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# INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

## MISSION

**TO**

# GUATEMALA

**GUATEMALA CITY, GUATEMALA**

***5-14 February 2017***

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated Regulatory Review Service

IRRS

Integrated
Regulatory
Review Service
IAEA | IRRS

# REPORT OF THE
# INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
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| **Mission dates:** | *5-14 February 2017* |
| **Regulatory body visited:** | *Dirección General de Energía, Ministerio de Energía y Minas* |
| **Location:** | *Guatemala City* |
| **Regulated facilities and activities in the mission scope:** | *Departamento de Protección y Seguridad Radiológica, Dirección General de Energía, Ministerio de Energía y Minas* |
| **Organized by:** | *IAEA* |

## IRRS REVIEW TEAM

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|---|---|
| MILLER Chris | Team Leader (United States of America) |
| VLAHOV Nikolay | Reviewer (Bulgaria) |
| GUTTERRES FRAGA Ricardo | Reviewer (Brazil) |
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| DWYER James | Reviewer (United States of America) |
| AL KHATIBEH Ahmad | Team Coordinator (IAEA) |
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| ALEXANDER Tom | Administrative Assistant (IAEA) |

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

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## EXECUTIVE SUMMARY

At the request of the Republic of Guatemala, an international team of senior nuclear and radiation safety experts met with representatives of the Ministry of Energy and Mines, the Ministry of Health, and the of Guatemala from 05 – 14 February 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of Guatemala's national regulatory framework for nuclear and radiation safety against IAEA safety standards as the international benchmark for safety. The IRRS Review Team received full cooperation from all parties in an open and transparent manner throughout the mission. The mission took place at the DGE Headquarters in Guatemala City.

The IRRS Review Team concluded that Guatemala has a regulatory framework for safety in place and a strong commitment to nuclear and radiation safety as demonstrated during the mission. DGE through self-assessment has identified some challenges that it faces. These challenges have been identified by the Guatemala Government and numerous measures are underway. It is necessary that the Government continues to support and provide resources to complete these important activities in a timely manner to ensure that effective regulatory oversight for operation has been established before the plant is placed in service. In particular, focus should be directed towards continued building of DGE's technical capabilities and establishing regulations and procedures for operations and emergency preparedness and response.

The country has a long history in the use and regulation of ionizing radiation in medical and industrial applications, as well as, in science. Notwithstanding, there are still challenges to be resolved related to the consistent and effective regulation of the use of ionizing radiation sources.

The IRRS Review Team identified 3 good practices and also made recommendations and suggestions to indicate where improvements are necessary or desirable to further enhance and more closely align the regulatory framework with IAEA safety standards. The IRRS Review Team noted that many of these areas had been identified by DGE prior to the mission and addressed in its action plan.

The good practices identified by the IRRS team include:

- Guatemalan Strategy for improving national competency and the detailed gap analysis for the country's needs in different aspects of science and technology is commendable;
- The DGE website provides the applicants with forms, instructions and requirements for submitting an authorization; and
- DGE is conducting proactive "verification" inspections to identify individuals and institutions that require an authorization but have never applied, and instruct them to obtain authorization or cease their activities.

The IRRS Review Team made observations that warrant additional emphasis. Specifically:

- Develop the national policy and strategy for safety and establish a strategy for radioactive waste management for facilities and activities;
- The Government should ensure that no promotional functions are assigned to DGE which might conflict with its regulatory responsibilities.
- The Government should provide DPSR with sufficient human and financial resources to ensure that it fulfils its statutory obligation;
- Continue efforts to update the regulatory framework for emergency preparedness and response to meet the latest IAEA safety standards;

- DGE/DPSR should establish requirements and criteria for reporting of operating events by licensees. It should also establish a system for analysing events and disseminating the lessons learned within the country and internationally, as well as learning from and providing feedback to international networks.
- DGE should revise its decision to assign the non-ionising radiation to DPRS and maintain those responsibilities in the designated Department for Non-Ionizing Radiation;

The IRRS mission covered all civilian nuclear and radiation facilities and activities regulated in Guatemala with the exception of transport of radioactive material. The mission was also used to exchange information and experience between the IRRS Review Team members and the Guatemala counterparts in the areas covered by the IRRS.

The IRRS team consisted of 8 senior experts from 7 IAEA Member States, 2 IAEA staff members and an IAEA administrative assistant. The IRRS Review Team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance.

The mission included observations of regulatory activities and interviews and discussions with the Deputy Minister of Energy of the MEM, Director General of Energy, and DGE staff. Activities included visits to: Radiotherapy and Nuclear Medicine Facilities (CIO HOPE); Installations of Industrial Irradiators (MOSCAMED) and Industrial Radiography and National Installations of Radioactive Waste -CENDRA. The members of the IRRS Review Team observed the regulated activities and performance of inspection activities, and held discussions with the licensee's staff and management.

In preparation for the IRRS mission Guatemala conducted a self-assessment and prepared a preliminary action plan to address weaknesses that were identified. The results of the self-assessment, action plan and supporting documentation were provided to the team as advance reference material for the mission.

The IRRS Review Team findings are summarized in Appendix V.

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

# I. INTRODUCTION

At the request of the Government of Guatemala, an international team of senior safety experts met representatives of the regulatory body of Guatemala, Dirección General de Energía (DGE) from 5 to 15 February 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Guatemalan regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Guatemala in October 2013. A preparatory mission was conducted 20-21 May 2015 at the regulatory body headquarters of DGE, to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Guatemala and their related safety aspects, and to agree the scope of the IRRS mission. Where specific facilities and/or activities would not be included in the scope of the IRRS mission, Guatemala undertook to provide explanation for the exclusion.

The IRRS Review Team consisted of 8 senior regulatory experts from 7 IAEA Member States, 2 IAEA staff members and 1 IAEA administrative assistant. The IRRS Review Team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; waste management and decommissioning, development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure and Control of radioactive discharges and materials for clearance.

DGE conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of DGE self-assessment and supporting documentation were provided to the IRRS review team as advance reference material for the mission. During the mission the IRRS Review Team performed a systematic review of all topics within the agreed scope through review of the Guatemala advance reference material, conduct of interviews with management and staff from DGE and direct observation of DGE's regulatory activities at regulated facilities. A meeting with the Vice Minister of Energy, Rodrigo Fernández, was also organized.

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

## II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Guatemala's radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Guatemala. It is expected this IRRS mission will facilitate regulatory improvements in Guatemala and other Member States, utilising the knowledge gained and experiences shared between DGE and IRRS reviewers and the evaluation of the Guatemalan regulatory framework for nuclear and radiation safety, including its good practices.

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

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Review Team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements; and

k) providing feedback on the use and application IAEA safety standards.

## III. BASIS FOR THE REVIEW

### A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Guatemala, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 20 to 21 May,2015. The preparatory meeting was carried out by the appointed Team Leader Mr Chris Miller, and the IRRS IAEA Team representatives, Mr Al Khatibeh Team Coordinator, Mr Ronald Pacheco-Jimenez Deputy Team coordinator.

- The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of DGE represented by Luis Alejandro González, Host Country Representative, Head of the Department of Safety and Radiological Protection (DPSR), 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;
- Radiation sources facilities and activities;
- Waste management;
- Decommissioning;
- Emergency prepareness and response
- Control of medical exposure;
- Occupational radiation protection;
- Control of radioactive discharges and materials for clearance.

Mr Luis Alejandro González made presentations on the national context, the current status of DGE 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 Guatemala in February 2016. However due to the out break of the ZIKA virus, the mission was postpond to be implemented from 5 to 14 Februay 2017.

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

The Guatemalan Liaison Officer for the IRRS mission was confirmed as Mr Luis Alejandro González, DGE provided IAEA with the advance reference material (ARM) for the review initially at the end of December 2015 and it was updated in December 2016. In preparation for the mission, the IAEA review team members reviewed the Guatemalan 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 relevant IAEA safety standards, were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII

### C) CONDUCT OF THE REVIEW

The initial IRRS Review team meeting took place on Sunday, 5 February, 2017 in DGE, 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 Review Team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 6 February, 2017, with the participation of the Vice Minister of Energy and Vice Minister for Hydrocarbons and Mines, DGE Director, Head of DPSR and DGE's senior management and staff. Opening remarks were made by Vice Minister, Rodrigo Fernández, and NLO, Ms Mayra Villatoro del Valle, Mr Chris Miller, IRRS Team Leader and Mr Ahmad Al Khatibeh, IRRS Team Coordinator. Mr Luis Alejandro González gave an overview of the Guatemala context, DGE activities and the action plan prepared as a result of the pre-mission self-assessment.

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

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

The IRRS exit meeting was held on Tuesday, 14 February, 2017. The opening remarks at the exit meeting were presented by the Minister of Energy and Mines, Luis Alfonso Chang Navarro and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Chris Miller. Closing remarks were made by Mr Peter Johnston, Director, Division of Radiation, Transport and Waste Safety, IAEA.

An IAEA press release was issued.

# 1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

Guatemala is a constitutional democratic republic with a multi-party system. The Constitution was adopted in May 1985, and amended in 1993. Article 46 of the Constitution, states "in the field of human rights, treaties and agreements approved and ratified by Guatemala has precedence over municipal law".

Guatemala is governed by a 3-branch system, consisting of the executive, legislative, and judicial powers.

The executive power is vested with the President who is elected for a single four-year term and acts as both chief of state and as head of government. The president is supported by a vice president and by a Council of Ministers (appointed by the president).

Legislative power is held by a unicameral national Congress, the Congress of the Republic (Congress), made up of 110 deputies who are directly elected by popular vote for a four-year term.

Judicial Branch is headed by the 13 member Supreme Court of Justice and involves a hierarchical series of upper and lower courts.

## 1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

In 1986 Guatemala has issued the DECREE LAW No. 11-86 "Law for Control, Use and Application of Radioisotopes and Ionizing Radiation" (the Law). This law forms elements of a national policy for safety. The Law identifies that use of ionizing radiation not only contributes to the economic and social development of the country but also involves a potential risk to health, property and the environment and respectively the process needs to be regulated. It also states the fundamental safety objective and specifies the scope of facilities and activities to be regulated.

In its self-assessment, DGE identified that "Guatemala doesn't have a policy and strategy for safety". During the mission, the IRRS Review Team identified that IAEA Fundamental Safety Principles (SF-1) has been adopted by the Ministerial Agreement (MA 73-2015) (Fundamental principles, regulatory environment, facilities management and basic rules). SF-1 states the fundamental safety objective and the ten associated safety principles, which provide the basis for the protection of people and the environment against radiation risks. The approval of SF-1, as a binding document, is an important step towards the establishment of country safety objectives and principles and promotes long term commitment to safety.

## 1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legislation in Guatemala is hierarchically structured. The top tier consists of laws, which are adopted by the Congress and approved by the President. The Constitution is the supreme law. This level also includes treaties and agreements approved and ratified by Guatemala, which have precedence over the national laws. The second tier in the legislation includes legislative acts adopted by the Government and approved by the President. These acts are called Governmental Agreements (GA), and they are binding to everyone in the country. Ministers are also vested with the power to issue binding legislative acts called Ministerial Agreements (MA). All legislative acts are published in the Official Gazette “Diario de Centro América”

The main Law in the area of safety is the Law for the Control, Use and Application of Radioisotopes and Ionizing Radiation (Decree 11-86). It sets out the basis for the legal and regulatory framework for safety and empowers DGE to "ensure that in the national territory this law and its regulations, as well as treaties,

conventions and other international agreements in the field of nuclear energy, signed and ratified by the State are met". A number of regulations (Government Agreements) were issued that further developed the requirements of the law, namely:

- Regulation of Safety and Radiation Protection (GA 55-2001);
- Regulation of physical security of nuclear and radioactive materials (GA 469-2014);
- Regulation of Radioactive Waste Management (GA 176-2015);
- National Waste Management Policy (GA 67-2016)
- Education and Training Strategy (MA 08-2016)
- DGE Tariff (MA 208-2016)

Additionally, there are 7 Ministerial Agreements, by which Guatemala adopts the IAEA Safety Standards in the areas of:

- Radioactive waste (MA 67-2015).
- Radioactive sources and radiation generators (MA 68-2015).
- Qualifications of people (MA 69-2015).
- Safe Transport of Radioactive Material (MA 70-2015).
- Inspections (MA 71-2015).
- Radiological Emergency (MA 72-2015).
- Fundamental principles, regulatory environment, facilities management and basic rules (MA 73-2015).

The Law, in combination with the implementing regulations, establishes the regulatory body, specifies the types of regulated facilities and activities, empowers the regulatory body for development and promulgation of regulatory requirements, requires authorization for the operation of facilities and for the conduct of activities, provides for the inspection of facilities and activities, and for the enforcement of regulations, etc. However, the IRRS Review Team identified that some of the prerequisites for the establishment of an effective legal and regulatory framework for safety are not completely addressed, namely:

- Graded approach for authorization, review and assessment and inspection;
- Provision for the involvement of interested parties and for their input to decision making;
- Responsibilities and obligations in respect of financial provision for the management of radioactive waste and for decommissioning of facilities and termination of activities.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *Some of the prerequisites for an effective legal and regulatory framework have not been established* | |
| **(1)** | **BASIS: GSR Part 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 ....."* |
| **R (1)** | **Recommendation: The Government should ensure that the national legal framework** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **addresses all of the provisions for an effective legal and regulatory framework for safety, including:**<br>• **Graded approach for authorization, review and assessment and inspection;**<br>• **Provision for the involvement of interested parties and for their input to decision making;**<br>• **Responsibilities and obligations in respect of financial provision for the management of radioactive waste and for decommissioning of facilities and termination of activities.** |

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

The Law establishes the DGE and the Director General for Energy as its head, of the MEM as the competent authority to control, supervise, monitor and establish the minimum conditions for safety in respect to radioisotopes and ionizing radiation.

The Law specifies the functions of DGE, including functions to ensure that laws and regulations, as well as treaties, conventions and other international agreements are complied with; to ensure that regulatory technical requirements are fulfilled; to be responsible for the relations with international organizations and other entities involved in nuclear energy; to develop regulatory requirements; to take decisions on the safety of regulated facilities and activities, including issuing licenses; take enforcement actions in the case of a non-compliance; etc. These functions of DGE to a large extent cover the main functions of a regulatory body as defined by the IAEA standards.

IRRS Review Team identified that in addition to those functions the Law authorizes DGE with some promotional functions, namely:

- Develop and propose to the Ministry, plans to research, development and application of nuclear energy;
- To promote and develop programmes of research and application of nuclear energy and disseminate the results to help develop the country;
- Investigate, promote and develop the irradiation of products for preservation, sterilization or other.

The IRRS Review Team was informed that with respect to research and development activities, the Government formed a new authority called National Board of Science and Technology (CONCYT). The law establishing CONCYT requires that all responsibilities of governmental bodies related to research and development are transferred to the CONCYT and repeals all laws that has conflicting articles. Irrespective of that, The Law had not been amended to reflect these changes in responsibilities. However, the Law still assigns promotional responsibilities of the application of nuclear energy to DGE.

The IRRS Review Team was informed that those responsibilities are not relevant anymore, and are not implemented by DGE. However, they are still part of the functions of DGE as authorized by the Law, which is not in line with the international standards.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE as regulatory body is assigned with promotional responsibilities* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 4, para 2.9 states that** *"No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities"* |
| **R (2)** | **Recommendation: The Government should ensure that no promotional functions are assigned to DGE which might conflict with its regulatory responsibilities.** |

DGE funding is provided by the state budget using a programme financing mechanism. DGE has two main programmes:

- Programme 13 Radiation Safety – funding the regulatory activities in the field of Radiation Safety, operated by DPSR; and
- Programme 15 Energy – funding the regulatory activities in the field of energy.

DPSR prepares the budget request and submits it to DGE which submits it to the Ministry on Public Finance (MFP) through MEM. Following discussions, the budget is approved and included in the annual budget of MEM and allocated to Program 13. The budget includes three main expenditure lines: Salaries; Inspections – travel and living expenses; and Procurement. It does not allocate any funds for some of the main and support regulatory functions, i.e. international cooperation, training and retraining of regulatory staff, contracting external review and assessment, drafting regulatory requirements, drafting internal procedures, etc.

For the last five years the allocated budget remained stable with small variations of the total amount. MPF approves around 50-55% of the request. As a result of that decision DPSR is forced to reconsider and reduce inspection programmes and other planned activities. Finally, some regulatory functions are not fully implemented due to this reduced budget, for example: inspection of practices; development of regulatory requirements, establishment of a management system; education and training of regulatory staff; sharing of international operating and regulatory experience; involvement in international activities.

The number of qualified and competent staff dedicated to licensing, inspection, review and assessment and development of requirements appears to be insufficient and not commensurate with the nature and the number of regulated facilities and activities. For example, four inspectors are responsible for the oversight of more than 2311 facilities and activities. The IRRS Review Team noted that DPSR staff are dedicated and committed to their work. Many of them frequently remain to work overtime in order to compensate for the understaffing.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **Observation:** *DPSR has insufficient human resources to effectively implement its functions. Additionally, financial resources provided to DPSR are quite limited and do not allow the department to fulfil its statutory obligation.* |
| **(1)** | **BASIS: GRS Part 1 (Rev.1) Requirement 3 states that** "*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* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *statutory obligation for the regulatory control of facilities and activities."* |
| **(2)** | **BASIS: GRS Part 1 (Rev.1) Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."* |
| **R (3)** | **Recommendation: The Government should provide DPSR with sufficient human and financial resources to ensure that it fulfils the statutory obligation.** |

## 1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

As already mentioned in section 1.1, MA 73-2015 adopts the IAEA SF-1 as binding for the country. This leads to the fact that the first principle of SF-1 is binding for everyone using nuclear energy, and assigns their prime responsibility for safety to the person or organization responsible for facilities and activities that give rise to radiation risks. This also means that the licensee retains the prime responsibility for safety throughout the lifetime of facilities and activities, and this responsibility cannot be delegated. Furthermore, the Law specifies that no license issued by the DGE may be transferred to third parties, directly or indirectly, without its prior authorization.

