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REVIEW SERVICE (IRRS)

MISSION

TO

LUXEMBOURG

Luxembourg

11-20 June 2018

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

Integrated
Regulatory
Review Service

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REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
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Mission dates:	*11 June-20 June 2018*
Regulatory body visited:	Ministry of Health, National Health Directorate, Department of Radiation Protection
Location:	Allée Marconi, Villa Louvigny L-2120, Luxembourg
Regulated facilities and activities in the mission scope:	Radiation sources in industrial and medical facilities, emergency preparedness and response, transport, medical exposure, occupational exposure
Organized by:	*IAEA*

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

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EXECUTIVE SUMMARY

At the request of the Government of Luxembourg, an international team of senior safety experts met representatives of the National Health Directorate (DiSa), Department of Radiation Protection (DRP) from 11 to 20 June 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review the Luxembourg regulatory framework for radiation safety. The mission took place at the premises of the Ministry of Health in Luxembourg. Meetings were organised with the Minister of Health Ms Lydia Mutsch, the Deputy Director of Health on Medical and Technical Matters Ms Elisabeth Heisbourg, the Deputy Director of Health for Administration Mr Xavier Poos and the Deputy Head of the High Commission on National Protection Mr Guy Bley.

The IRRS mission covered all civilian radiation sources facilities and activities regulated in the country. The radioactive waste management was not included in the scope of the IRRS mission, since Luxembourg will host an IAEA ARTEMIS Mission in September 2018. The review compared the Luxembourg regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS team members and the Luxembourg counterparts in the areas covered by the IRRS.

The IRRS team consisted of 8 senior regulatory experts from 8 IAEA Member States, one IAEA staff member and one IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, transport, and interface of safety with security. The areas of "Control of discharges, materials for clearance and existing exposures situation", and "Environmental monitoring for public radiation protection", were not included in the scope of the mission. Luxembourg will consider including these areas in the follow-up mission.

The IRRS mission included two policy issues discussions on the "Relation between a regulatory body and the licensees" and on the "Graded approach in the context of a small country". The outcome of the discussion will assist the DRP to further clarify the roles of the authorized parties and regulators and to formalize its interaction with them. DRP staff had also the opportunity to learn how regulatory bodies of other countries apply the graded approach to the authorization and inspection processes.

The mission included observations of regulatory activities and interviews and discussions with staff of the DRP. Activities included visits to the Rescue Services Agency, the Operation Centre (CGO), the 112 Call Centre and to the National Support Base (BNS). The IRRS team members observed the working practices during inspections carried out by the DRP, including discussions with the licensee personnel and management, at two facilities: Customs Truck Scanner and the Nuclear Medicine Department of the "Centre Hospitalier du Nord" (CHdN).

In preparation for the IRRS mission, the DRP provided the IRRS team with advance reference material and documentation including the results of the self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS team was extended full cooperation in regulatory, technical, and policy issues by all parties in a very open and transparent manner.

Luxembourg's legal and regulatory framework for safety attributes regulatory tasks to the Minister of Health, the National Health Directorate and the Department of Radiation Protection. The revision of the framework on the occasion of transposing the new BSS Council Directive 2013/59/Euratom provides a unique opportunity to Luxembourg to further enhance the regulatory control in the country and its compliance with the international safety standards.

The IRRS team observed that the DRP counterparts were committed to provide the regulatory oversight of all activities with radiation sources and for continuous improvement of safety. The invitation of the IRRS mission demonstrates the Government's and the DiSa/DRP commitment to improve the national legal and regulatory framework for radiation safety.

The IRRS team identified good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards. The IRRS team recognized that some of its findings confirmed the actions identified by the DRP as result of its self-assessment.

The good practices identified by the IRRS team concern Luxembourg's active participation in international activities for the enhancement of the global safety regime and the accomplishment of international best practices within the national emergency preparedness and response plan.

The IRRS team identified certain issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system. In this respect, recommendations and suggestions for improvements were provided, including:

- The Government should:
    - establish a national policy and strategy for safety;
    - define functions and responsibilities of the regulatory body within the legal framework and establish mechanisms to ensure its effective independence;
    - provide to the DRP the authority to issue technical requirements and guidance for implementation of regulations;
    - make provision for building and maintaining the competence and for the recognition of qualification for safety.
- DRP should:
    - establish an integrated management system, including a policy document, human resources plan, technical guides, processes and procedures;
    - formalize its interactions with authorized parties in carrying out its regulatory functions and responsibilities;
    - implement an inspection programme for all facilities and activities.
- The Government and DRP should revise the legal and regulatory framework to bring it in line with IAEA GSR Part 3 for strengthening the control of medical and occupational exposures.

The IRRS team findings are summarized in Appendix V.

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

Luxembourg is committed to publish the present report.

I. INTRODUCTION

At the request of the Government of Luxembourg, an international team of senior safety experts met representatives of the National Health Directorate (Direction de la Santé, DiSa) / Department of Radiation Protection (Division de la Radioprotection, DRP) from 11 to 20 June 2018 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Luxembourg regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Luxembourg in 22 July 2014. A preparatory mission was conducted 10-11 October 2017 at the DRP premises in Luxembourg to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Luxembourg and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS mission covered all civilian radiation sources facilities and activities regulated in the country. The radioactive waste management was not included in the scope of the IRRS mission, since Luxembourg will host an IAEA ARTEMIS Mission in September 2018.

The IRRS review team consisted of 8 senior regulatory experts from 8 IAEA Member States, one IAEA staff member and one IAEA administrative assistant.

The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, transport and interface of safety with security. The areas of "Control of discharges, materials for clearance and existing exposures situation" and "Environmental monitoring for public radiation protection", were not included in the scope of the mission. Luxembourg will consider including these areas in the follow-up mission. In addition, policy issues were discussed, on the "Relation between a regulatory body and the licensees" and on the "Graded approach in the context of a small country".

DRP conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the DRP self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics within the agreed scope through review of the Luxembourg advance reference material, conduct of interviews with management and staff from DRP and direct observation of DRP regulatory activities at regulated facilities. Meetings with the Minister of Health Ms Lydia Mutsch, the Deputy Director of Health on Medical and Technical Matters Ms Elisabeth Heisbourg, the Deputy Director of Health for Administration Mr Xavier Poos and with the Deputy Head of the High Commission on National Protection Mr Guy Bley were also organized. Activities included visits to the Rescue Services Agency, the Operation Centre (CGO), the 112 Call Centre and to the National Support Base (BNS). The IRRS team members observed the working practices during inspections carried out by DRP, including discussions with the licensee personnel and management, at two facilities: the Customs Truck Scanner and the Nuclear Medicine Department of the "Centre Hospitalier du Nord" (CHdN).

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Luxembourg 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 Luxembourg with the exception of the management of radioactive waste. It is expected this IRRS mission will facilitate regulatory improvements in Luxembourg and other Member States, utilising the knowledge gained and experiences shared between DRP and IRRS reviewers, and the evaluation of the Luxembourg regulatory framework for radiation safety, including its good practices.

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

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;
c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
d) promoting the sharing of experience and exchange of lessons learned among senior regulators;
e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;
f) providing the host country with recommendations and suggestions for improvement;
g) providing other states with information regarding good practices identified during 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 of the IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Luxembourg, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 10 to 11 October 2017. The preparatory meeting was carried out by the appointed Team Leader Ms Isabel Villanueva and the IRRS IAEA Team Coordinator Ms Vasiliki Kamenopoulou.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of DRP represented by Mr Patrick Majerus, 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.

- Radiation sources facilities and activities;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Selected policy issues.
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Mr Patrick Majerus made presentations on the national context, the current status of DRP 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 Luxembourg in June 2018.

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

The DRP Liaison Officer for the IRRS mission was confirmed as Mr Patrick Majerus.

DRP provided IAEA with the advance reference material (ARM) for the review at the begining of April 2018. In preparation for the mission, the IAEA review team members reviewed the Luxembourg ARM 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 and the Code of Conduct on the Safety and Security of Radioactive Sources, were used as review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 10 June 2018 in Luxembourg, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. IAEA NSRW Director Mr Peter Johnston attended the meeting. The list of the IRRS team menbers in given in Appendix I. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 11 June, 2018, with the participation of DiSa and DRP senior management and staff. Opening remarks were made by Mr Xavier Poos, Deputy Director of Health for Administration and Mr Peter Johnston, Director, Division of Radiation, Transport & Waste Safety, IAEA, Ms Isabel Villanueva, IRRS Team Leader and Ms Vasiliki Kamenopoulou IRRS Team Coordinator. Mr Patrick Majerus, Head of DRP and IRRS host Liaison Officer gave an overview of the Luxembourg context, DRP 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 Luxembourg and DRP 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 team performed its review according to the mission programme given in Appendix II.
The IRRS exit meeting was held on Wednesday, 20 June 2018. The opening remarks at the exit meeting were presented by Mr Patrick Majerus and were followed by the presentation of the results of the mission by the IRRS Team Leader Ms Isabel Villanueva. Closing remarks were made by Ms Elisabeth Heisbourg, the Deputy Director of Health on Medical and Technical Matters and by Ms Vasiliki Kamenopoulou, on behalf of the Director of the IAEA Division of Radiation, Transport and Waste Safety.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

Luxembourg has a governmental, legal and regulatory framework for safety in place that is based on the European Directives provisions. The main pieces are the Law of 1963 on the Protection of the public against the hazards of ionizing radiation (LRP63) with its amendments and the Regulations of 2000 concerning the Protection of the population against the dangers arising from ionising radiation (RRP00).

Within the legislation, regulatory tasks are attributed to the Minister of Health (Ministre de la Santé), the National Health Directorate (Direction de la Santé, DiSa) and the Department of Radiation Protection (Division de la Radioprotection, DRP), that constitute the Regulatory Body for safety in Luxembourg.

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The legislative framework for safety includes references to the Government's commitment to safety, and some of the important elements of a national policy and strategy for safety, such as the fundamental safety objective to protect people from harmful effects of ionizing radiation, the promotion and implementation of research in the field of health, including protection from ionizing radiations etc. However, some other important elements of policy and strategy for safety are not reflected in the legislation, such as the need and provision for human and financial resources development mechanisms for taking account of social and economic aspects; the bases for a graded approach are not established.

The Government has not published a clear statement to express a long-term commitment to safety and to cover all the relevant elements of the national policy and strategy in line with IAEA GSR Part 1 (Rev.1). This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A few elements of a national policy and strategy for safety are included in the legislation. However, the Government has not promulgated any statement on national policy and strategy for safety expressing long term commitment to safety including elements related to the need of provisions for human and financial resources, adequate mechanism for taking account of social and economic developments, promotion of leadership and management for safety, safety culture.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 1 states that "***The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*
R1	**Recommendation: The Government should establish a comprehensive national policy and strategy for safety.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

A legislative framework for radiation safety has been in place in Luxembourg since 1963 when LRP63 was enacted. This law, subsequently amended in 1995, constitutes the legal basis for regulating any use of ionizing radiation.

The legislative and regulatory system also comprises the following:

- Law of 1980 on the organisation of the National Health Directorate (LDS80);
- Law of 10 August 1983 concerning the medical use of ionising radiation (LUM83);
- Regulation of 11 August 1996 concerning the provision of information to the population on the applicable measures for the protection of public health and on the conduct to be adopted in the event of a radiological emergency (RIU96);
- Regulation of 14 December 2000 concerning the protection of the population against the dangers arising from ionizing radiation (RRP00);
- Regulation of 16 March 2001 on the sanitary protection of individuals against the dangers of ionising radiation during medical exposures (RUM01);
- Regulation of 3 March 2009 on the supervision and control of shipments of radioactive waste and spent fuel.

As Luxembourg is a member state of the European Union, the law and regulations have been amended several times in order to transpose into the national regulatory framework the Euratom Directives as well as the international modal transport regulations.

In particular, the RRP00, adopted in the context of the transposition of the Council Directive 1996/29/Euratom, has been amended for the transposition of directives issued in the fields of control of high-activity sealed radioactive sources and orphan sources (Council Directive 2003/122/Euratom), nuclear safety of nuclear installations (Council Directive 2009/71/Euratom) and on responsible and safe management of spent fuel and radioactive waste (Council Directive 2011/70/Euratom).

LDS80 assigns to the DRP of DiSa the authority for all aspects related to the protection against the risk of ionizing and non-ionizing radiation, nuclear safety and safety of radioactive waste management. LDS80 has been amended for the last time on 24 November 2015.

Medical exposures are regulated by the Law of 10 August 1983 concerning the medical use of ionizing radiation (LUM83) and by the regulation of 16 March 2001 on the health protection of individuals against the dangers of ionizing radiation during medical exposures (RUM01).

Maximum permitted levels of radioactive contamination of foodstuffs are directly applicable in Luxembourg, as in all EU member states, through specific Regulations of the European Parliament and the Council.

The Government is in the process of adopting a new law on radiation protection transposing the new Council Directive 2013/59/Euratom. This new law will replace LRP63 and LUM83 and the implementing regulations will replace RRP00 and RUM01.

The IRRS team was informed that new legislation will cover all the items listed in GSR Part 1 (Rev.1), Requirement 2. Also, IRRS team was informed that the new legislation will have a provision on the prohibition of construction and operation of nuclear installations in the country.

The new legislation will establish provisions related to the involvement of interested parties and their input into the decision-making process, as well as provisions assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities.

Even if the primary responsibility for safety is assigned to the license holder, for medical exposure the assignment of responsibilities is still not clear. This issue is addressed in **Recommendation 20** in Section 11.

Specific provisions on the interface between safety and security are not in place. This issue is addressed in **Recommendation 24** in Section 12.

According to the Constitution, matters related to health are regulated by law and this applies on radiation safety regulations as well. This is a lengthy process. Since the radiation safety regulations often contain several technical requirements and provide for the issuing of guidance for their implementation, the need for their update is frequent. The IRRS team was informed that as such, the promulgation of radiation safety related regulations takes 2 to 4 years.

Since the DRP does not have the power to bring into force technical requirements and regulatory guidance documents, delay is created for the implementation of changes in international standards, requirements and best practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *DRP does not have the power to bring into force technical requirements and regulatory guidance documents and delay is created for the implementation of changes in international standards, requirements and best practices.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 2, para 2.5 (9) 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:… (9) The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of regulations and preparing guidance for their implementation;*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 32 states that "***The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.*
R2	**Recommendation: The Government should make provisions to give the DRP the authority to issue binding technical requirements as well as guidance for implementation of regulations.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The LDS80 on the organisation of the National Health Directorate assigns regulatory duties to the DiSa with its DRP in relation to the protection of the population against the hazards of ionizing and non-ionizing radiation, as well as nuclear safety and the safety of radioactive waste management. Additionally,

LRP63 and RRP00 indicate which regulatory decisions are to be taken by the Minister of Health and which decisions are to be taken by the Director of Health (DiSa); the role of each of these administrations in the licensing process for different categories of installations is defined.

The Minister of Health has certain responsibilities regarding hospitals in financial assistance and planning, but does not have operational or managerial responsibilities in the hospitals. The IRRS team was informed that licensing decisions taken by the Minister of Health are based on advice given by the DRP and this advice has always been followed. However, the legislation does not entitle the DRP to make legally binding advice.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *(a) The Minister of Health has certain responsibilities regarding hospitals in financial assistance and planning.* *(b) In practice, the regulatory decisions on safety taken by the Minister of Health are always in line with an advice given by DRP, even if the legislation does not entitle DRP to provide advice of a binding character to the Minister of Health.* *(c) According to the organizational structure of DiSa, the Head of the DRP reports to the Deputy Director of Health.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 4 states that "***The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 4. para. 2.8 states that** "*To be effectively independent from undue influences on its decision making, the regulatory body:* *(c) Shall be able to make independent regulatory judgements and regulatory decisions, at all stages in the lifetime of facilities and the duration of activities until release from regulatory control, under operational states and in accidents;* (*e) Shall be able to give independent advice and provide reports to government departments and governmental bodies on matters relating to the safety of facilities and activities. This includes access to the highest levels of government."*
(3)	**BASIS: GSR Part 1 (Rev.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."*
R3	**Recommendation: The Minister of Health should establish a mechanism to ensure the effective independence of the DRP.**

The IRRS team also noted that the legislation does not include arrangements to provide DRP with the competencies, functions and resources required to fulfil its regulatory duties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *LDS states that the DRP is the authority for all the matters concerning the protection against ionizing and non-ionizing radiations, nuclear safety and the safety of radioactive waste management. However, there are no legal dispositions providing DRP authorities, functions and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
resources to fulfil the regulatory duties.	
(1)	**BASIS: GSR Part 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 statutory obligation for the regulatory control of facilities and activities."*
R4	**Recommendation: The Government should establish the regulatory body within the legal framework and define its functions and responsibilities.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

In the legislation a set of responsibilities (including radiation safety) are defined, that are allocated to the "head of the establishment". It is also stated that these responsibilities cannot be delegated.

