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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

ETHIOPIA

Addis Ababa, Ethiopia

3-12 December 2017

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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REPORT OF THE
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Mission dates:	***3-12 December 2017***
Regulatory body visited:	Ethiopian Radiation Protection Authority
Location:	*Addis Ababa*
Regulated facilities and activities in the mission scope:	*Radiation Sources in Industrial and Medical Facilities, Radioactive Waste Management, Decommissioning, Transport, Emergency Preparedness and Response, Control of Medical Exposure, Control of Occupational Exposure, Public and Environmental Monitoring*
Organized by:	*IAEA*

IRRS REVIEW TEAM	
MARKKANEN Mika	Team Leader (Finland)
SEVERA Reward Musekiwa	Reviewer (Zimbabwe)
SLOKAN DUSIC Darja	Reviewer (Slovenia)
MUNDIA Isaac	Reviewer (Kenya)
SAMBA Richard Ndi	Reviewer (Cameroon)
SERT Gilles	Reviewer (France)
PASKOVA Zuzana	Reviewer (Czech Republic)
HUSSAIN Muhammad Nadeem	Reviewer (Pakistan)
KHARIT Hassan	Reviewer (Qatar)
SHADAD Ibrahim	IAEA Team Coordinator
ALEXANDER Tom	IAEA Administrative Assistant

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 Ethiopia, an international team of senior radiation safety experts met with representatives of the Government and Ethiopian Radiation Protection Authority (ERPA) from 3 to 12 December 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of Ethiopian national regulatory framework for radiation safety. The mission took place at the ERPA Headquarters in Addis Ababa. Meetings were organized with representatives of the Government, the Ministry of Science and Technology (MOST), Medicine and Health Care Administration and Control Authority (FMHACA) of the Ministry of Health, and the Ethiopian Conformity Measurement Institute.

The IRRS mission covered all civilian radiation source facilities and activities regulated in the country. The review compared the national 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 counterparts in the areas covered by the IRRS.

The IRRS team consisted of 9 senior regulatory experts from 9 IAEA Member States, 1 IAEA staff members, and 1 IAEA administrative assistant. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes, development and content of regulations and guides; emergency preparedness and response; control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance, environmental monitoring, transport, and radioactive waste management.

The IRRS mission included two policy issue discussions on the “Radiation Protection of Pregnant and Breast Feeding Radiation Workers” and on the “Reading Frequency of Personal Dosimeter for Occupationally Exposed Workers”.

The mission included observations of regulatory activities and interviews and discussions with staff of ERPA, State Minister of MOST, the legal advisor of MOST, Food, Medicine and Health Care Administration and Control Authority (FMHACA) of the Ministry of Health, Occupational and Dosimetry Laboratories of the Ethiopian Conformity Measurement Institute. Activities included visits to: waste management facility, service providers for occupational exposure and calibration, St Gabriel General Hospital, and the National Institute for Control and Eradication of Tsetse and Trypanosomiasis. The IRRS team members observed regulated activities and performance of inspection activities, including discussions with the licensee personnel and management.

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

The IRRS team observed that the ERPA counterparts were committed to provide the regulatory oversight of all activities with radiation sources. The invitation of the IRRS mission demonstrates

the Government's and the ERPA's commitment to improve the national legal and regulatory framework for radiation safety.

An important observation of the IRRS review team is that Ethiopia needs to make provision for building and maintaining the competence in radiation safety of all parties having responsibilities in relation to activities with radiation sources.

The IRRS team also believes that the Government has challenges and opportunities over the next few years, which include:

- Implementing the new legislative and regulatory framework including developing of new regulations and directives in line with IAEA safety standards

The IRRS team also believes that ERPA has challenges and opportunities over the next few years, which include:

- Further development and implementation of its Management System;
- Implementation of a graded approach in all regulatory activities; and
- Enhancing its knowledge management arrangements to develop and maintain the necessary competence and skills of its staff.

The IRRS team 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 ERPA as a result of its self-assessment.

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.

The mission provided recommendations and suggestions for improvements, including:

The Government should:

- Establish national policy for safety and a national policy for the safe management of radioactive waste;
- Ensure that diagnostic reference levels, dose constraints and criteria and guidelines for the release of patients following radionuclide therapy are established;
- Establish a requirement that no person incurs a medical exposure unless there has been an appropriate referral.

ERPA should:

- Establish directives and guides consistent with IAEA safety standards that systematically cover all types of facilities and practices;
- Consider separating the operations of the waste management facility from the regulatory functions in order to minimize the potential for conflicts of interests;
- Establish requirements for identification, characterization and classification of radioactive waste;

- Establish a programme to ensure availability and reliability of adequate tools, equipment, instruments, and other essential facilities required for an effective emergency response.
- Establish a requirement for employers, registrants and licensees to develop and maintain a radiation protection programme for occupational exposure.

The IRRS team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of Ethiopia, an international team of senior safety experts met representatives of the Ethiopia Radiation Protection Authority (ERPA) from 3 to 12 December 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Ethiopia regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Ethiopia in July 2015. A preparatory mission was conducted 24-25 July 2017 at ERPA Headquarters in Addis Ababa to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Ethiopia and their related safety aspects and to agree on the scope of the IRRS mission.

The IRRS team consisted of 9 senior regulatory experts from 9 IAEA Member States, 1 IAEA staff members and 1 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, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning.

In addition, policy issues were discussed, including: “Radiation Protection of Pregnant and Breast Feeding Radiation Workers” and “Reading Frequency of Personal Dosimeter for Occupationally Exposed Workers”

ERPA conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of ERPA self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the advance reference material, conduct of interviews with management and staff from ERPA and direct observation of ERPA regulatory activities at regulated facilities. Meetings with the Ministry of Science and Technology (MOST), the Food, Medicine and Health Care Administration and Control Authority (FMHACA) of the Ministry of Health, Occupational and Dosimetry Laboratories of the Ethiopian Conformity Measurement.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Ethiopia radiation 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 Ethiopia. It is expected this IRRS mission will facilitate regulatory improvements in Ethiopia and other Member State, utilising the knowledge gained and experiences shared between ERPA and IRRS reviewers and the evaluation of the Ethiopia 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 Review Team members who have experience of other regulatory practices in the same field;

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

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

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

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

j) promoting the application of IAEA Safety Requirements; and

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Ethiopia, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 24 to 25 July 2017. The preparatory meeting was carried out by the appointed Team Leader Mr Mika Markkanen and the IRRS IAEA Team Coordinator Mr. Ibrahim Shadad.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of ERPA represented by Mr Solomon Getachew Director General of ERPA, and other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides;

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

Mr Surur Kedir Mohammed made presentations on the national context, the current status of ERPA 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 Ethiopia in December 2017.

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

The Ethiopian Liaison Officer for the IRRS mission was confirmed as Mr Surur Kedir Mohammed.

ERPA provided IAEA with the advance reference material (ARM) for the review at the begining of October 2017. In preparation for the mission, the IRRS team members reviewed the Ethiopia advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards 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, 3 December, 2017, directed by the Team Leader and the Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 4 December, 2017, with the participation of senior management staff of ERPA and other interested parties. Opening remarks were made by Mr Solomon Getachew, Director General, Radiation Protection Authority of Ethiopia, Mr Mika Markkenen Team Leader and Mr Ibrahim Shadad Team Coordinator. Mr Surur Kedir Mohammed gave an overview of the Ethiopia context, ERPA 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 Ethiopia and ERPA 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 Tuesday, 12 December, 2017. The opening remarks at the exit meeting were presented by H.E. Mr Afework Kasu, State Minister of MOST and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Mika Markkanen. Closing remarks were made by Mr Ibrahim Shadad, IAEA, on behalf of the Division of Radiation, Transport and Waste Safety Director, IAEA.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Ministry of Science and Technology has established a Science, Technology and Innovation Policy that identifies environmental development and protection as a critical policy issue and aims to "establish and implement a system that addresses the safety of the environment and of society in relation to the use of equipment emitting radiation

ERPA has drafted a Safety Policy document providing guidance for the control of sources and exposures to ionizing radiation that are within its jurisdiction. This document constitutes the safety policy of ERPA as part of its management system as required by GSR Part 2. The management system is further discussed on Section 4.

The draft ERPA Safety Policy does not constitute a National Safety Policy because:

- it does not cover, at the National level, the fundamental safety principles. nor the long-term commitment for safety;
- it is not promulgated as a statement of the Government's intent.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA has drafted a Safety Policy document providing guidance for the control of sources and exposures to ionizing radiation that are within its jurisdiction. However, there is no national policy for safety that addresses the fundamental safety objective, fundamental safety principles and a long-term commitment for safety.*	
(1)	**BASIS: GSR Part 1 Requirement 1 that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals".*
(2)	**BASIS: GSR Part 1 Requirement 1, para. 2.3 states that** "*The national policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following:* *(a) The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles* *(f) Adequate mechanisms for taking account of social and economic developments;* *(g) The promotion of leadership and management for safety, including safety culture*.
(3)	**BASIS: GSR Part 1 Requirement 1, para. 2.4 states that "***The national policy and strategy for safety shall be implemented in accordance with a graded approach, depending on national circumstances, to ensure that the radiation risks associated with facilities and activities, including activities involving the use of radiation sources, receive appropriate attention by the government or by the regulatory body.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R1	**Recommendation: The Government should establish a national policy on safety to fully address the fundamental safety objective, fundamental safety principles and long-term commitment to safety.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Government of Ethiopia has issued Proclamation No. 1025/2017 that has repealed Proclamation No. 571/2008. A number of provisions from Proclamation No. 571/2008 are still in force pending the re-establishment of ERPA through a Council of Ministers Regulations as provided for in Article 28 of Proclamation. The IRRS team was informed during the meeting with the State Minister of MOST that the draft regulations are currently being reviewed by the Attorney General's Office. The IRRS team was further advised that the regulations would have been finalised and issued by March 2018.

The Proclamation No. 1025/2017 empowers the Council of Ministers to issues regulations and the ERPA to issue directives that amplify and implement the provisions of the Proclamation. Both regulations and directives are legally binding. A regulation and several directives have been drafted but none of them have been finalised and issued.

The Proclamation No. 1025/2017 does not provide for, as required by GSR Part 1 Requirement 2 para 2.5;

1. The safety principles for protecting people including justification, optimization and limitations of risks. Individually and collectively — society and the environment from radiation risks, both at present and in the future;
2. Provision for acquiring and maintaining the necessary competence nationally for ensuring safety Provisions for management system requirements for facilities and activities;
3. Provisions for reducing exposure arising from unregulated or existing exposure situations

The IRRS team was informed that some of the provisions are foreseen to be addressed in regulations.

The provision in Article 14 (16) & (17) of the Proclamation No. 1025/2017 on authorisation of the natural person and the termination of the authorisation three months after the death of the authorised person does not ensure continuity of responsibilities. The lack of continuity of responsibility may result in radiation sources and facilities falling out of regulatory control and burdening the Government with costs of decommissioning of facilities and termination of activities including storage and disposal of radioactive sources.

Article 18 (6) of Proclamation No. 1025/2017 provides that suspension of non-compliant facility done by an inspector in cases where safety is compromised and immediate action is required, such suspension shall have no effect if the Head of the License issuing Department of ERPA fails to approve within 30 days. This implies that, if such failure occurs, facilities and activities where

safety is compromised may resume operations even in cases where no corrective actions have been carried out.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The legal framework is not fully in line with the IAEA safety standards, in particular GSR Part 1, GSR Part 2, GSR Part 3, GSR Part 5 and SSR-6.*	
(1)	**BASIS: GSR Part 1 Requirement 2, para. 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *(1) The safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future;* *(4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process;* *(5) Provision for the involvement of interested parties and for their input to decision making;* *(6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively;* *(7) The establishment of a regulatory body, as addressed in Requirements 3 and 4;* *(15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;* *(16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;*
(2)	**BASIS: GSR Part 1 Requirement 9 states that "***The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization*"**
R2	**Recommendation: The Government should review and revise the legal framework to align it with the IAEA safety standards.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Although there are draft regulations, there are no established regulations that amplify and implement the provisions of the proclamation.*	
(1)	**BASIS: GSR Part 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.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R3	**Recommendation: The Government should establish regulations in accordance with the IAEA safety standards.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Proclamation No. 1025/2017 provides for the re-establishment of ERPA as the sole regulatory body. ERPA reports to the Ministry of Science and Technology. ERPA is responsible for all regulatory functions of notification, authorisation, inspection and enforcement and development and issuance of directives and guides. The re-establishment has to be done through a Council of Ministers Regulations as provided for in Article 28 of Proclamation No. 1025/2017. The Council of Ministers Regulations re-establishing ERPA have been drafted and are expected to be finalised and issued by March 2018.

ERPA is presently functional through provisions of Proclamation No.571/2008 that are still in force until the promulgation of the Council of Ministers Regulations re-establishing ERPA as provided by Proclamation No. 1025/2017. Proclamation No. 571/2008 established a Radiation Protection Board, which is an integral part of ERPA, that would be appointed by the Minister of Science and Technology. The IRRS team was informed that the Radiation Protection Board was never appointed. A Director General who is appointed by Government runs ERPA.

Budget of ERPA is allocated by Treasury as provided for in Proclamation No. 571/2008. Proclamation No. 1025/2017 does not have a provision for the funding of ERPA. The IRRS team was informed that the provision would be stated in the Council of Ministers Regulations that will re-establish ERPA.

Ministry of Science and Technology (MOST) oversees the operations of ERPA. The Ministry reviews and approves ERPA's Annual Work Plan. ERPA's work is monitored through monthly progress reports that are submitted to the Ministerial Steering Committee, Quarterly review meetings and reports that are made to the Parliament Standing Committee of Science and Technology.

The Ministry of Science and Technology has 11 institutions including ERPA that report to it. The IRRS team was advised that two specialised Science and Technology Universities, the Ethiopian Biotechnology Authority, Ethiopian Space Technology Institute will in future be utilising radiation technology including plans to set up a research reactor.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Government of Ethiopia has not re-established the ERPA through the Council of Ministers Regulations as required by article 28 of the Proclamation No. 1025/2017.*	
(1)	**BASIS: GSR Part 1 Requirement 2 states that** "*The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.*"

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 Requirement 2 para. 2.5 states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *…..* *(7) The establishment of a regulatory body, as addressed in Requirements 3 and 4;…..*
(3)	**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 expedite re-establishment of ERPA and 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.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

Proclamation No. 1025/2017 assigns legal responsibility for safety to the persons or organizations responsible for the facilities and activities. However, the provision in Article 14 (16) & (17) of the 2017 Proclamation No. 1025/2017 on authorisation of the natural person and the termination of the authorisation three months after the death of the authorised person does not ensure continuity of responsibilities. This issue is addressed in Recommendation 2 in Section 1.2.

There are no provisions that specify that regulatory body requirements do not relieve the person or organisation responsible for a facility or activity from their prime responsibility for safety. This issue is addressed in recommendation 2 in Section 1.2.

ERPA has been granted the authority to require demonstration of compliance with safety requirements through the provisions in Proclamation No. 1025/2017.

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

ERPA, as the sole regulatory authority, is empowered through provisions of Proclamation No. 1025/2017 to enter into coordination and liaison arrangements with other authorities with responsibilities for safety. ERPA has signed MOUs with Ethiopian Customs and Revenues Authority, Ethiopian Ministry of Mines, Petroleum and Natural Gas, Ethiopian Fire Brigade, Metu University, Welikite University, National Meteorology Institute, Ethiopian Conformity Assessments, National Metrology Agency, Ethiopian Roads Authorities, Ethiopian Radiologist Association, Ethiopia Radiographers and Radiologic Association and seven out of nine Regional Health Bureaus.

There are no formalized coordination and liaison mechanisms between ERPA and the Ministry of Transport and between ERPA and Ministry of Health including FMHACCA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA has signed MOUs with several authorities having responsibilities for safety. However, ERPA has no formalised coordination and liaison with other authorities having key responsibilities for safety within the regulatory framework.*	
(1)	**BASIS: GSR Part 1 Requirement 7, para. 2.18 states that,** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned. This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings……"*
S1	**Suggestion: ERPA should consider formalising coordination and liaison with all other authorities having responsibilities for safety.**

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

There are no provisions in Proclamation No. 1025/2017 for a system for identifying situations with existing or unregulated radiation risks and assessing the level of radiation risks. There is no designation of organizations to be responsible for making the necessary arrangements for the protection of workers, the public and the environment and allocation of adequate resources including the assignment of the role of ERPA in dealing with existing and unregulated radiation risks. The Proclamation No. 1025/2017 focuses on regulated facilities and activities. However, ERPA has been conducting search and secure activities for radioactive sources out of regulatory control, conducting measurements and assessments for radon and carrying out environment monitoring. This issue is addressed in Recommendation 2 in 1.2.

1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

Proclamation No. 1025/2017 has provisions for decommissioning and management of radioactive waste including financial arrangements. The Proclamation No. 1025/2017 has provisions for appropriate research and development programmes on radioactive waste management. ERPA has drafted a national policy and strategy on radioactive waste management that has been submitted to government for consideration and adoption.

