS) of the Department of Labour Inspection (DLI). The Ministry has developed regulations and regulatory requirements to carry out its regulatory responsibilities and for compliance with the IAEA safety standards and international best practices. The IRRS team recognized that the Ministry continues to update its regulatory requirements and encouraged the Ministry to further enhance its regulatory framework. In this regard,

the team identified good practices that should be considered for implementation by other Member States, and identified recommendations and suggestions for improvement and for consistency of the regulatory framework with the IAEA safety standards.

The IRRS team recognized that Cyprus has a dedicated regulatory body for the protection of people and the environment, and for continuous improvement of safety. As a result, the team identified the following good practices:

- RICS/DLI has a system for continuous assessment, implemented annually, for establishing and addressing the competence and training needs among its staff aimed at improving their contribution to achievement of organizational goals.
- The Government has stipulated in the law that the regulatory body should periodically conduct self-assessment and invite an international peer review with the aim of continuously improving safety.

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

- The Government should review the legal framework to ensure compliance with the requirements of GSR Part 1 (Rev. 1).
- The Government should provide RICS/DLI with adequate human and financial resources.
- RICS/DLI should establish formal processes based on specific policies, principles and associated criteria and follows specified procedures.
- The Government should strengthen RICS/DLI's powers and responsibilities in the licensing decision-making process through the legal framework.
- The Government should make provision for a system to ensure building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.
- RICS/DLI should establish a programme of inspections that specifies the frequency of inspection taking into account the radiation risks associated with the facility or activity, and areas and programmes to be inspected in accordance with a graded approach.
- RICS/DLI should consider providing a documented record of the findings communicated verbally to authorized parties at the end of an inspection.
- The RICS/DLI should establish limits for radioactive discharges based on operational constraints.

## **I. INTRODUCTION**

At the request of the Government of The Republic of Cyprus, an international team of senior safety experts met representatives of the Radiation Inspection and Control Service (RICS) of the Department of Labour Inspection (DLI), Ministry of Labour, Welfare and Social Insurance, from 13 to 22 February 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the regulatory framework of The Republic of Cyprus for nuclear and radiation safety. The review mission was formally requested by the Government of The Republic of Cyprus in August 2015. A preparatory meeting was conducted on 28 to 29 July 2016 at RICS/DLI Headquarters in Lefkosia (Nicosia) to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in The Republic of Cyprus and their related safety aspects and to agree on the scope of the IRRS mission.

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

In addition, policy issues were discussed, including: Justification in medical exposure practices, including the justification in “non-medical” exposure, establishing an appropriate education and training system on radiation protection and safety, in accordance with IAEA safety standards; and management and final disposal of legacy disused sealed radioactive sources (DSRS).

In preparation of the mission, RICS/DLI conducted a self-assessment and prepared a preliminary action plan. The results of RICS/DLI self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the advance reference material, conduct of interviews with management and staff from RICS/DLI and direct observation of working practices during conduct of a regulatory inspection. Meetings with the Permanent Secretary of the Ministry of Labour, Welfare and Social Insurance (MLWSI) were also organized.

All through the mission the IRRS team received excellent support and cooperation from RICS/DLI.

## II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review The Republic of Cyprus's radiation safety regulatory framework and activities against the relevant IAEA safety standards; to review regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in The Republic of Cyprus.

It is expected this IRRS mission will facilitate regulatory improvements in The Republic of Cyprus and other Member States, utilizing the knowledge gained and experiences shared between the RICS/DLI and IRRS reviewers and through the evaluation of the effectiveness of The Republic of Cyprus's regulatory framework for radiation safety, including its good practices.

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

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

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

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

At the request of the Government of The Republic of Cyprus, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 28 to 29 July 2016. The preparatory meeting was carried out by the appointed Team Leader Mr. Christos Housiadas, and the IRRS IAEA team representative, Mr. Ahmad Al Khatibeh.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of RICS/DLI represented by Mr. Anastassios Yiannaki, Director of DLI, Mr. Panicos Demetriades, Head of RICS, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

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

Mr. Panicos Demetriades made presentations on the national context, the current status of the RICS/DLI and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in The Republic of Cyprus in February 2017.

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

RICS/DLI Liaison Officer for the IRRS mission was confirmed as Mr. Panicos Demetriades.

RICS/DLI provided IAEA with the advance reference material (ARM) for the review in December 2016. In preparation for the mission, the IAEA review team members reviewed the advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

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

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

## **C) CONDUCT OF THE REVIEW**

The initial IRRS team meeting took place on Sunday, 12 February 2017 in Lefkosia (Nicosia), directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 13 February 2017, with the participation of RICS/DLI senior management and staff. Opening remarks were made by Mr. Anastassios Yiannaki, Director of the Department of Labour Inspection and Mr. Andreas Ashiotis, Permanent Secretary of the Ministry of Labour, Welfare and Social Insurance, Mr. Christos Housiadas, IRRS Team Leader and Mr. Teodros Hailu, IRRS Team Coordinator. Mr. Panicos Demetriades gave an overview of RICS activities.

During the IRRS mission, a review was conducted for all review areas, within the agreed scope, with the objective of providing with recommendations and suggestions for improvement and, where appropriate, identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

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

The IRRS exit meeting was held on Wednesday, 22 February 2017. The opening remarks at the exit meeting were presented by Mr. Panicos Demetriades, Head of RICS and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr. Christos Housiadas. Mr. Andreas Ashiotis, Permanent Secretary of MLWSI then gave his remarks indicating that Cyprus is committed to address the recommendations and suggestions provided by the IRRS team. Closing remarks were made by Mr. Peter Johnston, IAEA, Director, Division of Radiation Transport and Waste Safety.

An IAEA press release was issued.

## 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

### 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The policy and strategy for safety in The Republic of Cyprus is reflected in the national legislative provisions and establishment of safety infrastructure, including meeting its obligations under relevant international conventions to which it is a party. The Government demonstrates its commitment to safety through the implementation of its national legislation for applying the fundamental safety objective and principles established in the IAEA Safety Fundamentals.

A ‘National Policy and Strategy on the Responsible and Safe Management of Radioactive Waste’ was adopted in 2015. The IRRS team was also informed that a national policy and strategy for establishing competence in safety through education and training is being developed and is expected to be finalized soon.

However, currently there is no comprehensive national policy and strategy as a statement of the government’s intent outlining the strategy for its ongoing implementation including a commitment to the provision of human and financial resources, provision and framework for research and development and a promotion of leadership and management for safety, including safety culture. At the level of the Department of Labour Inspection of the Ministry of Labour, Welfare and Social Insurance there is a vision and mission statement, which is published on the web page, but the vision and mission only briefly mentions “radiation hazards”.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The government has not yet established a national policy and strategy for safety taking into account current and future development and risk associated with radiation facilities and activities in The Republic of Cyprus.

(1) **BASIS: GSR Part 1 (Rev.1) Requirement 1 states that** *“The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.”*

(2) **BASIS: GSR Part 1 (Rev.1), Requirement 1; para 2.3 states that** *“National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government’s intent. The strategy shall set out the mechanisms for implementing the national policy.”*

**R1 Recommendation:** The Government should establish a national policy and strategy for safety.

### 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Cypriot framework for safety is primarily set out in the ‘Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011’, enacted in 2002 and amended in 2009 and 2011, which represent the legislative basis for radiation protection and nuclear safety in The Republic of Cyprus. The following sets of Regulations have been issued under the Laws:

- The Protection from Ionizing Radiation and Nuclear Safety (Basic Principles) Regulations of 2002, P.I. 494/2002.
- The Protection from Ionizing Radiation and Nuclear Safety (Information to the Public on Applicable Measures in case of Emergency) Regulations of 2002, P.I. 495/2002.
- The Protection from Ionizing Radiation and Nuclear Safety (Medical Exposure) Regulations of 2002, P.I. 497/2002.
- The Protection from Ionizing Radiation and Nuclear Safety (Control of High Activity Sealed Radioactive Sources and Orphan Sources) Regulations of 2006, P.I. 30/2006.
- The Protection from Ionizing Radiation and Nuclear Safety (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations of 2009, P.I. 86/2009.
- The Protection from Ionizing Radiation and Nuclear Safety (Responsible and Safe Management of Spent Fuel and Radioactive Waste) Regulations of 2014, P.I. 178/2014.
- The Protection from Ionizing Radiation and Nuclear Safety (Protection of the Health of the General Public with regard to Radioactive Substances in Water Intended for Human Consumption) Regulations of 2016, P.I. 54/2016.

Furthermore, the Republic of Cyprus has ratified, is signatory to or participates in a number of International Conventions, Protocols, Agreements and other Instruments in the area of nuclear energy/safety and also applies the relevant international standards for transport of radioactive materials.

The radiation safety legislation applies both for natural and artificial radiation sources and covers all aspects of ionizing radiation risk management and control, radiation protection and nuclear safety, such as occupational exposure, including outside workers; public exposure; medical exposure; shipments of radioactive material; radioactive waste management; and emergency preparedness and response.

The above legislation provides, inter alia, for:

- the establishment of the regulatory body [the Minister of Labour, Welfare and Social Insurance (MLWSI), acting through the Radiation Inspection and Control Service (RICS) of the Department of Labour Inspection (DLI)];
- the establishment of a Technical Licensing Committee (TLC) (advisory to the MLWSI on authorization matters);
- the establishment of a Council for Radiation Protection and Nuclear Safety (advisory to the MLWSI);
- the authorization of practices and sources in relation to custody, use, manufacture, supply, handling, distribution, storage, import, export, disposal, recycling, commissioning, decommissioning etc.;
- the justification, optimization and dose limitation of all practices,
- the provision for appeals;
- obligations of employers and licensees;
- appointment and powers of a chief inspector and inspectors;
- enforcement actions, offences and penalties;
- the design, erection, commissioning and decommissioning of nuclear installations,



- the storage, shipment and disposal of radioactive waste, radioactive discharges and spent or disused sources;
- the categorization of workplaces and workers;
- individual and area monitoring;
- health surveillance of the workers;
- environmental radioactivity monitoring;
- radiological/nuclear emergency preparedness and response;
- transport or shipment of radioactive materials, and
- the power of the Council of Ministers to issue Regulations.

The legislation which is in place provides for a framework for safety within The Republic of Cyprus, setting out the safety objectives for protecting people; the types of facilities and activities within the scope of the framework; the types of authorization that is required for the operation of facilities and for the conduct of activities; the provisions for assigning legal responsibility for safety; the provisions of the establishment of a regulatory body; provisions of inspections, and enforcement and appeals.

The MLWSI has so far issued several documents, such as the “Criteria for approval of radiation protection services”, the form of “Application for granting a licence” and the form of “Notification for a practice”, as guidance for implementing the regulations. The “General Authorization conditions for possession and use of radiology equipment for Dental Radiology practices” has been issued based on subsection (3) of Section 10 of the Protection from Ionizing Radiation and Nuclear Safety Laws, 2002-2011.

The Republic of Cyprus is the contracting party to the Convention on Physical Protection of Nuclear Material and Nuclear Installations (as well as to its amendments) and has concluded the bilateral “Safeguards Agreement” and “Additional Protocol” with the International Atomic Energy Agency. As for example, the ratification act of the CPPNM amendments stated clearly that the MLWSI is responsible regulatory body for application of the technical part of the aforementioned convention.

However, the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 does not require the promotion of safety culture. This issue is addressed in Recommendation R1 in Section 1.1.

The provision for acquiring and maintaining the necessary competence nationally for ensuring safety in Cypriot legislation is not sufficiently addressed. This issue is addressed in Recommendation R5 in Section 1.8.

The legislation also does not have explicit provisions such as criteria for release from regulatory control, and provision for review and assessment of facilities and activities.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Clearance levels for release of materials from regulatory control are not established. The provision for review and assessment of facilities and activities is also not clearly established in the legislation.

(1)

**BASIS: GSR Part 1 (Rev. 1) Requirement 2 para 2.5 states that** *“The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;</i> <i>(17) The criteria for release from regulatory control;”</i>
<b>R2</b>	<b>Recommendation:</b> The Government should review the legal framework to ensure compliance with the requirements of GSR Part 1 (Rev. 1).

### 1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The MLWSI, acting through the Radiation Inspection and Control Service (RICS) of the Department of Labour Inspection (DLI) (hereunder referred to as the RICS/DLI) is the regulatory body in the Republic of Cyprus for nuclear and radiation safety, and has the responsibility for the administration of relevant legislation and authorization of all sources and practices involving exposure to ionizing radiation.

RICS was established within DLI of the MLWSI, under Section 4 of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011. The objective of RICS is to protect individuals and the environment against risks of ionizing radiation during the use of sources or during exposure to ionizing radiation at work and from risks due to dispersion of radioactive substances.

RICS is presently staffed with one Senior Labour Inspection Officer as the Head and four Labour Inspection Officers, all qualified in engineering or science fields and well trained on radiation safety and radiation protection. The funding for RICS is provided by the Government through the annual budget of the DLI.

Section 6 of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 elaborates the responsibilities and powers of RICS.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The Government has established MLWSI, acting through RICS of DLI, as the regulatory body; however the resources provided to RICS/DLI are not adequate to perform all of its regulatory responsibilities.

<b>(1)</b>	<b>BASIS: GRS Part 1 (Rev.1) Requirement 3 states that</b> <i>“The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.”</i>
<b>(2)</b>	<b>BASIS: GRS Part 1 (Rev.1) Requirement 3 para 2.8 states that</b> <i>“To be effectively independent, the regulatory body (a) shall have sufficient authority and sufficient competent staff; (b) shall have access to sufficient financial resources for the proper discharge of its assigned responsibilities.”</i>
<b>R3</b>	<b>Recommendation:</b> The Government should provide RICS/DLI with adequate human and financial resources.

According to the procedures concerning licensing that are prescribed in Part I and II of ‘First Schedule’ of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011, except for granting of a licence for transport, import, export or supply of sources or radiation devices, before

imposing, approving, amending, preparing or taking a decision for conditions in relation to the granting of a licence, the Minister of MLWSI should ask for the advice of the Technical Licensing Committee (TLC), an advisory body that comprises representatives from different government Ministries.

According to the law, where there is a disagreement in the decision making process, any member of the TLC may ask the President of the TLC during a meeting, to send the case to the Council of Ministers. The Council of Ministers examines the case and takes a final decision. According to the law and the current practice, all licenses, except for transport, shipment or supply sources or radiation devices, are signed by the Minister of MLWSI. The IRRS team was informed during the mission that discussions between the MLWSI and DLI have been initiated with respect to delegation of powers from MLWSI to RICS/DLI to reduce the burden of the Minister and with the intention that the powers of the Minister to issue a licence would be delegated to RICS/ DLI. Additionally, this measure is expected to create an arrangement that in the case of disagreement between the members of TLC the case would be ultimately resolved by the Minister of Labour, Welfare and Social Insurance.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The provision that the Council of Ministers may make the final decision in a case where there is a disagreement among members of the TLC regarding conditions proposed for granting the licence may potentially compromise the regulatory body's independent judgements and decisions under its statutory obligations.

(1)

**BASIS:** GRS Part 1 (Rev.1) Requirement 4 para 2.8 states that *“To be effectively independent, the regulatory body: (c) shall be able to make independent regulatory judgements and decisions[...]*”

R4

**Recommendation:** The Government should strengthen RICS/DLI powers and responsibilities in the licensing decision-making process through the legal framework.

### 1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

According to the law, the Government has assigned prime responsibility for safety to the person or organization authorized to operate a facility or conduct an activity. The responsibility for safety covers all stages in the lifetime of facility or duration of the activity. However, it is not clearly established in the legal framework that where an authorization (approval or licence) is not in place this does not exonerate a person responsible for a facility or activity from the prime responsibility for safety.

Section 17 (2) of the law outlines that the licensee may appoint other persons to carry out actions or tasks related to his obligations but should retain the overall responsibility for the radiation protection and nuclear safety.

The prime responsibility of the licensee for safety is also established in the ‘Responsible and Safe Management of Spent Fuel and Radioactive Waste Regulations of 2014’ where in Section 10(1) it stipulates that subject to the provisions of Section 17(1) and (2) of the Law the prime responsibility for the safety of radioactive waste management facilities and/or activities rests with the licence holder and that the responsibility cannot be delegated.

There are provisions in the law enabling RICS/DLI to require that the authorized person should demonstrate compliance with the safety requirements. This requirement is complied with through the authorization process where RICS/DLI may request a person or organization to provide, or to have instant access, to all the necessary safety related information. Once an authorization is granted, the

demonstration of compliance with safety requirements is assured through the inspection process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<b>Observation:</b> There is no explicit provision in the legislation that the person or organization responsible for a facility or activity has prime responsibility for safety, although the legislation clearly stipulates provisions regarding the prime responsibility for safety of authorized parties.	
(1)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 5 states that</b> <i>“the government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.”</i>
(2)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 6 states that</b> <i>“the government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety.”</i>
S1	<b>Suggestion:</b> The Government should consider extending the prime responsibility for safety in the legislation so that where an authorization (approval or licence) is not in place this would not exonerate the person or organization responsible for a facility or activity from the responsibility for safety.

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

According to the legislation, the Minister of Labour, Welfare and Social Insurance, acting through the RICS/DLI, is the only regulatory authority for safety.

Its main authorities, responsibilities and/or powers are prescribed in the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 while other, specific powers and responsibilities of the regulatory body can also be found in secondary legislative acts (regulations).

In the areas where the powers of the MLWSI may interact with power of other governing bodies, the legislative framework (such as in the area of transport; import and export of radioactive material; site selection and/or construction) makes provisions that responsibilities and functions of each authority are clearly specified in relevant piece of legislation.

In radiological emergency preparedness and response, the MLWSI cooperates with other governmental services, such as Civil Defence, Police, Fire Brigade, hospitals, and other stakeholders involved in order to implement a comprehensive system of emergency preparedness and response, and a special action plan, ELECTRA.

The regulatory body has also established formal cooperation and coordination agreements with other organizations such as the national laboratory through a memorandum of understanding (MoU).

The IRRS team was also informed that the RICS/DLI has an intention to establish MoU's with some organizations in the near future.

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

The issue of orphan sources is dealt with in accordance with Directive 2003/122/Euratom on the control of high activity sealed radioactive sources and orphan sources, which is transposed into Control of High Activity Sealed Radioactive Sources and Orphan Sources Regulations of 2006. Based on this regulation the RICS/DLI, when deemed appropriate, may request the establishment or use of systems, devices or instruments aimed at detecting orphan sources in places such as large metal scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered; or at significant nodal transit points, such as customs posts. The RICS/DLI may request from any employer who has responsibility of such a facility to have insurance or any other equivalent means to cover intervention costs relating to the recovery of orphan sources. The IRRS team was informed that intensifying the national campaign for the potential discovery of orphan sources is envisaged in the near future and planned to be conducted on a continuous basis.

Provisions on existing or unregulated radiation risks are also made in Basic Principles Regulations of 2002. This regulation deals with situations of radiological accidents or radiological emergencies or lasting exposure resulting from the after-effects of a radiological accident or radiological emergency or past activities.

## **1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE**

In Cyprus, the main origins of radioactive waste are from activities in the field of medicine, industry and research. All sources and radioisotopes used in Cyprus are produced abroad. Radioactive waste is generated in low volumes, in solid or liquid form, mainly from medical laboratories as a result of application in nuclear medicine. There are also a number of legacy disused sealed radioactive sources that were used such as for cancer therapy, research, lighting rods, smoke detectors or other purposes in the past. No nuclear facilities that could lead to the generation of spent fuel, i.e. nuclear power plants, research reactors, nuclear fuel or waste treatment facilities, uranium or thorium mines etc. exist in the country.

The National Policy and Strategy on the Responsible and Safe Management of Radioactive Waste of 2015 provides the basic elements of governmental policy and corresponding strategy over the lifetime of facilities and the duration of activities with respect to the responsible and safe management of radioactive waste. The disposal of radioactive waste in dedicated facilities is recognized as the final end-point for sustainable management of radioactive waste. The generators of radioactive waste have the primary responsibility for the safe management of the waste they generate and that responsibility cannot be delegated. The Government takes responsibility for the management of radioactive waste where the generator no longer exists and for the provision of control over closed disposal facilities and the funding thereof, where applicable. An explanation of the diversity between types of radioactive waste and the radiological characteristic of radioactive waste and appropriate interim targets are included in this document as well.

The Responsible and Safe Management of Spent Fuel and Radioactive Waste Regulations of 2014 provide more specific legal requirements. These Regulations apply to all stages of radioactive waste management, from generation to disposal.

The National Policy and Strategy on the Responsible and Safe Management of Radioactive Waste as well as the Responsible and Safe Management of Spent Fuel and Radioactive Waste Regulations have general requirements regarding financial obligation of different players.

