PATIENT RADIATION DOSE ASSESSMENT DURING FLUOROSCOPIC

PROCEDURES: A SURVEY TO PROPOSE LOCAL DIAGNOSTIC

REFERENCE LEVELS FOR SELECTED FACILITIES

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DECLARATION

This thesis is the result of the research work undertaken by Joana Otoo in the Department of Medical Physics, School of Nuclear and Allied Sciences, University of Ghana, under the supervision of Prof. Mary Boadu and Dr. Edem Sosu.

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ABSTRACT

The primary aim of this work was to propose local diagnostic reference levels for fluoroscopic examinations in some selected radiological imaging facilities in Ghana. The work also aimed at investigating the distribution levels of patient radiation dose received during fluoroscopic examinations for subsequent improvement of optimization. Prior to the starting of this research a series of quality control tests were performed using the Piranha kit to assess the machine output. The patient data and dose descriptors collected during the work included, gender, age, Kerma-Area Product, number of images and screening time. The Diagnostic Reference Levels (DRLs) was estimated for each facility using the 75% percentile. A total of two hundred and forty nine (249) patient dose data were collected for this study. DRLs was established for the frequently performed procedures which includes, hysterosalpingogram (HSG), urethrogram and barium swallow (BaS) examinations. The DRLs for KAP and screening time values estimated for hysterosalpingography was 6.0 $Gy.cm^2$ and 0.60 minutes, Barium swallow was 12.1 $Gy.cm^2$ and 1.4 minutes and urethrogram studies was 7.0 $Gy.cm^2$ and 0.7 minutes for Facility A respectively. The DRLs for KAP and screening time values estimated for hysterosalpingography was 4.1 $Gy.cm^2$ and 0.50 minutes, Barium swallow was 11.2 $Gy.cm^2$ and 1.2 minutes and urethrogram studies was 6.5 $Gy.cm^2$ and 0.7 minutes for Facility B respectively. The standard errors for KAP values from the proposed DRLs for facilities A and B were found to be 0.23 and 0.22 for hysterosalpingography examination, barium swallow studies was 0.89 and 0.58 and urethrogram examination was 0.35 and 0.28 respectively. There were variation of values observed across facilities and were attributed mainly to difference in protocols and techniques used in the two facilities.

Proposed KAP DRLs for hysterosalpingography, barium swallow and urethrogram examinations for facility B was lower than facility A by factors of 1.46, 1.08 and 1.08 respectively. Due to the variations in DRL values, standardization of protocols across facilities as a means to increase optimization is recommended.

DEDICATION

This research work is dedicated to

The Almighty Father, Jehovah Nissi, who has been my banner since starting of my MPhil studies.

Rev. and Mrs. Ked Otoo, my loving parents for their prayers, financial support and encouragements.

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LIST OF ABBREVIATIONS

DRL	Diagnostic Reference Levels
ICRP	International commission on Radiological Protection
ALARA	As Low As Reasonably Achievable
LDRL	Local Diagnostic Reference Levels
KAP	Kerma Area product
DAP	Dose Area Product
IAEA	International Atomic Energy Agency
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
IPEM	Institute of Physics and Engineering in Medicine
EC	European Commission
GI	Gastrointestinal
FAO	Food and Agriculture Organization of the United Nations
BSS	Basic Safety Standards
ICRU	International Commission on Radiological Units and Measurements
CT	Computered Tomography
RD	Reference dose

CD Cumulative dose

IDRL International Diagnostic Reference Levels

Gy.cm^2 Gray Centimetres Squared

μGy.m^2 Micro Gray Metres Squared

mGy .MilliGray

CTDI$_w$ Weighted Ct dose Index

ESD Entrance Surface Dose

DWP Dose-width product

FT Fluoroscopy Time

NCRP National Council on Radiological Protection and Measurements

NRA Nuclear Regulatory Authority

SNAS School of Nuclear and Allied sciences

RAMSRI Radiological and Medical Sciences Research Institute

GAEC Ghana Atomic Energy Commission

IVU Intravenous Urogram

BAS Barium Swallow

HSG Hysterosalpingography

MCU Micturating Cystourethrogram

CHAPTER ONE

INTRODUCTION

This chapter gives a summary of the background, the research objectives, the problem statement, the significance and scope of the research work. Outline of the thesis is also presented in this chapter.

1.1 BACKGROUND

Fluoroscopy is a real-time X-ray imaging technique that is used in the clinical settings, for diagnosis allowing the physician to assess dynamic functions of the human anatomy. It makes use of X-rays to achieve real -time moving images of an object (body), because there is the use of X-rays, a form of ionizing radiation, there are risks accompanying the use of fluoroscopy (Gingold, 2014). This is due to the fact that, the patient will be exposed to a continuous source of ionizing radiation, a fluoroscopy examination in general subjects a patient to a high dose of ionizing radiation. X-ray examinations involving fluoroscopy, mostly those done in cardiology and gastroenterology in addition to angiography and interventional procedures, contribute significantly to the overall collective dose due to medical exposure even if their rate of recurrence is moderately low (Aroua, 2007). Although Fluoroscopy procedures gives high doses to patients, the images created appear in real-time, allowing valuation of dynamic biological processes and guiding interventions which is a unique advantage. Therefore determining DRLs for diagnostic fluoroscopic procedures is challenging, due to the wide distribution of doses typically observed in these procedures, it is recommended that the relative complexity of the procedure is also taken into account (ICRP, 2007).

Foley et al. (2012) state that, establishing of investigative reference levels is to facilitate the optimization of the image quality and dose in radiology, according to the (ALARA) principle which states, 'As Low As Reasonably Achievable'. This is sustained by several national and international bodies for example the International Commission on Radiological Protection (ICRP). Erskine et al. (2014), approves that theory of DRLs is of central significance in the managing of radiation doses delivered to the patient in both interventional diagnostic radiology. The ICRP indicated that DRLs are recommended and set by professional organizations, apply to intake of pharmaceutical or dose to patients and call for local review if regularly exceeded. DRLs are not proposed as absolute dose limits, but relatively for the optimization of radiation doses and a means for quality assurance in diagnostic and/or therapeutic (interventional) procedures. Where procedures regularly exceed the DRL, investigation is necessary.

For fluoroscopically guided examinations, DRLs in principle, can be employed in the management of patient doses so as to avoid unnecessary stochastic effects. However, there is a wide range of distribution for patient doses even for a specific protocol. This is because of the complexity and extent of the fluoroscopic exposure for each procedure that is intensely dependent upon individual clinical conditions. Multiple diagnostic reference levels may be required to evaluate patient dose and stochastic risk effectively (ICRP 2001 and ICRP 2007).

