Addis Ababa University

Addis Ababa Institute of Technology

Center of Biomedical Engineering

Investigating and Automating Ethiopia's radiation-generating medical device inspection system

A Thesis

Submitted to the Center of Biomedical Engineering Presented in partial Fulfillment of the Requirements for the Degree of Master of Science in Biomedical Engineering.

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This is to certify that the thesis prepared by Alemu Nigusse, entitled: Investigating and Automating Regulatory Inspection System of Radiation Generating Medical Devices in Ethiopia and submitted in partial fulfillment of the requirements for the degree of Master of Sciences in Biomedical Engineering compiles with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Declaration

I the undersigned, declare that this thesis is my original work, has never been presented in this or any other university, and that all resources and materials used here in, have been duly acknowledged.

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This thesis has been submitted for examination with my approval as a University advisor.

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Abstract

Ionizing radiation is energy in the form of wave or particles that have enough energy to remove electrons from the atoms**.** Since this radiation imposes a deterministic and stochastic effects on human being, the source needs strict regulation to minimize the risks and hazards as low as reasonably achievable. In the healthcare sector, the major sources of ionizing radiation are Radiation Generating Devices (RGDs) such as radiotherapy machine, CT-Scan machine, and X-ray machine. Ethiopian Radiation Protection Authority (ERPA) is established to regulate such sources during import, transport, use, and export. However, previous studies revealed the exposure of workers around this practice is above the exposure limit of International Basic Safety Standard.

The aim of this thesis is therefore to investigate the gaps around regulation of RGDs and showcase one way to improve the regulatory system. For the investigation, an institutional based cross-sectional study was carried out in nine hospitals and one authority (ERPA) from October in 2016 to February in 2017 in Addis Ababa. A total of 102 professionals were purposively selected as respondents based on the inclusive criteria, out of which 72 were selected from nine hospitals and the rest 30 were selected from ERPA. The data were collected through structured questionnaires, focused group discussion, document analysis and practical observation.

The result indicates the overall mean of respondents who reported that there were regulatory inspection was 73.8% in ERPA and 65.1% in hospitals; checked out each safety control parameters was 89.8% in ERPA and 80% in hospitals; and checked out each performance indicator parameters was 81.7% in ERPA as well as 66.9% in hospitals. Furthermore, more than 90% (27) of participants, for each item, in ERPA believed that there is no enough professional man power in ERPA; and 90% (27) of respondents disagreed that the expected inspection frequency is specified for each devices; and the overall mean of about 64.9% of participants in ERPA disagreed on each staff management requirements. Moreover, more than half (50.5%) of respondents in hospitals disagreed and strongly disagreed on availability and appliance of each inspection procedure.

The finding of this thesis revealed different gaps during regulatory inspection such as missing of RGDs, bypassing safety control and performance indicator parameters; and lack of material and human resource in the staff of ERPA. HTML5, MySQL, PHP, XAMPP, and CSS3 soft- wares

were employed to develop a Web-based scheduling and registration system. It is believed that the developed system can be a showcase solution for the problems related to accessing and retrieving, registering & scheduling, deleting & adding, editing, storing, and updating any necessary information of RGDs that the regulatory body needs to do its activities properly.

Key words: Automation, Investigation, Ionizing Radiation, Regulatory Inspection, Radiation Generating Devices, Medical devices registration system.

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List of Abbreviations

AAiT-Addis Ababa Institute of Technology

CNSC-Canadian Nuclear Safety Commission

CE-Clinical Engineering

CT-Computed Tomography

ECEI-Emergency Care Energy Institute

ERPA-Ethiopian Radiation Protection Authority

FDA-Food and Drug Administration

HTML-Hyper Text Markup Language

IAEA-International Atomic Energy Agency

IBSS-International Basic Safety Standard

IEEE-Institute of Electrical and Electronic Engineers

ICRP-International Commission for Radiation Protection

IPM-Inspection and Preventive Maintenance

IRGMD-Ionizing Radiation Generating Medical Devices

IRSRCD-Ionizing Radiation Sources Regulatory Control Directorate

ISO- International Standard Organization

LNT-Linear no-threshold

MDE-Medical Devices and equipment's

MIS- Management Information System

mSv- milli Sievert

mAs- milliamper second

NAD-National Agency Directorate

NCRP-National Commission for Radiation Protection

NRDD-Nuclear Research Development Directorate

NRSD-Non-ionizing Radiation Source Directorate

PA-posterior-Anterior

PHP-Hypertext Pre-Processer

PM-Preventive Maintenance

RGD-Radiation Generating Devices

SC-Safety Control

SM-Scheduled Maintenance

SPI-Safety and Performance Inspection

RGMD-Radiation Generating Medical Devices

UML-unified modeling language

UNEP-United Nations Environment Programme

UNSCEAR-United Nations Scientific Committee on the Effects of Atomic Radiation

QC-Quality Control

WHO- World Health Organization

Chapter1 Introduction

1.1 Background

Radiation is energy in the form of wave or streams of particles [1]. It comes from the source and travel through space and is able to penetrate various materials through its path. Radiation can be ionizing or non-ionizing based on the stability of the electron of the particular atom.

Ionizing radiation is defined as energy in the form of waves or particles that have enough energy to remove electrons from the atoms [2]. It can be classified as photons (x-radiation and gamma-radiation) and particulates (alpha, beta particles and neutrons).

Radiation is everywhere in our environment. Customer products, activities such as medical procedures that use radionuclides or x-rays, and nuclear power plants used to generate electricity are some of human made radiation sources. But the largest source of radiation exposure to human is natural background radiation which covers 70% of the total exposures. However, the medical sources are almost as large as about 20 % of the total exposure to ionizing radiation and on average, it covers 98 % of the radiation exposure of all man-made sources [3].

Following the discovery of ionizing radiation i.e. x-ray in 1895 by Wilhelm Röntgen and Gamma ray in 1896 by Henri Becquerel, its beneficial uses were rapidly discovered by medical professions [4]. Then after, new diagnostic and therapeutic techniques have been developed and the general level of healthcare has been improved over the years. Diagnostic radiology represents the largest manmade source of public exposure to ionizing radiation throughout the world. Its contribution to the annual collective effective dose from artificial radiation sources is about 90 percent [5]. But the average annual individual exposure values for the states of upper healthcare level and lower healthcare level is about 1.3 mSv and 0.02 mSv respectively. This indicates that there are wide differences in radiological practices between the upper and the lower healthcare levels throughout the world and [6].

Medical device means “any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

•diagnosis, prevention, monitoring, treatment or alleviation of disease
•diagnosis, monitoring, treatment, alleviation of or compensation for an injury
•investigation, replacement, modification, or support of the anatomy or of a physiological process
•supporting or sustaining life
•control of conception
•disinfection of medical devices
• providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" [7]. Radiation generating devices (RGDs) in this thesis refers to those devices that generate medical use of ionizing radiation only. Radiation in this study refers to ionizing radiation.

In general, medical practice involving exposure to ionizing radiation may be classified in to three broad categories: diagnostic radiology, nuclear medicine, and radiation therapy [8].
Diagnostic radiology refers to the analysis of images obtained by using x-ray. Plain radiographs, images of the breast, images obtained by using fluoroscopy, images by using computerized reconstruction techniques such as computerized Tomography (CT), and dental radiology are some of the practices included in this category [8].

Nuclear medicine refers to the introduction of unsealed radioactive substances in to the body. The substance is usually given orally, intravenously, or by inhalation. For example a radiopharmaceutical is formed by a radionuclide and distributed in the body according to its physical and chemical characteristics. Unsealed radionuclides, on the other hand, are less commonly administered in to the body to treat certain diseases most commonly thyroid cancer and hyperthyroidism [8].

Radiation therapy refers to the use of ionizing radiation to treat various diseases. It is sometimes referred as radiation oncology. It can be external or internal. The treatment of patient using high radioactive sources that is outside the patient is called external radiotherapy (like Cobalt-60 machine) and the treatment of patient using radioactive sources which is inside the body of patients is called internal radiotherapy (like Brachytherapy) [8].

Since all RGDs generate ionizing radiation, regulatory control through the government authority was found to be indisputable solution. Then radiation protection standards and the philosophy of governing these standards was becoming to be developed starting from the discovery of radiation and radioactivity. Based on the environmental agencies, the first organized effort at radiation protection was the British Rontgen society, adopted a resolution to protect the people against exposure to x-rays in 1915 and American organizations adopted the British protection rules in 1922 [9]. Gradually, awareness and education grew and more guide lines and organizations have become developed and formed to address radiation protection in different countries.

Even if radiation protection was nongovernmental function until the late 1940s, after World War II, the development of atomic bomb and nuclear reactors caused the government of US and other countries to establish policies dealing with human exposure to radiation [2] and [12]. However, based on the WHO 2010 report about worldwide medical devices regulation, 30% of countries in the world have developed their own regulation frame work, 30% of countries in the world partially have regulation of medical devices, and the rest 40% of countries are either developing a frame work or do not yet have any regulation [11].

Any regulation needs a regulatory body that has a legitimated authority by the government. Regulatory body is a relevant authority which controls particular sources or aspects of radiation safety and radiation practices and the governments should ensure that all aspects are covered regardless of any division of regulatory responsibilities. In this regard, the size, complexity and safety implications of the regulated radiation practices and sources, as well as the regulatory traditions in the country are some of the components which affect the type of regulatory regime adopted [12].
The regulatory body of the government should perform regulatory inspection and enforcement activities to control all aspects of radiation safety and performances of radiation facilities during different radiation practices. Inspection in short is the principal means by which direct personal contact between regulatory body's personnel and operators. Furthermore, regulatory inspection can be defined as ''an examination, observation, measurement or test undertaken by or on behalf of the regulatory body to assess structures, systems, components and materials, as well as operational activities, processes, procedures and personnel competences'' [12]. On the other hands, enforcement is defined as "the action taken by the regulatory body to correct non-compliance by operators with the relevant law, regulations and conditions established in the authorizations" [12].

In developing countries where at present medical facilities and services are often lacking, further growth in medical radiology and other medical modalities are expected. As a result of this boosting in medical radiation facilities, developing countries are expected to have effective regulatory system to minimize the risk and hazard of ionizing radiation.

In Ethiopia, the establishment of medical radiation facilities is growing from time to time in number and type. As the number of facilities increases, quality and safety control system, protective devices supply, Professional human resources, maintenance and support services need to be grown.

If not handled properly, the use of ionizing radiation producing materials can pollute the working area with radiation that is potentially hazardous to human health. As a result, healthcare providers, users, patients and other people who come to hospitals (and any other areas where the source is available) may be exposed to these ionizing radiation sources. Therefore, safe management of radiation sources is important particularly in hospitals and other areas where radiation sources are available.

The Ethiopian Radiation Protection Authority (ERPA) is governmental entity established in December 1993 with the proclamation of radiation protection No.79/1993 and by the revised new proclamation No.571/2008 [13].The authority is a competent government body that regulates ionizing radiation during import, export, use, transport, dispose, and other activities of any sources of radiation all over the country. Therefore, anyone who intends to practice any activities using radiation sources needs to notify the authority earlier and shall get a license to practice. During regulation the authority provides a specific regulatory control requirements needed for each type of activities.

ERPA is one of the institutions organized under science and technology. Currently the authority is structured in to four main core processes: Ionizing Radiation sources Notification and Authorization Directorate (IRSNAD), Ionizing Radiation Sources Regulatory Control Directorate (IRSRCD), Non-ionizing Radiation Sources Directorate (NRSD), and Nuclear Research and Development Directorate (NRDD) as well as other supportive services. In each directorate there are sub-departments to accomplish and process specific services.

The proper registration, licensing and inspection of any materials which can emanate ionizing radiation and any practices related to ionizing radiation are indispensable solution for the problem related to protection of the people against the stochastic and deterministic effects of radiation.

1.2 Statement of the Problem

ERPA is working on regulation of ionizing radiation emanating facilities in the country through licensing and inspection of its customers to make them fulfill the minimum requirements of the Authority. It works to protect the people and their property from the risk and hazards of ionizing radiation when the customers do import, export, use, transport, and dispose such facilities. However, studies on the levels of doses on radiological workers and patients in Ethiopia indicated that the exposure is above the acceptable range (threshold) with reference to international basic safety standard [14].

In addition, as the researcher observed that ERPA is using excel and manual system, to register, inspect, store RGDs and the like activities, which has many drawbacks such as problems related to periodic inspection and update of information, data redundancy, difficulty of access to the concerned body, lack of notification regarding data manipulation (adding, editing and deleting) and above all it is more bulky and time taking.

Therefore, the thesis intends to investigate the main challenges of regulatory inspection process in ERPA for RGDs in the case of government owned hospitals in Addis Ababa and develop web based registration and scheduling system to RGDs.

1.3 Research Objective

1.3.1 General Objective

The general objective of the thesis is to investigate the main challenge of regulatory inspection process by ERPA in government owned hospitals and develop web-based scheduling system for RGDs.

1.3.2 Specific Objectives

The specific objectives of this thesis were to:

- Review the national and international regulatory inspection process and parameters for RGDs;
- Assess the current inspection process of RGDs by ERPA in the selected government owned hospitals;
- Identify major parameters that influence regulatory inspection of RGDs;
- Design, develop and recommend an automatic (web based) solution that can narrow down the gap of regulatory inspection process in ERPA.

1.4 Scope and Limitation of the Study

The scope of this thesis is to assess the regulatory inspection process of RGD(s) made by ERPA in the case of nine government owned hospitals in Addis Ababa. The developed software can register, update, add, edit, search, access, schedule and the like functions for registered RGDs and users details in ERPA.

The study assesses all RGDs other than nuclear medicine with regard to some basic regulatory parameters or components.

1.5 Significance of the Study

The thesis intends to solve major problems related to RGDs management system by designing and developing a web based registration and scheduling system for RGDs regulatory inspection to be used by ERPA.

The document can serve as a pioneer study for regulatory authorities and decision makers in the radiation source facility managers. The system can be supported by software that can solve major problems related to registering, storing, editing, deleting, accessing, and transferring information to and from decision makers and other professionals in healthcare management system. As a result it saves time, cost and effort that can be exposed in the manual system.

1.7 Organization of the Thesis

The study contains six chapters. Chapter 1 is introduction, which presents the background, statement of the problem, objectives, scope and limitations, and finally significance of the thesis. Chapter Two deals with review of related literature that introduces the comprehensive literature review

to provide insight in to the current state of knowledge related to this thesis. Chapter 3 explains about methods and materials, which presents study design, description of the study area, sampling technique and data analysis, data collection process and period, inclusion and exclusion criteria to select respondents, medical devices inspection procedure design tools, and finally system development tools. Chapter 4 deals with the result and discussion of the thesis. It presents the final result of the study and discusses about the outcome of the assessment by using graphical presentation. Chapter 5 describes system analysis, which presents the requirements, technical design and flow chart for regulatory inspection process. It also describes how the system is developed and how it works in general. Finally, chapter 6 is about Conclusion and Recommendation, which realizes final conclusion based on the assessment of RGDs regulatory inspection process and recommends the area to be improved.

Chapter 2 Literature review

2.1 Overview of Medical Practices Involving Ionizing Radiation

Medical uses of ionizing radiation are among the longest established applications of ionizing radiation. Globally, more than 3.6 billion diagnostic radiology examinations are performed, 37 million nuclear medicine procedures are conducted, and 7.5 million radiotherapy treatments are provided annually [15]. The number of such examinations, procedures and treatments has still continued to increase rapidly.

Worldwide, the use of diagnostic imaging that uses ionizing radiation is increasing. For instance, the use of CT in the USA over the past 30 years has increased nearly 600% [16].The international average effective dose from diagnostic radiological procedures nearly doubled from 0.35 mSv in 1988 to 0.62 mSv in 2007 due to the wider use of CT. According to United Nations Scientific Committee on the Effects of Atomic Radiation's (UNSCEAR's) latest survey, CT scanning currently reaches about 43% of the total collective dose due to radiology. However, about 2/3rd of all radiological procedures are received by the 25% of the globe's population living in resource full countries. But the remaining 75 % of the world's population, the yearly frequency of procedures has remained fairly constant [3].

Radiotherapy has also a great role in the treatment of 40% of the patients who are cured of their cancer. Based on the UNSCEAR in the time period 1997–2007, the number of annual treatments with radiotherapy was 5.1 million. Out of that 4.7 million were treatments with an external beam and 0.4 million with brachytherapy. In line with new techniques and new procedures in radiotherapy, the major challenges of radiation protection are their complexity and the high radioactivity of the applied sealed or unsealed sources [16] and [17]. The 25% of the population living in resourceful countries got 70% of the radiotherapy treatment and 40% of all brachytherapy procedures worldwide [3].

Nuclear medicine constitutes a small number of investigations relative to diagnostic radiology. Globally, only 1% of the number of examinations in diagnostic radiology; in Sweden, 2%; in the United States of America, 5%. However, the contributions to the collective doses are more than: 2, 4 and 26%, respectively [16] and [17].

The number of diagnostic nuclear medicine procedures increased from about 24 million in 1988 to about 33 million in 2007 globally. Therapeutic applications in modern nuclear medicine are also raising, reaching about 0.9 million patients annually worldwide [3].

2.2 Medical Devices Management and Regulation System

Much attention has been paid to the theories, approaches, and methods to obtain regulatory compliance while few studies emphasized the role of the licensing visit and its effects, methods, and inspection regimes [18].

Impaired health service provision, poor patient outcomes and substantial health system might be the results of unsafe, ineffective and bad-functioning medical equipment which also in turn is the consequences of poor management and regulation of medical device and drugs [19].

In low- and middle-income countries, 40 to 70% of medical equipment are broken, unused or unfit for their intended purpose and this negatively affect service delivery to patients and results in lost resources. Even if the heart of this sanction is undiscerning procurement processes, a mismatch in technology design and demand, high costs as well as deployment, maintenance and human resource training challenges are also contribute towards this issue. Low and middle-income countries (LMICs) might lack the regulatory authorities and biomedical engineering capacities to regulate and advise on what medical devices are suitable for use in harsh deployment settings (i. e facilities with high temperature, fluctuating electricity or no clean water supply etc.)**.** Unsafe device handling practices with potentially harmful consequences for patients (especially in cases of misdiagnosis due to lack of calibration or other risks due to device re-use) resulted due to the traditionally absence of preventive and corrective maintenance services and user training programs in LMICs [20] and [21].

In Ethiopia, absence of proper regulation and management of medical devices has limited the capacity of health institutions to deliver adequate health care services. Only about 61% of medical equipment found in Ethiopian public hospitals and other health facilities are estimated to be functional and this non-functionality (39%) of the imported devices results in reduction of health care service deliveries in the country [22].

2.3 Authorization

The legal person responsible for any radiation source shall apply for an authorization from the National Regulatory Authority to control the radiation sources and to ensure that the operating organization meets the requirements of the safety and quality standards. A license or registration is usually a common form of authorization. So prior to acquiring any radiation producing materials, the applicants need to apply for such an authorization of the regulatory authority. The details such as: the purpose for which it will be used, the radionuclides and activity, manufacturer and model, details of the storage facility and installation site, copies of approval certificates, end of life considerations (disposal or return to supplier) etc. are some important information's that the regulatory authority needs [23]. It also needs information regarding the people who will be using the equipment's, such as their position, qualification and training in radiation safety etc. IAEA has further details about the relevant legal and governmental infrastructure, the regulatory control of sources, and the notification and authorization for the possession and use of radiation sources [23].Registrants may be inspected by the regulatory authority to audit their provisions for radiation safety and quality as well as to their premises. If the level of radiation protection and safety are considered unacceptable, enforcement action may be taken against the operating organization.