## 1.8. COMPETENCE FOR SAFETY

The Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011, in section 6(c), 17(5)c and 18(A) contains some provisions which provide for certain obligations of the regulatory body, the licensee and organizations providing services or expert advice on matters relating to safety with respect to education and training.

The Basic Principles Regulations of 2002 also have provisions which require the employer or licensee to provide basic and specific education and training in radiation protection for exposed workers, apprentices and students and for outside workers (Section 18 and 37).

The Control of High Activity Sealed Radioactive Sources and Orphan Sources Regulations of 2006 also has provisions on training (Section 12).

Schedule two of the Medical Exposure Regulations of 2002 also includes provisions on education and training requirements on radiation protection.

The IRRS team was informed that, there are provisions on qualification and training needed for certain tasks, such as for radiographers for diagnostic and therapeutic radiology practices or for the registration of medical physicists, in some other laws (for registration of Medical Physicists, for instance, the Ministry of Health is responsible).

With regard to the personnel of the RICS/DLI, the ‘Schemes of Service’ has specific requirements with respect to qualifications for the director, senior labour inspection officer and labour inspection officer (such as a university degree or title or equivalent qualification, certain years of work experience on issues related to the Department, competence, good knowledge of legislation etc.); but there are no provisions and arrangements made on training and maintaining of competences.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The existing provisions on education and training of parties having responsibility in relation to the safety of facilities and activities do not cover all aspects of building and maintaining the competence in radiation safety.

(1)

**BASIS: GSR Part 1 (Rev.1) Requirement 11 states that** *“The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.”*

R5

**Recommendation: The Government should make provision for a system to ensure building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.**

## 1.9. PROVISION OF TECHNICAL SERVICES

RICS/DLI is cooperating with national technical service providers and is supported in its duties with adequate provision of technical services related to safety, such as services for personal dosimetry, environmental monitoring and calibration of equipment.

There are technical services such as individual personnel monitoring, calibration and sample analysis services currently available in Cyprus. Support and technical services are also provided by other institutions and laboratories, with capabilities in radioactivity analysis, measurement and dosimetry. RICS/DLI may request as necessary assistance from laboratories in other countries including the EU, the International Atomic Energy Agency and other international organizations.

A bilateral agreement with the Greek Atomic Energy Commission is also in place, which covers all issues concerning the applications of ionizing radiation and nuclear safety, including the provision of technical services upon request.

The need for approval of dosimetry services and occupational health services from the regulatory body is stipulated in the Section 53 of the Protection from Ionizing Radiation (Basic Principles) Regulation.

#### **1.10. SUMMARY**

The policy and strategy for safety in The Republic of Cyprus is reflected in the national legislative provisions and establishment of safety infrastructure, including meeting its obligations under relevant international conventions to which it is a party.

A legislative framework for radiation safety exists which also established a regulatory body for safety. The Minister of Labour, Welfare and Social Insurance (MLWSI), acting through the Radiation Inspection and Control Service (RICS) of the Department of Labour Inspection (DLI) is the regulatory body.

There is a need for establishing a national policy and strategy for safety and provision of sufficient resources for carrying out regulatory responsibilities



## 2. THE GLOBAL SAFETY REGIME

### 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Republic of Cyprus is a contracting party to various safety related international conventions, agreements, treaties and other instruments, including the:

- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency;
- Convention on the Physical Protection of Nuclear Material (and its amendments);
- Convention on Nuclear Safety;
- Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- Comprehensive Nuclear Test Ban Treaty;
- The Treaty on the Non-Proliferation of Nuclear Weapons;
- The Safeguards Agreement and Additional Protocol between The Republic of Cyprus and the International Atomic Energy Agency;
- The Agreement between the European Community of Atomic Energy, the Member States that do not possess nuclear weapons and the International Atomic Energy Agency, in application of Annexes 1 and 4 of Section III of the Treaty for the non-Proliferation of Nuclear Weapons and its Additional Protocol and
- The International Convention for the Suppression of Acts of Nuclear Terrorism.

The Republic of Cyprus has declared its political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and to the associated Guidance on the Import and Export of Radioactive Sources.

RICS/DLI has a bilateral agreement with the Greek Atomic Energy Commission, which covers all issues concerning the applications of ionizing radiation and nuclear safety.

The IRRS team was informed that The Republic of Cyprus implements the UN SC Resolution 1540 and participates in the Global Initiative for Combatting Nuclear Terrorism (GICNT).

The IRRS team was informed that the regulatory staff are familiar with IAEA safety standards and the standards are taken into consideration in the development of safety regulations. The IRRS team was also informed that due to the limited resources The Republic of Cyprus has been unable to actively participate in the various IAEA Safety Standards Committees or safety review missions where the IAEA safety standards are used as basis. However, the IRRS team was informed that The Republic of Cyprus is a corresponding member to these committees and can fully participate in the meetings through video conference or being present in the meetings when funding is secured.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Cypriot experts have limited opportunities to participate in international cooperation activities for safety.

(1)

**BASIS: GSR Part 1 (Rev.1) Requirement 14 states that** *“The government shall fulfil its*



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.”</i>
<b>R6</b>	<b>Recommendation:</b> The Government should participate in international cooperation activities for safety such as participation in IAEA safety review missions.

The Government has clearly stipulated in the Law on Section 18 that the regulatory body should periodically conduct self-assessment and invite international peer review of relevant segments of authorities with the aim of continuously improving safety.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> The Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 contains explicit provisions on the requirements for the regulatory body to conduct self-assessment and invite peer-review periodically at least every ten years.	
<b>(1)</b>	<b>BASIS: GRS Part 1 (Rev.1) Requirement 14 para 3.2 states that</b> <i>“The features of the global safety regime include:</i> <i>(d) International peer reviews of the regulatory control and safety of facilities and activities, and mutual learning by participating States.”</i>
<b>GP1</b>	<b>Good Practice:</b> The Government has stipulated in the law that the regulatory body should periodically conduct self-assessment and invite an international peer review with the aim of continuously improving safety.

The IRRS team was informed about planned activities in the future in the area of international cooperation, such as the assessment of the need for inviting of the IAEA’s integrated review mission for radioactive waste, decommissioning and remediation programmes (ARTEMIS) and Emergency Preparedness Review (EPREV) mission, and exploration of the possibility to establish appropriate bilateral or multilateral agreements with the competent authorities of other states, members of IAEA and EU.

## 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

RICS/DLI receives relevant information on operating experience and regulatory experience from regulatory bodies of other States and from authorized parties through its participation in, among others, the review meetings of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and the Convention on Nuclear Safety. RICS/DLI staff represent The Republic of Cyprus at different international fora including the institutions of the European Union (EU), the IAEA, and the Heads of the European Radiological Protection Competent Authorities (HERCA). RICS/DLI also receives information on operating and regulatory experience through appropriate national and international knowledge and reporting networks.

The regulatory body carries out analysis to identify lessons learned from operating and regulatory experience, including the experience of other States, in order to disseminate the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities. However, there are no appropriate arrangements in place, and dissemination of information is done on a rather ad-hoc

basis (through announcements, e-mails and/or web site).

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** RICS/DLI has no formal arrangement in place for analysis and sharing and dissemination of information received regarding operating and regulatory experience.

(1)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 15 states that</b> <i>“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.”</i>
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R7	<b>Recommendation:</b> RICS/DLI should make arrangements for analysis to be carried out to identify lessons learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities. Such arrangement should also include feedback on measures that have been taken in response to information received.
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### 2.3. SUMMARY

The Republic of Cyprus is a contracting party to a various safety related international conventions, agreements, treaties and other instruments and the regulatory staff are familiar with IAEA safety standards, which are considered in the establishment of safety regulations.

RICS carries out analysis to identify lessons learned from operating and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities. Dissemination of information is conducted on ad-hoc basis. On the other hand, RICS has no formal arrangement in place for sharing and dissemination of information received regarding operating and regulatory experience.

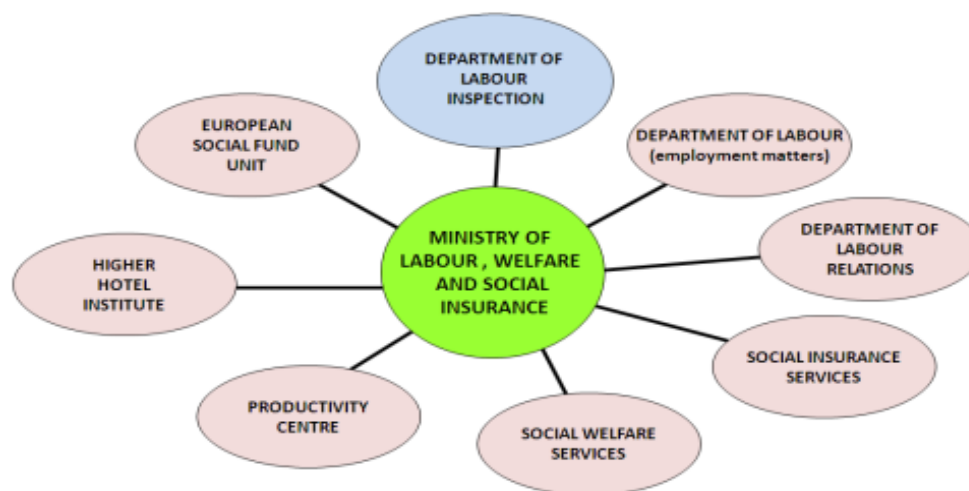
### 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Minister of Labour, Welfare and Social Insurance (MLWSI), acting through the RICS/DLI is the regulatory body in The Republic of Cyprus on nuclear and radiation safety and radiation protection, and has the responsibility for the administration of relevant legislation and authorization of all sources and practices involving exposure to ionizing radiation. The MLWSI has also other responsibilities which are related to labour and social insurance issues.

RICS was established within DLI of the MLWSI, under Section 4 of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011. The aim of RICS is to protect individuals and the environment against risks of ionizing radiation during the use of sources or during exposure to ionizing radiation at work and exposure of the public and from risks due to dispersion of radioactive substances.

The organizational structure of the MLWSI is shown below:



The RICS is not further divided into organizational units and it is currently staffed with only 5 inspectors, one senior inspector and four labour inspection officers.

An annual plan of activities is established and implemented. It sets the priorities for the RICS each year in relation to the regulation of facilities and activities using ionizing radiation.

All of the activities carried out by RICS are financed through the annual budget of DLI. The budget is prepared annually, by RICS in accordance with its foreseen needs and it is included in the DLI budget, which is approved by the Parliament.

#### 3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Staff recruitment for RICS lies within the general framework of governmental personnel recruitment, and is subject to the agreement and approval of the Director of the Department of Labour Inspection; the Permanent Secretary of the Ministry of Labour, Welfare and Social Insurance; the Director of the Department of Personnel and Public Administration; the Permanent Secretary and the Minister of the Ministry of Finance; the Council of Ministers and finally to the decision of the House of Representatives (Parliament).

Section 28 of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 stipulates that the Minister is responsible for the administration of the law and that he may appoint a Chief Inspector and Inspectors as well as any other persons he may deem appropriate, for the enforcement of this law and he may terminate such appointment of the Chief Inspector, the Inspectors or the other persons. Furthermore, the Chief Inspector coordinates the matters and the manner in which inspectors carry out their duties and exercise the powers under the Laws, and co-ordinates, in general, the functions of the RICS.

RICS personnel perform their duties in accordance with the principles set out in the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 and the Public Service and Public Administration Laws. There are strict regulations in place forbidding any external influences that could compromise the objectivity and adequacy of RICS decisions as part of a Government organization. Furthermore, the Public Service Law sets out the obligations and duties of civil servants.

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

RICS personnel recruitment process lies within the general framework of governmental personnel recruitment. Once a vacant position is declared within the Department of Labour Inspection, the vacancy is published in the Official Gazette of the Republic.

Staff of the RICS are civil servants with permanent positions and the IRRS team was informed that staff turnover is minimal. Qualifications and competences of recruited staff are included in the Schemes of Service for each different position, prepared based on the provisions of the Civil Service Law. RICS is part of the DLI which is, among others, responsible for the application of the legislation on Health and Safety at Work.

An assessment of human resources needs for RICS was prepared based on the internal analysis and reports from external audits issued by independent organizations, such as the Department of Personnel and Public Administration of the Ministry of Finance, the PWC (external audit organization) and including through a European Transition Facility Project and the Greek Atomic Energy Commission.

Such an assessment of human resources needs is reviewed and updated, as appropriate. However, a human resources plan for RICS that describe the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the regulatory functions, taking into account the nature and number of facilities and activities to be regulated as well as other responsibilities is not in place.

The IRRS team was informed that based on such assessment several attempts have been made to the Government to increase the number of RICS's staff but because of financial restrictions the number of staff remains unchanged. This issue is addressed in Recommendation R3 in Section 1.3.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Although assessments of human resource needs are made and proposals submitted to the government, a human resource plan for the regulatory body for safety is not yet in place.

(1)

**BASIS: GSR Part 1 (Rev.1) Requirement 18 para 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.”*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 18 para 4.11 states that</b> <i>“The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions.”</i>
R8	<b>Recommendation:</b> RICS/DLI should prepare and implement comprehensive human resource plan on the basis of the analysis made on necessary competence and skills.

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

The Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 provides for two formal ways of liaison of RICS with advisory bodies. The Laws have provisions in Section 10(3), that before granting a licence (except for granting a licence for transport, import, export or supply of sources or nuclear devices) the Minister asks for the advice of the Technical Licensing Committee (TLC).

The main responsibilities of the Committee are:

- to advise the MLWSI on licensing matters;
- to approve the general licensing conditions for granting licences by the MLWSI;
- to deal with issues of ethic and morality on the implementation of the Regulations relating to exposure to ionizing radiation for medical research purposes.

Besides the representative of the MLWSI (who acts as a President) the TLC comprises one representative from five different Ministries (Agriculture, Rural Development and Environment; Interior; Energy, Commerce, Industry and Tourism, Transport, Communications and Works and Ministry of Health). The IRRS team was informed that in cases where a licence is applied by applicant which is under one of the Ministry represented in the committee (such as for instance a public hospital under the Ministry of Health), the representative of that ministry would not take part in matters concerning the conditions for granting the licence under the Section 10 of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 and abstains from voting.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** With regards to deliberations of the TLC in considering applications for authorization, there is no clear provision in the existing legislation or other government provisions that members of the committee should not participate in the decision making process of the TLC, in cases where the application for authorization under consideration falls under the ministry or organization they are representing.

(1)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 20 para 4.20 states that</b> <i>“Arrangements shall be made to ensure that there is no conflict of interest for those organizations that provide the regulatory body with advice or services.”</i>
(2)	<b>BASIS: GSR Part 1 (Rev.1) Requirement 4 para 2.8 states that</b> <i>“The regulatory body shall be able to make independent regulatory judgements and decisions, free from any undue influences that might compromise safety, such as .... pressures from government departments or from other organizations.”</i>
R9	<b>Recommendation:</b> The Government should make provisions in the legislation or

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**make other arrangements for the services of TLC in providing advice in order to ensure that there is no conflict of interest.**

Furthermore, the Law provides for advice to the MLWSI on general policy matters, offered by the Radiation Protection and Nuclear Safety Council, which has been established by the MLWSI. The Council comprises representatives from governmental departments and ministries, professional associations, universities and other bodies. The members and the duration of their appointment are published in the Official Gazette.

The Council advises the Minister on:

- formulating national policy concerning radiation matters, including applications of nuclear techniques, nuclear safety and health and safety matters against the risk arising from ionizing radiation; and
- all matters concerning radiation or the nuclear energy, including matters of potential exposure to radiation risks arising from sources coming from abroad.

There are also technical service providers to the licensees, approved by the regulatory body, such as Qualified Expert, dosimetry services, and occupational health services.

The regulatory body is supported by a number of institutions which have capabilities for monitoring and analysis in the field of ionizing radiation, such as:

- the State General Laboratory, under the Ministry of Health, for laboratory environmental radioactivity analysis and measurements;
- the Department of Fisheries and Marine Research of the Ministry of Agriculture, Rural Development and Environment, for sampling in the sea (marine environment);
- the Medical Physics Unit, Lefkosia (Nicosia) General Hospital, Ministry of Health, for secondary standard dosimetry services (SSDL);
- the Nuclear Physics Laboratory of the Department of Physics and the Radiochemistry Laboratory of the Department of Chemistry, University of Cyprus, for specialized radioactivity analysis and measurements.

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

RICS/DLI has established formal and informal mechanisms and ways of communication with licensees on safety related issues. RICS/DLI has a web-based information dissemination system where information such as on application forms; prescribed criteria for approval of Qualified Experts, radiation services, dosimetry laboratories, etc.; licence and general conditions for radiological dental practices; can be found. In cases where it is decided that the licence is not granted, such a decision is justified in order to ensure that applicant fully understands arguments for the decision.

In case of issuing of a new regulation, the information is shared by RICS/DLI through the website.

There are also other formal and informal mechanisms used for communication and consultation between RICS/DLI and authorized parties such as by conducting a professional and constructive liaison through meetings and other open communication. Means of formal and informal communication also include: correspondence by mail, fax, e-mail, and oral communication.



### 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

There is a clear allocation of decision-making and other responsibilities within the regulatory body, which comprises, hierarchically, the Minister; the governing body, which is the Radiation Inspection and Control Service of the Department of Labour Inspection; and the powers of the Chief Inspector (the Director of RICS) and the Inspectors, who are in charge of the RICS's performance and implementation of decisions. Thus, a clear reference to hierarchy and relevant decisions is made through the organizational scheme of the RICS.

Furthermore, the subjectivity in decision making is minimized and predictability and consistency of the regulatory decision making is preserved, for example, through published criteria to be considered for exempted practices; published criteria for approval of Qualified Experts, radiation services, dosimetry laboratories, etc.; published general conditions for dental practice using ionizing radiation, etc.

Section 40 (1) of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 stipulates that the Council of Ministers, after a proposal by the Minister, may make regulations in relation to any matter that needs to be regulated for the improved implementation and achievement of the objectives of this law. Furthermore, the Third Schedule provides for the areas to which those regulations relate.

Based on proposal of MLWSI, the Council of Ministers has issued regulations for certain practices such as medical exposure, use of sealed sources of category 1-3 (HASS), management of radioactive waste, supervision and control of shipments of radioactive waste, etc. However, other practices and activities with ionizing radiation, such as the use of unsealed sources, sealed sources of category 4 or 5, industrial radiography, veterinarian radiology, use of cabinet X-ray or XRF, etc. are not covered. These practices are regulated only by providing conditions in the license.

As a consequence, these license conditions are applied to a large number of applications, which makes it difficult for applicants to know in advance what requirements they will need to fulfil prior to issuance of the license which might also lead to potential variation in decision making in the authorization process. The duration of the authorization of each license is also decided on a case by case basis and there are no clearly defined criteria.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Most licenses contain an extensive set of license conditions, which can vary between different licensees working within the same practice. Licenses are also issued for a duration that is selected on a case by case basis.

(1)

**BASIS: GSR Part 1 (Rev. 1) Requirement 22 para 4.26 states that** *“The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based.”*

R10

**Recommendation:** RICS/DLI should establish formal processes based on specific policies, principles and associated criteria and follows specified procedures.

### **3.7. SAFETY RELATED RECORDS**

A provision on record keeping exists in the legislation and requires such responsibility from the regulatory body as well as from the licensee.

RICS/DLI has established and maintains the following main registries and inventories:

- Registries of licensees authorized with special conditions;
- Registries of licensees authorized under general conditions such as dental radiology practices;
- Registries of sealed radioactive sources and irradiators;
- Records of occupational doses (National Registry);
- Records relating to the safety of facilities and activities;
- Records that might be necessary for the shutdown and decommissioning (or closure) of facilities;
- Records of radioactive releases or discharges to the environment from nuclear medicine practices;
- Inventories of sources and practices, including disused sealed radioactive sources;
- Inventories of radioactive waste;
- Records of environmental radioactivity monitoring.

The regulatory authority information management system (RAIS) is in place and such records are also kept and stored to support RICS/DLI's regulatory activities.

Authorized parties are also required by legislation to keep records related to their facilities and activities such as on sources, including their location, transfer and storage; personal record of individual monitoring for each exposed category A and B worker; medical records for category A workers and for the exposure of, and the doses received, by outside workers. Furthermore, the regulations require that records are kept for at least two years from the date on which they were made and for at least two years from the date of disposal of the radioactive substance.

There is a provision in the Control of High Activity Sealed Radioactive Sources and Orphan Sources Regulations of 2006 that each record holder should provide the RICS/DLI with an electronic or written copy of all or part of such records as required by the RICS/DLI.

RICS/DLI also verifies during inspections compliance of the authorized parties with these requirements.