Every individual or legal person who holds a license to conduct practices involving sources of ionizing radiation or exposure of peoples to ionizing radiation has the prime responsibility for safety and radiological protection. It´s stated on the Law for the Control, Use and Application of Radioisotopes and Ionizing Radiation, (Decree 11-86), Articles 6; and in the Regulation of Safety and Radiation Protection (Government Agreement 55-2001), Articles 4 and 67.

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

The Law specifies that DGE may request assistance from other public authorities or institutions, and they are obliged to provide it. In emergency situations, licensees are also required to give assistance. This statement establishes the bases for the coordination and cooperation of DGE with all other authorities having some responsibilities in ensuring the safety of facilities and activities.

Based on that, DGE has made an assessment of all other state authorities that participate in one way or another in joint initiatives with DGE in the regulation of nuclear energy in the country. Such authorities or institutions are:

- Ministry of Public Health and Social Assistance (MSPAS)
- Ministry of Environment and Natural Resources (MARN)
- Ministry of Foreign Affairs (MINEX)
- Ministry Public (MP)
- Ministry of National Defence (MINDEF)

- National Coordinator for the Reduction of Disasters (CONRED)
- Ministry of Agriculture, Livestock and Food (MAGA)
- Tax Authority (SAT)
- Ministry of Communications, Infrastructure and Housing (MICIVI)
- National Institute of Seismology, Volcanology, Meteorology and Hydrology (INSIVUMEH).

DGE identified that some arrangements had been in place with some of the authorities and institutions but their validity expired and they are not in force anymore.

The IRRS Review Team was informed that practical arrangements are in place, and the work is done in an effective and efficient manner. This is usually based on the joint efforts of the staff (individual experts) of the different authorities and their dedication to have the job done. However, as the legislation does not completely specify the allocation of responsibilities among those authorities, DGE initiated the preparation of formal agreements giving priority to certain authorities. DGE intention is in a longer term to formalize the relationship with all identified state bodies with which they have joint activities.

The IRRS Review Team concluded that irrespective of the large efforts by DGE to resolve this issue at the time of the mission, such formal agreements do not exist, which represents non-conformance with the IAEA standards.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *No formal agreements are in place to ensure effective coordination between DGE and other authorities with responsibilities in the regulation of nuclear energy* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 7, para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned ……..*<br>*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."* |
| **R (4)** | **Recommendation: Government should ensure that appropriate arrangements are established for the effective coordination of all national authorities with responsibilities for safety.** |

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

The Law aims to control, supervise and monitor all activities related to the use of radioisotopes and ionizing radiations in their various fields of application, in order to protect health, goods and the environment of the inhabitants of the Republic, as well as goods of the State. The Law covers only activities and facilities related to the use of ionizing radiation, but it does not extend to unregulated sources (of natural or artificial origin) and thus the Direction has no responsibility to regulate such sources.

The IRRS Review Team could not find any evidence of protective actions to reduce undue radiation risks associated with unregulated sources and concluded that those risks are not covered at all by the legislation.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** The *Legal and regulatory framework does not cover unregulated sources (of natural or artificial origin).* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 9 states that** *"The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization."* |
| **R (5)** | **Recommendation: Government should establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources** |

With regards to past activities, DGE has implemented a programme to timely detect and collect orphan sources from past practices. This includes the equipment of the steel melting factories and the largest scrapyard with portal detectors. The fact that only one orphan source was found during the last 5 years is a confirmation to the opinion of the experts that this may not be a significant current issue for the country.

## 1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

DGE developed and the Government approved the National Policy for radioactive Waste Management (GA 67-2016). The policy covers the main aspects of waste management such as safety of radioactive waste management, infrastructure needed, management of radioactive sealed sources no longer in use, reuse, clearance and discharges, options for the predisposal management of radioactive waste, centralized storage, potential options for the disposal of radioactive waste, and inter-institutional coordination; as well as the need for strengthening the existing infrastructure and final international cooperation.

The policy is required to be revised and updated every five years. The policy also requires the elaboration of an action plan, periodic monitoring of the performance, and periodic evaluation. These latter requirements have not yet been implemented.

The national policy establishes the need for the elaboration of an "Action Plan" for the implementation of this policy. This Action Plan has not yet been developed. The Action Plan for radioactive waste management needs to outline arrangements for ensuring the implementation of the national policy. It also needs to provide for the coordination of responsibilities and be compatible with other related strategies such as strategies for radiation protection.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *A National Policy for the safe management of radioactive waste was established by the Government. Some aspects of the safety requirements are not considered in this policy and the strategy for the implementation of the policy is still not established.* | |
| **(1)** | **BASIS: GSR Part 5 Requirement 2, para. 3.5 states that** *"The national policy on* |

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| | *radioactive waste management has to set out the preferred options for radioactive waste management. It has to reflect national priorities and available resources and has to be based on knowledge of the waste to be managed (e.g. knowledge of the inventory and of waste streams) now and in the future…"* |
| **(2)** | **BASIS: GSR Part 5 Requirement 2, para. 3.6 states that** *"The national strategy for radioactive waste management has to outline arrangements for ensuring the implementation of the national policy. It has to provide for the coordination of responsibilities. It has to be compatible with other related strategies such as strategies for nuclear safety and for radiation protection."* |
| **R (6)** | **Recommendation: The Government should develop the Action Plan for the implementation of the established policy on radioactive waste and review and update the policy as required.** |

## 1.8. COMPETENCE FOR SAFETY

The Law sets the fundamental requirement for ensuring the competence in all facilities and activities and requires that any person who is carrying out activities in radioactive facilities should receive adequate training on safety measures to be observed in the development of such activities. According to this Law and its regulations licensees are responsible for the indicated training and DGE will provide appropriate cooperation. In addition, GA 55-2001 specifies the requirements for the competence of persons with responsibilities for the safety of facilities and activities. The Government understands the importance of the availability of sufficient number of competent and qualified experts (physicists, engineers, scientists) for the safety of its radiation facilities.

The country identified the large gap in the needed and available experts in radiation safety users. As a result, a Guatemalan Education and Training Strategy in the Area of Radiation Protection was developed and approved. The strategy was initiated by DGE along with SEGEPLAN. It includes detailed assessment of the country's radiation facilities and activities and makes a detailed gap analysis of expertise available in this field to support their safe operation. It counts the available resources and competence and clearly defines the future needs.

The strategy sets mission, vision and goals and identifies DGE as the responsible authority for organization of the overall process. The strategy does not establish particular actions but assigns that responsibility to a Steering Committee to be formed by all interested parties including the licensees. The Strategy is addressed to qualified experts and users of nuclear technologies such as Radiation Protection Officers (RPOs) and operators.

This strategy started to give results even before the formation of the Steering Committee. After its distribution to all parties some professional associations requested assistance in the establishment of their own programmes for training of RPOs in order to cover the existing gap in the respective area.

The detailed analyses and assessment of current situation and future country needs for competence in the field is commendable and could be used as a model for other countries.

In addition, in the areas where Guatemala has no or limited own capabilities for providing education and training, it effectively relies on assistance from IAEA. In this respect an agreement between Guatemala and the IAEA was signed and is being implemented.

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| **Observation:** *Guatemala has developed a Strategy for improving national competency and conducted a detailed gap analysis for the country's needs in different aspects of science and technology.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 10 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."* |
| **GP (1)** | **Good Practice: Guatemalan Strategy for improving national competency and the detailed gap analysis for the country's needs in different aspects of science and technology is commendable** |

## 1.9. PROVISION OF TECHNICAL SERVICES

Technical services in Guatemala are provided by both public and private institutions. The Laboratories of Nuclear Applications belongs to the Unit of Technical Laboratories (UTL) of MEM provides services of personal dosimetry, calibration of radiation protection equipment and dosimeters, and management of radioactive waste, radioactive contamination analysis. For providing these services, the UTL has a laboratory of personal dosimetry based on thermoluminiscent technique; a Secondary Standards Dosimetry Laboratory (SSDL), which includes equipment for calibration of radiation protection measurement equipment, calibration of personal dosimeters, and calibration of measurement equipment for radiotherapy. Currently this last service of the SSDL is not being provided due to the depletion of the source of the radiotherapy unit located in the laboratory for this purpose. For waste management and storage services, UTL has a facility, CENDRA, which in practice is a facility for the initial conditioning and storage of radioactive waste and spent and disused sources.

In the private sector, several companies provide technical services. One of them, has been accredited by DGE for providing personal dosimetry services. Other entities provide radiation safety training courses on radiation protection and safety. All the services are provided on a contractual basis and funded by the users.

## 1.10. SUMMARY

Guatemala has established the basis for the legal and regulatory framework for safety. The Law and its implementing regulations establish some of the prerequisites for an effective regulatory framework. To further align its legislation with the international standards, the Government needs to complement the framework for safety in the areas as indicated in this Section and ensure that no promotional functions are assigned to the regulatory body. It also needs to establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin).

The Government needs to ensure that DPRS is provided with sufficient financial and human resources with the needed competencies to support the oversight of safety of facilities and activities in the country. The lack of sufficient financial and human resources results in some regulatory functions not being fully implemented: i.e. reduced scope of inspection programmes, delays in licensing and authorisation; regulatory requirements not being developed; as well as insufficient education and training of regulatory staff.

Further efforts are needed in the coordination with relevant Government agencies. This coordination needs to be strengthened and formalised. The national RAW management strategy needs to be supported by an Action Plan for its implementation.

The IRRS Review Team concluded that the Guatemalan Strategy for improving national competency, and the detailed gap analysis for the country's needs in different aspects of science and technology, is commendable.

# 2. THE GLOBAL SAFETY REGIME

## 2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Guatemala is committed to fulfil its international obligations and develop its legal framework in a manner commensurate with the internationally accepted principles and standards. The Constitution gives priority to international conventions and agreements in the field of human rights ratified by the country.

Guatemala is a contracting party to a number of international arrangements that are intended to enhance nuclear and radiation safety worldwide, namely:

- Convention on Physical Protection of Nuclear Material;
- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;

Additionally, in 2014 Guatemala has politically committed to follow the guidance of the Code of Conduct on the Safety and Security of Radioactive Sources, as well as the Supplementary Guidance on the Import and Export of Radioactive Sources. However, due to financial restrictions, DGE staff is not taking active part in the related meetings, on a regular basis, in order to foster exchange of experience and good practices,

Guatemala is not yet a contracting party to the Join Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The IRRS Review Team was advised that the country is taking actions to join to this binding instrument and the process of joining has already started.

Having no nuclear reactors, Guatemala is not a contracting party to the CNS. However, it is at close distance to the border with Mexico having nuclear reactors in operation. In this respect, it is the view of the IRRS Review Team that Guatemala could benefit from CNS review process.

Guatemala uses the IAEA safety standards as the basis for developing its national safety requirements. Furthermore, it directly adopts some of the requirements by Ministerial Agreements.

As already highlighted above, due to financial restrictions the Participation of Government experts in Safety Standards Committees and the working groups on development and revision of IAEA standards is quite limited.

The IRRS Review Team was informed that the present IRRS mission is the first IAEA peer-review to the country. Guatemala could benefit from the more effective use of the various IAEA peer review services. This will support the country self-assessment initiatives and the exchange of operating and regulatory experience. With regards to international cooperation, Guatemala is a member of the Regional Cooperation Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean (ARCAL). The country has signed bilateral agreements with Mexico and Colombia.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *Guatemala is not actively using the available IAEA peer review services* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *international peer reviews, and promote international cooperation and assistance to enhance safety globally"* |
| **S (1)** | **Suggestion: The Government should consider taking more benefit from the various IAEA peer review services.** |

## 2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

DPSR is actively using the regulatory experience of other States to identify useful information and to disseminate the lessons learned to other related country authorities. Information received is processed and, if applicable, used as a learning tool to strengthen the safety and security in the country. Similarly, Guatemala reports such information internationally through interactions with other regulatory authorities in the region (seminars, video conferencing, document sharing, and regional meetings).

General requirement on reporting of events is included in the Law where licensees are required to report the loss, abandonment or removal of radioactive substances, damage to the radioactive facility and/or ionizing radiation generating equipment that are under their responsibility. This requirement is also imposed as a license conditions.

The IRRS Review Team identified that there are no detailed requirements for reporting events and no criteria for reporting. In addition, DPSR is not reviewing and learning from internationally published events. DPSR will significantly benefit from the establishment of a separate Operating Experience Program, which collects and utilizes the national and international operating as well as regulatory experience.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *There are no detailed requirements for reporting events, as well as reporting criteria. DPSR is not reviewing learning from and sharing the experience in other States.* | |
| **(1)** | **BASIS: GSR Part 1, Requirement 15 states that** *"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"* |
| **R (7)** | **Recommendation: DPSR should establish requirements and criteria for reporting of operating events by licensees. It should also establish a system for analysing events and disseminating the lessons learned within the country and internationally, as well as learning from and providing feedback to international networks.** |

## 2.3. SUMMARY

Guatemala has ratified most of the international instruments related to radiation safety, except the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste and the Convention on nuclear safety. Guatemala is encouraged to become party to all relevant international

instruments. The country could further benefit from the various IAEA peer review services by inviting more international peer reviews.

Requirements and criteria for reporting of operating events by licensees needs to be established, as well as a system for analysing events and disseminating the lessons learned within the country and internationally.

# 3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

MEM is organized in three main branches "Hydrocarbons and Mines", "Sustainable Development" and "Energy", which are managed by Deputy Ministers. Additionally, several departments and laboratories are directly subordinate to the Minister. DGE is a Direction subordinate to the Deputy Minister for Energy.

DGE organizational structure is strictly following the functions assigned to it by the Law. The Director of DGE reports directly to the Deputy Minister for Energy who reports directly to the Minister.

The organizational structure of DGE, indicates that DGE is headed by a Director, who is supported by Deputy Director and has six departments, namely:

- Energy Development;
- Renewable Energy Sources;
- Safety and Radiological Protection;
- Non-ionizing Radiation;
- Legal; and
- Administrative and financial.

The IRRS Review Team identified that DGE may reallocate responsibilities internally among its departments on its own discretion. Recently, the responsibilities of the Department of Non-ionizing Radiation have been transferred for implementation to DPSR. This internal management decision assigns DPSR with responsibilities that are not related to radiation safety. Furthermore, DPSR does not have the competence and the human and financial resources to carry out these functions. Assigning DPSR with responsibilities that do not relate to radiation safety has resulted in diverting resources away from it.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DPSR has been assigned with the responsibility for oversight of non-ionising radiation. This resulted in diverting resources away from radiation safety.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 4, para. 2.9 states that** *"No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities…* |
| **R (8)** | **Recommendation: DGE should revise its decision to assign the non-ionising radiation to DPSR.** |

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

DGE safety related decisions are made by DGE in consultation with its legal department. In the absence of the DGE Director, safety related decisions are made by the Deputy. DGE could not issue a decision without the positive statements of DPSR and the legal department. The IRRS Review Team could not identify any dependences of DGE on entities having responsibilities or interests that could unduly influence its decisions.

Decree 119-96 "Law of Administrative Litigation" establishes the right of any person to appeal against administrative resolutions issued by any administrative authority in Guatemala, as well as the procedure for appealing. Any decision promoted by the DPSR and issued by DGE can be appealed to DGE Director who sends it to the Minister. The Minister can either reject the appeal or revoke DGE's decision on the basis of evidence provided by the appealing party. If further appeal is needed it needs to go to the court.

MEM owns and operates some facilities and carries out some activities with sources of ionizing radiation such as calibration of radiation protection equipment and dosimeters, management and storage of radioactive waste, and non-destructive testing, and other services without ionizing sources like personal dosimetry, and radioactive contamination analysis.

These facilities and activities are not part of DGE and according to the Law require licensing. The IRRS Review Team found out that most of these facilities and activities are licensed or in the process of being licensed and that the corresponding staff possess individual operator licences. However, the IRRS Review Team confirmed that the MEM Unit of Nuclear Applications uses an industrial X ray machine for non-destructive testing (a type 2 practice), which has not been licensed. Furthermore, the X ray machine operator licence expired at least 4 years ago and has not been renewed.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *MEM Unit of Nuclear Applications uses, for example an industrial X ray machine for non-destructive tests (a type 2 practice), which has not been licensed and the X ray machine operator does not have a valid licence.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 4, para. 2.11 states that** *"In the event that a department or agency of government is itself an authorized party operating an authorized facility or facilities, or conducting authorized activities, the regulatory body shall be separate from, and effectively independent of, the authorized party."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 17, para. 4.6 and 4.7. state that** *"... This imposes an obligation on the regulatory body to discharge its responsibilities in such a way as to preserve its effective independence. ....*<br>*The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework....* |
| **R (9)** | **Recommendation: MEM and DGE should make the appropriate arrangements to ensure that all MEM facilities and activities are licensed or authorized** |

The Law on Probity and Responsibility of Public Officials and Employees establishes a series of requirements to public officials, dedicated to prevention of conflicts of interest between their public duty

and their private interests. Additionally, GA 197-2004 establishes the ethical norms for the state authorities. Other requirements on identification and prevention of conflicts of interest are included in the State Hiring Law; the Tax Code; and the Organic Law of the Supervision of Tax Administration, as well as in the Civil Service Law. All these requirements support the establishment of the necessary conditions for prevention and timely elimination of staff conflicts of interest.

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

At the time of the mission, DPSR has a total number of 10 employees, head of department included. DPSR is responsible for the licensing, review and assessment and inspection of more than 2311 facilities and its activities. Furthermore, they have the responsibilities for development of regulatory requirements, establishing internal procedures and processes, organizing training courses and seminars for the licensees, issuing of individual licenses, ensuring the international cooperation of DPSR, etc.