Authorization and enforcement action are inalienable. The potential effects that an enforcement action might produce should be considered and anticipated by the regulatory authority. The potential effects may give rise to a situation with a greater economic, health and safety crises than improvement gained through the enforcement action if it is not managed properly [24].

2.4 RGDs Regulation

Periodic safety control (SC), quality control (QC) test and observation of components in the system using equipment and test tools designed for specific purpose, checking radiation levels, shielding studies, dosimeters and radiological protection administrative procedure are some of the most important parameters for the regulation of RGDs. All procedures and activities should be performed regularly and correctly; the result of all tests and visualizations should be evaluated accurately; and finally, the necessary actions should be taken. Recommendations regarding the responsibility for quality assurance action, staff training, equipment standards, and the selection of appropriate equipment for each examination and testing are necessary regulatory requirements. Quality control

test of the equipment is a series of standardized tests developed to detect changes in the equipment from its original performance of the equipment [25].

In the perspective of any planning of RGD, the main priority is to ensure those persons in a vicinity of the facility are not exposed to levels of radiations that exceed the current regulatory exposure limit which means based on ICRP "Radiation levels in controlled areas that are occupied routinely by radiation workers must be such that: first, no radiation worker is occupationally exposed to more than 20 mSv per year; and second, no public person receives more than 1mSv per year" [25].One of the areas in which regulators should continue to struggle is the need to assure a balance between safeguarding client health and safety and avoiding overzealous regulation [26]. According to Stigler [27], the goal of regulators should be to implement a rational enforcement system although complete enforcement is unachievable.

All devices which are used in the market must pass through some level of testing to verify that it is safe to use. There are various regulations that govern what tests are needed to be performed, the level of documentation needed to be proven that the devices are safe and to validate the potential risks inherited with the devices. In United States (U.S), Food and Drug Administration is the governing agency for medical devices and the Center for Devices and Radiological Health (CDRH) within FDA handles the regulatory concerns for companies that manufacture, repackage, re label and import medical devices which are to be sold within the U.S. Both U.S and European Union classify their devices based on the risk the devices have, to handle their medical devices easily or to simplify their regulation system [28] and [29].

According to the recommendations of BSS, a single regulatory body should be responsible for all aspects of radiation protection and safety [29]. The responsibility for regulating different radiation sources or different aspects of radiation safety and practices, in some states, however are divided between different authorities (e.g. transport, mining, environment, etc.).

2.5 Regulatory Inspection

Inspection process is of many different types ranging from very formal to very informal activities. The two major problems that account for the large variations in inspection research are first unavailability of accepted definition or standard of inspection process and second when process are fairly well-designed they are hard to follow. For instance, according to the report in the IEEE

transactions on software engineering, 84% of organizations performed inspection, but 0% of them performed entirely correct [26]. This implies that inspection processes have ambiguous or unclear definitions. The relatively little knowledge and theory about inspection effectiveness factors are another good reason for inconsistencies of regulatory inspection [30]. It is generally accepted that adopting any variation of the inspection process is much better than not doing any.

Informal inspections processes simply defined as the inspection which are, not planned, not structured, and not recorded [31]. According to some inspection literatures, although informal inspections are proven to get less defects than formal inspection, they are sometimes the best solutions for certain situations [31]. For example, formal inspections can be used on high-risk areas and informal inspections can be used on low-risk areas. In general, informal inspections require less resources than formal inspections.

The second type of inspection is formal inspection. It typically is defined as "in detail, carefully planned, very structured, multi-step, have assigned roles for participants, and recorded" [31]. Formal inspections require extensive training and up to 15 % of the resources of the project can be consumed to formal inspections so that it is relatively very important and quite expensive [30] and [31].

2.5.1 Inspection Procedure

It is not unusual activity to develop software for regulatory purpose. But there are some famous organizations such as ISO and International Electro Technical Commission (IEC) that define regulatory requirements of software for medical devices [32]. So that any inspection process and procedure might need web-based registration system software to deploy information to and from the regulatory body considering the proper inspection procedure of the authority. Besides, the proper inspection procedure and requirements which needs for regulatory bodies is clarified in the publication of International Atomic Energy Agency (IAEA) [33]. Based on this publication the implementation of the regulatory programs of the states may differ based on the form and the structure.

2.5.2 Determining the Number of Staff for Inspection Activity

To implement accurate and effective inspection program, first it needs a relevant registration of radiation sources in the country. The regulatory body needs to direct its resources to the most safety

critical areas and prioritize inspections accordingly. To conduct inspection activities, it needs appropriate devices to monitor, measure and protect radiation in addition to other requirements. All inspection personnel ought to ensure that the equipment is maintained and calibrated at relevant levels [34]. The regulatory body also needs to provide calibration laboratories for the devices measuring instruments to measure occupational radiation doses and other technical services. Figure 1 shows the procedure how to determine the number of staff required for inspection activities.

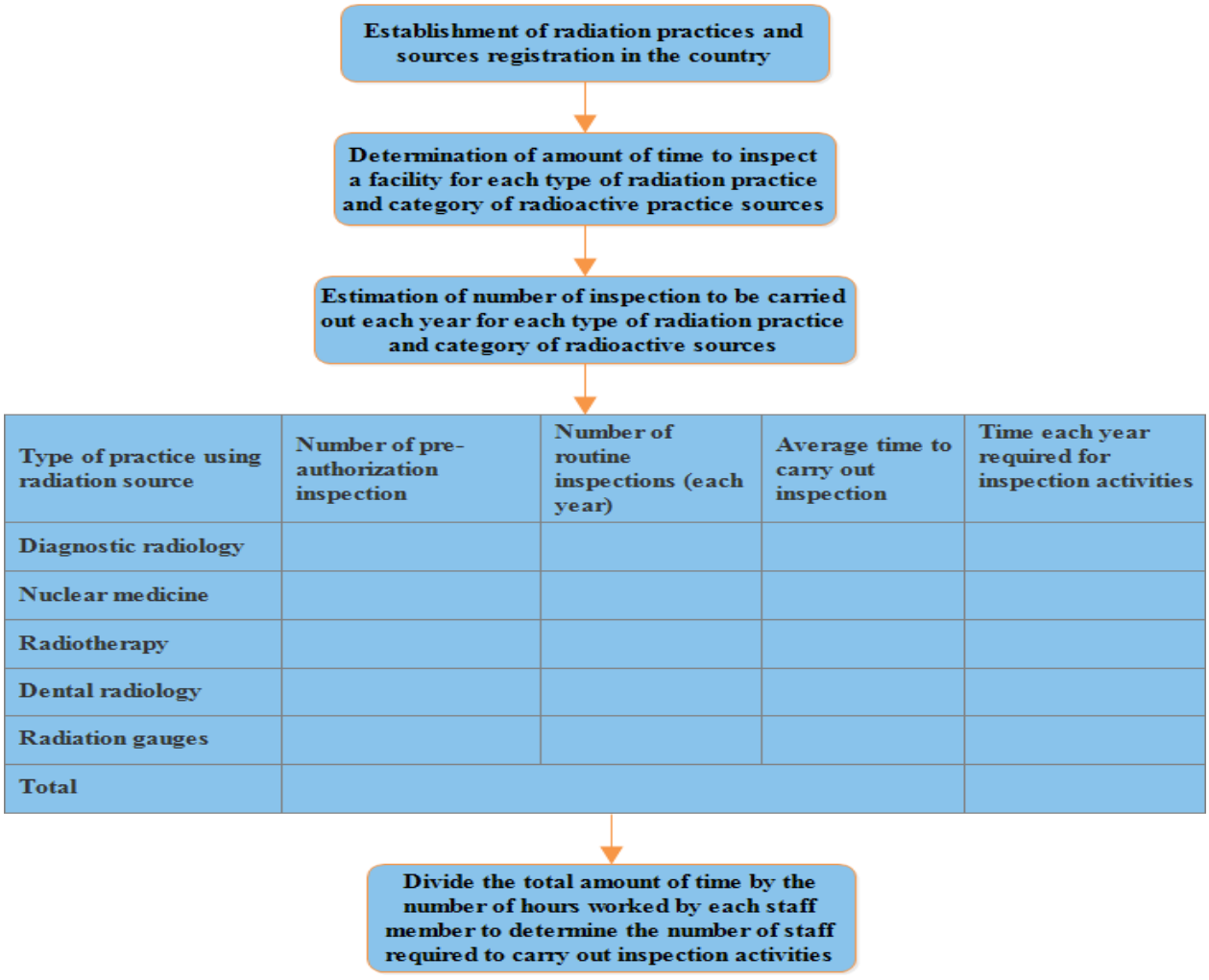

Figure 1: The process to determine number of staff required for inspection activities in the authority [34]

2.5.3 Inspection Process

The safety implications, size, and complexity of the regulated radiation practice sources, as well as regulatory tradition in the country are some factors which affect the type of regulatory regime

adopted for one country. The way for implementing regulatory duties may differ, in some authorities being completely self-sufficient and others delegating some inspection, assessment or other duties to different governmental, public or private agencies. Regulatory body may also require to accredit inspectors to insure competence in caring out inspections. Legislation and, in some cases, regulatory body may need delegation to accredit inspectors to ensure competence in implementing inspection. In general, regulatory inspection process design is shown in Figure 2.

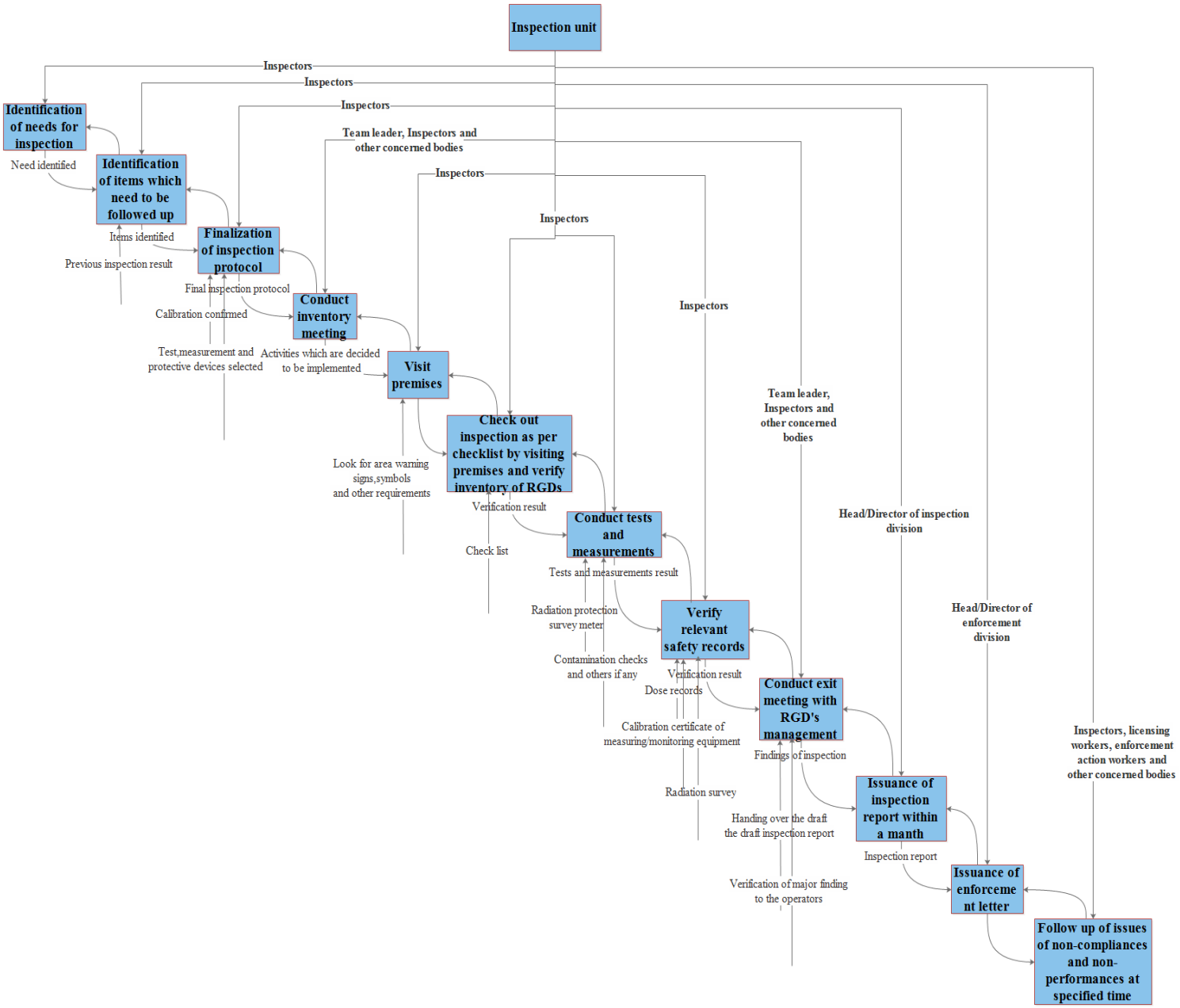

Figure 2: RGDs regulatory inspection process design [34]

2.5.4 Inspection Priorities and Frequencies

Establishing inspection priorities and frequencies is one of a key component of inspection program. Different countries such as U.S's and European's guidance document categorized radiation sources based on the hazard of an incident and the type and frequency of non-compliant issue found during inspections. This means establishing a relevant inspection program requires continuous analysis of inspection data for different types of radiation practices and sources. Therefore, if the inspection frequency is subjected to the regulatory body's available resources, the inspection priority could be resolved properly.

Inspection frequency, in some countries, is directly linked to the frequency of authorization renewal (or license renewal time). However, from technical point of view, this practice is not supported. In reality, the frequency of inspection must be directly related to the relative risk associated to each radiation practice or sources within the practices. The frequency of license renewal depends on the steadiness overtime of the radiation safety and performance conditions in each type of radiation practice and of the work load of the available regulatory body's assessment and staff of inspection [34]. The inspection frequency of the RGDs in Ethiopia should not be equivalent to but it needs to be shorter than the frequency of inspection amended by IAEA and BSS taking in to account different contexts in the country such as the current awareness of the user, patient and people about the equipment and effects of ionizing radiation; availability of training to the users and the patients; whether the devices imported are new or used; the area and facility in which the sources are going to be practiced (proper safety and quality issues) and so on. A range of minimum frequencies of inspection for RGDs practices and sources within the scope of BSS is shown in Table 1 bellow.

Table 1: Suggested inspection frequencies for ionizing radiation medical equipment's [36]

Type of practice using radioactive sources	Inspection frequency of IBSS (year)
Dental radiography	5
Nuclear medicine	1-2
Radiotherapy	1
Diagnostic radiology centers-with complex equipment (e.g. Computed tomography, Interventional radiology, Fluoroscopy, Mammography)	2-3
Diagnostic radiology centers with conventional equipment only	2-5

2.5.5 Safety Controls

Each type of medical devices has risks associated with it. There were 51,944 medical device incident reports in England in 2012. Out of these reports, there were about 313 deaths and about 4,577 sever injuries related to medical devices. Among these incidents, 40% (20,574 incidents) were failure of the devices and user error and 15% (7,610 incidents) were total causes of the incident [35]. In developing countries like Ethiopia these incidents are supposed to be increased.

To reduce the risks associated with the medical devices, there should be effective regulation and management of each device and health facilities should consider the national and international policies and standards which are used to ensure the safety, compatibility and functionality of medical devices [36].

A study carried out in Iran in 18 hospitals revealed that 71.1% of staffs have good radiation-safety awareness and about 8% had the worst level. In parallel to this awareness level of the patients is very poor, only 6%. The study concluded that the level of staff awareness was not associated with educational level, gender, field of study, age and job experience. In addition, the radiation safety status in the medical nuclear centers was 70% and in radiology facility was 74%. This study realized that radiation safety awareness is generally inadequate among radiologists and particularly poor in patients [37].

Another study conducted by Ahmed Hamarsheh and Ahmad Amro showed only 26.4% of radio technologists correctly answered the knowledge and awareness questions about radiation. About

66% of respondents correctly answered and about ALARA principles. The conclusion of the study as there was a deficit in knowledge and awareness of radiation hazards among radio technologists. Finally, study recommended for the need of training and education about radiation protection healthcare institutions [38].

A Similar research conducted at the Charlotte Maxeke Johannesburg academic hospital in department of radiation oncology on 85 staff members revealed the mean knowledge score about radiation safety score 73%. In this study about 58% (49) of respondents had a "Good" score, 35% (30) had a "Fair" score and 7% (6) a "Poor" score. For those who had over 10 years registration experiences, the mean Knowledge score was higher compared to those that had 0-5 years registration. In line with assessment for their preference to improve radiation safety awareness, departmental lectures were preferred method by 67% (57), while 32% (27) of respondents suggested formal refresher courses, and another 11% (9) participants suggested other options that included better orientation of new staff; the provision of educational material; and for clearer safety protocols to be displayed in the department. The study finally recommended that all new staff joining the radiology department should get orientations, regular and ongoing seminars and training programs in radiation safety [39].

Similar study also done in Ethiopia particularly in TASH showed that the majority of even medical doctors at the hospital have a very limited knowledge regarding radiation source, risk and essential protection. The study also showed there are misconceptions in the medical community of the hospital about exposure and risk. It reflected that this misconception problem affects the wider healthcare provider community nationwide because the teaching hospitals are the sources of most of the professionals practicing in the country. The study recommended a need to re-educate clinicians about ionizing radiation, the potential hazards associated, and the proper execution of protective measures. The need for revision of medical education curricula regarding the safe use and hazards of radiation was another recommendation of this study [40].

In general, unsafe and unskilled use of radiation technologies can lead to health hazards for all patients, radiation workers, and even general public. As a result, more attention should be paid to minimize the unnecessary exposure for patients, occupational workers and members of public.

2.5.6 Quality Assurance

The main purpose of diagnostic radiography is to give high quality diagnostic information about any process or anatomical detail within the patient's body and by doing so the dose that the patient

receives should be kept as low as reasonably achievable which is the basic aim of any QA program. Quality assurance is the overall planned and systematic management programs put in place to ensure provision of adequate and consistently high quality diagnostic images with minimum exposure of the patients. QA served as an integral and continues part of a quality healthcare service delivery in the health care sector [41].

Therefore QA is regarded as the measurement of the actual performance of the diagnostic equipment and the efforts to modify when necessary [41].

2.5.7 Quality control tests

The QC processes are techniques used in monitoring the components of an X-ray system at the departmental level, with the activities geared towards the area of interest to be monitored and evaluated. Miles et al. in Ramlaul & Hogg noted that QC involved the practical testing of the diagnostic imaging processes to ensure that the processes conform to a set of standard and ensure that quality requirements are met. This suggests that QC involves specific actions designed to keep measurable aspects of the process involved in providing a service within specified and acceptable periods. A QC process allows professionals to monitor the basic components of the imaging process at a low cost through the use of simple, inexpensive tools and minimal staff time to ensure that quality requirements are met [41].

For the diagnostic imaging equipment, the components of the system included light beam diaphragm alignment to check the accuracy of central X-ray beam with the center of the radiation field and the congruency between light and X-ray beam; grid alignment to check erect and horizontal Bucky systems are correctly centered and perpendicular to the X-ray beam [40]. Other QC tests included assessment of focal spot size; reproducibility and consistency of exposure parameters (tube potential and tube current-time product); and reject-repeat film analysis on periodic basis to identify the magnitude of problems and to determine the causes for the rejection. All these basic QC tests are to be performed by practicing radiographers at the department level in order to minimize repeat and wasted resources in radiography service delivery and also to reduce patient radiation dose and waiting times [41].