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

The RICS/DLI has several communication channels with interested parties, including licensees, public and private organizations. These communication channels include participation with the TLC and the Council of Radiation Protection and Nuclear Safety. The RICS/DLI web site provides information such as on relevant legislation, on notifications, licenses, approvals and related fees, on instruction notes and guides, etc.

With respect to the licensing process the Laws provide in Section 2 of Part I of the First Schedule that any District Administration, Municipality or Local Authority, with interest for any matters under discussion in a meeting, must be informed to send an observer to the meeting, who would have the right to comment but not to vote.

Any new draft piece of legislation is made open for consultation with the public prior to submission to the Council of Ministers.

The Republic of Cyprus has incorporated in its overall legal system provisions necessary to introduce specific requirements with regards to public (local and neighbouring) participation in general and in



administrative procedures.

RICS also prepares its part for the DLI monthly report for the MLWSI, while the Annual Report of the MLWSI is published on the ministry web page and is publicly accessible.

RICS/DLI produces a five year report on environmental radioactivity monitoring that is shared with all interested parties and published on its website. Furthermore, RICS /DLI annual report is included in the report of the ministry, which is available to the public.

RICS/DLI has at its disposal a budget to conduct workshops on radiation protection and thematic specific campaigns. Two to three such events are conducted on an annual basis.

### **3.9. SUMMARY**

Effective independence in the performance of RICS/DLI's regulatory functions is provided through existing legislation. RICS/DLI has established formal and informal mechanisms and ways of communication with licensees on safety related issues. An assessment of human resources needs for RICS was prepared based on the internal analysis and reports from external audits.

A human resource plan needs to be developed for the regulatory body for safety, based on the assessment of staffing and training needs conducted.

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

### **4.1. LEADERSHIP FOR SAFETY**

The management of RICS/DLI demonstrates good leadership and commitment to safety emanating from the department's overall responsibility for the health and safety of workers and the radiation protection and safety of workers, patients, the public and the. Prioritization of safety is reflected in the DLI's strategic plan in which all the goals focus on safety. All the sections in the department, including RICS, have developed strategies and activities linked to the strategic goals. Heads of sections have a responsibility of monitoring and ensuring a safe working environment and report to the senior management meetings held every week.

DLI conducts regular workplace risk assessment to identify and address safety concerns in line with national legislation. The first assessment exercise was conducted by an independent consultant in 2009 and successive assessments have been carried out by internal labour inspection experts. The risk assessment reports and action plans are communicated to all employees in the department.

DLI has established a safety committee made up of elected employee representatives, reporting to the director on matters of workplace safety. According to the national legislation and codes of practice, the committee is responsible for carrying out risk assessments and inspection of workplaces, communicating workplace safety issues, conducting drills and exercises for workplace emergencies, among other things. Workplace inspections are conducted every three months and the reports of findings are communicated to all employees together with the relevant action plan. The safety committee reports to the director and recommends actions to address safety deficiencies through various mechanisms such as training, hazards elimination and purchase of Past Performance Evaluation (PPE) reports and information from the safety committee is disseminated to all employees in the department via intranet and in the form of circulars

DLI has budgetary allocation for safety related interventions such as PPE, training and drills which is used for the implementation of the aforementioned action plan or in line with the plans of the different sections. An additional budget is made to cater for PPE focused on RICS.

### **4.2. MANAGEMENT FOR SAFETY**

DLI/ RICS management approach is based on the legislation on Public Service and on Health and Safety at Work. Senior management in DLI, consisting of the director and the section heads including RICS, have the responsibility for the establishment and implementation of organizational policies and goals in line with the ministerial goals and vision. The DLI operations are guided by its strategic plan developed on a three-year cycle, which outlines the department's vision, mission, values and goals. The strategic plan has an associated budget to support actions and activities required to attain the set goals. The current DLI strategic plan is for the period 2016-2018 and contains three broad goals, aimed at enhancing health and safety of workers, the public and the environment.

The Director of DLI and the section heads are responsible for coordinating the development, implementation and review of action plans and budgets in their respective areas. The work of individual employees is guided by annual action plans developed and approved in consultation with the section head. The management system of DLI allows for an annual review of planned activities and budgets to incorporate emerging issues that may have an impact on safety. In the event of unplanned safety significant events, the DLI management can reorganize internal resources or approach the Ministry of Finance to access emergency intervention funds.

### 4.3. MANAGEMENT SYSTEM

The RICS/DLI management system has various elements that have been developed to cover the various areas in the scope of the organization. A number of processes and procedures have been developed and documented, which include the organizational structure, levels of responsibilities, scheme of service for employees, strategic plan, vision, mission, annual work plans and performance review. While management processes used in the department apply to all sections including RICS, there are certain elements that are specific for RICS in its responsibility for radiation safety that need to be developed independently and integrated into a single framework for the attainment of its goals. As such, RICS needs to ensure that all elements including management, technical, human and financial resources are brought together by means of high level documentation and policies. The IRRS team observed that RICS has no single document/manual which describes all the management system elements that are used in the section.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The different elements of the existing management system of RICS are not integrated into a single framework that considers all aspects of the organizational goals such as safety, quality, environmental, health and economic elements.

(1)	<b>BASIS: GSR Part 2 Requirement 6 states that</b> <i>“The Management system shall integrate its elements, including safety, health , environmental, security , quality , human- and -organizational factor, societal and economic elements, so that safety is not compromise.”</i>
(2)	<b>BASIS: G-S.G 3.1 para 2.1 states that</b> <i>“An integrated management system should provide a single framework for the arrangements and processes necessary to address all the goals of the organization. These goals include safety, health, environmental, security, quality and economic elements and other considerations such as social responsibility.”</i>
R11	<b>Recommendation:</b> RICS/DLI should integrate all essential elements of the management system necessary for the attainment of its goals into single framework.

#### Management System Documentation

A number of management system documents have been developed and approved by senior management of RICS/DLI. These are accessible to all employees via intranet. Hard copy documents are kept in the central registry within the department. Contact information of most licenses and information concerning the sources of radiation are kept in the Regulatory Authority Information System (RAIS). Some of the management system documents and reports are available to the public via the department’s website.

The IRRS team was informed that control of documentation is performed in accordance with national legal requirements.

However, a number of elements of the RICS management system have not been documented. These relate to policies, processes, procedures, guides, checklists, and records as well as internal guidelines for RICS personnel that would assist in ensuring consistency in conduct of responsibility and realisation of safety goals.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** RICS has not documented all the elements of the management system.

(1)

**BASIS: GSR Part 2 Requirement 8 states that** *“The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use.”*

R12

**Recommendation:** RICS/DLI should document all the key elements of its management system and ensure that the documentation is readily available.

### 4.4. MANAGEMENT OF RESOURCES

RICS/DLI has a limited number of human resources to effectively undertake its responsibilities. DLI has conducted independent assessments on the human resource requirements for RICS and submitted the relevant recommendations to the government. These activities have been performed by different organizations such as the Greek Atomic Energy Commission and Price Waterhouse Coopers, an independent audit firm.

DLI has established a system to determine the competence of its employees. The department has a training committee consisting of representatives from all sections (including RICS) that independently assess the competences of employees and recommend to the senior management the training and resources required to improve performance. Annually, all employees are required to complete a competence assessment questionnaire that is submitted to the training committee, which conducts interviews of employees indicating deficiencies in specified areas as well as their supervisors/managers, assesses the training needs, compiles a report of and a budget to be approved by the director.

An annual budget is allocated for training and the DLI management ensures the provision of training through local institutions, consultants, technical cooperation arrangements and internal knowledge management initiatives. As such, DLI has been able to ensure that its employees continually improve their competence in line with the changing standards, and technology.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** DLI has established a mechanism to determine and address the competences and training needs of its employees on an annual basis. The assessment is conducted by a committee comprising employees, which makes recommendations to the director. A budget is provided annually to address the identified training needs.

(1)

**BASIS: GSR Part 2 Requirement 9 states that** *“Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them.”*

GP2

**Good Practice:** RICS/DLI has a system, implemented annually, for establishing and addressing the competence and training needs among its staff aimed at improving their contribution to achievement of organizational goals.

### 4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

RICS/DLI manages a number of processes in regulating the safe use of radiation in the country. These include management, core and supporting processes. The management processes (finance, human

resources, auditing, and procurement) apply to the whole department, while core processes are specific to RICS.

RICS has not adequately documented all key processes with the exception of the inspection process. Elements of the authorization process are described on the departmental website to assist licensees. RICS/DLI has not developed process flow maps/charts to illustrate the interactions, responsibilities and records among processes contributing to safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<b>Observation:</b> RICS has not documented and illustrated the interactions of all key processes contributing to the attainment of safety goals.	
(1)	<b>BASIS:</b> GSR Part 2 Requirement 10 para 4.28 states that <i>“Each process shall be developed and shall be managed to ensure that requirements are met without compromising safety. Processes shall be documented and the necessary supporting documentation shall be maintained.”</i>
R13	<b>Recommendation:</b> The regulatory body should identify, develop and document all key processes contributing to safety.

#### 4.6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

DLI/RICS has developed a system for measuring and assessing its planned activities. Performance reviews for individual employees are conducted every month by the head of section, where progress is measured against the work plan. The monthly performance review enables the employees to keep track of planned annual activities as well as address implementation challenges encountered during the month. RICS compiles and submits quarterly performance reports to the DLI director who is the Chief Inspector. Furthermore, RICS conducts an evaluation of its annual work plan and submits an annual report of its activities that included in the departmental report published annually (also available on the website).

The activities of RICS are subject to independent assessment through audits conducted at three levels. These are conducted by section heads, the Ministry’s internal auditors and the Office of the Auditor General. The audits cover the whole scope of the organization’s management system including financial issues and performance of core processes such as licensing and inspections.

While RICS employees conduct periodic self-assessments of their work and performance, there is no guidance provided to ensure that the results of the exercise contribute to continual improvement. As such, the frequency and scope of self-assessments varies from one employee to another.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<b>Observation:</b> DLI/RICS has not developed guidance for the self-assessment of work conducted by individual employees, in order to contribute to continual improvement in the organization.	
(1)	<b>BASIS:</b> GSR Part 2 Requirements 13 para 6.4 states that <i>“Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement. Lessons and any resulting significant changes shall be analysed for their implication on safety.”</i>
S2	<b>Suggestion:</b> The regulatory body should consider developing guidance for self-

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**assessment of work conducted by managers and individuals in the organization to ensure continual improvement.**

RICS is required to conduct independent assessment and self-assessment of leadership for safety and safety culture under the state legislation and within the framework of the EU. However, no such assessments have been conducted to-date.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** DLI/ RICS has not established a mechanism for independent and self-assessment of leadership for safety and safety culture for the enhancement of the organizational culture for safety.

**(1)** **BASIS: GSR Part 2 Requirements 14 para 6.9 states that** *“Senior management shall ensure that self-assessment of leadership for safety and of safety culture includes assessment at all organizational levels for all functions in the organization. Senior management shall ensure that such self-assessment makes use of recognised experts in the assessment of leadership and of safety culture.”*

**(2)** **BASIS: GSR Part 2 Requirements 14 para 6.10 states that** *“Senior management shall ensure that an independent assessment of leadership for safety and of safety culture is conducted for enhancement of the organizational culture for safety.”*

**R14** **Recommendation:** RICS/DLI should implement a system for self-assessment and independent assessment of leadership for safety and of safety culture in the organization.

### 4.7. SUMMARY

The system of assessing employee competence and training needs has been effective in ensuring that employees continually improve their performance. RICS/DLI has not fully developed and integrated the elements of its management system. There are gaps in the identification, documentation and implementation of key processes.

## 5. AUTHORIZATION

### 5.1. GENERIC ISSUES

The legislative basis for authorization is the Protection from Ionizing Radiation and Nuclear Safety Laws. The Minister of MLWSI, as the regulatory body, is responsible for the establishment and implementation of the national radiation protection and nuclear safety policy and strategy, the administration of relevant legislation, and the authorization of all sources and practices involving exposure to ionizing radiation.

A graded approach is used for authorization. RICS/DLI applies a three-level authorization system of approval, licensing and registration. The Radiation Protection and Nuclear Laws require that any person carrying out or planning to carry out practices/activities covered by the Laws must submit a notification to the MLWSI and subsequently apply for a licence in writing. All licenses issued are granted by the Minister. Currently dental radiography is authorized through registration.

There are exempted practices which fall under the provisions of Section 9 of the Law e.g. radioactive substances with activity concentrations below the limits of Part II of the Law. The Law provides for RICS to specify certain criteria for release from regulatory control but such criteria have not been specified yet. This issue is addressed in Recommendation R2 in Section 1.2. There are currently no sources of ionizing radiation or practices cleared from regulatory control.

A licence is required at different stages in the lifetime of a facility or the duration of an activity. The Minister seeks advice from the TLC on all licensing matters including applications, renewals, suspensions, revocations, and modifications to a practice or a source. RICS/DLI however has not established criteria and procedures for the amendment and renewal of a license. Any District Administration, Municipality or Local Authority with interest for any matter under discussion in a meeting can attend but has no right to vote. Licences are issued for periods ranging from five to eight years, depending on the activities carried out and the risks involved and the duration of the licence is selected on a case by case basis. The conditions imposed on the licensee are also given on a case by case basis. This issue is addressed in Recommendation R10 in Section 3.6. For all dental registrations a set of general conditions has been published in the official gazette.

Prior to the granting of an authorization the applicants must submit documentation in support of their application. This documentation includes a risk assessment and safety assessment report for all practices and activities, instructions and local radiation protection rules. The scope and content of the safety assessment required are commensurate with the radiation risks associated with facilities and activities in a graded approach. All safety assessments are required to be independently verified by a Qualified Expert that has got an approval from RICS/DLI. There are guidelines on the licence application form and on the website of RICS/DLI in relation to the format and content of documents to be submitted by the applicant in support of an application for authorization.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There is no formal procedure for the amendment, renewal, revocation or suspension of an authorization.

(1)

**BASIS:** GSR Part 1 para 4.37 states that “Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure.”



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**R15**

**Recommendation:** RICS/DLI should establish objective and clear criteria for amendment, renewal, suspension or revocation of a licence.

There is provision in the legislation for an authorized party or a person aggrieved by a regulatory decision to appeal against the decision. The RICS applies an appeals process but it is not formalized and documented.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There is provision in the Radiation Protection and Nuclear Safety Laws of 2002 to 2011 for an authorized party or a person aggrieved by a regulatory decision to appeal against the decision. The RICS/DLI applies an appeals process but it is not documented.

**(1)**

**BASIS:** GSR Part 1 Requirement 24 para 4.32 states that *“The regulatory body shall establish a process that allows the authorized party to appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization.”*

**R16**

**Recommendation:** RICS/DLI should develop a documented appeals process.

### 5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The main origins of radioactive waste are from activities in the field of medicine, industry and research. Radioactive waste is produced in The Republic of Cyprus in low volumes, in solid or liquid form, mainly from medical laboratories for nuclear medicine applications. There are also a number of disused sealed radioactive sources used for cancer therapy, research or other purposes in the past.

There are no dedicated facilities devoted to radioactive waste management in The Republic of Cyprus. Waste management is performed in research and medical facilities where the waste is generated. As the majority of the radioactive waste is short lived, the management is based on interim storage for the sources to decay, to be controlled, then cleared and released as common waste. The review, assessment and authorization of radioactive waste management activities is performed during the authorization process of the facilities.

According to the existing legislation and the conditions set in the license, the operators are required to establish and maintain a mechanism to provide and ensure adequate financial resources to discharge their responsibilities and to ensure an adequate level of protection and safety. The regulatory body verifies compliance with this requirement during inspection.

According to the provisions of the Law, the demonstration of the safety of an activity or a facility should cover the development and operation of an activity and the development, operation and decommissioning of a facility or closure of a disposal facility as well as the post-closure phase of a disposal facility. The extent of the safety demonstration should also be commensurate with the complexity of the operation and the magnitude of the hazards associated with the radioactive waste and the facility or activity.

The government has established a ‘National Programme on the responsible and safe management of radioactive waste in The Republic of Cyprus’, which covers all types of radioactive waste under its jurisdiction, and all stages of radioactive waste management from generation to disposal. This



Programme for the management of radioactive waste is implemented but it is not yet published in the official Gazette.

An old fertilizer plant has been decommissioned in 2005-2006 and scales containing NORM/TENORM and devices using sealed sources used in the plant have been exported to an appropriate treatment facility abroad. The surrounding area, including the area where phosphogypsum has been placed, has been appropriately treated, insulated and stabilized. This IRRS team was informed that the phosphogypsum lagoon was surveyed in the past by RICS/DLI in collaboration with the IAEA, the Hellenic Centre for Marine Research and the University of Cyprus, and is under environmental monitoring.

According to the regulations on the Responsible and Safe Management of Spent Fuel and Radioactive Waste, the operator is responsible for developing a disposal facility that is practicable and safe, and for demonstrating its safety consistent with the requirements of the regulatory body. This task is undertaken in consideration of: the characteristics and quantities of the radioactive waste to be disposed of; the site or sites available; the techniques of mining, excavation, construction and engineering available; and the legal and regulatory infrastructure and regulatory requirements. The operator is also responsible for developing a safety case, on the basis of which decisions on the development, operation and closure of the disposal facility have to be made.

There are no spent fuel or radioactive waste disposal facilities in The Republic of Cyprus, and it is not foreseen to develop such facilities in the short or medium term future, since the management of spent fuel in the Republic is prohibited by law and the amount of radioactive waste of present and foreseen from practices with sources of ionizing radiation is very limited.

### **5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES**

There is no production of radioactive material or manufacture, processing or recycling of radioactive sources in The Republic of Cyprus. The main uses of ionizing radiation in The Republic of Cyprus is for medical purposes (diagnostic and therapeutic), industrial and construction applications and in the area of research and education.

RICS/DLI does not have specific internal guidance for the practices or sources within practices to be authorized. There are currently about 140 licensees and 450 dental registrations. Import and export of radioactive sources must be conducted with prior approval granted by RICS/DLI.

To apply for an authorization a generic application form must be completed. RICS/DLI has identified in its action plan that it intends to prepare different types of application forms for licence, covering all practices and facilities in a graded approach.

The provision to exempt certain practices is included in the Radiation Protection and Nuclear Safety Laws. There are currently no sources of ionizing radiation or practices cleared from regulatory control although the Laws provide for RICS to specify criteria for release from regulatory control but this is yet to be performed by RICS.

The IRRS team was informed that transfers of sources from or to other EU Member States are regulated in accordance with the EU Council Regulation 1493/93. For the licensing of sealed sources, an agreement to return to the supplier must in place prior to the granting of authorization. In the case of High Activity Sealed Sources (HASS) financial provisions to implement that agreement must be in place. RICS/DLI have identified in their action plan an area of improvement for consideration that includes the imposition of special conditions to the licensees for proving their financial adequacy to conduct practices with ionizing radiation, including the deposit of a financial guarantee or a bank assurance etc.

For the import/export/shipment of a sealed source, the license granted has a limited duration, until the shipment is completed.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Authorization of facilities and activities is through a three-level authorization system of approval, licensing and registration. RICS/DLI does not have specific guidance for the practices or sources within practices to be either authorized by approval, licensing or registration.

(1)

**BASIS: GSR Part 3 Requirement 8 para 3.10 states that** *“The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, including the requirements for notification, registration or licensing, using as the basis for this determination the criteria for exemption specified in Schedule 1 or any exemption levels specified by the regulatory body on the basis of these criteria.”*

R17

**Recommendation:** RICS/DLI should develop internal guidance to outline which practices or sources within practices are to be authorized by approval, registration and licensing.

### 5.4. AUTHORIZATION OF TRANSPORT

MLWSI acting through RICS/DLI is the competent authority in The Republic of Cyprus for the safe transport of radioactive materials within, to, or from The Republic of Cyprus.

All transport of radioactive material in The Republic of Cyprus is required to be made with a license issued by RICS/DLI under the condition and the Laws “Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011”.

Radioactive material transported in The Republic of Cyprus mostly includes radioactive sources used in medical, industrial and research practices. Modes of transport used include road, sea, and air. The transport of radioactive material in The Republic of Cyprus is mainly conducted through accepted packages, industrial packages and type A packages.

There are no package manufacturers or maintenance and servicing companies for packages in the Republic of Cyprus.

The IRRS team was informed that transit of radioactive material or nuclear material is covered by the existing legislation and by the European Commission Regulations. The Euratom Regulation No. 1493/93 of 1993 applies directly in all the Member States for intra-Community (EU) shipments of radioactive sealed sources or waste. Prior to any shipment of sealed radioactive sources or radioactive waste, a written application should be submitted to the regulatory body, by completing the relevant documents. Consent from RICS/DLI is requested for a transiting radioactive or nuclear material following the above mentioned legislation.