The IRRS Review Team is of the view that the number of staff is insufficient for the amount of work to be done. This is most evident in the inspection area, where four inspectors are responsible for inspecting 2311 sites. The IRRS Review Team identified that the DPSR employees are committed and dedicated and that they work overtime to partially compensate for understaffing. A significant increase in staff will be needed to ensure that the DPSR is capable to perform its regulatory functions. Requests for increase of DPSR staff permanent position are being submitted every year but with no results.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DPSR does not have sufficient staff to effectively fulfil its functions* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.…* |
| **R** | **Recommendation: see R (3) in Section 1.3** |

The requirements for education, competence and training of regulatory staff are established by MA 69-2015. These requirements have been developed under an IAEA regional project. The MA includes the minimum training requirements that inspectors need to pass to become qualified inspectors. These trainings are obligatory for all of the staff and are a prerequisite for receiving a resolution for appointment as an "Official Inspector". Such a resolution is granted by the DGE Director on a request by the Head of DPSR and with the agreement of the legal department.

Newly employed staff have the status of "staff members" until they become qualified inspectors. Initially new staff are left for self-preparation and self-training inside the authority (reading laws and regulations, internal documents, etc.). They are allowed to accompany an Official Inspector and witness inspections but are not authorised to do the inspections unguided. A mentor is assigned for specific tasks to help new staff in selected cases.

Job descriptions exist for all positions. They had been adopted in 2009 and have not been updated since that time. The publication of MA 69-2015 makes some of the Job descriptions requirements obsolete and DPSR plans are to update them in the near future. DPSR is part of the human resources development plan of MEM, which also includes a general programme for replacement of staff.

The selection and recruitment process is done by MEM in cooperation with the National Office for Civil

Servants. The process provides for an internal selection to be made before opening a competition. Shortlisting includes: psychometric examination and a written exam (technical test) which is prepared by the Head of DPSR. Employment decision is taken by the minister on consultation with the human resource department and the Head of DPSR.

DPSR staff is trained mainly through international programmes. A systematic training programme that addresses training needs of inspectors and experts does not exist. Such a programme needs to be developed based on analysis of the competence and skills needed.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *Analysis of competence needed at the DPSR has not been done and specific training programme has not been implemented.* | |
| **(1)** | **BASIS: GSR Part 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. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements"* |
| **R (10)** | **Recommendation: DPSR should establish and implement a comprehensive training programme based on analyses of competence needs** |

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

As a country with limited technical resources, Guatemala is not in a position to establish and maintain a technical support organization working solely for the regulatory authority. Additionally, DGE has not established an advisory body and does not have plans to do so. It uses the opportunities provided by international and regional meetings to exchange information on the practices of other regulators in the region. In complex technical decisions DGE relies mostly on the IAEA.

DGE bears all the responsibility for making regulatory decisions and the establishment of an advisory body could provide greater confidence in the technical basis of the decisions taken. The advisory body may be composed of experts from scientific institutes, universities, and other competent organisations that will assist DGE by expert advice on the technical and scientific aspects of radiation protection.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *No advisory bodies on radiation safety have been established to support DGE* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 208, para. 4.18 states that** *"The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-technical in nature."* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| S (2) | **Suggestion: DGE should consider the use of technical advisory bodies of experts to support its decision making on important radiation safety issues.** |

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

DPSR has established both formal and informal mechanisms for communication with authorized parties and has ensured possibilities for professional and constructive liaison. Most frequently used mechanisms are: correspondence between DPSR and authorized parties; and inspections of authorized activities and organizations.

DPSR publishes its licensing requirements, instructions, and forms at the MEM website.

DPSR does not organize large meetings with all interested parties. It has established the practice to invite authorized parties to meetings. Such meetings could be organised on a request by the authorized parties for clarification of the requirements. DPSR also organises meeting with professional associations on issues of common interest.

DPSR organises and holds national training courses for the licensees. These forums are used to discuss with them licensing and inspection issues and to get feedback on regulatory activities. Eleven training courses in different areas were organized last year (weekly courses). Selection of participants is focused on involvement and training of RPOs.

DPSR has established a front office at its headquarters that provides interested parties with direct access to inspectors. Applicants and licensees may visit DPSR premises and request direct meetings with the staff. This is not possible only from the submission of the application till the issuance of a license in order to reduce the corruption opportunities. Meetings with applicants and licensees highlighted the frank and open communication of DPSR with the authorized parties.

DGE does not have the practice to publish or explain the basis of its decision to authorised parties. Authorisations and licenses are pot made public.

## 3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

Formal processes for core business in DGE are implemented by laws and regulations including the Law, GA 469-2014, and GA 55-2001. Consistency and stability of these core processes is also enhanced by technical guidelines, instructions, and training of staff members. The MEM website contains useful information available to the public about regulatory activities such as licensing, training, emergency preparedness, and physical security. Requirements, forms and information about licensing activities can be accessed directly from the part of the website dedicated to DPSR. However, details of processes for activities such as licensing actions were not always well understood by interested parties and applicants, and not well communicated to those with interests.

Requirements for review of license applications were subject to a national law (the constitution) requiring a 30 day review period. However, this period can be extended significantly under various conditions. The IRRS Review Team could not find clear expectations for timeliness of licensing actions or statistics of average or actual times. GSR Part 1 Requirement 22 states the need for consistency in the decision making process of the regulatory body in order to build confidence among interested parties. Interviews with some regulated parties indicated some lack of confidence in the accomplishment of regulated

activities within a reasonable time. In addition, GSR Part 1 Requirement 22 describes elements of the regulatory process that should be in place to ensure stability and consistency of regulatory control and prevent subjectivity in decision making. This requirement states that the regulatory body needs to be able to justify its decisions if they are challenged. The standard also requires the regulatory body to inform applicants of the objectives, principles and associated criteria for safety on which its judgments and decisions regarding reviews and assessments, as well as inspections are based. The IRRS Review Team found instances where important regulatory decisions were not well documented, and did not have sufficient information regarding the safety criteria on which they were based.

| • RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE does not provide sufficient justification of its licensing decision making. Additionally, adopted practice for managing license applications does not provide predictability and stability in the time frame for making the decisions.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 22, para. 4.26 and 4.28 state 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 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.*<br>*There shall be consistency in the decision making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties..* |
| **R (11)** | **Recommendation: DGE should ensure that justifications of decisions made are well documented and available. Licensing arrangements should be revised to ensure consistency in order to build confidence among interested parties.** |

### 3.7. SAFETY RELATED RECORDS

DPSR has adopted and uses two specialized software applications to maintain the record from its activities (registering the license files, sources inventory and regulatory actions). ARIS database was provided by the United States Nuclear Regulatory Commission (USNRC) and was used for some time. The IAEA RAIS was acquired later on and is in routine use by the DPSR. The two systems provide for:

— Data of sealed radioactive sources and radiation generators;

— Data on licenses and authorisations;

— Inventories of radioactive waste; etc.

Recently, DPSR upgraded RAIS with inclusion of an inspection records module. The two databases are not compatible and the data transfer is manual and time consuming.

DPSR receives the information on occupational doses in hard copy from the service providers. Establishment of a national register is in process. Intentions are to develop registers of the occupational doses using appropriate software in the near future.

No database for event reports is available as there are no reporting requirements. See Recommendation 7 in section 2.2.

By the conditions of the licences, authorized parties are required to maintain their own records.

The archives were stored in the DGE central archives building until 2015 when DPSR created their own archives. The IRRS Review Team visited the archives and verified availability of selected records, but was not convinced that data is easily retrievable. Further efforts are needed to complete the databases and improve traceability.

### 3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

In its communication with interested parties, DPSR works in close cooperation with the Department of Social Communication of MEM. All information that MEM considers to be of public interest is disseminated through the DPSR website.

The DPSR website (part of MEM website) contains useful information available to the public about regulatory activities such as licensing, training, emergency preparedness, and physical security. Requirements, forms and instructions about licensing activities can be accessed directly from the part of the website dedicated to DPSR.

DGE has not established the practice to organise, on a regular basis, public meetings or hearings. Such are organised only in the case of extensive public interest, mostly in the case of a radiological event. Licensees are made responsible to communicate safety issues to the local communities.

Regulatory decisions are not made publicly available, as well as safety justifications, opinions, statements, inspection protocols, and others. However, the interested parties are provided with all the information that they need on request.

DGE has the ability for direct communication with governmental authorities at a high level when such communication is considered necessary. This is done through the Minister or the responsible Deputy Minister.

IRRS Review Team identified that the DGE has not established a process to involve the public in making significant regulatory decisions.

| • RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE has not established a process to involve the public in making significant regulatory decisions.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 36, para. 4.67 states that** *"The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body. In particular, there shall be consultation by means of an open and inclusive process with interested parties residing in the vicinity of authorized facilities and activities, and other interested parties, as appropriate [1]. Interested parties including the public shall have an opportunity to be consulted in the process for making significant regulatory decisions, subject to national legislation and international obligations. The results of these consultations shall be taken into consideration by the regulatory body in a transparent manner e…* |
| **R** | **Recommendation: See R (1) in Section 1.2** |

## 3.9. SUMMARY

Licensing and authorisation decisions are made by DGE. It appears that DGE has established a system that allows safety related decisions to be made independently, without undue pressure from entities having responsibilities or interests that could unduly influence the decisions. DGE needs to ensure that these decisions are well justified, documented and available on request. Licensing and authorisation decisions need to be made within a reasonable timeframe to ensure consistency and to build confidence among interested parties. Establishment of an advisory body could provide greater confidence in the technical basis of the decisions taken.

Human and financial resources provided for the regulatory activities related to radiation safety appear to be insufficient (see Section 1.3). Staff are trained mainly through international programmes. A systematic training programme that addresses training needs of inspectors and experts needs to be developed based on analysis of the competence needs. DGE will benefit from revising its decision to assign the responsibilities for non-ionising radiation to the DPSR or ensure that sufficient resources are provided for that.

# 4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

While the self-assessment was performed according to the requirements of GS-R-3, the IRRS Review Team has performed the review based on the IAEA requirements in force at the time of the mission, namely GSR Part 1, Requirement 19 and GSR Part 2, "Leadership and Management for Safety".

## 4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

**GSR Part 1, Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."* As described in the Advanced Reference Material, DGE does not have a formally described Management System. However, elements of a management system are present in guidance and review efforts of MEM and DGE. MA 232-2009 provides the mission and vision statements, organization descriptions, and procedures for various practices in DGE.

MEM requires reporting of performance indicators about specified activities in the Annual Operating Plan (POA). Data is gathered monthly regarding progress of accomplishments outlined by the POA. The primary DPSR activities tracked in the POA include indicators of licensing inspections and training courses. However, the majority of key activities of DPSR are not tracked by the POA or any other formal means. Some important elements for ensuring the regulatory functions are being accomplished in an effective manner are not covered by this plan; including licensing activities, staff qualifications, key inspection activities of safety significant licensed material, inventories, regulatory infrastructure activities, international cooperation, staffing, and funding. While safety culture is mentioned in the ARM, no specific measures of safety culture or its promotion were evident in discussions about the management system.

The management system elements discussed and observed did not appear to put a prioritization on the most safety important activities or any particular graded approach to assessment of activities. In addition, it appeared very difficult to make meaningful changes to the indicators in the POA. There are initial efforts underway to initiate a management system better suited for activities in DPSR, including software to help track the efforts. However, DPSR would benefit from having a management system tailored to the key indicators important to accomplishing safety activities of the regulatory responsibilities, reporting on them, evaluating them, and taking action to improve performance based on them. DPSR Management indicated understanding of the benefits of using GSR Part 2 to develop a management system that will be effective in reviewing the activities of the regulatory body and assisting in continual improvement.

The IRRS Review Team identified that large efforts are needed to get the system in line with GSR Part 2 requirements, namely:

- development and documentation of main and support processes and integration of all elements with priority being given to safety;
- ensuring that management system documentation is controlled, usable, readable, clearly identified and readily available at the point of use; and
- ensuring that all individuals in the organization are trained in the relevant requirements of the management system.

| • RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE is in an early stage in the development of its management system. Processes for this management system are not documented. Regulatory performance in many key safety areas is not measured or assessed.* | |
| **(1)** | **BASIS: GSR Part 1, Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.* |
| **R (12)** | **Recommendation: DGE should establish and implement a comprehensive management system as stipulated in GSR Part 2.** |

## 4.2. MANAGEMENT RESPONSIBILITY

DGE and MEM officials interviewed by the IRRS Review Team expressed commitment to supporting a strong radiological safety programme with continuing improvements. Discussions with these officials and reviewing materials in the ARM indicated the beginning of plans to provide management support for a management system that includes key elements of DPSR activities. However, each department is responsible for establishing goals in accordance with MA 178-2006. While DPSR is aware of important goals to be monitored and improved upon in a management system, it has not yet included these key goals into the structure of a management system that effectively oversees these activities. DPSR will benefit from senior management support in getting a system fully in place that will clearly focus on the key goals, and then gain senior management support in being able to achieve them.

## 4.3. RESOURCE MANAGEMENT

GS-R-3, Paragraphs 4.1-4.5 provide requirements for resource management of the management system. While DPSR is committed to the safety mission required by its responsibilities, insufficient resources continue among the greatest challenges to fulfilling this mission. Therefore the management system needs to have goals, indicators, and strategies to focus clearly on the funding needed to accomplish the key regulatory responsibilities of DPSR. For example, lack of funding has caused planned inspections to be cancelled. Lack of resources such as vehicles and drivers has prevented inspections from being accomplished for activities in remote areas; activities using sources of high safety importance. Insufficient funds have prevented identified competency issues from being addressed with training. This has led to less efficient use of staff as lack of training has meant that some staff cannot participate in key activities. Even with the current status of shortage of funds, the POA uses a formula to add two percent to the number of required inspections each year, with no associated increase in funding to support them.

Staffing is also a key area of focus that will be important for the newly developed management plan. With only 9 permanent staff and 1 temporary staff in DPSR, and not these staff qualified for inspection and authorization activities, a staffing plan that includes competence and training requirements will need to be a key element of the new management system. The IRRS Review Team found there was not currently a detailed staffing plan with these elements included. Issues that present a challenge to timely completion of goals set in the plan need to be reviewed on a periodic basis during assessments and in performance indicators viewed by senior managers. In this way, senior managers can determine what areas need to be addressed for effective implementation of the regulatory responsibilities of DPSR, and can assist in reallocation of resources.

## 4.4. PROCESS IMPLEMENTATION

GSR Part2 describes the management system processes needed to support achievement of goals, and to provide the means to meet all requirements and deliver the products of the organization. These processes need to be determined, defined, and appropriately sequenced. Process outputs and measurement criteria need to be established. Once established, methods of reporting on the processes and outputs need to be established. In addition, audits need to be in place to assess the effectiveness of the system and to provide for continual improvement. The POA of the MEM has some elements of these activities that include DPSR. However, this plan does not constitute an effective management system for ensuring the required regulatory responsibilities. Processes that are in place in some form include control of documents, control of records, communication and managing organizational change. It will be important as DPSR and DGE continue to develop an integrated management system, that the key organizational goals of the regulatory body are considered in the process development.

## 4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

GSR Part 2 requires elements of measurement, assessment and improvement for an effective management system. Assessments, including independent assessments need to be conducted to evaluate the effectiveness of the processes in meeting and fulfilling goals, strategies, plans and objectives to determine the adequacy of work performance and leadership, to monitor quality, and to identify opportunities for improvement. The IRRS Review Team interviewed staff and management of DPSR and MEM, including those responsible for coordinating POA results. There was no evidence of documented assessment activity performed and provided to senior management, as it related to radiological safety activities. MEM coordinated monthly reviews of indicators covered in the POA, but assessments of results and plans to improve based on the results were not included. Also, effective assessments could not be performed using the POA because the POA did not include information on many key activities important to the performance of DPSR safety responsibilities. DPSR will greatly benefit by the completion of a management system that tracks key activities and provides senior management with independent assessments of how well processes are being accomplished and how senior management can take actions to ensure weaknesses and obstacles are identified and corrected in a timely manner.

## 4.6. SUMMARY

DGE is in early stages of development of an integrated management system. It needs to strengthen efforts to establish and implement a comprehensive integrated management system, as stipulated in GSR Part 2. Specifically, DGE needs to analyse the key elements and programmes needed to ensure that the regulatory responsibilities of DPSR are in place. It also needs to use focused assessments, performance indicators and corrective action processes to ensure continual improvement of the programme. Funding and staffing should be a focus of management attention in this management system. Staffing considerations need to include plans and actions to ensure that individuals in the organization are trained and competent in the relevant requirements of the management system.

# 5. AUTHORIZATION

## 5.1. GENERIC ISSUES

The authorization process is outlined in the Law and the Regulation 55-2001. The Law empowers DGE to license the production, use, handling, transport, marketing, import, export and application of radioactive substances, as well as the operation of radiation facilities.

The Regulations empowers DGE to:

- grant, modify, extend, suspend or cancel licenses for the import, export, distribution, sale, transfer, transport, warehousing and storage of radioactive sources, as well as construction or temporary or permanent closure of a radioactive facility;
- grant individual licenses for operators and for Radiation Protection Officers and
- impose sanctions established by the Law and its regulations.

The Law requires that people, institutions and entities performing all the following activities: install and/or operate equipment generating ionizing radiation, irradiate food or other products, produce, use, manipulate, apply, transport, commercialize, import, export or treat radioactive substances, or other activities related to them obtain the appropriate license. The right to appeal decisions of DGE is outlined in the Law.

All radioactive material facilities require special permission and/or authorization by DGE which grants it after prior review of the aspects of design, construction, safety and radiation protection systems installation.

No license issued by DGE may be transferred to third parties, directly or indirectly, without prior authorization.

The authorizations granted by DGE to individuals or corporations, domestic or foreign, as well as State facilities and decentralized, autonomous or semi-autonomous entities, are provided for specific fees which are fixed by the (MA 208–2016).

The Law authorizes DGE to request the assistance of any other public authority or institution and they are obliged to provide the assistance. The IRRS Review Team was informed that no coordination or cooperation with other public authorities except in the process of authorization as the General Direction of Customs is involved with in the import and export of radioactive sources. The General Direction of Customs is licensed by DGE for operating a fixed x-ray machine for control and the Customs Officers are trained by DGE, however, DGE has no formal agreement with the General Direction of Customs.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE and the General Direction of Customs are both involved in the process of import and export of radiation sources but they do not have any formal arrangements between them.* | |
| **(1)** | **BASIS: GSR Part 1 para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *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.* |
| **R** | **Recommendation: See R (4) in Section 1.5.** |

MA 178-2006 assigns the DPSR to be responsible for:

- drafting and providing forms for requesting a license;
- assessing all the documents submitted by an applicant to get a license; and
- establishing conditions under which a license is granted.