However, in the legislation there are no provisions related to the responsibility of the "head of the establishment" to verify that products and services provided by suppliers meet its expectations (e.g. in terms of completeness, validity or robustness) and that they comply with regulatory requirements. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission. Additionally, the legislation does not have provisions for the "head of the establishment" to actively evaluate progress in science and technology as well as relevant information from the feedback of experience, in order to identify and to make those safety improvements that are considered practicable.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The legislation does not have provisions on the "head of the establishment" responsibility to verify that products and services provided by suppliers meet its expectations, and to evaluate progress and make safety improvements that are considered practicable.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 6 states that** *"The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 6 para 2.14 states that** *"The legal framework for safety shall be established in such a way that the authorized party retains the prime responsibility for safety throughout the lifetime of facilities and the duration of activities, and shall not delegate this prime responsibility. Responsibility for safety may be transferred to a different authorized party when there has been a declared change, approved by the regulatory body, of general responsibility for a facility or activity. In addition, responsibility for safety may extend to other groups associated with the authorized party, such as designers, suppliers, manufacturers and constructors, employers, contractors, and consignors and carriers, in so far as their activities or products may be of significance for safety. However, in no case may this extension of responsibility relieve the authorized party of the prime responsibility for safety. The authorized party has the responsibility for verifying that products and services meet its expectations (e.g. in terms of completeness, validity or robustness) and that they comply with regulatory requirements)."*
(3)	**BASIS: GSR Part 1 (Rev.1) Requirement 6 para 2.15A states that** *"The person or*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	organization responsible for a facility or an activity, having prime responsibility for safety, shall actively evaluate progress in science and technology as well as relevant information from the feedback of experience, in order to identify and to make those safety improvements that are considered practicable."
R5	**Recommendation: The Government should establish provisions on the licensee's responsibility:** **(a) to verify that products and services provided by suppliers meet expectations for safety;** **(b) to actively evaluate progress in science and technology as well feedback of experience, in order to identify and to make safety improvements that are considered practicable.**

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

The DRP cooperates frequently with other authorities on aspects related to radiation safety. DRP performs joint inspections with other departments of DiSa in the medical field or performs controls of drinking water and cooperates with other competent authorities in the fields of fire protection (Rescue Services Agency), industrial safety (Inspectorate of Workplaces), transport and Emergency Preparedness and Response (EPR).

The IRRS team noted that the coordination and liaison with other competent authorities is not established in a formal manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DRP cooperates with other authorities on aspects such as industrial safety, transport, EPR, fire protection. However, this coordination is not formalized.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 7 states that** "*Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
(2)	**BASIS: GSR Part 1 (Rev.1), Requirement 7, para 2.18 states that** *"…The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such: …* *(11) Safety in the transport of dangerous goods, including nuclear material and radioactive material;* *… 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….."*
S1	**Suggestion: The DRP should consider formalizing coordination with other authorities having responsibility for safety so as to improve cooperation and liaison.**

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

RRP00 provides for detection and control of orphan sources. This is considered as the most relevant situation of unregulated risk potentially present in the country. In particular, these provisions assign the responsibility to instruct and inform workers at scrap metal recycling facilities and at facilities with significant modal transport activities or goods transit points. In case of orphan source events, information to the general public is provided through DiSa.

According to the regulations, the State covers intervention costs for the recovery of orphan sources, if the owners of the sources cannot be identified. The IRRS team was informed that the new law will define in a more precise and clear manner the responsibilities for detection and management of contaminated material potentially related to an orphan source.

RRP00 includes provisions related to the control of exposure situations arising from natural radiation. The IRRS team has been informed that in the new regulations a provision will be included stating that in case of an existing exposure situation with concerns from a radiation protection point of view, the Minister of Health may take decisions on protection or remedial measures. With these new provisions DiSa would be authorized to introduce optimised protection strategies for managing contaminated areas, ensuring that arrangements are in place for the control of exposure.

Regulations do not include the concept of reference levels to existing exposure situations; IRRS team has been informed that this concept will be introduced in new regulations.

The IRRS team has been informed that the DRP is in charge of the radiological assessment during an emergency or an existing exposure situation. Based on the assessment, DRP recommends protective actions to the decision maker. The DRP is responsible for assessing the effectiveness of a protective action from a radiological point of view and for the exchange of information with the authorities in other countries.

Issues related to the control of existing exposure situations will not be further elaborated in the present report since they are not included in the scope of the IRRS mission.

1.7. COMPETENCE FOR SAFETY

According to the legislation, certain professional positions having responsibility for safety need appropriate qualification. However, no specific requirements for the necessary level of competence and training for professionals (medical physicists, radiation protection officers (RPO), qualified experts (QE), occupational physicians charged with the medical supervision of exposed workers, medical and paramedical staff) are established. In addition, requirements for continuous training are not established. The qualification of the RPO is verified during the licensing of a facility. The other experts will need an authorization by the Minister of Health.

The IRRS team was informed that the new law, and its associated regulations, will introduce specific requirements for the necessary level of training of RPOs, RPEs, occupational physician charged with the medical supervision of exposed workers and medical physics experts. Requirements for on-going training will be also included.

The legislation does not contain provisions for building and maintaining expertise within DRP. A strategic plan for the continuous training of the DRP staff (e.g. inspectors) has not been established. In relation to training programmes the IRRS team was informed that considering the dimension of the country, the plan is to use training opportunities abroad. In this regard it is recognized that the establishment of specific agreements is not considered necessary as training courses are generally open to participants from Luxembourg.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Within legislation:* *(a) There are no specific requirements for the necessary level of competence and training for professionals having responsibility for safety (Medical Physicists, RPO, QE, occupational physicians charged with the medical supervision of exposed workers, medical and paramedical staff);* *(b) There are no provisions for the formal recognition of qualified experts;* *(c) Requirements for staff continuous training are not established.* *A strategic plan for the continuous training of DRP staff (e.g. inspectors) has not been established.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 11 para 2.36 (b,c) states that**. *"The government:* *(b) Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety;* *(c) Shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18 para 4.11 states that "***The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(3)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18, para 4.13 states that "***A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. 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."*
(4)	**Basis GSR Part 2 Requirement 9 states that** "*Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them."*
(5)	**BASIS: GSR Part 3 Requirement 2, para 2.21 states that** *"The government shall ensure that requirements are established for:(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;"*
(6)	**BASIS: GSR Part 3 Requirement 2, para. 2.22 states that** *"The government shall ensure that arrangements are in place for the provision of the education and training services required for building and maintaining the competence of persons and organizations that have responsibilities relating to protection and safety."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(7)	**BASIS: GSR Part 3 Requirement 4, para. 2.46 states that** *"The relevant principal parties shall ensure that qualified experts are identified and are consulted as necessary on the proper observance of these Standards."*
(8)	**BASIS: GSR Part 3 Requirement 35 states that** *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfil the requirements for education, training and competence in the relevant specialty."*
(9)	**BASIS: RS-G.1.5 para. 2.70 states that:** *"Changes that occur in equipment, instrumentation, practice, monitoring methods, recommendations and regulations make it essential that all the individuals involved in the use of ionizing radiation sources receive not just initial but also continuing education and training."*
R6	**Recommendation: The Government should make provision for building and maintaining the competence and for the recognition of qualification of all parties having responsibilities in relation to the safety of facilities and activities.**

1.8. PROVISION OF TECHNICAL SERVICES

The DRP offers services for personal dosimetry. DRP provides also through its laboratory radiation measurements on environmental samples and environmental monitoring throughout the country. The IRRS team has been informed that the new law will include more detailed provisions to allow commercial providers to offer dosimetry services in the country.

Within regulations there are criteria for approval of individual dosimetry services.

A laboratory for calibration of equipment does not exist in the country. The DRP accepts calibration certificates from calibration services in other countries.

1.9 SUMMARY

A few elements of a national policy and strategy for safety are included in the legislation. The Government should therefore establish a comprehensive national policy and strategy for safety.

A legislative framework on radiation safety has been in place in Luxembourg since 1963.

The law briefly states that the DRP has jurisdiction for all issues related to the protection against ionizing and non-ionizing radiations, nuclear safety and the safety of radioactive waste management. Additionally, within the legislation regulatory tasks are attributed to the Minister of Health, the National Health Directorate (DiSa) and the Department of Radiation Protection (DRP) that constitute the Regulatory Body for safety in Luxembourg. The Government should clearly establish the regulatory body within the legal framework and define its functions and responsibilities and should make provisions to give to the DRP the authority for issuing technical regulations and guidance.

The Government should make provision for building and maintaining the competence and for the recognition of qualification of all parties having responsibilities in relation to the safety of facilities and activities.

The Minister of Health has certain responsibilities regarding hospitals in the area of financial assistance and planning and issues authorizations for facilities and activities (based on DRP advice). In this respect, the Minister of Health should establish a mechanism to ensure the effective independence of the DRP.

In relation to the coordination and liaison with other authorities having responsibility for safety, the DRP should consider formalizing existing relationships.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Provisions for the active participation of Luxembourg representatives in international fora and activities are included in the law and regulations.

Luxembourg has ratified all international conventions relevant to safety. Only the conventions on nuclear liability have not been ratified.

Luxembourg has expressed its political support to the Code of Conduct on the Safety and Security of Radioactive Sources and its Supplementary Guidance on the Import and Export of Radioactive Sources and their provisions were reflected into the national regulations in 2006.

Regarding peer reviews, Luxembourg is having this current IRRS mission and has asked an IAEA ARTEMIS mission which will take place in the current year.

Luxembourg has put in place agreements with neighboring countries (France and Belgium) for exchanging information in case of emergencies and on nuclear safety.

The DRP is the point of contact for the relevant to safety international organizations (EC, IAEA, OECD/NEA, UNSCEAR, WHO).

Luxembourg has a remarkable pro-active attitude towards the objective of strengthening the global safety regime, given the small size of a non-nuclear country. In particular:

- The DRP Head and staff actively participate, contribute and report to international or European associations and networks, such as ENSREG, WENRA, HERCA, ERPAN, EAN;
- Luxembourg has provided officers for the review meetings of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and of the Convention on Nuclear Safety (CNS);
- The DRP has further contributed to the European Stress Test by providing an expert for the peer review and a chairperson for the meetings on public communication;
- The DRP provides an independent expert at the reactor safety expert group of the French regulatory body (ASN).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Luxembourg is a small non-nuclear country that is participating in a very pro-active manner, in international fora and activities aiming to the strengthening of the global nuclear safety regime.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 14, par. 3.2 (e) states that** "*Regular multilateral and bilateral cooperation between the relevant national and international organizations to enhance safety by means of harmonized approaches as well as to increase the quality and effectiveness of safety reviews and inspections, by means of sharing of knowledge and feedback of experience."*
GP1	**Good Practice: Active participation in many international activities related to nuclear safety shows how small non-nuclear countries can contribute to enhance global safety regime.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The DRP through its participation in European and international fora and networks disseminates and shares regulatory experience.

In the regulations there are provisions for reporting of significant events and within license conditions such a requirement is included. A mechanism for analyzing the reported events is not in place; this issue is further elaborated and addressed in **Suggestion 6** in Section 11. Therefore, the analysis of operating experience is mostly based on experience from other countries.

2.3. SUMMARY

Luxembourg is a contracting party to safety related international conventions and agreements. DRP receives relevant information from other States and from authorized parties through its participation in a wide variety of regional and international meetings. Luxembourg's participation in international fora and activities in a very pro-active manner towards the strengthening of the global safety regime, has been acknowledged.

In the regulations there are provisions for reporting of significant events and within license conditions such a requirement is included. Since a mechanism for analysing the reported events is not in place, the analysis of operating experience is mostly based on experience from other countries.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The LDS80 assigns regulatory duties to the National Health Directorate (DiSa) with its Department of Radiation Protection (DRP) in relation to the protection of the population against the hazards of ionizing and non-ionizing radiation, as well as nuclear safety and the safety of radioactive waste management.

LRP63 and RRP00 indicate which regulatory decisions are to be taken by the Minister of Health and which decisions are to be taken by the Director of Health (DiSa). In particular, the role of each of these administrations in the licensing process for different categories of installations is defined.

The organizational structure of DiSa is enclosed in Appendix VIII. DRP is one of the 9 Departments of DiSa.

DiSa has prepared a strategic work programme for the period 2018-2021; a chapter is dedicated to the DRP activities. This document states that the DRP has two strategic priorities:

- The continuous improvement of the regulatory control of practices using ionizing radiation;
- The strengthening of efforts in preparedness and response for radiological emergencies.

"Taking into account the number of received applications in the previous years this programme also sets the plan for the number of authorizations to perform (about 150 per year), transit applications to approve (about 400 by year) and recognition of professionals (about 25 per year)". All activities carried out by DRP are financed via State budget on an annual basis. These financial resources allow the DRP to fulfil its obligations. The DRP has the main responsibility for the implementation of the allocated budget. The exception is the budget for travel expenses, which is common for the Ministry of Health and the DiSa.

The budget proposal is prepared by DRP annually in accordance with its foreseen needs and it is approved by the Minister of Health and the Minister of Finance.

In order to receive the budget for additional staff, the DRP must justify its needs. Those are validated first by the Director of Health, then by the Minister of Health who transmits the request to the Minister of Finance. If accepted, the Minister of Finance includes the budget credits and the posts for new staff into the draft law for annual budget, which is then voted by the Parliament. In order to ensure the stability of the budget, the provision for financial resources should be included in the national policy and strategy. This issue is addressed in **Recommendation 1** in Section 1.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The Minister of Health has certain responsibilities regarding hospitals in financial assistance and planning, but does not have operational or managerial responsibilities in the hospitals.

The LDS80 defines the functions and competences of DiSa, whereas the RRP00 includes more detail on its functions and competences.

DiSa performs its functions through the DRP. The IRRS team was informed that the regulatory decisions taken by the Minister of Health or by the Director of Health are based on non-legally binding advice given by DRP. This issue is addressed in **Recommendation 3** in Section 1.

Additionally, the legislation does not establish legal dispositions providing DRP with competences, functions and resources to be effectively independent in its safety related decision making. This issue is addressed in **Recommendation 4** in Section 1.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The DRP total staff of 15 persons includes 9 experts on safety, all of them holding M.Sc. Degree. New staff is recruited through an open recruitment process: public announcement, preselection, interview and final selection are foreseen. Qualification is the main selection criterion.

The staff of the DRP are civil servants and public employees with permanent positions and the IRRS team was informed that staff turnover is minimal. Additionally, none of the experts working for DRP has previously worked in an authorized party. The IRRS team was informed that the average age of DRP`s staff is 46 years old. Due to the young staff composing the DRP, a plan to preserve staff knowledge within the organization in relation to future retirement has not been established.

There is no a human resources plan for the DRP stating the number of staff necessary and the essential knowledge, skills and abilities for them to perform their regulatory functions.

The IRRS team was informed that currently the number of experts composing the DRP staff allows them to properly discharge their functions. IRRS team was informed that the new regulations will assign to DRP new responsibilities and functions. A new human resources plan would be required to establish the number of staff necessary to perform the regulatory functions.

DiSa has drafted a document with the job description of all staff. The IRRS team was shown some examples of job description files of some DRP staff members. These files include the identification of the position, main functions, activities and the skills and abilities requested for this position.

For newly recruited staff there is an initial training programme on matters of public administration and the functioning of public service. There is no specific training programme on safety and radiation protection matters, but in some DRP positions the knowledge on these matters are a precondition. The necessity of establishing a strategic plan for continuous training of the DRP staff, is more critical for the inspectors training. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DRP has developed a strategic plan of activities for the coming years, as part of the more general plan of DiSa. However, there is no human resources plan that establishes the number of staff necessary and their essential knowledge, skills and abilities to perform the necessary regulatory functions.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.11 states that** "*The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	abilities for them to perform all the necessary regulatory functions."
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18, para. 4.12 states that** "*The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
R7	**Recommendation: The DRP should develop a human resources plan that establishes the number of necessary staff and the essential knowledge, skills and abilities.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

IRRS team was informed that the DRP has used the support of an external TSO in limited occasions. The DRP has not allocated for this activity its regular annual budget, but is able to request additional budget during the budget year. When it has been necessary, the DRP has requested the budget and it was approved according to the procedure described in Section 3.1.

Although the DRP does not have documented procedures on how to carry out this process, the IRRS team was informed that in order to avoid any conflict of interest, the organizations selected for providing these services would be organizations acting as TSO for regulatory bodies of other countries.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The DRP has not established formal mechanisms and ways of communication with authorized parties on safety related issues. The IRRS team observed that the mechanisms of communication are frequently based on informal relations as correspondence by email, oral communication and informal meetings.

The authorized parties have direct access to the DRP staff for addressing technical and regulatory issues. The DRP experts regularly provide advice on safety related matters to the authorized parties. This is viewed as benefit for the authorized parties but it builds a relationship that could generate the risk of leading to confusing roles and responsibilities in situations when the DRP exercises its regulatory functions, such as inspections. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission; additionally, the policy issue discussion held during the mission addressed this subject.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *DRP experts regularly provide advice on safety related matters to the authorized parties. This interaction enables the authorized parties to address technical and regulatory matters but presents the risk of confusing the respective roles and responsibilities.*	
(1)	**BASIS: GSR Part 1, (rev.1) Requirement 21 states that "***The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison."*
(2)	**BASIS: GSR Part 1, (rev.1) Requirement 21 para 4.24 states that** *"As its primary purpose, the regulatory body shall carry out oversight of facilities and activities. The regulatory body, while maintaining its independence, shall liaise with authorized parties to achieve their common objectives in ensuring safety…."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *DRP experts regularly provide advice on safety related matters to the authorized parties. This interaction enables the authorized parties to address technical and regulatory matters but presents the risk of confusing the respective roles and responsibilities.*	
(3)	**BASIS: GSR Part 2, Requirement 5 states that** *"Senior management shall ensure that appropriate interaction with interested parties takes place."*
R8	**Recommendation: The DRP should formalize its interaction with authorized parties in carrying out its regulatory functions and responsibilities.**

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The processes carried out by the DRP in exercising its functions are not documented. DRP has not put in place policies or procedures within an integrated management system which could be used to provide a formal process based on fulfilling the regulatory functions. This lack makes it more difficult to prevent subjectivity in decision making by individual staff members of the DRP. The issue of the establishment of a management system is addressed in **Recommendation 10** in Section 4 and the issue of the lack of safety requirements and guidance for safety of radiation sources, transport activities, and review and assessment is addressed in **Recommendation 16** in Section 9.

The Minister of Health, the Director of Health or the DRP do not communicate the basis of their decisions to the interested parties (e.g. authorization, licensing conditions, etc). This issue is addressed in **Suggestion 3** in Section 5.

3.7. SAFETY RELATED RECORDS

The DRP has established and maintains the following main registries, mostly in hard copies and some in electronic format:

- Folders containing documentation submitted by the facilities (containing communications and exchange of information, license and inspection reports);
- An inventory of radiation sources;
- An archive with the individual dose records;
- Records on the environmental monitoring programme;
- Records on radon measurements performed for establishing the national radon map.