Erskine, 2014 attributed challenges in attaining adequate sample sizes for fluoroscopic guided procedures due to the lack of ''standard'' procedures and ''standard'' sized patients. Thus, procedures are often not distinct, but grouped broadly together to attain realistic statistics. Currently there are no nationally or regionally recommended DRLs for

fluoroscopy procedures in Ghana. For this research, local diagnostic reference levels (LDRLs) at a major public hospital will be set for a wide range of detailed diagnostic fluoroscopic procedures. DRLs are set in terms of the practical dose qualities used to monitor practice. For fluoroscopy procedures kerma-area product (KAP) or dose area product (DAP) is the commended primary DRL quantity. Number of images and fluoroscopy time which are provided on the DAP console are recommended as valuable additional DRL quantities (ICRP 2001, IAEA 2007). DAP has been shown to correlate well using the total energy given to a patient, which is associated to the effective dose and therefore to overall cancer risk. The DRLs for fluoroscopic procedures for most performed examination or patient group are established on the basis of distributions of the typical (mean) doses detected in a national or regional survey, which are then compared with internationally recommended DRLs to provide investigation levels for uncommon practices (IPEM, 2004). This research determined doses received by patients undergoing fluoroscopic procedures and contribute data as reference essential in order to establish a reference of optimized fluoroscopy protocols for clinical usage in the hospital.

1.2 STATEMENT OF THE PROBLEM

Fluoroscopy varies from most X-ray imaging systems because the images produced appear in real-time. This process allows dynamic biological processes to be evaluated and helps to guide interventional procedures (Gingold, 2014). Though there is an increase in the use of fluoroscopy in medical settings a few research has been done on fluoroscopy procedures and assessment of patient dose which was conducted by Gyekye et al., 2009, Gyasi et al., 2013 and Mantebea et al., 2015 but no work has been done on establishing of

DRLs for fluoroscopy procedures in the facilities in Ghana. The ionising radiation (medical exposure) Regulations 2000 (IR(ME)R 2000), necessitate employers to establish DRLs and to undertake proper reviews if these are consistently exceeded.

Diagnostic reference levels (DRLs) or guidance levels are tools to optimize procedures and equipment use but currently there are no established DRL or guidance levels to guide the country's diagnostic radiology departments. IPEM (2004) commends that every nation should have or set its own DRLs, since practices and development in technology varies from one nation to another. Hence one country's DRL cannot be a good representation of another.

This research seeks to address the questions: (1) what is the estimated mean values of Dose Area product (DAP) by patients undergoing most performed fluoroscopic examinations in the facility. (2) Is there a substantial difference among DAP values received by patients in other countries? (3) Does values in the study show better optimization of practice in the hospital.

1.3 STUDY OBJECTIVES

The principal objective of this research was to separately propose LDRLs for Korle- Bu Teaching Hospital and Ridge Hospital. The specific objectives include investigating the dose distribution levels of patient radiation dose received during fluoroscopy examinations and identify if there is the need for optimization and perform inter-comparison studies of the data collected with international recommended DRLs, to minimize dose to patient that has no clinical significance to the procedure and finally to

give feedback to the facilities to encourage optimization of scan parameters in the hospitals.

1.4 SIGNIFICANCE OF THE STUDY

The outcome of the research will provide and improve a local distribution of observed results for general medical imaging tasks, by optimizing doses, since DRLs are recommended tools or guidelines in this regard for all practices involving medical use of ionizing radiation. Also the setting of DRLs will help narrow the range of values used for a particular examinations thus bringing about optimization.

Outcomes of this research will also enable suitable recommendations to be made to clinical authorities and the regulatory authority for the incorporation of DRLs into clinical practice and regulatory bodies. This research work is also expected to serve as a baseline for the establishment of the regional and national DRLs in fluoroscopy for Ghana.

1.5 SCOPE AND LIMITATIONS OF STUDY

This research was conducted at two Radiology Departments in the Greater - Accra Region, namely Korle Bu Teaching Hospital and Ridge Hospital.

 The research covered at least two hundred (200) patients undergoing fluoroscopically guided procedures above the age of 18 years, From December 2017 to April 2018. Only the most commonly performed fluoroscopy examinations of adults were included in this research. The major limitation of the study was that the researcher could not have early access to all the radiology departments in the hospitals with fluoroscopy machine. The data

collection time frame of four months was not enough to allow the inclusion of larger number of participants. Again, the frequent break down of machine at the Korle-Bu teaching hospital hence limiting the total number of participants that was surveyed. Although the number surveyed was enough to propose a DRL as specified by the EC, (1999) guideline. Thus, at least 10 patients in each examination group was achieved.

1.6 THESIS OUTLINE

This work is arranged in chronological order of five chapters. Chapter one provides a brief introduction to the research work, which includes the statement of problem, the objectives, the significance and scope and limitation of the research work. Chapter two reviews the current literature relevant to the research work. Chapter three focuses mainly on the materials and methods employed in the collection of patients dose data and the procedure for setting DRLs. Discussion of the results is given in chapter four. Whereas, conclusions are made with a comprehensive account of the estimated doses for current practice in the hospital, which will be used to propose the DRLs for the facilities before the establishment of a regional or national DRLs with recommendations and suggestions for further study is presented in chapter five.

CHAPTER TWO

LITERATURE REVIEW

2.0 INTRODUCTION

This chapter provides a summary of the relevant literature with respect to what is known about the topic of study and the breaches in knowledge that must be addressed. To adequately review the breaches, the following subsections are discussed: Background of Fluoroscopy, Medical exposure of patients, Benefits and detriments with fluoroscopy, Factors affecting dose in fluoroscopy, Dose measurements in fluoroscopy and Diagnostic Reference Levels for Diagnostic Radiology.

2.1 FLUOROSCOPY

Fluoroscopy is a real-time X-ray imaging technique that is used in the clinical settings. First, fluoroscopes consisted basically of a fluorescent screen and an X-ray source, in the middle of which the patient was placed as shown in figure 2.1. After the X-ray passes through the patient, the remnant beam impinges upon the fluorescent screen and produces a visible glow, which is directly observed by the practitioner.

In recent systems, the fluorescent screen is attached to an electronic device that transforms and amplifies the glowing light into a video signal appropriate for presentation on an electronic display. One advantage of the recent or modern systems compared to the former approach is that the operator of the fluoroscopy machine in order to observe the live image is not required to stand in close immediacy to the fluorescent screen. As a result, there is substantial decrease in dose to the radiographer and also there is minimum

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dose received by the patient, because of the amplification and total efficiency of the imaging system (Gingold, 2014).