Basic requirements and conditions for the licensing process are implemented in the Regulation 55-2001.

Only justified practices are permitted. The IRRS Review Team was informed that there is no procedure or criteria to justify a practice.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *The principle of justification is addressed in the regulations, however, it is not implemented.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 10, para. 3.16 states that** *"The government or the regulatory body, as appropriate, shall ensure that provision is made for the justification of any type of practice and for review of the justification, as necessary, and shall ensure that only justified practices are authorized."* |
| **R (13)** | **Recommendation: DGE should establish requirements and procedures for justification for all types of practices as appropriate.** |

The practices associated with ionizing radiation to be unauthorized and those to be exempted or authorized are detailed. The sources, materials or objects involved in authorized practices can be cleared from regulatory requirements if they comply with clearance levels established by DGE. The regulation 55-2001 states that exemption levels and clearance levels are described in tables. These tables are provided by the Fundamental principles, regulatory environment, facilities management and basic rules MA 73-2015 which has adopted GSR-Part 3 in which Schedule I proposes exemption and clearance values.

Practices to be authorized are classified in 4 Types corresponding to a graded approach. The requirements for authorization vary according to the level of risk of the practice. The Types 1 and Types 2 practices which are considered to be of higher risk have more stringent requirements than Type 3 and Type 4 practices. Moreover, those activities associated with practices which are not included in the previously classified practices; such as calibration, maintenance, change of sources, distribution, import, export, sale, transfer, and transport of radioactive material are evaluated and ranked by DGE. Specific authorizations are created for the construction of facilities. The closure of Type I and Type II practices require a decommissioning authorization.

Authorization of activities and facilities is through a one-level authorization system of licensing. The regulations provide partly for a graded approach for authorization, even if it includes a risk-based

categorization of practices and sources, and inspections before granting licenses for Type I and Type II practices. This is not completely in compliance with GSR Part 3.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **Observation:** *A graded approach is not fully implemented in the authorization process.* |
| **(1)** | **BASIS: GSR Part 1 Requirement 1, 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:*<br>*1) The safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future;*<br>*…*<br>*(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;*<br>*…*<br>*(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;* |
| **(2)** | **BASIS: GSR Part 3 Requirement 6 states that** *"The application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures."* |
| **(3)** | **BASIS: GSR Part 3 Requirement 7 states that** *"Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body a notification and, as appropriate, an application for authorization."* |
| **(R)** | **Recommendation: See R (1) in section 1.2** |

Operator licences and Radiation Protection Officer licences are also granted by DGE. Radiation workers are considered as operators and so they are required to be individually licensed by DGE.

The formal requirements for submission for an authorization are given in the forms provided by DGE via the web (http://www.mem.gob.gt/viceministerio-del-area-energetica-2/proteccion-y-seguridad-radiologica/formularios-de-licenciamiento/). These requirements are issued through the Regulation 55-2001. Available application forms cover various activities relating to irradiating devices and radioactive sources.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *For submission for an authorization, DGE provides on its website forms with instructions and a check list of the formal requirements.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 24, para. 4.33 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization."* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **GP (2)** | **Good Practice: The regulatory website provides the applicants with forms, instructions and requirements for submitting an authorization, which is considered as a good practice** |

DGE has procedures, which are being updated, for granting authorizations. The documents sent by the applicant to DGE are first reviewed by the Legal Department of DGE (DGL) to check the completeness of the file. Once completed, DGL requests fees to be paid by the applicant and, when the fees are paid, transfers the file to the DPSR. The Chief of the DPSR assigns the file to an inspector who will be in charge of the assessment. All the inspectors can assess any authorization file, whatever be the type of license to be granted. After assessing the file and determining the file is acceptable, the inspector writes a technical note to the Chief of the DPSR. The license is then drafted by the secretary of DPSR and sent to DGL with a technical note signed by the Chief of DPSR. DGL transfers the license to DGE for signature by the Director of DGE and finally notifies the applicant by sending him the signed license.

There is no time limit in the regulations for issuing a license and the applicants are not aware of the time needed for that. This situation can affect the quality and effectiveness of the regulatory activities. Refer to Recommendation 11 in Section 3.6.

DPSR does not have internal procedure for assessing the documents submitted by the applicant for an authorization. DPSR uses IAEA Safety Guides for authorization and inspection of different practices which have been adopted by MA 71-2015. These guides are not always adopted as a whole for the practices currently implemented in Guatemala. Moreover, as they are adopted in a ministerial agreement, these guides become binding, which should not be the case for a guide.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **Observation***: DPSR does not have internal procedure for assessing the documents submitted by the applicant for an authorization.* |
| **(1)** | **BASIS: GSR Part 1 Requirement 23, para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."* |
| **(R)** | **Recommendation: See R (12) in section 4.1** |

Authorizations to operate practices of Type I, II, III and IV are issued for five years. Licences for import, export, distribution, sale or storage are issued for one year. Operator licences and Radiation Protection Officer Licences are issued for two years. Construction licences are issued for an indefinite period. Other licences granted by DGE may be extended only once and with a term not exceeding five years.

Licences may be modified by notifying DGE. They may also be temporarily suspended or definitively cancelled by DGE, and can be renewed by the submission of the application form at least three months before the end of the term of the licence presented. On the basis of the reports of inspections, the licence will be renewed or denied.

During the authorization process, there is no participation of the interested parties or the public.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *There is neither interested parties participation nor public consultation before taking regulatory decisions or actions during the authorization process.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 2, Paragraph 2.5 states that** *" …This framework for safety shall set out the following:… (5) Provision for the involvement of interested parties and for their input to decision making;…."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 36 states that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."* |
| **(3)** | **BASIS: GSR Part 1 Para (4.66) states that** *"The regulatory body shall establish, either directly or through authorized parties, provision for effective mechanisms of communication, and it shall hold meetings to inform interested parties and the public and for informing the decision making process. This communication shall include constructive liaison such as:*<br>*(a) Communication with interested parties and the public on regulatory judgements and decisions;*<br>*……..*<br>*(d) Communication on the requirements, judgements and decisions of the regulatory body, and on the bases for them, to the public;*<br>*…….* |
| **(4)** | **BASIS: GSR Part 3 Requirement 2, para. 2.30 (f) states that** *"The regulatory body shall establish a regulatory system for protection and safety that includes [8]:*<br>*…*<br>*(f) Provision of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and other interested parties."* |
| **(R)** | **Recommendation: See R (1) in Section 1.2** |

## 5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

DGE is authorizing radioactive waste management activities as part of the general licence issued for a practice. In Guatemala, currently this is occurring mainly in the nuclear medicine practice. Special attention was given in the last years to the authorization process of (CENDRA).

The IRRS Review Team noted that there isn't an established procedure for the authorization process. In March 2015, the Ministry of Energy and Mines adopted on authorization and inspections of different practices including the radioactive waste management. The IRRS Review Team was informed that this guidance is in the implementation phase.

The IRRS Review Team also noted that the documentation on radioactive waste management provided by applicants for authorization in a nuclear medicine practice is so general and not customized to a particular facility that it can be applied to any installation. It was also noted that the old rule of storage for "ten half-lives" before release of the radioactive material from regulatory control is still in use.

The authorization issued for the licence of the centralized storage facility is very general and use to repeat the safety requirements instead of providing specific limits, conditions and controls for this specific facility. For example, no limits on the total activity or volume of the radioactive waste, time frame for the storage, dose constraints for the occupational workers are established in the document.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE had no established and clarified to the operator the processes used to evaluate safety and to review applications for the authorization of radioactive waste management facilities and activities.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 24, para 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant shall be required to submit or to make available to the regulatory body, in accordance with agreed timelines, all necessary safety related information as specified in advance or as requested in the authorization process."* |
| **(2)** | **BASIS: GSR Part 5 Requirement 3, para 3.8 states that** *"To facilitate compliance with regulatory requirements, the regulatory body has to do the following:*<br>*...—Establish and clarify to the operator the processes used to evaluate safety and to review applications;*<br>*—Document the procedures that operators are expected to follow in the licensing process;..."* |
| **R (14)** | **Recommendation: DGE should establish and clarify to operators the processes used to evaluate safety and to review applications for the authorization of radioactive waste management facilities and activities.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *The limits, conditions and controls established in the authorizations issued for predisposal radioactive waste management activities and facilities including the centralized storage facility are very general and used to repeat the safety requirements instead of providing facility or activity specific limits, conditions and controls.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 24, para 4.31 states that** *"In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party's subsequent activities."* |
| **(2)** | **BASIS: GSR Part 5 Requirement 4, para 3.11 states that** *"Depending on the complexity of the operations and the magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means, including:*<br>*... —Derivation of operational limits, conditions and controls, including waste acceptance criteria, to assist with ensuring that the predisposal radioactive waste management facility is operated in accordance with the safety case; ..."* |
| **R (15)** | **Recommendation: DGE, in the granting of an authorization for a radioactive waste management facility or an activity, should impose facility or activity specific limits, conditions and controls on the authorized party's subsequent activities and facilities.** |

**Legacy disposal site for disused sealed radioactive sources**

The IRRS Review Team noted that in the premises of CENDRA there are several disused sealed sources buried at three meters' depth from the surface. Per the available and provided information it is considered as a legacy disposal site for radioactive disused sealed sources and is not authorized on the basis of a comprehensive safety assessment and safety case. Due to this, the update on the CENDRA safety evaluation was required within the limits and conditions of the license granted.

On the other hand, the MEM adopted the MA 67-2015. With this Agreement, the country adopted, as complementary to the national regulations in force, IAEA Safety Standards, the requirements for predisposal (GSR Part 5) and disposal (SSR-5) management of radioactive waste. According to these requirements, disposal facilities that were not constructed following present safety standards may not meet all the safety requirements established in the Safety Requirements. In assessing the safety of such facilities, there may be indications that safety criteria will not be fully met. Final solution for this past practice is still not developed.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *Several disused sealed sources are buried in a legacy disposal site in (CENDRA) three meters deep. The safety of this "disposal facility" is not demonstrated yet and the decision on what to do with it still has not been formulated.* | |
| **(1)** | **BASIS: SSR-5 Requirement 3, states that** *"The operator of a disposal facility for radioactive waste shall be responsible for its safety. The operator shall carry out safety assessment and develop and maintain a safety case, and shall carry out all the necessary activities for site selection and evaluation, design, construction, operation, closure and, if necessary, surveillance after closure, in accordance with national strategy, in compliance with the regulatory requirements and within the legal and regulatory infrastructure."* |
| **(2)** | **BASIS: SSR-5 Requirement 4, states that** *"Throughout the process of development and operation of a disposal facility for radioactive waste, an understanding of the relevance and the implications for safety of the available options for the facility shall be developed by the operator. This is for the purpose of providing an optimized level of safety in the operational stage and after closure"* |
| **(3)** | **BASIS: SSR-5 Requirement 26, states that** *"… In the event that any requirements set down in this Safety Requirements publication are not met, measures shall be put in place to upgrade the safety of the facility, economic and social factors being taken into account."* |
| **R (16)** | **Recommendation: DGE should require the operator to provide them solutions on how to safely manage this legacy site based on a safety case.** |

## 5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

As stated before, the basic requirements and conditions for the licensing process are described in the Regulation 55-2001.

For purposes of the authorization or for granting the relevant licences, DGE is the competent authority.

Every individual or legal person who holds a licence to conduct practices involving sources of ionizing radiation or exposure of people to ionizing radiation is responsible to implement all safety measures and radiological protection.

Instructions and forms for granting licences for sources used in practices are provided by DGE to the applicants on the website of the MEM. The applicants are required to justify their skills and to submit risk assessments and radiation safety procedures to DGE to support their licence applications.

DPSR makes the assessment of the documents provided by the applicants and sends to DGL a draft licence supported by a technical analysis. After the signature of the licence by the Director of DGE, then DGL issues the license and notifies the licensee.

DGE establishes, for each licence, the limits and conditions under which the licence is granted and its validity. The operation licence duration is 5 years.

The IRRS Review Team was informed that the number of licences granted at the date of the mission, based on the national database is:

- Nuclear medicine: 12
- Radiotherapy: 5
- Diagnostic radiology: 1333
- Dental diagnostic radiology: 900
- Industrial: 48
- Operators: 4936
- RPOs: 388

DPSR is mandated by the MA 178-2006 to maintain a national source registry and uses the IAEA RAIS system for this purpose. The system also includes safety assessment reports, maintenance and calibration reports, personal dose records and training records, and a register of the radiation workers. The hard copies of all the documents in relation to the authorization process are stored on the DGE premises.

The IRRS Review Team was informed that, in the case of import/export of sources, the General Direction of Customs requires the submission of the appropriate authorization when they receive packages containing radiation sources. If the documents presented by the user do not comply with the regulations or, in the absence of an import/export licence, Customs informs DGE and Customs places the radiation sources in temporary storage. The IRRS Review Team was informed that this storage facility is not authorized by DGE. The General Direction of Customs is also required to process and clear shipments immediately and as a priority.

Import of radioactive sources of radium-226 or operation of practices involving such sources is prohibited. Import of lightning rods or operation of practices which use such radioactive sources is also prohibited.

## 5.4. SUMMARY

DGE has been provided with the necessary regulatory basis for issuing licences as required under the provisions of the Law. However, DGE should establish criteria and procedures for justification of practices to be authorized.

A complete graded approach for authorization should be adopted in the regulations, including notification and registration. A time limit for issuing the licenses should be acted in the regulations to strengthen the regulatory activities of DGE.

# 6. REVIEW AND ASSESSMENT

## 6.1. GENERIC ISSUES

### 6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

DPSR performs review and assessment of the information submitted by the licensees to determine whether radiation facilities and activities involving radiation sources comply with regulatory requirements. This is carried out in the different stages of the Guatemalan regulatory process that foresee, as appropriate, the construction, operation, modification and decommissioning authorizations. DPSR also performs review and assessment of the information, including the safety assessments, presented by the licensee prior to authorization and again over the lifetime of the facility or the duration of the activity. The Regulation 55-2001 also requires that any proposed modification that might significantly affect the safety of a facility or activity is to be subject to a review and assessment. In some cases, applications for construction authorization of radiotherapy facilities which include shielding design for example, the calculation methods and methodology, that are used to carry out the safety analysis are verified and reproduced in an independent manner during the regulatory review and assessment process.

The Law addresses superficially the responsibilities of the regulatory body connected with the review and assessment activities, mostly focused on the duties of inspectors. These aspects are covered, in a general manner, by ministerial agreements of the MEM.

The requirements addressed to the licensee, including those for obtaining the authorizations, are established in the Law and in the Regulation 55-2001 and they detail the documents necessary for the obtaining the authorization. This Regulation incorporates guidance on regulatory review and assessment of some practices, nevertheless, there are no clearly specified procedures for the regulatory review and assessment of the presented safety assessments necessary for the granting of the authorization. Graded approach in review and assessment is only partially observed from the establishment of different types of requirements addressed to the different type of facilities, as defined in the Regulation 55-2001. The Legal framework does not address any requirements on the frequency at which the safety assessment is to be updated.

| RECOMMENDATION | |
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| **Observation:** *DPSR did not establish procedures for reviewing and assessing the safety assessment submitted by the licensee prior to the granting of an authorization. Graded approach in review and assessment is only partially observed, from the establishment of different types of requirements addressed to the different type of facilities.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 23, para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."* |
| **R** | **Recommendation: See R (1) in Section 1.2 and R (12) in Section 4.1** |

| RECOMMENDATION | |
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| **Observation:** *DGE did not establish any regulatory requirement on the maximum intervals for the update of the periodic safety assessments carried out by the licensee.* | |
| **(1)** | **BASIS: GSR Part 4 Requirement 4, para. 4.8 states that** *"The frequency at which the safety assessment shall be updated is related to the radiation risks associated with the facility or activity, and the extent to which changes are made to the facility or activity. As a minimum, the safety assessment shall be updated in the periodic safety review carried out at predefined intervals in accordance with regulatory requirements. Continuation of operation of such facilities or conduct of such activities is subject to being able to demonstrate in the reassessment, to the satisfaction of the operating organization and the regulatory body, that the safety measures in place remain adequate."* |
| **R (17)** | **Recommendation: DGE should, taking into account a graded approach, establish regulatory requirements on the maximum intervals for the update of the periodic safety assessment carried out by the licensee.** |

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

Review and assessment activities are performed by the senior inspectors designated by DPSR, which are also responsible for conducting inspections. At the time of the mission, 4 inspectors were designated as senior and another 4 inspectors are being trained for taking on the duties and tasks of review and assessment and inspection. DPSR senior inspectors are qualified, through the technical cooperation training programs developed by the IAEA, for the review and assessment. Nevertheless, review and assessment can be affected by the limited number of personnel. Additionally, there is no ingenous implemented staffing and training plan focused on review and assessment. There are no external independent resources and support for review and assessment, including Technical Support Organization (TSO) and cooperation at international level, despite the generic provisions from ministerial agreement of the MEM. The regulatory activities related to review and assessment can be affected by budget constraints.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DRPS did not develop a specific training programme covering the relevant regulatory and technical aspects, for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements.* | |
| **(1)** | **BASIS: GSR Part 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. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."* |
| **R** | **Recommendation: See R (10) in Section 3.3** |

### 6.1.3. BASES FOR REVIEW AND ASSESSMENT

The conducting of safety assessments by the licensees is foreseen in the Law and it details the requirements for safety assessment. The Law requires licensees to provide information required by DGE for granting the authorization. It includes any additional information defined during the authorization process. DPSR issued guidance, and published it on the website of MEM, on the format and content of the documents to be submitted by the applicant in support of an application for an authorization. The applicant is required to submit to DGE all necessary safety related information as specified in advance or as requested in the authorization process. Nevertheless, a management system of the regulatory process, including review and assessment activities, is not developed and implemented yet. In addition, there are no formal procedures for documenting the bases, results and decisions derived from reviews and assessments and to using it as feedback information for the regulatory process.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DPSR has not developed and implemented a specified procedure, as a part of a management system, on the activities carried out in the regulatory process, including review and assessment.* | |
| **(1)** | **BASIS: GSR Part 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...."* |
| **R** | **Recommendation: See R (12) in Section 4.1** |

### 6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

The Law foresees that the licensees are to require, as appropriate, independent verification of the performed safety assessment. The independent regulatory review and assessment is carried out prior the granting authorization and also inspections are carried out prior the authorization of the higher risk facilities and activities. However, there are only general provisions on the regulatory independent verification of the performed safety assessments, which does not include:

- the review and assessment activities associated with different modalities of authorization that are foreseen in the Regulation 55-2001 for the different types of radiation facilities and activities and for the different stages in the lifetime of the facilities and activities;
- communicating the results to the licensees along with the bases of the performed review and assessment; and
- interface between review and assessment and inspections.