2.5.8 Calibration of Monitoring and Measuring devices

The quantitative determination, under a controlled set of standard conditions, of the indication given by a radiation measuring instrument as a function of the value of the quantity the instrument

is intended to measure is called calibration [42]. Measurements intended to confirm that an instrument is functioning correctly, and/or the quantitative determination of the variations of the indication of the instrument over a range of radiation, electrical and environmental conditions are referred as tests [42].

Considerable progress in standardizing reference radiation fields and calibration procedures has been made by the International Organization for Standardization (ISO) since the publication of Technical Reports Series No. 133 [43], in 1971. Plus to this, the International Electro technical Commission (IEC) has developed a lot of standards on the performance specifications and type testing of radiation protection monitoring instruments. WHO/IAEA arranged network of secondary calibration laboratories in many countries. These laboratories are increasingly becoming more concerned with calibrating radiation protection instruments although they were primarily concerned with therapy standards.

Every time the instrument manufacturer does not has facilities for complete type testing and sometimes even cannot calibrate the instrument over the complete dose equivalent range with a reference radiation. Each instrument should be calibrated before its first use periodically, every 12 to 14 months and then should be recalibrated. There were many examples in the past of inadequate calibration procedures having caused large errors in some dose estimates [43].

Based on IAEA primary objectives of calibration are [43]

"(1) To ensure an instrument is functioning properly and hence will be suitable for its intended monitoring purpose; (2) to determine, under a controlled set of standard conditions, the indication of an instrument as a function of the value of the measure and (3) to adjust the instrument calibration, if possible, so that the overall measurement accuracy of the instrument is optimized."

2.6 The Principles of International Radiation protection

The International Commission on Radiological Protection (ICRP) also recommended an effective use of the ionizing radiation by applying the principles of justification and optimization of X-ray exposure in limiting the radiation dose to patients. To manage any exposures to ionization radiation that may be potentially harmful to heath, international commission of radiation protection (ICRP) specified three fundamental principles [44].

I. Justifications

The justification of X-ray exposure takes in to account both the benefits and harmful aspect that the X-ray procedure could provide in managing the patients as well as the extent to which the practitioners and the general public are endangered. If it is not possible to demonstrate that the practice will lead to a positive net benefit, no activity involving ionizing radiation for any purpose can be justified.

II. Optimization

Considering economic and social factors, the number of people exposed, the probability of incurring exposures and the magnitude of individual exposures shall be kept as low as reasonably achievable (ALARA principle).

III. Limitation

In any normal circumstances, no one is to be exposed to a radiation risk that is judged unacceptable. Even if ICRP recognized the fact that everyone is subject to a significant background radiation exposure, even a smaller than background doses from occupational practice are unjustifiable without reasonable means.

2.7 Effects of Ionizing Radiation on Human Health

Human beings have become more and more exposed to radiation as a result of the technological development and the increased use of artificial radiation sources. However, people have also been irradiated as long as the universe has existed [45].

Sometimes cells and genes are injured by radiation but human body is able to repair most of these injuries. As the age of persons increases the amount of unrepaired damages will also increase .In parallel to age, the amount of exposure, rate of exposure, area of the body that is irradiated, type of radiation and individual biological variability are important risk factors for health damages [46]. In general, there are two categories of adverse effects of radiation on human being [47]. Deterministic and stochastic effects.

Deterministic effects depend on the threshold of the dose. Below the threshold there is no clinical effect. With dose exposure above the threshold severity of the injury increases with dose that it results cell killing.

The other effect of radiation on human is stochastic effect. In this incidence the frequency of response, but not severity, is proportional to dose. This effect results in cancer and heritable effects because of damage to DNA. Furthermore, there is no threshold "safe" with stochastic effects. In the low dose range, below about 100 mSv the ICRP explained that a given increment in dose will produce a direct proportionate increment in the probability of incurring cancer or heritable effects attributable to radiation and this approach is known as Linear no-threshold or LNT model [47].

2.8 Radiation Dose Monitoring

Based on U.S federal and state government administration and U.S food and drug administration's initiatives, radiation dose monitoring is one of the main concern for one state to protect the patient, users and other stakeholders from exposing to ionizing radiation [48].

In general, regulatory inspection of RGDs need different requirements such as safety and quality issues to be fulfilled. These requirements might be differ from country to country. Any inconsistency of regulatory inspection process that the regulatory authority follows might lead to unsafe use of radiation which can also in turn lead to health risks and hazards of patients, radiation workers, and even general public. As a result, more attention should be paid to these safety and quality issues of RGDs to minimize the unnecessary exposure of patients, workers and members of public as low as possible.

Chapter 3 Methods and Materials

3.1 Description of the Study Area

The study area was Addis Ababa, the capital city of the Federal Democratic Republic of Ethiopia. There were 23 hospitals (11 of them are governmental and the rest 12 are private hospitals), 28 health centers, 148 health stations, 46 health posts and 117 diagnostic x-ray institutions in those health facilities in the city. In the thesis, only nine government owned hospitals and one authority (ERPA) were investigated regarding to RGDs regulatory inspection process. These nine government owned hospitals were St. Paul's Hospital Millennium Medical College (SPHMMC), Tikur Anbessa Specialized Hospital(TASH), St. Peter's TB Specialized Hospital(SPTSH), Yekatit 12 Hospital and Medical College(YHMC), Menelik II Referral Hospital(MRH), Zewditu Memorial Hospital(ZMH), Ras Desta Damtew Memorial Hospital(RDDMH), Tirunesh Beijing General Hospital(TBGH),All Africa Leprosy, Tuberculosis and Rehabilitation Training Centre(ALERT).

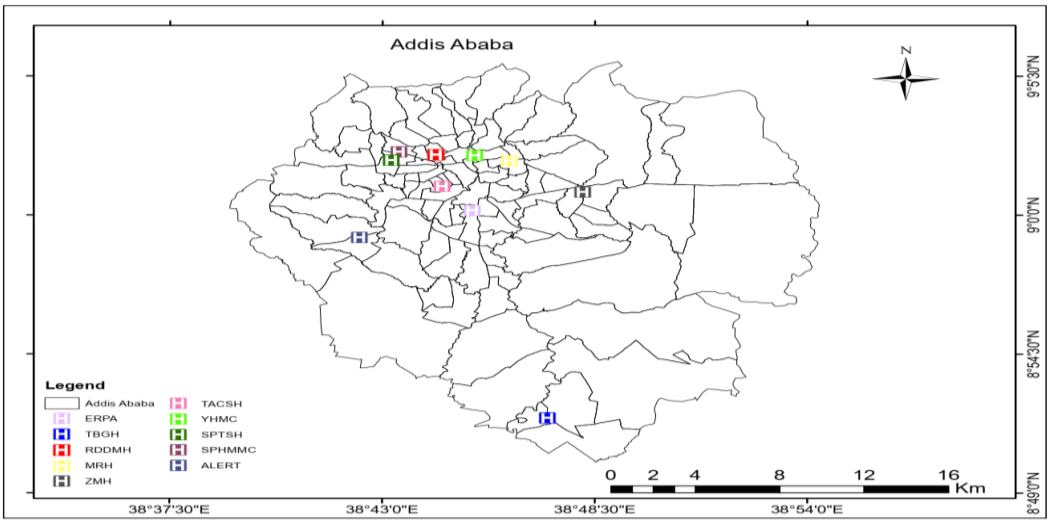

Figure 3: Geographical location of the study areas

3.2 Research Design/Type

Institutional based cross-sectional study was used in this thesis. The research design of this thesis was of descriptive type. The reason for selecting descriptive research design is to describe the effect of different inspection process parameters on regulatory inspection of RGDs to control ionizing radiation and determine different factors that affect regulatory inspection process. Both quantitative and qualitative research strategies were used in this thesis. Quantitative research strategies

emphasizes on facts, numbers, percentages and frequencies, in general, how and why the variables and relational statements are interrelated whereas qualitative research strategy emphasizes on explaining qualitative data collected through interview, focus group discussion and observation [49].

3.3 Sampling Technique and Data Analysis

Since there are enough number of RGDs in Addis Ababa especially in government owned hospitals that can represent all other RGDs it is preferred to conduct the study. Secondly, since the authority itself is located in Addis Ababa (i.e. at minimum distance from each hospital), it is likely to implement the inspection in these hospitals most frequently. Finally, ERPA implements the same regulatory inspection process for both government owned and private owned hospitals, it is enough to study these nine government owned hospitals.

Criterion sampling technique (one of the types of purposive sampling) was used in the thesis because respondents need enough information and knowledge about the study area to give quality data. Criterion sampling technique takes the criteria into consideration to select respondents. Therefore, in both organizations that is ERPA and hospitals, participants were selected based on inclusion and exclusion criteria.

The data was collected through distribution of structured questionnaire, document analysis, focused group discussion and observation. Edraw max tool was employed to analyze the data and the result was presented in frequency, percentile and mean.

3.4 Data Collection Process and Period

The questionnaire was distributed to the selected government owned hospitals and ERPA with the support letter from the Center of Biomedical Engineering of Addis Ababa Institute of Technology (AAiT). Then face to face explanation about the questionnaire and overall aim of the thesis is done with respondents. The assessment was done between October 2016 and February in 2017.

3.5 Inclusion and Exclusion Criteria

In the current set up of the Ethiopian health care system, there are different professionals who are working on medical equipment management system. However, in the thesis professionals partici-

pated as the respondents were medical radiology technologists, biomedical engineers, and biomedical technicians from hospitals and Inspectors, radiation protection officers, authentication workers and environmental safety experts from ERPA. In both organizations, professionals who have less than two years experiences and any of the workers other than what are listed above were not selected as respondents.

3.6 Source of Data Collection

Both primary data sources (through observation, interview, focus group discussion and structured questionnaire) and secondary data sources (through document analysis to supplement primary data) were used in this thesis.

3.7 Data Analysis Technique

After the data had been collected, it was processed through editing by checking for errors and omission, classifying and tabulating. In this study the researcher used both quantitative and qualitative analysis. The quantitative analysis was conducted through percentage, frequency and mean and the qualitative analysis was conducted by the interpreting and describing responses obtained through focus group discussion and interview. Descriptive statistics (percentage and mean) were used to analyze the data that were collected from sample respondents. The result of the data was summarized using tables and bar charts.

3.8 System Methodology

The system analysis diagrams that are activity diagrams, use case diagrams, and sequence diagrams were developed by using unified modeling language (UML) and in the case of system design, user interface design is developed by employing HTML5 and CSS3 and Class diagram is designed using UML.

HTML5 and CSS3 were used as front-end programing language and PHP and MySQL were used as a backend programming language and to construct a system a package of software called XAMPP and open source text editor NOTE PAD++ software development kit was used.

3.8.1 System Development Tools

3.8.1.1 HTML5

HTML is the acronym for Hypertext Markup Language and it is a client side scripting language. It is used to design the form, content and structure of the system that is it tells a computer how to display a web page. HTML5 is the latest version of HTML and as its version is developed from HTML1.0 to HTML5, its function and working browser is also increased. For instance, with the first version of HTML it was not possible to embed video and audio but now HTML5 is able to do this function and also HTML1.0 could not supported by chrome and Firefox but HTML5 can be supported by these browsers [50].

3.8.1.2 CSS3

CSS is the acronym for cascading style sheet and it was first released in 1999. It was also supported by browser in 2001 and revised in 2008. In 1998 software developers began to work on the second specification (CSS2) and its standard was finally completed in 2007. The specification for the development of the last version (CSS3) was started in 2001[51].

CSS is used to develop dynamic and attractive web page by applying styles. It can change colors, sizes, indentations, typefaces, shadows, effects, animations etc. It is an established server-side, cross platform embedded HTML scripting language for creating dynamic Web pages [51].

3.8.1.3 PHP

PHP stands for PHP preprocessor and was developed in 1994 by Rasmus Lerdorf. It is a very popular server side programing language for apache web servers and used to develop web based application. It is easy to learn, originally embedded on markup language source of web page and accessible for different plat forms such as lunix, windows, Mac OS X etc. Another popularity of PHP beyond its simplicity is that it can cooperate with more than 8 well known web server applications and 22 database management systems [52].

PHP can be integrated with different number of powerful databases such as MySQL, Sybase, Oracle, info mix, Microsoft SQL server etc. It supports different popular protocols including IMAP, LDAP, and POP3. It is used to perform system functions (i.e. from files on a system it can create, read, write, open and close them). It can handle forms (i.e. gather data from files, save dada to files, send and return data through email from and to the user). Using PHP you can add, delete,

modify data; access and set cookie's; encrypt data; restrict users to access pages of your website etc. [53].

3.8.1.4 MySQL database

MySQL is the most popular database management system used by web servers of over ten million installations and it is developed in the mid-1990s by Oracle Corporation. Like PHP, MySQL is easy to use, low cost, fast performance and that is some of the reasons for its success. But it is also exceptionally fast, extremely powerful, highly scalable (that is it can grow with your web site) and best performance in comparison of several database [51].

In MySQL, SQL stands for structured query language. MySQL database is a structured collection of records in a computer system. Data is organized in a way that it can be searched quickly and retrieved rapidly. It can be accessed using various powerful programing languages including PHP, Java , C, C++ etc. and it is preferred by the many popular web based social media sites such as Twitter, Facebook, yahoo, YouTube etc. [54].

3.8.1.5 XAMPP

XAMPP is a free and open source, cross-platform, apache distribution package of integrated software, consisting mainly of the Apache HTTP server, MySQL database, PHP, and Perl programing language. So that it contains the most common web development technologies in a single package. The portability, small size and content of XAMPP makes it ideal tool for the users developing and testing applications in PHP and MySQL [55]. It is available as a free download of two types of packages that is full and lite packages. Linux and Microsoft operating system are the two operating systems supported by XAMPP and it can also be run on all most all windows.

3.8.2 System Analysis and Design Tool

Edraw Max is an electronic, business technical diagraming software which helps to create flow charts, organizational charts, mind maps, network diagrams, floor plans, work flow diagrams, business charts, and engineering diagrams [56]. The use case diagrams, sequence diagrams, activity diagrams, system design, system analysis and entity relationships of the system were sketched using Edraw Max and unified modeling language (UML). UML is one of the parts of Edraw max. It is user friendly and easily accessible [56].

Chapter 4 Results and Discussion

4.1 Professional Status of the Respondents

As it is presented in Figure 4 , majority of all the respondents in hospitals 48(66.6%) were Medical radiology technologists, 13(18.1%) were Biomedical engineers and the remaining 11(15.3%) of the respondents were biomedical technicians.

In general the educational level of the respondents indicates that the study is represented by those who are educated and experienced in judgments of the questionnaire and the subject matter. They orally told the researcher that most of them filled such kinds of questionnaire repeatedly for different researches data and other purpose even if they have been hesitated.

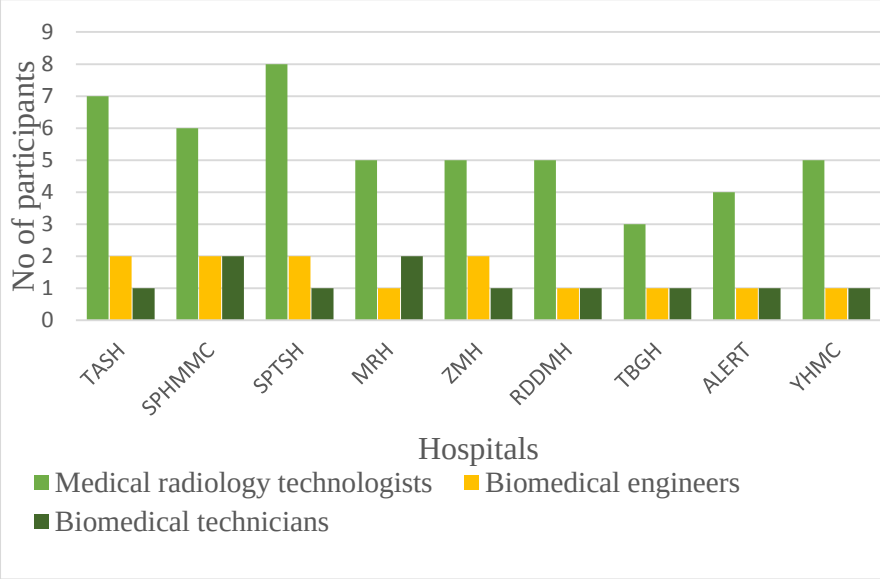

Figure 4: Professional status of respondents in each Hospital

As it is illustrated in Figure 5 , majority of the respondents taken from ERPA 15(50%) were inspection workers and 8(26.7%) were Radiation protection officers. 5(16.6%) were Authentication workers, and the remaining 2(6.7%) of the respondents were Environmental safety experts.

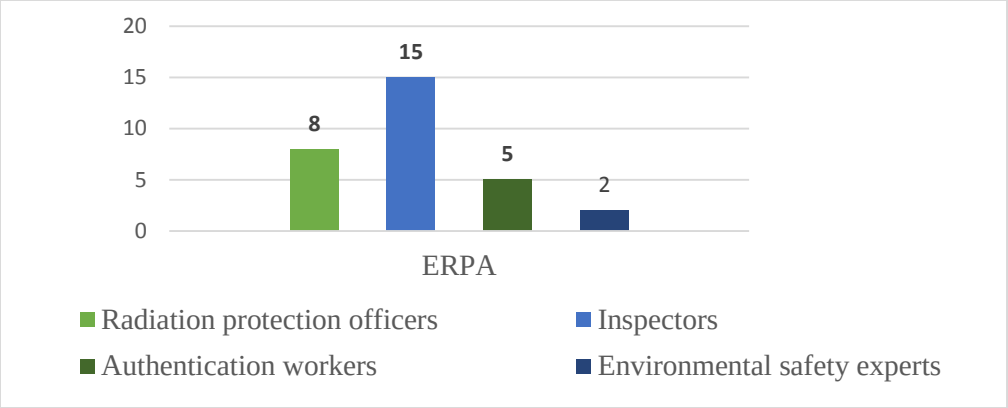

Figure 5: Professionals status of respondents in ERPA

4.2 RGDs Availability

As it is shown in Table 2, the questionnaire outcome revealed that majority of the devices such as General x-ray(in all 9 hospitals), Mammography (in 2 hospitals), Fluoroscopy (in 5 hospitals), Computed tomography (in 6 hospitals), Detected chest x-ray (in 7 hospitals), Cobalt-60 machine (in one hospital), Dental x-ray (in 3 hospitals), X-ray diffraction unit (in one hospital), Electron microscopes (in 4 hospitals), Dual energy x-ray scanner (DEXA) (in 2 hospitals), X-ray irradiator (in 2 hospitals), Brachytherapy (in one hospital), Radiotherapy(in one hospital) were available in hospitals that were selected for the study. However, some of the devices such as Linear accelerator and Circular accelerator, were not available in any of the hospitals that were taken for the study.

In line with this result, the student researcher observed that most of the above RGDs were available in the hospitals included in the study in addition to the reports of the participants.