A license is provided to a carrier for a period of five years, and yearly to a carrier of radiopharmaceutical product (radioisotopes used in nuclear medicine). The licence includes details of the characteristics of the radioisotope quantities frequency of imports/shipments, and any other relevant details and information about the carrier (if external transport services are used).

For each import and export of radioactive sources a transport license is also issued to the applicant. For the mobile device containing radioactive sources the user has to notify the regulatory body for each movement specifically for the radiography sources.

RICS/DLI requests relevant documents and information including the risk assessment of the activity, the qualification of the transport workers and the management system of the carrier. The IRRS team was informed that an audit of the management system of the carrier is made during inspection but there is no a formal procedure. Guides on regulatory requirements related to transport of radioactive material are also not in place.

The training for transport workers is provided by Ministry of Transport, Communications and Works with the cooperation of RICS/DLI. The training includes radiation protection for Class 7 carriers. Training is also provided by the expert of the carrier.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There are no guides in place concerning the safety of transport of radioactive material and regulatory requirements for carriers.

(1)	<b>BASIS: GSR Part 1 Requirement 24 para 4.34 states that</b> <i>“The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process.”</i>
(2)	<b>BASIS: GSR Part 1 Requirement 32 states that</b> <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.”</i>
R18	<b>Recommendation:</b> The regulatory body should issue guides on regulation of transport of radioactive material.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** RICS/DLI does not have a programme for auditing the management system of the organizations involved in transport of radioactive sources.

(1)	<b>BASIS: TS. G.1.5 Requirement 4.58 states that</b> <i>“The competent authority should put in place an auditing programme to verify that the user’s management system is implemented and followed correctly.”</i>
S3	<b>Suggestion:</b> RICS/DLI should consider developing an auditing programme for the management system of the licensee.

### 5.5. SUMMARY

The Law provides for RICS to issue authorization to facilities and practices. The Minister acting through RICS/DLI, is the regulatory body in The Republic of Cyprus on radiation protection and nuclear safety. The Minister is responsible for the authorization of all sources and practices involving exposure to ionizing radiation. Authorization from RICS/DLI is required before a radiation source is acquired. Applicants must submit documentation as required by RICS. This specified documentation is set out as guidelines on the licensing application form and on RICS website.

Authorization of facilities and activities is through a three-level authorization system of approval, registration and licensing. RICS/DLI does not have specific guidance for the practices or sources within practices to be either authorized by approval, licensing or registration.

The applicant is required to submit documentation to RICS/DLI that includes a risk assessment and safety assessment report for all practices and activities. The legislation provides for different types of authorization at different stages in the lifetime of a facility or the duration of an activity. Licenses are issued for periods ranging from one to five years and the duration is decided on a case by case basis. Once a licence has been granted, any modifications to practices, equipment or facilities require the applicant to seek authorization from RICS/DLI.

## 6. REVIEW AND ASSESSMENT

### 6.1. GENERIC ISSUES

#### 6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

An applicant for a license is required to submit a safety assessment report to RICS/DLI that includes analysis of potential risk of the practice or facility. An inspector from RICS/DLI reviews and assesses the information submitted to determine the safety of the facility or activity, and decides upon the completeness of the documentation which the applicant delivers. The assessment is done mainly based on knowledge and experience of the individual inspectors of RICS/DLI. Also, earlier performed assessments in a similar or the same practice, as well as existing requirements and license conditions for similar practices, are taken into account during the review and assessment. RICS/DLI inspector acquires an understanding of the design of the facility or equipment, as necessary, and the operating principles proposed by the applicant. The inspector reviews and assesses whether operational and technical provisions are in place. The review and assessment are commensurate with the associated radiation risks.

Documentation used to perform review and assessment is the existing legislation, regulations, license conditions from comparable practices and activities, and the application form. However, internal procedures on performing review and assessment for RICS inspectors have not been established yet.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<b>Observation:</b> RICS/DLI has no specified procedures for the review and assessment of the safety assessment submitted by an applicant prior to the granting of an authorization.	
(1)	<b>BASIS:</b> GSR Part 1 Requirement 24, para 4.33 states that <i>“Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures.”</i>
R19	<b>Recommendation:</b> RIC/DLI should establish procedures for the review and assessment of a safety assessment submitted by an applicant.

#### 6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

RICS/DLI carries out review and assessment, and findings and suggestions are sent to the TLC which consists of representatives from different ministries. In accordance with the law, before imposing, approving, amending, preparing or taking a decision for conditions in relation to the granting of a license, the Minister should ask for the advice of the TLC and may grant licenses, based on conditions suggested by the TLC. Where there is a disagreement by any member of the TLC, this member may ask to send the case to the Council of Ministers. The Council of Ministers would examine the case and take a final decision. Normally, a pre-authorization inspection is conducted shortly after assessment is completed and before the authorization is granted.

### **6.1.3. BASES FOR REVIEW AND ASSESSMENT**

The application form specifies the information and data that are required to be submitted in an application. When authorizing an activity or facility, the inspector may seek additional relevant information for review and assessment. The safety assessment, which takes into account different scenarios, is expected to show that safety principles including the optimization of protection are implemented.

The process for review and assessment covers all regulated facilities and activities and all aspects relevant to safety and is commensurate with the radiation risks associated with the particular practice or facility. RICS/DLI reviews and assesses facilities or activities in accordance with the stage in the regulatory process i.e. initial review, subsequent reviews if necessary, and reviews of changes to safety related aspects of the practice or facility.

On renewal of the license, a new safety assessment needs to be sent to RICS/DLI for review and assessment. The licensee is also obliged to notify RICS/DLI and submit relevant documentation for any proposed modification that may affect the safety of a practice or facility for a new review and assessment. The criteria for regulatory review and assessment are derived from the requirements stipulated in the national legislation and license conditions.

### **6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT**

RICS/DLI has four experienced inspectors performing review and assessments. They are familiar with safety and protection principles, regulatory requirements and various safety aspects of the regulated practices. RICS/DLI inspectors are also involved in different functions, like inspection, authorization and review of safety assessments. RICS/DLI verifies the comprehensiveness and quality of the safety assessment against regulatory requirements and the conditions of the license before a decision is made.

RICS/DLI takes into consideration the risks of the radiation practices; and in practice review and assessment of license applications pertaining to low-risk radiation practice, for instance dentistry, are not as detailed and lengthy as other practices of a higher risk.

RICS/DLI takes into consideration results of inspections and, reviews and assessments are taken into account in making decisions on the amendment, renewal, suspension or revocation of authorizations.

## **6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES**

The review and assessment of the radioactive waste management activities is performed within the authorization of the practice. The procedure for granting a license by the Minister is specified in Part II of First Schedule of the Laws.

Any District Administration, Municipality or Local Authority, with interest for any matter under discussion in a meeting, is invited as observer to the meeting, who has the right to speak but not to vote.

Where there is a disagreement by any member of the TLC, this member may ask the President during a meeting, to send the case to the Council of Ministers. The Council of Ministers would examine the case and take a final decision.

### **6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES**

RICS/DLI inspectors perform review and assessment for practices and facilities using radiation sources. The IRRS team confirmed during a site visit that prior to acquiring a new source of radiation, which would constitute a major modification; a new safety assessment needs to be conducted before a license will be issued. For minor changes, authorization amendments of existing authorization is utilized. The inspector at RICS/DLI reviews documentation and assesses the risk based on the documentation submitted by the applicant or licensee.

Information related to all practices and sources have to be reviewed and assessed before a new authorization or renewal is granted, except for dentistry where the assessment is relatively simple and the applicant will receive a registration certificate with standard license conditions issued by RICS/DLI. In 2016 a total of 23 safety assessments have been reviewed in combination with authorization processes. These assessments consist of both new applications and applications for renewal of expiring licenses and major licensing amendments.

### **6.4. REVIEW AND ASSESSMENT FOR TRANSPORT**

For the renewal of a license, the carrier needs to apply three months before the end of the validity of the license. RICS/DLI conducts a review and assessment of the provided information and documents based on the existing Laws and implementing regulations. The assessment of existing packages is made based on the validity of foreign certificates as appropriate.

There is no procedure for the review and assessment of the transport organizations, the review and assessment is made on a case by case basis. This issue is addressed in Recommendation R19 in Section 6.1.

### **6.5. SUMMARY**

RICS performs review and assessment related to facilities and activities according to the requirements set out in the Law. Review and assessments conducted are commensurate with the associated radiation risks in accordance with a graded approach.

Internal procedures for review and assessment are limited to existing legislation, regulations and license conditions. Dedicated procedures for review and assessment of the safety assessment submitted by an applicant prior to the granting of an authorization are not in place.

## 7. INSPECTION

### 7.1. GENERIC ISSUES

#### 7.1.1. INSPECTION PROGRAMME

RICS/DLI devises a regulatory inspection plan annually. This inspection plan includes the number of inspections to be carried out and the names of the licensees. This inspection programme takes into account feedback from inspections conducted. However, the inspection plan does not take into account the radiation risks associated with the facility or activity or the frequency of inspections and the areas and programmes to be inspected in accordance with a graded approach. The inspection plan also does not establish intervals between inspections and the level of effort to be applied, and be developed based on the appropriate considerations, to ensure that the inspections cover all areas of responsibilities of RICS/DLI within an established period of the inspection plan.

The regulatory body has established and documented its inspection process in the RICS/DLI internal Inspection Guide. The inspection process is supported by provisions in the Radiation Protection and Nuclear Safety Laws conferring the regulatory body and its inspectors with all the necessary authority. There are a range of enforcement tools available to inspectors which can be exercised during inspections when required.

#### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The annual inspection plan does not take into account the radiation risks associated with the facility or activity or specify the frequency of inspections and the areas and programmes to be inspected in accordance with a graded approach.

(1)	<b>BASIS: GSR Part 1 Requirement 29 states that</b> <i>“Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>
(2)	<b>BASIS: GSR Part 1 Requirement 29 para 4.50, states that</b> <i>“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach.”</i>
(3)	<b>BASIS: GSR Part 1 para 4.52 states that</b> <i>“Regulatory inspections shall cover all areas of responsibility of the regulatory body [...]. The manner, extent, and frequency of inspections shall be in accordance with a graded approach.”</i>
(4)	<b>BASIS: GS-G-1.3 para 4.3 states that</b> <i>“The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility.”</i>
(5)	<b>BASIS: GS-G-1.3 para 4.9 states that</b> <i>“The regulatory body should have an overall plan for the programme of inspections that it is to undertake at a facility. In determining the</i>



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>intervals between inspections and the level of effort to be applied, the regulatory body should take into account the relative significance for the safety of the facility of each authorization stage and each inspection area.”</i>
<b>R20</b>	<b>Recommendation:</b> RICS/DLI should establish a formalized programme of inspections that specifies the frequency of inspection, taking into account the radiation risks associated with the facility or activity, and areas and programmes to be inspected in accordance with a graded approach.

### 7.1.2. INSPECTION PROCESS AND PRACTICE

RICS/DLI has issued an Inspection Guide which sets out how inspections are to be conducted. This Guide sets out the criteria for the provision of verbal instructions, issuance and service of improvement and prohibition notices following an inspection as appropriate. The IRRS team was informed that IAEA TECDOC-1526 “Inspection of Radiation Sources and Regulatory Enforcement” is taken into account in the RICS inspection process.

Reactive and planned as well as announced and unannounced inspections are undertaken by RICS/DLI. The inspections undertaken assess compliance with regulatory requirements and with any conditions specified in authorizations. There are currently no TSO’s contracted to conduct inspections for RICS. RICS does not perform joint inspections with other regulators regarding radiation safety.

An inspection is typically undertaken with one or two inspectors. In preparation for the inspection the inspector reviews the file of the licensee/registrants including findings from previous inspections. The inspection involves discussion with licensee/registrant and workers representatives and visiting the areas where ionizing radiation is used and/or stored.

There is a checklist of legal requirements based on the Radiation Protection and Nuclear Safety Laws that is available for inspectors to use when conducting inspections. This checklist is used at the discretion of the inspector.

At the end of the inspection, either verbal instructions or enforcement actions are given depending on the nature of the findings. Improvement or prohibition notices are the enforcement actions that can be utilized by inspectors. The Inspection Guide includes reference to these actions and sets out the criteria for when they can be served. The enforcement actions are recorded and provided to the licensee and the time frame for taking the corrective action is also provided as set out in the Inspection Guide. A record of the findings of inspections communicated verbally is not given to the licensee or registrant representative. Confirmation that corrective actions have been carried out can be verified through inspection or written confirmation received.

The results of the inspection are maintained on the licensees/registrants file. The annual inspection programme takes into account of feedback from inspections conducted.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There is a checklist that is available for inspectors to use when conducting inspections. This checklist is used at the discretion of the inspector.

<b>(1)</b>	<b>BASIS:</b> GSR Part 1 Requirement 22 para 4.26 states that “ <i>The regulatory process shall be a formal process that is based on specified policies, principles and associated</i> ”
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## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body.”</i>
S4	<b>Suggestion:</b> RICS/DLI should consider the use of the checklist in conducting all inspections to ensure that the stability and consistency of approach to inspections.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> A formal record of improvement and prohibition notices are provided to the authorized parties but this is not the case for findings of inspections that are communicated verbally.	
(1)	<b>BASIS:</b> GSR Part 1 Requirement 29 para 4.51 states that <i>“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.”</i>
S5	<b>Suggestion:</b> RICS/DLI should consider providing a documented record of the findings communicated verbally to authorized parties at the end of an inspection.

### 7.1.3. INSPECTORS

The training of inspectors involves on the job training and mentoring by more experienced inspectors. Powers of inspectors is set out in the Radiation Protection and Nuclear Safety Laws and includes provisions to allow RICS/DLI inspectors access to authorized facilities and activities.

RICS/DLI is currently staffed with one senior and four labour inspection officers, with qualifications in science and engineering and training and experience in radiation protection and nuclear safety. The number of qualified staff for the proper discharge of its assigned responsibilities is an on-going challenge for RICS/DLI. Staffing and training of inspectors is addressed further in Sections 3.3.

### 7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

The inspection of radioactive waste management activities and stored radioactive waste is performed as part of the inspection plan of the facilities that generate the waste and the license conditions are controlled and enforced accordingly.

RICS/DLI verifies the safety of radioactive waste storage facilities and activities by periodic inspections, in accordance with the annual inspection plan. There are however no specific internal guidelines and procedures for inspection of waste management storage. This issue is addressed in Recommendation R10 in Section 3.6.

### 7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

RICS/DLI conducts inspections in accordance with its annual inspection plan to verify compliance with the Radiation Protection and Nuclear Safety Laws and with the conditions of authorization.

The IRRS team members accompanied two inspectors from RICS to observe an inspection at the Bank of Cyprus Oncology Centre, Lefkosia (Nicosia). This inspection included verification that the

corrective actions from a previous inspection had been addressed. Following introductions, the IRRS team were allocated time to discuss the hospital's views of its interactions with RICS/DLI. The licensee was satisfied at how RICS/DLI conducts its regulatory inspections.

A high-dose rate brachytherapy facility, radiopharmacy and radioactive waste storage were inspected during this visit. The inspectors verified elements related to occupational exposures, radioactive waste inventory and quality control checks through the review of records. The inspectors confirmed that the licensee had addressed the corrective action ordered previously. The communication with the licensee throughout the inspection was open and there was full cooperation of licensee staff.

The IRRS team members also observed an inspection undertaken by two inspectors from RICS at Nortest (Cyprus) Industrial Radiography facility, Kalavassos. The room where X-ray NDT work is carried out was inspected. This room also contained the iridium-192 and selenium-75 sources used for NDT radiography which were stored in a shielded cabinet. The inspection included general safety arrangements and dose rate measurements of the shielded cabinet. Further to this records required to be maintained by the licensee were reviewed by the inspectors e.g. dosimetry reports, logbook for the use of the NDT X-ray units and sources by radiographers and radiographers qualification certificates. During a tour of the facility an X-ray unit was discovered on the premises that may be a licensable unit and the licensee was verbally requested to address this issue within two days.

In a separate discussion, the licensee representatives highlighted to the IRRS team members the good relationship that RICS/DLI has established with the facility.

#### **7.4. INSPECTION OF TRANSPORT**

RICS/DLI is authorized through legislation to regulate the transport of radioactive material. The Ministry of Transport is in charge of providing training for carriers including on radiation protection with the collaboration of RICS; the issuing of certificates for drivers of road vehicles according to ADR; and issuing of certificates of approval for vehicles for the carriage of dangerous goods by road.

A pre-authorization inspection on the safe transport of radioactive material is made by RICS/DLI for a new applicant for all organizations involved in the transport of radioactive material.

RICS/DLI has in place an inspection guide to be used by inspectors and it includes a section relating to workplace monitoring. However, the requirement for workplace monitoring for transport activities is not assessed and enforced during inspection. This issue is addressed in Recommendation R22 in Section 8.2.

For a radioactive material in transit, the IRRS team was informed that RICS/DLI works with customs and border authorities to ensure continuity of control during transit and transshipment.

#### **7.5. SUMMARY**

RICS/DLI prepares a regulatory inspection plan annually. This inspection plan includes the number of inspections to be carried out and the names of the licensees. This inspection plan takes into account feedback from inspections conducted. The inspection plan however is missing some elements. It does not take into account the radiation risks associated with the facility or activity or the frequency of inspections and the areas and programmes to be inspected.

Inspections are performed to assess the authorized parties' compliance with license conditions and relevant legislation. Inspections are conducted with one or two inspectors. A checklist of regulatory requirements is available for use by inspectors but is not used by all inspectors. Inspections findings are recorded but only provided to authorized parties when the enforcement actions of improvement or

prohibition notice are exercised. Otherwise the inspection findings are given as verbal instructions to the authorized parties.

The IRRS team observed inspections performed by RICS inspectors. The IRRS team noted that the RICS/DLI inspectors select their own scope for inspection. It was clear from the inspections observed that RICS/DLI has built a good rapport with authorized parties.

## 8. ENFORCEMENT

### 8.1. ENFORCEMENT POLICY AND PROCESS

The enforcement tools and powers of RICS/DLI are clearly defined in the legislation, such as the power to amend, suspend, modify or revoke a license, shut down a facility, stop activities, require additional safety analysis, and require modifications in a facility. RICS/DLI can obtain legal advice on enforcement matters. RICS/DLI can also utilize the courts to prosecute particularly in situations where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance. Further enforcement tools available to RICS/DLI are the imposition of additional regulatory requirements and conditions, improvement and prohibition notices, written warnings, penalties.

Details of three enforcement actions available to inspectors are described in the Inspection Guide including when corrective actions have to be addressed.

There are additional enforcement tools set out in the legislation but these are not referred to in the Inspection Guide. There are no clearly established criteria when these tools can be exercised and the timeframe within which the corrective actions must be addressed. For all enforcement actions, there is no established procedure of what steps RICS/DLI would take in a harmonized manner if corrective actions imposed on licensees were not addressed; or what course of action RICS/DLI would take as subsequent actions if its enforcement tools of, improvement or prohibition notices issued to licensees were not addressed.

RICS/DLI appears to have fostered a good safety culture among authorized parties. This was noted by the IRRS team when observing inspection when the authorized parties demonstrated their willingness to report incidents/near misses to RICS/DLI and implement measures to ensure that incidents/near misses do not occur again.

An appeals process is in place for an authorized party or a person aggrieved by a RICS/DLI regulatory decision to appeal against the decision which includes enforcement actions issued.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There are a number of enforcement actions that are utilized by RICS/DLI. Legal advice can also be sought with regard to exercising an enforcement action. There are no documented procedures for all the enforcement actions available to RICS/DLI.

(1)

**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.”*

(2)

**BASIS: GS-G-1.5 para. 3.85 states that** *“The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures. The procedures should specify the policy of the regulatory body with regard to the use of regulatory actions and enforcement measures, and the associated delegated authority given to inspectors and to other staff of the regulatory body. ... The procedures should cover in detail the decision making approach of the regulatory body in determining the level of action to take and the way in which actions should be taken, including dealing*

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	<i>with the failure of the operator to comply with the regulatory enforcement requirements.</i>
<b>R21</b>	<b>Recommendation:</b> RICS/DLI should ensure a harmonized implementation of the enforcement tools provided in the legislation.

### 8.2. ENFORCEMENT IMPLEMENTATIONS

According to RICS/DLI Inspection Guide, where it is evident during an inspection that there are serious offences that constitute an immediate or high risk to workers, patients or third parties and where the inspector considers that the licensee demonstrates a spirit of cooperation and genuine willingness to comply immediately, then the inspector can give the inspection findings verbally to the licensee clearly expressing the requirements of the legislation.

In cases where the inspector finds after inspection that the authorized party violates any provision of the relevant legislation or has contravened any such provision under conditions which make possible the continuation or repetition of the offence, an improvement notice may be served to the authorized party, which is an enforcement action and a formal record provided at the inspection.