## 6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

To perform the safety assessment of the facilities and activities, applicants and the users are requested to follow the "Radiological safety file of the installation" which is in force since November 2016 and it is not fully in compliance with the IAEA Safety Standards. In this document outlines the scope of the safety assessment that needs to be performed by applicants and licensees. The provided guidance is general and does not cover all the aspects to be considered in performing a safety assessment. The way this guide is presented makes it difficult for applicants or licensees to follow. As stated before, MA 73-2015 establishes the IAEA Safety Standards GSR Part 3 as a regulatory provision on radiation safety and the GSR Part 4 on Safety Assessment of Facilities and Activities. These IAEA Safety Standards are currently

considered regulations and as such can be used to complement the document called "Radiological safety file of the installation".

In the case of the CENDRA, a complementary document was developed by DGE to be used as a guide to review and update the already performed safety assessment.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *The requested information for performing the safety assessment in the recently approved "Radiological safety file of the installation" is not fully coherent and consistent with the IAEA Safety Standards.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 13, states that** *"The regulatory body shall establish and enforce requirements for safety assessment, and the person or organization responsible for a facility or activity that gives rise to radiation risks shall conduct an appropriate safety assessment of this facility or activity."* |
| **S (3)** | **Suggestion: DGE should consider revising the recently approved "Radiological safety file of the installation" to comply with the IAEA Safety Standards on safety assessment.** |

The IRRS Review Team noted that the regulatory review and assessment of the documentation provided by the users of radiation sources, in support of an application for an authorization including radioactive waste management activities and facilities, is performed. It was noted that DGE is still not implementing the complementary disposition on inspection and authorization established with the Ministerial Decree No 71-2015.

The IRRS Review Team had the opportunity to review the regulatory review performed by DGE to the application for authorization of the CENDRA. The IRRS Review Team was informed that there is no procedure for performing the regulatory independent review and assessment which is crucial when more than one expert is taking part in the review process. The Review Team noted that despite the exhaustive review that was performed, the record keeping of the reviews and conclusions is not detailed enough. There is no evidence of the independent review of the evaluation or calculations presented by the applicant. This situation does not allow for a comprehensive follow up of the performed review when the reviewer is not available or left the organization.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *A procedure for performing the regulatory review and assessment is not in place and the record keeping of the independent review and the conclusions achieved is not detailed enough.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 25, para. 4.48 states that** *"The regulatory body shall record the results and decisions deriving from reviews and assessments, and shall take appropriate action (including enforcement action) as necessary. The results of reviews and assessments shall be used as feedback information for the regulatory process."* |
| **(2)** | **BASIS: GSR Part 5 Requirement 3, para. 3.8 states that** *"To facilitate compliance with regulatory requirements, the regulatory body has to do the following:*<br>*—Document the procedures that apply to the mechanisms for compliance verification and enforcement…"* |
| **R** | **Recommendation: See R (12) in Section 4.1** |

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

The Law includes provisions for the authorization of the radiation source's facilities and activities and defines the requirements for obtaining the authorization. There are only general administrative provisions on the regulatory independent review and assessment. Graded approach in review and assessment is partially observed from the different types of requirements addressing the different types of radiation facilities and activities as defined in the Law. Since there are no formal procedures on review and assessment, the graded approach is not a clearly established element of the review and assessment.

The Regulation 55-2001 adopts the provisions of the guides developed through IAEA technical cooperation project for authorization and inspection of cyclotrons, industrial irradiators, nuclear gauges, well logging, industrial radiography, intervention, nuclear medicine, radiodiagnosis, radiotherapy, decommissioning and waste management. These guides are gradually being used as reference for review and assessment.

## 6.4. SUMMARY

The lack of a management system or an organizational instrument for review and assessment does not allow the observation of the implementation of the IAEA requirements in the area, even though the requirements, defined for the licensees for the obtainment of the different modalities of authorizations for the different types of facilities and that general administrative provisions on this theme are in place. The limited personnel are also an issue for the implementation of the review and assessment.

# 7. INSPECTION

## 7.1. GENERIC ISSUES

## 7.2. INSPECTION PROGRAMME

DGE utilizes a graded approach to inspection and identified 4 activities or types of authorizations based on the radiation risk significance of the authorized activity with Type 1 having the highest risk significance and Type 4 having the least risk significance. Type 1 activities include: use of panoramic irradiators; use of cobalt teletherapy; use of linear accelerators with energy in the MeV range used for medical therapy; radioisotope production; industrial radiography performed outside of a designated and shielded area or facility; and use of a permanent radioactive waste storage facility. Type 2 activities include: industrial radiography performed inside of a designated and shielded area or facility; use of industrial gauges; use of self-shielded irradiators; well logging; use of lower energy linear accelerators for medical therapy; use of unsealed radioactive materials; use of radioactive materials in diagnostic nuclear medicine; use of a panoramic x-ray unit in dentistry; and use of a temporary radioactive waste storage facility. Type 3 activities include: use of an x-ray unit in medicine and dentistry; use of low activity industrial gauges; use of an x-ray diffraction unit; and use of sealed sources for therapeutic treatment of the lens of the eye. Type 4 activities include: using sealed sources for teaching and training of students; radioimmunoassay; and medical use of sealed sources or x-ray to perform bone densitometry. The regulatory body reported having a total of approximately 55 Type 1 and Type 2 activities and approximately 625 Type 3 and Type 4 activities. DGE also issued approximately 1765 authorizations to individuals authorized to conduct activities under the institutional authorizations. These individual authorizations are reviewed during inspections of the institutional authorizations where the individuals work.

DGE stated that the general expectation is for all activities or types of authorization to be inspected initially, whenever significant changes occurred to the authorization, and as necessary when events occurred. DGE also indicated that Type 1 authorizations are expected to be routinely inspected twice each year and Type 2 authorizations inspected once each year. DGE acknowledged they were unable to always meet these expectations due to the limited resources available. DGE indicated that Type 3 authorizations are expected to be routinely inspected once every 2 years and Type 4 authorizations are expected to be inspected once every 5 years. They reported they were rarely able, after the initial inspection was completed, to perform Type 3 and Type 4 authorization inspections because they did not have enough qualified inspectors and they focused on completing the Type 1 and Type 2 authorization inspections. During the discussion on these issues, the IRRS Review Team was informed that DGE has not developed and implemented a formal programme of inspection in which there can be stipulated the frequency of inspections and the areas and programmes to be inspected.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE does not have formal inspection programme for carrying out its regulatory inspections.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 28, para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | *(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."* |
| **R(18)** | **Recommendation: DGE should develop and implement a formal inspection programme of facilities and activities, following a graded approach, to confirm compliance with regulatory requirements and with any conditions specified in the authorization.** |

In 2016, DGE inspectors performed 7 Type 1 inspections, 49 Type 2 inspections, 13 Type 3 inspections, one Type 4 inspection and more than 300 verification inspections. These statistics indicate that essentially all of the Type 1 and Type 2 inspections were completed in 2016 but less than 5 percent of the available Type 3 and Type 4 inspections were completed.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE identified 4 activities or types of authorization based on radiation risk significance with Type 1 having the most significance and Type 4 having the least significance. Currently, DGE rarely inspects Type 3 and Type 4 authorized activities following the initial inspection of the license because of limited resources and the determination to focus on inspecting the higher priority Type 1 and Type 2 authorized activities.* | |
| **(1)** | **BASIS: GSR Part 1 (Rev. 1), Requirement 27, states that "***The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."* |
| **R** | **Recommendation: See recommendation R(3), Section 1.3.** |

As indicated above, industrial radiography activities conducted outside of a designated and shielded area or facility is considered by DGE to be a Type 1 high risk authorized activity; however, they do not inspect these activities because of the travel time and financial cost of performing the inspection. Instead, the inspection is limited to the review of the industrial radiography source storage site and the review of operational records.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE does not inspect industrial radiography activities conducted outside of a designated and shielded area or facility, an activity recognized by DGE as having high safety significance, because of the travel cost and inspection effort required.* | |
| **(1)** | **BASIS: GSR Part 1 (Rev. 1), "Requirement 27, states that "***The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."* |
| **(2)** | **BASIS: GSR Part 1 (Rev. 1), "***Requirement 29, states that inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity in accordance with a graded approach."* |
| **R (19 )** | **Recommendation: DGE should ensure that all facilities and activities with high risk are** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| | **inspected on a regular basis.** |

For several years, DGE has performed proactive verification inspections (limited scope inspections) to identify entities and individuals who never had an authorization and entities who had an authorization in the past. The IRRS Review Team was informed that when DGE inspectors first began the verification inspections, more than 30 percent of the facilities visited had no authorization.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation**: *DGE performs proactive "verification" inspections (limited scope inspection) to identify institutions and individuals who require an authorization but who have never applied, and require them to obtain authorization or cease their activities.* | |
| **(1)** | **BASIS: GSR Part 1 (Rev. 1),** *"Requirement 27, states that "The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."* |
| **GP (3)** | **Good practice: DGE is conducting proactive "verification" inspections to identify institutions and individuals who require an authorization but who have never applied, and require them to obtain authorization or cease their activities. This is considered a good practice.** |

As described in Module 5, inspectors are responsible for performing technical reviews of requests for authorization, responding to questions from authorized individuals and members of the public and providing training. The inspectors perform programmed and reactive inspections, as necessary. The inspectors informed the IRRS Review Team that they perform very few unannounced inspections which would provide an opportunity for the inspector to observe regulated activities being performed in a way they would be performed in the inspector's absence.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation**: *DGE performs very few unannounced inspections.* | |
| **(1)** | ***BASIS: GSR Part 1 (Rev. 1), "Requirement 28*** *– Inspections of facilities and activities shall include programmed inspections and reactive inspections, both announced and announced.* |
| **S (4)** | **Suggestion: DGE should consider conducting more unannounced inspections** |

DGE inspectors indicated that they used to collaborate with MSPAS inspectors to perform joint inspections; however, this became difficult to manage with the large number of inspectors often present to inspect in a facility and this practice was stopped.

## 7.3. INSPECTION PROCESS AND PRACTICE

Annually, the inspectors receive written authorization to perform inspections from the Director of DGE. This written authorization, known as a "resolution," provides the inspector with the authority needed. Specific written approval to perform each inspection is authorized by the Head of DPSR. Inspectors have access to various inspection checklists which they can also use to make notes from the inspection. Inspectors reported they can spend as much or more time preparing for the inspection than they need to spend on site. Inspectors were well prepared and had access to **calibrated** equipment**.** At the beginning of each inspection, the inspectors meet with authorized individuals to discuss the scope of the inspection. At the end of the inspection, the inspectors meet with the authorized individuals to review inspection's observations and findings. The inspector's observations and findings are also provided to the authorized individuals in writing in the form of an "Acta de Inspección de Licenciamento" form. The "Acta" form is a legal document to keep record of all compliances and non-compliances founded during the inspection.

After returning to the DGE headquarters, a technical report of the inspection is prepared by the inspectors and then it is approved or disapproved by the Head of DPSR. Then, the formal inspection document is sent to the legal department of DGE for a legal review and development of resolution, after which the Director of DGE signs it and the Legal Department of DGE notifies to the authorized party. Follow up inspections are scheduled to review the licensee's corrective and preventive actions to confirm that all non-compliance has been corrected.

### 7.3.1. INSPECTORS

DPSR have 4 "senior' inspectors and 3 "junior" inspectors with limited competence, also there is one inspector in process to become a senior inspector. DPSR have an internal policy to perform every inspection with two inspectors.

Inspectors stated that after being hired, they are required to spend several months reading regulations and relevant documents, reading inspection guidance documents, and learning DGE processes. During this time, they also accompany an official inspector for training purposes. Part of the process to complete the training qualification is to attend the IAEA-sponsored technical courses, and in some cases, the postgraduate programme in radiological protection. The Head of DPSR reported that junior inspectors are on the list to get the next available training course but have not been sent yet due the lack of funding resources.

## 7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

The IRRS Review Team noted that in general, the inspection was planned, performed, and finalised according to IAEA safety Standards and good practices. It was also informed that currently DGE does not have an inspection plan in place. Radioactive waste management activities that are performed in other facilities, as is the case in nuclear medicine facilities, are inspected as part of the inspections performed for the nuclear medicine practice. The CENDRA was recently inspected as part of the authorization process. But before that inspection, the previous one took place in August 2005.

During the visit, it was noted that inside the facility there was a legacy disposal site where several disused sealed radioactive sources are buried. The IRRS Review Team was informed by DGE staff and the

Operator that the decision is to leave these places as they are. Currently there is no institutional control based on the safety assessment for the "closure" of these facilities.

The IRRS Review Team was informed that some conditioning activities were performed in the facility as part of the IAEA assistance programme. Currently other activities with the IAEA assistance are in the planning phase to recover and repatriate some sources and to condition others stored in CENDRA facility. The IRRS Review Team discussed, with the operator and DGE, the responsibility of the operator for justifying and supporting any additional activity to be performed out of the scope of the granted authorization with a safety assessment and safety report in support of an authorization request for such activities. This requirement needs to be complied with even if the activities will be performed with international assistance.

**SITE VISITS**

As part of the activities for assessing the inspection activities, a representative of IRRS Review Team participated in an inspection to CENDRA. The inspection was prepared by the inspector the day before of the inspection. Records of the facility were reviewed and a check list for this inspection was prepared in advance as well as dosimeters and field monitors. The inspection was performed in a planned manner with a proper entrance meeting, review of the main reports, procedures and pending documentation. After that the inspection of the facility took place according to the plan prepared in advance. Measures of the dose rate in different points as well as photos of the facility were taken by the operator and the inspectors and results were compared and recorded. At the end an exit meeting took place where the preliminary report was prepared by the inspector, discussed with the operator and signed. At the office, the inspector started to draft the inspection report.

During the interview that took place with the licensee of CENDRA during the site visit the IRRS Review Team was informed that:

- There were some unplanned delays in the authorization process due to new requirements established by the regulatory body during the authorization process.-Even now when the licensee of the facility is at the last stage of approval, new documents were provided by the Regulatory Body to the CENDRA´s operator to be considered in the safety review of the facility.
- The involvement of the licensees or interested parties in the review and discussion process of new regulatory document almost does not exist.
- There is no direct communication to the licensees on new regulations in force that may affect the safety assessment and safety justification of the facility or activity.
- The licensee recognized that currently there is in place a more dynamic path for the approval of new regulations.

## 7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

**SITE VISITS**

As part of the activities for assessing the inspection activities, a representative of IRRS Review Team accompanied DGE inspectors in an inspection to a self-shielded irradiator facility (Type 2) and to a medical institution with medical therapy (Type 1).

With only a small sample to evaluate, inspectors were found to be well prepared, they interfaced professionally with the authorized individuals, reviewed records, observed authorized activities, toured facilities and made independent measurements of radiation.

The inspectors who visited the self-shielded irradiator facility interacted well with the authorized individuals and had checklists which they used sparingly. The inspectors reviewed the authorizations issued to the facility operators, reviewed dosimetry reports, and performed numerous surveys confirming the exposure rates emanating from each irradiator were minimal and unchanged.

The inspector who visited the medical institution used the checklist currently available for inspecting radiotherapy facilities using linear accelerators. The checklist needs to be updated because it includes several items applicable to cobalt-60 teletherapy unit. The inspector performed a performance based inspection. However, the inspector reported that DGE inspectors are not trained and are not experienced in inspecting linear accelerators used for medical therapy and that only one inspector has limited training based on self-study.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE inspectors have no competence to inspect linear accelerators used for medical therapy. DGE has one inspector with limited knowledge developed only through self-study.* | |
| **(1)** | **BASIS: GSR Part 1** *(Rev. 1), Requirement 18, states that "The regulatory body shall employ a sufficient number of qualified and competent staff commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions to discharge its responsibilities."* |
| **R** | **Recommendation: See R(10), Section 3.3** |

## 7.6. SUMMARY

DGE uses a graded approach to scheduling its inspections, focusing its limited inspection resources on the higher risk activities and facilities. However, DGE has not an inspection programme for carrying out its regulatory inspections. It was noted that due to resources limitations DGE is not inspecting high risk, Type 1, industrial radiography activities performed outside of designated and shielded facilities or areas and this should be corrected. It was identified as a "good practice" the proactive inspections, mostly of x-ray facilities, to identify facilities and individuals who have no license and cause them to obtain an authorization or cease the activity needing the authorization. Inspectors reported they performed very few unannounced inspections. It is suggested that DGE strive to perform more unannounced inspections. CENDRA was reminded about the responsibility of the operator for justifying and supporting any additional activity to be performed with a safety assessment and safety report in support of an authorization request for such activities. The IRRS Review Team also determined that DGE inspectors have no competence to inspect linear accelerators used for medical therapy because DGE provides no technical training in his area.