The DRP has two databases for radiation sources registry, one for medical applications and one for industrial/research ones. The DRP is encouraged to combine the two separate radiation source databases into one single national radiation source register.

The IRRS team was informed that the DRP has as objective to improve the individual dose records in short term by developing a new national dose registry. Additionally, the DiSa has started a process for the establishment of an integrated management system, including objectives to improve the DRP safety related records.

RRP00 requires that all documents related to authorizations issued by competent authorities are managed and recorded by the DRP, and also that the DRP is responsible for maintaining the inventory of the substances, materials and equipment at class I to IV facilities and activities. The IRRS team was informed that the new law will include the requirement for the DRP to maintain registries.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

RRP00 requires that public consultation is needed for the licensing process of class I and class II facilities and activities. The IRRS team was informed that the new regulations will only provide for public consultation for class I facilities and activities.

DRP has not developed a communication plan with the interested parties. DiSa has started a process for the establishment of the integrated management system which will establish processes and plans identifying appropriate means for routine and effective communication with interested parties on nuclear safety and radiation protection matters. This issue is addressed in **Recommendation 10** in Section 4.

The Minister of Health has developed an internet portal providing information on issues related to DRP´s duties and functions, such as relevant legislation, explanations and guidance for interested parties. However, there is no mechanism in place to inform authorized parties on regulatory body decision making.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DRP does not make information on regulatory decisions and inspection findings related to authorized facilities and activities publicly available.*	
(1)	**BASIS: GSR Part 1 Requirement 36 para 4.66 (d) 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:* *d) Communication on the requirements, judgements and decisions of the regulatory body, and on the bases for them, to the public;"*
S2	**Suggestion: The DRP should consider making regulatory documents (e.g. authorizations, inspection reports) and their respective bases for decision publicly available.**

3.9. SUMMARY

Regulatory decisions taken by the Minister of Health and by DiSa are based on regulatory advice given by DRP, however there is no legal provisions establishing a legal binding character for this advice. The current legislation does not establish the legal dispositions for providing DRP with competences, functions and resources to be effectively independent in its safety related decision making.

A human resources plan needs to be developed for the DRP, based on the assessment of staffing and their essential knowledge, skills and abilities to perform its regulatory functions.

The DRP interacts with authorized parties frequently and it should formalize this interaction.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

The DiSa and the DRP are in the process of establishing a management system. Towards this direction, a new top management team has been appointed in 2016 consisting of the General Director, the Deputy Director of Health for medical and technical matters and the Deputy Director of Health for administration matters and a working group consisting of the department heads and an external consultant has been formed.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The top management of the DiSa has made efforts to develop a common identity, including individual and institutional values and expectations. The issuing of identification badges and the drafting of clear job descriptions for each staff member are the first steps. Many discussions have been held to draft a common mission and policy document as the initial step to find a clear connection between the mandate of the DiSa and the DRP, and the role of each individual staff member.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no provisions or arrangement in place within the DiSa demonstrating managerial leadership and commitment for safety.*	
(1)	**BASIS: GSR Part 2, Requirement 2 states that** *"Managers shall demonstrate leadership for safety and commitment to safety."*
(2)	**BASIS: GSR Part 2, Requirement 3, para 4.2 states that "***Senior management shall be responsible for establishing safety policy."*
R9	**Recommendation: The DiSa should develop a policy document with the mission, vision, behavioral expectations, individual and institutional values and expectation for safety within the management system in line with IAEA Safety Standards.**

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The DiSa has started establishing a management system in 2016 following a legal obligation laying down the general status of the State officials. With the aid of an external consultant, the DiSa is in the process of developing a strategic plan to include the mission, strategic priorities and current activities of each department as well as the projects that are planned for the next three-year period. Since the DRP is a department within the DiSa, it contributes to the development of DiSa management system by drafting and integrating the parts relevant to its functions and responsibilities. As such, the DRP in 2015 has drafted a strategic work plan which has been updated at the end of 2017. Measurable safety goals in line with the strategic work, plans and objectives for each unit have not been set by the DRP; safety is not explicitly addressed in the DiSa work plan. This observation is addressed in **Recommendation 9 and Recommendation 10** in Sections 4.1 and 4.3 respectively.

4.3. THE MANAGEMENT SYSTEM

The elements of the management system for the DiSa and the DRP do not bring together in a coherent manner all the necessary requirements for safety; the basic components of a safety culture are also missing. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

The organization chart of the DRP is developed considering its current tasks. All DRP staff were involved in the chart development. The chart is approved by the DiSa. There is no provision to identify any changes in the management system (including organizational changes) that could have significant implications for safety and to ensure that these changes are appropriately analyzed.

According to a graded approach, the DRP has defined priorities to areas with high potential of radiation exposure; however, the graded approach concept is not reflected within routine regulatory functions.

Only a small part of the processes, procedures and records is documented such as job descriptions, inspection check lists and templates of the inspection reports; the documentation is not controlled. Most of the manuals and records are in draft forms and have not been incorporated into the management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DiSa and the DRP are in the process of establishing a management system, which does not include all the necessary elements relevant to safety (e.g. strategy, measurable goals, identification of processes - authorization, inspection and review and assessment - graded approach, documentation of the records and procedures, determination of competence and resources, measurement and assessment of the effectiveness of the management system and for leadership for safety).*	
(1)	**BASIS: GSR Part 1 (Rev.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."*
(2)	**BASIS: GSR Part 2, Requirement 3 states that** *"Senior management shall be responsible for establishing, applying, sustaining and continuously improving a management system to ensure safety."*
(3)	**BASIS: GSR Part 2, Requirement 4 states that** *"Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy.*
(4)	**BASIS: GSR Part 2, Requirement 6 states that** "*The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised*."
(5)	**BASIS: GSR Part 2, Requirement 7 states that** "*The management system shall be developed and applied using a graded approach*."
(6)	**BASIS: GSR Part 2, Requirement 8 states that** "*The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use*."
(7)	**BASIS: GSR Part 2, Requirement 9 states that** "*Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them*."
(8)	**BASIS: GSR Part 2, Requirement 13 states that** "*The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety*."
(9)	**BASIS: GSR Part 2, Requirement 14 states that** *"Senior management shall regularly*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	commission assessments of leadership for safety and of safety culture in its own organization."
R10	**Recommendation: The DiSa and the DRP should establish, implement, assess and continuously improve a documented integrated management system to ensure safety, using graded approach, in line with IAEA safety standards.**

4.4. MANAGEMENT OF RESOURCES

Annually, the DRP identifies the needs and proposes the budget needed to accomplish its tasks, including the new staff to be employed. The process of approving and hiring new staff requires long time. For the non-routine tasks, the strategic work plan of the DRP defines the financial and human resources needed for their accomplishment.

The staff of the DRP is encouraged to participate in training programmes relevant to their duties for one to two weeks per year, either by visiting similar organizations or by participating in seminars. Moreover, the DRP uses the training provided by the National Institute of Public Administration to all public administrations. However, there is no formal process regarding the training of the DRP staff in performing their assigned tasks including the fostering of a safety culture and the relevant requirements of the management system. Moreover, there is no formal procedure for the identification of competences and resources the organization should retain or should develop internally, and which competences and resources may be obtained externally, for ensuring safety.

The above observation is addressed in **Recommendation 6** in Section 1.7 and **Recommendation 10** in Section 4.3.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

Regarding the conduct of the DRP's projects, their progress and the respective reports are documented. However, processes and activities have not been identified, developed or documented. There are no process maps, including interfaces or interactions between processes having safety as first priority, inputs, outputs and measurable goals. There are no documented procedures for authorisation, inspection and review and assessment. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

The above observation is addressed in **Recommendation 10** in Section 4.3.

4.6. CULTURE FOR SAFETY

Frequent exchanges and discussions within the staff of the DRP are encouraged. Meetings take place whenever needed to develop a common position on safety related aspects. However, there is no fixed frequency or agenda for these meetings prepared in advance. The reporting of problems related to technical, human and organizational factors is encouraged, either directly to the department head or to the human resources department of the DiSa or to the top management team of the DiSa. This ensures that employees feel free to report any incident that may influence safety related process and/or procedures. Moreover, the top management team of the DiSa has appointed a contact person to whom anyone can raise any issues without fear of harassment, intimidation, retaliation or discrimination.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The management system does not include any provision for the assessment of its effectiveness. There is, however, a non-formal review of the strategic work plan of the DRP. The top management team of the DiSa reviews the strategic work plan of the DRP and schedules a meeting with the department head for discussing the findings of the review.

No independent assessment is foreseen within the management system and no assessment or self-assessment of leadership for safety and of safety culture are commissioned.

The above observations are addressed **in Recommendation 10** in Section 4.3.

4.8. SUMMARY

The DiSa and the DRP are in the process of establishing a management system. This system does not include all the necessary elements relevant to safety; moreover, identification and development of the basic processes and activities related to safety as well as the relevant documentation are missing. The DiSa and the DRP should develop a strategic plan and allocate the relevant resources.

Though progress has been made in the last two years by the top management team, there is still a lack in the demonstration of leadership for safety to establish and implement an integrated management system demonstrating leadership for safety and commitment to safety in accordance with IAEA standards.

5. AUTHORIZATION

5.1. GENERIC ISSUES

RRP00 provides for the Ministry of Health to regulate by license the production, manufacture, holding, sale, import, transport, export, transit or disposal of radioactive material or apparatus capable of emitting ionizing radiation.

According to a graded approach based on radiation risk, the facilities or activities with radiation sources are categorized into four classes (I to IV). Authorization of classes I to III is performed through licensing, while for class IV notification is needed. Class IV concerns radiation sources below the exemption levels as defined in IAEA GSR Part 3. Licenses for class I and II facilities are issued by the Minister of Health, while those for class III are issued by the Director of Health. Exemption levels are listed in the Annex of RRP00.

The license applications are reviewed and assessed by the DRP. The DRP drafts the license including the license conditions and provides this document to the Minister of Health or the Director of Health. Non-legally binding advice is provided by the DRP. This observation is further elaborated in Section 1 and addressed in **Recommendation 3** in Section 1.

The type of documentation to be submitted for the request of an authorization for the different classes is given in the RRP00. The applications for authorization of class I and class II facilities are sent for public consultation to the local communities of the planned facility or activity. IRRS team was informed that in the new legislation, public consultation will only be required for class I facilities.

For license application the DRP has developed standard forms which are provided upon request (in case of industrial facilities and activities) or are available on the Ministry of Health portal (in case of transport). The applicant is not required to use the standard forms. For license applications for medical facilities or activities, application forms are not available.

The legislation does not provide for different types of authorization for the different stages in the lifetime of a facility or the duration of an activity. However, since no nuclear facilities are or will be built in the country, the need for such a provision is rather limited and some examples given (e.g. establishment of a radiotherapy center) demonstrate that the legislation provides sufficient flexibility.

Licenses are generally issued for a period of five years, after which a new license application is required.

The use of license conditions is an important way to include safety requirements in addition to those stated in RRP00. As an example, dose constraints can be included as license conditions which are facility or activity specific. The license conditions depend on the type of facility or activity and the DRP has drafted templates of these license conditions for each type of facility or activity in the industrial area. The DRP has not made these templates available to the interested parties.

The Minister of Health or the Director of Health or the DRP have no legal authority to change license conditions or add license conditions during the period of validity of a license.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The legislation does not provide to the Minister of Health or the Director of Health or DRP the legal authority to change license conditions during their validity period.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 24 para 4.36 states that** *"An authorization may have to be reconsidered and/or renewed in the different stages in the lifetime of the facility or the duration of the activity concerned (e.g. as a result of a change in the conditions under which the authorization was granted). This would have to lead to a new regulatory decision which may require the amendment, renewal, suspension or revocation of the authorization."*
R 11	**Recommendation: The Government should make provisions to enable the license conditions to be changed during their validity period, if needed.**

The IRRS team was informed that few licenses issued under previous legislation without an expiring date are still valid, because the legislation subsequently entered into force had no transitional dispositions stating that licenses issued under the previous regime had to be renewed.

There are typically up to 60 applications for licenses each year, including 25 applications for dredging vessels with an expiry period of one year, and 10 to 15 transport licenses. License holders often apply for changes in the license terms.

The justification and bases of authorization or license conditions are not automatically communicated to the applicant, unless the authorization is denied. This information is communicated to the applicant only upon request.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: (a) *License conditions relevant to safety are included in the authorisation documentation which is granted by either the Director of Health or the Minister of Health depending on the class that the practice belongs to. However, the generic license conditions are not made available in advance to the interested parties.* *(b) When a regulatory decision on authorisation is issued, its basis and justification is not provided to the applicant unless the authorization is denied.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 24, para 4.39 states that** *"The regulatory body shall record formally the basis for its decision on the authorization of a facility or an activity, or on its amendment, renewal, suspension or revocation, and shall inform the applicant, in a timely manner, of its decision, and provide the applicant with reasons and a justification for the decision."*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 34 states that "***The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available."*
(3)	**BASIS: GSR Part 1 (Rev.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, and shall provide adequate coverage commensurate*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	with the radiation risks associated with the facilities and activities, in accordance with a graded approach"
(4)	**BASIS: GSR Part 1 (Rev.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."*
S3	**Suggestion: The Minister of Health, the Director of Health and DRP should consider making available in advance the generic license conditions to the interested parties and providing to the applicant in a timely manner the justification for their regulatory decisions.**

The authorization process to be followed by the regulatory staff is not documented within the management system. This observation is addressed in **Recommendation 10** in Section 4.

5.2. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

For all sources above the exemption levels an authorization is required, even for low risk facilities (e.g. dental X-rays). Applicants are required to submit a facility design plan and risk assessments to support license applications. The total amount of licensees is about 135, including 4 hospitals and 1 radiotherapy centre.

The DRP requests to be notified for all radiation sources, even for sources that are below the exemption levels. The DRP maintains a register of licensed and notified sources. The register however is split in two parts: sources used for non-medical applications and sources used for medical purposes.

Regarding the authorisation of facilities or activities with radioactive sources, and in addition to the above, evidence should be shown in the application for authorisation that there is an agreement with the supplier to take back the source at the end of its useful life. Another prerequisite for a high activity sealed source is the liability assurance which will also cover the insolvency of the licensee.

DRP is motivated to reduce the number of disused sources in the country. Recent campaigns in this respect have significantly reduced the number of disused sources, especially within schools. DRP is planning to expand the campaigns in pharmacies and to the general public. DRP considers these campaigns very successful since they contribute to reducing the radiation risks significantly.

There are no facilities in Luxembourg to recycle or collect disused radioactive sources. Luxembourg has a bilateral agreement with Belgium under which radioactive waste can be stored in Belgium.

Financial security arrangement to cover disposal costs at the end of the life-cycle of radioactive sources and measures concerning site security are foreseen in RRP00.

Transfers of radioactive sources from or to other EU Member States are regulated in accordance with the Council Regulation 1493/93.

5.3. AUTHORIZATION OF TRANSPORT

According to RRP00, the Minister of Health has the responsibilities of the competent authority in respect of matters relating to the carriage of class 7 radioactive materials, including the approvals required by the SSR-6. However, within the legislation, the authority to issue approvals based on the SSR-6 is not clearly stated. This issue is addressed in **Recommendation 4** in Section 1.

Compliance with the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) is included as a condition in the authorization. Compliance with the modal regulations (e.g. ADR, IACO-TI) is a requirement in RRP00 and is expressed also as a license condition. Other commonly used license conditions include the UN numbers of allowed packages and the requirement to contact DRP in case of incidents. In case of foreign carriers, conditions are similar to those of the home country.

In addition to the authorization of transport as a practice, each transit of radioactive material through Luxembourg requires an authorization. These transits mainly go through the national airport, and a special electronic system is in place to facilitate this. Carriers are requested to inform the DiSa of their transports every three months.

Authorizations are valid only for a given period of time. A new carrier's authorization is usually valid for one year, and should be renewed by applying at least 2 months before it is due to expire. The information to be provided in the application is given in RRP00. All the requirements for carriers in SSR-6 are not included in this information. The Government could benefit from including more elements from the SSR-6 in the application for an authorization, such as the radiation protection programme and the management system to further enhance the compliance with the SSR-6 provisions.

There is no process or guidance on issuing the transport approvals. This issue is addressed in **Recommendation 10** in Section 4. It should be noted that there is no manufacture or design of material or packages requiring such competent authority approval (special form radioactive material, low dispersible radioactive material, fissile material, packages containing 0.1 kg or more of uranium hexafluoride, Type B(U), Type B(M) packages or Type C packages) in Luxembourg, nor has there been an application for transport under special arrangements.

Other authorities than the Minister of Health, have also a role in the transport of radioactive material and other dangerous goods, such as Customs, Police and the Department of Transport (within the Ministry of Sustainable Development and Infrastructure) that authorizes air transport of other dangerous goods. There are communications on a working level but this coordination is not formalized. For example, there is an open communication between the Department of Transport and the DRP regarding authorization of airlines and changes in authorization (black listing of airlines). Contrary, joint roadside inspections are rare, due to organizational or coordination reasons. The coordination between different authorities should be enhanced and formalized. This issue is addressed in **Suggestion 1** in Section 1**.**

Training certificates for transport are given by the Department of Transport. Training for class 7 drivers (ADR) or the ICAO-TI are given abroad.

5.4. SUMMARY

The classification of facilities (class I-IV) provides for a graded approach in the authorization process. Notification is applied for class IV and licensing for all other classes. According to the regulations, the

Minster of Health (for class I and II facilities) and the Director of Health (for class III facilities) have the legal right to issue licenses which are prepared by the DRP.

The legislation does not provide for different types of authorization at different stages in the lifetime of a facility or the duration of an activity. Licenses are generally issued for a period of five years.

The generic license conditions are not made available to the interested parties. Specific license conditions for each facility or activity are usually included in the license documents and cannot be changed once a license is issued. As such, the Government should make provisions for changing license conditions, if needed, and make available in advance the generic license conditions to the interested parties.