Fluoroscopy varies from most X-ray imaging modalities because the production of images are obtained in real-time, which allows changes in biological processes to be evaluated and helps to guide interventional procedures (Gingold, 2014). Also it allows the observation of gross physiology, which is the physiology concerned with motion of the diaphragm, heart and transport of contrast media through the alimentary tract and out. The great significance of fluoroscopy lies in the opportunity for correlation of anatomy and physiology, abnormal or normal. Added value amasses through the ready adjustment of the patient's position under fluoroscopic observation. This serves to localize an irregularity in relationship to other structures and to establish which positions will be useful in radiography. Additionally, procedures such as the bronchial tree with contrast medium or progressive filling of sinus tracts may need fluoroscopic guiding to ensure that films will be exposed at the proper time, that is, neither incomplete outlining nor overfilling. Fluoroscopic systems produce and display images at very high frame rates, usually 25 or 30 series of frames in one second, making it difficult for the human sight to differentiate frame-to-frame variations and continuous movements without visual trace (Gingold, 2014). The radiation per image should remain reasonably low during diagnostic radiography. The dose should be within 0.1% in order to get a high frame rate while minimizing cumulative radiation dose (Gingold, 2014).

Fluoroscopic image appears with an inverted grayscale as compared to conventional radiographs (Gingold, 2014).

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Figure 2.1: Schematic representation of a fluoroscopy system

Source: (Gingold, 2014, Modern Fluoroscopy Imaging Systems)

2.1.1 FLUOROSCOPY TECHNIQUES AND SOME PROCEDURES

Fluoroscopy examination and techniques do not only differ from each other but are also dependent on the radiologist. A radiologist can develop his/her own procedure for a particular examination. All these procedures involve teamwork between the radiographer and other specialists; hence familiarity with the routine is vital if the procedure is to be accelerated.

Some of the examinations requiring the use of fluoroscopy to investigate the gastrointestinal (GI) system are usually; barium meal, barium swallow, barium enema and enteroclysis (Gyasi, 2013).

Chest fluoroscopy regularly precedes a gastrointestinal examination done with the patient in supine position if the clinical condition of the patient undergoing the examination permits. It involves mainly of examining the various parts of the chest in various stages of respiration and projections, a paste of barium is swallowed which shows the outline of the esophagus. The upper gastrointestinal fluoroscopy is also performed first with the patient upright and then horizontal. A barium swallow is an imaging examination that uses X-rays to look at the upper GI tract; also this test may be performed as part of an upper GI series. Barium swallows are very common procedures for the diagnosis and treatment of swallowing disorders (Slovarp et al., 2018).

A myelogram is another fluoroscopic diagnostic imaging examination generally performed by a radiologist (Netter, 2014). Fluoroscopy is used in myelogram which is performed to detect tumor, problems with the spine or an infection. This procedure focuses mainly on the central nervous system structures within the spinal cord. Another surgery in which fluoroscopy is used is retrograde pyelography which focuses mainly on the urinary tracts and reproductive systems of males.

Hysterosalpingography (HSG) is also one of the commonest procedures that requires the use of fluoroscopy. HSG has traditionally been the first line of investigating the anatomy and outline of uterine cavity along with fallopian tube and its patency (Maiti and Lele, 2018). Fluoroscopic procedures are performed by other subspecialty services, such as gastroenterology, cardiology, and orthopedics and from the above stated uses of fluoroscopy, it clearly indicates that fluoroscopy is a valuable tool which helps

enormously in the imaging of the human body and without it many medical procedures wouldn't have been performed in the medical field.

2.2 MEDICAL EXPOSURE IN DIAGNOSTIC RADIOLOGY

Medical exposure is acquired by patients due to radiation used in medicine or allied health for diagnostic and therapeutic purpose. The use of medical radiation is widespread in the world examples in CT and fluoroscopically guided examinations. Medical radiation is the major contributor of artificial ionizing radiation. It contributes about 90% of all man-made sources (UNSCEAR, 2010). According to Parry et al., 1999, medical exposure accounts for more than 14% (0.4 mSv) of the yearly average dose of radiation. FAO et al., 1996 reported that, The International Basic Safety Standards defines medical exposure to be exposure acquired by patients due to their personal dental or medical diagnosis or treatment; by none occupationally exposed individuals, knowingly though voluntarily assisting in the comfort and support of patients. Radiological protection in medical exposures involves weighing the therapeutic or diagnostic benefits against radiation detriment and optimization by keeping radiation dose to a minimum to produce required purpose and guidance level (ICRP, 2007). According to the IAEA, 2014, no patient shall be administered a therapeutic or diagnostic medical exposure except upon recommendation by a medical practitioner. In medical exposure, the benefits must offset the associated risks of the procedure. Therefore medical imaging equipment and other sources must be well-defined for clinicians and their patients.

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2.2.1 PATIENT EXPOSURE IN DIAGNOSTIC RADIOLOGY

Diagnostic examinations or procedures by X-ray have been used in medicine settings for over a century, even though its complexity is increasing. During the last Twenty years to be specific, technological revolution of medical imaging has been experienced and it has allowed the improvement of imaging of the human anatomy (Hendee et al, 1993).

Ayad et al, 2000 and Faulkner et al., 1991 reported that diagnostic radiology and nuclear medicine contributed about 88% of collective dose from man-made sources in the United States. Steady advances in the quality of X-rays images and in patient protection have guaranteed a continuing role for diagnostic X-rays in health care, even though other modalities for diagnosis are becoming ever more available, such as fluoroscopy .Consequently, it is essential that X-ray examinations are performed using techniques that keep the patient's exposure very low as possible but still meet the purposes of the medical examinations (ICRP, 1991).

2.2.2 PATIENT RADIATION DOSE MANAGEMENT GUIDELINES

Miller, 2008 reports the need for intra-procedural management, pre-procedural planning and post-procedural care in radiation dose management. The informed approval process provides the representatives of the patients and the patients with adequate information to allow them make a suitable conclusion concerning a proposed examination or procedure. The guideline ensures that elements of radiation of the outlined approval processes are orderly applied. The operator assesses the radiation data all through the process of the procedure. The user has the responsibility to be well knowledgeable of dose levels in order to consider the risks or benefits of continuing a procedure.

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Involvement of the radiologist in the follow-up and monitoring of patients at risk is essential in the management of radiation-induced injury or referral to another specialist (Miller, 2008).

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2.3 RISKS AND BENEFITS ASSOCIATED WITH FLUOROSCOPY

The radiation used in fluoroscopically guided procedure is known to cause the risks of erythema. These may cause persistent pain and damages to the skin (Miller et al, 2012). Risks associated with radiation exposure may also be related to the cumulative number of X-ray examinations and treatments over a long period of time. Where fluoroscopy is medically required, the ALARA principle must be employed.