# 8. ENFORCEMENT

## 8.1. ENFORCEMENT POLICY AND PROCESS

DGE has an enforcement policy, described in (GA 55-2001), that has been implemented within the legal framework using a graded approach. DPSR and DGE Legal Department carry out the enforcement policy. Inspectors have been trained on the enforcement policy, and are annually provided by the Director DGE with written authorization, known as a resolution, to conduct inspections on behalf of the DGE. The authorization includes the ability of inspectors to immediately stop unsafe activities; however, inspectors state that they would need to contact the Head DPRS and the DGE legal department to take emergency actions necessary to shut down an authorized facility or activity. The enforcement policy includes financial penalties that are calculated based on the significance of the finding(s). Typical findings identified are minor and result in a small financial penalty. Many findings involve x-ray workers who have no authorization and these findings typically result in a significant financial penalty.

## 8.2. ENFORCEMENT IMPLEMENTATIONS

Immediately following an inspection, and before leaving the site, a DPSR inspector verbally describes any findings to the authorized party and leaves a written record of the inspection, including any findings, with the authorized party. This written record is known as the ACTA or "Acta de Inspección de Licenciamiento" form. This is the part when the authorized party has the first knowledge of the findings. Inspectors said that authorized parties take corrective actions based on the findings described on the ACTA. Immediate and substantial corrective actions are expected for significant findings. When the inspectors return from the inspection, they give an inspection brief summary to the Head of DPSR and then issue the technical report that was approved by the Head of DPSR and finally sent to the Legal Department of the DGE. After that, the Legal Department issues a resolution that is signed by the Director of DGE, which is sent to the authorized parties through the Legal Department. Inspectors stated that they are occasionally asked to assist the lawyers of the Legal Department of DGE to advise on some technical issues. Authorized parties are required to implement corrective actions. The authorized party is required to travel to the DGE Offices to pay the penalty. The right to appeal enforcement decisions is described in the Law, as discussed above. Inspectors perform follow up inspections to confirm effective implementation of corrective actions.

## 8.3. SUMMARY

DGE has an enforcement policy, which has been implemented within the legal framework using a graded approach. The enforcement policy is implemented by DPRS management and inspection staff in collaboration with the DGE legal department. Inspectors have been trained on the enforcement policy. Authorization for carrying out inspections that are issued by DGE to inspectors empowers them to immediately stop unsafe activities, but in practice inspectors contact the Head of DPRS and the DGE legal department prior to taking actions for shutting down an authorized facility or activity. The enforcement policy includes financial penalties that are calculated based on the significance of the finding(s). At the end of inspections, inspectors leave an unofficial report with the findings and conclusions of the inspection. This is considered as a notification to the authorized party about any concerns. Official reports are sent to the authorized parties later who are required to implement corrective actions. The right to appeal enforcement decisions is described in the Law. Inspectors perform follow up inspections to confirm effective implementation of corrective actions.

# 9. REGULATIONS AND GUIDES

## 9.1. GENERIC ISSUES

General regulations are in place and they detail the types of authorizations, classification of facilities in terms of risk, requirements for granting the authorization, exemption and clearance criteria, enforcement and they include provisions on safety assessment. Some elements of a graded approach may be considered to be present in the regulatory framework. The legal and regulatory framework also includes regulations on waste management and radioactive sources security. The MA 67,68,69,70,71,72 and 73 published in 2015 adopted the provisions of 52 documents relating to inspections, training, transport, radioactive waste, emergencies, radioactive sources, radiation generators. These documents include 36 International Atomic Energy Agency safety standards, like SF-1, GSR Part 1, GSR Part 3 and GS-G-1.4, which includes provisions on the development of regulation and guides and is used as a reference for this purpose, within all adopted documents, there are three with the scope focused on nuclear facilities: Organization and staffing of the regulatory body for nuclear installations GS-G-1.1; Documentation used in the regulation of nuclear installations No.GS-G-1.4 and Regulatory Inspection of Nuclear Installations and Regulatory Enforcement Function No. GS-G-1.3

The Legal and regulatory framework in Guatemala, before June 2015, was composed of nationally developed legal and regulatory documents, based on IAEA standards, including GA 55-2001, GA 469-2014 and 176-2015. In June 2015 MA 67 to 73 adopted a number of IAEA safety standards documents, which included many safety guides and safety requirements, in particular GSR Part 1, GS-R-2, GSR-3, GSR Part 3, GSR Part 4 and GSR Part 5. The direct adoption of these IAEA standards, caused the occurrence of legal overlaps and duplications and contradictions in some very specific parts of the regulatory framework of the country. When the IAEA documents were adopted, they assigned some responsibilities to the Government and DGE

The adoption of the IAEA documents was done through Ministerial Agreements which imposed significant challenges for the regulatory authority to implement them.

In practice, the newly adopted standards have not been used and all the regulatory activities and decisions continue at this moment to be based on the previous regulation, which is based on the IAEA standards. A process of implementation of adopted standards is still pending and it will require efforts from the DGE and other interested parties.

Regulations and Guides are prepared by DGE and include interdepartmental consultation as well as consultations with professional associations. The public is not directly involved in this consultation process. The IRRS Review Team could not find a formal instrument or criteria for determining when regulations and guides need to be reviewed and/or updated. Inspection guides are available through the adoption of guides developed through regional cooperation projects. Regulations and instructions for licensees are available on the website of MEM.

The IRRS Review Team could not find a formal instrument or criteria for determining when regulations and guides need to be reviewed and/or updated. Inspection guides are available through the adoption of guides developed through regional cooperation projects. Regulations and instructions for licensees are available on the website of MEM.

| RECOMMENDATIONS | |
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| **Observation:** *DPSR does not have clear criteria or procedures to determine when it is necessary to review or revise the regulations in force and approved guides.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."* |
| **R** | **Recommendation: See R (12) in Section 4.1** |

| RECOMMENDATIONS | |
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| **Observation:** *The development of regulation and guides does not include consultation with interested parties.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 34, para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides."* |
| **R** | **Recommendation: See R (1) in Section 1.2** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *Specific regulations published in 2015 (MA) adopt the provisions of many International Atomic Energy Agency safety standards. These regulations are in the process of implementation and by this reason some formal duplications and contradictions are still in place.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 22, states that "***The regulatory body shall ensure that regulatory control is stable and consistent."* |
| **(2)** | **BASIS: GSR Part 1 Requirement 22, para 4.28 states that "***4.28. There shall be consistency... in the regulatory requirements themselves, to build confidence among interested parties."* |
| **(3)** | **BASIS: GSR Part 1 Requirement 34, para 4.62 states that "***The regulations and guides 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..."* |
| **R (20)** | **Recommendation: DGE should continue efforts to implement the documents adopted in the country, considering the mandate of MEM, the scope of the IAEA standards and specific national circumstances.** |

## 9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The regulatory framework for the safe management of radioactive waste is established mainly through the "Regulation on radioactive waste management" (GA 176-2015). This regulation covers most of the safety requirements established in the IAEA Safety Requirements GSR Part 5. The regulation is prescriptive enough to be understood and to be applied by the users of radiation sources which generate radioactive waste including radioactive disused sealed sources. This regulation establishes requirements for the identification and compliance with the interdependences among all steps in the predisposal management of radioactive waste, as well as the impact of the anticipated disposal option. The regulation also provides requirements on the identification, control and minimisation of radioactive waste and the characterization and its classification. The regulation covers the requirements on derivation, structure and use of waste acceptance criteria as well as the ability to retrieve radioactive waste from storage facilities.

However, GA 176-2015 does not cover requirements on preparation of the safety case and supporting safety assessment; scope and documentation of the safety case and supporting safety assessment as well as requirements for the periodic safety reviews. In addition, safety requirements for the development of predisposal radioactive waste management facilities are missing such as requirements for location and design, construction and commissioning, operation and shutdown and decommissioning of facilities. It is missing the clarification when the disused sealed source is becoming a radioactive waste and it is conditioned, stored and disposed of as such.

GA 176-2015 establish the clearance levels for solid (Table 1) and for liquid (Table 2) radioactive waste. In both cases references are made to the outdated IAEA TECDOC 855 which addressed only solid radioactive materials. Also, reference is made to the GSR Part 3 which is the correct reference in this case. But neither the TECDOC 855 nor the GSR Part 3 establish any value for clearance of liquid radioactive materials. In addition, the criteria for clearance and the clearance levels (collective dose and equivalent dose to the skin) established in the "Regulation on radioactive waste management" are not consistent with the criteria and levels established in the GSR Part 3

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *GA 176-2015 is not fully in compliance with IAEA Safety Requirements Series.* | |
| **(1)** | **BASIS: GSR Part 5 Requirement 3, states that** *"The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities…The regulatory body shall review and assess the safety case and the environmental impact assessment for radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation…"* |
| **R (21)** | **Recommendation: DGE should revise the "Regulation on radioactive waste management" (Governmental Agreement No. 176-2015) to be fully in compliance with IAEA Safety Requirements Series.** |

The IRRS Review Team noticed that a number of requirements in GA 176-2015 assign the responsibility to DGE to establish some limits, conditions or periodicity for providing information by the licensees, but are still not implemented. It is important to note that requirements are intended to apply to all facilities and activities. Since existing facilities might not follow all the requirements, decisions have to be taken with regard to the safety of these facilities and DGE together with the licensees need to establish a

timeframe when safety related upgrades need to be made by the operator in line with these requirements. In such a case, those facilities that are not in compliance with all the requirements need additional modifications, operational restrictions, or need to be shut down.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE did not fully implement the provisions of GA 176-2015.* | |
| **(1)** | **BASIS: GSR Part 5 Requirement 3, para 3.8 states that** *"To facilitate compliance with regulatory requirements, the regulatory body has to do the following:*<br>*-Provide necessary guidance on the interpretation of national standards and regulatory requirements that takes into consideration the complexity of the operations and the magnitude of the hazards associated with the facility and operations…"* |
| **R (22)** | **Recommendation: DGE should fully implement the "Regulation on radioactive waste management" (GA 176-2015).** |

**Decommissioning of facilities**

GA 76-2015 provides the main requirements on planning for decommissioning and financial assurance and they are in compliance with the IAEA Safety Requirements GSR Part 6. In addition, MA 67-2015 adopted twelve IAEA Safety Standards, among which is the Safety Requirement WS-R-5 which was superseded by GSR Part 6. Considering the existing inventory of radiation sources and facilities in the country, and applying a graded approach, it may be noted that the currently in force regulatory framework for decommissioning of facilities is consistent with the IAEA safety Standards and is sufficient to regulate the safe decommissioning of facilities.

The IRRS Review Team noted that in the documentation provided, authorized facilities including the CENDRA there is no initial decommissioning plan as required in the regulatory framework. There is also no evidence of the financial assurance that needs to be provided by the licensees for decommissioning.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *The regulatory framework for safe decommissioning of facilities is not yet implemented*. | |
| **(1)** | **BASIS: GSR Part 6 Requirement 5, states that** *"…The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met."* |
| **(1)** | **BASIS: GSR Part 6 Requirement 6, states that** *"The licensee shall plan for decommissioning and shall conduct the decommissioning actions in compliance with the authorization for decommissioning and with requirements derived from the national legal and regulatory framework. The licensee shall be responsible for all aspects of safety, radiation protection and protection of the environment during decommissioning."* |
| **R (23)** | **Recommendation: DGE should implement the regulatory framework in force for the safe decommissioning of facilities.** |

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

Regulations for radiation source facilities are available and define different types of authorizations for facilities and individuals including, Construction and Operation Licence and Import and Export of Sources Licences. It defines enforcement actions and requires that licensees carry out safety assessments. The regulations also establish the requirements for obtaining the specific authorizations, including the need of presenting the adopted safety procedures. It also defines four groups of facilities and provides specific requirements for authorizing the facilities classified in one of these groups. Forms, guidance, and instructions are provided on the MEM web site.

The regulation on inspection adopts the inspection related provisions of the guides for authorization and inspections, developed through IAEA technical cooperation project, for cyclotrons, industrial irradiators, nuclear gauges, well logging, industrial radiography, interventional radiology, nuclear medicine, diagnostic radiology, radiotherapy, decommissioning and waste management. This regulation is gradually being used as a reference for regulatory activities, even though the regulation in force limits their use to inspection activities.

## 9.4. SUMMARY

Regulatory framework is in place and covers most of the essential points for an effective control on regulated facilities and activities. The opportunities of improvement are related to the implementation of a management system including the development and review of regulations and guides. This system should clearly specify the criteria for review of regulation and guides and also put in place the tools for the effective implementations of the regulation provisions. The adoption of IAEA standards and guides developed through regional projects need to be done considering the scope of the standard and the effective participation of the interested parties and the public.

# 10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

## 10.1. GENERAL EPR REGULATORY REQUIREMENTS

The Law establishes and assigns the requirements, responsibilities and obligations in case of emergency to the DGE and the licensees.

The Director of DGE within the MEM has a limited description of its responsibilities. As a law, it mixes very specific technical aspects with general aspects; however, limited references to emergency activities are mentioned (only 2 articles).

The Law requires the users to get a license to use radioactive material; including having an emergency plan. In case of emergency, licensees are required to provide assistance, however it doesn't give further information on how this assistance is going to be provided. This might be stated in the plans, but there are no specific guides to fulfil this requirement.

GA 55-2001 provides detailed requirements on the licensee's emergency plans, responsibilities and obligations.

The MA 72-2015 complements the Law. Through this Ministerial Agreement, the Government adopts, as part of the regulations, the following IAEA documents:

- **IAEA Requirements No. GS-R-2** "Preparedness and Response for a Nuclear or Radiological Emergency" (**superseded by IAEA GSR Part 7)**
- **IAEA General Safety Guide No. GSG-2** "Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency"
- **IAEA Safety Guide No. TS-G-1.2** "Planning and Preparing for Emergency Response to Transport Accidents Involving Radioactive Material"

According to the Law, the DGE is mandated to take all necessary actions to prevent and minimize the consequences of a radiological emergency, including the licensing and inspection processes. According to MA 72-205, the Government agreed to adopt the IAEA GS-R-2 Requirements, however, no further legal regulatory framework indicates the roles and responsibilities of the DGE in case of a radiological emergency in particular, or the effective application of IAEA GS-R-2 requirements in general. Furthermore, IAEA GS-R-2 has been superseded by GSR Part 7 and no provisions are in place to update MA 72-205 accordingly.

A National Response Plan (PRN) which was issued by the National Commission for the Disasters Reduction (CONRED) is in place. NRP assigns responsibilities to the MEM as a support institution in case of emergencies related to dangerous materials, but no further roles and responsibilities are assigned to DGE in case of radiological emergencies.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE has not implemented arrangements with other response organizations to establish an effective coordination during a radiological emergency.* | |
| **(1)** | **BASIS: GSR Part 1 Requirement 7, para. 2.18 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned ……..*<br>*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."* |
| **R** | **Recommendation: See recommendation 4 in section 1.5** |

CONRED and DGE have established informal agreements on the role DGE plays in case of a radiological emergency and efforts are being made to modify the legal framework to clearly establish these roles in the new version of PRN being drafted.

The role of the licensees in case of a radiological emergency at the facilities is established in the Radiological Safety and Protection Regulation, including communication to other emergency response organizations.

Licensees are required to prepare emergency response plans according to DGE not taking into account hazard assessment as required by GS-R-2 paragraph 3.6. The emergency response plans are authorized by DGE during the licensing process and verified during inspections.

DGE has made efforts to have a licensee's internal database containing information on the hazard categorization according to Table 1 of GS-R-2 in order for DGE staff to be aware of the hazard categorization if an emergency occurs in a facility, besides other information needed in case of an emergency.

Guatemala has signed and ratified the Conventions on Early Notification and Assistance in case of Nuclear or Radiological Accidents. DGE is appointed to be the National Competent Authority Domestic and Abroad and CONRED to be the National Warning Point.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *IAEA recommendations are mandatory to be adopted according to the Ministerial Agreement 72-2015, but no specific legal regulatory framework is in place to effectively implement IAEA GS-R-2 requirements.* | |
| **(1)** | **BASIS: GSR Part 1 (Rev. 1) Paragraph 2.5 states that "***The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety."* |
| **R** | **Recommendation: see recommendation 21 in Section 9.1.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *MA 72-2015 mandates adoption of IAEA Requirements GS-R-2, however it has been superseded by IAEA General Safety Requirements GSR Part 7 and no legal update of Ministerial Agreement is being carried out.* | |
| **(1)** | **BASIS: GSR Part 1 (Rev. 1) Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated"* |
| **(2)** | **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"* |
| **R(24)** | **Recommendation: The Ministry of Energy and Mines should update the MA 72-2015 to take the requirements of GSR Part 7 into account.** |

## 10.2. FUNCTIONAL REGULATORY REQUIREMENTS

The Radiological Safety and Protection Regulation requires the licensee to prepare the emergency plan including the emergency management structure and the need for the prompt transition from normal operation to emergency operation command and control.

DGE has prepared and made available a guide for the licensee to prepare the emergency plan, this guide provides detail instructions on how to prepare the facility's emergency response plan however this guide is not mandatory.

The requirements to prepare the emergency plans are based on 4 types of practice classifications; the emergency classification considers only site facility.

GA 55-2001 clearly requires the licensee to identify, activate and notify DGE of any emergency occurring in the facility according to the authorized emergency response plan. (GA 55-2001) states that the notification is to be made promptly, but no time frame is specified. It was also identified the contacts to notify DGE in case of emergency are not updated in the licensee's procedures. The procedures, however, include the notification contacts of the CONRED, which is a 24-hour contact point number.

DGE has informal agreements on the contact points in case of an emergency with other response organizations and the draft new version of PRN is taking these contact points to be official.

There is an informal communication agreement in which a scrap metal processor notifies DGE in case of a discovery of an orphan source. DGE conducts an inspection on site to verify the information and, if needed, the inspectors retain the source in order to be send to storage. In this process, (CONRED) can be notified in case of public exposure. If assistance is required, (CONRED) is the response organization appointed to require such assistance.

Mitigatory actions taken by licensees are required to be incorporated in the emergency response plan according to GA 55-2001.

GA 55-2001 requires the emergency plans off-site be part of an agreement of the facility's legal representative with the national organizations or local civil protection representatives. These requirements are verified during the licensing process and inspections.