Luxembourg complies with the international regulations for the transport of dangerous goods, including radioactive materials. The Minister of Health authorizes the transport of radioactive material for both modes of transport. Compliance with the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) is included as a condition in the authorization.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

The DRP reviews and assesses authorization documents to evaluate whether the facilities and activities comply with the regulatory requirements of RRP00.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

A graded approach to the process of review and assessment is implicitly built in, by the fact that the requirements for the license applications are different for the different classes of facilities and activities, since the classification scheme is based on the risk of the sources.

No documented process, including guidance and criteria for performing review and assessment, are available for the DRP staff. This issue is addressed in **Recommendation 10** in Section 4.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The documents provided to the DRP with the application for the authorization of medical facilities or activities are produced by the applicant in conjunction with a foreign specialized company. The medical staff of DRP usually discusses with the applicant and with the specialized companies on the technical information to be provided in the license application and on calculation codes to be used to verify the required shielding.

The IRRS team was informed that in many authorization applications the DRP gives technical advice about the required radiation protection measures which should be taken. This is because the legislation does not require the authorized party to obtain the services of QE. The IRRS team has been informed that in the new legislation provisions will be included to request the applicant to appoint RPOs and QEs to be consulted for advice. This issue is addressed in **Recommendation 6** and **Recommendation 8** in Section 1.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Review and assessment is based on the information submitted by the applicant. This includes design plans, risk assessments and waste management plans. In case of facilities and activities of class I and class II with high activity sources, a safety report should be provided. This documentation can be taken as the safety assessment which forms the basis for DRP's review and assessment. The safety assessment is expected to demonstrate the implementation of fundamental safety principles, including justification and optimization of protection. The IRRS team was informed that in the new legislation there will be a requirement to submit a risk assessment for occupational exposure.

For new practices there is no guidance on justification. No information is available on which practices are justified with generic justification in Luxembourg. This issue is addressed in **Recommendation 15** in Section 9. On the contrary, the medical equipment regulations contain a list of equipment which is allowed. The IRRS team was informed that in the new legislation provisions will be made for the justification of practices.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

Usually review and assessment is carried out by one staff member of the DRP. In case of a high- risk practice or a new type of practice, more staff members are involved. Advice from an external independent expert may also be sought during this process.

According to the RUM01, the DRP receives yearly quality assurance reports from the hospitals. These reports are reviewed and assessed by the DRP, but the results of the review and assessment are not documented. If during the review and assessment process the DRP finds any non-conformities, a letter is sent to the hospital or to the practitioner.

The documentation related to review and assessment of license applications is archived.

6.2. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The paragraph 6.1 above essentially covers the review and assessment for radiation sources facilities and activities and is thus not repeated in this paragraph.

6.3. REVIEW AND ASSESSMENT FOR TRANSPORT

The review and assessment of applications for new or for renewal of transport authorization for all modes is undertaken by the DRP. In case of a foreign applicant, the review and assessment is not done in depth since the DRP relies on the carrier's license issued by another country. The DRP has appointed a member of the staff to review and assess transport applications.

Within the DRP there is no documented process, including guidance and criteria to be used for review and assessment of applications from domestic and foreign applicants, available for the staff. This issue is addressed in **Recommendation 10** in Section 4.

A formally established coordination between the DRP and the Department of Transport might strengthen the review and assessment process especially with air transport. This issue is addressed in **Suggestion 1** in Section 1.

6.4. SUMMARY

The DRP reviews and assesses applicant information to determine whether the facilities and activities comply with the regulatory requirements. The classification of facilities provides for a graded approach in the review and assessment process.

Review and assessment is carried out before issuing a license, upon receipt of a request for an amendment to a license, during regulatory inspections and at the license renewal stage. It is usually carried out by one or more DRP staff members depending on the complexity of the case.

As RPOs and QEs have not been recognised yet, the DRP may provide technical advice to the authorised parties. If needed, during the review and assessment process, DRP may request advice from external independent experts.

The process of review and assessment is not sufficiently documented; guidance to the authorized parties is not available. The DRP should document the process for review and assessment including guidance and criteria to be used for by domestic and foreign applicants.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION PROGRAMME

The DRP has established an inspection program, where the type of inspections to be performed is defined (routine inspections, reactive and additional inspections, prior to operation inspections and end of authorization inspection) together with the related scope and frequency.

The frequency is defined for the different classes (yearly for class I, every 2 years but preferably yearly for class II and between 3 and 5 years for class III). An inspection guidance has been developed that gives an outline on the inspection process (preparation, conduction, reporting and follow-up of non-compliances). This guidance also contains a list of typical non-conformities with reference to the regulations. There are annexes for non-medical, medical and thematic inspections.

The DRP does not establish an annual inspection plan. The inspections to be performed are based on the date of the last inspection performed, non-conformities recently found, incidents reported, etc.

In some cases, newly introduced practices may need to be inspected prior to the authorization.

The IRRS team was informed that the DRP conducts 20-30 inspections per year in the non-medical facilities and activities. Apart from a few inspections in the medical facilities and activities in the last years, between 5 and 10 acceptance tests are done every year and around 5 inspections of dental facilities. The number of inspections planned to be performed every year according to the strategic plan 2018 -2021 of the DiSa is 70.

In the medical field, new radiation sources are frequently installed and the DRP inspectors always perform acceptance tests in public hospitals. This activity presents the risk of confusing the respective roles and responsibilities between the regulatory body and licensees. This issue is addressed in **Recommendation 8** in Section 3.

For private practitioners, acceptance tests and yearly quality assurance tests are performed by foreign consultants. When a licensee terminates its activities and when there is a significant risk of activation or of contamination, the DRP inspection programme foresees an inspection in order to release the site.

The IRRS team was informed that in the medical field not many regular inspections have been performed. Regarding hospitals, the DRP mostly performs visits and audits to verify the compliance with regulations. An important subject dealt in this respect is the exposure of patients.

Dental facilities are inspected mostly by performing reactive inspections.

The IRRS team was informed that for some foreign companies (about 10) authorized in Luxembourg to perform industrial radiography and density measurements using mobile sources, only a few inspections have been performed in the past; inspections in these companies are not included in the inspection programme. The information on when and where these activities are performed is made available to the DRP only on short notice since these activities are performed irregularly. Foreign transport companies

who are authorized in Luxembourg (about 50 transporters) are not included in the inspection program for the same reason.

Regularly, the non-conformities in the non-medical field are collected and analysed. The results are used in the planning of the forthcoming inspections. Results can also be used to inform licensees about regulations or safety issues. Daily there is exchange of information between inspectors and other staff of the DRP.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DRP does not:* • *perform regulatory inspections to 10 authorized foreign companies that perform activities in the country with radiation sources and 50 authorized foreign transport companies.* • *fully implement an inspection programme for medical facilities and activities.* • *inspect licensee arrangements for EPR or exercise performance of class I and II licensees that are required to have emergency plans and perform emergency exercises.*	
(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 7 Requirement 2, para. 4.13 states that** *"The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions. Appropriate emergency arrangements shall be established by the time the source is brought to the site, and complete emergency arrangements shall be in place before the commencement of operation of the facility or commencement of the activity. The regulatory body shall verify compliance with the requirements for such arrangements."*
R12	**Recommendation: The DRP should implement an inspection programme covering all facilities and activities and all topical areas (such as EPR), including medical facilities and activities and foreign companies which have been authorized to perform in the country, taking into account the graded approach.**

7.1.2. INSPECTION PROCESS AND PRACTICE

The regulatory processes, including the inspection, have not been formally documented in internal procedures since the management system is still under development. The need to establish, implement, assess and continuously improve a documented integrated management system to ensure safety, using graded approach, in line with IAEA safety standards is addressed in **Recommendation 10** in Section 4.

The DRP makes use of inspection checklists for their inspections, both for inspections in medical and for non-medical facilities and activities. These checklists contain an extensive range of topic to be inspected, like radiation protection procedures, inventory of sources, display of radiation signs in appropriate language, designation of controlled and supervised areas, access control, equipment for occupational dosimetry and area monitoring etc.; radiation measurements and wipe testing by the DRP inspectors are also performed.

An inspection is normally conducted by one inspector but in the case of a complex facility more than one inspectors may be involved. The inspections are announced by a letter to the licensee, in which the purpose, the schedule and the required documents for the inspection are outlined. An inspection commences with an entrance meeting at which the inspector informs the RPO of the licensee on the purpose of the inspection, the areas to be inspected and the structure/format of the inspection. If needed, a representative from licensee's senior management is expected to be present. The inspection involves review of documents, visiting the areas where radiation sources are used and/or stored appropriate to the scope of the inspection. The inspection ends with an exit meeting in which the inspector explains any identified non-conformities and possible corrective measures to be implemented. The inspection reports are prepared according to standard formats. When possible, non-conformities are evidenced with a photo in the report.

The inspection reports are signed by the inspector. There is no performance indicator for the timing to transmit the inspection report to the licensee. The licensee is required to address the non-conformities within a certain timeframe, usually a few months, depending on the seriousness of the non-conformity. The inspection reports are archived. The database of licensees contains information on the most recent inspection dates and dates of the follow-up corrective actions.

The IRRS-team observed that in the medical field some inspections are performed as acceptance tests. In such cases the DRP checks the lay-out and the shielding of the room of new equipment and the installed equipment or radioactive sources. These visits are not conducted as regular inspections but the DRP informs the licensee about the results of the test performed. This issue is addressed in **Recommendation 8** in Section 3**.**

7.1.3 INSPECTORS

LRP63 assigns Doctors of the DiSa, Radiation Protection Experts, nuclear engineers and staff members of the DRP amongst others the authority to identify non-compliances with the radiation protection regulations. There are differences in the assignments of inspectors, depending on their professional status: "civil servants" or "public employees". Only "civil servants" have the authority to conduct inspections.

The legislation does not provide to the inspectors of DRP with administrative rights to have unconditional access to the facilities of licensee. Also, they have no authority to require documents, samples, pictures or any other information needed for the evaluation of the inspection. Three DRP inspectors are entitled with the power of police officers. They can use their authority when they suspect serious non-conformities. In that case they have the right to enter any premises and require documents, samples, pictures etc. When an inspector acts as a police officer he acts under the jurisdiction of the federal prosecutor.

The DRP has not issued any guidance for newly hired inspectors who have worked previously for authorized parties. It would be helpful to issue guidance on the engagement with these authorized parties (like performing inspections or review and assessment of license applications or safety reports), to be able to secure the independence of the DRP in these activities. DRP is encouraged to include such guidance within its management system.

There is no documented training program for inspectors to develop and maintain the necessary competence and skills to perform inspections in their specific field of competence.

Staffing and training of inspectors is addressed in Section 3.3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The legislation, does not assign to DRP inspectors the authority for free access to facilities to carry out regulatory inspection at any time, with the exception of cases of suspicion of serious non-compliances. Additionally, the authority of performing inspections is granted only to a part of DRP inspectors that belong to the category of "fonctionnaires" and not to other staff members that have similar duties, qualification, competence and training.*	
(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, para. 4.52 states that** *"The regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach."*
(3)	**BASIS: GSR Part 1 (Rev.1) Requirement 4, para. 2.13 states that** *"The regulatory body shall be conferred with the legal authority to require an authorized party or an applicant, whether a person or an organization, to make arrangements to provide:* *(a) All necessary safety related information, including information from suppliers, even if this information is proprietary;* *(b) Access, solely or together with the authorized party or applicant, for making inspections on the premises of any designer, supplier, manufacturer, constructor, contractor or operating organization associated with the authorized party."*
R13	**Recommendation: The Government should make provisions for the DRP to assign the duties of the inspectors and to have the authority for unconditional access to the facilities and to their safety related information in order to perform regulatory inspections.**

7.2. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

In general, the inspection program, processes and practices are discussed in Section 7.1 above and is thus not repeated here.

7.3. INSPECTION OF TRANSPORT

The DRP is responsible for the inspections of all modes of transport of radioactive material. In practice this includes only road and air, since radioactive material is not transported by other means in Luxembourg.

Inspections of transport activities are done regularly, but there is no inspection program. In case the authorized party carries the radioactive sources that it possesses (such as industrial radiography), inspection can include transport or focus only on transport issues (thematic inspections). During

inspections the conformity with basic transport requirements, such as training, vehicle markings and documentation is assured and non-conformities identified.

The 2 domestic road carriers and 3 domestic air carriers, are inspected. The companies authorized to carry their own radioactive sources (e.g. industrial radiography companies) are inspected. Foreign road carriers (around 50) are not inspected. There are approximately 400 transits of radioactive material through Luxembourg yearly, mostly through the national airport. Most packages transported in Luxembourg are for medical purposes within the category of excepted or Type A packages.

The documentation required the by the SSR-6 related to radiation protection programme and to the management system is not inspected. Some elements of the management system (e.g. instructions, incidents, notification, follow-up) have been checked during air carrier inspections. The DRP has not established the requirements for an acceptable management system (SSR-6 para. 306).

DRP might benefit from formalizing its coordination with the Department of Transport in conducting air carrier inspections. This issue is addressed in **Suggestion 1** in Section 1.

The Customs perform searches of illicit items in trucks at different locations in Luxembourg. The searches might also include inspection of the radioactive contents of a package. The locations are secure and conform to the SSR-6 relevant provisions.

All the packages for the transport of radioactive material in Luxembourg are designed and manufactured abroad, and the DRP has not inspected the documentary evidence of the compliance of the package design.

7.4. SITE VISITS

Observations of inspections conducted

The IRRS team members observed the working practices during inspections carried out by DRP, including discussions with the licensee personnel and management, at two facilities: the Customs Truck Scanner and the Nuclear Medicine Department of the “Centre Hospitalier du Nord” (CHdN).

Customs Truck Scanner

The IRRS team members observed an inspection of a Customs mobile truck scanner which operates an accelerator. Customs operate in a number of locations in Luxembourg where they scan trucks for illegal cargo. The sites are individually authorized and detailed requirements are given in license conditions.

Two DRP inspectors conducted the inspection both having agreed on their tasks prior to the inspection; checklists were used to record the findings.

The inspection began with a short entrance meeting to introduce the participants. The inspectors checked the Customs procedures for informing the truck driver about the inspection and the importance of emptying the truck of passengers (a Customs information sheet in almost all European languages is used for this purpose) as well as the function of the mandatory infrared switches that turn off the accelerator if needed. Dose rate measurements were performed using both inspectors and Customs equipment.

Some non-conformities relevant to calibration of equipment were recorded and the inspectors informed the Customs officials accordingly. At the end of the inspection the IRRS team had the opportunity to discuss in private with the Customs officials on site. The officials expressed appreciation of the inspection and the inspectors. It became, however, apparent that the Customs relies on the DRP advise for the safety of its actions (e.g. the DRP provided training to the Customs RPO). This issue is addressed in **Recommendation 8** in Section 3.

In general, the inspection was carried out in a professional and open manner.

Nuclear Medicine Department of the "Centre Hospitalier du Nord" (CHdN).

The inspection began with an entrance meeting where the participants introduced themselves. The meeting was attended by all relevant parties of the establishment, including the manager, RPO, medical physicists, medical radiological technologist and one nuclear medicine doctor.

The DRP had officially announced the inspection in advance and had asked certain documents to be delivered prior to the inspection which had been reviewed. Some deficiencies had been discovered which were discussed during the meeting.

The hospital has been built in 2005 and several audits or visits have been performed by the DRP, however, this was the second regulatory inspection performed. During the audits some non-conformities with the authorization application and conditions had been discovered.

The IRRS team members observed one inspection focusing on occupational exposure and one on medical exposure control.

In the first part, the inspector noticed a number of non-conformities, such as lack of information in controlled area signs and the presence of an untrained worker. Other topical areas inspected were training and equipment for contamination. It was noted that the hospital hasn't established guidelines on the kind of incidents to be reported to the DRP. For the inspection related to the medical field, some of the subjects discussed were justification, optimization, QC tests, information of patients, identification of the patients and verification of facility plans provided during the authorization process. It was noticed that there were no separate waiting areas for non-injected and patients injected with radionuclides. The work place monitoring equipment either did not have a calibration label fixed on it or the calibration label indicated a calibration date made several years ago. The issue of calibration frequency is addressed in **Recommendation 21** in Section 11.

In the exit meeting the non-conformities were discussed and some recommendations were given. These will also be recorded in the inspection report to be sent to the hospital. The licensee should respond by written on non-compliances within 3 months.

At the end of the inspection the IRRS team had the opportunity to discuss in private with the hospital staff that expressed its gratitude of the ease of co-operation with the DRP. It was expressed that it is easy to contact the DRP when they have problems, both regulatory and technical. IRRS team considers that this interaction enables the authorized parties to address technical and regulatory matters but presents the risk of confusing the respective roles and responsibilities. This issue is addressed in **Recommendation 8** in Section 3. Nonetheless, the inspection was conducted in a professional manner.

7.5. SUMMARY

The DRP has established a guidance on inspections, including an inspection program and check lists. The DRP does not implement an inspection programme for all facilities and activities (e.g. foreign companies that perform activities in the country with radiation sources, authorized foreign transport companies, medical facilities and activities). In this respect, the DRP should implement an inspection programme covering all facilities and activities within the country and all topical areas based on a graded approach.

The DRP inspectors do not have the authority for free access to facilities to carry out regulatory inspection at any time, except for cases of suspicion of serious non-compliances. Additionally, the authority of performing inspections is granted only to a certain category of DRP inspectors and not to other staff members that have similar duties, qualification, competence and training. The Government should make provisions for the DRP to assign the duties of the inspectors and to have the authority for unconditional access to the facilities to perform regulatory inspections.

The inspections are performed on a comprehensive manner, however the DRP will benefit by clarifying the roles and formalizing its relations with authorized parties. Inspection findings are reviewed regularly.

The DRP might also benefit from formalizing its coordination with the Department of Transport in conducting air carrier inspections.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

In Luxembourg, enforcement policy for radiation safety is not established.