A disused radioactive storage and radioactive waste management facility is in place which is operated by the Regulatory Control Department of ERPA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A national policy for radioactive waste management is drafted but it is not yet established.*	
(1)	**BASIS: GSR Part 1 Requirement 10, para. 2.28 states that** "*Decommissioning of*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	facilities and the safe management and disposal of radioactive waste shall constitute essential elements of governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities...” “
(2)	**BASIS: GSR Part 5 Requirement 2, states that** “*To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established…”*
(3)	**BASIS: GSR Part 7 Requirement 15 states that** “*The government shall ensure that radioactive waste is managed safely and effectively in a nuclear or radiological emergency”.*
(4)	**BASIS: GSR Part 7 Requirement 15, para 5.84 states that** “The national policy and strategy for radioactive waste management shall apply for radioactive waste generated in a nuclear or radiological emergency…”
R5	**Recommendation: The Government should establish a national policy for the safe management of radioactive waste.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: *ERPA operates a waste management facility within the radiation control department.*
(1)	**BASIS: GSR Part 1 para. 4.7 states that** “*The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework.*”
S2	**Suggestion: ERPA should consider separating the operations of the waste management facility from the regulatory functions in order to minimize the potential for conflicts of interests.**

1.8. COMPETENCE FOR SAFETY

There are no provisions in the Proclamation No. 1025/2017 that have been made to require and promote competence for safety for all parties with safety responsibilities. This includes the persons and organizations responsible for facilities and activities, service providers, qualified experts, research and development centers, radiation workers/ operators and staff of ERPA. Necessary competence levels have not been defined and there is no formal mechanism for recognizing qualified experts.

The IRRS team was informed that the government has plans to establish a human capacity building program with Addis Ababa Science and Technology University in radiation and nuclear science.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no governmental provisions for building competence for the parties having responsibilities in relation to safety, including ERPA staff. Additionally there is no formal system in place for the recognition of qualified experts.*	
(1)	**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;* *(b) The formal recognition of qualified experts;* *(c) The competence of organizations that have responsibilities relating to protection and safety."*
(2)	**BASIS: GSR Part 3 Requirement 11 states that** "*the government shall make provisions for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."*
R6	**Recommendation: The Government should make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities as well as for the formal recognition of qualified experts.**

1.9. PROVISION OF TECHNICAL SERVICES

The National TLD Laboratory at the Ethiopian Conformity Measurement Institution is a public institution that provides personal dosimeters for workers in different medical and industrial facilities from both governmental and private sectors. The laboratory uses TLD readers. Nearly 1400 workers are monitored in 2017 and likely to increase as the service has received additional 1000 TLD dosimeters from the IAEA. The laboratory became operational in 2002 and was licensed and recognized by the ERPA recently. The calibration of the TLD systems is usually done through the Secondary Standard Laboratory (National Measurement Institute).

The National Measurement Institute runs a Secondary Standards Dosimetry Laboratory that offers calibration services. The SSDL is currently not functional.

One private company is providing personal dosimeters for workers in different medical and industrial facilities from both governmental and private sectors. The laboratory uses an OSL Reader. The service started operating in May 2017 and monitored approximately 300 workers in 2017. The company is licensed and recognized by the ERPA.

There are no dosimetry services in Ethiopia providing dosimeters to assess doses to extremities or the lens of the eyes. This issue is addressed in Recommendation 28 in Section 11.2.

1.10. SUMMARY

ERPA has drafted a Safety Policy document providing guidance for the control of sources and exposures to ionizing radiation that are within its jurisdiction. However, there is no national policy for safety that addresses the fundamental safety objective, fundamental safety principles and a long-term commitment for safety Proclamation No. 1025/2017 regulates the peaceful uses of nuclear and radiation technology. There are no regulations that have been issued. The legal framework for safety, need to be reviewed and revised to be in line with the IAEA Safety Standards. Provisions for competency for safety are yet to be established. ERPA has a number of formalised coordination and liaison arrangements with other authorities with responsibilities for safety, however, some are still to be formalized. There are no provisions for a system for protective actions to reduce existing or regulated radiation risks. National policy for radioactive waste management need to be finalised and approved by the government. Currently the only calibration service laboratory in the country is not functioning. Occupational dosimetry services are available but it does not cover extremities and the lens of the eyes.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The Government of Ethiopia is state party to the Treaty on the Non-Proliferation of Nuclear Weapons and the African Nuclear Weapons Free-Zone Treaty (Pelindaba Treaty), expressed its political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources. Ethiopia participates in the Incident and Trafficking Database.

Ethiopia is not state party to the following conventions and treaties that are relevant to nuclear and radiation safety; Convention on the Physical Protection of Nuclear Material and its Amendment, Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, Convention on Early Notification of a Nuclear Accident, or Radiological Emergency, Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management, Convention on Nuclear Safety. The government has not expressed its political commitment to the Supplementary Guidance on the Import and Export of Radioactive Sources.

Ethiopia participates in some international activities that contribute to the global safety regime including hosting international and regional trainings workshops and conferences, IAEA General Conference and the Senior Regulators Meeting, Regulatory Cooperation Forum and providing experts for IAEA expert missions.

ERPA is a member of the Forum of Nuclear Bodies in Africa (FNRBA).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The country is not state party to a number of international conventions that establish common obligations and mechanisms for ensuring protection and safety.*	
(1)	**BASIS: GSR Part 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 to enhance safety globally."*
(2)	**BASIS: GSR Part 1 Requirement 14 para 3.2 states that** *"The features of the global safety regime include: (a) International conventions that establish common obligations and mechanisms for ensuring protection and safety."*
S3	**Suggestion: The Government should consider to be a party to international conventions that establish common obligations and mechanisms for ensuring protection and safety.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

ERPA staff participate in international conferences and meetings and expert missions sharing operating experience and regulatory experience with peers from other countries. ERPA ensures that its staff makes presentations to their colleagues to share what they will have learnt at international

conferences and workshops.

There is no formal mechanism to evaluate operating experience and regulatory experience and documenting it for disseminating lessons learned with licensees and other interested parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no formalized arrangements for identifying lessons to be learned from operating experience and regulatory experience and for the dissemination of the lessons learned.*	
(1)	**BASIS: GSR Part 1 Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities."*
R7	**Recommendation: ERPA should make formalized arrangements for identifying lessons to be learned from operating experience and regulatory experience and for the dissemination of the lessons learned.**

2.3. SUMMARY

Government of Ethiopia is not state party to a number of relevant conventions and treaties that establish a common framework for nuclear and radiation safety. ERPA actively participates in activities and events that promote the global safety regime.

There are no formalised arrangements for identifying and disseminating lessons learnt from operating and regulatory experience.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Director General of ERPA is appointed by the Government. ERPA is organized in four main core directorates; Notification and Authorization Directorate, Regulatory Control Directorate, Research and Development Directorate and a Non-Ionizing Radiation Directorate and supportive directorates such as human resource, planning, financial and communication. (see Annex VIII).

Notification and Authorization Directorate is responsible for notification, authorization, Regulatory Authority Information System, registry and awareness creation activities. Regulatory Control Directorate is responsible for conducting inspections, enforcement, environmental monitoring, radioactive waste management and emergency and preparedness and response. Research and Development Directorate is responsible for carrying out research and development required to strengthen the regulatory activities of ERPA.

Financial resources of ERPA are provided directly from treasury. Each directorate submits its financial needs based on its planned activities in each year and this is consolidated and sent to the government as a budget request for the following year. Approved funds are allocated from the government and are distributed in accordance to the need of each directorate by the management of ERPA.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

ERPA is responsible for taking regulatory decisions related to notification, authorisation, inspections and enforcement. Though ERPA reports to the Ministry of Science and Technology, there are no current conflicts of interest as the institutions reporting to Ministry of Science and Technology are currently not utilising nuclear and radiation technologies. The situation might change, as there are plans for some of the institutions to embark on radiation technology-related research and the setting up of a research reactor.

A provision in article 17 (3)(b) of Proclamation No. 1025/2017 provides that the decision of an enforcement action by an inspector may not be enforced when complaint-handling body reverses the order or decision of the inspector. Since this complaint-handling body is not well defined in the Proclamation No. 1025/2017, this may lead to a decision being made that may allow a non-compliant facility to continue functioning without having carried out corrective actions. This provision potentially compromises the effective independence of ERPA in performing its regulatory functions. See Recommendation 2 in Section 1.2.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

ERPA has an approved establishment of 46 posts for technical staff. This is based on an estimation of future needs. Current number of technical staff is 26 and support staff 43. The IRRS team was

informed that ERPA will fill the currently vacant 20 technical staff posts allowed by the approved establishment, when the need arises.

The IRRS team noted a lack of competence and skills of the ERPA staff in the conduct of its regulatory activities including those related to authorization, review and assessment, inspections and preparation of directives and guides. Examples of these are discussed in the relevant parts of this report. The IRRS team was informed that causes for this situation include the lack of institutions offering post-graduate programs in nuclear and radiation related fields. The IRRS team noted that ERPA also loses competence due to the departure of some qualified staff.

ERPA has taken measures to improve the competence and skills of its staff through establishing "Human resource management strategy" and "training programme". These measures are discussed in paragraph 4.2.3. However, the various examples of lack of competence noted by the Team demonstrate that these measures have not yet been sufficient to solve this challenge.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA does not have sufficiently qualified and competent staff commensurate with the nature of facilities and activities to be regulated.*	
(1)	**BASIS: GSR Part 1 Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	**BASIS: GSR Part 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 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."*
(4)	**BASIS: GSR Part 1 Requirement 18 para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills….."*
S4	**Suggestion: ERPA should consider reviewing and revising its knowledge management arrangements to develop and maintain the necessary competence and skills of its staff.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

ERPA has no dedicated advisory bodies. The Proclamation No. 571/2008 provides for the establishment of the Ethiopian Radiation Protection Board which is a part of the Regulatory Body. Issues related to the Board are discussed in paragraph 1.3.

ERPA has no dedicated Technical Support Organizations. The IRRS team was informed that ERPA could use external experts to provide advice in support of its regulatory functions, although there is no provision on this in the Proclamation. However, in practice ERPA has not used this possibility because of the lack of independent qualified experts in the country. Effective use of external experts is also challenged by the lack of competence within the ERPA to act as an "intelligent customer". The issue of competence for safety, including the recognition of qualified experts, is discussed in paragraphs 1.8 and the competence of the ERPA staff in paragraph 3.3. (See Recommendation under 1.8 and Suggestion under 3.3)

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Formal communication between the ERPA and the authorized parties on safety related issues takes place as part of ERPA carrying out its regulatory functions. Practical means for formal communication include documents providing guidance for applying for authorization, submitted applications, requests of further information, license and conditions attached to it, and inspection reports.

The IRRS team was informed that ERPA uses several different ways for informal communication between the ERPA and the authorised parties on safety related matters, including providing information through its web site, workshops, meetings, and face-to-face discussion.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

ERPA provides assurance that regulatory controls are stable and consistent with the national legal framework, for example, by means of establishing regulatory requirements, defining internal procedures, using check-lists and that inspection reports are reviewed by senior management before being issued. Establishment of regulatory requirements is discussed in Section 9.1 and related consultation and communication with interested parties is discussed in Section 3.8. The issue of processes related to establishing requirements in regulations, directives and guides is addressed in Recommendation 12 in Section 9.1. Policies, processes and criteria related to actions prescribed in above are part of the ERPA management system being established. Issues related to the management system are discussed further in Section 4.

3.7. SAFETY RELATED RECORDS

ERPA maintains national inventory of sources using the Regulatory Authority Information System RAIS 3.2 which is provided by IAEA. ERPA regularly updates the national inventory in RAIS. Authorization records are also captured in RAIS. Full demonstration on use of RAIS and the inventory of sources was provided by the Notification and Authorization Directorate.

Dosimetry service providers send dose reports to the licensees and ERPA. The service providers maintain hard and soft copies of the records including an electronic backup which is kept on site. ERPA maintains the records in hard copy. The IRRS team was informed that this started only 4 months back. There is no national dose register, however, there is a requirement for the service providers to keep the dose records for 30 years as specified on the conditions stated on the license.

The IRRS team noted that retrieving relevant documents from hardcopy archives required some effort and occasionally the status (draft, approved/not approved) of the document remained unclear. This applied to management system documentation maintained by ERPA. Document control and management could be improved by introducing an electronic document management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Retrieving relevant documents from hardcopy archives requires some effort and occasionally the status of the documents reviewed remained unclear.*	
(1)	**BASIS GS-G-3.1 para 2.1. states that** *"...An electronic document management system can be used to aid in document control and management."*
S5	**Suggestion: ERPA should consider introducing an electronic document management system.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

ERPA has established a communication strategy which comprises various mechanisms to communicate to the public, other governmental agencies, and other stakeholders of its activities. Communication activities are supported by ERPA's communication service, including the following mechanisms:

- ERPA's website;
- Email communication;
- Postal letters;
- Print and electronic media;
- Posting on the notice boards;
- Press conferences and media interviews;
- awareness training;
- meetings, workshops and seminars;
- quarter report to the public wing (see below for further details);
- reports to the Parliament.

The IRRS team was informed about activities related to the "public wing". All governmental agencies in Ethiopia have the obligation to communicate their activities regularly to different "wings" like governmental wing and the public wing. The public wing comprises 13 different stakeholders, as identified by the ERPA, representing the interests of the public. These include associations and public organisations having interests in areas of consumer products, medical and health sector and public construction. The public wing holds regular quarterly meetings based on the agenda prepared by the ERPA. In addition, all the members may raise issues to be discussed.

Agenda items include ERPA annual plans and proposed new regulations. Feedback received from the meetings are noted and considered by the ERPA.

ERPA prepares and publishes printed magazines on selected areas of its activities. The print of these magazines is 3000 – 5000 pieces and they are distributed in different workshops, seminars, and training events to different interest groups including teachers, journalists and representatives of professional associations. ERPA also published news letters on its website.

The ERPA website allows for the public to send feedback or questions. ERPA also uses Facebook to communicate with the public.

3.9. SUMMARY

ERPA has 46 established posts for technical staff. 26 of these posts are currently filled. ERPA reports to the Ministry of Science and Technology and has independence in exercising its regulatory functions. ERPA funding is provided through a budget from Treasury. There is lack of sufficiently qualified and competent staff. There are no dedicated advisory bodies and technical support organizations. There are procedures and mechanisms to ensure stability and consistency of regulatory control. ERPA uses the Regulatory Authority Information System for maintaining sources inventory and authorization documents. There is no national dose registry. ERPA has developed and implemented communication strategies with interested parties.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

ERPA prepared for the module 4 ARM report where the activities of the regulatory body are compared against the IAEA Safety Standard GS-R-3 "Management System for Facilities and Activities". Since in 2016 the new IAEA Safety Standard was issued, namely, GSR Part 2 "Leadership and Management for Safety" which supersedes the GS-R-3, the Module 4 of the IRRS report is based on the requirements of the new IAEA Safety Standard GSR Part 2.

4.1. LEADERSHIP FOR SAFETY

According to the IAEA Safety Standard GSR Part 2, leadership for safety can be expressed among other also through establishing vision, mission, values, establishing behavioral expectations and fostering a strong safety culture.

The senior management of ERPA demonstrates leadership for safety and commitment to safety by establishing its mission, vision, values and objectives.

The ERPA mission is to see Ethiopian people highly protected against radiation hazards and to create a favourable conditions for the contribution of radiation and nuclear technology towards accelerating sustainable national development, without causing undue burden to future generation of Ethiopia and by protecting people, property, and the environment against the risk of damage from radiation, through strengthening and implementing an efficient radiation protection and regulatory infrastructure.

The mission, as well as the vision and objectives, are published in different ERPA documents and on the ERPA website. Management at all levels periodically communicates the mission, vision, policies, strategies and objectives to ERPA employees.

Demonstration of leadership for safety is expressed also through conducting different meetings at all organizational levels. Director General conducts meetings with senior management /heads of departments at least once a month. He also conducts meetings with all the staff every three months. The heads of departments conduct meetings with their employees weekly. At the meetings management inform the employees about current activities of the organization. Safety is usually also one of the issues of these meetings. Informal communications are also available based on individual interest.

4.2. MANAGEMENT FOR SAFETY

4.2.1. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

It is the responsibility of the senior management to ensure that an integrated management system is established, applied, sustained, and continually improved in order to ensure safety. This responsibility is now defined in the ERPA "Quality Manual".

The Director General appointed a Quality Manger and a Committee which consisted of the ERPA employees from different departments that are responsible for establishment and implementation of the management system.

As a part of the management system the ERPA senior management is developing a set of policies, namely:

- Quality Policy;
- Safety Radiation Policy and;
- Enforcement Policy.

Further the ERPA management has developed two strategies:

- Communication Strategy and;
- Human Resource Management Strategy.

IRRS team was informed that ERPA on the basis of "Strategic Plan" each year prepares "Annual Plan" where the goals for the whole organization are defined. Additionally, more detailed "Annual Plans" are also prepared on department levels. In the preparation of plans all employees are involved. Plans are communicated to employees and are reviewed twice a year. "Strategic Plan" and "Annual Plan" of the Regulatory Body and their implementation are also evaluated by the House of the Representative Science, Technology and Communication Standing Committee of the national Parliament.

Interaction with interested parties is defined in "Communication Strategy". On the basis of the "Communication Strategy", the annual plan for communicating with the Interested Parties is defined. The plan defines all interested parties and the way of communicating with them and the frequency of communications. The plan also defines training programs for the concerned interested parties.

ERPA has also developed a special procedure for conducting internal and external communications.

4.2.2 THE MANAGEMENT SYSTEM

ERPA has been developing a documented management system. Currently, the management system does not fully integrate all elements, including safety, health, environmental, security, quality, human-and-organizational factor, societal and economic elements, so that safety is not compromised. The implementation of ERPA management system is still in initial phase. This issue is addressed in Recommendation 7 below.

In 2017 ERPA issued the "Quality Manual" which is in line with the standard ISO 9001:2015. However, the "Quality Manual" does not consider all additional specific requirements posed by IAEA Safety Standard GSR Part 2 "Leadership and management for safety". The quality manual does not capture, for example:

- Graded approach;
- Description of some processes, or references to the procedures that describe processes (not clear);

- Safety culture;
- Measurement, assessment and improvement of leadership for safety and of safety culture.

The IRRS team observed that the existing implementation plan, for the management system, attached to the ARM, has not been updated. The detailed implementation plan which identifies all key activities for implementing, assessing and improving integrated management system where the priorities are considered, is not developed. This issue is addressed in Recommendation 7 below.