Taking urgent protective actions during an emergency is a process made by (CONRED) and DGE on a case by case basis taking into account IAEA recommendations.

In case information and issuing instructions to the public during an emergency is needed, the (CONRED) has taken the responsibility to provide such information with the support of DGE.

(GA 55-2001) clearly establishes the dose limits for the radiation workers, however, no clear dose limits for the workers or first responders in case of an emergency are established.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE has not clearly established the dose limits for emergency workers and helpers participating in a radiological emergency.* | |
| **(1)** | **BASIS: GSR Part 7 Requirement 11, para. 5.53. states that** *"The operating organization and response organizations shall ensure that all practicable means are used to minimize exposures of emergency workers and helpers in an emergency in the response to a nuclear or radiological emergency (see para. I.2 of Appendix I), and to optimize their protection."* |
| **R (25)** | **Recommendation: DPSR should clearly establish dose limits for emergency workers and helpers during an emergency** |

(GA 55-2001) clearly requires the licensees to assess the initial phase taking into account plant/site conditions and radiation levels. This assessment is evaluated by DGE prior to issuing a licence and is verified during inspections.

The medical response management is carried out by (CONRED) in case of an emergency and during those situations DGE provides technical support on the technical management.

PRN does not consider other activities in emergency preparedness related to defining criteria for agricultural countermeasures and countermeasures against ingestion and longer-term protective actions and on the need for mitigating the non-radiological consequences. For these cases, DGE would provide technical support to (CONRED).

(GA 55-2001) provides specific requirements for the licensee to conduct recovery operations, and to declare the emergency termination. DGE has the responsibility to verify that the licensee has conducted those operations according to the emergency response plan and to declare the emergency termination.

### 10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

DPSR drafted an emergency response plan describing the roles and responsibilities of DGE staff in case of emergency.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE has not specified its staff functions and responsibilities during a radiological emergency.* | |
| **(1)** | **BASIS: GSR Part 7 Requirement 2, para. 4.7. states that** "*The government shall ensure that all roles and responsibilities for preparedness and response for a nuclear or radiological emergency are clearly allocated in advance among operating organizations, the regulatory body and response organizations."* |
| **S (5)** | **Suggestion: DGE should consider implementing its Emergency Response Plan draft in a short timeframe**. |

Even though there is no organization manual describing the specific functions of DGE staff, the Head of DPSR is responsible for coordinating radiological emergencies. Radiological emergencies preparedness and response (EPR) responsibilities are assigned to a particular inspector. The inspector responsible for EPR has received specific training on EPR and is responsible to organize the staff to be prepared to respond to an emergency. Seven inspectors will participate during the response in case of a radiological emergency. The activities assigned during an emergency to the inspectors depend on their experience and the training they have previously received.

PRN assigns the coordination of emergencies in Guatemala to (CONRED). According to the (PRN), (CONRED) can request DGE to participate during the coordination of a radiological emergency; however no specific agreements are in place between these two organizations. A new draft of the NRP assigns particular responsibilities to DGE in case of radiological emergencies.

The detection equipment used for inspections is the same equipment used to respond to radiological emergencies as well. In case more detection capabilities are needed (environmental monitoring, sampling and analysis and internal dose assessment) DGE would ask for assistance to other departments of MEM, however no special agreements are in place on how to request these capabilities. No special facilities are devoted to be used in case of radiological emergencies other than DGE premises.

Training, drills and exercises for DGE staff to be prepared to respond to an emergency are done through the participation of the staff in IAEA workshops (national and regional). The inspector appointed as responsible for EPR activities keeps records of DGE staff who has received IAEA training and involves the staff whenever an exercise is conducted by IAEA, however, there is no formal programme to train the staff on regular basis.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *DGE has not implemented an analysis of competence and specific training programmes to be prepared to respond to radiological emergencies.* | |
| **(1)** | **BASIS: GSR Part 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. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements"* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **R** | **Recommendation: See recommendation (10) in section 3.3** |

Training, drills and exercises the licensees are required to implement according to their emergency plans are reviewed by DGE staff through inspections on site.

The inspector responsible for EPR within the DPSR keeps records of different activities DGE performed in this regard, but no internal procedures are in place to verify the emergency response activities within DGE as part of a quality management system.

## 10.4. ROLE OF REGULATORY BODY DURING RESPONSE

PRN establishes different emergencies for which the Plan must be activated. One of these emergencies is the dangerous materials emergency, for which the primary responder is CONRED and the support organization is the MEM. As radiation emergencies are not clearly mentioned in the NRP as part of the dangerous materials, CONRED and DGE have established informal agreements on the role of each organization. DGE is appointed to be the radiological assessor.

DGE has responded to radiological emergencies in the past, giving advice and technical support to CONRED by deploying its resources on the field to provide assistance. An emergency response plan for DGE is being drafted to specify its roles and functions during a radiation emergency.

## 10.5. SUMMARY

Guatemalan EPR legal framework establishes clear requirements for licensees to prepare emergency response plans, roles and functions. These emergencies response plans are authorized and inspected by DGE It also establishes requirements for DGE and other response organizations to be prepared and respond to radiological emergencies. Furthermore, the EPR legal framework mandates to adopt IAEA recommendations regarding EPR activities. It was identified however that even though IAEA recommendations are legally binding, these have not been effectively implemented.

DGE has established informal agreements with other emergency response organizations to be prepared to respond to a radiological emergency. DGE is recognized to be the radiological assessor in case of an emergency by the response organizations, but it was identified DGE infrastructure is limited in case of a severe radiological emergency.

# 11. ADDITIONAL AREAS

## 11.1. CONTROL OF MEDICAL EXPOSURES

There are 5 medical radiotherapy facilities (Including LINACS, Brachytherapy), 11 nuclear medicine facilities (diagnostic and/or therapeutic); 1 Nuclear Medicine (PET/CT) 1333 X Ray Medical (Including: Conventional, Computed Tomography, Mammography, Fluoroscopy), 900 X ray dental diagnostic radiology facilities in Guatemala.

The regulation on medical exposure is included in GA 55-2001 and in MA 68-2015 which refers explicitly to IAEA Guide RS-G-1-5. During the discussions, the IRRS Review Team was informed that these IAEA guides have not been implemented yet. GA 55-2001 provides most of the basic requirements of the new IAEA safety standards. According to the information provided by DGE, efforts are being made to strengthen the protection of patients through updating requirements to be in line with GSR part 3.

The Law empowers DGE to issue radiation protection regulations for medical exposure. According to the Law, DGE can request the assistance from any other public authority or institution, which is obligated to provide it. However, there is no formal agreement between DGE and MSPAS related to the control of medical exposure. This is not in compliance with Requirement GSR Part 3.

GA 55-2001 requires that health professionals with responsibilities for medical exposure are specialized in the appropriate area. The regulation states that for therapeutic procedures the calibration, dosimetry and quality assurance is to be performed under the responsibility of medical physicists. It also requires that quality assurance in radiologic diagnosis is to be carried out under the supervision of a qualified expert or a medical physicist. Fulfilment of provisions established in this regulation is to be demonstrated during the licensing and inspection processes.

The IRRS Review Team was informed that currently only radiotherapy services have medical physicists. In these services medical physicists work on part time basis, with the exception of one facility where the medical physicist works full time. (MA 137-2016) adopted the IAEA document "The medical physics: criteria and recommendations on clinical training and certification for Latin America". This document provides support for the establishment of a Medical Physicist Commission, with the participation of DGE, for the certification of the competence of medical physicists in Guatemala.

**Responsibilities of licensees**

GA 55-2001 establishes the responsibilities of licensees with regard to medical exposure. These include, the responsibilities for referral, protection and safety and information for patients as well as provisions for competence of relevant health professionals. Requirements established by this regulation are in compliance with GSR part 3.

**Justification**

GA 55-2001 makes provisions for justification of radiological medical procedures. Referral guidance has not been developed and provision for the involvement of health authorities in the justification process are not in place. Justification of therapeutic procedures are verified during inspection

**Optimization**

Specific arrangements for optimization are included in GA 55-2001, which establishes the need for optimization of medical exposure. Design considerations of medical devices including the need to comply with international standards are also covered in GA 55-2001. This regulation includes general requirements for operational considerations are for diagnostic radiology and nuclear medicine. The requirement for calibration of the radiotherapy equipment is also included where it is established that this is to be carried out according to a quality control programme. Calibration need to be carried out prior to clinical use and after maintenance procedures that could affect dosimetry. This programme is to be designed and submitted with the application for the license.

Dosimetry of patients is required for both diagnostic and therapeutic procedures according to GA 55-2001. This requirement is enforced by DGE for radiotherapy but not for diagnostic radiology.

General requirements related to quality assurance and quality control programmes are included in this regulation. Details of review, assessment and inspection of these programmes are described in guidance documents developed for the region and adopted by MA 71-2015.

GA 55-2001 sets a value of 5 mSv as the dose constraint for carers (patient helpers) and comforters and requires compliance with this dose constraint. Although GA 55-2001 requires Diagnostic Reference Levels (DRL) to be set, the IRRS Review Team concluded that the DRL values have not been set yet. There is a comprehensive check list of inspection related to medical exposures although it should be reviewed to reflect up to date medical practices.

**Pregnant women and breast feeding women, release of patients after radionuclide therapy**

Requirements related to pregnant women and breast feeding women protection for radiology, nuclear medicine and therapeutic procedures are covered in the GA 55-2001. This regulation also includes requirement for the release of patients after radionuclide therapy, however, no criteria or values are defined by the competent authority.

**Unintended and accidental medical exposures**

The prevention of unintended and accidental medical exposures are covered in the same regulation which also covers investigation of such exposures and, if appropriate, implementation of corrective actions. (GA 55-2001) requires information to the patient and to the physician on the incident. However this is not enforced by DGE.

**Reviews and records**

GA 55-2001 requires the licensee to maintain and have available the records containing the elements necessary to estimate the dose in diagnostic and therapeutic procedures as well as the results of the calibrations and periodic verifications of physical and medical parameters used during treatments. This is verified during inspections.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
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| **Observation:** *There is no formal agreement between DGE and health authorities related to the control of medical exposure.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 2 paragraph** 2.15. states that: *The government shall establish legislation that, among other things:*<br>*……*<br>*e) Provides for coordination between authorities with responsibilities relevant to protection and safety for all exposure situations* |
| **R** | **Recommendation: see Recommendation 4 in section 1.5.** |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Diagnostic Reference Levels and patient release criteria are not established.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 34, para.147-149 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* |
| **R(26)** | **Recommendation: The Government should ensure that Diagnostic Reference Levels and criteria and guidelines for the release of patients are established.** |

## 11.2. OCCUPATIONAL RADIATION PROTECTION

**Legal and Regulatory Framework**

Guatemala has established a legal and regulatory framework for safety in accordance with Requirement 2 in GSR Part 1 (rev. 1). This framework includes provisions for protection against occupational exposure. Relevant requirements for the control of occupational exposures are established in the GA 55-2001. In general, these requirements are in compliance with GSR Part 3. DGE in its role as regulatory body is responsible for enforcing regulatory requirements for the control of occupational exposures in planned exposure situations.

According to MA 73-2015, IAEA document GSR Part 3 has been adopted at the level of regulatory requirements in the national regulatory framework. This fact represents duplication in regulations, which

in some cases implied the existence of some contradictions in the regulatory documents. In addition, MA 68-2015 and MA 69-2015 refer to IAEA safety regulatory guides which have not been implemented yet.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Requirements in regulatory documents in place are duplicated and in some cases are contradictory. IAEA safety standards adopted by the Ministerial Agreements 68-2015 AND 69-2015 are not being implemented.* | |
| **(1)** | **BASIS: Requirement 22 in GSR Part 1 (rev. 1) states that** *"The regulatory body shall ensure that regulatory control is stable and consistent."* |
| **(2)** | **BASIS: GSR part 1 (rev1) Requirement 22, Paragraph 4.28 states that** *"There shall be consistency in ….the regulatory requirements themselves, to build confidence among interested parties"* |
| **R** | **Recommendation: see recommendation 21 in Section 9.1** |

**Responsibilities of the Regulatory Body**

Regulations establish dose limits, and require occupational protection and safety to be optimised and exposures to be kept below dose limits and as low as reasonably achievable. The concept of dose constraints exists in regulations, but no figures have been provided in regulatory documents. The annual dose limits established in GA 55-2001 are in compliance with GSR part 3 except for annual equivalent dose for the lens of the eye (150 mSv). The regulatory framework requires DGE to establish and enforce requirements for the monitoring and recording of occupational exposures in planned exposure situations. For its internal control, DGE is developing with the support of the unit of nuclear application of MEM a database for recording occupational doses.

**Responsibilities of Registrants, Licensees and Employers**

GA 55-2001 assigns responsibilities to registrant and licensees for the protection of the workers and for compliance with the requirements of the regulations. These regulations require employers and licensees to ensure that optimization and dose limitations are applied. Main responsibility for safety is assigned to the licensee. Responsibilities of the licensee for providing means and resources for the radiation protection program, training on radiation protection as well as health surveillance of worker are established in the regulations. Licensee shall designate a Radiation Protection Officer (RPO) with the responsibility of developing the radiation protection program. Responsibility for promoting safety culture is included in the regulations, as well as responsibilities of licensee related to the protection of female worker and persons under 18 years of age undergoing training.

**General Responsibilities of Workers**

GA 55-2001 establishes that the worker is responsible for complying with safety regulations, for observing the radiation protection rules and for adequately using the radiological equipment provided by the licensee. Cooperation between employers and licensees for compliance with the safety requirements is established in this regulation as well. Sharing of information on previous occupational dose records of the workers is also addressed in regulation.

### Requirements for Radiation Protection Programmes

Regulations in place require licensees to establish and maintain organizational, procedural and technical arrangements for the designation of controlled and supervised areas, for local rules according and for monitoring of the workplace and workers as part of a radiation protection program for occupational exposure.

### Monitoring Programmes and Technical Services

Monitoring programs for the assessment of occupational exposure are addressed in regulations. For this assessment it is required to define the periodicity and the calculation methodology of calculation for the case of the evaluation of intake of radionuclides. Regulations establish that individual monitoring shall be provided to workers carrying out activities in controlled areas. In practice this is determined by the type of practice.

Individual dosimetry services for the control of external exposure are provided by two entities: the Unit of Nuclear Applications of MEM and a private entity. Currently about 3500 workers are monitored. Guatemala has one secondary standards dosimetry laboratory that provides calibration services of radiation protection equipment and in support of individual monitoring service. This laboratory is authorized for using cobalt-60 and cesium-137 sources and other radioactive sources for calibration. Guatemala does not have any internal dosimetry service.

### Training of Workers and Training Services

Requirements for training in occupational radiation protection are included in GA 55-2001. These requirements include provisions for education and training of radiation protection officers and for workers obtaining the operator license. There is a National Education and Training Strategy approved in order to raise the competence of the workers, RPOs and qualified experts. Furthermore, two documents were approved to establish training requirements for regulatory body staff and for different categories of workers, which were developed in the frame of a regional IAEA project. The IRRS Review Team was informed that professional associations provide radiation protection training courses.

## 11.3. CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISITNG EXPOSURES SITUATION; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

### Control of discharges and material for clearance

GA 55-2001 and GA 176-2015 establish requirements and generic criteria for the control of radioactive discharges to the environment. Responsibilities of licensees and requirements for authorization and setting of discharge limits based on characterization and evaluation of discharges are defined in GA 176-2015. A dose constraint of 100 μSv per year for the representative person due to authorized radioactive discharges has been defined in this regulation. Although requirements in regulations are in compliance with relevant requirements in GSR Part 3, the IRRS Review Team was informed and verified that in practice they are not enforced and discharge limits are not included in the conditions for the authorization of facilities and activities dealing with unsealed sources.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Requirements established in national regulations for the control of radioactive discharges to the environment are not enforced and discharge limits are not included in the conditions for the authorization of facilities and activities dealing with unsealed sources.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 31 states that** *"Relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization".* |
| **(2)** | **BASIS: GSR Part 3 Requirement 28 paragraph 3.123 states that** *"The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges. These operational limits and conditions:*<br>*……*<br>*(b) Shall correspond to doses below the dose limits with account taken of the results of optimization of protection and safety;…."* |
| **R(27)** | **Recommendation: DGE should enforce requirements established in national regulations for the control of radioactive discharges to the environment.** |

Criteria for clearance of materials from regulatory control are established in Regulation 176-2015. These criteria, as well as clearance levels included in the regulation are not in compliance with relevant requirements in GSR Part 3. Regulation considers the possibility of clearance of materials with radioactive content above these levels in specific situations after being properly authorized by the regulatory body (conditioned clearance).

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Criteria for clearance of materials from regulatory control and clearance levels included in the regulation are not in compliance with relevant requirements in GSR Part 3.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 8 states that** *"….. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control".* |
| **(2)** | **BASIS: GSR Part 3 Requirement 8 paragraph 3.12 states that** *"The regulatory body shall approve which sources, including materials and objects, within notified or authorized practices may be cleared from regulatory control, using as the basis for such approval the criteria for clearance specified in Schedule I or any clearance levels specified by the regulatory body on the basis of these criteria. By means of this approval, the regulatory body shall ensure that sources that have been cleared from regulatory control do not again become subject to the requirements for notification, registration or licensing unless it so specifies".* |
| **R (28)** | **Recommendation: DGE should establish criteria for clearance of materials from regulatory control, and clearance levels, in compliance with relevant requirements in GSR Part 3.** |

**Environmental monitoring**

Both (GA 55-2001) and (GA 176-2015) establish requirements for monitoring of radioactive discharges to the environment with purposes of radiation protection of the public. Provisions for monitoring in these regulations are not in full compliance with GSR Part 3. The IRRS Review Team was informed that, in practice, the requirements relevant for monitoring that exist in the regulations are not enforced and the implementation of monitoring programmes is not required for facilities and activities releasing radioactive materials to the environment.