According to the LRP63, the Minister of Health has the authority to impose measures to the license holder, but only in case of a significant safety risk. According to RRP00 the Minister of Health has the authority to withdraw a license.

Prosecution is a final option for severe non-compliances. LPR63 states that offenses against the law, regulations or ministerial decrees shall be punished by imprisonment from eight days to one year and/or by a fine.

The inspectors of the DRP report on the non-conformities and require from the inspected party to comply with the rules within certain time, typically a few months. Inspectors who work under the jurisdiction of the federal prosecutor as police officers have the possibility to seize objects for their investigation in case they find serious non-compliances.

Additional administrative powers like sending warnings, give administrative fines, which could provide the regulatory body with a more balanced authority to enforce are however not envisaged.

The above provisions and measures do not constitute an enforcement policy for radiation safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no enforcement policy for radiation safety established. There are no legal provisions for the DRP inspectors for the cessation of activities or the shutting down of a facility when necessary. Only assigned police officers can ask permission from the magistrate to stop an activity or shut down a facility.*	
(1)	**BASIS: GSR Part 1 (Rev.1) Requirement 30, states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization"*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 31, para 4.54 states that** *"The response of the regulatory body to non-compliances with regulatory requirements or with any conditions specified in the authorization shall be commensurate with the significance for safety of the non-compliance, in accordance with a graded approach."*
(3)	**BASIS: GSR Part 1 (Rev.1) Requirement 31, para 4.55 states that** *"Enforcement actions by the regulatory body may include recorded verbal notification, written notification, imposition of additional regulatory requirements and conditions, written warnings, penalties and, ultimately, revocation of the authorization. Regulatory enforcement may also entail prosecution, especially in cases where the authorized party does not cooperate satisfactorily in the remediation or resolution of the non-compliance."*
(4)	**BASIS: GSR Part 1 (Rev. 1) Requirement 31, para. 4.58 states that** *"The regulatory body shall establish criteria for corrective actions, including enforcing the cessation of activities or the shutting down of a facility where necessary."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R14	**Recommendation: The Government should establish an enforcement policy and strategy in accordance with a graded approach and make the necessary provisions for DRP to implement it.**

The IRRS team has been informed that the new law will contain provisions to strengthen the enforcement power of the Minister of Health.

8.2. ENFORCEMENT IMPLEMENTATIONS

There is a general administrative assignment in Luxembourg which says that all governmental administrations should prefer to use administrative measures instead of bringing a report to the federal prosecutor.

During the conduct of an inspection, where a DRP inspector believes there is or may be an immediate danger, the inspector has no authorization for the cessation of the activities. The inspectors with police officer rights should ask a magistrate permission to cease these activities or shut down the facilities.

Regarding the implementation of corrective actions, an inspection report is issued to the licensee and this includes a period to comply with the regulations on the issues of non-compliance. After this period, the DRP inspectors will perform a second inspection to check if the non-compliances are solved. The IRRS team was informed that in almost all cases the licensees have solved the non-compliances.

IRRS team was informed that to date there was no need for a license to be revoked.

8.3. SUMMARY

An enforcement policy for radiation safety is not established; enforcement authority is given to the Minister of Health.

There are no legal provisions for the DRP inspectors for the cessation of an activity or the shutting down of a facility, when necessary. Only assigned police officers can ask permission from the magistrate to stop an activity or shut down a facility. In this respect, the Government should establish an enforcement policy and strategy in accordance with a graded approach and make the necessary provisions for the DRP to implement it.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

As introduced in Section 1, in Luxembourg, the main law on radiation safety is LRP63. The Law of 10 August 1983 concerns the medical use of ionising radiation (LUM83).

The main regulations include:

- Regulation of 11 August 1996 concerning the provision of information to the population on the applicable measures for the protection of public health and on the conduct to be adopted in the event of a radiological emergency (RIU96);
- Regulation of 14 December 2000 concerning the protection of the population against the dangers arising from ionizing radiation (RRP00);
- Regulation of 16 March 2001 on the sanitary protection of individuals against the dangers of ionising radiation during medical exposures (RUM01);
- Regulation of 3 March 2009 on the supervision and control of shipments of radioactive waste and spent fuel.

As Luxembourg is a member of the European Union, the law and regulations have been amended several times in order to transpose the Euratom directives as well as the international modal transport regulations into the national regulatory framework. Luxembourg is in the process of transposing Council Directive 2013/59/Euratom into the national legislation.

Within RRP00, the main regulations for radiation safety, provisions for the following main topics are introduced:

- Classification of facilities and activities;
- Authorization process;
- Extension and modification of the authorization for facilities and activities;
- Employment of outside workers;
- Suspension and withdrawal of authorization;
- New types of practices;
- Devices and instruments for measuring radiation;
- Registers for high activity sources;
- Transport and transit of radioactive substances.

Amendments of legislation and regulations go through a formal process that includes a consultation stage as a mechanism to communicate with the interested parties.

For any amendment of regulations, it is required to go through the entire legal and administrative process, including the request for the opinion of the Council of State. Within DRP action plan, actions are included to consult other government administrations to find solutions to make the technical regulations easier to change. DRP does not have the authority to issue binding technical requirements either guidance for implementing the regulations. This issue is addressed in **Recommendation 2** in Section 1.

Justification of new practices is mentioned in the RRP00. The Minister of Health can forbid practices, that it finds unjustified. There are, however, no clear requirements or guides on what provisions apply for

justification and what kind of information is required for the justification of new practices. IRRS team was informed that such provisions will be included in the new legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The justification of practices is not properly addressed in the legislation since it is not clear what provisions apply for justification and what kind of information has to be provided for the justification of new practices.*	
(1)	**BASIS: GSR Part 1 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."*
(2)	**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, and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach"*
R15	**Recommendation: The Government should establish legal provisions for justification and communicate them to the interested parties.**

All the types of documents to be submitted when applying for an authorization are given in the RRP00. Guidance on safety assessment and emergency situations have been published in the DRP's website.

The regulatory requirements are completed by imposing licensing conditions that are frequently used in the authorizations process. The DRP addresses similar standard conditions that apply to similar practices.

There are no sufficient technical guides for the implementation of the requirements addressed in regulations.

It was observed by the IRRS team that the DRP does not have documented procedures and guides within its management system to be used by the DRP staff. Examples of the areas where guidance is missing are:

- Review and assessment;
- Application for an authorization and granting of authorization, including license conditions;
- Types of modification and related documentation for authorization;
- The level of appropriate training and competence required for personnel;
- Assessment of radiological effects on the public.

It is acknowledged that there is a guidance document on performing inspections but this guidance is not yet integrated into the DRP management system. This issue is addressed in **Recommendation 10** in Section 4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no sufficient technical guides (to be used by the authorized parties or by DRP staff) on the implementation of the regulations.*	
(1)	**BASIS: GSR Part 1 Requirement 2 para 2.5 (9) 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: -The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for the implementation."*
(2)	**BASIS: GSR Part I Requirement 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
(3)	**BASIS: GSR Part I Requirement 22 para 4.28 states that** *"There (i.e. prospective changes in regulatory requirements) shall be consistency in the decision-making process of the regulatory body and in the regulatory requirements themselves, to build confidence among interested parties."*
(4)	**BASIS: GSR Part I 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."*
R16	**Recommendation: The DRP should issue additional guidance to assist both its staff and the authorized parties for the implementation of the regulations.**

Some activities can be done by the QE, but this is not mandatory for class I – III activities. There is also no provision for the formal recognition for QE within legislation. IRRS team was informed that such provisions will be included in the new legislation. This issue is addressed in **Recommendation 6** in Section 1.

Even though inspection experience can indicate the need to change license conditions, the DRP has not the authority for that. The issue on license conditions is addressed in **Recommendation 11** in Section 5. Inspection experience has been used to revise future license conditions or regulatory requirements, however there is no established or documented process to review and revise periodically the regulations and license conditions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Inspection experience has been used to revise future license conditions and regulatory requirements. However, there is no established or documented process to review and revise periodically the regulations and license conditions.*	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
R17	**Recommendation: The DRP should establish the process for the review and revision of**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	regulatory documents.

9.2. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

There are no requirements for the safe and secure storage of radioactive sources, except for the disused ones. Security requirements to prevent theft of sources are limited to the administrative procedures. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission. IRRS team was informed that requirements for the safe storage of radioactive sources will be included in the new legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no requirements for the safe and secure storage of radioactive sources, with the exception of the disused ones. Security requirements to prevent theft of sources are limited to the administrative procedures.*	
(1)	**BASIS: Code of Conduct on the safety and security of radioactive sources, para. 8b states that** *"Every State should have in place an effective national legislative and regulatory system of control over the management and protection of radioactive sources. Such a system should: b) minimize the likelihood of a loss of control*;"
(2)	**BASIS: Code of Conduct on the safety and security of radioactive sources, para. 18d states that** *"Every State should have in place legislation and regulations that:* *(d) specify the requirements for the safety and security of radioactive sources and of the devices in which sources are incorporated"*
R18	**Recommendation: The Government should make provisions within the regulations for the safe and secure storage of radioactive sources in line with the requirements of the Code of Conduct on the safety and security of radioactive sources.**

9.3. REGULATIONS AND GUIDES FOR TRANSPORT

The Department of Transport, within the Ministry for Sustainable Development, implements international transport regulations into national requirements. For example, ratification of the ADR agreement was done through legislation in 1970 (loi du 23 avril 1970, mém. A-N°30 1970) and approval of subsequent amendments. The annexes A and B are modified and updated regularly. Compliance with the international modal transport regulations is required in RRP00.

There is no process or guidance on issuing approvals based on the SSR-6, such as transports under special arrangements. It should be noted that no such approvals have been needed until now. This issue is addressed in **Recommendation 10** in Section 4.

The regulatory body is therefore not responsible for the publication and periodic review and revision of national regulations for the safe transport of radioactive material. The DRP is encouraged to appoint a representative to the IAEA Transport Safety Standards Committee (TRANSSC).

9.4. SUMMARY

The main law concerning the protection of the population against the dangers arising from ionizing radiation is in force since 1963. Other important legislative or regulatory documents concern the protection of the population against the dangers arising from ionizing radiation, the medical use of ionizing radiation and the sanitary protection of individuals against the dangers of ionizing radiation during medical exposures.

The DRP does not have the power to issue legally binding technical regulations or guidance. There are no sufficient technical guides (to be used by the authorized parties or by DRP staff) on the implementation of the regulations and therefore the DRP should issue additional guidance for the implementation of the regulations.

Even if inspection experience has been used to revise future license conditions and regulatory requirements, the DRP should establish a process for the review and revision of regulatory documents.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

The scope of the Emergency Preparedness and Response (EPR) arrangements in Luxembourg are a function of the activities performed in or near the country. Luxembourg is a non-nuclear country and does not produce radioactive substances. It has a relatively small number of radioactive sources, with only three sources defined as IAEA Category 2 (all others are of lower category). Accordingly, the requirements and arrangements for on-site EPR are quite limited, more closely related to procedures for abnormal operation rather than traditional emergency plans for larger facilities. Nonetheless, the regulatory framework does account for the possibility of activities or facilities that would require more intensive EPR arrangements.

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

Regulation for on-site EPR arrangements is included in the regulatory framework as previously defined. Furthermore, regarding authority to take regulatory action during an emergency, the LRP63 gives authority to the Minister of Health to take any required action towards a licensee during an emergency to protect public health.

Arrangements for preparedness and response to a nuclear or radiological emergency for facilities and activities under the responsibility of the operating organization are dealt with through the regulatory process. Regulatory requirements for emergency arrangements are included in the regulatory framework and are addressed within the license application requirements of the RRP00. For example, RRP00 requires that a hazard analysis be performed for higher risk activities as part of the license applications, identifying the possible hazards and emergency scenarios, or the licensee of higher risk activities is required to develop on-site emergency plans and to perform periodic exercises.

The Minister of Health and the Director of Health have the authority to review and assess emergency preparedness and response requirements of a licensee during licensing, prior to commencement of activities and for the duration of the authorization.

DRP coordinates with other national authorities to coordinate efforts on domestic response activities, as well as on cross-cutting emergency topics such as Chemical Biological Radiological and Nuclear Threats (CBRN) or nuclear accidents in foreign territory.

The Minister of Health and the Director of Health have in place the authority and responsibility required to effectively regulate emergency arrangements of licensees.

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

Regulations and guides specify requirements and criteria for emergency arrangements in a graded approach. Classes of facilities are set up in a risk informed manner, with class I and II only requiring EPR arrangements. The RRP00 describes the general information required for class I and II applications, and specifically requires a safety report (item 11) assessing the probability and consequences of accidents for workers and the public (for all class I and for class II facilities with higher risk sources).

RRP00 outlines in detail the requirements and responsibilities of the licensee, for example notification, assessment of risk, mitigating measures and accident event review. In particular, the licensee's responsibility for onsite response is established in RRP00, requiring the licensee to have sufficient authority to promptly take necessary protective actions on site in response to a nuclear or radiological emergency that could result in off-site consequences.

RRP00 requires the development of emergency plans for all class I and class II facilities, as well as requiring licensees to perform exercises periodically. In support of this requirement, a guide is available to applicants outlining the various expectations of the DRP for the emergency plan (Guide et Conseils sur la Planification d'Intervention Interne concernant des Accidents Radiologiques).

In the regulatory framework, there is no requirement for the licensee to perform regular up-date of the onsite EPR plans. The IRRS team was informed that this is proposed to be included in the new law.

Overall, there is an effective set of regulatory requirements and guides for emergency preparedness and arrangements given the scope of activities in the country.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The *Regulatory framework requires emergency plans to be submitted with the license application for class I facilities and those class II facilities with high activity sources. For all other applications, there is no provision for submitting emergency plans during the authorization process.*	
(1)	**BASIS: GSR Part 1 Requirement 26, para. 4.45 states** *"In the process of its review and assessment of the facility or activity, the regulatory body shall take into account such considerations and factors as…* *(10) Arrangements for preparedness for, and response to, emergencies"*
S4	**Suggestion: The Government should consider making provisions within the regulations for requiring, within the authorisation process, facilities on-site emergency preparedness and response arrangements for all class II facilities.**

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

In principle, the DRP has responsibility to verify the effective implementation of emergency arrangements against the regulatory requirements before commencement of operation of the facility or before the conduct of the activity, and afterwards during the lifetime of the facility or the conduct of the activity through:

- Review and assessment of the documentation elaborating operator's emergency arrangements during the licensing process;
- Inspections on EPR arrangements of operating organizations;
- Evaluating some of exercises conducted by the operating organizations.

Although the regulatory framework makes provisions for on-site EPR arrangements, and the Minister of Health and the Director of Health have authority required to verify these arrangements, in practice no verifications are performed of licensee EPR arrangements. Verifications should be performed both prior to the commencement of authorized activities to confirm that arrangements are in place, and during the licensing period to verify that EPR arrangements and regulatory requirements continue to be met. Verifications prior to commencement of operations are established in RRP00 and should include EPR

topics and is the subject of a recommendation below. The issue of EPR inspections has been included in the general **Recommendation 12** in Section 7, referring to the addition of EPR topics in routine inspections. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission.

In practice however, inspection prior to start the operation are generally not done. In addition, EPR arrangements are only required to be submitted with a license application for class I facilities and class II facilities with higher risk sources. Thus, there is no formalized mechanism for the review and assessment of emergency arrangements for other class II activities that may require them. Finally, there are no provisions within the DRP to perform inspections of licensee's emergency response arrangements and exercise results. While this may be acceptable for the very low risk licensees, it should be applied in a graded manner for higher risk activities (e.g. gamma industrial radiography) and the licensing and compliance processes should account for how this would be done if higher risk activities or facilities were licensed in the future.

In general practice, the DRP performs very little verification of compliance of the on-site emergency arrangements of operating organizations against the regulatory requirements. While this may be explained given the lower risk profile of currently licensed activities, it should nonetheless be part of the oversight process and applied in a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Licensee's onsite EPR arrangements are not verified prior to the commencement of authorized activities.*	
(1)	**BASIS: GSR Part 7 Requirement 2, para. 4.14 states that** *"Before commencement of operation of the facility or commencement of the activity, the regulatory body shall ensure, for all facilities and activities under regulatory control that could necessitate emergency response actions, that the on-site emergency arrangements:* *(a) Are integrated with those of other response organizations, as appropriate;* *(b) Are integrated with contingency plans in the context of Ref. [9] and with security plans in the context of Ref. [10];* *(c) Provide, to the extent practicable, assurance of an effective response to a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7 Requirement 2, para. 4.13 states that** *"The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions. Appropriate emergency arrangements shall be established by the time the source is brought to the site, and complete emergency arrangements shall be in place before the commencement of operation of the facility or commencement of the activity. The regulatory body shall verify compliance with the requirements for such arrangements."*
R19	**Recommendation: The DRP should review on-site emergency preparedness and response arrangements prior to the start of operation of the facility or activity, that could necessitate emergency response actions.**

10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

In relation to the role of the DRP in off-site emergency response, the responsibilities and functions are clearly described in RRP00. The IRRS team was informed that the new law has omitted to clearly specify these responsibilities and the Government should consider including them in the legal framework to maintain the clarity of roles. While the regulatory framework clearly establishes that the licensee is responsible for on-site response and mitigation, there is provision in the law for the Minister or Health and Director of Health to direct licensee to act during emergencies to protect public health.