In the improvement notice the inspector can set a logical and feasible period waiver of any contravene identified and stated in the notice. According to the Radiation Protection and Nuclear Safety Laws, the compliance period should not be less than 14 days. There is flexibility in that the duration of the period can be discussed with the authorized party but should not exceed six months, depending on the nature and extent of the practice or other actions required for compliance.

In cases where during an inspection, the inspector found that the activities carried out at the premise involve serious risk of health detriment for workers, patients or other persons, or serious loss of use of property or serious degradation of the quality of the environment arising from radiation, a prohibition notice may be served on the authorized party, prohibiting the use of the premises or installation until the risk involved is eliminated to the inspector's satisfaction. The prohibition notice has immediate effect. The applicable provision of the legislation must be indicated when an inspector exercises an enforcement action.

Training of inspectors on enforcement actions also includes on using procedures set out in the Inspection Guide, the provisions set out in the legislation on enforcement and mentoring by more experienced inspectors and coordinated by the Chief Inspector. In activities related to transport of radioactive material, the requirements on radiation dose assessment are not enforced.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<b>Observation:</b> RICS does not enforce the requirement of the radiation dose assessment for transport workers, or monitoring of workplace which are established in the national law for radiation safety.	
<b>(1)</b>	<b>BASIS:</b> SSR6 requirement 308 states that <i>“The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards.”</i>
<b>R22</b>	<b>Recommendation:</b> RICS/DLI should enforce the assessment of radiation doses to workers, public and workplace monitoring in activities related to transport of radioactive material.

### **8.3. SUMMARY**

The Radiation Protection and Nuclear Safety Laws assign a comprehensive set of powers to RICS/DLI to enforce regulatory requirements. This includes enforcement tools which are utilized when required on case by case basis.

The Inspection Guide sets out the procedures to be followed where activities or incidents have been identified that may require a verbal instruction or the issuance of improvement or prohibition notices. It would be beneficial to document the procedures for all enforcement tools to ensure a harmonized and consistent approach by inspectors.

## **9. REGULATIONS AND GUIDES**

### **9.1. GENERIC ISSUES**

The MLWSI is the sole authority that has been allocated responsibilities and functions of a regulatory body for activities relating to the control of radiation sources and radioactive material.

Section 40 of “The Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011”, stipulates the Council of Ministers is empowered to issue regulations. Consequently “The Protection from Ionizing Radiation (Basic Principles) Regulations of 2002” and other area specific regulations, and a guide on general license conditions for dental practices in order to regulate activities and facilities using ionizing radiation have been published and are made available on the website. These regulations are:

- The Protection from Ionizing Radiation (Basic Principles) Regulations of 2002 (P.I. 494/2002);
- The Protection from Ionizing Radiation (Informing the Public about Measures to be applied in Case of Emergency) Regulations of 2002 (P.I. 495/2002);
- The Protection from Ionizing Radiation (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations of 2009 (P.I. 86/2009);
- The Protection from Ionizing Radiation (Supervision and Control of Shipments of Radioactive Waste and Spent Nuclear Fuel) Notification of 2009 (P.I. 183/2009) (in Greek);
- The Protection from Ionizing Radiation and Nuclear Safety (Responsible and Safe Management of Spent Fuel and Radioactive Waste) Regulations of 2014 (P.I. 178/2014);
- The Protection from Ionizing Radiation (Medical Exposure) Regulations of 2002 (P.I. 497/2002);
- The Protection from Ionizing Radiation (Control of High-Activity Sealed Radioactive Sources and Orphan Sources) Regulations of 2006 (P.I. 30/2006);

As well as the following guide on general license conditions:

- The Protection from Ionizing Radiation and Nuclear Safety (General license Conditions for possession and use of radiological equipment in practices of Dental Radiology) Notification of 2014 (P.I. 470/2014).

The current regulations or guides however do not comprehensively cover all practices and activities under regulation.

Legislation and regulations are reviewed and revised, as necessary, to be up to date, with due consideration of relevant European (EURATOM) and international safety standards, technical standards and relevant experience gained. The IRRS team was informed that The Republic of Cyprus, as a European Union member state has to transpose by February 2018 the directive 2013/59/Euratom that lays down basic safety standards for protection against hazards from ionizing radiation.

Information concerning laws, regulations and guides, directed to the public, and persons using ionizing radiation is available on the websites of RICS/DLI.



## 9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The radioactive waste generated by different licensees in the research or medical areas are mainly short lived radioactive waste which need to be managed safely and stored for decay and release or clearance from the regulatory control.

The regulatory body has established the national policy and strategy to address the establishment of regulatory requirements for the development of different types of disposal facility for radioactive waste.

Section 17 of the law clearly establishes the primary responsibility of the operator for the safety of predisposal radioactive waste management facilities or activities.

The Responsible and Safe Management of Spent Fuel and Radioactive Waste Regulations of 2014 provide more specific legal requirements. These regulations apply to all stages of radioactive waste management, from generation to disposal of radioactive waste resulting from civilian activities. These regulations include the licensing process, obligations of licence holders, expertise and skills, financial resources, transparency, national programme and its content, notification and reporting.

Since there are no nuclear installations in The Republic of Cyprus, decommissioning activities in The Republic of Cyprus is mostly removing the sources, handling them appropriately, monitoring and wipe-testing the facilities for contamination, decontamination, and finally delivery of the facilities for general use.

A national programme for the management of radioactive waste has been established and covers all types of radioactive waste, and all stages of radioactive waste management from generation to disposal. The national programme is regularly reviewed and updated, taking into account technical and scientific progress as appropriate as well as recommendations, lessons learned and good practices from peer reviews. The national programme sets out how the Competent Authority intends to implement the national policy, referred to in Regulation 6 of the Responsible and safe management of radioactive waste.

## 9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

In addition to the Laws and the Basic Principles, MLWSI has established and issued regulations. However, the current regulations or guides in place do not cover all activities comprehensively such as for specific activities with radiation sources in the use of unsealed sources or sealed sources of IAEA category 4 or 5, industrial radiography, use of accelerators, veterinary X-ray diagnostics, use of X-ray cabinets, XRF, etc. These practises are regulated with an extensive set of conditions in each license.

Additionally, the existing regulations are not fully in line with requirements in GSR Part 3, for example: dose limits to the lens of the eye which is set to an effective dose of 50 mSv per year. This issue is addressed in Recommendation R30 in Section 11.2

The IRRS team was informed that these gaps are expected to be addressed with the planned transposition of the EU directive 2013/59/Euratom into the Cypriot legislation by February 2018.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** RICS does not have guides that provide adequate coverage commensurate with the radiation risks associated with the facilities and activities.

(1)	<b>BASIS: GSR Part 1 Requirement 34 para 4.62 states that</b> <i>“the regulations and guides</i>
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	<i>shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach.”</i>
<b>S6</b>	<b>Suggestion:</b> RICS/DLI should consider ensuring that its regulations or guides provide adequate coverage of facilities and activities commensurate with the radiation risks.

### 9.4. REGULATIONS AND GUIDES FOR TRANSPORT

The transport of UN class 7 materials is governed by a set of regulations on the transport of dangerous goods. In accordance with these, the Ministry of Transport, Communications and Works has also some assigned competence in relation to the transport of all dangerous goods, with respect to different modes of transport:

Road transport - the Department of Road Transport is responsible for the transposition of EU Directives and the ratification/transposition of conventions and application of regulations concerning road transport; the licensing of road carriers and the issue of approvals of the road transport of dangerous goods.

Air transport - the Department of Civil Aviation is responsible for the ratification/transposition of conventions and regulations concerning air transport; the licensing of air carries and the issue of approvals of the air transport of dangerous goods.

Sea transport - the Department of Merchant Shipping is responsible for applying the legislation concerning merchant marine issues, including technical issues; inspection of cargo.

Post - The Republic of Cyprus Postal Services has the competency of performing inspections in order to supervise and monitor postal services.

The IRRS team was informed that The Republic of Cyprus has implemented Laws which adhere to relevant European Directives and International Conventions and Treaties, specifically:

- The European Agreement on International Road Transport of Dangerous Goods Law (ADR) (Ratification) (N.9(III)/2004);
- The European Agreement on International Road Transport of Dangerous Goods Law (ADR) (Ratification) (Amendment) (N.2(III)/2006);
- The European Agreement concerning the International Carriage of Dangerous Goods (ADR) (Ratification) Laws 2004 to 2006 (P.I 175/2007);
- Transposition of the European Directive 2012/45/EU, The law 80 (I) of 2013 “Amendment of the law Road Transport of Dangerous Goods”.

The IRRS team was informed that other international regulations are adopted at national level such as:

- the Technical Instructions for the Safe Transport of Dangerous Goods by Air of the International Civil Aviation Organization (ICAO);

- International Maritime Organization (IMO) International Maritime Dangerous Goods (IMDG) Code for sea transport;

The IRRS team was informed that there is good cooperation with other governmental bodies with responsibilities for the transport of dangerous goods, but it is not formalized. There are also currently no guides in place for carriers of radioactive material.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The coordination in place with relevant authorities involved in the regulation on the transport of radioactive material is not formalized.

(1)	<p><b>BASIS: GSR Part 1 Requirement 7 states that</b> <i>“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.”</i></p> <p><b>BASIS: GSR Part 1 Requirement 7 para 2.18 states that</b> <i>“This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other’s experience.”</i></p> <p><b>BASIS: GSR Part 1 Requirement 7 para 2.19 states that</b> <i>“If responsibilities and functions do overlap, this could create conflicts between different authorities and lead to conflicting requirements being placed on authorized parties or on applicants. This, in turn, could undermine the authority of the regulatory body and cause confusion on the part of the authorized party or the applicant.”</i></p>
R23	<p><b>Recommendation:</b> The Government should ensure a formal coordination of the authorities involved in the regulation of the transport of radioactive material.</p>

### 9.5. SUMMARY

The MLWSI is the sole authority that has been allocated responsibilities and functions of a regulatory body for activities relating to the control of radiation sources and radioactive material.

The existing regulations are not fully in line with requirements in such areas as dose limits to the lens of the eye which is set to an effective dose of 50 mSv per year. A consistency between license conditions and regulations needs to be ensured, since the regulations do not cover all facilities and activities, and licenses contain extensive license conditions. There are no guides in place that provide adequate coverage commensurate with the radiation risks associated with the facilities and activities.

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

### **10.1. GENERAL EPR REGULATORY REQUIREMENTS**

#### **Roles and responsibilities in EPR**

The scope of the regulatory mandate of the regulatory body over emergency preparedness and response for licensees involved in nuclear, radiological and transport activities is to co-ordinate the assessment of the hazards and the preparedness and response mechanism, the arrangements and potential resolution of differences between the various response organizations and ensure that the functions and responsibilities of operators and response organizations are clearly assigned and are understood by all response organizations, and that arrangements are in place for achieving and enforcing compliance with the requirements.

The role and responsibilities of the national coordinating authority are defined in the legislative framework and in the national emergency preparedness and response plan in case of nuclear or radiological event, titled ELECTRA.

The regulatory body is responsible with respect to emergency preparedness and response (EPR) to propose regulations, conduct licensing, review and assessment, inspections, enforcement, witnessing testing and exercises etc.

RICS/DLI is empowered to ensure that the functions and responsibilities of operators and response organizations are clearly assigned and are understood by all response organizations.

The existing legislation clearly states the role of the licensees in EPR (basic Laws and P.I. 494/2002). The Government has allocated responsibilities for the management of interventions in emergency exposure situations between the regulatory body, national and local response organizations and the operators/licensees.

#### **Hazard assessment**

Section 17 of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 provides for the obligations of the license holders to take all necessary technical and administrative measures, in relation to the license granted to them, for securing safety and health of any individual and for protecting the use or property of any person and the environment, including the measures taken from their side to build, develop and maintain the necessary competences. The license holder compliance with the provisions of existing legislation is verified by the regulatory body through the licensing process, inspections and evaluation of risk assessment and emergency procedures reports.

The licensees are required to have in place and update regularly an assessment of hazards as the basis of its EPR plans. This is also a condition of the license granted to the licensees by the Minister. For the purpose of the requirements, nuclear and radiation related hazards are grouped according to the Emergency Preparedness Categories shown in Table I of GSR Part 7. (The categorization was made based on the previous IAEA Safety Standards GS-R-2 but the planned revision of the hazard assessment will not change the established categories, considering the fact that the existing Emergency Preparedness Categories (EPC) in The Republic of Cyprus are limited to EPC III and IV.)

The regulatory system (review and assessment, authorization, inspection and enforcement) provides reasonable assurance that emergency preparedness and response arrangements are in place for all facilities/practices.

Moreover, the application form for authorization clearly states the documents required for safety demonstration in support of the application, such as risk assessment and safety report for all practices and activities. The conditions of the license are specified as the case may be and refer, among others, to the preparations for dealing with, and the measures to be taken on the occurrence of a radiological accident or a radiological emergency.

No nuclear power plants, research reactors or any other nuclear installations (e.g. waste treatment or disposal facilities etc.) that could be categorized in EPCs I and II operate in the Republic of Cyprus. The main use of ionizing radiation in The Republic of Cyprus is in medicine, with also some applications in industry (industrial radiography, industrial gauges etc.), construction and education/research; they fall into EPC III and IV. There are no EPC I or II facilities operating beyond the borders but within the emergency planning zones (EPC V) but The Republic of Cyprus is mindful of all potential nuclear activities (e.g. reactors to be built in Turkey and Egypt) which could affect the safety of the country in case of a nuclear emergency in these facilities.

The hazard assessment and, in general, the whole emergency plan and associated arrangements are updated or revised, if necessary, when a new potential hazard has been identified, and based to the outcomes of theoretical or practical exercises or to lessons learned after an emergency etc.

The legal basis and regulations used for the regulatory control of nuclear and radiological emergency preparedness and response (EPR) was developed based on the outdated IAEA Safety Standards GS-R-2, therefore the concepts, terminologies and criteria used in the relevant legal documents are not always in compliance with the current safety standards GSR Part 7. The work of revision has started but has not been completed yet. More work is needed to implement the new amendments of ELECTRA regarding the protection strategy.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The concepts developed for the hazard categorization, classification and protection of the public in case of a radiological emergency were originally based on the outdated IAEA Safety Standards GS-R-2 and have been revised only recently based on GSR Part 7, but this revision is not yet complete and is yet to be implemented.

(1)	<b>BASIS: GSR Part 7 para. 4.27 states that</b> <i>“The government shall ensure that, on the basis of the hazards identified and the potential consequences of a nuclear or radiological emergency, protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency to achieve the goals of emergency response.”</i>
S7	<b>Suggestion:</b> The regulatory body should consider completing the review and revision of the EPR related legal framework and implementing the protective actions for the protection of the public in case of a nuclear or radiological emergency, in accordance with the requirements of GSR Part 7.

## 10.2. FUNCTIONAL REGULATORY REQUIREMENTS

### Managing operations in an emergency response

Regulatory requirements on the licensee’s emergency management structure are in place. These requirements include arrangements for coordinating activities and for developing strategies, including resolution of disputes in case of a nuclear or radiological emergency.

Regulatory requirements on the licensee's emergency management structure address the need for the on-site emergency to be promptly executed and managed without impairing the performance of the continuing operational safety functions.

The licensees are required, based on the existing legislation and the conditions of the license granted by the Minister, to regularly assess, test, update and revise their emergency management functions, as well as any other organizational or administrative procedures as regards the protection from ionizing radiation. Licensees are required to notify the regulatory body for any significant change, as well as for the revisions/updates of this structure, plans and procedures.

The licensee compliance is verified by the regulatory body through the licensing process, inspections and evaluation of risk assessment and emergency procedures reports.

### **Identifying and notifying a nuclear or radiological emergency and activating an emergency response**

Regulatory requirements have been developed for identifying a situation that warrants emergency response. There are requirements in place for licensees to classify emergencies and to provide prompt notification to the authorities. Also, adequate information needs to be generated promptly and communicated to the responsible authorities in case of an emergency. The aims of these arrangements are:

- the early prediction or assessment of the extent and significance of any unplanned discharge of radioactive substances to the environment;
- rapid and continuous assessment of the emergency as it progresses, and
- determining the need for countermeasures.

Contact (notification) points have been defined in the emergency preparedness and response plan ELECTRA, which are responsible for receiving emergency notifications 24/7. The notification points are continuously available to receive any notification or request, including any request for assistance, and to respond promptly or to initiate an off-site response.

A single focal point, RICS/DLI, is in place, where all relevant information about emergency conditions, emergency assessments and the protective actions recommended and/or taken are gathered and assessed.

The emergency classification procedure contains instrument readings to be used as Emergency Action Levels (EALs), in order to indicate the conditions warranting declaration of different classes of emergency. The EALs are in the units displayed by instruments available. The procedure does not rely on a single indicator as the basis for an assessment and, to the extent achievable, measurements that are direct indicators of the condition of interest should be used. The procedure and operator training address response of instruments under abnormal conditions.

All notification procedures of off-site response organizations and the initiation of the pre-planned and coordinated response are covered by ELECTRA.

In case of an emergency situation abroad, such as a nuclear accident, RICS/DLI also gathers information that may originate from radioactivity environmental monitoring measurements, EU and IAEA relevant information networks (ECURIE, USIE), other organizations (NEA/OECD, WMO, WHO, etc.), RASFF network, diplomatic missions of the Republic abroad, media, from local stakeholders and citizens etc.

The Operations Centre of the Civil Defence has been determined as the single warning and contact point in the country, and is responsible for receiving emergency notifications and information from other States and information from the IAEA, and has been made known to the IAEA/IEC. This warning point is continuously available to receive any notification, request for assistance or request for verification of information from the IAEA and to initiate promptly a response or verification. All information and notifications from the IAEA should be promptly communicated to RICS/DLI. The emergency contact details of the personnel of RICS/DLI in charge in case of an emergency situation are available to the Civil Defence and are updated, as necessary.

RICS/DLI is the responsible organization for promptly notifying and providing relevant information, directly or through the IAEA, to other States that may be affected by a transnational emergency. RICS/DLI is also responsible to address requests from other States or from the IAEA for additional information in respect of a transnational emergency.

### **Taking mitigatory actions**

Regulatory requirements for mitigating actions require the establishment of emergency operating procedures and severe accident guidelines for operator response to severe emergencies. Through the procedures, the operator needs to monitor the symptoms that indicate success or failure of key functions critical to the protection of workers, the public and the environment. The procedures should state the immediate action to be taken to restore the performance of the functions whenever a symptom indicates that these functions have been lost, degraded or threatened.

Arrangements are in place to provide expertise and services in radiation protection promptly to local personnel, i.e. capability of assessing hazards involving radioactive or fissile material, assessing radiological conditions, mitigating the radiological consequences and managing the exposure of responders, until dedicated personnel reach the scene.

As soon as highly-qualified radiological assessors from RICS i.e. the so-called Intervention Team etc. reach the scene of a radiological event, they take over responsibility for assessing risks and radiological conditions, mitigating radiological consequences and managing the exposure of first responders.

Arrangements are in place for the operator of a practice using a dangerous source in EPC IV (such as practices in industrial radiography or in metal scrap yards) to respond promptly to an emergency involving the source in order to mitigate any consequences. These arrangements include availability and access to shielding, and tools and instruments needed during an emergency to return the source to a safe and stable condition. The radiological assessor(s) or radiation protection officer(s) are qualified and properly trained to conduct radiological surveys, perform contamination control, assess doses, and support emergency response actions. 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.

Operators are obliged to have their own internal (on-site) action plans built, and to prepare personal instructions for their personnel for quick reference in case of an emergency. Such instructions include life saving actions, determination of any cordoned area on the basis of information that can be directly observed or on the basis of dose rates and environmental measurement EALs when these data become available. A list of observables that can be used to identify a dangerous source may include items such as an unshielded or damaged potentially dangerous source; a major spill from a potentially dangerous source; a fire, explosion or fumes involving a dangerous source; a suspected bomb (possible radiological dispersal device), exploded or unexploded; a conventional (non-nuclear) explosion or a fire involving a nuclear weapon (no nuclear yield) etc.

External emergency services are part of the licensees' plans to take mitigatory actions (e.g. police, medical and firefighting services). Regulatory requirements regarding the use of external services for

mitigatory actions include support promptly from police and medical and firefighting services off the site. Off-site support personnel should be afforded prompt access to the facility and should be informed of on-site conditions and the necessary protective actions.

### **Taking urgent protective actions and other response actions**

ELECTRA is the document which specifies the national intervention levels for nuclear or radiological events. These levels are identical to those included in the IAEA publications related to emergency preparedness and response.

ELECTRA has recently been updated and the protection strategy (with reference levels, generic criteria and Operational Interventional Levels etc.) have been established, in compliance with the requirements of GSR Part 7.