Table 2: List of RGDs available in hospitals and to be regulated by ERPA in 2017

TYPE OF RGD		No OF HOSPITALS	
No	**RPDs**	**Available**	**Not available**
1	General x-ray	9	0
2	Mammography	2	7
3	Fluoroscopy	5	4
4	Computed tomography	6	3
5	Detected chest x-ray	7	2
6	Linear accelerator	0	9
7	Circular accelerator	0	9
8	Cobalt-60 machine	1	8
9	Dental x-ray	3	6
10	X-ray diffraction unit	1	8
11	Electron microscope	4	5
12	Dual energy x-ray scan-ner(DEXA)	2	7
13	X-ray irradiator	2	7
14	Brachytherapy	1	8

4.3 List of RGDs to Be Inspected

The questionnaire outcome revealed from General X-ray up to X-ray irradiator, more than 93.3% (28) of participants in ERPA reported that each RGDs were inspected (as shown below in Figure 6). Besides, based on respondents in hospitals from General X-ray to x-ray irradiator, greater than 90.3 %(65) participants replied each of the devices were inspected. However, in the cases Electron microscope 100 % (30), Dual energy x-ray scanner 96.7% (29), and Brachytherapy 93.3 (28) majority of respondents in ERPA responded they were not inspected. Similarly, a frequency of 100 % (72), 95.8 % (69) and 97.2% (70) of participants in hospitals replied that Electron microscope, Dual energy x-ray scanner, and Brachytherapy were not inspected respectively.

In this regard, the questionnaire outcome indicated an overall mean of 73.3% of respondents in ERPA reported there was regulatory inspection for each of the device while the rest of participants responded there was no regulatory inspection. On the other hand, an overall mean of about 71.7%

of respondents in hospitals replied there was regulatory inspection for each device and the rest of them reported that there was no regulatory inspection for each of the device.

However, in interview and focus group discussion participants in ERPA explained that "*the absence of inspection for equipment might occur because of lack of information from different institutions which needs to inform ERPA prior to import, use, and change in location of the devices".* For instance, they said *"we have ever found new IRGMDs while we were inspecting another registered devices and when we had asked the operation manager why it is there without legal permission of ERPA, they replied that this is because of the distribution method of Pharmaceuticals Fund Supply Agency (PFSA)*". This means there are IRGMDs which were not registered by ERPA. Which indicates that there were lack of communication between ERPA and PFSA until the study period of this research. This could be one of the reasons for the absence of regulatory inspection for some devices. Some participants reported there was also lack of human resources and material resources that might result in the absence of inspection.

In line with this result, some studies revealed that impaired health service provision, poor patient outcomes, and substantial health system that we are observing in the country might be the results of unsafe, ineffective and bad-functioning of medical equipment which is also in turn the consequence of poor regulation of medical device and drugs. For example, one recent study realized that most of the medical equipment in the developing world is broken with estimates ranging up to 96% are out of service and more than 50% of medical equipment and laboratory in resource-poor settings are not in service [19]. This also true for Ethiopia as it is one of the developing countries.

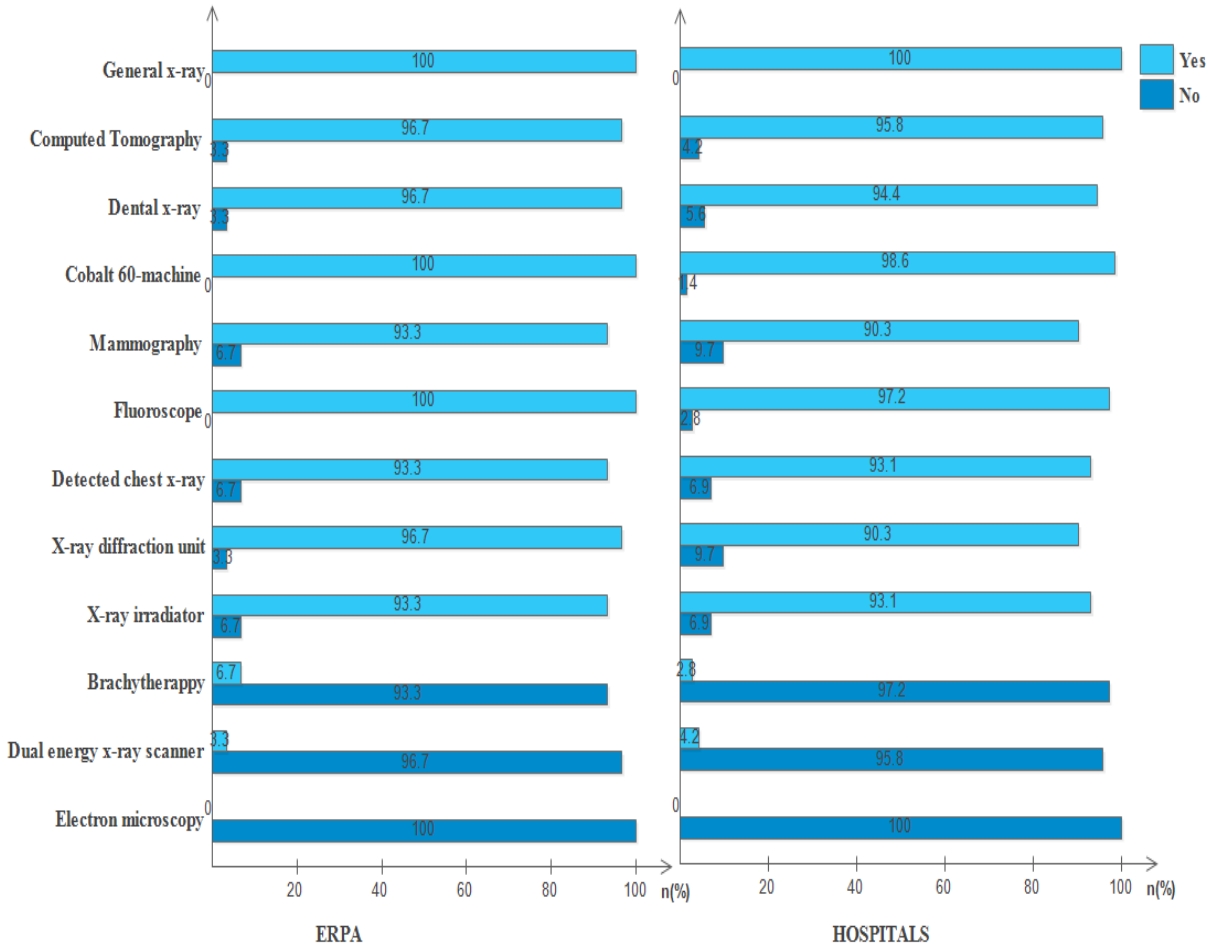

Figure 6: The status of regulatory inspection for RGDs by ERPA in Addis Ababa government owned hospitals in 2017

4.4 Inspection Frequency for Each Devices

In line with awareness of participants in ERPA about the inspection frequency, majority 28(93.3%), 27(90%),27(90%),29 and (96.7%) of the respondents responded that the inspection frequency of General x-ray, Mammography, Fluoroscopy, and CT respectively, was 2 years for each. Likewise, most 27(90%) of the respondents replied that the inspection frequency of Cobalt-60 machine was one year while majority 26(86.7%) of the respondents reported that the inspection frequency for Dental x-ray was 4 years. Furthermore, 26(86.7%) and 27(90%) of the respondents new the inspection frequency for X-ray diffraction units and X-ray irradiator, respectively, was 2 years for each while 27(90%) of participants replied the inspection frequency of Detected chest x-ray was 3 years.

The mean inspection frequency of each device was 3.07(2 years), 3.10(2 years), 2.97(2 years), 2.97(2 years), 4(3 years), 1.96(1 year), 4.83(3 years), 4.13(3 years), and 3.86(3 years) for General x-ray, Mammography, Fluoroscopy, Computed Tomography, Detected chest x-ray, Cobalt-60 machine, Dental x-ray, X-ray diffraction units, and X-ray irradiator respectively(as it is illustrated in Table 3).

In line with inspection frequency, International Basic Safety Standard recommended the inspection frequency of nuclear medicine, radiotherapy and diagnostic radiography is 1-2 years, 1 year and 2 years respectively [34]. However, based on the result of this thesis, the inspection frequency of some devices like detected chest x-ray and General x-ray goes to the maximum limit of the inspection frequency specified by IBSS. This is one gap that is too long inspection frequency considering the context of this country where there were no enough training, lack of personal protective devices, lack of knowledge of radiation protection of users and even medical doctors [40]. Because, according to IBSS, establishing a relevant inspection program requires continuous analysis of inspection data for different types of radiation practices and sources. The frequency of inspection must be directly related to the relative risk associated to each radiation practice or sources within the practices [34]. Since most of the devices imported to developing countries are risk full and unsafe [57], the inspection frequency of the RGDs in developing countries like Ethiopia should not be equivalent to but it needs to be shorter than the frequency of inspection specified by IAEA and BSS taking in to account different contexts in the country such as the current awareness of the user, patient and people about the equipment and effects of ionizing radiation, availability of training to the user and the patient, whether the devices imported are new or used, the area practiced (proper safety and quality issues) and so on. However, the result of this this did not realized that rather the inspection frequency of some devices such as detected chest x-ray was about to exceed the frequency specified by IAEA and IBSS

From interview and focus group discussion, some participants reported that "*There might not be periodic inspection for some devices due to long inspection frequency interval (the length of inspection interval increases, the probability of forgetting inspection date also increases) of the device; lack of inspectors and other concerned personnel since there are a lot of risky sites that needs to be prioritized; unknown installation time to fix inspection time. That is unless the concerned body do not inform weather the devices installed at a particular fixed day, inspection may not be*

performed regularly which also a consequence of unlawful way of using RGDs". From this we can deduce that there were a lot of reasons in order not to perform periodic inspection. In addition to this the researcher observed that the authority performs all of the operation manually and in excel. There was no means of technology to notice inspection time, register, store the information and data of the devices confidentially etc. and these gaps were also another reason for the absence of periodic inspection.

Table 3: Inspection frequency for RGDs in Addis Ababa government owned hospitals during regulatory inspection by ERPA in 2017

		ERPA (n=30=100%)					
No	**IRPMD**	**SAB**	**A**	**TYs**	**THYs**	**FYA**	**Mean**
1	General x-ray (f)	0	0	28	2	0	3.07
	%	0	0	93.3	6.7	11.1	
2	Mammography(f)	0	1	27	2	0	3.10
	%	0	3.3	90	6.7	0	
3	Fluoroscopy(f)	0	2	27	1	0	2.97
	%	0	6.7	90	3.3	0	
4	Computed Tomography(f)	0	1	29	0	0	2.97
	%	0	3.3	96.7	0	0	
5	Detected chest x-ray(f)	0	1	1	27	1	4
	%	0	3.3	3.3	90	3.3	
6	Cobalt-60 machine(f)	2	27	1	0	0	1.96
	%	6.7	90	3.3	0	0	
7	Dental x-ray(f)	0	0	1	3	26	4.83
	%	0	0	3.3	10	86.7	
8	X-ray diffraction units(f)	0	1	1	26	3	4.13
	%	0	3.3	3.3	86.7	10	
9	X-ray irradiator(f)	1	1	0	27	1	3.86
	%	3.3	3.3	0	90	3.3	
	Overall mean						**3.33**

1=Semi-annually and below (SAB), 2=Annually (A), 3=Two years (TYs), 4= Three years (THYs), 5=Four years and above (FYA).

4.5 Safety Control Parameters

As shown in Figure 7 for the question "which safety parameters were checked during inspection?" a frequency of more than 26(86.7%) of the respondents in ERPA replied that each parameters were checked out by the authority during inspection. However, for three parameters: incident notification, Mechanical stability, and ports, majority of participants in ERPA 27(90%), 27(90%), and 28(93.3%) respectively, replied 'Not checked'. On the other side in hospitals, a frequency of greater than 62(86.1%) of participants reported that each parameters were checked out and in contrast, majority 67(93.1%), 69(95.8%), and 68(94.4%) of respondents for incident notification, Mechanical stability, and ports reported 'Not checked'.

In general, the result of the questionnaire showed that an overall mean of 76.7% of respondents in ERPA reported that each parameters were checked out during inspection and the rest overall mean of 23.3% of participants responded the parameters were not checked out. In parallel to this, the overall mean of 74.6% of participants in hospitals reported each parameters were checked out and the rest total composite mean 25.4% of them reported each of the parameters were not checked out.

From the interview and focus group discussion, it has been assured that some respondents lack information about these safety control parameters of RGDs so that they might fill wrong information in the questionnaire. Some of them also might not always be available during inspection so that they will not get enough information to fill the questionnaire correctly. These and the like reasons might be the cause for wider gaps of the safety control parameters in addition to the reality of the findings.

A recent study which supports this result revealed that in Ethiopia the absence of proper regulation and management of medical devices has limited the capacity of health institutions to deliver adequate health care. The study further explains that only about 61% of medical equipment found in Ethiopian public hospitals and other health facilities are estimated to be functional and the rest of the device are unsafe and not functional at all [22]. This finding further revealed that there is poor control of safety control and other parameter in Ethiopia and one of the cause of poor management is lack of proper regulatory inspection.

To reduce the risks associated with the medical devices, there should be effective regulation and management of each devices and health facilities should consider the national and international policies and standards which are used to ensure the safety, compatibility and functionality of medical devices [36].

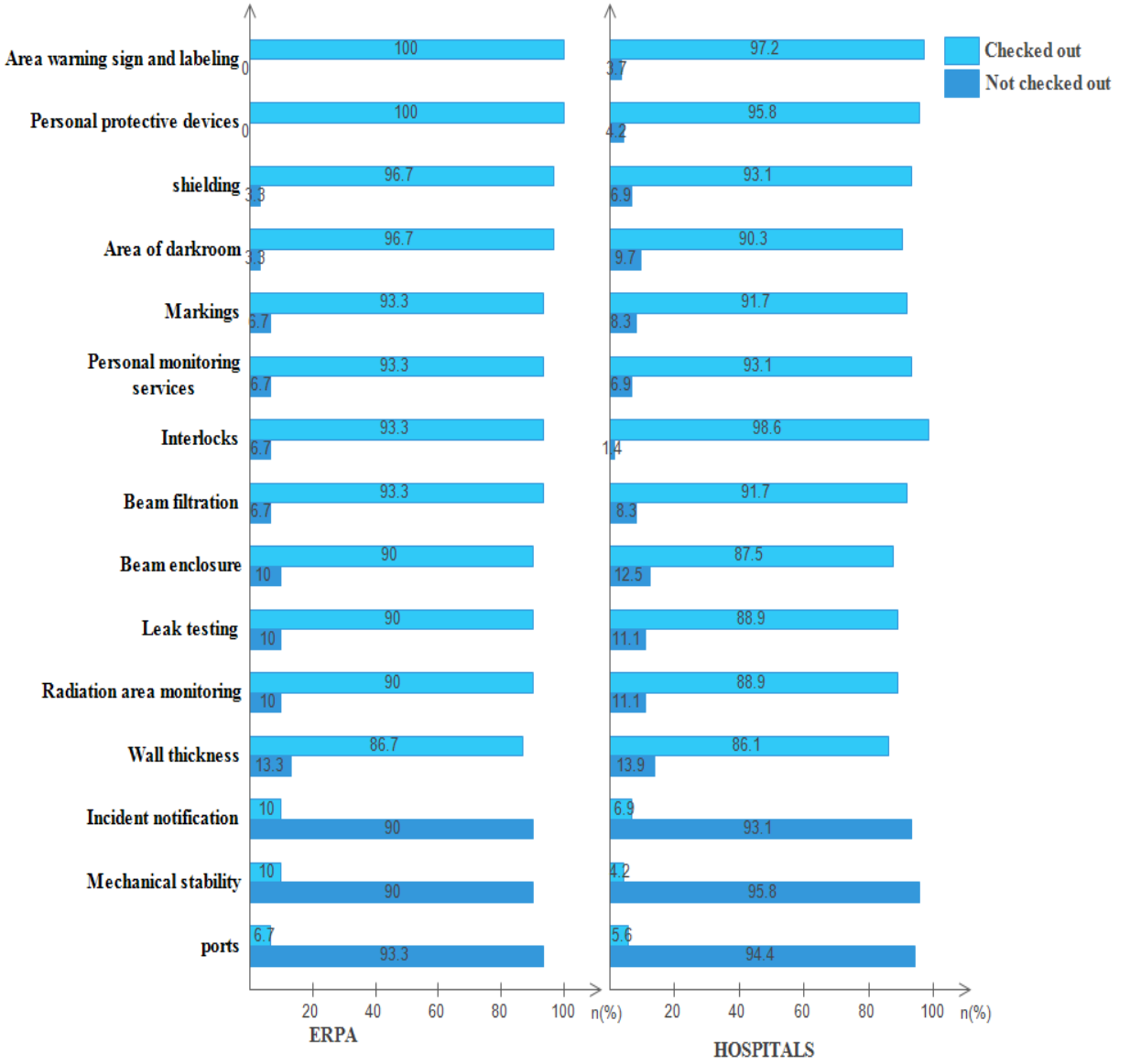

Figure 7: Checking RGD's Safety control parameters in Addis Ababa government owned hospitals during regulatory inspection by ERPA in 2017

4.6 Performance Indicator Parameters

From Figure 8 , out of ten for nine performance indicator parameters, greater than 27(90%) of the respondents in ERPA replied ‘checked out’ for each. However, for light field congruence and grid alignment, about 29(96.7%) participants in ERPA responded ‘Not checked out’.

On the other hand, in the case of hospitals, out of ten questions for nine of them, more than 64(88.9%) of respondents reported that each parameters were checked out during inspection. That is 70(97.2%), 69(95.8%), 67(93.1%), 68(94.4%), 69(95.8%), 67(93.1%), 65(90.3%), 64(88.9%), and 65(90.3%) participants reported that Voltage accuracy, Output consistency, x-ray timer accuracy, Beam alignment, Kilovolt peak(kVp), Collimation, Half value layer, Milliampere second(mAs), and leakage measurement were checked respectively. However, 69(95.8%) of the respondents in hospitals reported that light field congruency and grid alignment was not checked.

With regard to performance indicator parameters, in general, the questionnaire outcome revealed that an overall mean of 86.3% of respondents in ERPA reported that each parameter was checked during inspection and the rest over all mean (13.7%) of participants responded each parameter was not checked. Similarly, an overall mean of 84.3%% of respondents in hospitals reported each parameter was checked and the rest overall mean (15.7%) of them reported that each parameter is not checked during inspection. This small gap in report between ERPA’s respondent and hospital’s respondent might ensure that most performance indicator parameters were inspected exception of some parameters like light field congruency and grid alignment.

From the interview and focused group discussion, like reasons in safety control parameters, the student researcher ensured that some respondents reported that participants might not be always available while inspectors were performing inspection so that they did not get enough information to fill the questionnaire correctly. Furthermore, some of respondents may be hesitated to read the questionnaire correctly so that they may fill by default because the researcher of this study observed some of the participants were hassled. This might has some negative impacts on the result beyond the reality.

Similar studies indicated that lack of proper procurement is estimated to be one of the main factors for the presence of poor performance or quality of RGDs. It revealed that many types of equipment have been procured without a clear medical equipment management plan of how to maintain them to ensure functionality, safety, accuracy and durability.

It has been recommended that all basic QC tests needs to be performed by practicing radiographers at the department level in order to minimize repeat and wasted resources in radiography service delivery and also to reduce patient radiation dose and waiting times [41].

Another study indicated that based on WHO report, more than 95% of medical equipment in developing world hospitals are imported; 70% of medical equipment coming from the most developed nations does not work when they reach in developing nation hospitals, 96% are not working just 5 years after and 39% never worked due to lack of training, manuals or accessories. As Ethiopia is part of the developing world, it have this all challenges). In the case of buyer-supplier relationships, the ultimate goal of most buyers in developing countries is not to increase performance or quality rather to reduce costs [57].This means that most of the equipment imported to the developing countries had poor performance or did not perform their intended purpose and other ways stop working with short period of time.