Application of the graded approach to the management system is used in practice in the implementation of different regulatory activities, i.e. inspection process, authorization process etc. However, the use of the graded approach, as an important part of the management system, is not identified in the Quality Manual. The IRRS team noted that some criteria used to grade the management system and its processes are not relevant. These criteria are discussed in sections 6.3 and 5.3 and addressed in Recommendation 10 in Section 6.3 and Suggestion 5 in Section 5.3

Regarding management system documentation ERPA has already developed:

- Set of policies (addressed in chapter 4.2.1);
- Set of strategies policies (addressed in chapter 4.2.1);
- Quality Manual;
- 17 procedures which describe some processes and activities and;
- 90 forms.

The IRRS team was informed that ERPA regularly familiarizes all ERPA employees with the manual and other management system documentation.

However, from the discussion it was observed that management system documents are not always efficiently disseminated through the organization, since there is no common network for all employees, i.e. Intranet or LAN, etc. This issue is addressed in Suggestion 5 in Section 3.7.

ERPA documentation control system is not fully centralized. Each department has its own documentation system. Only some departments, i.e. Notification, Authorization Department, and Human Resource Department managed the documents partly electronically. This issue is addressed in Suggestion 5 in Section 3.7.

Further, the IRRS team observed that status and identification of documents are not always defined. This issue is addressed in Recommendation 8 below.

Observation: *The ERPA management system does not consider some requirements of the IAEA safety standards relating to the management systems.*	
(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 1 Requirement 19, para. 4.15 states that** *"The management system of the regulatory body has three purposes:* *(1) The first purpose is to ensure that the responsibilities assigned to the regulatory body are properly discharged.* *(2) The second purpose is to maintain and improve the performance of the regulatory body by means of the planning, control and supervision of its safety related activities.* *(3) The third purpose is to foster and support a safety culture in the regulatory body through the development and reinforcement of leadership, as well as good attitudes and behaviour in relation to safety on the part of individuals and teams.*
(3)	**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."*
(4)	**BASIS: GS-G-3.1 para 2.1. states that** *"An integrated management system should provide a single framework for the arrangements and processes necessary to address all the goals of the organization. These goals include safety, health, environmental, security, quality and economic elements and other considerations such as social responsibility."*
(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 10 states *that*** *"Processes and activities shall be developed and shall be effectively managed to achieve organisation's goals without compromising safety."*
(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: GS-G-3.1 para.2.24 states that** *"Senior management should prepare a plan to achieve full implementation of the management system. …"*
R8	**Recommendation:. ERPA should improve and complete its management system to be in line with IAEA safety standards.**

4.2.3 MANAGEMENT OF RESOURCES

Senior management is responsibly to determine and to provide the competences and resources necessary to carry out activities of the regulatory body safely.

The need for financial resources is defined in the "Strategic Plan" and in the "Annual Plan". The financial resources are directly allocated by the Government. The IRRS team was informed that there is no shortage of financial resources for running the routine activities. However, it is not possible to utilize the budget for educational and training purposes abroad and for buying foreign equipment due to the shortage of foreign currency.

ERPA developed “Human Resource Management Strategy” and “Training program”. On the basis of the training program the training plan is prepared as a part of the general “Strategic Plan” and “Annual Plan”. The plan is not appropriately implemented which leads to lack of well-trained individuals and needed competences for ERPA to carry effectively its regulatory functions. This issue is addressed in Suggestion 4 in Section 3.3.

The knowledge management is limited only to some activities i.e. experience sharing program, keeping different presentations, etc. Information and knowledge are not always systematically managed and disseminated in the way that everybody in the organization has an access to the relevant information. This issue is addressed in Suggestion 5 in Section 3.7.

The IRRS team was informed that there is no relevant training program on national level. Most of the current training activities are provided by IAEA, KINS and US-DOE. ERPA technical personnel regularly participates in these trainings, i.e. 10 - 15 trainings days per year per employee.

ERPA monitors the performance of activities defined in the “Annual Plan” through Balanced Score Card and also on the basis of performing every day activities. On the results of measurements, the gaps are determined and corrective action are taken. To overcome the gaps ERPA organizes several educational and training activities defined in the ERPA’s “Strategic plan” and “Annual Plan”.

4.2.4 MANAGEMENT OF PROCESSES AND ACTIVITIES

All ERPA processes are not documented and formalized, yet. These processes are implemented according to current practice, for example: process for drafting, reviewing and revising regulations, directives and guides (see Recommendation 13 in Section 9.1) and emergency preparedness process (see Recommendation 18 in Section 10.4). Regarding core processes ERPA currently documented four core processes. IRRS team noted that some processes have not been developed on the way that ensures effective implementation of activities, for example, review and assessment process (see Recommendation 10 in Section 6.3) and inspection process (see Suggestion 8 in Section 7.1).

ERPA has prepared a process map where interfaces within majority of the processes are identified. However, the process map does not include all ERPA processes, and an overarching transparent process map identifying all management, core and supporting processes and covering all activities of the regulatory body is not in place.

4.3. CULTURE FOR SAFETY

The culture for safety of the Regulatory Body is not directly formalized in Regulatory Body’s management system documents. This issue is addressed in Recommendation 8 in Section 4.2.

However, ERPA has applied some elements of safety culture in several activities implemented. The IRRS team was informed that, in relation to safety culture, even if it is not directly addressed in the ERPA organizational documents, the related principle is applied in several activities carried out.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Self-assessment and independent assessments of leadership for safety and safety culture are not addressed in the regulatory body's management system documents.*	
(1)	**BASIS: GSR Part 2 Requirement 12 states that** *"Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture."*
(2)	**BASIS: GSR Part 2 Requirement 12 para 5.2 states** *"that Senior managers and all other managers shall advocate and support the following:* *(a) A common understanding of safety and of safety culture, including: awareness of radiation risks and hazards relating to work and to the working environment; an understanding of the significance of radiation risks and hazards for safety; and a collective commitment to safety by teams and individuals;* *(b) Acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety;* *(c) An organizational culture that supports and encourages trust, collaboration, consultation and communication;* *(d) The reporting of problems relating to technical, human and organizational factors and reporting of any deficiencies in structures, systems and components to avoid degradation of safety, including the timely acknowledgement of, and reporting back of, actions taken;* *(e) Measures to encourage a questioning and learning attitude at all levels innthe organization and to discourage complacency with regard to safety;* *(f) The means by which the organization seeks to enhance safety and to foster and sustain a strong safety culture, and using a systemic approach (i.e. an approach relating to the system as a whole in which the interactions between technical, human and organizational factors are duly considered);* *(g) Safety oriented decision making in all activities;* *(h) The exchange of ideas between, and the combination of, safety culture and security culture."*
(3)	**BASIS: GS-G-3.1 para 2.32 states that** *"the management system should provide structure and direction to the organisation in a way that permits and promotes the development of a strong safety culture together with the achievement of high levels of safety performance. …"*
(4)	**BASIS: GSR Part 2 Requirement 14 states that** *"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization."*
R9	**Recommendation: ERPA should improve its management system to foster, in a documented manner, a strong safety culture and leadership for safety and ensure that self-assessment and independent assessment of both safety culture and leadership for safety are implemented.**

4.4. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

ERPA defined measurement, assessment and improvement process in the "Quality Manual" and additionally in some procedure, namely:

- Non-Conforming Services Control Procedures;
- Corrective and Preventive Action Procedure;
- Internal Audit Procedure;
- Management Review Procedure.

Management system documentation does not address the following activities:

- Self-assessment of the management system (see Recommendation 8 in Section 4.2);
- Measurement, independent assessment, self-assessment and improvement of leadership for safety and safety culture (See recommendation 9 in section 4.3).

Management review do not include the following inputs (see GSR Part 2 Para 6.7):

- Lessons from experience gained and from events that have occurred, both within the organization and outside the organization, and lessons learned from identifying the causes of events (see Recommendation 7 in Section 2.2).
- Technical advances and results of research and development
- Lessons from identifying good practices; (see Recommendation 6 in Section 2.2);

Currently measurement, assessment and improvement processes are mainly related to the evaluation of the ERPA performed activities using the ERPA "Annual Plan". However, the IRRS team was informed that the first internal audit on inspection process has already been performed.

4.5. SUMMARY

The ERPA management system in place does not cover some requirements, defined in IAEA Safety Standard GSR Part 2 "Leadership and Management for Safety". In the "Action Plan" the Regulatory Body has recognized the need for the establishment and implementation of its own integrated management system. However, the implementation of ERPA management system is still in the initial phase.

Elements of the ERPA management system are captured in different documents. ERPA Quality Manual is developed in accordance with Standard ISO 9001:2015 and as such does not cover some requirements of an integrated management system.

There is a need to continue the development, implementation and continual improvement of a robust and effective integrated management system in line with IAEA Safety Standards, which should foster and sustain a strong safety culture in order to achieve a high level of safety.

5. AUTHORIZATION

5.1. GENERIC ISSUES

According to Proclamation N^{o} 571/2008 and Proclamation No. 1025/2017, ERPA is responsible for the authorization of facilities and activities in relation to radiation safety {Article 5 and Article 7 (1) of the proclamation N^{o} 571 and part 2 of the Proclamation No. 1025/2017}.

ERPA has developed a range of authorization application forms for different facilities and activities. There are also requirements to guide applicants to apply for authorization of different facilities and activities. The Proclamation requires that the applicants submit a detailed safety assessment report.

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The license issued by ERPA includes expiration dates and conditions of the authorization. A pre-authorization inspection is conducted before an operation license is issued or renewed for all facilities and activities. A license issued for a facility includes licenses for all the activities within the facility. Licence certificates are also issued to Service Providers.

The Authorization process consists of the following main steps:

- Reception and acceptance of an application;
- Review of the application which may include requests for additional information by ERPA from the applicant;
- Evaluation of assessment report;
- Submission of the assessment report and licensing recommendations by the Authorization team leader to the Director of Notification and Authorization Directorate (NAD) for decision.

The Director of NAD has delegated powers from the Director General to take decisions and issue licenses.

ERPA has identified more than 373 sealed sources in different activities like construction, irradiation, medicine and research institutes. There are more than 1260 X-ray machines. National registry of these ionizing radiation sources is established and regularly updated in IAEA RAIS 3.2 web. Authorizations are also regularly recorded in RAIS. However, other regulatory activities like Review and Assessment, Inspection, Enforcement, Radiological Events and Dose Registry are still to be recorded.

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The regulatory framework in the area of management of radioactive waste is not yet established. There are stipulated formal requirements for licensing, but no specific requirements (principle, characterization, classification of radioactive waste...) are defined.

Proclamation No. 1025/2017 states that no activities involving management of radioactive waste, disused sources shall be carried out without fulfilling the requirements in obtaining authorization. A license is required for radioactive waste management that includes treatment, conditioning, handling, transport, storage and disposal excluding transport outside the area of management. No

such operation can commence before the authorization is issued by ERPA.

In Ethiopia, there are no nuclear facilities in operations or in the process of decommissioning nor research reactor. There is only one facility for the storage of radioactive waste originating from disused sources, orphan sources and other radioactive waste.

The central storage facility has been established and operational under the control of ERPA since 2014. The responsibility of operation lies with ERPA and all the operators of this facility are employees of ERPA. The License for radioactive waste facility is issued by ERPA every year. The interim storage facility keeps inventory of the sources (26 unconditioned, 17 conditioned and 5 orphan).

IRRS team was informed that the draft "Radioactive Waste Management Policy for the Ethiopian Radiation and Nuclear Protection Authority" (November 2017) and "Ethiopian Radiation and Nuclear Protection Authority Directive for Radioactive Waste Management" (September 2017) are available.

The IRRS team was informed that ERPA is planning to establish disposal for high level and long lived radioactive waste in 2019. The IRRS team was also informed that the requirements for regulating such types of facilities will be established in the near future.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The proclamation provides for a graded approach in authorization in the form of registration or licensing, or exemption. ERPA does not consistently apply these options. There are no specific guides for conducting site evaluation, design, construction, commissioning, operation, shutdown and decommissioning of complex facilities. Authorization of complex facilities is not being done through a multi stage authorization process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: *The proclamation provides for exemption, registration and authorization of facilities and activities. However, ERPA does not fully implement those provisions.*
(1)	**BASIS: GSR Part 1, Requirement 23:** *Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process*
(2)	**BASIS: GSR Part 3 Requirement 8, para 3.10 states that** *"The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, including the requirements for notification, registration or licensing, using as the basis for this determination the criteria for exemption specified in Schedule I or any exemption levels specified by the regulatory body on the basis of these criteria."*

(3)	**BASIS: GSR Part 3 Requirement 7, para 3.7 states that** *"Any person or organization intending to carry out any of the actions specified in para. 3.5 shall submit a notification to the regulatory body of such an intention18. Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible."*
S6	**Suggestion: ERPA should consider implementing a graded approach in authorization as provided in the proclamation.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA does not implement a multi-stage authorization system for complex facilities and activities.*	
(1)	**BASIS: GSR Part 1 para. 4.29 states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure)…"*
R10	**Recommendation: ERPA should implement a multi-staged authorization system for complex facilities and activities.**

5.4. AUTHORIZATION OF TRANSPORT

The practice of transport of radioactive materials in Ethiopia covers a wide range of activities of radioactive materials, including NORMs, consumer products, nuclear gauges containing low activity sources and packages containing high activity sources for irradiators or radiotherapy.

Not all organisations involved in transport of radioactive materials have been authorized or exempted by the regulatory body. These include air carriers and subsidiary companies for handling, loading and unloading in airports, road carriers that are not identified as source owners and organizations involved in the distribution of consumer products containing radioactive substances. According to international standards, in-transit handling and storage operations are considered as transport operations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Not all legal or physical persons involved in transport of radioactive materials have been authorized or exempted by the regulatory body.*	
(1)	**BASIS: GSR Part 1 Requirement 23 states that "***Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	or approved by means of a notification process."
(2)	**BASIS: GSR Part 3 Requirement 7 states that** *"Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body a notification and, as appropriate, an application for authorization"*
(3)	**BASIS: SSR-6, paragraph 106 states that "***Transport comprises all operations and conditions associated with, and involved in, the movement of radioactive material; these include the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage including in-transit storage, unloading and receipt at the final destination of loads of radioactive material and packages"*
S7	**Suggestion: The Regulatory Body should consider measures to ensure that all consignors, carriers and in-transit handling companies involved in the transport of radioactive materials are appropriately authorized, unless exempted.**

There is an apparent need for ERPA to liaise with the Civil Aviation Authority (within the Ministry of Transport) to define the respective licensing responsibilities, as well as for other regulatory functions, regarding the companies involved for this mode of transport. These functions include establishing and implementing transport safety regulations for the air mode, inspection of licensees and transport operations, organization of emergency response in case of an airplane accident. Ministry of Transport (MoT) is also responsible for the control of transport of dangerous goods by road, so liaison to define respective responsibilities of ERPA and MoT is also needed in this area. The need for liaison between ERPA and the MoT and the Civil Aviation Authority is addressed in Suggestion 1 in Section 1.5.

ERPA currently licenses individual shipments. This has potential to overwhelm ERPA due to the future growing transport needs. Repetitive transportation of radioactive materials of similar nature by the same organization is a permanent activity for which multiple shipments can be authorized simultaneously.

No graded approach has been noted regarding the authorization requirements, with respect to the hazards raised by the shipments. It is generally considered that transport of consumer products in excepted packages and of low specific activity materials of group LSA-I in industrial packages raise less hazards than others. ERPA could then envisage a graded approach consisting in registering the companies involved in such transports, without requiring application for license.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *No graded approach has been noted regarding the authorization requirements, with respect to the hazards raised by shipment.*	
(1)	**BASIS: GSR Part 3 Requirement 7, states that** *"Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body a notification and, as appropriate, an application for authorization"*
	BASIS: GSR Part 3 Requirement 6, states that *"The application of the requirements*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures"
S8	**Suggestion: ERPA should consider establishing and implementing a graded approach in licensing consignors and carriers.**

Proclamation No.1025/2017 does not provide for requirements for the contents of the application that is to be transmitted to ERPA in view of authorization of transport activities.

5.5. SUMMARY

The existing Proclamation No. 1025/2017 defines authorization process. The authorization process prepared by ERPA is not commensurate with the radiation risk associated with facilities and activities, in accordance with a graded approach and no legal document prescribing requirements in detail for complex facilities and activities and radioactive waste management facility are established. Areas of improvements are suggested to ensure completeness and consistency in the development of regulatory framework in line with IAEA Safety Standards.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

ERPA undertakes review and assessment of licence applications to determine whether facilities and activities comply with regulatory requirements. ERPA has developed a general procedure of review and assessment of licence applications. However, there are no activity-specific procedures for review and assessment of applications that would ensure consistency and the application of a graded approach.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

An officer in the notification team reviews a licence application and if the officer is satisfied with the completeness of the documentation, the application is forwarded to the Director of Directorate of Notification and Authorisation (NAD). The Director assigns the application to an authorisation team for further review and assessment and recommendation for authorization. The Director of NAD grants the licences.

ERPA has one document describing the general procedure for review and assessment but there are no practice specific procedures related to the review and assessment process. ERPA has no activity-specific guidelines or checklists to guide the authorization and notification teams on the review and assessment of various facilities and activities. In addition, graded approach is not applied during the review an assessment process..