All appropriate measures are taken to save lives and all urgent protective actions are taken in accordance with international standards, to prevent, to the extent practicable, the occurrence of severe deterministic health effects and to avert doses. Urgent protective actions should be modified as appropriate to take into account any new information relating to the emergency that becomes available. Protective actions are discontinued when it is no longer justified.

There are no EPC I and II facilities in The Republic of Cyprus. For all other type of facilities, arrangements should be made for effectively making and implementing decisions on the need of establishing urgent protective actions, including the specification of off-site emergency zones for which arrangements should be made for taking urgent protective action. These arrangements should make use of existing public infrastructure to limit the occurrence of severe deterministic health effects and to avert doses, in accordance with international standards, for the full range of possible emergencies.

### **Providing instructions, warnings and relevant information to the public for emergency preparedness and response**

The regulatory body is responsible for issuing guidance and instructions regarding the role of licensees in keeping the public informed. This guidance refers to providing timely, truthful, consistent and appropriate information to the public in the event of a nuclear or radiological emergency.

The ability of the licensee to provide information and issue instructions to the public during emergency is verified by the regulatory body.

### **Protecting emergency workers and helpers in an emergency**

The regulatory body is responsible for issuing guidance and instructions regarding the protection of off-site emergency workers involved in the on-site support to the licensee. Those called upon to respond at a facility (as police, fire fighters, medical personnel etc.) are designated as emergency workers.

Arrangements to provide protection for emergency workers include, among others, recording of the doses received by emergency workers (special working sheets are provided as well), procedures for dose and contamination control, provision of appropriate specialized protective equipment, procedures and training for emergency response, designation of a person within each response organization responsible for the protection of workers etc. These arrangements are consistent with GSR Part 7, Appendix 1, GS-G-2.1, Table 4 and Section 4.

### **Managing the medical response in a nuclear or radiological emergency**

The regulatory body is responsible for regulating medical response management by the licensees. Facilities in EPC III should make arrangements to treat a limited number of contaminated or overexposed workers, including arrangements for first aid, the estimation of doses, medical transport



and the initial medical treatment of contaminated or highly exposed individuals in local medical facilities.

Facilities of EPC III (industrial radiography facilities and medical centres) have arrangements in place to treat a limited number of contaminated or overexposed workers. These arrangements include arrangements for first aid, estimation of doses by external qualified experts, medical transport and the initial medical treatment. The initial treatment, as well as the treatment of severe overexposures can be performed by the large district hospitals located at each major town.

**Other activities in emergency preparedness (Communicating with the public; Taking early protective actions; Managing radioactive waste; Mitigating non-radiological consequences; Terminating an emergency)**

The regulatory body is responsible for defining the criteria for agricultural countermeasures, countermeasures against ingestion and longer-term protective actions. National intervention levels and action levels for these early protective actions are in accordance with the international standards. These numeric criteria are included in ELECTRA.

Criteria and process to discontinue the agricultural countermeasures and relocation when assessments show that continuation of the actions is no longer justified are in place.

Default OILs developed for environmental measurements (such as deposition exposure rates and contamination due to deposition) and food concentrations are included in ELECTRA, as well as arrangements for revising these OILs and for providing instructions promptly to members of the public, governmental agencies, farmers and food production and distribution activities to take action to protect food (e.g. take animals off pasture), water supplies and cisterns. Arrangements are also foreseen for preventing immediate consumption of contaminated food (e.g. local milk or home grown garden vegetables), and protecting the food and agricultural product system (e.g. prevent introduction of potentially contaminated food into the food processing/distribution system by restricting harvesting and marketing until monitoring has been implemented).

The management of radioactive waste generated during a radiological emergency is regulated by the rules developed for the management of the radioactive waste originating from normal practices.

The non-radiological consequences of the response to public concern in an actual or potential nuclear or radiological emergency have been considered in order to ensure that the response actions do more good than harm. Arrangements are in place for providing useful, timely, truthful, consistent and appropriate information to the public in the event of a nuclear or radiological emergency, including justifying, optimizing and authorizing different intervention levels or action levels following an event for which agricultural countermeasures or longer term protective actions are in place.

The recommendations to the public are accompanied by a plain language explanation that enables the public to understand them and reasonably consider them. These recommendations make it clear to the people that the actions recommended or taken ensure their safety and that of all other family members, including their unborn children.

The regulatory body has regulatory responsibilities in recovery, including for example transitions threshold, worker's protection and response criteria. The regulatory body has established the principles and criteria for removal of restrictions and return to normal. The differences in authority, management and coordination between the emergency and recovery responsibilities have been identified and the process how the transition would be made has been defined. Objectives for recovery have been made clear, as well as the process for making decisions and methods to involve the public and other relevant parties.

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

#### **Authorities for EPR**

The regulatory body has full authority for regulating licensees with respect to EPR. All the operating organizations and local and national organizations involved in the performance of the functions specified in Section 5 of GSR Part 7, document their own roles, functions, authorities and responsibilities in an emergency response and are in assent to the authorities, roles and responsibilities of other response organizations.

The existing legislation clearly states the role of the licensees in EPR. The Government has allocated responsibilities for the management of interventions in emergency exposure situations between the regulatory body, national and local response organizations and the operators/licensees.

The role of the licensees in EPR as stated in the legislation is consistent with the assignment of roles and responsibilities in the national EPR framework established by the regulatory body, and given in details in ELECTRA. All arrangements and obligations with regard to emergency preparedness and response are described in this plan.

#### **Organization and staffing for EPR**

Regulatory requirements for the staffing of licensee emergency response organizations are in place.

In ELECTRA, positions have been assigned about who is responsible within each operating and response organization for the performance of the response functions (managing the response, first responders, initial assessment, notification, mitigation, etc.). Each stakeholder involved in the national plan, including the regulatory body, is responsible to assign in its emergency plans and procedures (internal action plans, concept of procedures) the personnel responsible for performance of the response functions specified in the plan. The personnel responsible must be assigned as part of the routine organizational structures. All personnel who are assigned to positions in all operating organizations and response organizations to perform the functions necessary to meet the requirements must be qualified and should be assessed for their initial fitness and continuing fitness for their intended duties.

#### **Coordination of emergency preparedness and response**

There are regulatory requirements addressing the coordination of licensees and off-site (for a facility) or emergency services (EPC IV) during an emergency.

The functions and responsibilities of operators and response organizations are clearly assigned and understood by all of them and arrangements are in place for ensuring that these organizations maintain the capability to perform their responsibilities.

Emergency response facilities or locations to support an emergency response under the full range of postulated hazardous conditions are designated and the main response and coordination functions are assigned.

The effectiveness of the coordination arrangements is verified by the regulatory body by conducting inspections, as far as the licensees are concerned, and by organising and conducting drills and exercises, as far as off-site emergency services is concerned.

## **Plans and procedures for emergency response**

Plans and procedures for on-site response and for interfacing with the authorities and off-site emergency response organizations are obligations of the operating organizations/licensees and must be developed as a condition of the license granted by the Minister. The regulatory body has a regulatory role in this procedure.

The approval of the licensee's plans and procedures for on-site response and for interfacing with the authorities and off-site emergency response organizations are part of the licensing process.

All operating organizations and local and national organizations involved in the emergency response and preparedness have documented their own roles, functions, authorities and responsibilities, based on the roles and responsibilities allocated to them in ELECTRA.

Responsible authorities for emergency situations prepare their own internal emergency plans for any practice or source that could give rise to a need for an emergency intervention. These internal plans should be based on the directions given in ELECTRA that provides for the involvement of appropriate response organizations and are approved by the regulatory body. The plans should be tested, updated and reviewed regularly.

The internal plans of the responsible authorities should take into account the results of the hazard assessment analysed in ELECTRA, and any lessons learned from operating experience and from emergencies that have occurred with sources of a similar type. All operating organizations and local and national organizations involved in the emergency response and preparedness have documented their own roles, functions, authorities and responsibilities, based on the roles and responsibilities allocated to them in the national plan.

## **Logistical support and facilities for emergency response**

The regulatory body has in place regulatory requirements on EPR logistics and facilities for the licensees.

Adequate tools, instruments, supplies, equipment, communication systems, emergency facilities and documentation, such as procedures, checklists, telephone numbers and manuals, needed to provide adequate response in case of emergency, are listed in the emergency preparedness and response plan.

Equipment used for emergencies is more or less the same as that used in normal situations but with controls to ensure that their availability is not compromised. Items and facilities were designed to be operational under the postulated conditions, such as the radiological, working and environmental conditions. These support items are located in suitable storages or locations, which allows their effective use under postulated emergency conditions.

Also, arrangements are in place to ensure that replacement of supplies of items that are likely to be expended, contaminated or need replacement (perishables) such as cables/connectors, batteries, tanks, filters, clothing, sample containers, and clerical supplies are available. This includes a central store of radiological monitoring and protective equipment that can be provided to RICS personnel, in the event of an actual or potential radiological emergency. Each other stakeholder involved in an emergency, based on its internal action plan, should have similar arrangements in place.

The effectiveness and adequacy of the logistical support and facilities is verified through licensing and by conducting inspections.

## **Training, drills and exercises for EPR**

The regulatory body has regulatory requirements in place for training, drills and exercises in EPR by licensees. The operator is required to identify the knowledge, skills and abilities necessary to be able to perform the functions specified in Section 5 of GSR Part 7. The operator is required to make arrangements for the selection of personnel and for training to ensure that the personnel have the required knowledge, skills, abilities, equipment, and procedures and other arrangements to perform their assigned response functions. The regulatory body has a regulatory role in making sure the operator complies with these requirements.

The license holder compliance with the provisions of existing legislation is verified by the regulatory body through the licensing process, inspections and evaluation of risk assessment and emergency procedures reports.

The performance of exercises at facilities in EPC III is evaluated against established response objectives that demonstrate that identification, notification, activation and other initial response actions can be performed in time to achieve the practical goals of emergency response.

## **Quality assurance programme for EPR**

Operating organizations are required to prepare and put in place a comprehensive quality assurance programme covering all activities which may affect the emergency response programme. A quality assurance/quality management system is in place, ensuring that logistical support items and facilities are continuously available, including inventories, re-supply, tests and calibrations on an appropriate schedule, e.g. as recommended by the manufacturer. Regular quality assurance review of the emergency plans and procedures, including updating perishable information (phone numbers etc.) have been arranged. Critical deficiencies observed in procedures are corrected within a short while, and improvements and modifications that are not critical are made within a longer period e.g. 12 months. Lessons learned from around the world and during drills and exercises are taken into account. Procedures have been developed for each facility, team or system e.g. warning system, for the conduct of inventories, tests, calibrations, and restocking of perishable items such as batteries, fuel, and food. Radiological analysis capability (both monitoring teams and laboratories) are covered by a control programme to ensure that it produces consistent and adequate results. As part of these arrangements, laboratories are taking part in the IAEA intercomparison programme, and other tests/checks are conducted for groups that are expected to work together during an emergency.

Regulations require periodic reviews and revisions of the plans and procedures, as well as continuous improvement of the licensee's EPR arrangements.

## **10.4. ROLE OF REGULATORY BODY DURING RESPONSE**

The regulatory body has a primary role and has various functions (coordination, situation assessment, consequence analysis etc.) in responding to an actual nuclear or radiological emergency, with special regards to liaising with and giving advice to the government in matters of radiation emergency.

The MLWSI, acting through RICS/DLI, has been defined as the national coordinating authority for emergency preparedness and response in case of nuclear or radiological event. RICS has been established within the Ministry of Labour, Welfare and Social Insurance in 2002.

Function of the national coordinating authority, among others, is to coordinate the assessment of the hazards and the resolution of differences and incompatible arrangements between the various response organizations. RICS/DLI ensures that the functions and responsibilities of operators and response organizations as specified in these requirements are clearly assigned and are understood by all response

organizations, and that arrangements are in place for achieving and enforcing compliance with the requirements.

The role and responsibilities of the national coordinating authority are defined in the legislative framework and the national emergency preparedness and response plan in case of nuclear or radiological event.

The Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 apply in all cases where exposure occurs or there is potential exposure and such cases include any intervention in cases of radiological emergency or in cases of lasting exposure resulting from the after-effects of a radiological emergency or a past or old practice or work activity.

RICS/DLI should, among others, coordinate or ensure, in collaboration with other services when necessary, that a national system and plans for the prevention of or response to radiological accidents and radiological emergencies are established.

ELECTRA established a comprehensive system and a special action plan for RICS/DLI, and for other collaborating agencies and organization (e.g. the Civil Defence) to identify, assess, prepare and respond to such situations.

RICS/DLI has powers to ensure that the functions and responsibilities of operators and response organizations are clearly assigned and are understood by all response organizations.

The limited number of staff of RICS is a challenge in implementing all the functions required from them in case of a major radiological emergency. This issue is addressed in Recommendation R3 Section 1.3.

The role and responsibilities of the national coordinating authority are defined in the legislative framework and the national emergency preparedness and response plan in case of nuclear or radiological event.

All arrangements and obligations with regard to emergency preparedness and response are described in ELECTRA.

A quality assurance/quality management system is in place, ensuring that logistical support items and facilities are continuously available, including inventories, re-supply, tests and calibrations on an appropriate schedule, e.g. as recommended by the manufacturer. Regular quality assurance review of the emergency plans and procedures, including updating perishable information (phone numbers etc.) have been arranged.

Critical deficiencies observed in procedures are corrected within a short while, and improvements and modifications that are not critical are made within a longer period e.g. 12 months.

On-going training requirements for each position and team within the response organizations have been established and documented to ensure that response personnel have the required knowledge, skills, abilities, equipment, and procedures to perform their assigned response functions.

The tools, instruments, supplies, equipment, communication systems, facilities and documentation, such as procedures, checklists, telephone numbers and manuals, are listed in the emergency preparedness and response plan.

Equipment used for emergencies is more or less the same as that used in normal situations but with controls to ensure that their availability is not compromised. Items and facilities were designed to be operational under the postulated conditions, such as the radiological, working and environmental conditions. These support items are located in suitable storages or locations, which allows their effective use under postulated emergency conditions.

## 10.5. SUMMARY

The Republic of Cyprus conforms to the Requirement 8 of GSR Part-1 and the outdated IAEA Safety Standards GS-R-2. More work is needed to review and revise the EPR related legal framework to fully comply with the current Safety Standards GSR Part 7.

The Government has allocated responsibilities for the management of interventions in emergency exposure situations between the regulatory body, national and local response organizations and the operators/licensees through the national emergency preparedness and response plan in case of nuclear or radiological event ELECTRA. The regulatory body has a primary role and has various functions (coordination, situation assessment, consequence analysis etc.) in responding to an actual nuclear or radiological emergency, with special regards to liaising with and giving advice to the government in matters of radiation emergency.

ELECTRA takes into account a comprehensive hazard assessment performed as the input for defining the scope and response strategy, including events with potentially severe consequences.

The regulatory body is responsible for:

- establishing guidance and levels for the protection of the public during an emergency;
- issuing guidance and instructions regarding the role of licensees in keeping the public informed;
- issuing guidance and instructions regarding the protection of off-site emergency workers involved in the on-site support to the licensee;
- issuing guidance medical response management by the licensees;
- defining the criteria for agricultural countermeasures, countermeasures against ingestion and longer-term protective actions.

The regulatory body has in place regulatory requirements on EPR logistics and facilities for the licensees and for training, drills and exercises in EPR by licensees.

## 11. ADDITIONAL AREAS

### 11.1. CONTROL OF MEDICAL EXPOSURES

- **Regulatory framework and responsibilities**

Medical exposures are regulated via the Protection from Ionizing Radiation (Medical Exposure) Regulations of 2002 issued under virtue of section 40 of the Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011 and fall within the scope of RICS/DLI. The Medical Exposure Regulations cover, among others, responsibilities of the employers or licensees, clinical audits, justification and optimization, education and training, medical physics expert, clinical audits. The responsibilities of practitioners, operators and referrers are extensively described.

Qualifications and registration requirements for medical physicists, radiographers and physicians are prescribed in the legislative framework. Similar provisions for radiopharmacists or radiochemists are not in place.

- **Justification of medical exposure**

There are regulatory provisions, in the Radiation and Nuclear Safety Laws and in the Medical Exposure Regulations, for the justification of new practices and the review of existing class or type of practice, including the ones involving medical exposure, whenever new and important evidence about their efficacy or consequences is acquired. Furthermore, the existing regulation assigns to the practitioner, the responsibility for individual medical exposure justification and requires the provision of sufficient medical exposure information to the practitioner on behalf of the referrer. There is no procedure in place, for the generic justification of radiological procedures and new techniques and technologies.

The referral guidelines for imaging, published by the European Commission in 2000, are provided in the medical exposure section of the DLI website. However no relevant guidance or evidence of consultation among the relevant parties is available in order to ensure their harmonized implementation in the country. Employers or licensees are required, to ensure that referral criteria are established and used with respect to medical exposures and to make these criteria available to referrers; an approach that eventually results in the implementation of non-harmonized referrals.

There are no standardized procedures or regulatory requirements regarding the justification of health screening programmes or for asymptomatic individuals undergoing radiological procedures.

In the case of medical exposure of volunteers participating in medical or biomedical research programmes, the opinion of the TLC on deontology and ethics is sought, prior to authorization provided by the Minister of Labour, Welfare and Social Insurance. The IRRS team was informed that there are no biomedical research programmes in The Republic of Cyprus.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Procedure for the generic justification of radiological procedures and new techniques and technologies, for the justification of health screening programmes and for asymptomatic individuals undergoing radiological procedures are not in place. Referral criteria are to be set by licensees and made available to referrers.

(1)

**BASIS: GSR Part 3 Requirement 37 states that** *“Relevant parties shall ensure that medical exposures are justified.”*

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R24

**Recommendation:** The Government should ensure that generic justification of radiological procedures, including new techniques and technologies, is effectively carried out; health screening programmes, biomedical research programmes and radiological procedures conducted to asymptomatic individuals are justified; harmonized referral guidelines are practically applied.

### • Optimization of medical exposure

Regulatory provisions related to the optimization of medical exposure are in place. The Medical Exposure Regulations require the employers or licensees to ensure that dose constraints are set for volunteers participating in medical and biomedical research programmes and that strict adherence to the dose constraints is provided in local procedures. A dose limit of 5mSv is established in the regulation for carers and comforters which is not in line with the principle of dose constraint.

National diagnostic reference levels (DRLs) for all medical imaging, including image guided interventional procedures have not been established, although relevant provisions do exist in the Medical Exposure Regulations as follows:

- diagnostic reference levels are set and used for medical exposure situations, including occupational health surveillance, health screening programmes and medico-legal procedures, taking into account the diagnostic reference levels which are published by the Minister, through a Notification in the Official Journal of the Republic;
- the operator should pay special attention to the diagnostic reference levels set by the employer or the licensee;
- whenever the diagnostic reference levels are systematically exceeded, the employer or licensee should proceed with an investigation of the matter and make sure that all necessary corrective measures are taken.

Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients, who still retain implanted sealed sources, have not been established. The IRRS team was informed that therapeutic radiological procedure with implanted sealed sources has not been applied in The Republic of Cyprus to date. In the case of patients undergoing treatment or diagnosis with radionuclides, the Medical Exposure Regulations require the employer's procedures should provide instructions and information, setting out their general contents.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Diagnostic reference levels for all medical imaging, including image guided interventional procedures, dose constraints and criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources or patients who still retain implanted sealed sources have not been established.

(1)

**BASIS: GSR Part 3 Requirement 34 states that** *“The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established.”*

R25

**Recommendation:** The Government should ensure that diagnostic reference levels,



## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**dose constraints and criteria and guidelines for the release of patients are established.**

The Medical Exposure Regulations require the involvement of an expert in medical physics in medical exposures, by adopting a graded approach. In relation to therapeutic nuclear medicine practices, there is no provision in the legislation to ensure the involvement of an expert in medical physics in treatments incorporating newly introduced radiopharmaceuticals that could be considered as non-standardised practices. Patient dosimetry, development and use of complex techniques and equipment, optimization, quality assurance, quality control and issues relating to radiation protection from medical exposures are explicitly mentioned as areas that an expert in medical physics should be involved in.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** There is no provision for the involvement of a medical physics expert in new therapeutic nuclear medicine practices.

(1)	<p><b>BASIS:</b> GSR Part 3 Requirement 36 para 3.154 states that “Registrants and licensees shall ensure that:</p> <p>... (d) For therapeutic radiological procedures, the requirements of these Standards for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in paras 3.167, 3.168(c), 3.170 and 3.171, are fulfilled by or under the supervision of a medical physicist.”</p>
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R26	<p><b>Recommendation:</b> RICS/DLI should establish requirements to ensure that calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment for all therapeutic radiological procedures are fulfilled by or under the supervision of a medical physicist.</p>
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Requirements and license terms concerning the conformity to international or national standards of medical radiological equipment and software, which could influence the delivery of medical exposure, operational considerations, calibration, dosimetry of patients, quality assurance for medical exposures are generally in line with the IAEA GSR Part 3. However, licensees and employers are not required to ensure regular and independent audits of the quality assurance programme for medical exposures.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Provision for conducting independent audits of the programme of quality assurance for medical exposures is not in place.