There is a danger for allergic reaction if the patient is allergic to the contrast dye being administered. Patients who are sensitive or allergic to medications, contrast media, iodine, or latex should report to their clinician. Also, patients with kidney problems or kidney failure should report to their clinician. There may be other risks depending on your specific medical condition. Medically, during a fluoroscopy procedure clinical benefits provided must offset the associated risk as a result of the radiation. When used by radiologic technologists and board certified radiologists, fluoroscopic examinations provide significant diagnostic benefit to patients and is helpful in guiding treatment plans (ICRP, 1991).

2.4 FACTORS AFFECTING PATIENT DOSE IN FLUOROSCOPY

The radiation dose depends on the type of the patient size, the type of examination, the equipment and technique, and many other factors (Mahesh, 2001).

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2.4.1 The patient size

Fluoroscopy is limited to a category of patients. A patient's weight must not exceed the table weight limit, which is generally 350 pounds but differs from one manufacturer to another. The maximum clearance between the table and image intensifier is approximately 45 cm. Radiation dose is severely influenced by the patient's body habitus for bigger patients. The amount of tissue that will reduce the quantity of X-rays to half the original number is referred to as half value layer, therefore at 60 kV, an increase in patient thickness by 3.5 cm doubles the number of X-rays which is essential to penetrate the patient. It is important to ensure that the protocol selected prior to the procedure, which sets variables such as automatic brightness control and tube current, is appropriate for both the patient and procedure (Huang, 2014).

2.4.2 Type of examination

The time spent on an examination is determined by the type of examination being performed or the part of the patient's body that's to be examined or treated. Management of patient exposure involves clinical monitoring of patient doses not only measurement of these rates. (Mahesh, 2001). Monitoring the length of fluoroscopy examination has been recommended as part of an overall reduction in both fluoroscopy times and radiation exposure (Boix, 2011).

2.4.3 The equipment and technique

The performance of the fluoroscopy system with respect to radiation dose is best characterized by the skin entrance exposure rates and receptor entrance exposure, which at regular intervals should be assessed. Appropriate training of fluoroscopic operators, use of various dose reduction techniques and understanding the factors that influence radiation

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dose may allow effective management of patient dose. Skin doses may be reduced by using discontinuous exposures, last image hold, grid removal, beam filtration, pulsed fluoroscopy, dose spreading and other techniques for dose reduction (Mahesh, 2001).

2.5 PATIENT-SPECIFIC FACTORS AFFECTING RADIATION DOSE LEVEL IN FLUOROSCOPY

2.5.1 Patient Position

Patient positioning during a fluoroscopy examination is very vital in optimizing patient radiation dose, visualizing anatomy and enhancing image quality. Radiation exposure is influenced by passage through the body. Therefore, positioning which results in high dose rates, example tube angulation, should be used only when totally essential.

The post-operative patient is a unique challenge for radiologists. Prone position for a patient following laparotomy may not be feasible. In such cases, patient comfort and safety must be weighed against the radiation dose and technical success of the procedure (Huang, 2014).

2.5.2 Patient Cooperation

The cooperation of the patient is necessary during a fluoroscopy procedure. Patients are not only expected to suspend respiration for periods up to 10-20 seconds, but also they may be asked to remain motionless during the procedure. Any patient movement may create motion artifact, which may cause the user to increase the fluoroscopic frame rate or repeat the imaging, thus increase in the radiation dose. The patient's ability to cooperate

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throughout the exam should be assessed during the pre-procedure consent with anesthesia consultation, if required (Huang, 2014).

2.5.3 Pregnancy

If Fluoroscopically-guided procedures may be required during pregnancy a consent statement must be given. As required for all medical procedures, benefits associated with fluoroscopically-guided procedure must offset the unforeseen exposure risks to the fetus and mother. The extent of the risk to the fetus is dependent on the fetus' absorbed dose and gestational age.

Radiation risks are most prominent during pre-implantation, the development of organs and during the first trimester. The techniques required for the reduction of radiation dose to the fetus are usually the same radiation reduction techniques used elsewhere. Additional considerations are to consider use intravascular ultrasound, increase tube voltage and decrease tube current (Huang, 2014).

2.6 RISK ASSESSMENT IN DIAGNOSTIC RADIOLOGY

Diagnoses in radiological examinations generally lead to partial body irradiation. The required accuracy used in dosimetric measurements and the estimation of absolute risks during radiology examination of adults is 20%. An accuracy of 7% is more appropriate where deterministic effects are expected and for estimating relative risks associated with different procedures. It should be noted that one technique may produce a lower dose compared to another and thus a reduced risk of radiation induced cancer. Evidence shows that there is a higher risk associated with a given absorbed dose to children as compared

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to adults. It is believed that an uncertainty of 7% in dosimeter reading is adequate for assessing the potential risk for both adults and pediatric examinations. During pregnancy the embryo or fetus is assumed to be at about the same level of carcinogenic risk as children. In addition, developmental effects in unborn children are vital. These include growth defects, disturbances and lethal effects. Significant side effects of radiation risks occur during the gestation period. Again, a 7% uncertainty in the measurement is much less than other uncertainties in the estimation of dose to a fetus and this value should be sufficient (Alm-Carlsson et al, 2007).

2.7 DOSE MEASUREMENT IN FLUOROSCOPY

Radiation-induced effects are separated predictably into stochastic and deterministic effects. When the patient's history of radiation exposure is not well-known, the possibility of the effects cannot be predicted accordingly. Therefore it is necessary to keep patient radiation dose records. Recording and monitoring dose data of patients can also be valuable for improving patient safety and quality-assurance purposes. There are various ways of recording and measuring patient radiation dose (Miller et al, 2004). Fluoroscopic Interventional procedures are measured with four established metrics. These are Reference air Kerma, Kerma–area product; Peak skin dose and Fluoroscopy time (Miller et al., 2010). Measurement of dose per image and fluoroscopic dose rate are used in estimation of patient dose from the fluoroscopic images taken and the fluoroscopic time used. Number of fluorography images and fluoroscopy time are the seldomly useful measures of patient dose (Miller et al., 2004). The ICRU recommended KAP for patient

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monitoring during fluoroscopy procedures, because it correlates with the operator and staff dose and also shows stochastic risks for patient.

2.7.1 PATIENT RADIATION DOSE METRICS FOR FLUOROSCOPY

Radiation dose estimation in fluoroscopic procedures has four special developed metrics. These include:

2.7.1.1 Peak Skin Dose

This is maximum dose to the patients' skin during an examination. The primary X-ray beam and scatter are the contributors of the peak skin dose. It is quantified in grays (to soft tissue) (Miller et al., 2004).