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

The directorate of notification and authorization reviews license applications. The directorate has 9 technical officers, who are all involved in the review and assessment process. ERPA does not have sufficient competence and skills for effectively carrying out review and assessment of complex facilities. This issue is addressed in Suggestion 4 in Section 3.3.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Article 8 of the proclamation specifies necessary documents that must be submitted with application for authorization for facilities and activities. Article 9 specifies the required documentation for an application for mining and processing radioactive material. Article 11 specifies required documentation for import and export application. The information submitted by the applicant must include details of the source, plans of the facility, details of the Radiation Safety Officer (RSO), radiation workers and safety assessment. Conduction of the Safety Assessment is the responsibility of the licensee. The facilities hire services of approved service providers to conduct safety assessment. However, ERPA conducts safety assessment for facilities holding radioactive materials of category 1 and 2. The IRRS team was informed the service providers lack competence for performing the assessment for those categories of sources.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

ERPA has a general procedure for review and assessment. It has no practice specific procedures for the review and assessment of licence applications. The IRRS team was informed that the general procedure includes the generation of safety assessment report based on the review of the written material submitted to applicant and the pre-authorization inspection of category 1 and 2 facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA has not documented procedures that ensure consistency and application of a graded approach in review and assessment.*	
(1)	**BASIS: GSR Part 1 Requirement 22, paragraph 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principals and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body……*
(2)	**BASIS: GSR Part 1 Requirement 26 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility of activity, in accordance with a graded approach.*
R11	**Recommendation: ERPA should develop practice specific procedures to ensure consistency and application of a graded approach in the review and assessment process.**

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The documentary basis on which the review and assessment for radioactive waste management facility are performed is not clearly and sufficiently stated in the proclamation. The specific requirements for review and assessment for radioactive waste management facility are not established. See Recommendation11 in Section 6.1.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The safety assessment reports are the basis of the review and assessment of applications for authorization. The format sets out the requirements and expectations on the content of these assessments. The format is available on the website of ERPA.

6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

ERPA is not performing review and assessment of safety documentation of package and special form radioactive material designs. For Ethiopia, there is need for checking the documentary evidence establishing the compliance of non-approved package designs to the regulatory criteria

including in testing conditions, when the package is designed to contain radioactive material with limited activity.

Ethiopian licensees currently use package designs of foreign origin, but there is no systematic obligation for foreign competent authority to formally confirm the compliance of these package designs. The non-approved package designs used in Ethiopia include freight containers when used as packages, as well as nuclear density gauges, well logging gauges, etc.

ERPA lacks skills and competence in the review and assessment of transport safety documents. Some of the personnel have received training on regulatory design criteria for packages and sources, but they have limited experience in review and assessment, in particular regarding the TYPE IP1, TYPE IP2 and TYPE A package designs that are raising greater hazard than excepted packages. This issue is addressed in Suggestion 4 in Section 3.3.

6.5. SUMMARY

ERPA carries out review and assessment as part of the authorization process to determine whether facilities and activities comply with regulatory requirements. However, the graded approach is not applied and there is lack of practice specific guidelines for review and assessment.

7. INSPECTION

7.1. GENERIC ISSUES

The *Proclamation of 2017* provides ERPA with the authority to carry out inspections of radiation facilities and activities including radioactive waste management facilities, transport of radioactive materials and import/export radioactive substances. The primary objective of the inspections is to ensure that any authorized facility or activity complies with the regulatory requirements, conditions specified in the granted authorization and to verify information provided by the licensee. The Proclamation requires the authorised party to facilitate entry of inspectors to conduct inspections.

ERPA has a generic inspection procedure to guide the inspectors on inspection. It has developed an inspection methodology for conventional radiology and it is working on the inspection methodology for CT scan facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: *ERPA has a generic inspection procedure but it does not give details of how to carry out inspection. It has developed an inspection methodology for conventional radiology.*
(1)	**BASIS: GS-G-1.5 para 3.61 states that** *"To ensure that all operators are inspected to a common standard and that the level of safety is consistent, the regulatory body should establish procedures for its inspectors. The procedures should be such as to ensure a systematic and consistent approach to inspection, allowing sufficient flexibility for inspectors to take the initiative in identifying and addressing new concerns as they arise. Appropriate information and guidance should be provided to the inspectors concerned and each inspector should be given adequate training in following the procedures……"*
S9	**Suggestion: ERPA should consider developing and implementing detailed inspection procedures for all facilities and activities.**

7.1.1. INSPECTION PROGRAMME

ERPA has an annual inspection plan, which includes announced and unannounced inspections. ERPA also conducts reactive inspections, mainly upon receiving complaints about non-compliance or unlicensed activities. The inspection reports are shared with the Notification and Authorization Directorate for use during review and assessment of licence applications. ERPA also carries out pre-authorization inspections before issuing authorization to Category 1 and 2 facilities and activities, as well as inspections that are conducted at the request of an authorized party.

The target frequencies on the inspection plan range from once every 6 months to once every 4 years, depending with the level of risk associated with the facility. For example, ERPA has targeted to conduct more than 300 planned inspections in 2017. This number does not include the reactive inspections. The number of planned inspections per year does not correspond with the number of

available inspectors as ERPA currently has 5 inspectors. The IRRS team was informed that it takes an average of 3 - 4 hours to inspect a conventional x-ray facility. The inspection plan cannot be fulfilled taking into account the time required to inspect a facility and number of inspectors available. As a result the inspection programme is not being fully implemented. Therefore, the inspection programme is not fully implementing an appropriate graded approach.

ERPA does not conduct joint inspections with other regulators.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The inspection programme is not being fully implemented. Therefore, the inspection programme is not fully implementing an appropriate graded approach.*	
(1)	**BASIS: GSR Part 1 Requirement 29, para. 4.50 states that "***The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
(2)	**BASIS: GSR Part 1 Requirement 29, para. 4.52 states that "***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"*
S10	**Suggestion: ERPA should consider improving the implementation of the graded approach in its inspection programme.**

7.1.2. INSPECTION PROCESS AND PRACTICE

ERPA has an *Inspection Procedure (OP/ERPA/IN/002)* to guide the inspectors on how to conduct an inspection. The procedure covers the preparatory phase and field inspection phase. Various inspection checklists are used during inspections. An inspection methodology for conventional diagnostic x-ray facilities is available. A similar inspection methodology for CT-Scan facilities is being developed. The *Inspection Procedure (OP/ERPA/IN/002)* does not clearly address the post-inspection process, as there is no documented procedure dealing with the follow-up process and the close out of the inspection findings.

The IRRS team was informed that the inspections findings are used as input for the licence decision-making process and for the enforcement process.

The inspection starts with an entrance meeting with the management, where the inspectors highlight the purpose of the inspection. The inspectors then proceed to review documents, carry out staff

interviews and visits to the locations where radiation sources are housed. The inspection ends with an exit meeting, where the inspectors report their findings to the responsible staff of the facility.

ERPA uses a range of inspection methods consistent with the IAEA Safety Guides, such as direct observation of practices and equipment, interviews and discussion and examination of records and documentation. The inspection includes carrying out measurements and tests by the inspectors. Inspectors also use detailed checklists for various radiation facilities and activities some of which have been adopted from IAEA TECDOC 1526.

7.1.3. INSPECTORS

ERPA currently has 26 technical staff members, 5 of these are in the inspection section to carry out inspections. Inspectors are required to have a minimum qualification of an undergraduate degree in Physical Science. Inspectors undergo internal training, mentored by senior officers and training by the IAEA. ERPA recently documented a manual for training inspectors but has not yet started implementing it. The inspectors lack competence in inspecting complex facilities. This issue is addressed in Suggestion 4 in section 3.3.

The Proclamation empowers an inspector to have access to authorized facilities and activities.

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

Currently, the country has one radioactive waste management facility operated by ERPA. The facility has been in operation since 2014. ERPA verifies the safety of radioactive waste management facility and activities through periodic inspections, in accordance with the annual inspection plan. The facility is inspected twice a year. The last inspection was done in November 2017.

The Checklist for Inspection of Radioactive Waste Facility (OF/ERPA/IN/7.3) and general rules for performing inspection (Inspection Procedure OP/ERPA/IN/002) are in place. There are however no specific internal guidelines and procedures for inspection of radioactive waste management facility.

The IRRS team visited the Radioactive Waste Storage Facility in Addis Ababa City Administration. The capacity of facility storage is enough (but there is no specific information about maximum storage activity).
The IRRS team observed the following gaps :

- no identification and characterization of radioactive waste;
- no documentation and records for radioactive waste;
- no written information about position of each item as the rooms and positions in rooms are not labelled;
- no available equipment for measuring contamination or dose rate are on-site;
- no records of visitors in controlled area.

The IRRS team concluded that these gaps are due to lack of requirements, competence, independence. These issues are addressed in Recommendation 13 in Section 9.1, Suggestion 2 in Section 1.7, and Suggestion 4 in Section 3.3.

The facility is secured (24 hours) and off-site monitoring is regularly ensured by ERPA during the regular inspections.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Inspection of radiation sources facilities and activities are covered in section 7.1. ERPA conducts inspections of authorized facilities and activities to ensure they comply with its safety requirements. The IRRS team followed two inspections.

Site visit to a medical installation

Three members of the IRRS team accompanied three ERPA inspectors during an inspection of a radiology department of the St Gabriel General Hospital of Addis Ababa. Preparation was done that included review of licensee documents and instrumentation. The individual dosimeters of the inspectors were not labelled.

The inspections started with an entrance meeting, led by the ERPA Inspection Team Leader.

The Hospital team was briefed on the scope and the objectives of the inspections during the entrance meeting.

Inspection was carried out at the conventional radiology Department of the Hospital. Practice specific checklists for conventional radiology were used as guidance for the inspections. The inspectors conducted their work in a professional manner and kept redirecting the inspection to the objectives using the checklists. This is commendable as at times focus was lost as hospital staff began to provide explanations on the operations of the facility. The checklist was adhered to throughout the inspection. The preparation prior to the inspection provided focus and identified key issues to be addressed during the inspection.

The inspection was a routine inspection. The inspection was focused on issues identified in previous inspections. Completion of corrective actions required after the previous inspection were verified as well as other parameters subject to change over time, including performance of the equipment through quality control checks. At the end of the inspection, the inspector shared the outcome of the inspection with the hospital personnel especially the importance of wearing their dosimeters.

The management of the licensee appreciates the effectiveness of ERPA in promoting compliance with radiation protection requirements and expressed concern that ERPA should strengthen their relationship with the Medicine and Health Care Administration and Control Authority (FMHACA) to avoid conflicting ideas.

Site visit to an irradiation facility

Three members of the IRRS team accompanied three ERPA inspectors to witness an inspection at National Institute for Control and Eradication of Tsetse and Trypanosomiasis, Addis Ababa. The inspection was a routine inspection. The facility has two Co-60 category 1 sources used for irradiation of blood and male tsetse flies. Status report on the licensee and inspection check lists was circulated amongst the inspectors prior to departure for the inspection.

The inspection started with an entrance meeting with the Director, Radiation Protection Officer and Tsetse Machine Operator. The scope of the inspection was presented to the licensee. Following this, inspection documentation and interviews were done. The ERPA inspectors performed the inspection in a professional manner. The inspectors performed several independent measurements of the radiation levels around the sources during operation and around the vicinity of the facility. The inspectors communicated proficiently both in English and local language. The serial numbers of sources and source containers were recorded. The security system to the sources was also checked.

During the exit meeting, the head of the ERPA inspection team provided a briefing to the licensee on the findings of the inspection and elaborated on ERPA expectations, especially with respect to personal monitoring of all workers.

The management of the licensee appreciated the effectiveness of ERPA in offering constant training to some of their workers. However, they raised a concern on lack of guides for developing facility's Emergency Preparedness and Response plan. The licensee expressed concern on the non-calibration of survey meters due to the non-functioning of the SSDL facility.

7.4. INSPECTION OF TRANSPORT

ERPA performs transport inspections when gauges containing radioactive sources are moved by road by the user to a different working place. Checklists have been prepared to facilitate the implementation of these inspections which are of a repetitive nature. The current transport requirements retained by ERPA do not cover the minimum operational requirements stated in the international regulations. The checklists currently used in transport inspections do not cater for the checking of the majority of the operational transport requirements stated in the international standards. ERPA has drafted Transport Directives which are awaiting adoption.

In case of air transport of radioactive materials, ERPA shares responsibilities with the Civil Aviation Authority (within the Ministry of Transport) to ensure compliance with the regulatory requirements and the licensing conditions. ERPA is currently not involved in inspections of companies involved in air transport. MOT is also covering the control of transport of dangerous goods by road. There is currently no formal coordination and liaison between ERPA and MOT. This issue is addressed in Suggestion 1 in Section 1.5.

7.5. SUMMARY

Proclamation empowers inspectors to carry out inspections. ERPA currently has 5 inspectors. ERPA carries out inspections of radiation facilities and activities, transport and radioactive waste management facility. It conducts planned and reactive, announced and unannounced, pre-authorization inspections following an established inspection procedure. ERPA does not have practice-specific inspection methodologies covering all facilities and activities. The inspection programme is not fully implementing an appropriate graded approach. IRRS team witnessed inspections at a diagnostic radiology facility and an irradiation facility. The equipment used for the inspection had no valid calibration certificates.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The Proclamation has provided ERPA with the legal basis to carry out enforcement actions in accordance with a graded approach. The Proclamation confers enforcement powers on ERPA to act in the case of non-compliance with the legal requirements. The enforcement actions provided for include revocation of a licence, suspension or amendment of an authorization, prosecution or closure.

ERPA has an approved enforcement policy and procedures.

Article 17 (1) empowers the inspectors to take enforcement actions in cases where safety is compromised, and an immediate action is required. However, according to Article 18 (6) an enforcement action will have no effect if the head of the license issuing department of ERPA fails to approve within 30 days. This implies that facilities and activities where safety is compromised may resume even in cases where no corrective action has been carried out.

Article 19 of the *Proclamation* provides a legal basis for an authorised party to make an appeal to the Director General of ERPA against an enforcement action. EPRA has a procedure of appeal.

Currently, there is a lawyer and one technical officer trained on enforcement. ERPA does not have a sufficient training on enforcement for its technical staff. The IRRS Review Team noted that some of the members of the staff are not aware of contents of the enforcement. This issue is addressed in Suggestion 4 in Section 3.3.

8.2. ENFORCEMENT IMPLEMENTATIONS

The IRRS team was informed that not all the enforcement options provided for in the *Promulgation* are being utilized. ERPA has undertaken actions such as issuance of warning letters, closure of facilities and prosecution at court of law. In some cases, the inspectors have undertaken closure actions for facilities having a serious safety lapse. For example, a government medical facility was arraigned to court, where the administrator and radiographer were penalized. To date no facility licence has been revoked apart from a licence of a service provider due to submission of incorrect report readings.

The IRRS team was informed that ERPA expects a licensee to provide written correspondence informing on the corrective action carried out to address the non-compliances. ERPA is not consistently confirming that the licensee has effectively implemented all necessary corrective actions in response to its findings. The inspection plan does not allow time for follow-up inspections and the *Inspection Procedure (OP/ERPA/IN/002)* does not clearly address the post-inspection process, as there is no documented procedure dealing with the follow-up process and the close out of the inspection findings.

The IRRS team noted that there was a case where non-compliance issue was raised by inspectors against a medical facility, and then a written directive was sent by the enforcement section. A follow-up inspection to the facility was conducted six years later.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA is not consistently confirming that the licensee has effectively implemented all necessary corrective actions in response to its findings.*	
(1)	**BASIS: GSR Part 1 Requirement 31, para 4.60 states that states *that*** *"Finally, the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions".*
R12	**Recommendation: ERPA should make provisions to confirm that the licensee has implemented all necessary corrective actions**.

8.3. SUMMARY

The Proclamation provides ERPA with a legal basis to carry out enforcement actions in accordance with a graded approach. ERPA has an enforcement policy and procedures. The IRRS team noted that some of the members of the staff are not aware of contents of the enforcement.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Proclamation empowers the Council of Ministers to issues regulations and the ERPA to issue directives that amplify and implement the provisions of the Proclamation. Both regulations and directives are legally binding. In addition, ERPA may issue non-binding guidance documents.

Currently, no regulations have been enacted. However, two regulations have been drafted and are in the process for approval:

- establishment of ERPA as provided under the Proclamation No. 1025/2017
- Ethiopian Radiation and Nuclear Protection Regulation

Several directives are being prepared for different practices incorporating a larger set of the international requirements, but they have not yet been issued. These include:

- Diagnostic and Interventional Radiology,
- Industrial radiography,
- Transport of Radioactive material for safety,
- Emergency and Preparedness,
- Waste management,
- NORM and fixed and portable gauges and well logging.

To date the following guidance documents have been published by ERPA:

- Guide for completing Application for X-Ray Facilities;
- Guide for completing Application for import-export;
- Guide for completing Application for transport of Radioactive Material;
- Regulatory Requirements to Practice Conventional Diagnostic Radiology;
- Regulatory Requirements for Dental X-ray machine;
- Regulatory Requirements for Radiotherapy;
- Regulatory Requirements of Nuclear Gauges;
- Regulatory Requirements to Practice CT – Scan;
- Regulatory Requirements to Practice Mammography;
- Requirements for Industrial Radiography or Accelerator.

The amount of information and guidance needed by licensees in view of correctly implementing the requirements need to be commensurate with the amount and complexity of new requirements under preparation. More detailed information about the areas needing guidance is provided for different practises in the other subchapters of chapter 9.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no directives establishing requirements and associated criteria for regulating facilities and activities. The existing documents providing guidance to the licensees are not fully consistent with the IAEA standards.*	
(1)	**BASIS: GSR Part 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."*
R13	**Recommendation: ERPA should establish directives and guides consistent with IAEA safety standards that systematically cover all types of facilities and activities.**

Ethiopia's legal framework include provisions that, when developing or reviewing a regulation, a directive or a guide, ERPA has to engage stakeholders, service providers and relevant government entities.

The proposed regulations are then to be reviewed by the Minister of Science and Technology for advice and comments. The Minister will then forward the proposed recommendation to the Council of Ministers, who are mandated by Law to approve recommendations.

There are no documented procedures describing how new regulations, directives, guides are developed, or existing ones reviewed, including provisions for consultation with interested parties.