(1)	<p><b>BASIS:</b> GSR Part 3 Requirement 38 para 3.172 states that “Registrants and licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks.”</p>
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R27	<p><b>Recommendation:</b> RICS/DLI should establish and verify requirements for regular and independent audits of the programme of quality assurance for medical exposures, to be conducted with frequency appropriate for the complexity of the performed radiological procedures and the associated risks.</p>
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- **Pregnant women and breast feeding women**

The Medical Exposure Regulations explicitly state that before conducting medical radiological procedures to a female of childbearing age, she needs to be asked whether she is pregnant or breastfeeding. The practitioner and the operator are requested to pay special attention to medical exposures of females who could be pregnant, in particular if the abdominal and pelvic regions are involved and to include this interview to the local procedures.

- **Release of patients after radionuclide therapy**

During the site visit to observe the inspection carried out by RICS/DLI inspectors in the Lefkosia (Nicosia) General Hospital, the IRRS team was informed that a dose rate of 15µSv/h measured at 1m distance from the patient, who has undergone therapeutic radiological procedures in which radiopharmaceuticals are administered, is used as a criterion for patient release.

- **Unintended and accidental medical exposures**

With regard to unintended and accidental medical exposures, the employers or licensees are only required to preliminary investigate medical exposures that resulted in overexposure of the patient, whenever the initiating factor was other than malfunction or failure of the equipment. As stated in the existing regulation, if the preliminary investigation proves beyond any reasonable doubt that the overexposure did take place, the employers or licensees are required to immediately notify RICS and proceed with or arrange for a detailed investigation and an assessment of the dose received by the patient. In case of malfunction or failure of the equipment, the employers or licensees are required to immediately take action to repair or replace the equipment.

Regulatory requirement for ensuring that all necessary technical and administrative measures are taken for ensuring the safety and health of any individual is included in the Medical Exposure Regulations. Nevertheless, the licensees are not specifically required to take all practicable measures to minimize the likelihood of unintended or accidental medical exposures.

Unintended or accidental medical exposures, other than patient overexposure, as described in the IAEA GSR Part 3, are not explicitly mentioned in the Medical Exposure Regulations. Moreover, following the investigation of any unintended or accidental medical exposure, the appropriate radiological medical practitioner is not required to inform the referring medical practitioner and the patient or the patient's legal authorized representative.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** General provision for minimizing the likelihood of unintended or accidental medical exposures is not in place. Requirements for the prompt investigation of unintended or accidental medical exposures, other than patient overexposure, the timely notification and the implementation of any appropriate corrective actions are also not in place. There is no specific requirement for informing the referring medical practitioner and the patient or the patient's legal authorized representative.

(1)

**BASIS: GSR Part 3 Requirement 41 states that** *“Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures. Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions.”*

**R28**

**Recommendation:** RICS/DLI should establish requirements for minimizing the

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**likelihood of unintended or accidental medical exposures, initiating the prompt investigation and implementation of appropriate corrective actions for any case of such medical exposures and ensuring that the referring medical practitioner and the patient or the patients' legal authorized representative are properly informed.**

### Reviews and records

The Medical Exposure Regulations require the employers or licensees to include in the local procedures, provision to carry out clinical audits. According to the definition given in these regulations “*clinical audit is a systematic examination or review of medical radiological procedures*”. Considering that clinical audits can be internal or external, the involvement of the radiological medical practitioners at the medical radiation facility, the medical radiation technologists and the medical physicists as required in IAEA GSR Part 3, is not assured. Similarly the performance of investigation and critical review of the current practical application of the justification and optimization principles for the radiological procedures that are performed in the medical radiation facility are also not assured.

Employers and licensees are required to maintain records with information about all practitioners, operators, medical physics experts, including training, inventory of equipment, records of clinical evaluation of the outcome of each medical exposure, including patients doses, records of calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients, dosimetry and quality assurance. Nevertheless, the relevant retention period is not stipulated.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Provisions for the investigation and critical review of the current practical application of the justification and optimization principles for the radiological procedures that are performed in the medical radiation facility, by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists, are not in place.

(1)

**BASIS:** GSR Part 3 Requirement 42, para. 3.182 states that “*Registrants and licensees shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.*”

R29

**Recommendation:** RICS/DLI should establish and verify requirements for the periodic investigation and critical review of the current practical application of the justification and optimization principles for the radiological procedures performed in the medical radiation facility.

## **11.2. OCCUPATIONAL RADIATION PROTECTION**

### **11.2.1. GENERAL RESPONSIBILITIES OF LICENSEES AND EMPLOYERS**

Occupational protection, in general, has been covered by the Health and Safety at Work legislation, administered by DLI/MLWSI. A special legislative and regulatory framework providing for Occupational Radiation Protection has also been established since 2002 through:

- (a) The Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011; and
- (b) The Protection from Ionizing Radiation (Basic Principles) Regulations of 2002.

The RICS/DLI has requirements to ensure that protection and safety is optimized, and for compliance with dose limits for occupational exposure. Category A workers mainly represented in nuclear medicine and interventional radiology, are obliged to monitor doses whereas most workers in The Republic of Cyprus, including in industrial radiography, are category B workers, and need to prove that their categorisation is correct by dose monitoring.

The IRRS team was informed that radon levels in The Republic of Cyprus are mapped and reported to the European Union and are below  $100 \text{ Bq/m}^3$ , while the limit used by RICS is  $300 \text{ Bq/m}^3$  in accordance with the Directive 2013/59/EURATOM. The IRRS team was also informed that the radon maps will be published on the RICS/DLI website. There is one phosphogypsum landfill in Vasilikos, and the IRRS team was informed that the level of radon in that site is also below  $100 \text{ Bq/m}^3$ . According to RICS/DLI, the level of radon in all working places in The Republic of Cyprus is below  $100 \text{ Bq/m}^3$  therefore no action needs to be taken.

There is regulation for air-crew in the Protection from Ionizing Radiation (Basic Principles) regulations of 2002; however, for the time being no flight companies with long haul flights registered in The Republic of Cyprus exist, and therefore this regulation is not practically implemented.

### **11.2.2. GENERAL RESPONSIBILITIES OF WORKERS**

There is appropriate regulation for workers including outside workers that they should be informed that radiation protection and safety are integral parts of a general occupational health and safety programme, and that they have certain obligations and responsibilities for their own protection and the protection of others against radiation and for the safety of sources. The Basic Principle indicates that every employer or licensee should ensure that none of his employees, who is engaged in activities, involving or which may involve exposure to ionizing radiation is exposed to radiation doses above the limits prescribed in Part A of the First Schedule. The Health and Safety at Work legislation defines some duties of every employer.

Workers are classified in the Basic Principles in two classes:

- class A : workers who may receive, per year, an effective dose greater than  $6 \text{ mSv}$  or more than three tenths of the limit for the lens of the eye:
- class B : workers who are not classified as category A workers and whose effective dose lies between  $1$  and  $6 \text{ mSv}$  per year.

The dose limits for workers are clearly defined in the Basic Principles. However, the dose limits for the lens of the eye are defined as  $50 \text{ mSv}$  per year.

The Basic Principles describe the obligations and the rights of workers on their health and safety in workplaces.

## RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** The dose limit for the lens of the eye is set to an effective dose of 50 mSv per year.

(1)

**BASIS:** GSR Part 3 Requirement 21, para. 3.76 (a) states that “Occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in Schedule III are not exceeded.”

**R30**

**Recommendation:** RICS/DLI should assure that occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in Schedule III of GSR Part 3 are not exceeded.

### 11.2.3. REQUIREMENT FOR RADIATION PROTECTION PROGRAMES

Effective and equivalent dose limits for exposed workers, for apprentices and students are described in Regulations 6 and 8 of the Protection from Ionizing Radiation (Basic Principles) Regulations of 2002. Requirements are given for any single year and in practice, the doses are checked against the last twelve running months through the National Dose Register, maintained by RICS/DLI.

The Basic Principles make provisions for female workers who notify their pregnancy or their breastfeeding situation. During the information or training sessions for new workers, female workers are advised to inform their employer as soon as possible about pregnancy.

The Qualified Expert assures compliance with the radiation safety requirements, starting when establishing a safety assessment together with the application for the license. This information should include the full description of the planned activity and all the information concerning the setup of a Radiation Protection Programme. The Qualified Expert assures compliance with the radiation safety requirements.

### 11.2.4. MONITORING PROGRAMMES AND TECHNICAL SERVICES

Monitoring of workplaces and workers is performed by the licensee and doses are also reported to the registry at RICS on a bimonthly bases. Dosimetry services are offered by approved dosimetry centre that reports recorded doses both to the licensee and to RICS/DLI every second month. There are around 300 workers monitored mainly employed in the medical sector.

The IRRS team visited the Bank of Cyprus Oncology centre, Lefkosia (Nicosia) as well as an industrial radiography facility, Nortest in Kalavassos. Dose records and other documentation of the licensee shows that the employees receive very low doses as well as incidents have been very rare. The counterparts, medical physicists/Qualified Experts demonstrated their high level of engagement and knowledge in radiation protection within their facilities. Nortest, performing industrial radiography, showed that the sources were stored and properly protected, and the behaviour of workers present showed they were aware of the rules on how to handle radioactive sources safely. The present personnel reflected a sound radiation safety culture by the way they reasoned, handled and described their NDT work in terms of radiation protection aspects. The licensee had also well-structured documentation like dose records, source handling record and other source related data in place. At the Bank of Cyprus Oncology Center, the Chief Medical Physicist made it clear by exemplifying that a sound radiation protection culture is essential for workers and the licensee. The Chief Medical Physicist presented dose reports from staff in radiotherapy. The brachytherapy room, a hot lab for nuclear medicine as well as a radioactive waste storage were inspected. The Chief Medical Physicist demonstrated good knowledge of the relevant requirements.

### 11.3. CONTROL OF RADIOACTIVE DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

#### Control of radioactive discharges

The main origin of radioactive waste that can be taken into consideration as an exposure pathway for the members of the public, comes from activities in the field of medicine, mainly discharges to the sewage system of excreta from patients undergoing radioiodine ablation treatment.

According to the “Protection from Ionizing Radiation and Nuclear Safety (Basic Principles) Regulations of 2002”, the dose limit for a member of the public is 1 mSv per year and the sum of doses from all relevant activities should not exceed this dose limit. RICS/DLI poses optimized operational limits and conditions to the licensee for the release of solid radioactive waste, taking into account dose constraints. However, no limits and conditions are established for the discharges of radioactive effluents.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<b>Observation:</b> Authorized limits for liquid radioactive discharges are not established.	
(1)	<b>BASIS: GSR Part 3 Requirement 29 para 3.123 states that</b> <i>“The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges.”</i>
(2)	<b>BASIS: GSR Part 3 Requirement 29, para. 3.120 states that</b> <i>“The government or the regulatory body shall establish or approve constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public.”</i>
R31	<b>Recommendation:</b> The RICS/DLI should establish limits for radioactive discharges based on operational constraints.

#### Materials for clearance

The national legislations do not clarify the concept of exemption levels and clearance levels. While section 8 of “The Protection from Ionizing Radiation and Nuclear Safety Laws of 2002 to 2011” states that *no person shall use in any manner any radioactive substance or radioactive waste, unless, he has a license or the activity concentration and the total activity of the radioactive substance are below the “clearance levels” prescribed*, the prescribed levels under part II of the Second Schedule of this law are “exemption levels” for which no reporting or licensing is requested.

Additionally, “clearance levels” are defined in this law as *values at or below which radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or licensing may be released from its requirements*, but these values have not been established. This issue is addressed in Recommendation R2 in Section 1.2. The IRRS team was informed that RICS/DLI issues conditions to the licensee for clearance of radioactive materials and release from regulatory control following the Schedule I of IAEA GSR Part 3 and Safety Guide RS-G-1.7.



## Existing exposure situations

According to the legislation, RICS/DLI is responsible for identifying existing exposure situations. In The Republic of Cyprus, indoor and outdoor radon surveys that have been carried out in recent years by the RICS/DLI in collaboration with respective departments of universities in the country, did not identify radon-prone areas, thus, radon levels are not of particular concern for public health in The Republic of Cyprus. Additionally, the RICS/DLI performs its own measurements for control, inspection, monitoring and dose assessment purposes and provides the information to the public and any other interested party, as appropriate.

Remediation is among the practices covered by existing legislation, which indicates that responsibilities are assigned and RICS/DLI licenses remediation activities. Additionally, the RICS/DLI performs periodic inspections to ensure that the approved safety requirements are being maintained.

There is only one identified site as an existing exposure situation in The Republic of Cyprus which is an old fertilizer plant in the area of Vasilikos, which, as a result of decommissioning and further remediation has a phosphogypsum lagoon next to the seafront, which is now insulated with a plastic membrane and a 1m thick layer of soil. The sea front has been stabilized using stone blocks. The IRRS team was also informed that it has established measures of demarcation of the area, access control and post-remediation monitoring of the sea water, and inspects the facility when appropriate. Data collected are available for consultation by interested parties.

Reference levels in existing exposure situations are in place for radionuclides in water through “The Protection from Ionizing Radiation and Nuclear Safety (protection of the health of the general public with regard to radioactive substances in water intended for human consumption) Regulations of 2016”. Although the RICS/DLI uses a reference level of 300 Bq/m<sup>3</sup> for exposure of workers or members of the public to indoor radon and a reference value of 1 mSv for construction materials, based on the Directive 2013/59/EURATOM, they have not been prescribed in the national legislation. For radionuclides in food and feed after a nuclear or radiological emergency, the IRRS team was informed that RICS/DLI takes the guideline levels published in the European Regulations and the Joint FAO/WHO Codex Alimentarius into consideration.

### RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

**Observation:** Reference levels for existing exposure situations and building materials are not established.

(1)	<b>BASIS: GSR Part 3 Requirement 47 para 5.2. states that</b> <i>“The government shall ensure that, when an existing exposure situation is identified, responsibilities for protection and safety are assigned and appropriate reference levels are established.”</i>
(2)	<b>BASIS: GSR Part 3 Requirement 51 para 5.22 states that</b> <i>“The regulatory body or other relevant authority shall establish specific reference levels for exposure due to radionuclides in commodities such as construction materials, food and feed, and in drinking water.”</i>
R32	<b>Recommendation:</b> The RICS/DLI or other relevant authority should establish reference levels for existing exposure situations and construction materials.

## Environmental monitoring

The national environmental monitoring system in The Republic of Cyprus consists of a well-equipped dedicated telemetric network operated by RICS/DLI, which also serves as the early notification system

of the country in case of a radiological incident or nuclear accident. Furthermore, RICS/DLI performs sampling and measurements of radioactivity levels in soil, water, marine environment, food, feed, building materials and in various goods, in cooperation with the State General Laboratory (SGL) and the Department of Fisheries and Marine Research (DFMR).

Additionally, RICS/DLI carries out an environmental radioactivity monitoring programme around the decommissioned and remediated old fertilizer plant in the area of Vasilikos in collaboration with the Department of Fisheries and Marine Research who performs the sea water sampling. As RICS/DLI is responsible for carrying out all of these measurements, the independence of the radioactivity monitoring programmes is achieved.

The RICS/DLI reviews and inspects these monitoring programmes in order to ensure that they are sufficient for verifying compliance with the requirements for public exposure, although this issue is not included in the “Public protection from exposure to ionizing radiation” chapter of the “Radiation Inspection and Control Service’s Inspection Guide”.

RICS issues every five years a publication with the results of the environmental monitoring programmes for purposes of information dissemination to the public, and has been available to the public and the data of the national monitoring network will also be available in real-time via a web-based online application.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<b>Observation:</b> The RICS/DLI reviews environmental monitoring programmes by conducting inspections, but in the Inspection Guide the review of environmental monitoring programmes is not included within the section on “Public Protection from exposure to ionizing radiation”.	
(1)	<b>BASIS:</b> GSR Part 3 Requirement 32, para. 3.135, (a) states that <i>“The regulatory body shall be responsible, as appropriate, for: (a) Review and approval of monitoring programs of registrants and licensee.”</i>
S8	<b>Suggestion:</b> The RICS/DLI should consider including the review of environmental monitoring programmes in its Inspection Guide.

#### 11.4. SUMMARY

Existing requirements on occupational exposure regulations cover aspects like optimisation of protection and safety, protection of the worker, dose monitoring, and the role of the Qualified Experts.

RICS/DLI fulfils radiation protection of the public and the legislation contains provisions for control of radioactive discharges, materials for clearance, existing exposure situations and environmental monitoring for public radiation protection, although some aspects are not fully consistent with GSR Part 3. The establishment of limits for liquid radioactive discharges, clearance levels for the release of materials from regulatory control and reference levels for radon indoors and construction materials should be addressed in the national regulations.

The legal and regulatory framework in The Republic of Cyprus, addresses medical exposure control, in a manner that it is in line with GSR Part 3. Generic justification of radiological procedures, diagnostic reference levels, referral guidelines, prompt investigation of unintended/accidental medical exposures, are some of the areas where improvements should be implemented.



## APPENDIX 1 POLICY ISSUES

The policy discussions were focused on three topics, namely, Justification in “medico-legal” exposure practices; “Establishing an appropriate education and training system on radiation protection and safety” and “Management and final disposal of legacy disused sealed radioactive sources (DSRS)”.

The discussions were chaired by the IRRS Team Leader and attended by the IRRS Team, the observer and representatives from the RICS/DLI.

### **Justification in “medico-legal” exposure practices;**

RICS/DLI, presented the current situation and explained that certain government organisations have shown interest in using full body scanners for security purposes.

RICS/DLI believes that this does not satisfy the radiation protection principle of justification by which no practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individual or to society to offset the detriment. The regulations in force state that the exposure to ionizing radiation has to be justified by the practitioner and doses to individuals for non-medical reasons have to be as low as reasonably achievable. Therefore, in their opinion, this practice should not be allowed unless certain conditions are satisfied.

Regarding this issue, some meetings have taken place, where RICS/DLI recommends that the organisations should consider the use of alternative control methods, i.e. without the use of ionizing radiation, to achieve its purpose.

The floor was then open for comments. One of the IRRS team members introduced existing international requirements and guidance material related to this issue. Whereas, according to the IAEA GSR Part 3, the government should ensure that the use of ionizing radiation for human imaging for purposes other than medical, is subject to the system of radiation protection and safety, the Directive 2013/59/Euratom states that Member States should ensure the identification of such practices, the generic and particular justification of them and if circumstances warrant non-medical imaging exposures without individual justification of each exposure, they should be subject to regular review. In conclusion, these practices need to be justified before being generally accepted, taking into account that the radiation safety regulatory body is unlikely to have any special competence in assessing detriments other than radiation safety related.

Other views were offered stating that in case the government deems that these practices, regulatory measures and competencies should be established in order to empower regulators to take action.

Finally, some IRRS team members presented some actions carried out in their countries to decrease the potential doses, such as limiting the number of individuals, the frequency at which an individual should go through the scanner or providing dosimeters to assess the levels of exposure.

### **Establishing an appropriate education and training system on radiation protection and safety**

The second policy issue discussion focused on the problem of complying with the goal of establishing an education and training system on radiation protection for licensees, users and staff of the regulatory body with the funding and structure currently available in Cyprus.

One of the IRRS team members shared his views by describing a three-step approach for the establishment of an overall strategy at national level by which the government would establish the legal framework, the regulatory body would provide the guidance and minimum provisions needed in education and experience, and finally, the means of approval or accreditation of those educational and

training institutes to provide the training would be defined. Meanwhile, some other ways of reaching this target were also discussed, as considering the IAEA PGECs or some other mechanism, such as e-learning material, as well as establishing bilateral agreements with other countries for this purpose.

### **Management and final disposal of legacy disused sealed radioactive sources (DSRS)**

The last policy issue was related to the final disposal of DSRS in Cyprus. The Head of RICS/DLI presented the current situation, where the regulations establish that these sources have to be repatriated and is implemented by RICS/DLI. However, the problem arises with legacy sources, which are actually stored in a licensed temporary storage site at the Nicosia General Hospital as a temporary solution.

The strategies considered by RICS/DLI are the following: (1) To send sources abroad, (2) To build a central storage for short term and long term radioactive wastes and (3) To construct a borehole for disposal, which is a technique that has been already developed by other countries such as South Africa and seems to be a workable method.

The discussion that followed showed several good approaches to address the problem. One of the IRRS team members also presented the situation in his country, where similar sources are conditioned and stored in a long-term storage facility for radioactive waste.