Radiological and nuclear emergency response is strongly integrated within the national all-hazards emergency management system. Radiological incidents or emergencies are reported into the national all hazard Administration Service Secours (ASS) which operates the national emergency call center. When assistance calls arrive involving radioactive material, or suspected radioactive material, the ASS procedures are to contact the DRP. Some of the DRP staff carry pagers for access 24/7 to provide this support. The ASS then coordinates all national rescue and response services in support of the on-scene command of the incident and a radiological risk assessment group made of DRP staff will be located at the ASS operations center. If required, DRP staff may be deployed to the scene to perform field work. In this case, DRP has a fully equipped response vehicle with detection and protective equipment. If additional human resources or equipment is necessary, the DRP has arrangements with the civil protection National Support Base, which stores, maintains and provides logistical support including several transport containers setup for radiological field response (detection and protection equipment, decontamination facilities, reception facilities). The DRP's field work during emergency response is supported by professional and volunteer Civil Defence staff.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Radiological and nuclear emergency response is strongly integrated within the national all-hazards emergency management system. The Administration Service Secours (ASS) has national call centre for all events. They are also official point of contact for France/Cattenom NPP and act as National Warning Point for IAEA and ECURIE. Initiation and escalation of a nuclear emergency response follows the same steps and uses the same processes as for other incidents and emergencies. DRP is engaged immediately and integrates itself as radiological risk advisory group to the national response system both at the ASS operations management centre, and also at the national crisis centre to support the Government "Cellule de Crise". The DRP's field work during emergency response is supported by professional and volunteer Civil Defence staff, which includes storage, maintenance and prompt logistical deployment of specialized response equipment containers from the National Support Base.*	
(1)	**BASIS: GSR Part 7 Requirement 1, para. 4.3 states that "***The emergency management system shall be integrated, to the extent practicable, into an all-hazards emergency management system (see paras 5.6 and 5.7)."*
(2)	**BASIS: GSR Part 7 Requirement 6, para. 5.7 states that** *"Arrangements shall be made for the establishment and use of a clearly specified and unified command and control system for emergency response under the all-hazards approach as part of the emergency management system (see paras 4.1–4.3). The command and control system shall provide sufficient assurance for effective coordination of the on-site and off-site response. The authority and responsibility for directing the emergency response and for making decisions on emergency response actions to be taken shall be clearly assigned. The responsibility for*

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	directing the emergency response and for decision making on emergency response actions to be taken shall be promptly discharged following a notification of an emergency."
GP2	**Good Practice: The IRRS team acknowledges the strong integration of the radiological and nuclear emergency response arrangements into the national all-hazards emergency management system. A single all hazard response structure is used, leveraging the expertise of the DRP effectively for nuclear emergencies.**

The Administration Service Secours (ASS) call center is the official point of contact for France/Cattenom NPP and acts as national warning point for IAEA and ECURIE. Initiation and escalation of a full scale nuclear emergency response follows the same steps and uses the same processes as for other incidents and emergencies. The DRP is engaged immediately and integrates itself as the radiological risk advisory group in the national response system both at the ASS operations management center, and at the national crisis center to support the Government "Cellule de Crise", which is activated in accordance with the National Nuclear Response Plan.

The National Nuclear Emergency Plan is approved by the Government Council as well as multiple supporting Operational Plans signed by ministers and directors. These clearly describe the preparedness and response activities to a nuclear emergency in a neighboring nuclear country. Within the framework of the national plan, the role of the DRP as radiological advisor is clearly described and documented. The DRP acts within the national response structure as advisor to the "Cellule de Crise" headed by the Prime Minister. The DRP is in contact with the regulator and TSO of the accident state to gather information on the current and assumed future status of the accident and what protective actions are being taken by the accident state. In accordance with the HERCA-WENRA approach, the DRP will advise the Government on protective actions required in Luxembourg, with the documented default approach being to harmonize protective actions with those in the accident state.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Operating Plan for radiological risk assessment, signed by the minister of Health, specifically highlights the need to harmonise response actions with the accident country, and align the national protective actions with the accident state whenever possible.*	
(1)	**BASIS: GSR Part 7 Requirement 22, para. 6.14 states that** *"Arrangements shall be made to coordinate with other States in the event of a transnational emergency any protective actions and other response actions that are recommended to their citizens and to their embassies in order either to ensure that they are consistent with those recommended in other States, or to provide an opportunity for them to explain to the public the basis for any differences (see para. 5.73)".*
(2)	**BASIS: GSR Part 7 Requirement 7, para. 5.22 states that** *"Appropriate emergency response actions shall be initiated in a timely manner upon the receipt of a notification from another State or of information from the IAEA on a notification relating to an actual or potential transnational emergency that could have impacts on the State or its nationals".*
(3)	**BASIS: GSR Part 7 Requirement 9, para 5.39 states that "***Within the emergency planning zones and emergency planning distances, arrangements shall be made for taking appropriate protective actions and other response actions effectively… …The arrangements shall be coordinated with all jurisdictions (including, to the extent practicable, jurisdictions beyond*

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	national borders, where relevant) within any emergency planning zone or distance."
(4)	**BASIS: GSR Part 7 Requirement 10, para 5.48 states that** *"Arrangements shall be made by response organizations in a State to promptly provide information and advice to its nationals and to those people with interests in other States29 in the event of a nuclear or radiological emergency declared beyond national borders, with due account taken of the response actions recommended in the State in which the emergency occurs as well as in the State(s) affected by that emergency (see paras 5.73 and 6.14)."*
GP3	**Good Practice: When making protective action decisions during a nuclear emergency in a foreign country, the Government of Luxembourg default action is to implement the same protective actions as prescribed by the accident country for its residents. Coordinating response actions with another state in this manner is efficient and prevents unnecessary delays in implementing protective actions and enhances public confidence by avoiding confusion or justification of differences in protective actions.**

The DRP has a well-documented and integrated role during radiological and nuclear emergencies that complements the documented national response without compromising DRP in performing its regulatory role. Although a well-documented and fully integrated response system is in place, the approach to radiological and nuclear exercises is not formalized. DRP staff regularly participate in nuclear emergency exercises, such as those organized by the IAEA and neighboring countries, and some ad-hoc large-scale exercises do include parts of the national response organization. However, this is not carried out in a systematic manner with documented lessons learned and improvement actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The DRP staff regularly participate in nuclear emergency exercises, such as those organized by IAEA and neighbouring countries. However, there is no formal nuclear emergency exercise program in place for exercising all functions of the national response to a nuclear emergency.*	
(1)	**BASIS: GSR Part 1 Requirement 8, para. 2.24a states that:** *"The government shall ensure that adequate training, drills and exercises, involving authorized parties and response organizations, including decision makers, are carried out regularly to contribute to an effective emergency response [5]. The training, drills and exercises shall cover a full range of postulated emergencies (e.g. events affecting several facilities on the same site, emergency exercises of long duration and emergencies with transboundary consequences).*"
(2)	**BASIS: GSR Part 7 Requirement 25, para. 6.30 states that** "*Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response, all organizational interfaces for facilities in category I, II or III, and the national level programmes for category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of, as appropriate and feasible, all the organizations concerned, people who are potentially affected, and representatives of news media. The exercises shall be systematically evaluated (see para. 4.10(h)) and some exercises shall be evaluated by the regulatory body. Programmes shall be subject to review and revision in the light of experience gained (see paras 6.36 and 6.38).*"
(3)	**BASIS: GSR Part 7 Requirement 25, para. 6.32 states that** "*Officials off the site who are responsible for making decisions on protective actions and other response actions shall be*

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	trained and shall regularly participate in exercises. Officials off the site who are responsible for communication with the public in a nuclear or radiological emergency shall regularly participate in exercises"
S5	**Suggestion: The Government should consider formalising the exercise program to ensure that all organizations and functions of a nuclear emergency response are tested at suitable intervals, including the officials who are responsible for making decisions on protective actions, and analysed to identify lessons learnt.**

10.5. SUMMARY

Overall, DRP has the authority and responsibility required to effectively regulate emergency arrangements of licensees and there is an effective set of regulatory requirements and guides for emergency preparedness and arrangements, given the scope of activities in the country. In general, the DRP performs very little verification of compliance of the on-site emergency arrangements of operating organizations against the regulatory requirements. While this may be due to the lower risk profile of currently licensed activities, it should nonetheless be part of the oversight regulatory process (e.g. inspections) and applied in a graded approach.

Finally, the roles and responsibility of the regulatory body are clearly defined and well documented and integrated within the national emergency preparedness and response framework. In particular, good practice was identified relating to integration of the nuclear response system into the national all-hazard emergency response system, and to the harmonization of protective actions with those of accident states during NPP emergencies.

11. ADDITIONAL AREAS

11.1 CONTROL OF MEDICAL EXPOSURES

In the medical field, the applications of ionising radiation are allocated in 4 public hospitals on 10 sites and 291 private radiology cabinets (287 dental cabinets and 5 specialists' cabinets). Radiotherapy practices are performed within hospitals: one external radiotherapy and brachytherapy department with 3 linear accelerators, 1 cyber-knife accelerator and 4 brachytherapy facilities. In the nuclear medicine field, 4 services are in operation, carrying out diagnostic (using 1 PET-CT, 3 SPECT-CT and 4 gamma-cameras) and therapy procedures. The country has also 10 radiology departments (with 10 CT-scanners and around 120 X-ray devices); some image guided procedures in cardiology and neurology are also implemented.

The LRP63 and RRP00, apply to medical facilities regarding the processes of registration/licensing and inspection. The detailed provisions for patient protection against radiation are mainly given in the LRP83 and RUM01.

The draft legislation and its relevant regulation will put into force provisions on medical exposure control that are in line with IAEA GSR Part 3.

Independent control of medical facilities

Except for dental facilities and a few specialist's facilities, all medical facilities are public. Among other responsibilities, as further elaborated in Section 1, the Ministry of Health defines the list of devices that can only be installed in hospitals. In this respect, there could be a risk of conflict of interest in the regulatory control of medical radiation sources. This issue is addressed in **Recommendation 3** in Section 1.

Responsibility of the licensees and the medical practitioners

According to the regulation, the head of an establishment carrying out medical practices, should obtain a license from the Minister of Health or the Director of Health.

According to the legislation, the radiological medical specialists are responsible for the medical practices involving ionising radiation. In three of the four public hospitals in the country, the medical procedures are carried out by private practitioners. There is no requirement specifying the allocation of responsibilities in patient protection between the head of the establishment and the medical practitioners. The IRRS team was informed that the new law will provide for the clear allocation of these responsibilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The legal and regulatory framework does not define the allocation of responsibilities in patient protection between the head of the establishment and the medical practitioners.*	
(1)	**BASIS: GSR Part 3 Requirement 4, para. 2.40 states that:** *"The principal parties responsible for protection and safety are:*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(a) Registrants or licensees, or the person or organization responsible for facilities and activities for which notification only is required; *(b) Employers, in relation to occupational exposure;* *(c) Radiological medical practitioners, in relation to medical exposure;"*
(2)	**BASIS: GSR Part 3 Requirement 34, para. 3.147 states that:** *"The government, in accordance with paras 2.13–2.28, shall ensure with regard to medical exposures that, […], the relevant parties identified in paras 2.40 and 2.41 are authorized to assume their roles and responsibilities, and shall ensure that they are notified of their duties in relation to protection and safety for individuals undergoing medical exposures."*
R20	**Recommendation: The Government should make provisions in the legal framework for the clear allocation of responsibilities in medical exposure between the authorized party (head of the establishment) and the medical practitioners.**

Licensing process of medical facilities

RUM01 does not provide for the list of mandatory documents relevant to patient protection to be checked by the DRP during the licensing process prior to first clinical use. IRRS team has been informed that the new regulation will include provisions in this aim (CE marking for medical devices, medical staffing, procedures carried out). The IRRS team was informed that the DRP provides to the medical applicants an informal check-list of documents needed in the authorisation process. Nevertheless, neither regulation, nor guidance are in place to ensure consistency and completeness of the applications for requesting an authorisation for medical facilities. This issue is addressed in **Suggestion 3** in Section 5 and in **Recommendation 16** in Section 9.

Diagnostic Reference Levels (DRL(s))

Diagnostic Reference Levels are specified for medical imaging in the RUM01; the requirement of comparison of the assessed or measured dose in the diagnostics procedures (including some pediatric procedures and some image guided procedures as well) with the DRL(s) and informing the DiSa in case of DRL(s) have been exceeded, are also requested. However, the establishment of DRL(s) values is not based on Luxembourgish data as they were not available in 2001 (use of EU data). The IRRS team was informed that the new regulation will up-date the DRL(s) with the more recent Luxembourgish data. Nevertheless, the process of regulatory up-dating of DRL(s) is not efficient as it should be done in a short timespan to obtain continuous improvement. The DRP should be empowered to issue some technical regulations regarding the need of their quick up-dating. This issue is addressed in **Recommendation 2** in Section 1. The same recommendation can be addressed for the up-dating of the content of quality control tests.

Medical Physicists

Eleven medical physicists currently work in Luxembourg. Six of them are employed by the Hospital Federation (association of the four public national hospitals). They are involved in nuclear medicine, image guided procedures and radiology (CT-scan and X-ray devices) facilities. The five other medical physicists are employed by the only radiotherapy facility in the country.

As the profession of medical physicist is not yet a recognised profession, there are no requirements in place on their education and training. However, the regulation states that the medical physicists should obtain an authorisation from the Ministry of Health. The DRP, following an informal process, examines the application file which should be in line with the qualification framework recommended by the European Commission on the document RP 174 "European Guidelines on Medical Physics Expert". This issue is addressed in **Recommendation 6** in Section 1.

The IRRS team was informed that the new legislation and implementing regulation will introduce requirements for recognition, competence, education and ongoing training.

Ongoing training of medical and paramedical staff

The legislation and regulation do not require updating of the training for medical and paramedical staff. The IRRS team was informed that new legislation will provide for the continuous training for referring medical practitioners, radiological medical practitioners, medical physicists and medical radiation technologists. Moreover, there are no regulatory provisions to ensure the competence of the institutions involved in training of the radiation protection of patients.

There are no provisions in the regulation about the continuous training or its frequency of updating for all medical and paramedical staff. This issue is addressed in **Recommendation 6** in Section 1.

Calibration of radiation sources/ Patient's dosimetry

There is no national standards dosimetry laboratory (SDL) for patient dosimetry and calibration of medical equipment available in Luxembourg. There is no requirement in place to ensure that an agreement is in place to provide for calibration services by a foreign SDL. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission. Independent verification for radiotherapy units prior to their first clinical use are neither requested. Nevertheless, it can be noticed that for the unique radiotherapy facility operating in the country, an external yearly audit of dosimetry is conducted by Belgian dosimetry audits in radiotherapy (BELdART) for the three linear accelerators and was once conducted by EQUAL ESTRO (French TSO) for the cyber-knife. These audits have not revealed non-compliance yet. The action plan prepared by DRP as a result of the self-assessment addressed this issue.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The requirements for patients' dosimetry and calibration of equipment are not specifically defined in the regulations including the traceability to a standards dosimetry laboratory, neither the obligation of an independent verification prior to first use for the calibration of radiotherapy units.*	
(1)	**BASIS: GSR Part 3 Requirement 38, para. 3.167 states that:** *"In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that […]:* *(c) Calibrations of radiation therapy units are subject to independent verification prior to clinical use;* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."*
(2)	**BASIS: RS-G.1.5 para. 5.12 states that:** *"The BSS require that calibration of radiotherapy*

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	sources, […], be traceable to a SDL (BSS, para. II.19). The Regulatory Authority should require that registrants and licensees have their dosimetry instrumentation calibrated by an SSDL […]. It may be necessary for instruments to be sent to another State if there is not a national standards laboratory in the State of use."
R21	**Recommendation: The DRP should make provisions to ensure that:** **(a) the calibration of dosimeters used for patient dosimetry or for calibration of sources is traceable to a SDL;** **(b) the calibration of radiotherapy units is subject to an independent verification prior to first use.**

Justification

The regulation requires that each medical exposure must be requested by a referring medical practitioner in a written prescription including the clinical context. It is also requested that both referring and radiological practitioners are bound to consider alternative techniques before performing every radiological procedure. However, the regulation does not stipulate that the radiological practitioner can perform another examination than the one prescribed.

Regarding the improvement of individual justification in medical practices, in order to reduce the radiation doses for the population, it is appreciated that the Ministry of Health and the Ministry of Social Security have put in place an action plan since 2015, dedicated to the process of justification for radiological imaging procedures and that the 10 radiology facilities (with CT scanners and X-ray equipment) participated in this project.

Justification for health screening programs is carried out by the Ministry of Health. Specific justification for asymptomatic exposure in case of self-referred patients is not explicitly covered by the regulation.

Regarding biomedical research programs, the regulations do not address the need of approval of an ethic committee regarding radiation protection issues.

The IRRS team was informed that provisions on the final decision of the radiological practitioner to carry out or not the radiological procedure, the justification of asymptomatic exposure (including information of benefits and risks of the radiation ionising procedures) as well as the need of the resort to an ethic committee for biomedical research, will be included in the new legislation and implementing regulation. This issue is addressed in **Recommendation 15** in Section 9.

Information of patients, carers and comforters

The regulation requires that the patient receives information about benefits and risks of the procedure he/she is to undergo as will the carers and comforters in the case of nuclear medicine practices. The IRRS team was informed that provisions extending relevant information to patients, carers and comforters for all medical practices involving radiation sources will be added in the new legislation. This issue is addressed in **Recommendation 22** in this Section.

Medical and paramedical staff

The Ministry of Health has not defined criteria to ensure sufficiency of medical and paramedical staff (i.e. radiological medical practitioners, medical physicists, medical radiation technologists) for medical radiation practices. The Law of the 8th of March 2018 concerning the hospital planning requires the definition of these criteria for each medical field through a forthcoming regulation. This issue is addressed in **Recommendation 22** in this Section.

Design consideration

The regulation does not address the compliance of software influencing the dose delivery to international standards. The IRRS team was informed that this requirement will be included in the new regulation. The issue is addressed in **Recommendation 22** in this Section.

Patient dosimetry record

There is no requirement to maintain records of the relevant medical procedures carried out and the dose delivered to the patients (except in image guided procedures). The IRRS team was informed that the patient dosimetry record will become mandatory for all diagnostic and therapeutic procedures through the new legislation and regulation. The issue is addressed in **Recommendation 22** in this Section.