Some information about the external organizations concerned by this process is provided for different practises in the other subchapters of chapter 9.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no documented processes for developing, reviewing, revising, and issuing regulations, directives, and guides, including provisions for consultation with interested parties*	
(2)	**BASIS: GSR Part 1 Requirement 34, para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides".*
R14	**Recommendation: ERPA should establish and document processes for developing, reviewing, revising and issuing regulations, directives and guides, which should include provisions for consultation with interested parties.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

No requirements have been established for the identification, characterization and classification of radioactive waste.

No formal process for issuing new regulatory requirements, or changing existing ones regarding radioactive waste, is prescribed by ERPA. This issue is addressed in Recommendation 13 in Section 9.1.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no established requirement for identification, characterization and classification of radioactive waste.*	
(1)	**BASIS: GSR Part 5 Requirement 9, para. 4.10 states that** *"Radioactive waste has to be characterized in terms of its physical, mechanical, chemical, radiological and biological properties"*
R15	**Recommendation: ERPA should establish requirements for identification, characterization and classification of radioactive waste and ensure their implementation.**

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The relevant information has been addressed as a generic issue in section 9.1.

9.4. REGULATIONS AND GUIDES FOR TRANSPORT

The current regulatory framework does not provide for a set of transport requirements at a level that could be compared with those defined in the IAEA Specific Safety Standards for transport safety, No. SSR-6. A draft Transport Directive is being prepared, and incorporate a larger set of the requirements of SSR-6, but it has not yet been established. In addition licensees need more complete information about the recommended methods for implementing the requirements.

For transport activities, guides would be needed by consignors, carriers and consignees for the correct implementation of the new regulatory requirements incorporated in the draft Directive regarding at least the following actions:

-notification/registration/application for licensing of consignors, carriers and consignees;
-training of workers;
-emergency plans;
-radiation protection programmes;
-management systems;
-notification and reporting for non-compliances and events occurred during transport of radioactive materials.

This observation is addressed in Recommendation 13 in Section 9.1.

The development and issuing of transport regulations has several interfaces with other national authorities that share responsibilities with ERPA for the control of safety and protection of transports of radioactive materials. There are no formal cooperative arrangements between ERPA and relevant transport authorities. This is addressed in Suggestion 1 in Section 1.5.

9.5. SUMMARY

There is no formal process for developing, reviewing, revising and issuing regulations, directives and guides. A set of regulations, directives and guides are under preparation. They should be reviewed and completed to reflect the international standards related to the safety of faciltites and activities.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

The new IAEA Safety Requirements on Preparedness and Response for a Nuclear or Radiological Emergency have been published since November 2015 as General Safety Requirements Part 7 (GSR Part 7), superseding GS-R-2 (2002), however, the country performed self-assessment based on GS-R-2. During this mission, the appraisal on Emergency Preparedness and Response (EPR) has been performed based on GSR Part 7.

According to the IAEA Safety Standards for hazard assessment, currently, Ethiopia is a country with facilities and activities belonging to Emergency Preparedness Category (EPC) III and IV. Facilities in EPC III are facilities using radioactive sources at fixed locations without any offsite consequences while activities in EPC IV are activities using mobile dangerous radioactive sources and requiring response at unforeseen locations in case of accident.

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

Authority and responsibility for regulating the on-site arrangements for preparedness and response to nuclear or radiological emergencies for licensed facilities and activities has been assigned to ERPA through Proclamation (1025/2017). This authority for regulating the on-site Emergency Preparedness and Response (EPR) is not shared with any other organization or department. As per Proclamation (1025/2017), the application for authorization should contain information about emergency preparedness and procedures for dealing with radiation accidents. ERPA has authority and mandate for establishing the regulations (through Council of Ministers) and Directives for implementation of EPR requirements by licensees.

ERPA inspectors have power to investigate any incident or accident involving nuclear material or radiation sources and verify the compliance of on-site emergency arrangements against the regulatory requirements before commencement of operation/conduct of the facility or the activity as well as thereafter. The Proclamation sets obligations for the licensees to immediately notify to the Authority not later than 24 hours after any incident or accident and comply with the emergency measures prescribed by the Authority.

As a part of authorization process, ERPA requires applicants to submit emergency preparedness plans along with other essential documents and review of the plans is one of the important functions of the regulatory body. ERPA inspectors are empowered to conduct inspections before issuance of the authorization and afterwards during the lifetime of the facility.

In the organizational structure of ERPA, a small unit is designated responsible for inspections, waste management and emergency preparedness and response activities.

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

ERPA has not established any regulations and guides specifying the requirements and associated guidance for on-site emergency preparedness and response. Only few requirements for the licensees

related to notification of an incident or accident and procedure for mitigating and taking necessary measures are included in the Proclamation No. 1025/2017.

Currently, there are no requirements for licensees to perform hazard assessment, initiate and manage on-site emergency response, classify and declare emergency, take on-site mitigatory and urgent protective actions, request assistance from off-site emergency services, protect workers and public on the site, public communication, manage radioactive waste and medical response, mitigate non-radiological consequences, terminate emergency, analyse emergency and emergency response, record keeping, organization and staffing, emergency plans and procedures, necessary tools and equipment, training and exercises and quality management program. This issue is addressed Recommendation 12 in Section 9.1.

ERPA has drafted a Directive on nuclear and radiological emergency preparedness and response which contains requirements mostly following GSR Part 7 however it is not fully consistent with the IAEA Safety Standards. For example, the Directive does not address the requirements to specify emergency preparedness categories, generic criteria for protective actions, mitigate non-radiological emergency, analyse emergency and emergency response, quality management, guidance levels for protection of emergency workers etc. This issue is addressed Recommendation 12 in Section 9.1.

Currently, ERPA has not yet established any requirement, criteria or guidance for the licensees to perform hazard assessment as basis for emergency preparedness. During the interviews, the IRRS team noted that hazard assessment is not performed by the licensees and emergency plans are being prepared without taking into account the hazards associated with the facility. Therefore, so far graded approach for EPR is not being implemented. Similarly, there is no mechanism in place to ensure that the licensee review and revise emergency arrangements based on hazard assessment when there is any change in the facility or new information become available. ERPA does not have any requirement to ensure that the operator's emergency arrangements are coordinated with those of other organizations and integrated with contingency plans and security plans.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA has not established requirements for performing and periodically reviewing hazard assessment as basis for emergency preparedness and response.*	
(1)	**BASIS: GSR Part 7 para. 4.18 states that** *"Hazards shall be identified and potential consequences of an emergency shall be assessed to provide a basis for establishing arrangements for preparedness and response for a nuclear or radiological emergency. These arrangements shall be commensurate with the hazards identified and the potential consequences of an emergency."*
(2)	**BASIS: GSR Part 7 para. 4.25 states that** *"The government shall ensure that a review of the hazard assessment is performed periodically with the aims of: (a) ensuring that all facilities and activities, on-site areas, off-site areas and locations where events could occur that would necessitate protective actions and other response actions are identified…"*
(3)	**BASIS: GSR Part 7 para. 4.26 states that** *"The government through the regulatory body shall ensure that operating organizations review appropriately and, as necessary,*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	revise the emergency arrangements (a) prior to any changes in the facility or activity that affect the existing hazard assessment and (b) when new information becomes available that provides insights into the adequacy of the existing arrangements."
(4)	**BASIS: GSR Part 7 para. 4.12 states that** *"The regulatory body is required to 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 [7]. These regulations and guides shall include principles, requirements and associated criteria for emergency preparedness and response for the operating organization (see also paras 1.12 and 4.5)."*
R16	**Recommendation: ERPA should establish requirements and prepare guidance for licensees, in line with IAEA Standards, to perform and periodically review on-site hazard assessment as basis for emergency preparedness and response.**

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

ERPA has authority for verification of compliance of on-site emergency arrangements of licensees against the regulatory requirements. As a part of authorization process, ERPA requires the applicants to submit emergency preparedness plan along with other essential documents. The emergency plans are reviewed and accepted by ERPA. However, so far there is no guidance for the licensees for preparing the emergency plans. ERPA need develop guidelines for preparing emergency plans including contents of the emergency plan. These guidelines will also support ERPA to review the plans, as currently, ERPA does not have any criteria or checklists to ensure consistency during review of the plans.

Before issuance of the authorization, ERP conducts inspections to verify the emergency plans and arrangements for EPR made by the licensees. Afterwards, EPR arrangements are verified by the ERPA inspectors during regular inspections, as it is the part of inspection checklists. The findings of the inspections are communicated to licensees for improving arrangements for EPR.

For the protection of onsite workers, the licensee has arranged the personal protective equipment and dosimeters. As informed by the counterpart, it is also responsibility of the licensee to ensure the protection of off-site workers if their assistance is requested for onsite response. There are currently no arrangements for medical management of contaminated, injured and overexposed personnel.

During the interviews, it was noted that the licensees are not conducting drills and exercises to test their arrangements for EPR. ERPA need to enforce the licensees to conduct the drills and exercises regularly. It was informed that occasionally ERPA arrange some training courses for the licensees and these training courses also include hands-on training and exercises.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA is not ensuring that licensees are conducting regular exercises to test emergency response arrangements. Also, ERPA has not established mechanism for the systematic evaluation of trainings and exercises of licensees.*	
(1)	**BASIS: GSR Part 7 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 (see paras 6.36 and 6.38)"*
(2)	**BASIS: GSR Part 7 para. 6.33 states that** *"The conduct of exercises shall be evaluated against pre-established objectives of emergency response to demonstrate that identification, notification, activation and response actions can be performed effectively to achieve the goals of emergency response (see para. 3.2)."*
(3)	**BASIS: GSR Part 7 para. 6.28 states that** *"The operating organization and response organizations shall identify the knowledge, skills and abilities necessary to perform the functions specified in Section 5. The operating organization and response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions…"*
R17	**Recommendation: ERPA should ensure that licensees regularly conduct exercises and trainings and systematically evaluate the exercises. ERPA should evaluate some of these exercises.**

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

Pursuant to the Proclamation 571/2008, ERPA has been assigned role for formulating the national emergency response plan in collaboration with other concerned bodies, setting up emergency response teams for accidents involving radiation and take measures or advise on measures to be taken as needed. However, recently a new Proclamation No. 1025/2017 has been issued and under which the regulatory body will be re-established by Council of Ministers Regulations. It is very important to highlight that the role of ERPA in a nuclear or radiological emergency has not been included in the new Proclamation. Therefore legal basis for the role of the ERPA in the event of an emergency will not be available after transition period that will end as soon as ERPA is re-established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *ERPA's role to formulate national emergency plan, setting up emergency response teams as well to provide advice on protective measures in the event of an emergency was*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
mentioned in Proclamation 571/2008. However, the new Proclamation No. 1025/2017 does not have provision for ERPA's role in responding to a nuclear or radiological emergency.	
(1)	**BASIS: GSR Part 1 para. 2.24 states that** *"In preparing an emergency response plan and in the event of an emergency, the regulatory body shall advise the government and competent authorities, and shall provide expert services (e.g. services for radiation monitoring and risk assessment for actual and expected future radiation risks)…"*
R18	**Recommendation: The Government should maintain, in the legal framework, the role of ERPA for advising the government and competent authorities and providing expert services in the event of an emergency.**

As per Proclamation 571/2008, ERPA has coordinated with all the relevant parties and a National Radiological Emergency Plan (NREP) has been developed. The NREP has been finalized after agreement of all the parties however it is not yet published. Role of all participating organizations including ERPA, Environmental Protection Agency, Disaster Risk Management and Food Security, Police, Fire and Emergency Prevention and Rescue Agency, National Meteorological Agency and Several Ministries is defined in the plan. The NREP will be an integral part of National Disaster Management Plan. As per NREP, EPRA has been assigned a role as Lead Technical Agency (LTA) to perform radiological monitoring and analyses, disseminate information and provide advice to government, licensees and public about taking mitigatory and protective actions. However, to perform the roles assigned under NREP and the Proclamation, ERPA has not yet developed its internal plans and procedures to define allocation of responsibilities, coordination mechanism, availability of resources and covering other essential elements for effective response.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In the event of an emergency, ERPA acts as a lead technical agency, performs radiological monitoring and provides advice to government, public and licensees on protective measures. However, ERPA has not prepared its plan, procedures, and associated tools to fulfil these functions.*	
(1)	**BASIS: GSR Part 7 para. 6.17 states that** *"Each response organization shall prepare an emergency plan or plans for coordinating and performing their assigned functions as specified in Section 5 and in accordance with the hazard assessment and the protection strategy. An emergency plan shall be developed at the national level that integrates all relevant plans for emergency response in a coordinated manner and consistently with an all-hazards approach. Emergency plans shall specify how responsibilities for managing operations in an emergency response are to be discharged…"*
(2)	**BASIS: GSR Part 7 para. 6.20 states that** *"The operating organization and response organizations shall develop the necessary procedures and analytical tools to be able to perform the functions specified in Section 5 for the goals of emergency response to be achieved and for the emergency response to be effective."*
(3)	**BASIS: GSR Part 7 para. 6.21 states that** *"Procedures and analytical tools shall be tested under simulated emergency conditions and shall be validated prior to initial*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	use. Any arrangements for the use of analytical tools early in an emergency response for supporting decision making on protective actions and other response actions shall be made in due recognition of the limitations…"
R19	**Recommendation: ERPA should prepare and maintain its own emergency plan, necessary procedures and analytical tools to effectively perform its assigned functions. The procedures and tools should be tested and validated prior to initial use.**

The training of ERPA staff is conducted through on-the-job trainings and by participation in some of training activities arranged through IAEA. ERPA does not have a defined program for training of its personnel having responsibilities assigned for emergency response. It is noticed during the interviews that ERPA does not conduct drills and exercises to test its arrangements for response to an emergency.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA does not have its internal program for conducting training, drills and exercises to test its response functions. Also, there is no mechanism in place for the systematic evaluation of exercises.*	
(1)	**BASIS: GSR Part 7 para. 6.28 states that** *"The operating organization and response organizations shall identify the knowledge, skills and abilities necessary to perform the functions specified in Section 5. The operating organization and response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel selected have the requisite knowledge, skills and abilities to perform their assigned response functions. The arrangements shall include arrangements for continuing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities in an emergency response undergo the specified training.*
(2)	**BASIS: GSR Part 7 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…"*
(3)	**BASIS: GSR Part 7 para. 6.33 states that** *"The conduct of exercises shall be evaluated against pre-established objectives of emergency response …"*
R20	**Recommendation: ERPA should develop and implement a comprehensive training and exercise program as well as a mechanism for systematic evaluation of exercises.**

As per Proclamation, licensees shall immediately notify ERPA in case of any incident or accident involving radiation sources and fully comply with planned emergency measures. However, ERPA has not established a notification point for receiving the emergency notifications. It was pointed out

during the interviews that the contact number of ERPA mentioned on the different letters sent to the licensees or the contact numbers available at ERPA website may be used for notification of an emergency to the Authority.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Proclamation requires licensees to immediately notify ERPA in case of any incident or accident involving radiation sources. However, there is no designated notification point at ERPA for receiving such notifications.*	
(1)	**BASIS: GSR Part 7 para. 5.11 states that** *"An off-site notification point, or more than one, shall be established to receive notification of an actual or potential nuclear or radiological emergency. The notification point(s) shall be maintained in a state of continuous availability to receive any notification or request for support and to respond promptly, or to initiate a preplanned and coordinated off-site emergency response appropriate to the emergency class or the level of emergency response. The notification point(s) shall be able to initiate immediate communication by suitable, reliable and diverse means with the response organizations that are providing support.*
S11	**Suggestion: ERPA should consider establishing a designated notification point for receiving emergency notification and initiating response actions in a timely manner.**

As mentioned in above paragraphs, ERPA has very important functions to perform during response to an emergency as assigned under the Proclamation and NREP. Currently, ERPA has very limited number of equipment and developed few forms for recording the results of radiological survey during an emergency. Some Personnel Protective Equipment (PPEs) are available at waste management facility operated by ERPA and during the discussion it was informed that these PPEs may be used for the protection of radiation monitoring teams of ERPA. Considering the response functions of ERPA, adequate tools, equipment, instruments, communication facilities, documentation (like procedures, checklists, manuals etc.) required for an effective emergency response are not available. Arrangements are not in place to ensure continuous availability and reliability of these equipment and tools, their tests and calibrations, provision of additional supplies and inventories etc.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ERPA does not have a programme to ensure availability and reliability of adequate tools, equipment, instruments, and other essential facilities required for an effective emergency response.*	
(1)	**BASIS: GSR Part 7 para. 6.22 states that** *"Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as documentation of procedures, checklists, manuals, telephone numbers and email addresses) shall be provided for performing the functions specified in Section 5. These items and facilities shall be selected or designed to be operational under the conditions (such as radiological conditions, working conditions and environmental conditions) that could be encountered in the emergency response, and to be*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	compatible with other procedures and equipment for the response (e.g. compatible with the communication frequencies used by other response organizations), as appropriate. These support items shall be located or provided in a manner that allows their effective use under the emergency conditions postulated."
(2)	**BASIS: GSR Part 7 para. 6.34 states that** *"The operating organization, as part of its management system (see Ref. [14]), and response organizations, as part of their emergency management system, shall establish a programme to ensure the availability and reliability of all supplies, equipment, communication systems and facilities, plans, procedures and other arrangements necessary to perform functions in a nuclear or radiological emergency as specified in Section 5 (see para. 6.22). The programme shall include arrangements for inventories, resupply, tests and calibrations, to ensure that these are continuously available and are functional for use in a nuclear or radiological emergency."*
R21	**Recommendation: ERPA should establish a programme to ensure availability and reliability of adequate tools, equipment, instruments, and other essential facilities required for an effective emergency response.**

At the moment, only two persons who are also responsible for waste management and other activities are dealing with emergency preparedness and response activities. As a Lead Technical Agency and Coordinator, ERPA has to perform several functions in the event of an emergency. However, ERPA does not have suitable arrangements for ensuring availability of sufficient number of qualified and trained personnel. From within its routine organizational structure, ERPA need to establish an emergency response team responsible for performing the assigned functions during an emergency. Responsibilities of all the team members need to be clearly allocated and included in emergency plans and procedures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A very limited number of personnel are assigned for EPR activities, along with other assignments, which are not sufficient to ensure the availability at all the times for performing emergency response activities.*	
(1)	**BASIS: GSR Part 7 para. 6.8 states that** *"The positions responsible within each operating organization and response organization for performance of the response functions specified in Section 5 shall be assigned in the emergency plans and procedures. The positions responsible in each operating organization, in each response organization and in the regulatory body for the performance of activities at the preparedness stage, in accordance with these requirements, shall be assigned as part of the routine organizational structures and shall be specified, as appropriate, in the emergency plans and procedures."*
(2)	**BASIS: GSR Part 7 para. 6.10 states that** *"Appropriate numbers of suitably qualified personnel shall be available at all times (including during 24 hour a day operations) so that appropriate positions can be promptly staffed as necessary following the declaration and notification of a nuclear or radiological emergency. Appropriate*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	numbers of suitably qualified personnel shall be available for the long term to staff the various positions necessary to take mitigatory actions, protective actions and other response actions
(3)	**BASIS: GSR Part 1 para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall…."*
S12	**Suggestion: Within its organizational structure, ERPA should consider designating an emergency response team with sufficient number of suitably qualified personnel for performing its tasks during an emergency.**

ERPA has developed a Public Relation and Communication Strategy for dealing matters related to public communication. During the discussion, IRRS team highlighted that ERPA should also consider including public communication aspects during an emergency in the strategy.