2.7.1.2 Reference Point Air Kerma

This is the air kerma accumulated at a specific point in space relative to the fluoroscopic gantry during a procedure. Reference point air kerma or cumulative dose exclude**s** backscatter. It is quantified in gray (Gy) (Miller et al., 2012).

2.7.1.3 Fluoroscopy Time

This is the total time that the fluoroscopy is used during interventional procedure or an imaging (Miller et al., 2004). The measurement of the fluoroscopy time is done from the starting to the ending of the production of the X-ray.

2.7.1.4 Kerma-Area-Product (KAP)

DAP is the abbreviation used for this quantity in earlier publications. The integral of air kerma across the entire X-ray beam emitted from the X-ray tube. Kerma-area-product formerly Dose Area-Product serves as a surrogate measurement for the entire amount of

energy delivered to the patient by the beam. Kerma-area-product is measured in $Gy \cdot cm^2$. Kerma area- product is usually measured without scatter (Miller et al., 2010, Stecker et al., 2009).

2.8 SETTING OF DRLs

Health and Radiation protection authorities in association with professional medical societies are responsible for setting or establishing diagnostic reference levels. DRLs are representations for a distinctive practice in a region or country. This is because procedure and equipment protocols differ among different institutions in a country or region, it is an acceptable practice to set regional or national diagnostic reference levels (ICRP, 1996). Establishing of reference levels and dose measurement levels for patients from radiologic procedures two methodologies are used, these are phantom-based dosimetry and patient-based dosimetry (Protection et al., 1999). The usage of a phantom has the benefit that only single or double exposures would be required for each radiologic facility and for each type of examination though it has limitations of giving the clinical implication and the same phantom must be used for uniformity. Patient sample selected should match the mean body indexes if patient dose measurements are used, example patient height and weight or body mass to the pre-defined "standard-sized" patient. The patient sample to be used should be sizeable enough, 20 patients at least within a predefined range of body indexes to certify that averaged values characterize the distinctive practice in the centre or facility. DRLs are established independently for adult patients and groups of pediatric patients based on their body size, weight and age.

To set diagnostic reference levels, four stages are useful. First of all, the most commonly done routine diagnostic examinations are identified for each kind of examination, reference dose quantity or quantities are accepted and identified and measuring method is standardized. Dose measurements are performed succeeding the standardized methods; mean dose from the patient sample or phantom measurements is estimated for each examination and set as a typical dose, usually by a medical physicist that is what must be done secondly, in each imaging facility. Thirdly, typical doses from all or a representative sample of facilities in the country or region are collected and statistically analyzed; diagnostic reference levels are established on doses measured in several types of hospitals, clinics, and practices representing the typical practice in the country or region. Lastly, National and regional diagnostic reference levels are usually established at the 75% percentile of the distribution of typical doses for the sample for diagnostic radiology; for nuclear medicine, diagnostic reference levels are usually established as values of administered activities needed to achieve acceptable or good image quality (Vassileva et al., 2015).

2.8.1 GUIDELINES FOR SETTING DIAGNOSTIC REFERENCE LEVELS

Institute of physics and Engineering (IPEM) 2004, states that the principles guiding for setting DRL are: (i) the local, regional and national objective must be clearly stated, with the descriptions and specifications of technical conditions surrounding the clinical aspect of the imaging task. (ii) The chosen value for the DRL must be set on significant local, regional and national data. (iii) There must be a practical way of determining the quantity to be used for the setting of a DRL (iv)The quantity used for setting the DRL must be an

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appropriate quantity of the relative change in patient doses and therefore, of a relative change in patient risk for the given imaging task. (v) The means in which the DRL is to be use in practice must be clearly illustrated (Do, 2016). It is obvious that DRL can be used as a standard upon which medical exposure can be evaluated practically. An appropriate parameter derived from the exposures of a sample of standard sized phantoms or patients is compared to the DRL to identify unusual practice. The 97/43 Euratom proposes that, a medical practice is revised against the local value of the DRL then a practice leading to an 'outlier' in the relevant distribution can be identified. It must therefore be noted that, DRL values themselves are subject to refinement as medical practices evolve (IPEM, 2004).

Note that patient dose is the major determinant for the acceptability of a set DRL value. However, in the case of an under-exposure, the proposed clinical efficacy is not attained and the patient is given unnecessary burden of radiation. In future, possibly, DRL values should incorporate upper and lower limits.

In summary, DRL is established for a standardized procedure or examination, a standard phantom or for groups of standard sized patients.

2.8.2 FEATURES OF DIAGNOSTIC REFERENCE LEVELS

The most significant features of Diagnostic Reference Levels are that, they are not considered as dose limits; for occupational exposures. As opposed to dose limits, DRLs are not used in constraining patient exposures since a higher dose may be required to compensate for the patient's body weight and size. DRLs do not represent a boundary

between good and bad medical practice. However, DRLs do assist in investigating unusual high or low doses in facilities. Hence DRLs are tools for promoting the process of optiization in clinical settings (Vassileva et al, 2015).

ICRP, 1996 stated that Diagnostic Reference Levels is a form of investigation level, applied to a measurable quantity, usually tissue-mimicking material or the absorbed dose in air at the surface of a representative patient or standard phantom.

Procedure protocols differ among facilities in a country or region because of this, separate or different DRLs have been set for each region or country. Diagnostic Reference Levels are set for standard phantoms or for patients with standard size body in highly reproducible and easily measurable dose metric; they should not be established as effective doses. When setting DRLs, Image quality must be considered (Vassileva et al, 2015).

The measurements of dose are initially done with previously standardized methods for each category of examination when setting Diagnostic Reference Levels. The 75th percentile is generally used to set DRLs of the typical dose distribution for patient measurement or phantom.

2.8.3 DIFFERENCES BETWEEN DOSE LIMTS AND DIAGNOSTIC REFERENCE LEVELS

Diagnostic reference levels are not considered to be dose limits. It is possible to exceed DRLs depending on clinical demands unlike dose limit (ICRP, 1996). DRLs serve as a guide to recognize facilities which irregularly uses high doses in a particular radiological examination. Dose limits is used in public and occupational exposure but not to medical exposure of patients because patient care may be compromised by the limits. Contrary to

occupational dose limits, DRLs cannot be applied to each and every patient, due to differences in body mass between the patient and that of a reference patient (Vassileva et al, 2015).

2.9 DOSIMETRIC QUANTITIES USED IN THE ESTABLISHMENT OF DIAGNOSTIC REFERENCE LEVELS

Table 2.1 Dosimetric Quantities used in the establishment of DRLs.