The Unit of Nuclear Applications of MEM carries out a National Monitoring Program for evaluation of radiation level in soil, grass and water samples. Sampling places are established and results are recorded but they are not sent to DGE.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Requirements relevant for monitoring with public protection purposes in national regulations are not in full compliance with GSR Part 3 and are not being enforced by DGE for facilities and activities releasing radioactive materials to the environment.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 32 states that** *"The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available".* |
| **R (29)** | **Recommendation: DGE should establish and enforce requirements for monitoring with public protection purposes that are in compliance with relevant requirements in GSR Part 3.** |

**Existing exposure situations and control of radon**

In Guatemala no areas have been identified as contaminated with residual radioactive material. Scenarios of chronic exposure of the public to radiation have not been identified as well. Scope of requirements in Regulation (GA 55-2001) related to the control of chronic exposure situations is quite limited and they are not in compliance with requirements for existing exposure situations in GSR Part 3. Same conclusion can be drawn up regarding the control of exposures of the public to radon. For this last source of public exposure some studies are being carried out by the Unit of Nuclear Applications of MEM. Specific reference levels for exposure due to radionuclides in commodities have not been established in Guatemala.

At request of companies exporting certain commodities DGE issues certificates on radioactive content on the basis of the results of the analysis carried out by Unit of Nuclear Applications of MEM.

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| **Observation:** *Provisions in used national regulations for the protection of the public in existing exposure situations, including the control of the exposure to radon and exposure due to radionuclides in commodities, are limited, incomplete and are not in compliance with relevant requirements in GSR Part 3.* | |
| **(1)** | **BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that existing exposure situations that have been identified are evaluated to determine which ……* |

| RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES | |
|---|---|
| | *public exposures are of concern from the point of view of radiation protection".* |
| **(2)** | **BASIS: GSR Part 3 Requirement 50 states that** *"The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors".* |
| **(3)** | **BASIS: GSR Part 3 Requirement 51 states that** *"The regulatory body or other relevant authority shall establish reference levels for exposure due to radionuclides in commodities.* |
| **(4)** | **BASIS: GSR Part 3 Requirement 51paragraph 5.22 states that** *"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, each of which shall typically be expressed as, or be based on, an annual effective dose to the representative person that generally does not exceed a value of about 1 mSv".* |
| **R** | **Recommendation: see recommendations 21 in Section 9.1** |

## 11.4. SUMMARY

Guatemala legal and regulatory framework addresses medical and occupational exposure control, but in a way that it is not in full compliance with GSR Part 3. There is no a formal agreement between DGE and health authorities related to the control of medical exposure. The establishment of Diagnostic Reference Levels and patient release criteria, as well as provisions for reporting of accidental/unintended medical exposures are some of the areas where improvements should still be done. In addition, some of the existing regulatory provisions are not implemented. The contradiction in dose limits to the lens of the eye for workers exposed to ionizing radiation needs to be resolved.

Regulations establish provisions for the control of discharges and discharge limits are derived on the basis of dose constraints for public exposures. It was observed that national regulations for the control of radioactive discharges to the environment are not enforced and discharge limits are not included in the conditions for the authorization of facilities and activities dealing with unsealed sources. Criteria for clearance of materials from regulatory control and clearance levels included in Guatemala the regulation are not in compliance with relevant requirements in GSR Part 3. Requirements on monitoring with public protection purposes are not in full compliance with GSR Part 3 and are not being enforced by DGE. There are no reference levels for radon with public radiation protection purposes in regulations. Currently existing exposure situations due to the presence of radionuclides in commodities have not been identified and reference levels for them have not been established.

## APPENDIX I – LIST OF PARTICIPANTS

| | | |
|---|---|---|
| MILLER Chris | U.S. Nuclear Regulatory Commission (NRC) | Chris.Miller@nrc.gov |
| VLAHOV Nikolay | Bulgarian Nuclear Regulatory Authority | N.Vlahov@bnra.bg |
| GUTTERRES FRAGA Ricardo | Comissao Nacional de Energia Nuclear (CNEN) | rgutterr@cnen.gov.br |
| JOVA SED Luis | Centro Nacional de Seguridad Nuclear (CNSN) | jovaluis@gmail.com |
| PERRIN Marie-Line | France (ASN Retiree) | marie-line.perrin@wanadoo.fr |
| CORTES Alejandro | Comisión Nacional de Seguridad Nuclear y Salvaguardias (CNSNS) | acortes@cnsns.gob.mx |
| RAMIREZ-VERA Maria Luisa | Consejo de Seguridad Nuclear (CSN) | mlrv@csn.es |
| DWYER James | U.S. Nuclear Regulatory Commission (NRC) | James.Dwyer@nrc.gov |

## APPENDIX II MISSION PROGRAMME

### Sunday, 5 February to Tuesday, 14 February

| IRRS MISSION PROGRAMME | |
|---|---|
| **Sunday, 5 February** | |
| **IRRS Initial IRRS Review Team Meeting** | |
| 13:30 - 19:00 | Opening remarks by the IRRS Team Leader<br>Introduction by IAEA<br>Self-introduction of all attendees<br>IRRS Process (IAEA)<br>Report writing (IAEA)<br>Schedule (TL, IAEA)<br>First impression from experts arising from the Advanced Reference Material (ARM) (All Experts)<br>Administrative arrangements (DGE and IRRS Liaison Officer, IAEA): Detailed Mission Programme |
| **Monday, 6 February** | |
| **IRRS Entrance Meeting** | |
| 10:30 – 11:30 | 10:30 Arrival and registration |
| 11:30-12:30 | 11:30 Opening remarks NLO – Guatemala-IAEA<br>11:40 Welcoming Address – Minister of Energy and Mines<br>11:50 IRRS Coordinator – The IRRS programme<br>12:00 IRRS Team Leader – Expectations for the Mission and introduction of the<br>IRRS Team<br>12:20 Head of Department of Radiological Protection – Regulatory Overview, SARIS<br>results (strength, challenges, action plan) |
| 12:40 – 14:00 | Lunch and Welcome Activity (Minister of Energy and Mines) |
| 14:00 – 17:00 | Interviews and Discussions with Counterparts (parallel discussions) |
| 17:00 - 18:00 | Daily IRRS Review Team meeting |
| **Tuesday, 7 February** | |
| **Daily Discussions / Interviews** | |
| 09:00 – 17:00 | Interviews and discussions with counterparts (parallel discussions) |
| 12:00 – 13:00 | Lunch |
| TBD | Visit Ministry (TBD) (TL, TC, Reviewer Modules 1,2 and 3) |
| 17:00 – 18:00 | Daily IRRS Review Team meeting |
| **Wednesday, 8 February** | |
| **Daily Discussions / Interviews** | |
| 09:00 – 17:00 | Follow-up interviews and discussions with counterparts for all modules |
| 08:30 – 13:30 | Radiotherapy and nuclear medicine facility (CIO HOPE) am (Maria Luisa Ramírez-Vera) |

| IRRS MISSION PROGRAMME | |
|---|---|
| 07:30 – 13:30 | Industrial Irradiators facility (MOSCAMED) and Industrial Radiography facility-Gammagraphy- (Ricardo Gutterres, James Dwyer) |
| 08:30 – 13:30 | National Radioactive Waste Facility –CENDRA- (Luis Jova Sed) |
| 12:00 – 13:30 | Lunch |
| 13:30 – 17:00 | Report preparation |
| 17:00 – 18:00 | Daily IRRS Review Team meeting |
| **Thursday, 9 February** | |
| **Daily Discussions / Interviews** | |
| 09:00 – 16:00 | Follow-up Interviews and discussions with counterparts (parallel discussions) |
| 13:00 – 14:00 | Policy issue discussion: |
| 16:00 – 18:00 | Daily IRRS Review Team Meeting: recommendation, suggestions and good practices |
| **Friday, 10 February** | |
| | |
| 08:30 – Open | Report preparation |
| **Saturday, 11 February** | |
| | |
| 08:00 – 10:00 | Cross reading (TL, TC, Deputy TC and Administrative Assistant) |
| 10:00 | Final draft to be sent to Department of Radiological Protection, DGE - MEM |
| 10:00 – Monday | Department of Radiological Protection will analyze the final draft (DPSR) |
| **Sunday, 12 February** | |
| **Daily Discussions** | |
| 09:00 – | Free Day for experts : Cultural event |
| **Monday, 13 February** | |
| **Daily Discussions** | |
| 08:30– 10:30 | Department of Radiological Protection, DGE – MEM returns report with comments |
| 10:30- 12:30 | IRRS Team and DGE - final review |
| **Tuesday, 14 February** | |
| **Exit Meeting** | |
| 09:00 – 11:00 | Main findings of the IRRS mission (Team Leader)<br>Remarks by Ministry of Energy and Mines in response to the Mission findings.<br>Closing remarks by IAEA Official (TBD) |

# APPENDIX III SITE VISIT

| | |
|---|---|
| 1 | Radiotherapy and nuclear medicine facility (CIO HOPE) |
| 2 | Industrial Irradiators facility (MOSCAMED) |
| 3 | National Radioactive Waste Facility – CENDRA |

## APPENDIX IV LIST OF COUNTERPARTS

Mission Counterpart

- Luis Alejandro González Barrios
  Head of the Department of Safety and Radiological Protection (DPSR)

Module Counterparts DPSR

| | |
|---|---|
| • Pedro Flaviano Telón Bajxac | Official Inspector |
| • Carmen Jacqueline Patricia Feijoó Sánchez | Official Inspector |
| • Félix Aníbal Guzmán Castro | Official Inspector |
| • Mildred Angélica Jiménez de Mendoza | Official Inspector |
| • Yadira Celeste Santos Carias | Official Inspector |
| • Ana Lorena Donis Bolaños | Official Inspector |
| • Rosa Elisa Sagastume Lorenzo | Official Inspector |
| • Freddy Javier Estuardo Pérez Zelada | Official Inspector |
| • Cristian Alfredo Raxón Soc | Staff |
| • Edgar Méndez Subuyuj | Staff |

Interviewed People of DGE

| | |
|---|---|
| • Licda. Maria Andrea Batres | Head of Legal Department |
| • Licda. Silvia Alejandra Lemus | Human Resources Department |
| • Ing. Felipe Robles | Statistics Department |
| • Sr. Néstor Herrera | Administrative Department |
| • Sr. Roberto Joge | Financial Department |

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

| Area | | R: Recommendations S: Suggestions G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| 1. | RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT | R1 | **The Government should ensure that the national legal framework addresses all of the provisions for an effective legal and regulatory framework for safety, including:**<br>• **Graded approach for authorization, review and assessment and inspection;**<br>• **Provision for the involvement of interested parties and for their input to decision making;**<br>**Responsibilities and obligations in respect of financial provision for the management of radioactive waste and for decommissioning of facilities and termination of activities.** |
| | | R2 | **The Government should ensure that no promotional functions are assigned to DGE which might conflict with its regulatory responsibilities.** |
| | | R3 | **The Government should provide DPSR with sufficient human and financial resources to ensure that it fulfils the statutory obligation.** |
| | | R4 | **Government should ensure that appropriate arrangements are established for the effective coordination of all national authorities with responsibilities for safety.** |
| | | R5 | **Government should establish an effective system for protective actions to reduce undue radiation risks associated with unregulated** |

| Area | | R: Recommendations S: Suggestions G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | | **sources** |
| | | R6 | **The Government should develop the Action Plan for the implementation of the established policy on radioactive waste and review and update the policy as required.** |
| | | GP1 | **Guatemalan Strategy for improving national competency and the detailed gap analysis for the country's needs in different aspects of science and technology is commendable** |
| **2.** | **GLOBAL SAFETY REGIME** | S1 | **The Government should consider taking more benefit from the various IAEA peer review services.** |
| | | R7 | **DPSR should establish requirements and criteria for reporting of operating events by licensees. It should also establish a system for analysing events and disseminating the lessons learned within the country and internationally, as well as learning from and providing feedback to international networks.** |
| **3.** | **RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY** | R8 | **DGE should revise its decision to assign the non-ionising radiation to DPSR.** |
| | | R9 | **MEM and DGE should make the appropriate arrangements to ensure that all MEM facilities and activities are licensed or authorized.** |
| | | R10 | **DPSR should establish and implement a comprehensive training programme based on analyses of competence needs.** |
| | | S2 | **DGE should consider the use of technical advisory bodies of experts to support its decision making on important radiation safety issues.** |
| | | R11 | **DGE should ensure that justifications of decisions made are well documented and** |

| Area | | R: Recommendations S: Suggestions G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | | **available. Licensing arrangements should be revised to ensure consistency in order to build confidence among interested parties.** |
| **4.** | **MANAGEMENT SYSTEM OF THE REGULATORY BODY** | R12 | **DGE should establish and implement a comprehensive management system as stipulated in GSR Part 2.** |
| **5.** | **AUTHORIZATION** | R13 | **DGE should establish requirements and procedures for justification for all types of practices as appropriate.** |
| | | GP2 | **The regulatory website provides the applicants with forms, instructions and requirements for submitting an authorization, which is considered as a good practice** |
| | | R14 | **DGE should establish and clarify to operators the processes used to evaluate safety and to review applications for the authorization of radioactive waste management facilities and activities.** |
| | | R15 | **DGE, in the granting of an authorization for a radioactive waste management facility or an activity, should impose facility or activity specific limits, conditions and controls on the authorized party's subsequent activities and facilities.** |
| | | R16 | **DGE should require the operator to provide them solutions on how to safely manage this legacy site based on a safety case.** |
| **6.** | **REVIEW AND ASSESSMENT** | R17 | **DGE should, taking into account a graded approach, establish regulatory requirements on the maximum intervals for the update of the periodic safety assessment carried out by the licensee.** |

| Area | | R: Recommendations S: Suggestions G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | S3 | **DGE should consider revising the recently approved "Radiological safety file of the installation" to comply with the IAEA Safety Standards on safety assessment.** |
| **7.** | **INSPECTION** | R18 | **DGE should develop and implement a formal inspection programme of facilities and activities, following a graded approach, to confirm compliance with regulatory requirements and with any conditions specified in the authorization.** |
| | | R19 | **DGE should ensure that all facilities and activities with high risk are inspected on a regular basis.** |
| | | GP3 | **DGE is conducting proactive "verification" inspections to identify institutions and individuals who require an authorization but who have never applied, and require them to obtain authorization or cease their activities. This is considered a good practice.** |
| | | S4 | **DGE should consider conducting more unannounced inspections.** |
| **8.** | **ENFORCEMENT** | | |
| **9.** | **REGULATION AND GUIDES** | R20 | **DGE should continue efforts to implement the documents adopted in the country, considering the mandate of MEM, the scope of the IAEA standards and specific national circumstances.** |

| Area | | R: Recommendations S: Suggestions G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | | R21 | **DGE should revise the "Regulation on radioactive waste management" (Governmental Agreement No. 176-2015) to be fully in compliance with IAEA Safety Requirements Series.** |
| | | R22 | **DGE should fully implement the "Regulation on radioactive waste management" (GA 176-2015).** |
| | | R23 | **DGE should implement the regulatory framework in force for the safe decommissioning of facilities.** |
| **10.** | **EMERGENCY PREPAREDNESS AND RESPONSE-– REGULATORY ASPECTS** | R24 | **Recommendation: The Ministry of Energy and Mines should update the MA 72-2015 to take the requirements of GSR Part 7 into account.** |
| | | R25 | **DPSR should clearly establish dose limits for emergency workers and helpers during an emergency** |
| | | S5 | **DGE should consider implementing its Emergency Response Plan draft in a short timeframe**. |
| **11.1** | **CONTROL OF MEDICAL EXPOSURES** | R26 | **The Government should ensure that Diagnostic Reference Levels and criteria and guidelines for the release of patients are established.** |
| **11.2** | **OCCUPTIONAL RADIATION PROTECTION** | | |
| **11.3** | **CONTROL OF** | R27 | **DGE should enforce requirements established** |

| Area | | R: Recommendations S: Suggestions G: Good Practices | Recommendations, Suggestions or Good Practices |
|---|---|---|---|
| | **DISCHARGES, MATERIALS FOR CLEARANCE, AND EXISITNG EXPOSURES SITUATION; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION** | | **in national regulations for the control of radioactive discharges to the environment.** |
| | | R28 | **DGE should establish criteria for clearance of materials from regulatory control, and clearance levels, in compliance with relevant requirements in GSR Part 3.** |
| | | R29 | **DGE should establish and enforce requirements for monitoring with public protection purposes that are in compliance with relevant requirements in GSR Part 3.** |

# APPENDIX VI REFERENCE MATERIAL USED FOR REVIEW

- Decree Law 11-86, Control, Use and Application of Radioisotopes and Ionizing Radiation
- Governmental Agreement 55-2001, Regulation on Safety and Radiation Protection
- Governmental Agreement 176-2015, Regulation on Radioactive Waste Management
- Ministerial Agreement 67-2015, Guides to follow related to Radioactive Waste
- Ministerial Agreement 68-2015, Guides to follow related to Radioactive Sources and Radiation Generators
- Ministerial Agreement 69-2015, Guides to follow related to Training
- Ministerial Agreement 70-2015, Guides to follow related to Transport of radioactive material
- Ministerial Agreement 137-2016, Guides to follow related to Criteria for Medical Physics
- Ministerial Agreement 71-2015, Guides to follow related to Inspections
- Ministerial Agreement 72-2015, Guides to follow related to Radiological Emergencies
- Ministerial Agreement 73-2015, Guides to follow related to Fundamental Principles, Regulatory framework and new standards
- Ministerial Agreement 208-2016, Tariff of the DGE in matter of Radioisotopes and Ionizing Radiation
- Governmental Agreement 382-2006, Internal Regulation of Ministry of Energy and Mines
- Ministerial Agreement 178-2006, Internal Regulation of DGE-Direction General de Energy
- Government Agreement 67-2016, National Policy of Radioactive Waste
- Ministerial Agreement 08-2016, Education and Training Strategy

# APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW


1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1(Rev. 1) (Vienna2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY – Leadership and Management for Safety General Safety Requirement Part 2 (Vienna2016)
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).
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 VIII DGE ORGANIZATION CHART