10.5. SUMMARY

ERPA has the authority for regulating on-site arrangements for EPR however currently no regulation or guide is in place setting the requirements for EPR. ERPA has drafted a Directive for nuclear and radiological emergency preparedness and response and it contains requirements for EPR mostly following GSR Part 7, however, the regulatory framework need to be made consistent with the IAEA standards.

Some training courses are arranged by ERPA which also include exercises and hand-on training for use of radiation detection equipment. However, both the regulator and licensees do not conduct regular emergency exercises to test their arrangements for emergency response. Also there is a lack of a program for training and systematic evaluation of emergency exercises. ERPA needs to strengthen its enforcement process to ensure that the licensees conduct and evaluate the exercises.

ERPA's role to formulate national emergency plan, setting up emergency response teams as well as to provide expert advice on protective measures during an emergency was mentioned in Proclamation 571/2008. However, it is omitted in the new Proclamation No. 1025/2017. The role of ERPA regarding response to an emergency should be maintained in legal framework.

ERPA needs to further work to develop its own emergency plan and procedures, conduct emergency exercises, and ensure continuous availability of sufficient number of trained staff and equipment for effective response during an emergency.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

There are one radiotherapy centre, one nuclear medicine facility and about 1000 facilities for diagnostic and interventional radiology in Ethiopia. The total number of the x-ray units are 1153 (870 conventional, 42 CT, 6 fluoroscopy, 17 mammography, 2 angiography, 163 dental x-ray).

The National Institute of Metrology operates a Secondary Standards Dosimetry Laboratory (SSDL) that verifies radiotherapy beam calibrations and provides radiation protection level calibrations but does not have capabilities to perform diagnostic level calibrations.

Responsibilities of the Government

Requirements for medical exposures to radiation are not included in Proclamation No. 1025/2017. The Draft Regulation does not also addressed the requirement on medical exposure. However, these requirements have been detailed in the Draft Directives of different practices such as radiotherapy, diagnostic radiology and nuclear medicine.

Specific aspects of medical use of radiation, such as roles and responsibilities of different organisations; dose constraints; diagnostic reference levels (DRLs); and criteria for the release of patients after radiopharmaceutical therapy, have not been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients following radionuclide therapy are not established.*	
(1)	**BASIS: GSR Part 3 Requirement 34 states that "***The government shall ensure that relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established.***"**
(2)	**BASIS: GSR Part 3 Requirement 40 states that "***Registrants and licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.***"**
R22	**Recommendation: The government should ensure that diagnostic reference levels, dose constraints and criteria and guidelines for the release of patients following radionuclide therapy are established.**

The licensing of medical professionals and medical practices, including radiological professionals, is in the hands of the Ministry of Health and is based upon published criteria "National Minimum Standards for Medium Clinics". These criteria are included in Proclamation N^{o} 661/2009 and Regulation N^{o} 299/2013 that established the Food, Medicine and Healthcare Administration and

Control Authority (FMHACA) as the Regulatory Authority for Health in the Ministry of Health (MoH).

There was some overlap of responsibilities between ERPA and the MoH in the regulation of medical facilities. This overlap has been minimised to certain extent, but the demarcation between these two authorities is still not clear. This can possibly be sorted out through a more effective memorandum of understanding to be signed between the two parties.

The IRRS team was informed that there are only few medical physicists in the country and that no education and training programme in medical physics is available nationally. This seems to be fine for the time being as there is only one radiotherapy centre with two Co-60 units and only one Nuclear Medicine Centre currently available in the country. However, the expected large expansion in radiotherapy and nuclear Medicine will put pressure on the Government to ensure that the medical physicists can fully assume their roles and responsibilities very soon. Therefore, the Government is encouraged to develop and implement education and training program of medical physicists. This issue is addressed in Recommendation 6 in Section 1.8.

Responsibilities of the Regulatory Body

Radiological medical facilities are authorized and regularly inspected by ERPA. Radiological Medical Practitioners, Medical Radiation Technologists and Medical Physicists are licensed by the competent authority of the Ministry of Health (FMHACA) with the relevant education and special training necessary to carry out their roles in medical exposure. ERPA verifies compliance with this requirement through inspection using ERPA inspection procedure (checklist) for medical exposure, which requires assessment of the qualifications and training of all persons involved in medical exposure.

Proclamation No. 1025/2017 makes provisions for authorized persons not to employ a radiation worker who does not have adequate training. ERPA also provides regular Radiation Protection training for Radiographers and Radiologists and even owners and users.

Justification of Medical Exposure

There is no requirement in the Proclamation No. 1025/2017 on justification of medical exposure and neither in the Draft Regulation to ensure that no person incurs a medical exposure unless there has been an appropriate referral. However, the "National Minimum Standards for Medium Clinics" (Prepared by Food, Medicine and Healthcare Administration and Control Authority (FMHACA) - and approved by Ethiopian Standard Agency (ESA)) Article 6.6.1.9 requests that X-ray examinations shall contain a concise statement of reason for the examination but fall short of requiring justification of the medical exposure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no requirement to ensure that no person incurs a medical exposure unless there has been an appropriate referral.*	
(1)	**BASIS: GSR Part 3 Requirement 36 states that "***Registrants and licensees shall*

	ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks."
R23	**Recommendation: The Government should establish a requirement that no person incurs a medical exposure unless there has been an appropriate referral.**

Optimization of Medical Exposure

Design considerations

All medical equipment are required to pass specific requirements from the FMHACA and to fulfil certain radiation safety requirements by ERPA. The equipment has to comply with international standards. ERPA has not developed guidelines for shielding calculations to be applied in different medical facilities but some of the ERPA staff have the essential knowledge and skills to review the shielding of medical facilities.

Calibration

The requirements for dosimetry and calibration of equipment are defined in the Draft Regulation. The calibration is carried out in the secondary standards dosimetry laboratory.

Dosimetry of Patients

Medical physicists are required to be involved, when appropriate, in the consultations on optimisation, including patient dosimetry which is not fully in line with GSR Part 3 that requires patient dosimetry to be carried out under the supervision of a medical physicist.

Quality Assurance for Medical Exposures

Requirements on Quality Control (QC) programmes are embedded in all directives about Radiotherapy, Nuclear Medicine and Diagnostic Radiology. However, MoH (FMHACA) has similar guidelines that have to be implemented but this overlap has been addressed and the future memorandum of understanding between ERPA and FMHACCA will clarify these and other overlapping issues.

Pregnant Women and Breast Feeding Women

The Proclamation N^{o} 1025/2017 and the Draft regulation do not address the protection of pregnant and breast-feeding patient. However, the draft directives provide requirements for the protection of pregnant patients.

Release of patients after radionuclide therapy

This part is not incorporated in the Draft Regulations but it is mentioned in the directive for Nuclear Medicine that "National regulation on the release of patients after administration of therapeutic doses of radiopharmaceuticals shall be absolutely followed".

Unintended and Accidental Medical Exposures

There is no requirement on licensees to minimise the likelihood of unintended or accidental medical exposures, these exposures are also not explicitly mentioned in Proclamation N° 1025/2017nor in the Draft Regulations either in terms of prompt investigation or in terms of implementation of corrective actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no requirement on licensees to minimise the likelihood of unintended or accidental medical exposures and to promptly investigate and record such accident and as appropriate implement corrective actions.*	
(1)	**BASIS: GSR Part 3 Requirement 41 states that "***Registrants and licensees shall ensure that all practicable measures are taken to minimise the likelihood of unintended and accidental medical exposures. Registrants and licensees shall promptly investigate any such exposure and, if appropriate, shall implement corrective actions.***"**
(2)	**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,"*
R24	**Recommendation: ERPA should establish a requirement to minimise the likelihood of unintended or accidental medical exposures, to promptly investigate them, record them and implement corrective actions.**

Reviews and records

This part is mentioned in the Draft Regulations and is incorporated in the Draft Directive. Licensees are required to keep dose records, maintenance records, instrument calibration records, records of training of personnel in radiation protection.

Summary

Requirements for medical exposures to radiation are not included in Proclamation No. 1025/2017 and in the Draft Regulation. However, these requirements have been detailed in the Draft Directives of different practices such as radiotherapy, diagnostic radiology and nuclear medicine.

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and Regulatory Framework

Proclamation No. 1025/2017 provides legal and regulatory framework for occupational radiation protection in accordance with the IAEA Safety Standards. Although it is acknowledged that the Proclamation, the Draft Regulation and the Draft Directives cover most of the requirements of GSR Part 3, there are several requirements that are not addressed or are not in full compliance with the IAEA Standards.

The regulatory framework requires ERPA to establish and enforce requirements for monitoring and recording of occupational exposures. ERPA provides authorization for the service providers for individual monitoring. The service providers are required to report the doses received by each worker on a regular basis to ERPA. ERPA also requires the service provider to maintain dose records for 30 years for each worker.

According to the Draft Regulation the regulatory authority may issue Directive for dose limit for workers and public; however, no dose limits have been established and several Draft Directives included some dose limits that are not consistent with GSR Part 3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Dose limits for workers and public have not been established in the legal framework.*	
(1)	**BASIS: GSR Part 3 Requirement 19 states that "***The government or the regulatory body shall establish and enforce requirements to ensure that protection and safety is optimized, and the regulatory body shall enforce compliance with dose limits for occupational exposure.***"**
(2)	**BASIS: GSR Part 3 requirement 19, para. 3.71 states that** "*The government or the regulatory body shall establish, and the regulatory body shall enforce compliance with, the dose limits specified in Schedule III for occupational exposure."*
(3)	**BASIS: GSR Part 3 Schedule III, para. III.1 states that** "*For occupational exposure*

	of workers over the age of 18 years, the dose limits are: *(a) An effective dose of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;* *(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;* *(c) An equivalent dose to the extremities (hands and feet) or to the skin of 500 mSv in a year."*
(4)	**BASIS: GSR Part 3 Schedule III, para. III.2 states that** "*For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are:* *(a) An effective dose of 6 mSv in a year;* *(b) An equivalent dose to the lens of the eye of 20 mSv in a year;* *(c) An equivalent dose to the extremities (hands and feet) or to the skin of 150 mSv in a year."*
(5)	**BASIS: GSR Part 3 Schedule III, para. III.3 states that** "*For public exposure, the dose limits are:* *(a) An effective dose of 1 mSv in a year;* *(b) In special circumstances68, a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;* *(c) An equivalent dose to the lens of the eye of 15 mSv in a year;* *(d) An equivalent dose to the skin of 50 mSv in a year."*
R25	**Recommendation: The Government should ensure that dose limits for occupational and public exposure are established in line with GSR- part 3.**

Proclamation No. 1025/2017 article 14/6 states that the licensee shall ensure that the radiation workers are supplied with professional risk allowance. The IRRS team considers that this Article may have an adverse impact on the credibility of the system of radiation safety in the country, since it does not ensure that the conditions of service of workers are independent of whether they are or could be subject to occupational exposure to ionising radiation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Proclamation No. 1025/2017 provides for professional risk allowance for radiation workers. But there are no specific requirements stating that these benefits, shall neither be granted nor be used as substitutes for measures for protection and safety.*	
(1)	**BASIS: GSR Part 3 Requirement 27 states that "***Employers, registrants and licensees shall not offer benefits as substitutes for measures for protection and safety.***"**
(2)	*BASIS: GSR Part 3 Requirement 27, para 3.111 states that "The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements, or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits, shall neither be granted nor be used as*

	substitutes for measures for protection and safety in accordance with the requirements of these Standards."
R26	**Recommendation: The Government should establish a requirement to explicitly state that employers, registrants and licensees should not offer benefits to workers as substitutes to providing protection and safety measures.**

GSR Part 3 require "Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate shall designate, as appropriate, a radiation protection officer in accordance with criteria established by the regulatory body". However, the radiation protection officer was not mentioned in Proclamation No. 1025/2017 and his role seems to have been assigned to the "radiation worker". The Draft Regulation should address this issue and define the "radiation protection officer" as in the GSR Part3 "a person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of regulatory requirements".

General Responsibilities of Registrants, Licensees and Employers

Proclamation No. 1025/2017 assigns responsibilities to registrant and licensees for the protection of the workers and for compliance with the regulatory requirements. In Proclamation No. 1025/2017, article 14/7 states that "the licensee shall ensure that the radiation workers are given proper instruction on radiation safety and receive a periodic medical check-up every six months and shall ensure that workers are supplied with dose limit monitoring device accessories and professional risk allowance necessary to carry out radiation work with the lowest reasonable achievable risk that commensurate with the level of potential risk expected from the authorized source, or activities and radiation:". This requirement is well incorporated in the Draft Regulations and Directives.

Proclamation No. 1025/2017 requires employers and licensees to ensure that optimization and dose limitations are applied.

Proclamation No. 1025/2017 states that any authorized person shall have duty to cooperate with the authority when requested for the performance of its regulatory functions.

The Proclamation No. 1025/2017 and the Draft Regulation do not mention radiation protection programme or its elements such as designation of controlled and supervised areas, local rules and monitoring of the workplace. The Draft Regulations stating that written warning to be sent to the licensee if controlled areas are not identified or workers not complying with local rules.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The requirement for radiation protection programme is not covered in the legal framework.*	
(1)	**BASIS: GSR Part 3 Requirement 24 states that "***Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for*

	occupational exposure."
(2)	**BASIS: GSR Part 3 requirement 24, para. 3.88. states that** "*3.88. Registrants and licensees shall designate as a controlled area any area in which specific measures for protection and safety are or could be required for:* *(a) Controlling exposures or preventing the spread of contamination in normal operation;* *(b) Preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions."*
(3)	**BASIS: GSR Part 3 requirement 24, para. 3.96. states that** "*Registrants and licensees, in cooperation with employers where appropriate, shall establish, maintain and keep under review a programme for workplace monitoring under the supervision of a radiation protection officer or qualified expert."*
R27	**Recommendation: ERPA should establish a requirement for employers, registrants and licensees to develop and maintain a radiation protection programme for occupational exposure.**

Special arrangements for female workers

Proclamation No. 1025/2017 requires licensees to make special arrangements for female workers for protection of the infant (it should be embryo or foetus) but no mention of breast-feeding infants. This was detailed in the Draft Regulations in line with GSR part 3.

General responsibilities of workers

Proclamation No. 1025/2017 mentioned the responsibility of workers to their obligations and carry out their duties for protection and safety. The Draft Regulation states the responsibilities of the radiation worker and covers all the responsibilities in line with GSR Part 3.

Monitoring Programmes and Technical Services

There are three monitoring service providers providing personal dosimeters in Ethiopia two of them are licensed by ERPA according to criteria set in document in Amharic (the working language in Ethiopia) that include the licensing of service providers such as personal monitoring services and calibration laboratories.

1. The ERPA dosimetry laboratory provides services to its staff only. The Laboratory started only few months ago and it is monitoring all the 26 technical staff in ERPA. The equipment used is Optically Stimulated Luminescence (OSL) Readers manufacture by Landauer and provided by the IAEA.

2. The National TLD Laboratory at the Ethiopian Conformity Measurement Institution is a public institution that provides personal dosimetry for workers in different medical and industrial facilities from both governmental and private sectors. Only two staff are available in this service. It monitors approximately 1400 workers and the number is likely to increase

since the laboratory has received additional 1000 TLD dosimeters from the IAEA. The Service uses the Harshaw 4500 TLD reader manufactured by Thermo Fisher Scientific.

3. The DosiMed Testing Laboratory is a private company providing personal dosimeters for workers in different medical and industrial facilities from both governmental and private sectors. Five full time staff are working in the service. The service started 7 months ago and currently monitors about 300 workers. The equipment used is OSL Reader manufactured by Dosimetric PLC. Germany.

The above three service providers are using monitoring frequencies of one month for all radiation practices.