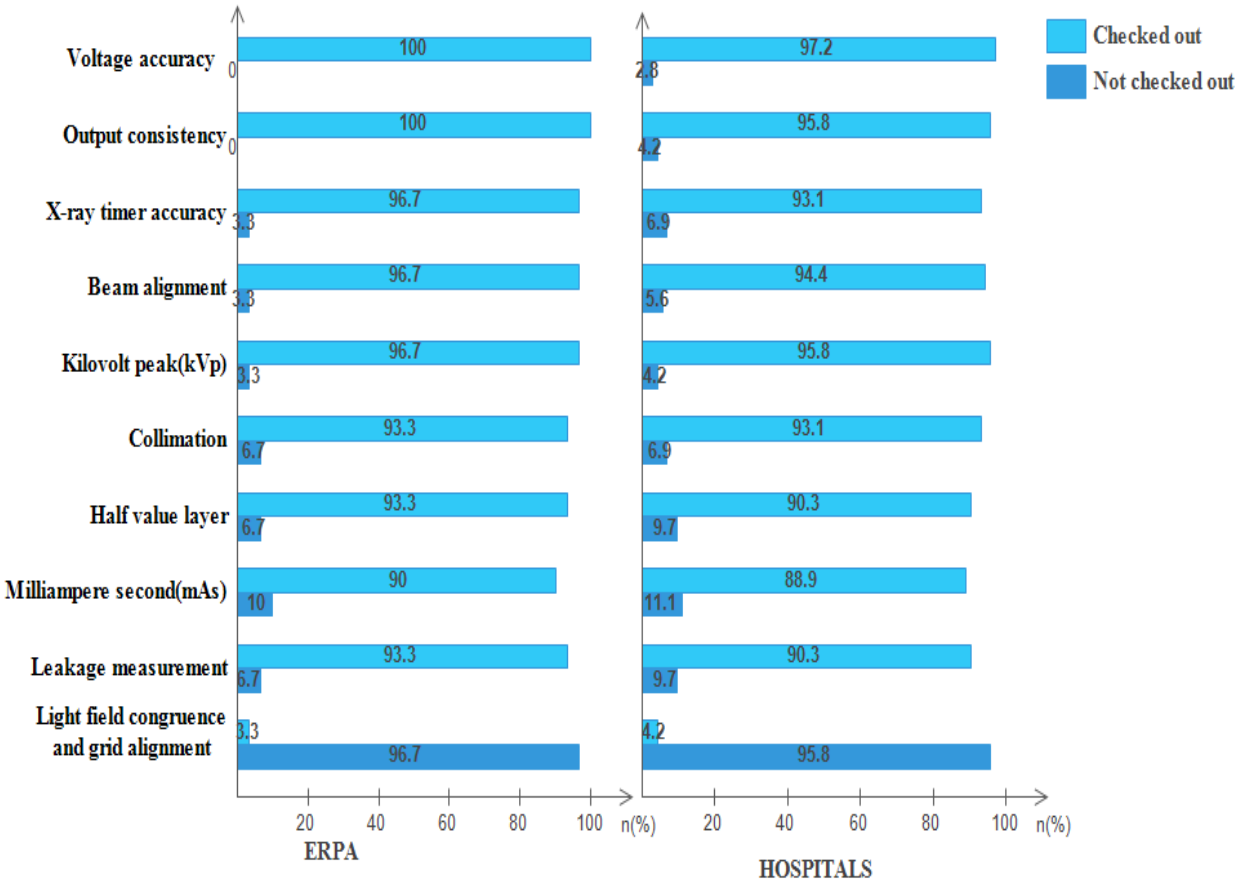

Figure 8: Checking RGD's performance indicator parameters in Addis Ababa government owned hospitals during regulatory inspection by ERPA in 2017

4.7 Fulfilment of Preconditions for Regulatory Inspection

As shown in Figure 9, more than 66% (20) of respondents agreed and strongly agreed on the issue that who will perform inspection is decided prior to inspection time. However, greater than 90% (27) of participants disagreed and strongly disagreed on availability of enough technical and professional man power and also about 90% (27) of respondents disagreed and strongly disagreed on the expected inspection frequency is specified for each devices under the control of ERPA.

Moreover, more than 63%(19),60%(18), and 73%(22) of participants agreed on availability of identified global system requirements for inspection, identified area of greatest expected inspection, and availability of system to control unsatisfactory(defective) devices.

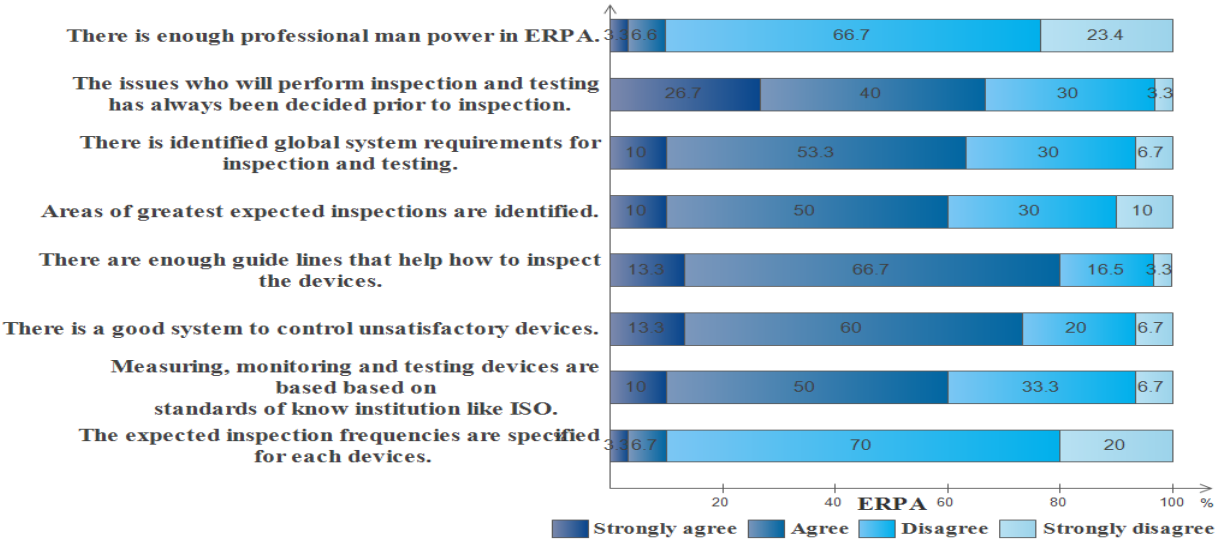

Figure 9: Preconditions of regulatory inspection in ERPA in 2017

4.8 Implementation of Inspection Procedures

The questionnaire outcome reveals that about 66% (20) respondents in ERPA agreed and strongly agreed on inspection protocols are reviewed whereas more than 62% (45) participants agreed on inspection protocols are reviewed. A frequency of 18(60%) of the participants in ERPA agreed and strongly agreed on inspectors perform entrance briefing and a frequency of 49(68%) in hospitals agreed and strongly agreed on this issue.

However, 66.7% (48) of respondents in hospitals disagreed and strongly disagreed on inspectors were viewed records such as inventory and occupational exposure prior to inspection whereas 50% (15) and 20% (6) of participants in ERPA disagreed and strongly disagreed on the follow up of non-compliances at agreed time as shown in Figure 10.

In general the overall mean of 57.9% of ERPA's respondents agreed and strongly agreed on each of the sub-parameters of inspection procedure for their availability and performance and the rest of them disagreed and strongly disagreed. On the other hand, the overall mean of less than half (49.5%) respondents in hospitals agreed and strongly agreed for each of the parameter and the remaining (50.5%) of the respondents disagreed and strongly disagreed on each parameter.

Thus, the questionnaire outcome indicates that poor performance of each inspection procedure might be one of the gaps for regulatory inspection of RGDs.

However, as it is clarified in the publication of IAEA, the proper inspection procedure and requirements which needs for regulatory bodies should be fulfilled for one state to control radiation exposure emanated from any sources in the a country [33].

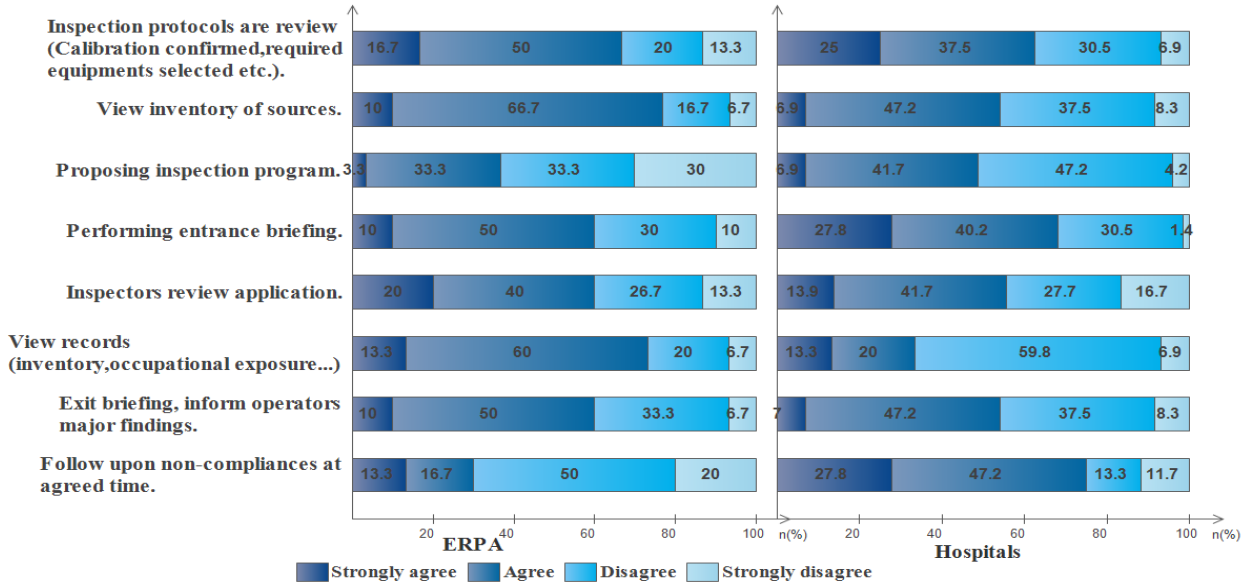

Figure 10: Inspection procedures in Addis Ababa government owned hospitals during regulatory inspection by ERPA in 2017

4.9 Calibration for Testing and Measuring Devices

As it is shown in Figure 11 , the result indicates majority of participants greater than half (53.4%) of respondents in ERPA agreed and strongly agreed that calibrators use standards traceable to the standards of the known institutions like ISO whereas less than half (36.2%) of participants in hospitals agreed and strongly agreed on this issue. Besides, 10% and 50% of respondents in ERPA strongly agreed and agreed on the presence of set of written procedures for calibration of testing, monitoring devices respectively and 12.5 and 52.7% of participants strongly agreed and agreed on the presence of set of written procedures for calibration of testing, monitoring devices respectively in ERPA.

However, 53.3% and 6.6% of respondents in ERPA disagreed and strongly disagreed, respectively, on calibration is always being performed periodically and majority (74.8%) of respondents in hospitals disagreed and strongly disagreed on calibration is always being performed periodically.

The overall mean of greater than 55% of participants in ERPA agreed and strongly agreed on each issue of calibration and the rest of less than half (45%) of them disagreed and strongly disagreed on each issue. However, an overall mean of less than half (46.1%) of the participants in hospitals agreed and strongly agreed on each sub parameters of calibration and greater than half (53.9%) of them disagreed and strongly disagreed on each issue of calibration.

However, IBSS and IAEA suggested that to conduct inspection activities, it needs appropriate devices to monitor, measure and protect radiation in addition to other requirements and all inspection personnel ought to ensure that the equipment is maintained and calibrated at relevant levels [34].Furthermore, based on International Electro technical Commission, each instrument should be calibrated before its first use periodically, every 12 to 14 months and then should be recalibrated. There were many examples in the past of inadequate calibration procedures having caused large errors in some dose estimates [43]

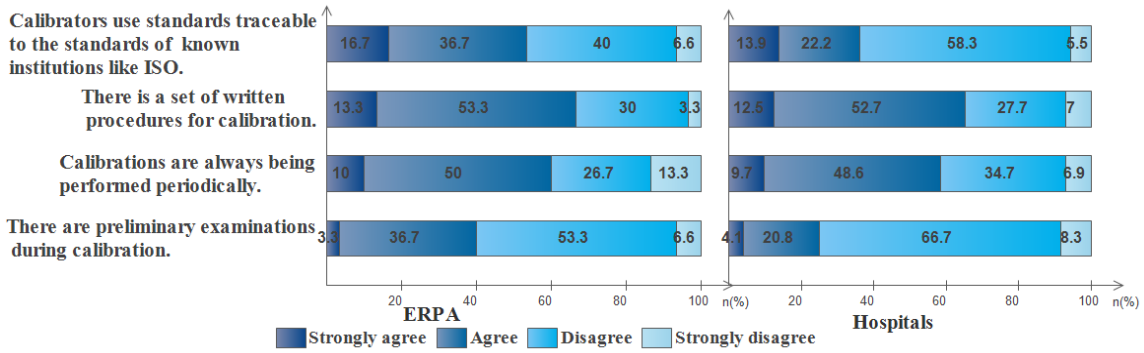

Figure 11: Calibration for protective, testing and measuring tools used by ERPA during regulatory inspection in Addis Ababa government owned hospitals in 2017

4.10 Staff Management Conditions in ERPA

In this parameter, More than 63% (19) of respondents agreed and strongly agreed on the management of ERPA provides adequate resources (time and money) for training; greater than 73%(22) of the respondents disagreed and strongly disagreed on the management provides periodic program review and recommendation; and above 83%(25) of participants disagreed and strongly disagreed on the management employs enough staffs as shown in Figure 12.

The questionnaire outcome showed that the staff management of ERPA did not provide enough requirements for the staff because the overall mean of about 64.9% of participants disagreed and strongly disagreed on each of the issue of staff management requirements.

Related to this issue WHO informed that low-income countries may lack not only fund but also experience required to run and create an efficient medical equipment management system**.** Without qualified person it is difficult to make efficient procurement, inventory management, utilization, repair and maintenance, and other requirements for utilization of medical equipment. Until such a proper systems are in place, there exists the major barriers to using medical equipment. Appropriate regulation and management of medical equipment is also the responsibility of the managers of individual health-care facilities, biomedical engineers, physicians, and nursing staff, in addition to the policy choices at health ministry level [21].

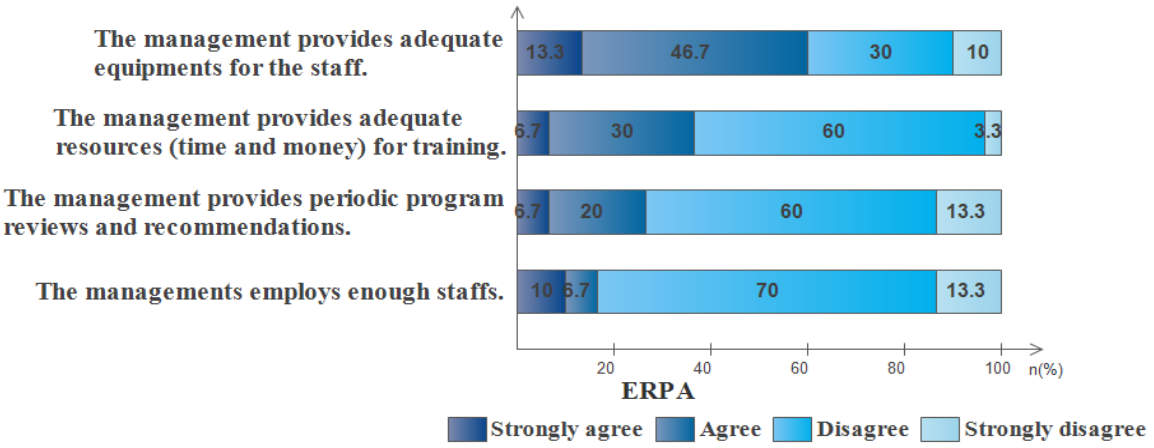

Figure 12: Staff management condition in ERPA in 2017

4.11 Summary of the Result

Based on the observation and interview, ERPA was using paper-based registration system which has many drawbacks. It is very difficult for the regulatory authority to manage any information regarding to RGDs, for instance, to store, access, update etc, to remember which RGD was inspected when and where, to inspect any premises and devices periodically, follow up on noncompliance and nonperformance issues, and finally take corrective action.

According to the outcome of the questionnaire, participants that reaches up to 100% in both ERPA and Hospitals reported that there were no regulatory inspection for some devices like Electron microscope and Dual Energy X-ray.

The overall mean of respondents who reported that there were regulatory inspection was 73.8% in ERPA and 65.1% in hospitals; checked out each safety control parameters was 89.8% in ERPA and 80% in hospitals; and checked out each performance indicator parameters was 81.7% in ERPA as well as 66.9% in hospitals.

In line with inspection procedure about 66.7% (48) of respondents in hospitals disagreed and strongly disagreed on inspectors were viewed records such as inventory and occupational exposure prior to inspection whereas 70% (21) of participants in ERPA disagreed and strongly disagreed on the follow up of non-compliances at agreed time as shown in Figure 10. This shows that there was a wide gap in the implementation of inspection procedures by ERPA.

With respect to calibration of testing and measuring devices, more than 59.9% of respondents in ERPA disagreed and strongly disagreed on calibration is always being performed periodically and majority (74.8%) of respondents in hospitals disagreed and strongly disagreed on calibration is always being performed periodically. And also an overall mean greater than half (53.9%) of participants in hospitals disagreed and strongly disagreed on each issue of calibration.

Moreover, more than 90% (27) of participants disagreed and strongly disagreed on availability of enough technical and professional man power in ERPA; about 90% (27) of respondents disagreed on the expected inspection frequency is specified for each devices.

Finally, the questionnaire outcome showed that the staff management of ERPA did not provide enough requirements for the staff because the overall mean of about 64.9% of participants disagreed and strongly disagreed on each of the issue of staff management requirements.

These gaps lead us to design and develop a web-based registration system for RGDs. The system developed can be used for facilitating communication between system users; decrease energy, time and money to get data; reduce data redundancy; allow all user to access the data at the same time, notify inspection time of RGDs etc. This automated registration system also will helps the total management of RGDs by ERPA at all levels of medical radiation practicing areas enhance decision making process concerning licensees of medical radiation practices and ionizing radiation exposures.

The developed system contains RGD's registration and inventory, RGD's inspected inventory, user's registration and inspection procedures. System user can add, modify, search, sort, access, analyze and generate a report related to the devices, view notification, can also export the data from database into Microsoft excel and download for further evaluation. The next chapter explains the details of design and development of the system.

Chapter 5 Web based System Analysis, Design and Development

5.1 System Analysis

5.1.1 Constraints of the System

Some of the constraints which should be considered in our system are listed below.

Quality issue: The system should permanently keep stored information only.

System modification: The system can be modified when the authority needs modification.

Maintainability: The developed system can be maintained easily. But it is impossible to change the database or application setting.

Reliability: The information stored is permanent and consistent.

Error handling: The system will handle any error made by the user when he/she feeds data to the system.

Security issue: Some operation must be done by authorized persons for the sake of security. The software is planned so as to use password protected login. It is user-friendly and easily understandable by the user.