Modality	Doimetric Quantity	Abbreviation	Unit
Computered Tomography	Weighted Ct dose Index, per Slice Or Rotation.	CTDIw	mGy
	Dose-Length Product, per Examination	DLP	mGy.cm
Angiography And Interventional Radiology	Dose-Area Product, per Examination	DAP	$Gy.cm^2$
	Number Of Images, per Examination	-	-
	Fluoroscopy Time, per Examination	-	min
Fluoroscopy	Dose-Area Product, per Examination	DAP	$Gy.cm^2$
	Fluoroscopy Time, per Examination	-	min
Dental Radiology	Entrance Surface Dose, per View For Intra-Oral Exminations (Apical, Bitewing)	ESD	mGy
	Dose-Width Product For Opg	DWP	mGy.mm
Mammograpy	Air-Kerma at the breast surface, Per View	ESAK	mGy
	Entrance Surface Dose, per view	ESD	mGy
Radiography	Dose-Area Product, per Examination	DAP	$Gy.cm^2$

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2.9.1 DOSIMETRY METHODS USED TO SET DRL FOR FLUOROSCOPY

Dose area product (DAP) or Kerma area product (KAP) meter is used in to measure patient dose during fluoroscopy examinations. The meter is comprised of an ionization meter which is attached to the collimator of the X-ray tube and it measures the patient's dose in Gray. Square centimeter ($Gy.cm^2$) which is proportional to the beam area and incident air kerma, the backscatter is not measured by the unit unfortunately. The measure of backscatter is important in higher dose examinations such as cardiac and vascular interventional procedures. However, during fluoroscopic and radiographic examinations such as barium meals, angiography and on mobile image intensifiers the meters (KAP or DAP) are used (Edmonds, 2009).

Kerma area product (KAP) is the integral of air kerma across the X-ray beam. Therefore, it is a function of field non-uniformity effects, such as anode-heel effect, and the use of partial transparent beam-equalizing shutter. KAP meters make use of large-area transmission ion chambers between the patient and final collimator shutters. An algorithm in real-time that uses the X-ray generator settings combined with collimator data can also be used to determine KAP (Balter, 2006). Similar KAP values are observed with low skin doses and large fields as with high skin doses and small fields. A reasonable estimation of field size can be done for a number of clinical procedures. This is useful when obtaining a rough value of skin dose or a field size of interest. However, KAP does not provide information concerning the spatial distribution of the skin surface entrance radiation. It yields an overestimate of the likelihood of a higher than expected deterministic threshold when there is substantial motion during the examination. Approximations the beams motion can be obtained for usual cases. Number of images and fluoroscopy time which

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are provided on the console of the machines are recommended as valuable additional DRL quantities (Balter, 2006).

Fluoroscopic Image; a digital flat panel are as image receptor or an image intensifier to record a single image called fluoroscopic image. A digital angiographic "run" consists of a series of fluoroscopic images (Stecker et al., 2009).

Fluoroscopy Time (FT); the total time that fluoroscopy is used during an interventional procedure or imaging. Measurement of the fluoroscopic time covers the period from the initial to the end of X-ray production (beginning of the initial pulse to the end of the final pulse). It excludes the time for fluorography. Contemporary fluoroscopy machines incorporate a 5-minute time counter (Miller et al., 2012).

Fluoroscopic time is an old metric used in the clinical situation for radiation management. Even with readily available information from the X-ray systems, fluoroscopic time (with or without a cine runs or count of the number of images) is still a dose metric generally employed in a number of interventional fluoroscopy laboratories. The fluoroscopic timer does not offer an adequate skin surface dose estimate in the interventional laboratories for numerous reasons. The most observable of these is the lack of information concerning fluoroscopic dose rate. Additionally, fluorographic contributions are ignored. Finally, beam's entrance ports are not accounted for in the set-up (Balter, 2006).

2.10 APPROACHES USED FOR SETTING DIAGNOSTIC REFERENCE LEVELS

When a dose normally used at a facility is higher than the DRL without contributing to the clinical requirements, review must be carried out to decide whether there has been

dose optimization. In general, the protocols or procedures and equipment performance are examined, the reason for higher doses must be ascertained and correct actions implemented to bring about optimization. After the implementation measures, the usual dose at the facility should be continually monitored to ensure that it is below Diagnostic Reference Level. NCRP recommends that protocols and practice must be periodically reviewed, least annually to ensure that the protocols and practices have not unconsciously changed periodically (NCRP, 2012). Initially, protocols for new machines should be evaluated before using the equipment for patient's examinations. This must be repeated in intervals of three to six month to evaluate its performance in accordance with the required standards.

The establishment of DRLs is for dose optimization and not dose reduction. If a necessary examination does not give the required information clinically as a result of low dose leading to inadequate image quality, then the patient has been exposed to unnecessary burden of radiation. Practically, the use of the essential dosage, including to the margins is applicable.

In medical situation, it is a requirement to first check a facility's doses with DRLs in the effort of optimization. However, in a situation where a dosimeter is not available, the dose comparison may be difficult. A possible way to overcome this problem with the use of values calculated using Non Dosimeter Dosimetry or conventional software for determining radiation dose or values shown on equipment as a substitute. Additionally, systems must be made in which phantoms or dosimeters owned by the allied institute or other facility can be used (Moris et al., 1997).

DRLs may also be established from inter-comparison bearing in mind that they are based on 'standard' patients and as such caution is necessary because the size or weight of Western and Ghanaian patients obviously vary.

CHAPTER THREE

MATERIALS AND METHODS

This chapter outlines the study site, the materials and methods, the sampling size and the study population, inclusion and exclusion criteria, data collection, data analysis used in the study and ethical clearance are also presented.

3.1 SELECTION OF STUDY SITES

Before the start of the research, a letter was sent to the Nuclear Regulatory Authority (NRA), Ghana requesting for the number of licensed fluoroscopy facilities in the Greater Accra Region. A total number of seven licensed facilities were reported. Upon further inquiries, only three of these facilities were functional at the time. Introductory letters from the Department of Medical Physics, Graduate School of Nuclear and Allied Sciences (SNAS) and Radiological and Medical Sciences Research Institute (RAMSRI) of the Ghana Atomic Energy Commission (GAEC) were sent to the three facilities requesting their involvement in the research (APPENDIX I) and (APPENDIX II). However, one facility declined the request and as such the study was conducted at the Korle-Bu Teaching Hospital and Ridge Regional Hospital. This was done for patients undergoing fluoroscopy examinations for the period December 2017 – April 2018. Data collected from the facilities were coded to ensure confidentiality and anonymity of the facilities (APPENDIX V).

3.2 RESEARCH MATERIALS

3.2.1 Piranha Quality Control Kit

A calibrated Pirahna kit as shown in figure 3.1, from the Ghana Atomic Energy Commission, Type: Pirahna 657 with serial number: CB2-15020088, calibrated in March 11, 2015 was used to perform some quality control tests on both Facility A and B machines.