Release of patients after radionuclide therapy

The discharge of patients who have undergone a brachytherapy procedure with Iodine-125 is not regulated in the regulation. The IRRS team was informed that this requirement will be included in the new regulation. The issue is addressed in **Recommendation 22** in this Section.

Unintended and accidental medical exposures

There is a provision in the regulation to oblige the authorized party to prevent likelihood and magnitude of unintended doses in medical exposures, especially in radiotherapy treatments, but there is no provision for the investigations in case of their occurrence neither to inform the patient or the regulatory body. Some provisions for the prompt information of the DRP are usually addressed in the authorisation process as licence conditions. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission. The IRRS team was informed that the new legislation will introduce the obligation for the manager of the establishment (class I & class II facilities) to record and to declare every significant event to the authorities. The manager of the establishment will also be requested to provide a written report with the analysis of causes and the remedial measures taken. The information to the patient and his referring medical practitioner will be mandatory as well as the study of the possible risks that radiotherapy procedures might cause.

Nevertheless, neither the regulation nor guides provide for the mechanisms of notification, of investigation and feedback for the events to take into account (including the cases of underexposure of radiotherapy practices) and the content of the report. This is acknowledged by the DRP and an action is included in the action plan resulting from the self-assessment performed prior to the IRRS mission. This issue is addressed in **Suggestion 6** in this Section.

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Observation: *Not all requirements of the GSR Part 3 relating to medical exposure are addressed in the regulatory framework including those related to:* *- justification comprising asymptomatic patients and patients undergoing a biomedical research program;* *- patients, carers and comforters' information;* *- sufficient staffing of medical and paramedical resources;* *- design considerations for software;* *- record of the dosimetry of patients;* *- release of patients after radionuclide therapy;* *- unintended and accidental medical exposure.*	
(1)	**BASIS: RS-G.1.5 para. 2.43 states that** *"[…] The decision to perform or to reject a diagnostic or a therapeutic procedure with ionizing radiation that has been required by a referring physician is incumbent on the relevant nuclear medicine physician, radiologist or radiation oncologist."*
(2)	**BASIS: GSR Part 3 Requirement 36, para. 3.151. (d) states that** *"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless: - The patient or the patient's legal authorized representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks."*
(3)	**BASIS: GSR Part 3 Requirement 36, para 3.152 states that** *"Registrants and licensees shall ensure that no individual incurs a medical exposure as part of a programme of biomedical research unless the exposure has been approved by an ethics committee […]"*
(4)	**BASIS: GSR Part 3 Requirement 36 para 3.153 states that** *"Registrants and licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. […]"*
(5)	**BASIS: GSR Part 3 Requirement 36 para 3.154. (d) states that:** *"Registrants and licensees shall ensure that: - Sufficient medical personnel and paramedical personnel are available as specified by the health authority."*
(6)	**BASIS: GSR Part 3 Requirement 38, para 3.162 states that** *"[…], registrants and licensees, in cooperation with suppliers, shall ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization or to national standards adopted by the regulatory body."*
(7)	**BASIS: GSR Part 3 Requirement 40, para 3.178. (b) states that** *"The radiological medical practitioner shall ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source or an unsealed source is discharged from a medical radiation facility until it has been established by either a medical physicist or the facility's radiation protection officer that: - The patient or the legal guardian of the patient is provided with:* *(i) Written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination;* *(ii) Information on the radiation risks."*
(8)	**BASIS: GSR Part 3 Requirement 41, para 3.180 states that** *"Registrants and licensees*

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	shall promptly investigate any of the following unintended or accidental medical exposures: *(a) Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;* *(b) Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;* *(c) Any exposure for diagnostic purposes that is substantially greater than was intended;* *(d) Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;* *(e) Any inadvertent exposure of the embryo or foetus in the course of performing a radiological procedure;* *(f) Any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended."*
(9)	**BASIS: GSR Part 3 Requirement 41, para 3.181 states that** *"Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180:* *(a) Calculate or estimate the doses received and the dose distribution within the patient;* *(b) Indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure; (c) Implement all the corrective actions that are under their own responsibility;* *(d) Produce and keep, as soon as possible after the investigation or as otherwise required by the regulatory body, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a)–(c) above, as relevant, and any other information as required by the regulatory body; and for significant unintended or accidental medical exposures or as otherwise required by the regulatory body, submit this written record, as soon as possible, to the regulatory body, and to the relevant health authority if appropriate;* *(e) Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure".*
(10)	**BASIS: GSR Part 3 Requirement 42, para 3.184. (b) states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance:* *- Records of dosimetry of patients, as required in para. 3.168."*
R (22)	**Recommendation: The Government and the DRP should revise the current legal and regulatory framework to bring it in line with the requirements of IAEA GSR Part 3 for strengthening the medical exposure control and should ensure their full implementation.**
S6	**Suggestion: The DRP should consider specifying criteria when and how the investigation should be conducted regarding unintended medical exposure.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

The occupational radiation protection is regulated through RRP00. The new legislation is based on Council Directive 2013/59/EURATOM that reduces the annual dose limit for the lens of the eye (limits compatible to GSR Part 3), mentions the education, training and re-training, the activities and the recognition (where appropriate) of RPOs, the possibility of systematic use of dose constraints, the establishment of planned exposure situations for workplaces where the annual effective dose could be above 6 mSv due to radon, among other improvements.

New practices go through a justification process and may not obtain an authorization. The IRRS team was informed that the new regulation will define in more detail justification criteria and the justification procedure for the introduction of new practices. The RRP00 requires the keeping of occupational doses as low as reasonably achievable. It is stated that the DRP may require dose constraints in the licensing conditions, however dose constraints have not usually been required from authorized parties.

Dose limits consistent with IAEA GSR Part 3 are in place for occupational exposure of workers, and persons undergoing training or education for working with sources of ionizing radiation. The dose limit for the lens of the eye will be revised to bring it in line with the IAEA GSR Part 3. Luxembourg employs a rolling 12 months effective dose limit for workers of 10 mSv which is more conservative than GSR Part 3. The new legislation will increase the annual effective dose for occupationally exposed persons to 20 mSv. Compliance with the limits is verified by the DRP through monthly verification of individual dosimetry results. If a monthly dose result above 0.5 mSv is seen the authorized party is contacted and invited to comment on the dose.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Not all requirements of the GSR Part 3 relating to the control of occupational exposure are addressed in the regulatory framework, such as those related to:* *- Dose limits to the eye;* *- Keeping of dose records by the authorized parties;* *- Occupational exposure control for radon.*	
(1)	**BASIS: GSR Part 3 Schedule III, III.1 states that "***For occupational exposure of workers over the age of 18 years, the dose limits are:…* *(b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;"*
(2)	**BASIS: GSR Part 3 Requirement 25, para. 3.103 states that** *"Employers, registrants and authorized parties shall maintain records of occupational exposure for every worker for whom assessment of occupational exposure is required in paras 3.99–3.102."*
(3)	**BASIS: GSR Part 3 Requirement 52, para. 5.27 states that** *"The regulatory body or other relevant authority shall establish a strategy for protection against exposure due to ^{222}Rn in workplaces, including the establishment of an appropriate reference level for ^{222}Rn. The reference level for ^{222}Rn shall be set at a value that does not exceed an annual average*

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	activity concentration of ^{222}Rn of 1000 Bq/m^3, with account taken of the prevailing social and economic circumstances."
R23	**Recommendation: The Government and the DRP should revise the current legal and regulatory framework to bring it in line with the requirements of GSR Part 3 for strengthening the occupational exposure and should ensure their full implementation.**

General responsibilities of authorized parties

The RRP00 defines a set of responsibilities, including radiation safety, that are allocated to authorized parties. The head of the establishment has the general responsibility for occupational radiation protection. The responsibilities include optimisation, risk evaluation, zoning (delimitation, control), working conditions, display of signs, procedures/local rules, emergency procedures, worker classification, medical examination, monitoring, information and training, provision of protective and measurement devices, prevention of loss, designation of RPO and/or QE, individual and workplace monitoring when necessary. The authorized parties are not required to keep the dose records. IRRS team was informed that with the revision of the regulations, dose record keeping will be required (identified in the DRP action plan performed following self-assessment).

The above responsibilities are in accordance with GSR Part 3.

General responsibilites of workers

RRP00 states the obligations and responsibilities of workers in terms of occupational radiation protection. Workers must fulfil their obligations and carry out their duties for protection and safety. Occupationally exposed workers must accept training, implement all radiation protection and safety measures to protect themselves and to report unsafe conditions. The IRRS team was informed that the above obligations have not yet been included in the new regulations, but it has been identified in the action plan DRP performed following self-assessment, and will be added.

Requirements for radiation protection programmes

Authorized parties conduct a risk analysis and apply radiation protection and safety measures commensurate with the risks associated with the practice or activity (RRP00). Authorized parties must designate a RPO with responsibility for implementing the radiation protection and safety measures and where necessary a QE can be appointed. The criteria for RPO and QE education, training, qualification and competence have not been established in the regulations. This issue is addressed in **Recommendation 6** in Section 1.

RRP00 requires the establishment of controlled and supervised areas. It also contains provisions on the display of signs indicating radiation risk. However, those provisions are not the same for all facilities or activities. The provisions may be interpreted and implemented differently by the authorized parties. There is no guidance that would help standardize the radiation postings, designation of controlled areas and so on. The publication of guidance documents by the DRP would harmonize compliance by the authorized parties (identified in the action plan). This issue is addressed in **Recommendation 16** in Section 9. Neither the RRP00 nor the new regulations include a requirement that records of occupational exposure should include information on the general nature of the work in which the worker was subject to

occupational exposure. However, DRP has included an action in this respect within its action plan performed after the self-assessment. Radiation protection training programs are reviewed by the DRP and approved. Training is carried out by the RPO before the worker starts and periodic re-training is foreseen.

Monitoring programmes and technical services

The DRP has operated since 1983 an external individual monitoring service (the DRP dosimetry service) based on the TLD technique. At present, around 2000 monitors for Hp(10) dose, 20 finger rings for Hp(0.07) and a few neutron dosimetry dosimeters are distributed monthly. The service is officially recognized in RRP00 as the "official dosimetry service" of Luxembourg. The service has an internal quality management system and has shown good results in international intercomparison exercises. In the case a protective lead apron is worn the user is instructed to wear the dosimeter under the lead apron. The highest monthly doses are seen in the PET installation. However, with rare exceptions from the past, all annual effective doses are below the 10 mSv dose limit. Some facilities request eye lens monitoring dosimeters Hp(3) from private companies.

A policy decision was made in the DRP to consider ending the operation of the external monitoring service in four to five years. The service should be continued by one or more private companies located either in Luxembourg or abroad. To assure the quality of the new service, the ISO 17025 accreditation and additional QA requirements will be required. DRP should establish recognition criteria for individual monitoring services. This issue is addressed in **Recommendation 6** in Section 1.

There is a low risk of a significant intake of radionuclides in the medical area. The DRP operates an ISO 17025 accredited environmental monitoring laboratory. The laboratory also measures urine samples for analysis of ^{131}I and ^{99m}Tc from occupationally exposed staff in the medical area for screening purposes. The results are obtained in Bq/kg of urine and are quite low (100 Bq/kg level). Committed effective dose calculations are not made and the doses are not registered in the National Dose Register. Foreseeing the possibility of a higher intake of a gamma emitter DRP is encouraged to liaise with a Whole-Body Counter Laboratory accredited according to the ISO 17025 standard or with a similar quality management system that will accept to conduct measurement on an emergency basis on occupationally exposed workers from Luxembourg.

There is no secondary or tertiary standard calibration laboratory in Luxembourg. Normally, the equipment is purchased with a calibration certificate valid for a certain time. However, the equipment seen during the IRRS-mission either did not have a calibration label attached, or the label indicated that the calibration had been performed several years ago. As workplace monitoring equipment may suffer a loss of efficiency over time, an annual calibration frequency is recommended in IAEA guides. The calibrations should be made in an ISO17025 accredited laboratory or laboratory with a comparable quality management system. As contamination limits in controlled and free areas are defined in Bq/cm^2, it is necessary to calibrate the surface contamination equipment in this unit, for each radionuclide expected in the workplace.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The calibration frequency of workplace monitoring equipment is not mentioned in the regulations.*	
(1)	**BASIS: GSR Part 3 Requirement 2, para. 2.23 states that** *"The government shall ensure that arrangements are in place for the provision of technical services relating to protection*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	and safety, such as services for personal dosimetry, environmental monitoring and the calibration of monitoring and measuring equipment."
S7	**Suggestion: The DRP should consider establishing an appropriate calibration frequency for workplace monitoring equipment.**

The DRP maintains a National Dose Registry (NDR) that consists of two separate data bases: one produced by the DRP dosimetry service, and the other from information provided by the airlines Luxair and Cargolux regarding air crew exposure. The information contained in the NDR includes the name of the occupationally exposed person, an identification number, the monthly dose record and, the company where the person is employed. The NDR suffers from lack of report formats; for example, it is not possible to automatically emit a 5-year dose history for one occupationally exposed person. Trend analysis should be made by compiling manually the annual data.

The IRRS Team was informed that the NDR will be up-graded so that the two sets of dose information will be merged, and the dose information can be accessed through the internet. The new system will also accommodate the dose information produced by the future dosimetry services and will also enable the trend analysis to be carried out more efficiently.

There are no training courses for RPOs, or QEs in medium to high risk areas. The DRP gives short radiation protection courses for information purposes, as basic training in low risk areas, and as continuous training. RPOs and QEs in medium to high risk areas are required to obtain their qualifications outside Luxembourg in recognized or certified courses.

11.3. SUMMARY

The regulation on medical exposure covers most of the requirements of GSR Part 3 for medical exposure. More emphasis should be given to ensure that the DRP is authorized to issue technical regulations and that relevant parties are aware of assuming their roles and responsibilities. Special care should be taken to dosimetry and calibrations, ongoing training for all persons involved in the use of ionizing radiation sources, education, duties and missions of the medical physicist and analysis and feedback of medical events.

The occupational radiation protection regulatory framework is well established and has been successfully applied to workplaces in Luxembourg. Occupational radiation protection infrastructure has a service provider with ISO 17025 accreditation. There are neither high level radiation protection training courses nor accredited calibration laboratories in Luxembourg.

As not all requirements of the GSR Part 3 relating to medical and occupational exposure control are addressed in the legal and regulatory framework, the Government and the DRP should revise the current framework to bring it in line with the requirements of IAEA GSR Part 3 for strengthening the medical exposure control and the occupational exposure control and should ensure their full implementation.

12. INTERFACE WITH NUCLEAR SECURITY

12.1 LEGAL BASIS

The RRP00 contains provisions regarding the physical protection of radioactive sources with the purpose to prevent exposure of workers and the public to ionising radiation arising from inadequate control of high-activity sealed radioactive sources and orphan sources.

This regulation includes provisions entitling the DRP to request appropriate physical protection arrangements to licence holder. However, there is no specific legal provision requiring that safety measures and nuclear security measures shall be designed and implemented in an integrated manner.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: *There is no specific legal provision requiring that safety measures and nuclear security measures shall be designed and implemented in an integrated manner.*
(1)	**BASIS: GSR Part 1 Requirement 12, para. 2.40 states that** *"Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security"*
R24	**Recommendation: The DRP should make provisions to ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.**

12.2 REGULATORY OVERSIGHT ACTIVITIES

There is no provision in the legal and regulatory framework assigning the competences and responsibilities for physical protection to DRP. This issue is addressed in **Recommendation 4** in Section 1. The IRRS team was informed that currently during the licensing process of a facility or activity including class III or class II radioactive sources, a physical protection programme or plan is not requested. Only general elements or criteria regarding the physical protection of radioactive sources are assessed during the licensing stage of facilities including class III or class II radioactive sources.

The inspection checklists of these facilities include criteria related to physical protection such as storage place, locks, alarms etc. No topical inspections dedicated to physical protection issues have been conducted and planned. There are no regulatory requirements regarding security of radioactive sources as provided in the CoC. This issue is addressed in **Recommendation 18** in Section 9.

12.3 INTERFACE AMONG AUTHORITIES

The IRRS Team was informed that there is a National Crisis Centre which coordinates all the involved national organisations in case of emergency. This National Crisis Centre also deals with nuclear safety and nuclear security emergencies.

There is a National Intervention Plan for emergencies in case of malevolent acts involving radioactive material.

12.4 SUMMARY

A specific provision stating that the integrated approach should be designed and implemented in a manner that nuclear security measures do not compromise safety, and safety measures do not compromise security should be introduced in the regulations.

POLICY ISSUES DISCUSSION

The policy issues discussions were focused on two topics: the "Relationship between the regulatory body and the licensees" and the "Graded approach in the context of a small country".

The discussions were chaired by the IRRS Team Leader and attended by the IRRS Team and DRP staff members. The DRP Head and Liaison Officer for this mission gave the introductory remarks.

Relation between a regulatory body and the licensees

The DRP presented the current situation and explained that Luxembourg, as a very small country, with few licensees and a small number of staff, is faced with a situation where professional contacts are frequent between the regulatory body staff and licensees.

The DRP believes that the current practice used by which authorized parties have direct access to DRP staff for addressing technical and regulatory issues and the DRP provides advice on a regular basis on safety related parties, enhances the communication and the radiation protection in the country. This benefits the authorized parties in the implementation of the regulatory requirements. However, this working practice builds a relationship that could endanger effective independence of the regulatory body.

The floor was then opened for comments. All IRRS team members presented relevant examples carried out in their countries and views were given on the need to state that the prime responsibility for safety remains with the license holder, on the need to formalize the relationship with the authorized parties such as, for example, establishing Terms of Reference for all the working groups composed by the Regulator and authorized parties, addressing common objectives to facilitate the understanding and implementation of regulatory requirements. The possibility was raised of establishing workshops or training activities with the objective to clarify the application of the regulatory requirements. It was pointed out that the Regulator should not be involved in the development of authorized parties' capabilities. The IRRS Team encouraged the carrying out of discussions on the implementation of requirements through Professional Associations.