The Head of RICS/DLI stated that the main issue that they have to deal with, is public opinion, and asked the IRRS team for advice on this matter. The attendants agreed on the importance of communication and transparency in radiation safety matters, and that although this issue is something to be achieved in the long run, it is necessary and challenging. Finally, some of the attendants introduced some ideas for public outreach; for instance, issuing informative leaflets or brochures or establishing a state compensation for the people directly affected by a disposal site.

## APPENDIX II

## LIST OF PARTICIPANTS

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## APPENDIX III      MISSION PROGRAMME

Time	Activity	Venue and Participants
<b>Sunday 12 February 2017</b>		
<b>12:00 – 13:00</b>	<b>Team lunch</b>	
<b>13:30 - 17:30</b>	<b>Initial IRRS Review Team Meeting</b>	
	<ul style="list-style-type: none"> <li>• Opening remarks (IRRS Team Leader: Mr Christos Housiadass)</li> <li>• Introduction (IAEA)</li> <li>• Self-introduction of all attendees (All IRRS team, LO)</li> <li>• IRRS Process (IAEA)</li> <li>• Report writing (IAEA)</li> <li>• Schedule (TL, IAEA, LO)</li> <li>• First impression from experts arising from the Advanced Reference Material (ARM) (All IRRS team)</li> <li>• Administrative arrangements (LO, IAEA)</li> <li>• Detailed Mission Programme (LO, IAEA)</li> </ul>	<b>Venue:</b> Hotel Semeli , <b>Participants:</b> the IRRS Team + LO
<b>Monday 13.2.2017</b>		
<b>08:30</b>	<b>Pick up from the hotel</b>	
<b>IRRS Entrance Meeting</b>		
<b>09:00 – 12:00</b>	09:00 Arrival of IRRS Team at DLI premises – 09:30 Registration Welcoming Address (Mr. Andreas Ashiotis, Permanent Secretary of MLWSI) 09:45 The IRRS programme (IRRS Coordinator) 10:00 Expectations for the Mission and introduction of the IRRS Team (IRRS Team Leader) 10:15 Introduction of the Cyprus counterparts 10:25 Group photo of the meeting participants	<b>Venue:</b> DLI headquarters <b>Participants:</b> Permanent Secretary of MLWSI, DLI Director, RICS management (+ LO) and staff, Officials from relevant organizations, the IRRS team.
<b>10:30</b>	<b>Coffee break</b>	
	11:00 RICS/DLI presentation – Regulatory Overview – SARIS results (strengths, challenges, action plan) 11:45 (RICS/DLI) Discussion – Questions	
<b>12:00 – 13:00</b>	<b>Lunch</b>	
<b>Daily Discussions / Interviews</b>		
<b>13:00 – 17:00</b>	Interviews and Discussions with Counterparts (parallel discussions) Modules 1-3	<b>IRRS Reviewers and Counterparts:</b> DLI headquarters
<b>13:00 – 17:00</b>	Interviews and Discussions with Counterparts (parallel discussions) Module 11.2 Occupational Exposure	

Time	Activity	Venue and Participants
17:00 – 18:00	Daily IRRS Review Team meeting	<b>Venue:</b> DLI headquarters conference room <b>Participants:</b> the IRRS team + LO
18:00	<b>Transport to the hotel</b>	
18:30 -	Writing draft report	
<b>Tuesday 14 February 2017</b>		
08:30	<b>Pick up from the hotel</b>	
<b>Daily Discussions / Interviews / Visits</b>		
09:00 – 12:00	Interviews and discussions with counterparts (parallel discussions) <ul style="list-style-type: none"> <li>• Modules 1-3 (cont'd if needed),</li> <li>• Module 10</li> <li>• Module 4 (following module 10)</li> </ul>	<b>IRRS Reviewers and Counterparts:</b> DLI headquarters
09:15 -14:00	(a) Bank of Cyprus Oncology Centre, Lefkosia (Nicosia) (b) Nortest (Cyprus) Industrial Radiography facility, Kalavassos	<b>IRRS experts + RICS inspectors</b>
12:00 – 13:00	<b>Lunch</b>	
14:00 – 17:00	Visit to the Ministry of Labour, Welfare and Social Insurance (MLWSI)	<b>Participants:</b> TL, TC, Reviewer on Modules 1, 2 and 3 + LO
14:00 – 17:00	Interviews and discussions with counterparts (parallel discussions) <ul style="list-style-type: none"> <li>• Module 10</li> <li>• Module 4 (following module 10)</li> </ul>	<b>IRRS Reviewers and Counterparts:</b> DLI headquarters
17:00 – 18:00	Daily IRRS Review Team meeting (including quick briefing on Site Visits)	<b>Venue:</b> DLI headquarters conference room <b>Participants:</b> the IRRS team + LO.
18:00	<b>Transport to the hotel</b>	
18:30 -	Writing draft report	<b>IRRS Team (each reviewer individually in his/her specific area e.g. hotel room).</b>
<b>Wednesday 15 February 2017</b>		
08:30	<b>Pick up from the hotel</b>	
<b>Daily Discussions / Interviews / Site visits</b>		
09:00– 17:00	Interviews and discussions with counterparts for all modules <ul style="list-style-type: none"> <li>• Modules 5-9 for (a) radiation sources (b) Waste and Decommissioning and (c) transport</li> </ul>	<b>IRRS Reviewers and Counterparts:</b> DLI headquarters

Time	Activity	Venue and Participants
09:00-17:00	Module 11.1 Medical Exposure	<b>IRRS Reviewers and Counterparts:</b> DLI headquarters
09:00– 17:00	<ul style="list-style-type: none"> <li>Module 11.3 Public Exposure and Existing Exposure.</li> </ul>	<b>IRRS Reviewers and Counterparts:</b> DLI headquarters
12:00 – 13:00	<b>Lunch</b>	
17:00 – 18:00	Daily IRRS Review Team meeting	<b>Venue:</b> DLI conference room <b>Participants:</b> IRRS team + LO.
18:00	<b>Transport to the hotel</b>	
18:30 -	Writing draft report	
<b>Thursday 16 February 2017</b>		
08:30	<b>Pick up from the hotel</b>	
<b>Daily Discussions / Interviews / Site visits</b>		
09:00– 16:00	Follow-up interviews and discussions with counterparts (parallel discussions)	<b>IRRS Reviewers and Counterparts:</b> DLI headquarters
09:15 – 12:00 <sup>1</sup>	Site visits Lefkosia (Nicosia) General Hospital	<b>Participants:</b> IRRS Team members + RB staff
12:00 – 13:00	<b>Lunch</b>	
16:00 – 16:30	Quick briefing on all site visits	<b>IRRS team</b>
16:30	<b>Transport to the hotel</b>	
17:00 – 22:00	Daily IRRS Review Team Meeting	<b>Venue:</b> Hotel conference room <b>Participants:</b> the IRRS team + LO.
22:00 -	Writing draft report	
<b>Friday 17 February 2017</b>		
<b>Report drafting</b>		
09:00 – 14:00	Team members finalize observations, recommendations, suggestions and good practices Team members write draft report	<b>Venue:</b> DLI headquarters IRRS team
12:00 – 13:00	<b>Lunch</b>	
13:00	<b>Final draft report of each chapter (Text +Boxes)</b>	
14:00 – 16:00 <sup>2</sup>	Policy issues discussion	<b>Participants:</b> IRRS

<sup>1</sup> More time may be given if needed for all site visits.

<sup>2</sup> Counterparts need to introduce the topic and their concern for all Policy Discussions.

Time	Activity	Venue and Participants
		team + RICS staff <b>Venue:</b> DLI headquarters
<b>16:00 – 18:00</b>	Daily IRRS Review Team Meeting: the team finalizes recommendations, suggestions and good practices (Cross reading)	<b>Venue:</b> DLI headquarters (Hotel?) <b>Participants:</b> the IRRS team + LO.
<b>Saturday 18 February 2017</b>		
<b>Report drafting and finalization</b>		
<b>09:00 –</b>	The Team finalizes the draft report together	<b>Venue:</b> Hotel conference room IRRS team + LO
<b>Sunday 19 February 2017</b>		
<b>IRRS Team Free Day – Cultural Programme</b>		
<b>08:00 -12:00</b>	TL + TC review the draft report	TL + TC Venue: Hotel
<b>12:00</b>	The draft report is submitted to LO for RB comments	
<b>10:00 –</b>	IRRS Team rest day + Excursion (IRRS Team, RICS staff)	Sites Lefkosia (Nicosia)-Limassol-Paphos
<b>Monday 20 February 2017</b>		
<b>Report commenting and discussions</b>		
<b>08:00 – 17:00</b>	RICS reviews the draft report	
<b>17:00</b>	RICS submits comments on the draft report	
<b>17:00 – 21:00</b>	IRRS team reviews RICS comments	
<b>Tuesday 21 February 2017</b>		
<b>Report reviewing and finalization</b>		
<b>09:00 – 14:00</b>	IRRS team finalizes the draft report together with RICS	The IRRS team + LO + RICS
<b>12:00 – 13:00</b>	<b>Lunch (as convenient)</b>	
<b>14:00</b>	Draft report handed over to RICS	The IRRS team
<b>Wednesday 22 February 2017</b>		
<b>IRRS mission exit meeting</b>		
<b>09:00 – 11:00</b>	<ul style="list-style-type: none"> <li>• Main findings of the IRRS mission (Team Leader)</li> <li>• Remarks by RICS in response to the mission findings</li> <li>• Closing remarks by IAEA Official (Director NSRW)</li> <li>• IAEA press release</li> </ul>	<b>Venue:</b> DLI Headquarters <b>Participants:</b> Government officials, RICS/DLI management and staff, officials from relevant organizations, the IRRS team + LO



## **APPENDIX IV      SITE VISITS**

1. Bank of Cyprus Oncology Centre, Lefkosia (Nicosia)
2. Nortest (Cyprus) Industrial Radiography facility, Kalavassos
3. Lefkosia (Nicosia) General Hospital

## APPENDIX V LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART
<b>RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT</b>	
Aleš Škraban Christos Housiadas Teodros Hailu	Panicos Demetriades Michalis Tzortzis
<b>GLOBAL SAFETY REGIME</b>	
Aleš Škraban Christos Housiadas Teodros Hailu	Panicos Demetriades Michalis Tzortzis
<b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>	
Aleš Škraban Christos Housiadas Teodros Hailu	Panicos Demetriades Michalis Tzortzis
<b>MANAGEMENT SYSTEM</b>	
Justice Chipuru	Panicos Demetriades Michalis Tzortzis
<b>AUTHORIZATION</b>	
Noeleen Cunningham Richard Holzwarth Mohamed Geleel Soumia Zeroual	Panicos Demetriades Demetris Sakkas Melpo Agathocleous Anastasia Sisou
<b>REVIEW AND ASSESSMENT</b>	
Noeleen Cunningham Richard Holzwarth Mohamed Geleel Soumia Zeroual	Panicos Demetriades Demetris Sakkas Melpo Agathocleous Anastasia Sisou
<b>INSPECTION</b>	
Noeleen Cunningham Richard Holzwarth Mohamed Geleel Soumia Zeroual	Panicos Demetriades Demetris Sakkas Melpo Agathocleous Anastasia Sisou

IRRS EXPERTS	COUNTERPART
<b>ENFORCEMENT</b>	
Noeleen Cunningham Richard Holzwarth Mohamed Geleel Soumia Zeroual	Panicos Demetriades Demetris Sakkas Melpo Agathocleous Anastasia Sisou
<b>REGULATIONS AND GUIDES</b>	
Noeleen Cunningham Richard Holzwarth Mohamed Geleel Soumia Zeroual	Panicos Demetriades  Melpo Agathocleous Anastasia Sisou
<b>EMERGENCY PREPAREDNESS AND RESPONSE</b>	
Peter Zombori	Panicos Demetriades Michalis Tzortzis
<b>ADDITIONAL AREAS - Medical Exposure</b>	
Stavroula Vogiatzi	Demetris Sakkas
<b>ADDITIONAL AREAS - Occupational Exposure</b>	
Noeleen Cunningham Richard Holzwarth	Demetris Sakkas Melpo Agathocleous Anastasia Sisou
<b>ADDITIONAL AREAS</b>	
<b>Environmental monitoring associated with authorized practices for public radiation protection purposes, Control of chronic exposure remediation</b>	
Sofía Luque	Michalis Tzortzis

## APPENDIX VI      RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	<b>RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT</b>	R1	The Government should establish a national policy and strategy for safety.
		R2	The Government should review the legal framework to ensure compliance with the requirements of GSR Part 1 (Rev.1).
		R3	The Government should provide RICS/DLI with adequate human and financial resources.
		R4	The Government should strengthen RICS/DLI powers and responsibilities in the licensing decision-making process through the legal framework.
		S1	The Government should consider extending the prime responsibility for safety in the legislation so that where an authorization (approval or licence) is not in place this would not exonerate the person or organization responsible for a facility or activity from the responsibility for safety.
		R5	The Government should make provision for a system to ensure building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.
2.	<b>GLOBAL SAFETY REGIME</b>	R6	The Government should participate in international cooperation activities for safety such as participation in IAEA safety review missions.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		GP1	The Government has stipulated in the law that the regulatory body should periodically conduct self-assessment and invite an international peer review with the aim of continuously improving safety.
		R7	The RICS/DLI should make arrangements for analysis to be carried out to identify lessons learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities. Such arrangement should also include feedback on measures that have been taken in response to information received.
3.	<b>RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY</b>	R8	RICS/DLI should prepare and implement comprehensive human resource plan on the basis of the analysis made on necessary competence and skills.
		R9	The Government should make provisions in the legislation or make other arrangements for the services of TLC in providing advice in order to ensure that there is no conflict of interest.
		R10	RICS/DLI should establish formal processes based on specific policies, principles and associated criteria and follows specified procedures.
4.	<b>MANAGEMENT SYSTEM OF THE REGULATORY BODY</b>	R11	RICS/DLI should integrate all essential elements of the management system necessary for the attainment of its goals into single framework.
		R12	RICS/DLI should document all the key elements of its management system and ensure that the documentation is readily available.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R13	The regulatory body should identify, develop and document all key processes contributing to safety.
		S2	The regulatory body should consider developing guidance for self-assessment of work conducted by managers and individuals in the organization to ensure continual improvement.
		R14	RICS/DLI should implement a system for self-assessment and independent assessment of leadership for safety and of safety culture in the organization.
		GP2	RICS/DLI has a system, implemented annually, for establishing and addressing the competence and training needs among its staff aimed at improving their contribution to achievement of organizational goals.
5.	AUTHORIZATION	R15	RICS/DLI should establish objective and clear criteria for amendment, renewal, suspension or revocation of a licence.
		R16	RICS/DLI should develop a documented appeals process.
		R17	RICS/DLI should develop internal guidance to outline which practices or sources within practices are to be authorized by approval, registration and licensing.
		R18	The regulatory body should issue guides on regulation of transport of radioactive material.
		S3	RICS/DLI should consider developing an auditing programme for the management system of the licensee.
6.	REVIEW AND ASSESSMENT	R19	RIC/DLI should establish procedures for the review and assessment of

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			a safety assessment submitted by an applicant.
7.	INSPECTION	R20	RICS/DLI should establish a formalized programme of inspections that specifies the frequency of inspection, taking into account the radiation risks associated with the facility or activity, and areas and programmes to be inspected in accordance with a graded approach.
		S4	RICS/DLI should consider the use of the checklist in conducting all inspections to ensure that the stability and consistency of approach to inspections.
		S5	RICS/DLI should consider providing a documented record of the findings communicated verbally to authorized parties at the end of an inspection.
8.	ENFORCEMENT	R21	RICS/DLI should ensure a harmonized implementation of the enforcement tools provided in the legislation.
		R22	RICS/DLI should enforce the assessment of radiation doses to workers, public and workplace monitoring in activities related to transport of radioactive material.
9.	REGULATION AND GUIDES	S6	RICS/DLI should consider ensuring that its regulations or guides provide adequate coverage of facilities and activities commensurate with the radiation risks.
		R23	The Government should ensure a formal coordination of the authorities involved in the regulation of the transport of radioactive material.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
10.	EMERGENCY PREPAREDNESS AND RESPONSE	S7	The regulatory body should consider completing the review and revision of the EPR related legal framework and implementing the protective actions for the protection of the public in case of a nuclear or radiological emergency, in accordance with the requirements of GSR Part 7.
11.1	CONTROL OF MEDICAL EXPOSURES	R24	The Government should ensure that generic justification of radiological procedures, including new techniques and technologies, is effectively carried out; health screening programmes, biomedical research programmes and radiological procedures conducted to asymptomatic individuals are justified; harmonized referral guidelines are practically applied.
		R25	The Government should ensure that diagnostic reference levels, dose constraints and criteria and guidelines for the release of patients are established.
		R26	RICS/DLI should establish requirements to ensure that calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment for all therapeutic radiological procedures are fulfilled by or under the supervision of a medical physicist.
		R27	RICS/DLI should establish and verify requirements for regular and independent audits of the programme of quality assurance for medical exposures, to be conducted with frequency appropriate for the complexity of the performed radiological procedures and the associated risks.
		R28	RICS/DLI should establish requirements for minimizing the likelihood of unintended or accidental medical exposures, initiating the prompt



Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			investigation and implementation of appropriate corrective actions for any case of such medical exposures and ensuring that the referring medical practitioner and the patient or the patients' legal authorized representative are properly informed.
		R29	RICS/DLI should establish and verify requirements for the periodic investigation and critical review of the current practical application of the justification and optimization principles for the radiological procedures performed in the medical radiation facility.
11.2	<b>OCCUPATIONAL RADIATION PROTECTION</b>	R30	RICS/DLI should assure that occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in Schedule III are not exceeded.
11.3	<b>CONTROL OF RADIOACTIVE DISCHARGES, MATERIAL FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION</b>	R31	The RICS/DLI should establish limits for radioactive discharges based on operational constraints.
		R32	The RICS/DLI or other relevant authority should establish reference levels for existing exposure situations and construction materials.
		S8	The RICS/DLI should consider including the review of environmental monitoring programmes in its Inspection Guide.

## APPENDIX VII REFERENCE MATERIAL USED FOR THE REVIEW

1.	REGS Drinking Water EN.pdf
2.	REGS EMERG EN.pdf
3.	REGS HASS EN.pdf
4.	REGS MEDICAL EN.pdf
5.	REGS SF and RW EN.pdf
6.	REGS SHIPMENTS EN.pdf
7.	RP and NS LAWS Consolidated EN.pdf
8.	Dental General Conditions EN.pdf
9.	List of THE REPUBLIC OF CYPRUS International Agreements.pdf
10.	National RW Policy and Strategy EN.pdf
11.	REGS BSS EN.pdf
12.	Export Questionnaire - Regulation of Nuclear Power Plants.bin
13.	Export Questionnaire - Regulatory Framework for Research Reactors.bin
14.	Export Questionnaire - Safe Transport of Radioactive Material.bin
15.	Export Questionnaire - Safety of Radioactive Sources (in accordance with the CoC).bin
16.	SARIS ATTACHEMENTS.pdf
17.	Saris final CY.doc
18.	Export Lifecycle - SARIS Country Information.bin
19.	Export Questionnaire - Control of Medical Exposure Regulator.bin
20.	Export Questionnaire - Core Questions (Core IRRS modules).bin
21.	Export Questionnaire - Fuel Cycle Facilities.bin

22.	Export Questionnaire - Interface with Nuclear Security.bin
23.	Export Questionnaire - Occupational Radiation Protection.bin
24.	Export Questionnaire - Public and Environmental Exposure Control, Waste Management and Decommissioning
25.	FORM Notification for Practice.pdf
26.	Inspection Guide RICS EN.pdf
27.	Schemes of Service.pdf
28.	Criteria Technical Support Services EN.pdf
29.	FORM Application for license.pdf
30.	Cyprus Country Information.pdf
31.	CyprusCountryInformation.bin
32.	CyprusMain.bin
33.	IRRS ARM Summary CYPRUS.pdf

## **APPENDIX VIII IAEA REFERENCE MATERIAL USED FOR THE REVIEW**

1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1(Rev 1) (Vienna2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety Requirement GSR Part 2 IAEA, Vienna (2016)
4. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirement Part 7, No. GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 6, No. SSR 6, IAEA, Vienna (2012)8.
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
14. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
15. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)

18. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)
19. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
20. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
21. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)
22. INTERNATIONAL ATOMIC ENERGY AGENCY – Establishing the Safety Infrastructure for a Nuclear Power Programme Specific Safety Guide No SSG-16, IAEA, Vienna (2011)
23. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements 5, No. SSR 5, IAEA, Vienna (2011)

## APPENDIX XI ORGANIZATIONAL CHART

Organisation chart and personnel of DLI