Figure 3.1: Piranha Kit

3.2.2 Fluoroscopy Machines

3.2.2.1 Characteristics of Fluoroscopy machine at Facility A

Figure 3.2 shows a SHIMADZU CORPORATION systems fluoroscopy unit model (CE 0197) with serial number 3Z0FF7D22045, Collimator type R- 30H and manufactured in Japan in February 2012 was used for the study. The machine operates at a maximum tube

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voltage 150 kV and has an Al equivalent of 1.0 mm. The fluoroscopy system is powered

by Generator which was manufactured in April 2013, with serial number 130451, model:

Servo-REG and Power 75 W.

Figure 3.2: Fluoroscopy Machine at Facility A

3.2.2.2 Characteristics of Fluoroscopy machine at Facility B

Figure 3.3 shows a Ralco s.r.l fluoroscopy system unit BEAM LIMITING DEVICE

series: R 302/A DHHS, model: R 302 MLPI/A DHHS, serial number: 1603990 with a

minimum inherent filtration Al equiv. of 1 mm Al/75 IEC 60522/1999 fluoroscopy

system powered by generator was manufactured in March 2016 in Italy. It has an X-ray

rating up to 150 kVp and supply 24 V/DC, 8 A, 50/60 HZ, 12V DC, 0.5. It has a VOLTS

AC 400, AMPS AC 155, FREQ: 50/60 Hz and PHASE: 3, with model number:

VZW2930FD2-28 and serial number: AM19646C16.

Figure 3.3: Fluoroscopy Machine at Facility B

3.2.3 KAP Meter

Figure 3.4 shows a calibrated kerma-area product meter, KERMA X-plus iba dosimetry with serial number: 01A04042 and model: 120-131 HS. It has an aluminium thickness (less than 0.01 mm, voltage: 15- 20 V and current: 80 mA) and connected to kerma x-plus iba (model: 120-210 and serial number: 01E004774) which gives the values of the KAP measurements was used for the work.

Figure 3.4 KERMA X-plus iba dosimeter (KAP meter)

3.2.2 RESEARCH METHODS

Quality control measurements were performed to ensure that the X-ray equipment were consistent in their performance. The procedures performed were; Timer Accuracy, kVp Accuracy, mAs Linearity, Collimation Accuracy, Half value layer measurements, Tube Voltage, Exposure and Exposure Time Reproducibility. The research was done at two public hospitals, located in the Greater Accra Region, between December 2017 and April 2018. A prospective quantitative research method was adopted to obtain frequency of fluoroscopic examinations in the Radiology Departments. Some of the fluoroscopy examinations performed included: barium studies, micturating cystourethrogram (MCU), hysterosalpingogram (HSG), and urethrogram. These were the common examinations performed at the two Facilities. KAP data values were obtained from the machine's console after each examination. No additional adjustments or scan protocols were used for this research, to ensure the study reflected the actual normal practices in all the facilities.

3.2.2.1 MEASURING OF DOSE USING KAP METER

Two KAP meters were used in this research, one built-in and an external KAP.

3.2.2.1.1 Machine with built-in KAP meter

The KAP meter was built into the exist surface of the collimator housing of the X-ray machine. The KAP meter was mounted into the machine by the manufacturer and does not use one that was externally mounted by the researcher. The KAP meter does not disturb the examination and gives real time information which was displayed on the KAP console.

3.2.2.1.2 Machine without a built-in KAP meter

A calibrated KAP meter, Kerma XPlus iba dosimetry (model 120-131 HS, serial number: 01A04042) was used to measure the KAP for the facility without built-in KAP meter.

In use, the KAP meter with all associated electronics was placed perpendicular to the central beam axis and in position to completely intercept the entire area of the X-ray beam. The radiation output depends on the thickness of the patient, the part of the body being radiographed, the selected technique factors, number of radiographs taken per examination and the fluoroscopy time used. KAP meter readings are displayed in real-time in $\mu Gy.m^2$ by a monitor. KAP measurements are a valuable and convenient method for dose assessment, especially for fluoroscopy.

3.3 STUDY POPULATION

Data for adult patients undergoing fluoroscopy examinations was collected. The commonly performed fluoroscopy examinations of adults were used to propose local diagnostic reference levels in this research work.

3.4 SAMPLE SIZE

At least 10 patients per examination were required for this research work. Surveys to establish diagnostic reference levels should be based on measurable patient data (Vano et al., 2017). Data should represent at least 10 patients per examination for each procedure. A total sample size of 249 patients was collected. The distribution of patient sample for the study sites is described in table 3.1.

Table 3.1: Distribution of Patient Sample

FACILITIES	NUMBER OF PATIENTS
FACILITY A	111
FACILITY B	138

3.5 INCLUSION AND EXCLUSION CRITERIA

3.5.1 Inclusion Criteria

The target group employed in this project included:

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1. Only adult male and female patients (18 years and above) undergoing fluoroscopy examinations.

2. Authorized fluoroscopy facilities by the Nuclear Regulatory Authority, Ghana.

3.5.2 Exclusion Criteria

The non-target group and materials excluded from this study included:

1. Pediatric patients.

2. All facilities with fluoroscopy machines that are not functioning.

3.6 DATA COLLECTION

A data collection sheet (as indicated in APPENDIX 1V) was designed to record extracted data for the research work. Dose data of the patient was obtained from the KAP meter that was fixed on the fluoroscopy machine and other additional information was also obtained from the machine's console. Other information of the patient that was recorded included the weight, gender and age. Patient selection for the studies was done at random and did not follow a particular pattern.

3.7 DATA ANALYSIS

Statistical analysis was performed using the Microsoft excel 2013 version. The results of the data were presented in descriptive statistics of tables, charts and graphs. In other to calculate the 75th percentile the method of weighted mean was used. Inter-Comparison studies were done between KAP meter values from the two facilities. DRLs values

obtained were compared with the data recommended by internationally established DRLs (Hart et al., 2012).

3.8 ETHICAL ISSUES

Ethical approval was sought from the ethical and protocol review committees and heads of the facilities where the study were undertaken. To ensure confidentiality and anonymity of patient information leading to patient identity, facilities were coded with Roman numerals. There was no need to recruit patients separately for this research. The information needed was mostly obtained during the medical examination, therefore, there was virtually no vulnerability to the patient.

CHAPTER FOUR

RESULTS AND DISCUSSIONS

4.0 INTRODUCTION

In this Chapter, the results from the research work conducted at the two facilities are presented in the form of charts and tables. Discussions and comparison of the results at the facilities and with relevant literature has been presented.

4.1 QUALITY CONTROL MEASUREMENTS

Table 4.1 represents the summary of results for quality control tests performed on Facilities A and B. The results were found to be within the acceptable criteria according to well established international protocols such as the AAPM.