5.1.2 System Use Case Modeling

Use case diagrams give an outside view of system. It models the functionality of a system. It describes a sequence of actions that provide something of measurable value to an actor. A use case is made up of a set of scenarios. The use case brings scenarios together that accomplish a specific goal of the user. It needs only one actor or the director who involves in the overall activities of the system. This relationship indicates that to perform or to do all other six use cases, its uses a login to account. Figure 13 shows a use case diagram to the basic system functionality.

Actors of the system

Admin, management and inspectors are the three of the main users of the system. Admin users are professionals in the authority who have full privileges on the system. Inspectors are those professionals who physically go to premises to observe, measure and examine all equipment and practices if the customer fulfil the minimum requirements of the authority and have certain privileges like view inventory, search equipment registered, view equipment inspected and see any guide

posted on the system and management users are employees within the authority and have privileges to view any ionizing radiation source and employee's information.

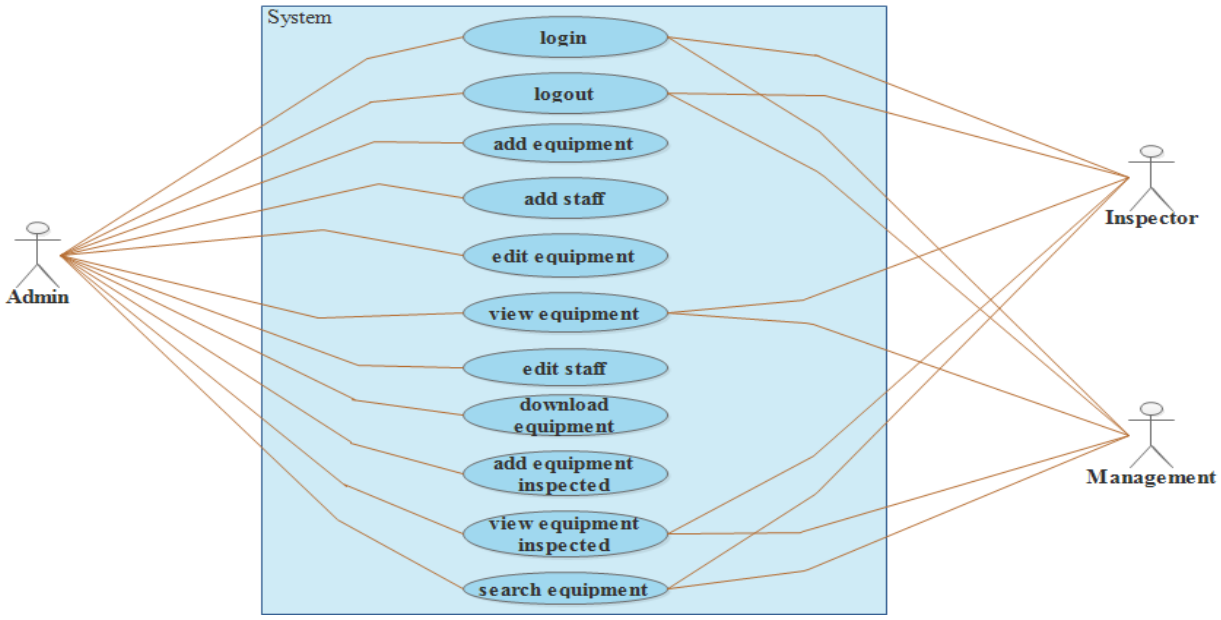

Figure 13: Sample use case diagram

Table 4: Lists of use cases for admin user

Admin user use cases		
Login	Change password	View inspection procedure
Logout	Reset password	Add manufacturer
Add equipment	View user's detail	View manufacturer
Add inventory	Down load user's detail	Search manufacturer
View equipment	Add equipment for inspection	
Search equipment	View inspected equipment	
Edit equipment	Edit inspected equipment	
Down load equipment	Delete inspected equipment	
View inventory	Add comment	
Search inventory	Edit comment	
Edit inventory	Delete comment	
View inventory detail	View comment	

Add user	Add licensee
Update user	View licensee's detail
Activate/deactivate user	Edit licensee's detail
Delete inventory	Delete licensee
	Search licensee

5.1.3 Use Case Scenarios

Table 5: Use case scenario for Login to account

Use case	Use case 1
Use case name	Login
Actors	Admin Inspector Management
Description	Used for security and the system validates users details in order to access.
Precondition	The system user should have user name and password
Post condition	The user login and can perform her/his tasks.
Normal flow: or basic course of action	1. The user wants to log in to the system 2. the user fill user name and password 3. The system validates entered user name and password from the system data base 4. The system displays the main window 5. End case
Alternative course of action A	A.1 If user name or password is not correct A.2 The system displays an error message A.3 The admin user refills user name and password A.4 The system rolls back in to basic course of action (2)

Table 6: Use case scenario for manipulate RGDs

Use case ID	Use case 2
Use case name	Manipulate RPD detail
Actors	Admin
Description	The admin users access, delete and edit the RGD detail information with inspection periods which are performed within the authority
Precondition	The admin user logs in to the system
Post condition	Manipulated RPD information
Normal flows	1.Admin user searches " Material management" button 2.Admin user clicks " Material management" button 3. Admin user searches the equipment that he/she wants to manipulate(i.e access, delete, edit etc) 4. Admin user clicks on the equipment that he/she wants to manipulate 5.The system displays information of the equipment clicked 6. Admin user manipulates the equipment 7. Admin user clicks "Yes" button 8, The system performs the manipulation task and saves or deletes

Table 7: Manipulate inspectors detail

Use case ID	Use case 3
Use case name	Add users
Actor	Admin
Description	To interact with the system, the admin users login first and select the user link button and then click on "Add user"
Include use case	Login to account
Precondition	Admin user logs in to the system

Post condition	The admin fills the users registration form
Normal flow	1.The system shows the users registration form 2. Enter first name, last name, phone number, email address, address, username, password and click "yes" button 3. Save their profile in the database successfully
Alternative course of actions	A1. if any of the place holder is empty: It gives error message A2.if the email address is invalid: It gives error message A3.If the password and confirm password doesn't match: It gives error message A4. If the user name and email are not unique: It gives error message

5.1.4 Sequence Diagram

Sequence diagram is a type of interaction which describes how objects in the system or classes within code interact with each other and what order a group of objects works together. It is sometimes known as event diagram or event scenario. It shows a sequence of events or interactions between two or more objects or actors or actors and objects. The sequence diagram of the system is illustrated from Figure 14 to Figure 16.

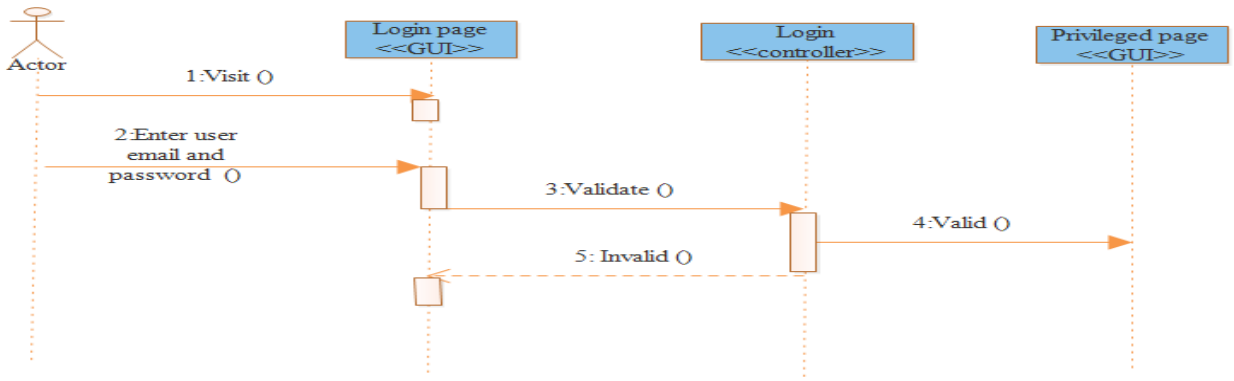

Figure 14: Sequence diagram for login

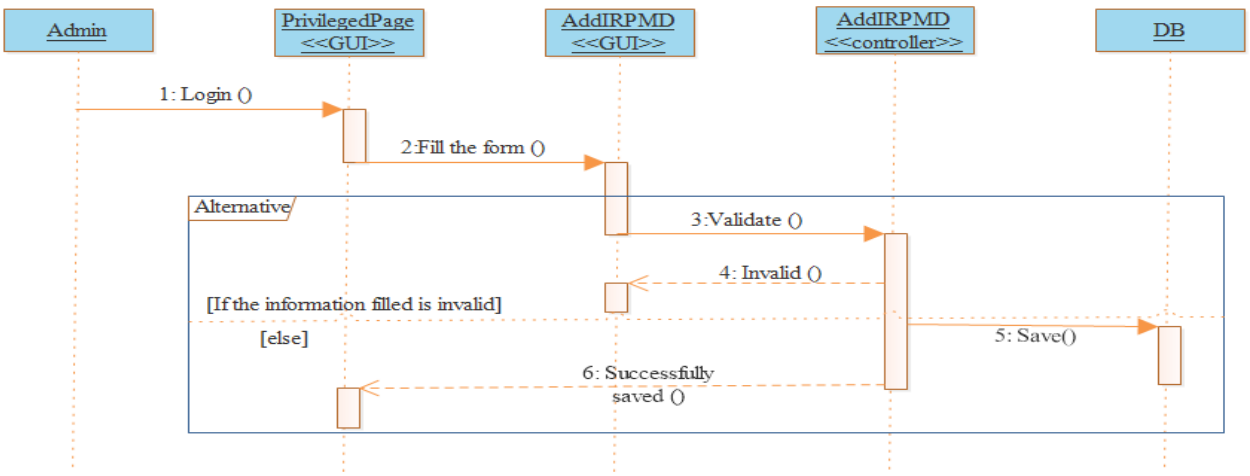

Figure 15: Sequence diagram for add new equipment

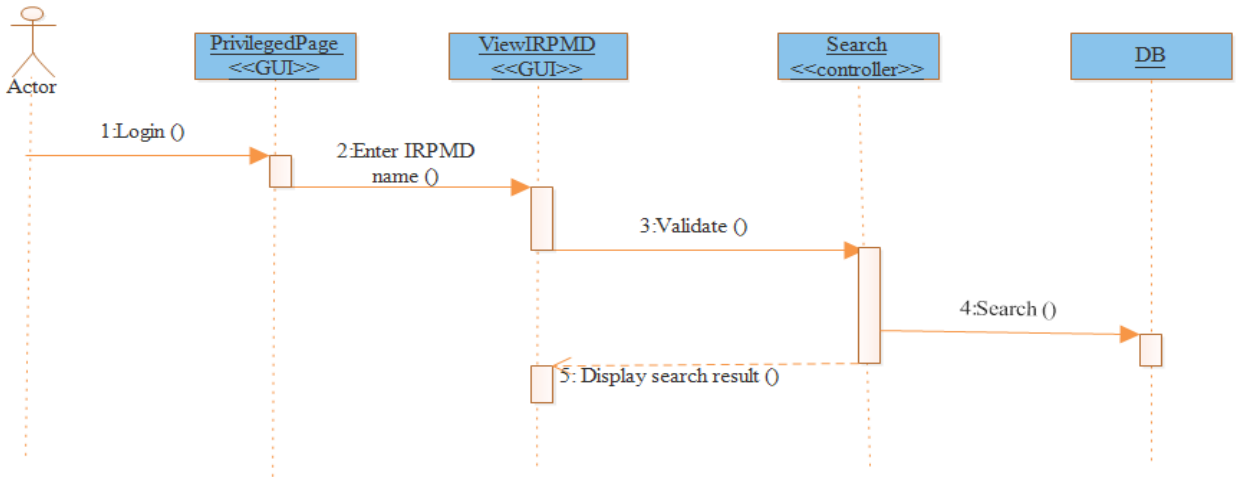

Figure 16: Sequence diagram for search registered equipment

5.1.5 Activity Diagram

Activity diagram shows the series of activities which are done in single use case's basic course of action. In this section, there are use case basic course of action and alternate course of a single use case. Some of the activity diagram are illustrated below.

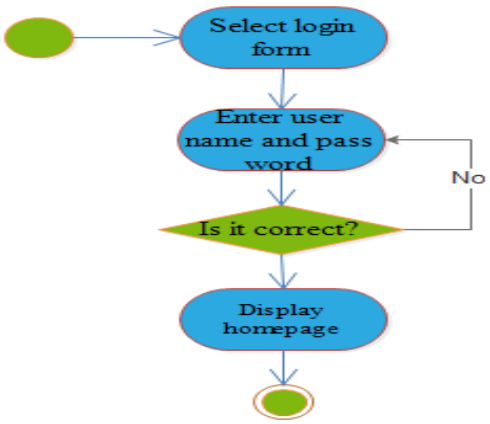

Figure 17: Activity diagram for login to account

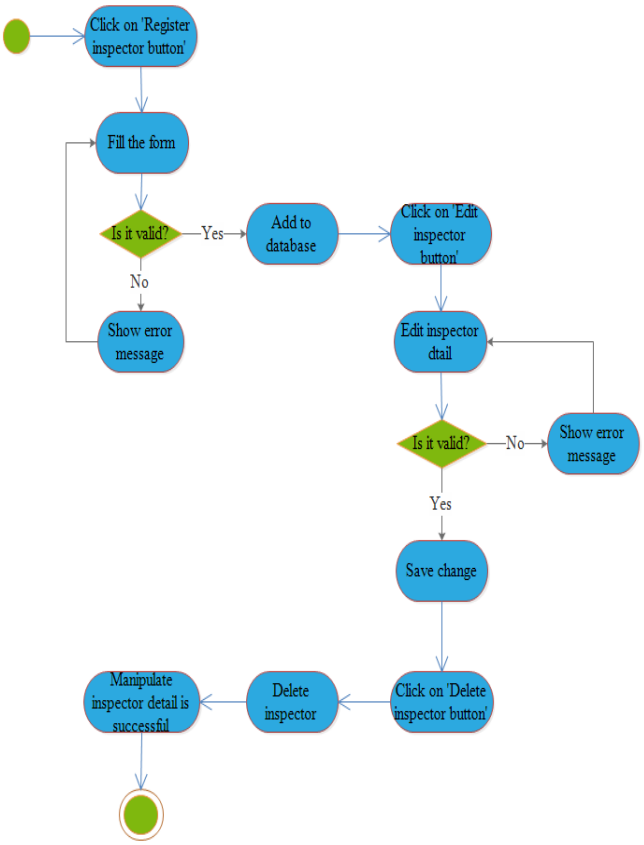

Figure 18: Activity diagram for manipulate inspector's detail

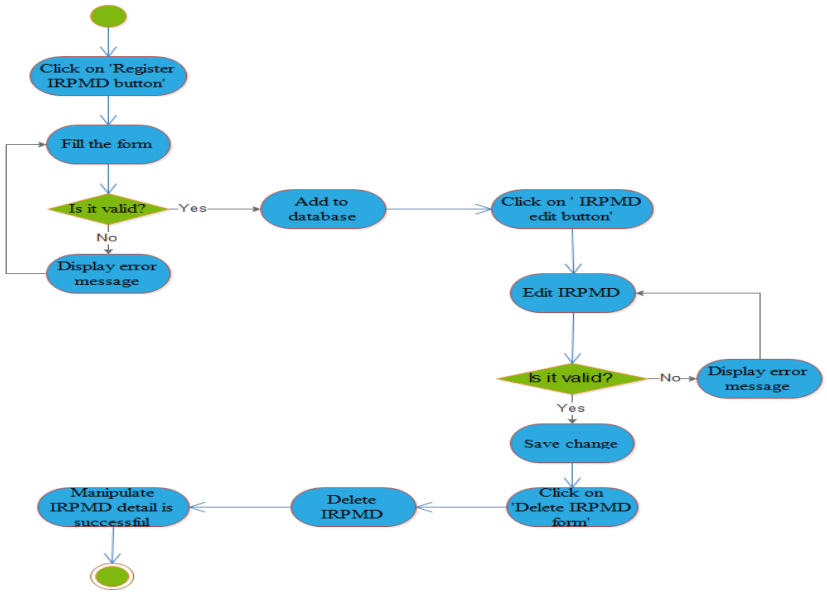

Figure 19: Activity diagram for RGD's information manipulation

5.2 System Design

5.2.1 System User Interface Design

User interfaces design is a computer design process used by software developer to build interaction sites in software or computerized devices focusing on looks or style. It is sometimes called graphical user interface and other forms for instance voice-controlled interfaces. The user interface design of this system was developed using HTML and CSS. Some of the user interfaces of the system is illustrated from Figure 20 to Figure25.