One of the IRRS team members raised the fact that Independence is an attitude for regulatory bodies and staff members, and should be promoted.

Graded approach in the context of a small country

The second policy issue discussion focused on the problem of complying with the graded approach in the application of safety requirements in Luxembourg, considering that it is a non-nuclear country with a limited number of regulated facilities and activities.

The floor was then opened for comments. All IRRS team members presented the application of the graded approach in licensing, review and assessment, inspection and enforcement processes in their own countries. Some of the IRRS team members introduced some ideas on how to establish graded approach regulatory decisions based on results coming from, for example, the analysis of inspection findings, or the analysis of annual collective effective dose and average effective dose trends for facilities and activities.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
VILLANUEVA Isabel	Consejo de Seguridad Nuclear (CSN), Spain	ivd@csn.es
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CARINOU Eleftheria	Greek Atomic Energy Commission (EEAE), Greece	Eleftheria.Carinou@eeae.gr
HELLSTÉN Santtu	Radiation and Nuclear Safety Authority (STUK), Finland	Santtu.Hellsten@stuk.fi
ARENDS Patrick	Authority for Nuclear Safety and Radiation Protection, the Netherlands	patrick.arends@anvs.nl
SIGOUIN Luc	Canadian Nuclear Safety Commission (CNSC), Canada	luc.sigouin2@canada.ca
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HUNT John	Instituto de Radioproteção e Dosimetria (IRD/CNEN), Brazil	john@ird.gov.br
IAEA		
KAMENOPOULOU Vasiliki	Division of Radiation, Transport and Waste Safety	V.Kamenopoulou@iaea.org
ALEXANDER Tom	Division of Radiation, Transport and Waste Safety	T.Alexander@iaea.org

APPENDIX II - MISSION PROGRAMME

LUXEMBOURG IRRS MISSION PROGRAMME 10 JUNE TO 20 JUNE 2018

IRRS MISSION PROGRAMME		
Sunday 10 June 2018		
IRRS Initial IRRS Review Team Meeting		
14:00 – 18:00 18:30-20:00	Opening remarks by the IRRS Team Leader Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA, LO) First impression from experts arising from the Advanced Reference Material (ARM) (All Experts) Administrative arrangements (IRRS Liaison Officer, IAEA): Detailed Mission Programme Guided Visit Tour of Luxembourg City Old Town followed by welcome drink.	Venue: Hotel (Vauban Style U) Participants: the IRRS Team + the LO
Monday 11 June 2018		
IRRS Entrance Meeting		
09:00 – 12.00	09:00 Arrival, registration, 09:30 (*Government Official and NSRW Director*) – Welcoming Addresses 09:45 IRRS Coordinator – The IRRS programme – 10:00 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team Introduction of the main Luxembourg Counterparts Group photo of the meeting participants 10:30 Coffee 11:00 RB Presentation – Regulatory Overview, SARIS results (strength, challenges, action plan)	Venue: Hotel (Pétrusse Style U) Participants: Government Official, RB Management and staff, Officials from relevant organizations, the IRRS Team + the LO
12:00 – 13:00	Installation of team at the Ministry	Lunch-pack provided by hotel
13:30 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)	IRRS Reviewers Counterparts offices:

IRRS MISSION PROGRAMME		
		Reviewer of Module 1 – 3, TL and TC and Reviewer of Module 4: Office 105.2 and Meeting Room (alternatively) Reviewers of Modules 5 – 9: Office 101.3 Reviewer of Module 10: Office 101.5 Reviewer of Module 11 (Occupational): Office 101.4 Reviewer of Module 11 (Medical): Office 101.6
17:00 - 18:00	Daily IRRS Review Team meeting	Venue: Ministry of Health (salle auditoire) Participants: the IRRS team + LO.
19:30 –	Writing the report	IRRS team
Tuesday 12 June 2018		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions)	Counterparts offices: Reviewer of Modules 1-3, TL and TC and Reviewer of Module 4: Office 105.2 and Meeting Room (alternatively). Reviewer of Modules 1-3, TL and TC and Reviewer of Module 4: Meeting with DG Poos and DG Heisbourg at 9 am. Reviewers of Module 5 – 9: Office 101.3 Reviewer of Module 10: Office 101.5 Reviewer of Module 11 (Occupational): Office 101.4 Reviewer of Module 11 (Medical): Office 101.6
12:00 – 13:00	Lunch	Lunch-pack provided by hotel
	Visit Government /Ministry(ies) Site Visit	Reviewer of Modules 1-3, TL and TC: meeting with Minister of Health at 4:30pm Inspectors and Reviewer(s) of Modules 5-9 (Inspection at customs) Reviewer of Module 10: Visit at Civil Protection Operation Centre. (departure 9am) Reviewer M10
17:00 – 18:00	Daily IRRS Review Team meeting	Venue: Ministry of Health (salle auditoire) Participants: the IRRS team + LO
19:30 –	Writing the report	IRRS team

IRRS MISSION PROGRAMME		
		Hotel: Vauban (Style U is booked)
Wednesday 13 June 2018		
Daily Discussions / Interviews		
09:00 – 17:00	Follow-up interviews and discussions with counterparts for all modules	Counterparts offices Reviewer of Modules 1-3, TL and TC and Reviewer of Module 4: Office 105.2 and Meeting Room (alternatively). Reviewer of Module 5 – 9: Office 101.3 Reviewer of Module 10: Office 101.5
08:30 – 17:00	Site Visit	Inspectors and IRRS Team Reviewers of Modules 5-9, Module 11 medical and Module 11 occupational Inspection at a hospital (departure 8:15)
12:00 – 13:00	Lunch	Lunch-pack provided by hotel
13:00 – 17:00	Writing first draft of preliminary findings (Rs, Ss and GPs)	Participants: IRRS team Venue: Salle auditoire
17:00 -17.30	Quick briefing on site visits	Participants: IRRS team Venue: Salle auditoire
17:30–	Daily IRRS Review Team meeting (First draft of Rs, Ss)	Venue: Salle auditoire Participants: the IRRS team + LO.
19:30 –	Writing the report	Hotel: (Vauban Style U is booked)
Thursday 14 June 2018		
Daily Discussions / Interviews		
9:00 -17:00	Follow-up Interviews and discussions with counterparts (parallel discussions as needed)	IRRS Team Counterparts Offices Reviewer of Modules 1-3, TL and TC and Reviewer of Module 4: Office 105.2 and Meeting Room (alternatively). Reviewers of Modules 5 – 9: Office 101.3 Reviewer of Module 10: Meeting with High Commission of National Protection (Crisis Coordination Body) (10am – 11:30) Reviewer of Module 11 (Occupational):

IRRS MISSION PROGRAMME		
		Office 101.4 Reviewer of Module 11 (Medical): Office 101.6
12:00 -13:00	Lunch	Lunch-pack provided by hotel
19:00 –	Daily IRRS Review Team Meeting: observations, recommendation, suggestions and good practices	Venue: Hotel: (Vauban Style U is booked) Participants: the IRRS team + LO.
Friday 15 June 2018		
Daily Discussions / Interviews		
09:00 – 12:00	Finalize Observations, Recommendations, Suggestions and Good Practices and the first draft report Draft the report.	IRRS Team Ministry (Salle auditoire)
12:00 -13:00	Lunch	Lunch-pack provided by hotel
13:00 – 15:00	Policy issue discussion:	Reviewers and Counterparts and Officers Venue: Ministry (Salle auditoire)
15:00 – 18:00	Discussion of draft mission report with Counterparts by module	Reviewers and Counterparts
19:00 –	Daily Team Meeting: Cross Reading Team finalizes Observations, Recommendations, Suggestions and Good Practices	IRRS Team + LO Venue: Hotel: (Vauban Style U is booked)
Saturday 16 June 2018		
Daily Discussions/ Interviews (if needed)		
08:30 –	Team finalize the report together	IRRS Team + LO Venue: Hotel: (Vauban Style U is booked) Lunch is booked from 12:30 to 13:30
Sunday 17 June 2018		
8:30 -11:30	TL and TC review the draft report before it is submitted to RB for comments	TL and TC Venue: Ministry or Hotel (TBC)
12:30-18:30	IRRS Team rest day and Social Event	Visit of the Castel in Vianden

IRRS MISSION PROGRAMME		
		(http://www.castle-vianden.lu)
Monday 18 June 2018		
Daily Discussions		
08:00 – 16:00	RB review draft report TL and TC finalize the executive summary, press release, TL presentation	
16:00 –	RB submits comments to IRRS team	
16:00- 19:00 19:00 –	IRRS Team Reviews comments Daily Team Meeting	IRRS Team Venue: Ministry (Salle auditoire) Venue: Hotel: (Vauban Style U is booked)
Tuesday 19 June 2018		
Daily Discussions		
09:00 – 12:00	Finalize the draft report with RB	Venue: Ministry (Salle auditoire) IRRS Team and RB
13:00 -	Draft report hand over to RB	IRRS Team
19:00	Official Dinner	Venue: Hotel:
Wednesday 20 June 2018		
09:00 – 11:00	EXIT MEETING Main findings of the IRRS mission (Team Leader) Remarks by RB in response to the mission findings Closing Remarks by IAEA (on behalf of NSRW Director) Press release	Venue: Hotel (Pétrusse Style U) Participants: Government Officials, RB Management and staff, Officials from relevant organizations, the IRRS Team + the LO + counterparts

APPENDIX III - SITE VISITS

No.	Object
1	National Dose Register (DRP)
2	Inspection of Customs Truck Scanner (Customs)
3	Nuclear Medicine Department of Centre Hospitalier du Nord (CHdN)
4	Rescue Services Agency; National Support Base (BNS)
5	Rescue Services Agency; Operation Centre (CGO)

APPENDIX IV– LIST OF COUNTERPARTS

Module/Function	**Counterpart**
Liaison Officer Modules 1-4 and Module 12	Patrick Majerus Head Department of Radiation Protection
Module 5-9	Jean Claude Thiry
Module 10	Patrick Breuskin
Module 11 Occupational	Nico Harpes
Module 11 Medical	Alexandra Schreiner Aurélien Bouëtté
Module 11 Transport	Natasha Jerusalem

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 establish a comprehensive national policy and strategy for safety.**
		R2	**The Government should make provisions to give the DRP the authority to issue binding technical requirements as well as guidance for implementation of regulations.**
		R3	**The Minister of Health should establish a mechanism to ensure the effective independence of the DRP.**
		R4	**The Government should establish the regulatory body within the legal framework and define its functions and responsibilities.**
		R5	**The Government should establish provisions on the licensee's responsibility:** **(a) to verify that products and services provided by suppliers meet expectations for safety;** (b) **to actively evaluate progress in science and technology as well feedback of experience, in order to identify and to make safety improvements that are considered practicable.**
		S1	**The DRP should consider formalizing coordination with other authorities having responsibility for safety so as to improve cooperation and liaison.**
		R6	**The Government should make provision for building and maintaining the competence and for the recognition of qualification of all parties having responsibilities in relation to the safety of facilities and activities.**
2.	**GLOBAL SAFETY REGIME**	GP1	**Active participation in many international activities related to nuclear safety shows how small non-nuclear countries can contribute to enhance global safety regime.**
3.	**RESPONSIBILITIES**	R7	**The DRP should develop a human resources**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
	AND FUNCTIONS OF THE REGULATORY BODY		**plan that establishes the number of necessary staff and the essential knowledge, skills and abilities.**
		R8	**The DRP should formalize its interaction with authorized parties in carrying out its regulatory functions and responsibilities.**
		S2	**The DRP should consider making regulatory documents (e.g. authorizations, inspection reports) and their respective bases for decision publicly available.**
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	R9	**The DiSa should develop a policy document with the mission, vision, behavioral expectations, individual and institutional values and expectation for safety within the management system in line with IAEA Safety Standards.**
		R10	**The DiSa and the DRP should establish, implement, assess and continuously improve a documented integrated management system to ensure safety, using graded approach, in line with IAEA safety standards.**
5.	**AUTHORIZATION**	R11	**The Government should make provisions to enable the license conditions to be changed during their validity period, if needed.**
		S3	**The Minister of Health, the Director of Health and the DRP should consider making available in advance the generic license conditions to the interested parties and providing to the applicant in a timely manner the justification for their regulatory decisions.**
6.	**REVIEW AND ASSESSMENT**		

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
7.	**INSPECTION**	R12	**The DRP should implement an inspection programme covering all facilities and activities and all topical areas (such as EPR), including medical facilities and activities and foreign companies which have been authorized to perform in the country, taking into account the graded approach.**
		R13	**The Government should make provisions for the DRP to assign the duties of the inspectors and to have the authority for unconditional access to the facilities and to their safety related information in order to perform regulatory inspections.**
8.	**ENFORCEMENT**	R14	**The Government should establish an enforcement policy and strategy in accordance with a graded approach and make the necessary provisions for DRP to implement it.**
9.	**REGULATION AND GUIDES**	R15	**The Government should establish legal provisions for justification and communicate them to the interested parties.**
		R16	**The DRP should issue additional guidance to assist both its staff and the authorized parties for the implementation of the regulations.**
		R17	**The DRP should establish the process for the review and revision of regulatory documents.**
		R18	**The Government should make provisions within the regulations for the safe and secure storage of radioactive sources in line with the requirements of the Code of Conduct on the Safety and Security of Radioactive sources.**
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	S 4	**The Government should consider making provisions within the regulations for requiring, within the authorisation process, facilities on-site emergency preparedness and response arrangements for all class II facilities.**
		R19	**The DRP should review on-site emergency preparedness and response arrangements prior to the start of operation of the facility or activity, that could necessitate emergency response actions.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		GP2	**The IRRS team acknowledges the strong integration of the radiological and nuclear emergency response arrangements into the national all-hazards emergency management system. A single all hazard response structure is used, leveraging the expertise of the DRP effectively for nuclear emergencies.**
		GP3	**When making protective action decisions during a nuclear emergency in a foreign country, the Government of Luxembourg default action is to implement the same protective actions as prescribed by the accident country for its residents. Coordinating response actions with another state in this manner is efficient and prevents unnecessary delays in implementing protective actions and enhances public confidence by avoiding confusion or justification of differences in protective actions.**
		S5	**The Government should consider formalising the exercise program to ensure that all organizations and functions of a nuclear emergency response are tested at suitable intervals, including the officials who are responsible for making decisions on protective actions, and analysed to identify lessons learnt.**
11.1	**CONTROL OF MEDICAL EXPOSURES**	R20	**The Government should make provisions in the legal framework for the clear allocation of responsibilities in medical exposure between the authorized party (head of the establishment) and the medical practitioners.**
		R21	**The DRP should make provisions to ensure that:** **(a) the calibration of dosimeters used for patient dosimetry or for calibration of sources is traceable to a SDL;** **(b) the calibration of radiotherapy units is subject to an independent verification prior to first use.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R22	**The Government and the DRP should revise the current legal and regulatory framework to bring it in line with the requirements of IAEA GSR Part 3 for strengthening the medical exposure control and should ensure their full implementation.**
		S6	**The DRP should consider specifying criteria when and how the investigation should be conducted regarding unintended medical exposure.**
11.2	**OCCUPTIONAL RADIATION PROTECTION**	R23	**The Government and the DRP should revise the current legal and regulatory framework to bring it in line with the requirements of GSR Part 3 for strengthening the occupational exposure and should ensure their full implementation.**
		S7	**The DRP should consider establishing an appropriate calibration frequency for workplace monitoring equipment.**
12	**INTERFACE WITH NUCLEAR SECURITY**	R24	**The DRP should make provisions to ensure that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.**

APPENDIX VI - REFERENCE MATERIAL USED FOR REVIEW

- Amended Law of 25 March 1963 concerning the protection of the population against the dangers arising from ionizing radiation.
- Law of August 10, 1983 concerning the Medical Use of Ionizing Radiation.
- Grand-Ducal Regulation of 16 March 2001 on the protection of the health of individuals against the dangers of ionizing radiation during medical exposures.
- Grand-Ducal Regulation of 14 December 2000 concerning the protection of the population against the dangers arising from ionizing radiation.
- Law of 21 November 1980 concerning the organization of the Directorate of Health.
- Grand-Ducal regulation of 11 August 1996 concerning the provision of information to the population on the applicable measures for the protection of public health and on the conduct to be adopted in the event of a radiological emergency.
- Emergency intervention plan in case of a nuclear accident, adopted by the Government in Council on15 October 2014.
- National programme for the management of spent fuel and radioactive waste.
- National Action Plan: Implementation of national guidance on medical imaging.
- Draft Strategic Work Program of the Health Directorate.
- Draft Law
    1. on the protection of persons against the dangers of exposure to ionising radiation
    2. and security measures protecting ionising radiation sources against malicious acts;
    3. on the management of radioactive waste, the transport of radioactive materials and imports;
    4. establishing electronic radiological health records.

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 Requirements, IAEA Safety Standards Series No GSR Part 1 (Rev. 1), IAEA, Vienna (2016).
3. INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, General Safety Requirements, IAEA Safety Standards Series No GSR Part 2 IAEA, Vienna (2016).
4. INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements, IAEA Safety Standards Series No GSR Part 3, IAEA, Vienna (2014).
5. INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, General Safety Requirements, IAEA Safety Standards Series 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 Requirements, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).
8. INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Requirements, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).
9. INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, Specific Safety Requirements IAEA Safety Standards Series No. SSR 6, IAEA, Vienna (2012).
10. INTERNATIONAL ATOMIC ENERGY AGENCY, Organization and Staffing of the Regulatory Body for Nuclear Facilities, IAEA 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, IAEA 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, IAEA Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002).
13. INTERNATIONAL ATOMIC ENERGY AGENCY, Documentation for Use in Regulatory Nuclear Facilities, IAEA 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, IAEA 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, IAEA General Safety Guide Series No. GSG-2, IAEA, Vienna (2011).

16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides, IAEA 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, IAEA 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, IAEA Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001).

APPENDIX VIII - ORGANIZATIONAL CHART

LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Direction de la Santé

DISA ORGANIGRAMME