The dosimetric quantities used for monitoring external radiation doses are personal dose equivalent Hp(10) and Hp(0.07) to assess effective dose and skin dose, respectively. However, there are no service providers using dosimeters capable of assessing doses to the extremities or to the lens of the eyes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There are no dosimetry services providing dosimeters to assess doses to the extremities or to the lens of the eyes.*	
(1)	**BASIS: GSR Part 3 requirement 19, para. 3.71 states that** "*The government or the regulatory body shall establish, and the regulatory body shall enforce compliance with, the dose limits specified in Schedule III for occupational exposure.*"
(2)	**BASIS: GSR Part 3 Schedule III, para. III.1 states that** "*For occupational exposure of workers over the age of 18 years, the dose limits are:* *(a) An effective dose of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;* *(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;* *(c) An equivalent dose to the extremities (hands and feet) or to the skin of 500 mSv in a year.*"
R28	**Recommendation: The Government should ensure that the dosimetry services for assessing the equivalent doses for the lens of the eyes and the extremities are available.**

Dose reports are sent to the users and to ERPA. They are kept in hard and soft copies by the services providers. The soft copy is kept on a backup system. There is no national dose register for workers dose record, however, there is a requirement for the service provider to keep the dose records for 30 years as specified on the conditions stated on the license.

ERPA has communicated the specific criteria or "requirements to conduct personnel dosimetry services" to the dosimetry service providers. They include: proof of ISO/IEC certificate, recent performance test, calibration certificate, quality assurance programme, accreditation by the

Ethiopian Accreditation office within two years of operation and proof of competence of operating personnel.

The issued certificate have several conditions including: dose reports of the radiation workers shall be submitted to ERPA, dose records should be kept by the service providers for at least 30 years, dosimetry system shall be calibrated regularly and the certificate of competency shall be renewed every year.

Service providers for radiation protection

There are 7 private companies authorized by ERPA to provide safety assessment reports for different facilities. These companies act as qualified experts in providing verification of regulatory compliance to different facilities. The safety assessment reports can be used for licensing or relicensing of the facilities.

Calibration laboratories

There is only one calibration laboratory (the Secondary Standard Dosimetry Laboratory) under the National Measurement Institute (NMI). This laboratory is licensed by ERPA to possess and use radiation sources (Cs 137 and X-ray unit), but it is not licensed as service provider for calibration. The capabilities of the SSDL are limited to verification of radiotherapy beam calibrations, radiation protection level calibrations and irradiation of personal dosimeters. Calibrations of diagnostic level equipment are not possible in this SSDL.

Visit to Personal Monitoring TLD Laboratory in the Ethiopian Conformity Measurement Institution

Two members of the IRRS team accompanied ERPA staff in a visit to the National TLD Laboratory at the Ethiopian Conformity Measurement Institution. The Laboratory is a public institution that provides personal dosimeters for workers in different medical and industrial facilities from both governmental and private sectors. Only two staff are available (one of them is new and need some specific training) in the dosimetry laboratory. The Laboratory became operational 15 years ago and it was licensed and recognized by the ERPA recently.

The IRRS team was informed that, nearly 1400 workers are monitored by the service provider and the number is likely to increase as it has received additional 1000 TLD dosimeters from the IAEA. The Laboratory is using TLD readers Harshaw 4500. The dosimetric quantities used for monitoring external radiation doses are personal dose equivalent Hp(10) and Hp(0.07) to assess effective dose and the skin dose, respectively. Frequency of dose evaluation is fixed at monthly intervals. The calibration of the TLD systems is usually done through the Secondary Standard Dosimetry Laboratory in the National Metrology Institute. No calibration was done recently since the SSDL laboratory is not functioning.

The IRRS team was informed that the dose reports are sent to the users and to ERPA. They are kept in hard and soft copies by the service. There are no national dose register, however, there is a requirement for the service provider to keep the dose records for 30 years as specified on the conditions stated on the license.

The number of qualified staff is not sufficient given the scale of the work. Also some specific training especially about the calibration of the TLD system should be considered for the new staff. The IRRS team noticed that no soft copy of dose record are kept in a safe place outside the TLD laboratory.

Visit to Personal Monitoring Service Provider: DosiMed Testing Laboratory

Two members of the IRRS team accompanied ERPA staff in a visit to the DosiMed Testing Laboratory in Addis Ababa. The DosiMed Testing Laboratory is a private company providing personal dosimeters for workers in different medical and industrial facilities from both governmental and private sectors. Five full time suitably trained staff working in the service including one physicist.

The IRRS team was informed that the service started in 2017 and approximately monitored 300 workers. The Laboratory is using OSL Reader type Dosimetric PLC Germany. The dosimetric quantities used in this service for monitoring external radiation doses are personal dose equivalent Hp(10) and Hp(0.07) to assess effective dose and the skin dose, respectively. Frequency of dose evaluation is fixed at monthly intervals.

The Laboratory became operational 7 months ago and it is licensed by the ERPA. The calibrations of the OSL system are performed regularly using control badges irradiated and provided by the manufacturer Dosimetric PLC Germany.

The IRRS team was informed that the dose reports are sent to the users and to ERPA. They are kept in hard and soft copies by the service. There is no national dose register, however, there is a requirement for the service provider to keep the dose records for 30 years as specified on the conditions stated on the license.

The IRRS team noticed that no soft copy of dose record kept in a safe place outside the laboratory.

Visit to the Secondary Standard Dosimetry Laboratory (SSDL) at the National Metrology Institute (NMI)

Two members of the IRRS team accompanied ERPA staff in a visit to the SSDL laboratory. This is the only calibration laboratory in Ethiopia. It is licensed by ERPA to possess and use radiation sources (Cs 137 and X-ray unit). It is not licensed as service provider for calibration.

The capabilities of the SSDL are limited to verification of radiotherapy beam calibrations, radiation protection level calibrations and irradiation of personal dosimeters. Calibrations of diagnostic level equipment are not possible in this SSDL.

The IRRS team noted that the laboratory is not functioning due to renovation and upgrading work. The team met the Deputy Director of the National Metrology Institute who explained that the main reference dosimetry system (UniDose) in the SSDL needs maintenance and calibration. He also

added that there is a national project with the IAEA to upgrade the SSDL to extend it services to offer other calibration services.

Summary

In general, the existing Proclamation No. 1025/2017 and Draft Regulation requirements related to the occupational radiation protection include provisions related to the control of occupational radiation protection; however there is a lack of important elements of the IAEA Safety Standards.

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

11.3.1. CONTROL OR RADIOACTIVE DISCHARGES AND MATERIALS FOR CLEARANCE

The dose constraints for public exposure control are not established. Consequently, discharge limits for liquid and gaseous radioactive discharges are not defined in the legal framework. The IRRS team was informed that effluents generated by the nuclear medicine diagnosis and therapeutic activities are directly discharged in the sewerage system of the hospital without monitoring. ERPA does not require the licensees to annually report the estimated amount of discharged activity for verifying that dose constraints are not exceeded.

ERPA has not established the requirements to perform risk analyses by licensees to evaluate the exposure of members of the public due to discharges.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Limits for liquid and gaseous radioactive discharges and related dose constraints have not been established.*	
(1)	**BASIS: GSR Part 3 Requirement 11, para. 3.22 states that** *"The government or the regulatory body:* *(a) Shall establish and enforce requirements for the optimization of protection and safety;* *(b) Shall require documentation addressing the optimization of protection and safety;* *(c) Shall establish or approve constraints on dose and on risk, as appropriate, or shall establish or approve a process for establishing such constraints, to be used in the optimization of protection and safety."*
(2)	**BASIS: GSR Part 3 Requirement 14, para. 3.37 states that** "*The regulatory body shall establish requirements that monitoring and measurements be performed to verify compliance with the requirements for protection and safety. The regulatory body shall be responsible for review and approval of the monitoring and measurement programmes of registrants and licensees."*
(3)	**BASIS: GSR Part 3 Requirement 29, para. 3.123 states that "***The regulatory body shall establish or approve operational limits and conditions relating to public exposure,*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	including authorized limits for discharges."
(4)	**BASIS: GSR Part 3 Requirement 31** *states that: "Relevant parties shall ensure that radioactive waste and discharges of radioactive material to the environment are managed in accordance with the authorization."*
R29	**Recommendation: ERPA should establish discharge limits for liquid and gaseous radioactive discharges and related dose constraints.**

11.3.2. ENVIRONMENTAL MONITORING

ERPA carries out national environmental monitoring according to its environmental programme. However, there are no provisions for environmental monitoring in the legal framework. The environmental samples are measured and analyzed by Radioanalytical Team of ERPA. The measurements are done according to the Standard for Measurement of Environmental Samples established by Ethiopian Standard Agency. The results are reported to the Ministry of Science and Technology every 3 months.

Thermoluminiscence Dosimeters are installed at 92 points throughout the country for measurement of ambient dose. The TLDs (TLDs) are replaced every three months.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The national environmental monitoring programme of Ethiopia is in place but there are no legal bases for it.*	
(1)	**BASIS: GSR Part 3 Requirement 32, states that**"*The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available.* *Para.3.135:* *The regulatory body shall be responsible, as appropriate, for:* *(a) Review and approval of monitoring programmes of registrants and licensees, which shall be sufficient for:* *(i) Verifying compliance with the requirements of these Standards in respect of public exposure in planned exposure situations;* *(ii) Assessing doses from public exposure.*
R30	**Recommendation: The Government should establish regulatory framework and assign responsibilities regarding environmental monitoring.**

11.3.3. EXISTING EXPOSURE SITUATIONS, INCLUDING REMEDIATION OF AREAS CONTAMINATED WITH RESIDUAL RADIOACTIVE MATERIAL

There are no provisions in the legal framework for controlling existing exposure situations. ERPA has drafted a directive "Ethiopian Radiation and Nuclear Protection Authority NORM and NORM

Waste Management Directive (November 2017)," that includes requirements for regulating existing exposure situations.

ERPA has done some radon monitoring at some resorts. However, there is no programme for monitoring of radon. Similarly, there is no programme for monitoring the exposure of aircrew due to cosmic radiation.

11.4. SUMMARY

The legislation does not contain provisions for control of radioactive discharges, control of existing exposure situations and environmental monitoring. The principle of optimization is provided for in the Proclamation, but the requirements on dose constraints for the public are not established. ERPA carries out environmental monitoring and reports the results to the Ministry of Science and Technology every 3 months.

POLICY DISCUSSION WITH INTEGRATED REGULATORY REVIEW MISSION TEAM

During Integrated Regulatory Review Mission in Ethiopia, ERPA proposed two policy issues to be discussed and share different countries experience. The policy issues are:

- Radiation protection of pregnant women for ensuring the protection of the fetus from radiation hazard and
- personal dosimeter reading frequency

1. Radiation protection of pregnant women for ensuring the protection of the fetus from radiation hazard and

A presentation was made by ERPA to seek advice and suggestion from IRRS Team. The discussion was found to be important to gain experiences from the experts in their respective countries and the international scenario. Based on the points raised for discussion; the following suggestions and advices were drawn:

- A dose limit of 1msv is the maximum limit for the exposure of the pregnant women to consider the fetus as a public. The experts reflected their views on this matter and the meeting agreed that this limit (1msv) exposure should also be maintained as a maximum acceptable limit for the exposure of the fetus of a pregnant radiation worker women.

- A pregnant women should be treated as a potential worker during the time of her pregnancy without discrimination. However; conducive working environment should be arranged for her for the delivery of a healthy child without compromising radiation safety. In view of this; the Ethiopian radiation Protection Authority is advised by the team of experts to make the radiation monitoring frequency of a pregnant women in every one month.

- The experts reflected the experiences of their countries with regard to the exemption of pregnant women from radiation exposure as a result of her job. Some country experts explained that a pregnant women is exempted from the work of radiation facility if she presented an approval from a medical doctor. Some experts mentioned that the employer is obliged to accept an oral notification to exempt from radiation exposure work. Finally the meeting advised that the pregnant women are not obliged to disclose her pregnancy to the employer since it is a personal issue. The employer should emphasis declaration of pregnancy on voluntary basis. However; the employer is obliged to ensure the protection of the fetus of a pregnant women from the time of the awareness that she is pregnant. The experts also advised that pregnancy dose limit should be considered for all activities.

- The annual radiation dose intake for breast feeding mother should be seriously considered especially for Nuclear Medicine ingestion and diagnosis doses and treatment practices and other practices using open sources.

- The experiences of some countries showed that female worker shall be engaged in unsealed source as long as the dose limit is below 6 mSv. On the other hand; the practices of some countries indicate that breast feeding worker shall not work in unsealed sources. ERPA is advised to ensure that the dose limit of breast feeding worker should not exceed public exposure in the facility of sealed or unsealed sources.

- The experts shared their experiences that a pregnant woman wears protective cloth with additional dosimeter around her belly depending on the frequency to ensure the limit not to exceed 1mSv.

2. Reading of personal Dosimeter

- The experts reflected that radiation monitoring period of workers are related to the potential risk of the facilities. Classification of areas is also depending on the potential risk but not on the annual monitoring. The team of experts advised ERPA
  - ✓ Potential exposure is the main parameter to decide whether radiation monitoring is needed or not. If the potential exposure is above 1mSv then radiation monitoring is needed.
  - ✓ It is advised to make the radiation monitoring frequency every one month for high category sources like radiotherapy, nuclear medicine, Cardiac and industrial radiography centres and check the reading not to exceed the dose limit either by direct measurement or by reading analysis of service provider.
  - ✓ To make the radiation monitoring frequency every two months for Mammography, CT scan and other x-ray diagnosis practices. The experts advised to exempt dental x-ray.

  However; it is reiterated that protection is not ensured by increasing monitoring frequency but it is optimized by ensuring safety.
- The experts agreed that the monitoring period should depend on the potential risk. The experience of Europe standard showed that if the reading is b/n 1mSv-6 mSv the frequency is for three months.
- Experiences of some countries showed that in industrial radiography of high category sources; a personal arming device is recommended in addition to the personal dosimeter.
- The experts reflected their views that the geographical location should not be a factor for the determination of personal radiation monitoring frequency. There should be a separate dosimeter to be rotated. The user should not be without dosimeter while it is sent to the service provider for reading. i.e each radiation workers should have to have two personal dosimeters.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
MARKKANEN Mika	Radiation and Nuclear Safety Authority (STUK)	Mika.Markkanen@stuk.fi
SEVERA Reward	Radiation Protection Authority of Zimbabwe	rsevera@rpaz.co.zw
SLOKAN DUSIC Darja	Nuclear Safety Administration	darja.slokan-dusic@gov.si;
MUNDIA Isaac	Radiation Protection Board of Kenya	ismundia@gmail.com;
SAMBA Richard Ndi	Agence Nationale de Radioprotection (ANRP)	samba_ndi@yahoo.co.uk
SERT Gilles	Consultant	gsert@orange.fr
PASKOVA Zuzana	M.G.P. Zlin	zuzana.paskova@mgp.cz;
HUSSAIN Muhammad Nadeem	Pakistan Nuclear Regulatory Authority (PNRA)	m.nadeem@pnra.org;
KHARIT Mohammad	Hamad Medical Corporation (HMC)	MKharita@hamad.qa;
IAEA		
SHADAD Ibrahim	Division of Radiation, Transport and Waste Safety	I.Shaddad@iaea.org
ALEXANDER Tom	Division of Radiation, Transport and Waste Safety	T.Alexander@iaea.org

APPENDIX II MISSION PROGRAMME

Activities	Titles/Details of activities	Date/Time	Venue	Participants
Sunday 03 December 2017				
Initial IRRS Review Team Meeting	Opening remarks by IRRS Review Team Leader	13:30-13:40	Blue Nest Hotel	IRRS Review Team and LO
	Give Introduction about the IRRS Mission (IAEA)	13:40-14:00		
	Self-introduction of all attendees	14:00-14:10		
	Briefing on the IRRS Process IAEA, Briefing to the IRRS Review Team by IAEA about Report writing	14:10-15:30		
	First impression from each IRRS team member arising from the Advanced Reference Material (ARM)	15:30-16:30		
	Briefing to the IRRS Review Team by LO and IAEA about Administrative arrangements	16:30-16:40		
	Modification and adoption of the Detailed Mission Programme (LO, IAEA)	16:40 - 17:30		
Monday 04 December 2017				
IRRS Entrance Meeting	Registration of the attendees of the meeting representatives	08:45 - 09:00	Blue Nest Hotel	Participants: Senior Government representative, Senior management of ERPA (+ LO) and staff, Officials from relevant organizations the IRRS Team
	Welcome Remarks (ERPA and MOST)	09:00-09:20		
	Introduction of the IRRS Review Team	09:20-09:30		
	Introducing participants from ERPA and government	09:30-09:45		
	Presentation on the Objectives of the IRRS mission (IAEA)	09:45-10:15		
	Group photo of the meeting participants	10:15-10:25		
	Coffee break	10:25-11:00		

	Presentation on the current status of ERPA regulatory activities (ERPA) Briefing to the IRRS team on information such as: Overview – SARIS results (strengths, challenges, action plan) Discussion – Questions	11:00 - 12:00		
	Lunch	12:00 - 13:00		IRRS Reviewers and ERPA Counterparts
	Transfer IRRS team from the Hotel to the ERPA's Office	13:00 - 13:15	ERPA	
	Interviews and Discussions with Counterparts (parallel discussions	13:15 - 17:00		
	Transport to the Hotel	17:00 – 17:10		
	Daily IRRS Review Team meeting	17:10 – 18:00	Blue Nest Hotel	
	Writing draft report by the team	18:00 –		
	Tuesday 05 December 2017			
	Transfer IRRS team from the Hotel to the ERPA's Office	08:45 – 9:00		
	Interviews and discussions with counterparts (parallel discussions)	09:00 – 11:00		IRRS Reviewers and ERPA Counterparts:
	Meeting with the Government Officials (will be decided)	11:00 – 12:30	ERPA Meeting room	MOST .TL+TC+ Reviewer of Modules 1-3
	Lunch	12:30 – 13:30		
	Interviews and discussions with counterparts (parallel discussions)	13:30-17:00		IRRS Reviewers and ERPA Counterparts
	Transport to the Hotel	17:00 – 17:10		
	Daily IRRS Review Team meeting	17:10 – 18:00		
	Writing draft report by the team	18:00 –		
	Wednesday 06 December 2017			
	Transfer IRRS team from the Hotel to the ERPA's Office	08:45 – 9:00		IRRS Reviewers and ERPA Counterparts:
Daily Discussions / Interviews / Site visits	Interviews and discussions with counterparts for all modules	09:00 – 12:30		
	Visit to the Waste Management Facility			
	Travel to the Waste Management facility	09-00:9:45	RWPSF	IRRS Reviewer of Waste and ERPA Staff
	Meetings and discussions with the facility staff	09:45-11:45		
	Back to the ERPA"s Office	11:45-12:30		
	Observe inspection conducted by ERPA inspectors to a medical facility			
	Observe Inspection Preparation	09:00-09:30	Medical Facility	IRRS Reviewers and ERPA Inspectors
	Travel to Medical facility to observe inspection	09:30-10:00		
	Entrance briefing at the medical facility	10:00-10:15		