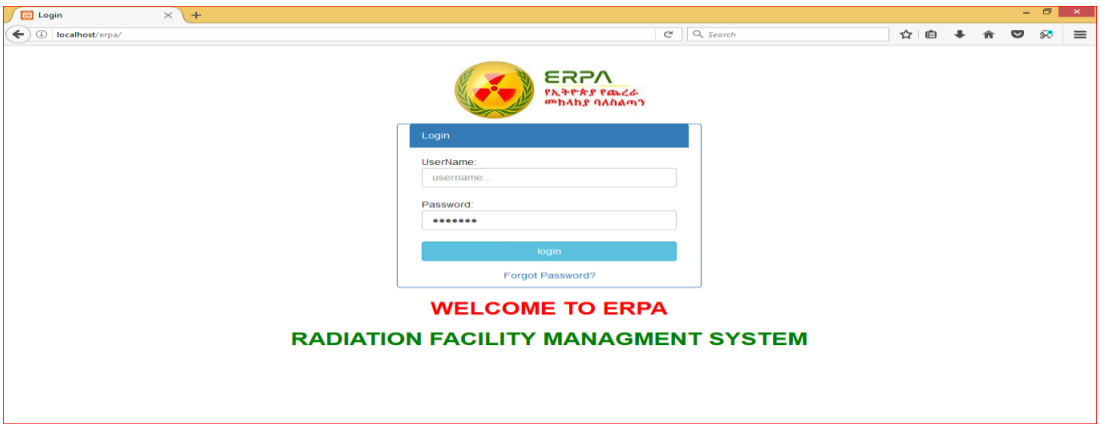

Figure 20: User interface for login page

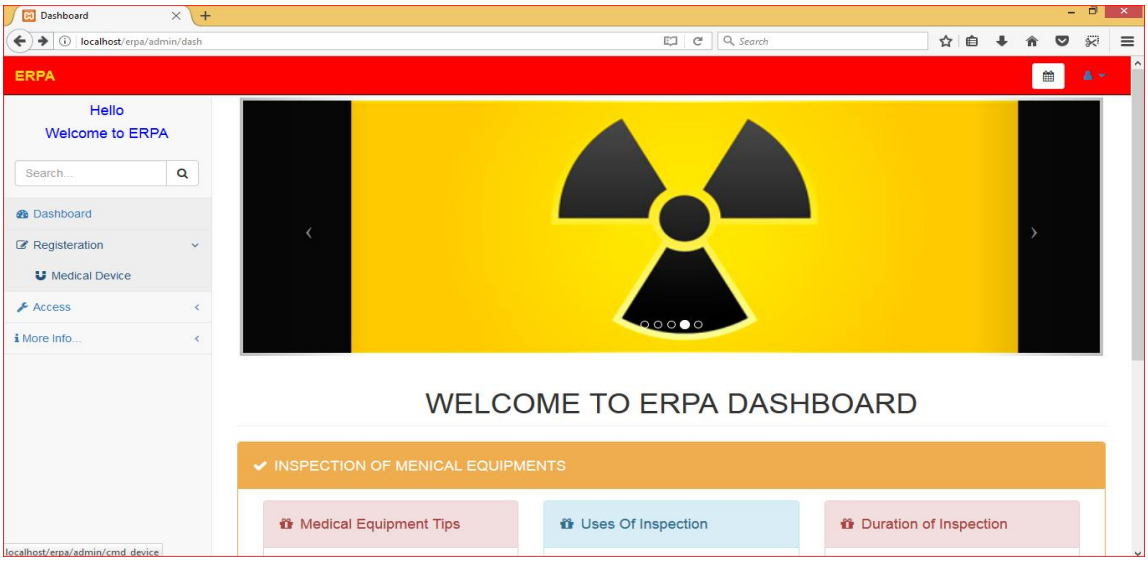

Figure 21: User interface for ERPA home page

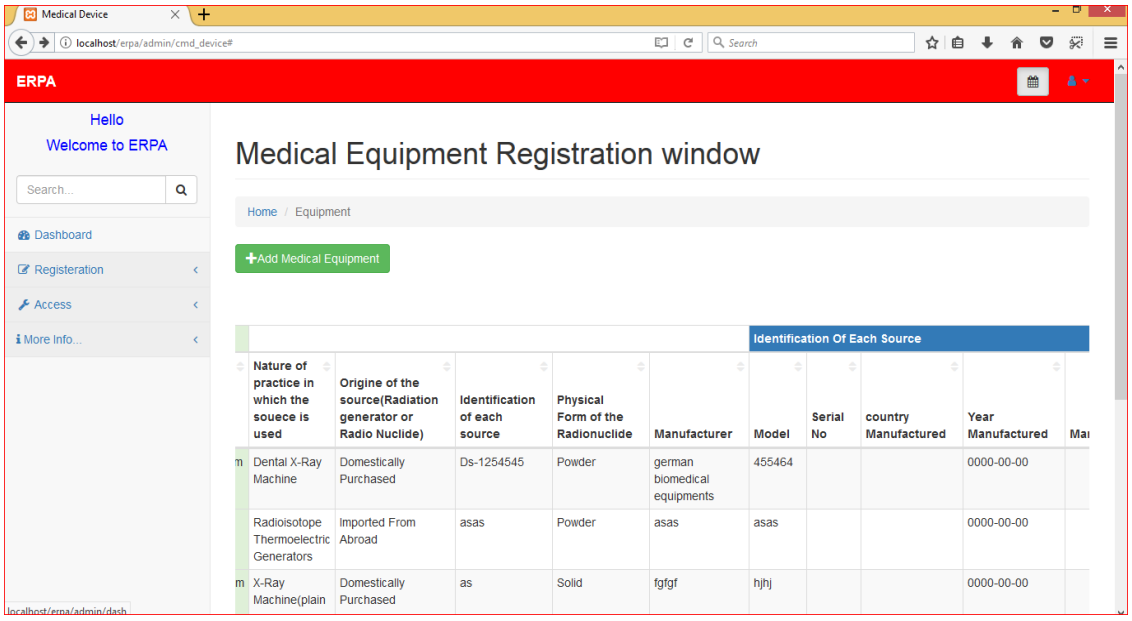

Figure 22: User interface for new medical devices registration page

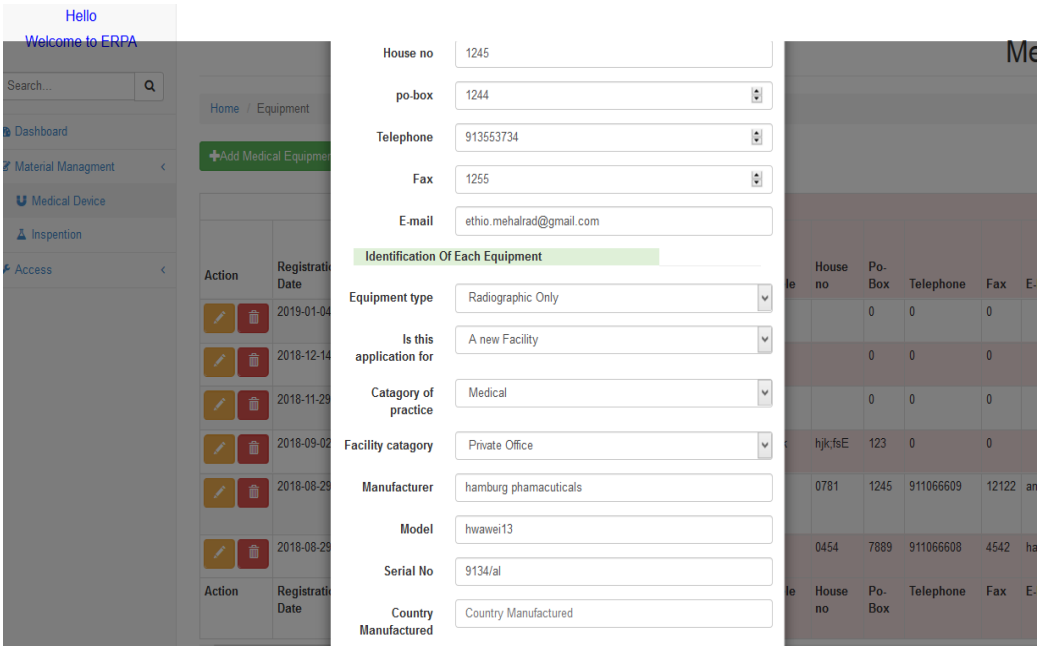

Figure 23: User interface for RGD edit page

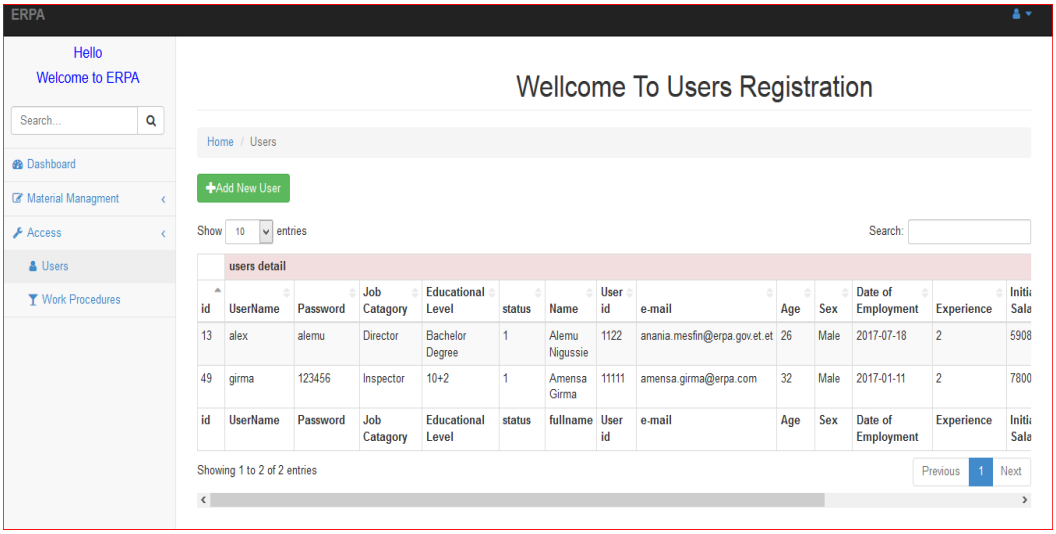

Figure 24: User interface for user's registration page

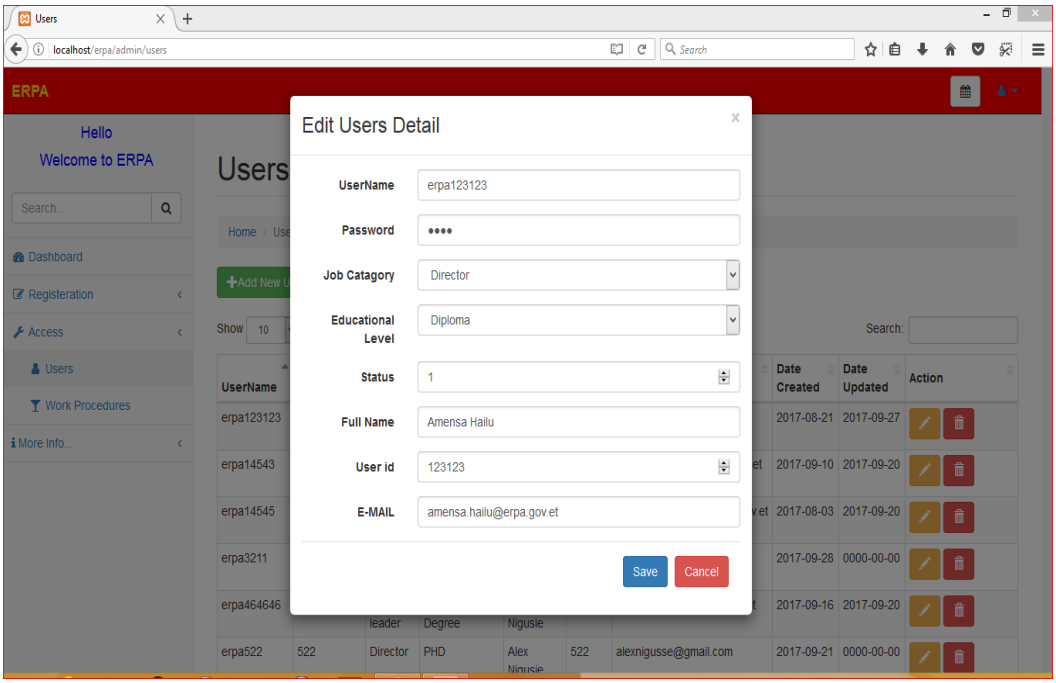

Figure 25: User interface for users detail edit page

5.2.2 Class Diagram

The class diagram indicates how the various entities such as people, things, and data relate to one another; or, class diagram indicates the structures of the system. It can be used to display logical classes that are typically the kinds of things the business people in an organization talk about. It can also be used to indicate implementation classes that are the things the programmers typically deal with. A class is depicted on the class diagram as a rectangle with three sections, the upper section shows the class's name; the middle section contains the class's attributes; and the lower section contains the class's operations as shown in Figure 26 below [58].

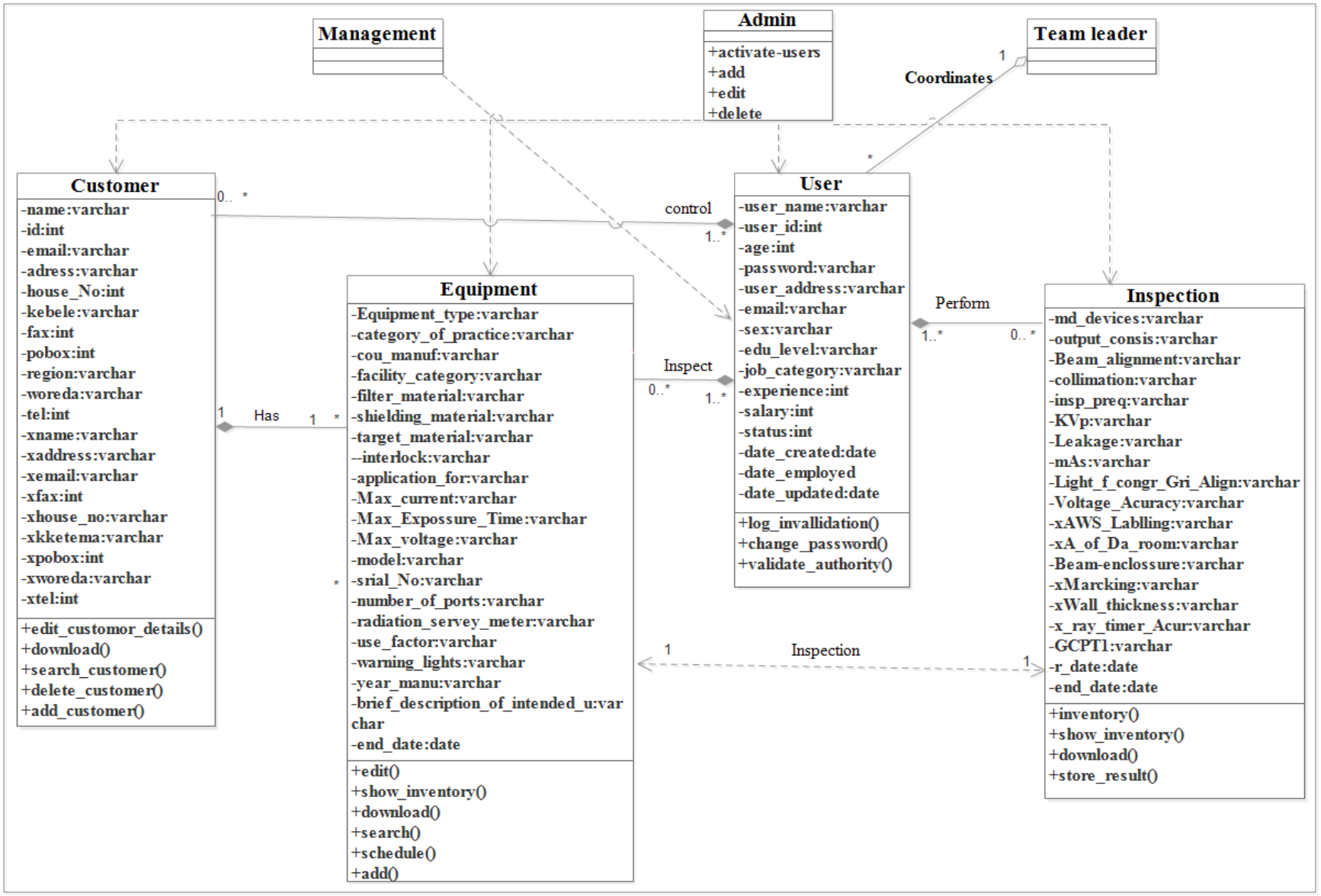

Figure 26: Class diagram for web-based RGDs registration and inspection system

Chapter 6 Conclusion and Recommendation

6.1 Conclusion

Radiation Generating Devices (RGDs) are one and inalienable part of the healthcare deliveries and used to diagnose, treat, and monitor patients. However, unsafe use and improper regulation of RGDs could result in unaccepted exposures of patients, users and even public to ionizing radiation emanating from these devices which is dangerous to health. Safe utilization by proper regulation of these devices, in contrast , could also result in reliable diagnostic results and good treatment outcomes with minimum and limited exposure to these radiation so that it could have a constructive impact on the safety, quality and effectiveness of the health services. Therefore avoiding overzealous and improper regulatory inspection process of these devices by the regulatory body is inevitable solution for the gap of regulation of the devices. There are different elements that influence the proper regulatory of RGDs. Some of these are implementation of formal inspection for each device, periodic inspection, checking safety control parameters, checking performance (quality) indicator parameters, fulfilment of preconditions for formal inspection, implementation of inspection procedures, Calibration of measuring and testing devices, staff management conditions of regulatory authority.

The finding of study revealed that there were many gaps in RGD's regulatory inspection processes. For some devices like electron microscope and Dual energy x-ray up to 100% of respondents in both ERPA and hospitals reported they were not inspected. From the focus group discussion, they reported that "*The absence of inspection for equipment might sometimes occur because of lack of information from different institutions which needs to inform ERPA prior to import, use, and change in location of the devices."*

The overall mean of respondents who reported that there were regulatory inspection was 73.8% in ERPA and 65.1% in hospitals; checked out each safety control parameters was 89.8% in ERPA and 80% in hospitals; and checked out each performance indicator parameters was 81.7% in ERPA as well as 66.9% in hospitals.

In line with inspection frequency, International Basic Safety Standard recommended the inspection frequency of nuclear medicine, radiotherapy and diagnostic radiography is 1-2 years, 1 year and 2 years respectively [34]. However, based on the result of this thesis, the inspection frequency of

some devices like detected chest x-ray and General x-ray goes to the maximum limit of the inspection frequency specified by IBSS (2 years). This is one gap that is too long inspection frequency because most of the devices imported to developing countries like Ethiopia are risk full and unsafe [57], so that the inspection frequency of RGDs in Ethiopia should not be equivalent to but it needs to be shorter than the frequency of inspection specified by IAEA and BSS taking in to account different contexts of the country such as the current awareness of the user, patient and general public about the equipment and effects of ionizing radiation; knowledge of professionals including medical doctors about radiation protection (which is confusing and inadequate) [40]; availability of training to the user and the patient; whether the devices imported are new or used, quality and safety of the RGDs imported, the quality and safety of medical radiation facilities(area, set up, wall thickness etc.) and so on. Moreover, according to IBSS, establishing a relevant inspection program requires continuous analysis of inspection data for different types of radiation practices and sources and the frequency of inspection must be directly related to the relative risk associated to each radiation practice or sources within the practices [34].

With respect to fulfilment of preconditions for formal inspection, this the study revealed more than 90% (27) of participants believe that there are no enough technical and professional man power in ERPA; about 90% (27) of respondents disagreed on the expected inspection frequency is specified for each devices.

In line with inspection procedure about 66.7% (48) of respondents in hospitals disagreed and strongly disagreed on inspectors were viewed records such as inventory and occupational exposure prior to inspection whereas 50% (15) and 20% (6) of participants in ERPA disagreed and strongly disagreed, respectively, on the follow up of non-compliances at agreed time as shown in Figure 10. This shows that there was significant gaps in the implementation of inspection procedures by ERPA.

In the case of calibration of testing and measuring devices, more than 53.3% and 6.6% of respondents in ERPA disagreed and strongly disagreed, respectively, on calibration is always being performed periodically and majority (74.8%) of respondents in hospitals disagreed and strongly disagreed on calibration is always being performed periodically. And also an overall mean greater than half (53.9%) of participants in hospitals disagreed and strongly disagreed on each issue of calibration.

Finally, questionnaire outcome showed that the staff management of ERPA did not provide enough requirements for the staff because the overall mean of about 64.9% of participants disagreed and strongly disagreed on each of the issue of staff management requirements.

The developed web based system really has not only a benefit of deploying (register, confidentially keep, transfer, access, update, schedule, store etc.) RGD's and user's information in the regulatory body (ERPA) but also it helps to make decisions for taking measurements in the case when the operators and licensees do not fulfil the minimum requirements given by the authority as well as to follow on noncompliance and nonperformance issue

6.2 Recommendation

By taking in to account the result of the study, the following issues are recommended:

- In addition to the system developed in this work, in the future it can be greatly recommended to develop a country level RGDs auto-license renewal system which reduces inspection and licensing cost, time and effort which can be exposed for transportation, daily cost and other rental issues for both authority and licensees (registrants).
- It is also advisable to provide RGDs users and inspectors regular training program in the country because both the number and technology of these devices are in a way of increasing from time to time.
- The RGDs must be calibrated to accurately produce the desired voltage, current, and exposure time, and the radiology technologists should be aware of burdens of unnecessary exposure to the patient undergoing so that they can achieve as low as reasonably achievable (ALARA) principle.
- ERPA should strengthen its effort in the case of tools, human and financial resources, and technology that are relevant to regulatory inspection of RGDs to control ionizing radiation.
- RGDs professionals should use the three basic principles of radiation protection that are: Justification, Optimization and dose limitation.
- It is strongly recommended that ERPA should deliver adequate protective, measuring and testing tools to inspectors and other stakeholders as well as make periodic

calibration to these tools prior to inspection of RGDs because inspectors are at risk when they are performing inspection and users are also always at high risk during operation.