	Observe visual inspection	10:15-10:45		
	Observe quality control test inspection	10:45-11:45		
	Exist briefing	11:45-12:00		
	Back to ERPA's office	12:00- 12:12：30		
	Lunch	12:30 – 13:30		
	Report preparation	13:30-16:45 16:45 – 17:00		
	Daily IRRS Review Team meeting (Briefing on all site visits) Discussing the available Recommendations and Suggestions	17:10- 20:00	Blue Nest Hotel	
	Writing draft report, Observations (Os), Recommendations (Rs), Suggestions (Ss) and Good Practices (GPs)	20:00 –		
	Thursday 07 December 2017			
	Transfer IRRS team from the Hotel to the ERPA's Office	08:30 – 8:45		IRRS Reviewers and ERPA Counterparts:
	Interviews and discussions with counterpart	09:00 – 12:30		
	Observe inspection conducted by ERPA inspectors in a Industrial facility			
Daily Discussions / Interviews / Site visits	Observe Inspection Preparation	08:45-09:00	Industrial Facility	IRRS Reviewers and ERPA Inspectors
	Travel to Industrial facility to observe inspection 30	09:00-10:00		
	Entrance briefing at the Industrial facility	10:00-10:15		
	Conduct Inspection	10:15-11:15		
	Exist briefing	11:15-11:30		
	Back to the ERPA"s Office	11:30-12:30		
	Meeting with the Service Provider facility			
	Travel to the service provider facility	09:00-09:45	Service Provider facility	IRRS Reviewer of Module 11 (occupational) and ERPA Staff
	Meetings and discussions with the facility staff	09:45-11:30		
	Back to the ERPA"s Office	11:30-12:30		
	Lunch	12:30-13:30		
	Team members finalize Os, Rs, Ss and GPs Team members finalize their part draft report text individually	13:30-17:00	ERPA meeting Room	IRRS team
	Transport the IRRS team to the Hotel	17:00 – 17:10		IRRS team
	Daily IRRS Review Team Meeting: Team finalizes Rs, Ss and GPs	18:00 –	Blue Nest Hotel	the IRRS team + LO
	Writing draft report: Reviewers complete report text individually.	22:00--		IRRS Team (each reviewer individually in

				his/her specific area.
	Friday 8 December 2017			
	Pick up from the Hotel	08:45 – 9:00		IRRS Team
	Team members finalize draft report.	09:00 – 12:30	ERPA meeting Room	
	Lunch	12:30 – 13:30		
	Team members finalize draft report	13:30 – 17:00		
	Transport the IRRS team to the Hotel	17:00 – 17:10		
	Team members finalize draft report	17:10 –	Blue Nest Hotel	
Report drafting and finalization	Saturday 09 December 2017			
	Review the draft report	08:00 -16:00	Blue Nest Hotel	TL and TC
	Submit the draft report to LO for ERPA comments	17:00--		TC
IRRS Review Team Free Day – Cultural Programme	Sunday 10 December 2017			
	Travel to National Museum	9:00-9:45		IRRS Team +ERPA
	Make visit at the National Museum	09:45-12:00		
	Back to the Hotel	12:00-13:00		
	Travel to the Social events	18:00-18:45		
	Social event	18:45-21:00		
	Back to the Hotel	21:00-21:45		
Report commenting and discussions Report reviewing and finalization	Monday 11 December 2017			
	Pick up from the Hotel	08:45 – 9:00	ERPA meeting Room	
	ERPA submits comments on the draft report	9:00		LO
	IRRS team reviews ERPA comments	09:00-12:30		IRRS Team
	IRRS team finalizes the draft report together with ERPA	11:00 – 12:30		The IRRS team + LO + ERPA
Finalizes the draft	Lunch	12:30 – 13:30		
	IRRS team finalizes the draft report together with ERPA	13:30 – 17:00	ERPA meeting Room	The IRRS team + LO + ERPA
	Transport the IRRS team to the Hotel	17:00 – 17:10		
IRRS	Tuesday 12 December 2017			

mission exit meeting	Registration of the attendees of the meeting	08:45 – 9:00	Blue Nest Hotel	Government officials, senior management and staff, officials from relevant organizations, the IRRS team + LO
	Remarks by Senior Government Official	09:00 – 09:15		
	Present Main findings of the IRRS mission by Team Leader	09:15 – 10:00		
	Remarks by ERPA in response to the mission findings	10:00 – 10:20		
	Remarks by Official Director NSRW(IAEA)	10:20 – 10:30		
	press release	10:30 – 11:00		
	Departure of the Team Members			

APPENDIX III SITE VISIT

The mission took place at the ERPA Headquarters in Addis Ababa.

Site Visits (Inspection, Service Providers, Other stakeholders)

	Name	Contact Person
1.	Saint Gabriel General Hospital	
2.	National Institute Of Control And Eradication Of Tsetse Fly And Trypanosomosis.	Dr bekele Lemma Mr. Amanuel Abera, RSO
3.	National Meteorology Institute	Mr Mulugeta Deribew
4.	Ethiopian Conformity Assessment Enterprise, Personal Monitoring Service Laboratory	Mr Zerihune Abebe Ms Elzabet Nega, Assistant Technician
5.	Food, Medicine And Health Care Administration Control of Ethiopia	Mr Yehulu Deneke,DG Ms Seble Mr. Daniel.T
6.	Ministry of Science and Technology	Professor Afework Kassu,State Minister Mr Abdurezak Umer,NLO Mr Abebe Tesfa,OLA

APPENDIX IV LIST OF COUNTERPARTS

Integrated Regulatory Review Service (IRRS) Mission to Ethiopia
December 04 – 12, 2017, Addis Ababa, Ethiopia,
Attendance of Participants in the Opening Ceremony

No.	*Name*	*Organization*
1	Ms Elsa Zeray	Infinity Advanced Technology Solutions Plc.
2	Mr Shambele G/medhin Birage	Ethiopia Consumer Association
3	Ms Yirgalem Kassa	Dosimed Testing Laboratory
4	Dr Seife Teferi	RaySafe Radiation Protection Service
5	Ms Rahel Tilahun	Ethiopian Radiologist Radiographer Technology Association for Female
6	Mr Demeru Yeshitla	Ethiopia Biomedical Association
7	Dr Adane Abraham	Addis Ababa Science Technology University
	Mr Worku Wedaje	Alpha Radiation Protection Service
8	Mr Samson Hagos	BMY Medical Technologies PLC
9	Mr Ermias Girma	Communication
10	Ms Yodit Admassu	Communication
11	Ms Eyerusalem H/Michael	Ethiopia Cancer Association
12	Mr Yenusse Molla	Ethiopian Radiologist Radiographer Technology Association
13	Mr Dejene Kebede	Ministry of Trade
14	Mr Solomon Getachew	Ethiopian Radiation Protection Authority
14	Mr Fassika Abebe Beyene	Ethiopian Radiation Protection Authority
15	Mr Aniteneh Zenebe	“ “
16	Ms Azeb Tayework	“ “
17	Ms Lidia Kassahun	“ “
18	Mr Birhun Asfaw	“ “

No.	*Name*	*Organization*
19	Mr Surur Kedir	“ “
20	Mr Abdulaziz Nuredin	Ethiopian Radiation Protection Authority
21	Mr Gatahun Nigussie	“ “
22	Mr Berhane Meskel Kumbi	“ “
23	Mr Birhanu Turi	“ “
24	Mr Sahelmariam Tefessa	“ “
25	Mr BiruK Alemu	“ “
26	Mr Daniel Kidene	“ “
27	Mr Negash	“ “
28	Mr Endalew Ayalew	“ “

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 national policy on safety to fully address the fundamental safety objective, fundamental safety principles and long-term commitment to safety.**
		R2	**The Government should review and revise the legal framework to align it with the IAEA safety standards.**
		R3	**The Government should establish regulations in accordance with the IAEA safety standards.**
		R4	**The Government should expedite re-establishment of ERPA and 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.**
		S1	**ERPA should consider formalising coordination and liaison with all other authorities having responsibilities for safety.**
		R5	**The Government should establish a national policy for the safe management of radioactive waste.**
		S2	**ERPA should consider separating the operations of the waste management facility from the regulatory functions in order to minimize the potential for conflicts of interests.**
		R6	**The Government should make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities as well as for the formal recognition of qualified experts.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
2	**THE GLOBAL SAFETY REGIME**	S3	**The Government should consider to be a party to international conventions that establish common obligations and mechanisms for ensuring protection and safety.**
		R7	**ERPA should make formalized arrangements for identifying lessons to be learned from operating experience and regulatory experience and for the dissemination of the lessons learned.**
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	S4	**ERPA should consider reviewing and revising its knowledge management arrangements to develop and maintain the necessary competence and skills of its staff.**
		S5	**ERPA should consider introducing an electronic document management system.**
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	R8	**ERPA should improve and complete its management system to be in line with IAEA safety standards.**
		R9	**ERPA should improve its management system to foster, in a documented manner, a strong safety culture and leadership for safety and ensure that self-assessment and independent assessment of both safety culture and leadership for safety are implemented.**
5.	**AUTHORIZATION**	S6	**ERPA should consider implementing the graded approach in authorization as provided in the proclamation.**
		R10	**ERPA should implement a multi-staged authorization system for complex facilities and activities.**
		S7	**The Regulatory Body should consider measures to ensure that all consignors, carriers and in-transit handling companies involved in the transport of radioactive materials are appropriately authorized, unless exempted.**
		S8	**ERPA should consider establishing and**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			implementing a graded approach in licensing consignors and carriers.
6.	**REVIEW AND ASSESSMENT**	R11	**ERPA should develop practice specific procedures to ensure consistency and application of a graded approach in the review and assessment process.**
7.	**INSPECTION**	S9	**ERPA should consider developing and implementing detailed inspection procedures for all facilities and activities.**
		S10	**ERPA should consider improving the implementation of the graded approach in its inspection programme.**
8.	**ENFORCEMENT**	R12	**ERPA should make provisions to confirm that the licensee has implemented all necessary corrective actions.**
9.	**REGULATION AND GUIDES**	R13	**ERPA should establish directives and guides consistent with IAEA safety standards that systematically cover all types of facilities and activities.**
		R14	**ERPA should establish and document processes for developing, reviewing, revising and issuing regulations, directives and guides, which should include provisions for consultation with interested parties.**
		R15	**ERPA should establish requirements for identification, characterization and classification of radioactive waste and ensure their implementation.**
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R16	**ERPA should establish requirements and prepare guidance for licensees, in line with IAEA Standards, to perform and periodically review on-site hazard assessment as basis for emergency preparedness and response.**
		R17	**ERPA should ensure that licensees regularly conduct exercises and trainings and systematically evaluate the exercises. ERPA should evaluate some of these exercises.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R18	**The Government should maintain, in the legal framework, the role of ERPA for advising the government and competent authorities and providing expert services in the event of an emergency.**
		R19	**ERPA should prepare and maintain its own emergency plan, necessary procedures and analytical tools to effectively perform its assigned functions. The procedures and tools should be tested and validated prior to initial use.**
		R20	**ERPA should develop and implement a comprehensive training and exercise program as well as a mechanism for systematic evaluation of exercises.**
		S11	**ERPA should consider establishing a designated notification point for receiving emergency notification and initiating response actions in a timely manner.**
		R21	**ERPA should establish a programme to ensure availability and reliability of adequate tools, equipment, instruments, and other essential facilities required for an effective emergency response.**
		S12	**Within its organizational structure, ERPA should consider designating an emergency response team with sufficient number of suitably qualified personnel for performing its tasks during an emergency.**
11.1	**CONTROL OF MEDICAL EXPOSURES**	R22	**The government should ensure that diagnostic reference levels, dose constraints and criteria and guidelines for the release of patients following radionuclide therapy are established.**
		R23	**The Government should establish a requirement that no person incurs a medical exposure unless there has been an appropriate referral.**

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R24	**ERPA should establish a requirement to minimise the likelihood of unintended or accidental medical exposures, to promptly investigate them, record them and implement corrective actions.**
11.2	**OCCUPTIONAL RADIATION PROTECTION**	R25	**The Government should ensure that dose limits for occupational and public exposure are established in line with GSR- part 3.**
		R26	**The Government should establish a requirement to explicitly state that employers, registrants and licensees should not offer benefits to workers as substitutes to providing protection and safety measures.**
		R27	**ERPA should establish a requirement for employers, registrants and licensees to develop and maintain a radiation protection programme for occupational exposure.**
		R28	**The Government should ensure that the dosimetry services for assessing the equivalent doses for the lens of the eyes and the extremities are available.**
11.3	**CONTROL OF RADIOACTIVE DISCHARGES AND MATERIAL FOR CLEARANCE, ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES CONTROL OF CHRONIC EXPOSURES**	R29	**ERPA should establish discharge limits for liquid and gaseous radioactive discharges and related dose constraints.**
		R30	**The Government should establish regulatory framework and assign responsibilities regarding environmental monitoring.**

APPENDIX VI REFERENCE MATERIAL USED FOR REVIEW

1. Radiation and Nuclear Protection Proclamation 1025 of 2017
2. Ethiopian Radiation Protection Authority Proclamation 571 of 2008
3. Notification of practices and sources
4. Application for authorization to use diagnostic X-ray equipment and facility
5. Application for authorization and review plan for a gamma irradiator facility
6. Application for authorisation to use industrial radiography equipment and facilities
7. Application for authorization to use luggage check/screen x-ray equipment and facilities
8. Application for authorisation for fixed (installed) gauging, detection and other devices
9. Application for authorisation and review plan for well logging, portable gauging detection and analytical devices
10. Application for authorisation and review plan for radiotherapy
11. Application for authorization and review plan for use of unsealed radioactive sources in medicine
12. Computed Tomography Safety And Quality Assurance Checklist
13. Conventional Radiology QC Checklist
14. Dental X-Ray QC Checklist
15. Industrial Radiography, Irradiators and accelerators QC Checklist
16. Mammography Radiographic QC Checklist
17. Radiotherapy Facility QC Checklist
18. Inspection Quality Manual
19. Inspection Procedure
20. Radiographic Inspection Method for conventional radiography
21. Summarized Regulatory Requirements for Import of X-ray Machines and authorization of Dental Radiography
22. Mandatory Regulatory Requirements to Practice Conventional Diagnostic Radiology and for Issuance of a License
23. Summarized Regulatory Requirements of the Ethiopian Radiation Protection Authority – ERPA on Import, Possession, Commissioning and Decommissioning of Nuclear Gauges
24. Summarized Regulatory Requirements of the Ethiopian Radiation Protection Authority – ERPA on Import, Possession, Commissioning and Decommissioning of Radiotherapy Sources
25. Procedures and regulatory requirements for fixed facilities for industrial/screening radiography
26. Application for authorization to import / export radiation device(
27. Application Guide for authorisation to transport/transit radiation device(s)/ materials
28. Application for authorisation to transport/transit radioactive sources
29. Application for authorization to import / export radiation device(s)
30. Guide for completing application form: authorization for diagnostic x-ray equipment and facilities
31. Sample Inspection General report 2
32. Sample Inspection Letter
33. Operational Permit sample
34. Operational License Sample 2

35. PERMIT TO IMPORT permit sample
36. PERMIT TO OPERATE Sources
37. Sample communication Letters
38. Draft National Radioactive Waste Policy
39. Draft National Emergency and Preparedness Plan
40. Draft National Policy for Safety
41. SELF-ASSESSMENT FINDINGS FOR GOVERNMENT RESPONSIBILITIES FOR SAFETY
42. SELF-ASSESSMENT FINDINGS FOR THE GLOBAL SAFETY REGIME
43. SELF-ASSESSMENT FINDINGS FOR RESPONSIBILITIES AND
44. FUNCTIONS OF THE REGULATORY BODY
45. ASSESSMENT FINDINGS FOR AUTHORIZATION
46. SELF-ASSESSMENT FINDINGS FOR REVIEW AND ASSESSMENTS
47. SELF-ASSESSMENT FINDINGS FOR INSPECTION
48. SELF ASSESSMENT FINDINGS FOR ENFORCEMENT
49. SELF ASSESSMENT FINDINGS FOR REGULATION AND GUIDES
50. SELF-ASSESSMENT FINDINGS FOR MANAGEMENT SYSTEM
51. SELF-ASSESSMENT FINDINGS FOR CONTROL OF MEDICAL EXPOSURE
52. SELF-ASSESSMENT FINDINGS FOR EMERGENCY PREPAREDNESS AND RESPONSE
53. SELF-ASSESSMENT FINDINGS FOR OCCUPATIONAL RADIATION
54. PROTECTION
55. SELF-ASSESSMENT FINDINGS FOR RADIOACTIVE WASTE

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

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

14. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)

15. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)

16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)

17. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)

18. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)

19. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)

20. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)

21. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)

22. INTERNATIONAL ATOMIC ENERGY AGENCY – Establishing the Safety Infrastructure for a Nuclear Power Programme Specific Safety Guide No SSG-16, IAEA, Vienna (2011)

23. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements 5, No. SSR 5, IAEA, Vienna (2011)

APPENDIX VIII ORGANIZAIONAL CHART