- Finally it is also recommended that the inspection frequency of RGDs in Ethiopia could not be equivalent to but it needs to be shorter than the frequency of inspection specified by IAEA and BSS taking in to account different contexts of the country such as the current awareness of the user, patient and general public about the equipment and effects of ionizing radiation; knowledge of professionals including medical doctors about radiation protection (which is confusing and inadequate) [40]; availability of training to the user and the patient; whether the devices imported are new or used, quality and safety of the RGDs imported, the quality and safety of medical radiation facilities(area, set up, wall thickness etc.) and so on.

6.3 Suggestions for future work

There are a lot of factors that affect the regulatory inspection of radiation generating medical devices as explained in literature review and background. The study addressed only some of these factors an in small geographical area in Addis Ababa. Therefore, further studies need to be conducted on the rest of factors other than what is being investigated in this thesis, and by covering broader geographical area.

The researcher identified other areas for further studies. Although, the studied parameters were some of the factors for the challenge of regulatory inspection which in turn contribute to the raise of radiation exposure level of patients, users and publics, the other factors that can contribute directly for the raise of the level of radiation need further investigation. Finally, in addition to the developed web-based registration and scheduling system, further study should be conducted and RGDs automatic license renewal system needs to be developed to minimize cost, time, and energy that can be paid by customers and workers of ERPA.

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Annex A: Questionnaire for assessment of ionizing radiation producing medical devices inspection to be filled in ERPA

Addis Ababa University

Addis Ababa Institute of Technology

Center of Biomedical Engineering

Questionnaire for investigating the follow-up of ionizing radiation producing medical devices in Ethiopia

Introduction

Radiation generating devices (RGDs) are the devices that can emit ionizing radiations such as x-rays and used for medical purposes. Ionizing radiation is energy emitted in the form of waves or particles that have high energy to remove electrons from the atoms, thereby causing tissue damage. The importance of a proper management of RGD is not only providing appropriate standard protection for humankind against these harmful effects of ionizing radiation without unduly limiting the beneficial practice of such exposures but also for the proper utilization and safety of the device itself.

General objective:

- To investigate the challenges and future prospects of management of RGD in Ethiopia.

Specific objectives of this questionnaire are to investigate:

- major challenges of inspection and licensing process of medical devices in Ethiopia
- inspection and licensing system requirements of RGMD in Ethiopia

How to fill in the questionnaire? Please answer all questions according to your knowledge, skill and position within your organization. Most of the questions have multiple choice. Please tick one of the given multiple choice in each question and also tick all of the necessary answer given in the table provided bellow

Personal information format

1. City:_____

2 .Country:_____

3 .Organization you work at:

A. government B. non-government C. your own business D. unemployed

4. Educational level:

A. grade 12 complete B. diploma C. bachelor degree D. MSC E. PHD and above

5. Profession:_____

6. Work experience in this organization:_____Year

7. Total work experience in your current profession:_____Year

1. Availability of the devices

1.0.Which medical equipment's are there in your hospital?

No.	Ionizing Radiation Producing Medical Devices	Yes	No
1.1	General x-ray	☐	☐
1.2	Mammography	☐	☐
1.3	Fluoroscopy	☐	☐
1.4	Computed tomography	☐	☐
1.5	Detected chest x-ray	☐	☐
1.6	Dual x-ray absorptiometry(DXP)	☐	☐
1.7	Linear accelerator	☐	☐
1.8	Circular accelerator (cyclotron, betatron, microtron…)	☐	☐
1.9	Cobalt-60 machine	☐	☐
1.10	Dental x-ray (intra oral x-ray equipment, extra oral x-ray equipment)	☐	☐
1.11	X-ray diffraction units	☐	☐
1.12	Electron microscopes	☐	☐
1.13	Static eliminators functioning by emitting ionizing radiation	☐	☐
1.14	Beta-ray gauges gas chromatographs with ECD	☐	☐
1.15	Devices using sealed gamma-radiation sources (e.g. teletherapy units, irradiators, moisture density gauges, etc.)	☐	☐
1.16	Dual energy x-ray scanner(DEXA)	☐	☐

1.17	X-ray irradiator	☐	☐
1.18	Cabinet X-ray (faxitron...)	☐	☐
1.19	Brachytherapy	☐	☐
1.20	Radiotherapy	☐	☐
1..21	List if there are any other……		

2. Regulatory inspection by the authority

2.0.From those devices that are available in your hospital/health center/heath post, which medical devices are inspected by Ethiopian Radiation Protection Authority (ERPA)?

No.	**Ionizing Radiation Producing Medical Devices**	**Inspected**	**Not Inspected**
2.1	General x-ray	☐	☐
2.2	Mammography	☐	☐
2.3	Fluoroscopy	☐	☐
2.4	Computed tomography	☐	☐
2.5	Detected chest x-ray	☐	☐
2.6	Dual x-ray absorptiometry(DXP)	☐	☐
2.7	Linear accelerator	☐	☐
2.8	Circular accelerator (cyclotron, betatron, microtron…)	☐	☐
2.9	Cobalt-60 machine	☐	☐
2.10	Dental x-ray (intra oral x-ray equipment, extra oral x-ray equipment)	☐	☐
2.11	X-ray diffraction units	☐	☐
2.12	Electron microscopes	☐	☐
2.13	Static eliminators functioning by emitting ionizing radiation	☐	☐
2.14	Beta-ray gauges gas chromatographs with ECD	☐	☐

2.15	Devices using sealed gamma-radiation sources (e.g. Teletherapy units, irradiators, moisture density gauges, etc.)	☐	☐
2.16	Dual energy x-ray scanner(DEXA)	☐	☐
2.17	X-ray irradiator	☐	☐
2.18	Cabinet X-ray (faxitron...)	☐	☐
2.19	Brachytherapy	☐	☐
2.20	Radiotherapy	☐	☐
2.21	List if there are any other…….		

3. Inspection frequency

3.0. The awareness of the in authority (ERPA) about the inspection frequency the devices? (Tick each of the inspection frequency for each devices in the table below?)

No.	**Medical devices**	**Inspection frequency(in years)**				
		Semiannu-ally and below	Annually	Every 2 yrs	Every 3 yrs	Every 4 yrs and above
3.1	General x-ray	☐	☐	☐	☐	☐
3.2	Mammography	☐	☐	☐	☐	☐
3.3	Fluoroscopy	☐	☐	☐	☐	☐
3.4	Computed Tomog-raphy (CT)	☐	☐	☐	☐	☐
3.5	Detected chest x-ray	☐	☐	☐	☐	☐
3.6	Dual X-ray Absorp-tiometry(DXA)	☐	☐	☐	☐	☐
3.7	Linear accelerator	☐	☐	☐	☐	☐
3.8	Circular accelera-tor (cyclotron, beta-tron, microtron....)	☐	☐	☐	☐	☐

3.9	Cobalt-60 machine	☐	☐	☐	☐	☐
3.10	Dental x-ray(intra oral x-ray equipment, extra oral x-ray equipment)	☐	☐	☐	☐	☐
3.11	X-ray diffraction units	☐	☐	☐	☐	☐
3.12	Electron microscopies	☐	☐	☐	☐	☐
3.13	Static eliminators functioning by emitting ionizing radiations	☐	☐	☐	☐	☐
3.14	Beta-ray gauges as chromatographs with ECD	☐	☐	☐	☐	☐
3.15	Devices using sealed gamma-radiation (e.g. teletherapy units, irradiators, moisture density gauges, etc.)	☐	☐	☐	☐	☐
3.16	Dual energy x-ray scanner(DEXA)	☐	☐	☐	☐	☐
3.17	Cabinet X-ray (Faxitron….)	☐	☐	☐	☐	☐
3.18	X-ray irradiator	☐	☐	☐	☐	☐
3.19	Brachytherapy	☐	☐	☐	☐	☐
3.20	Radiotherapy	☐	☐	☐	☐	☐

3.21	List if there are any other……..					

4. Performance indicator parameters

4.0. Which quality control parameters are checked out during inspection?

No.	Quality control test	Checked out	Not checked out
4.1	Voltage accuracy	☐	☐
4.2	X-ray timer accuracy	☐	☐
4.3	Collimation	☐	☐
4.4	Beam alignment	☐	☐
4.5	Output consistency	☐	☐
4.6	Leakage measurement	☐	☐
4.7	Half value layer	☐	☐
4.8	Light field congruence and greed alignment	☐	☐
4.9	Kilovolt peak(kVp)	☐	☐
4.10	Milliampere (mAs)	☐	☐
4.11	List if there are any other….		

5. Performance indicator parameters

5.0. Which safety control parameters are checked out by the authority during inspection?

No.	Safety parameters	Checked out	Not checked out
5.1	Area warning sign and labeling	☐	☐
5.2	Interlocks	☐	☐
5.3	Shielding	☐	☐
5.4	Surfaces	☐	☐
5.5	Ventilation	☐	☐
5.6	Leak testing of sealed radioactive sources	☐	☐
5.7	Incident notifications	☐	☐
5.8	Markings	☐	☐

5.9	Mechanical stability	☐	☐
5.10	Indicator light	☐	☐
5.11	Indication of loading factor	☐	☐
5.12	Irradiation control	☐	☐
5.13	Control timer	☐	☐
5.14	Beam filtration	☐	☐
5.15	Lead apron, lead gloves and lead glass goggle	☐	☐
5.16	Personal monitoring services	☐	☐
5.17	Area of darkroom	☐	☐
5.18	Wall thickness	☐	☐
5.19	Patient identification system	☐	☐
5.20	Auxiliary room	☐	☐
5.21	Beam enclosure	☐	☐
5.22	Viewing box	☐	☐
5.23	Radiation area monitoring	☐	☐
5.24	Beam stops	☐	☐
5.25	Ports	☐	☐
5.26	List if there are any other……		

6. Preconditions of regulatory inspection

No.	**Questions**	Agree	Strongly agree	Disa-gree	Strongly disagree
6.1	Has it been decided who will perform the inspection and testing within the authority?	☐	☐	☐	☐
6.2	Are there enough inspectors within the authority?	☐	☐	☐	☐
6.3	Has the expected frequency of inspection and testing for each devices been defined within the authority?	☐	☐	☐	☐

6.4	Does the authority identify global system requirements for inspection and testing?	☐	☐	☐	☐
6.5	Are area of greatest expected inspections identified?	☐	☐	☐	☐
6.6	Does the authority have guidelines how to inspect and test the devices?	☐	☐	☐	☐
6.7	Does the authority have a system to control unsatisfactory devices?	☐	☐	☐	☐
6.8	Are measuring, monitoring and test equipment inspected and calibrated prior to use?	☐	☐	☐	☐
6.9	Are measurement standards traceable to the known institute of standards like ISO	☐	☐	☐	☐

7. Inspection procedure

7.0. Which inspection procedure does the authority performs during inspection?

No.	**Inspection procedures**	Agree	Strongly agree	Disagree	Strongly di-agree
7.1	Proposing inspection program	☐	☐	☐	☐
7.2	Inspectors review application	☐	☐	☐	☐
7.3	Inspection protocol reviewed(required equipment selected, calibration confirmed , checking that it is functioning)	☐	☐	☐	☐
7.4	Inspectors' arrival at agreed time, showing their authority, entrance briefing….	☐	☐	☐	☐
7.5	View inventory of sources, make any measurement…	☐	☐	☐	☐
7.6	View records (inventory, occupational exposure…)	☐	☐	☐	☐
7.7	Exit briefing, inspectors inform operators major findings	☐	☐	☐	☐

7.8	Follow up on issue of non-compliances at specified time.	☐	☐	☐	☐

8. Calibration of testing and measuring devices

No	**QUESTION**	Agree	Strongly agree	Disa-gree	Strongly disagree
8.1	Is there a routine calibration according to written procedures for your monitoring devices and personal dosimeters within the authority for inspection?	☐	☐	☐	☐
8.2	Does the authority have a procedure for controlling or preventing out-of-service tools/equipment from being used?	☐	☐	☐	☐
8.3	Do the calibrators use standards traceable to the known institute of standards like ISO?	☐	☐	☐	☐
8.4	Is there a set of written procedures for calibration within the organization?	☐	☐	☐	☐
8.5	Is the calibration being performed based on the frequency of calibration?	☐	☐	☐	☐
8.6	Is there preliminary examination and operation during calibration?	☐	☐	☐	☐

9. Staff management in ERPA

No.	**QUESTION**	Agree	Strongly agree	Disa-gree	Strongly disagree
9.1	Does the management provide adequate staffing level?	☐	☐	☐	☐
9.2	Does the management provide adequate resources for personnel training (time and money)?	☐	☐	☐	☐
9.3	Does the management provide adequate equipment?	☐	☐	☐	☐
9.4	Does the management provide adequate periodic program review and recommendations?	☐	☐	☐	☐

Annex B: Questionnaire for assessment of ionizing radiation producing medical devices inspection to be filled in Hospitals

Part I: To be filled in Hospitals

Addis Ababa University

Addis Ababa Institute Technology

Center of Biomedical engineering

Questionnaire for investigating the follow-up of ionizing radiation producing medical devices in Addis Ababa

Introduction

Radiation generating devices (RGDs) are the devices that can emit ionizing radiations such as x-rays and used for medical purposes. Ionizing radiation is energy emitted in the form of waves or particles that have high energy to remove electrons from the atoms, thereby causing tissue damage. The importance of a proper management of RGD is not only providing appropriate standard protection for humankind against these harmful effects of ionizing radiation without unduly limiting the beneficial practice of such exposures but also for the proper utilization and safety of the devices.

General objective:

- To investigate the challenges and future prospects of management of RGD in Ethiopia.

Specific objectives of this questionnaire are to investigate:

- major challenges of inspection and licensing process of medical devices in Ethiopia
- inspection and licensing system requirements of RGD in Ethiopia

How to fill in the questionnaire? Please answer all questions according to your knowledge, skill and position within your organization. Most of the questions have multiple choice. Please tick one of the given multiple choice in each question and also tick all of the necessary answer given in the table provided bellow

Personal information format

1. City:_____

2 .Country: _____

3. Organization you work at:

A. government B. non-government C. your own business D. unemployed

4. Educational level:_____

A. grade 12 complete B. diploma C. bachelor degree D. MSC E. PHD and above

5. Profession:_____

6. Work experience in this organization:_____Year.

7. Total work experience in your profession: _____Year.

1. Type of medical devices available

1.0. Which medical equipment are inspected by the authority (ERPA)? (Tick each of which are inspected or not inspected by the authority)

No.	Ionizing Radiation Producing Medical Devices	Inspected	Not inspected
1.1	General x-ray	☐	☐
1.2	Mammography	☐	☐
1.3	Fluoroscopy	☐	☐
1.4	Computed tomography	☐	☐
1.5	Detected chest x-ray	☐	☐
1.6	Dual x-ray absorptiometry(DXP)	☐	☐
1.7	Linear accelerator	☐	☐
1.8	Circular accelerator (cyclotron, betatron, microtron…)	☐	☐
1.9	Cobalt-60 machine	☐	☐
1.10	Dental x-ray (intra oral x-ray equipment, extra oral x-ray equipment)	☐	☐
1.11	X-ray diffraction units	☐	☐
1.12	Electron microscopes	☐	☐
1.13	Static eliminators functioning by emitting ionizing radiation	☐	☐
1.14	Beta-ray gauges gas chromatographs with ECD	☐	☐
1.15	Devices using sealed gamma-radiation sources (e.g. teletherapy units, irradiators, moisture density gauges, etc.)	☐	☐
1.16	Dual energy x-ray scanner(DEXA)	☐	☐
1.17	X-ray irradiator	☐	☐

1.18	Cabinet X-ray (faxitron …)	☐	☐
1.19	Brachytherapy	☐	☐
1.20	Radiotherapy	☐	☐
1.21	List if there are any other…….		

2**. Safety control parameters**

2.0. Which safety control parameters does the authority check out during inspection?

No.	**Safety parameters**	**Checked out**	**Not checked out**
2.1	Area warning sign and labeling	☐	☐
2.2	Interlocks	☐	☐
2.3	Shielding	☐	☐
2.4	Surfaces	☐	☐
2.5	Ventilation	☐	☐
2.6	Leak testing of sealed radioactive sources	☐	☐
2.7	Incident notifications	☐	☐
2.8	Markings	☐	☐
2.9	Mechanical stability	☐	☐
2.10	Indicator light	☐	☐
2.11	Indication of loading factor	☐	☐
2.12	Irradiation control	☐	☐
2.13	Control timer	☐	☐
2.14	Beam filtration	☐	☐
2.15	Lead apron, lead gloves and lead glass gog-gle	☐	☐
2.16	Personal monitoring services	☐	☐
2.17	Area of darkroom	☐	☐
2.18	Wall thickness	☐	☐
2.19	Patient identification system	☐	☐
2.20	Auxiliary room	☐	☐
2.21	Beam enclosure	☐	☐

2.22	Viewing box	☐	☐
2.23	Radiation area monitoring	☐	☐
2.24	Beam stops	☐	☐
2.25	Ports	☐	☐
2.26	List if there are any other……..		

3. Performance indicator parameters

3.0. Which quality control test parameters are checked out by the authority?

No.	**Quality control test**	**Checked out**	**Not checked out**
3.1	Voltage accuracy	☐	☐
3.2	X-ray timer accuracy	☐	☐
3.3	Collimation	☐	☐
3.4	Beam alignment	☐	☐
3.5	Output consistency	☐	☐
3.6	Leakage measurement	☐	☐
3.7	Half value layer	☐	☐
3.8	Light field congruence and greed alignment	☐	☐
3.9	Kilovolt peak(kVp)	☐	☐
3.10	Milliampere (mAs)	☐	☐
3.11	List if there are any other…….		

4. Inspection procedure

4.0. How do you agree on the implementation of each inspection procedure given below during inspection?

No.	**Inspection procedures**	Agree	Strongly agree	Disagree	Strongly di-agree
4.1	Proposing inspection program	☐	☐	☐	☐
4.2	Inspectors review application	☐	☐	☐	☐
4.3	Inspection protocol reviewed(required equipment selected, calibration confirmed , checking that it is functioning)	☐	☐	☐	☐

4.4	Inspectors' arrival at agreed time, showing their authority, entrance briefing….	☐	☐	☐	☐
4.5	View inventory of sources, make any measurement…	☐	☐	☐	☐
4.6	View records (inventory, occupational exposure…)	☐	☐	☐	☐
4.7	Exit briefing, inspectors inform operators major findings	☐	☐	☐	☐
4.8	Follow up on issue of non-compliances at specified time.	☐	☐	☐	☐

5. Calibration for testing, measuring and monitoring devices

No	**QUESTION**	Agree	Strongly agree	Disagree	Strongly disagree
5.1	Is there a routine calibration according to written procedures for your monitoring devices and personal dosimeters within the authority for inspection?	☐	☐	☐	☐
5.2	Does the authority have a procedure for controlling or preventing out-of-service tools/equipment from being used?	☐	☐	☐	☐
5.3	Do the calibrators use standards traceable to the known institute of standards (like ISO, NIST …) to calibrate the equipment used for inspection and testing?	☐	☐	☐	☐
5.4	Is there a set of written procedures for calibration within the organization?	☐	☐	☐	☐
5.5	Is the calibration being performed based on the frequency of calibration?	☐	☐	☐	☐
5.6	Is there preliminary examination and operation during calibration?	☐	☐	☐	☐