Table 4.1: Summary of Quality Control Tests Results on Facilities A and B

Parameter	Deviation facility A	Deviation facility B	Acceptable Deviation	Remarks
Timer Accuracy	4.7%	5.3%	$\leq \pm 10.0\,\%$	Pass
kVp Accuracy	-3.1 %	-0.7%	$\leq \pm 6.0\,\%$	Pass
mAs Linearity	0.03	0.06	≤ 0.10	Pass
Collimation Accuracy	6.1 mm	5.4 mm	≤ 10.0 mm	Pass
HVL @ 80 kVp	3.17 mm Al	3.82 mm Al	≥ 2.3 mm Al	Pass
Tube Voltage Reproducibility @ (10 mAs, 80 kVp)	0.3 %	0.1%	COV $\leq 5.0\,\%$	Pass
Exposure Reproducibility @ (10 mAs, 80 kVp)	0.2 %	0.1%	COV $\leq 5.0\,\%$	Pass
Exposure Time Reproducibility @ (10 mAs, 80 kVp)	0.03 %	0.9%	COV $\leq 5.0\,\%$	Pass

4.2 PATIENT DEMOGRAPHIC DATA

A total of 111 patient data was collected at Facility A, of which 55.86% were HSG examinations, 21.62% for urethrogram examination, 10.81% for barium swallow (BaS), micturating cystourethrogram (MCU), intravenous urogram (IVU) and fistulogram all had 2.7%. Barium enema had 1.8%, sialogram and barium follow through had 0.9% each as shown in figure 4.1. Some of the examinations at Facility A did not meet the minimum recommended number of patients (at least 10) required to propose a DRL for each examination type within the data collection period. However, some of the fluoroscopy examinations met the requirement and DRLs were proposed from this study.

Figure 4.1: Percentage Distribution of Fluoroscopy Examination Types at Facility A.

For Facility B, a total of 138 patient data was collected, out of which 53.62% were HSG examinations, 12.32% representing urethrograde, 15.94% was recorded for barium swallow (BaS), MCU and fistulogram 3.62% each, barium enema had 6.52% and barium meal recorded 4.35% respectively.

Figure 4.2: Percentage Distribution of Fluoroscopy Examination Types at Facility B

From Figure 4.1 and Figure 4.2, HSG examinations had the highest number of patient data at facilities A and B which represented 55.86% and 53.62% respectively of all the examinations respectively. This might be due to the fact that a lot of women visit the Hospital for fertility treatments. For facility A HSG examinations were followed by urethrogram and then barium swallow. These are the examinations that passed the

minimum requirement for setting a DRL for Facility. For Facility B, barium swallow had the second highest patient data followed by urethrogram, these examinations also had the recommended number of patients data needed to propose a DRL.   The remaining examinations which are fistulogram, MCU, barium enema, sialogram, IVU, barium follow through and barium meal recorded a lower number of patients and did not meet the recommended number of patient data to be used for proposing DRLs.

4.3 GENDER PERCENTAGE DISTRIBUTION

Figure 4.3: Gender percentage distribution for the most Performed Fluoroscopy examination at Facility A.

From Figure.4.3, gender percentage distribution was done for the most performed fluoroscopy examination at Facility A. This data analysis was based on ninety- eight (98) patient data out of a total of one hundred and eleven (111) patient data at Facility A .The examinations considered for this analysis were HSG, barium swallow and urethrogram examinations. Sixty-two (62) patients underwent HSG examination of which all were female while for Urethrogram all the twenty-four (24) patients were males. For barium swallow examination, twelve (12) patients were recorded, seven (7) females which represented to 58.3% and 41.7% corresponding to five (5) males. This means there were more females than males who underwent barium swallow examinations.

Figure 4.4: Gender Percentage distribution for the most Performed Fluoroscopy examination at Facility B

From Figure 4.4, the gender percentage distribution analysis was done for Facility B, one hundred and thirteen (113) patient data was used out of the total of one hundred and thirty-eight (138) patient data recorded. HSG examination recorded seventy- four (74) patient data of which all were females. For barium swallow examination females and males were represented by 27.3% and 72.2% respectively. There was a gender frequency switch for the barium swallow examination when comparing facility A and B. This means there were less females than males that undergoing barium swallow examination at facility B and more males underwent the examination. Only males were recorded for urethrogram examination.

4.4 AGE DISTRIBUTION FOR EACH FLUOROSCOPY EXAMINATION

Figure 4.5: Comparison of Age Distribution for HSG Examination at Facilities A and B.

As seen in Figure 4.5, the age range which recorded the highest number of patients for hysterosalpinogography (HSG) examination at Facilities A and B were found to be 25-44 years. The lowest age ranges at both Facilities were recorded as 19-24 years and 50-54 years.

Age ranging from 25-44 years recorded highest number of patients for HSG examination because it is performed on women to check the patency of the fallopian tubes. In this age range a lot of women want to start a family. Hence, during the procedure it is possible not to only examine the permeability of the fallopian tubes but also the size, shape and

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possible changes and features of the uterine cavity. Also the number of eggs within the ovaries decreases with the age therefore higher age ranges being at risk this could have been the reason for the low turnouts of patients for ages 50-54 years. For ages 19-24 years a fewer number of patients. This may be attributed to a lot of women being unmarried and as such fertility not a priority.

Figure 4.6: Comparison of Age distribution for Barium Swallow examination at Facilities A and B.

From the Figure 4.6 above, a comparative analysis was done, age ranging from 33-42 years recorded the highest number of patients undergoing the barium swallow examination. The second highest was ages between 63-72 years, followed by ages above 83years all of which was recorded at facility B. Ages ranges 33-42 years, 43-52 years and 53-62 years received the same number of patients undergoing the barium swallow

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examination but lower number of patients comparing to Facility A. Barium swallow examination is basically performed to check the alignment of the oesophagus to the stomach when a patient is having difficulty in swallowing.

Figure 4.7: Comparison of Age distribution for Urethrogram examination at Facilities A and B.

From Figure 4.7, age ranging from 32-38 years recorded the highest number of patients that underwent urethrogram examination for both Facilities A and B. This could have been due to a lot of men being prone to urethra infections as a result of high sexual activity within this age range. This was followed by age ranges 60-66 years and 67-73 years at facility A, recording higher number of patients than Facility B. Age ranging from 25-31

years, 39-45 years, 46-52 years, above 74 years and 53-59 years recorded the lowest numbers respectively in both Facilities. Urethrogram examination is performed to investigate stricture diseases in the urethra (pathway between the bladder and the opening where urine exits the body).

4.5 MEAN KERMA AREA PRODUCT VALUES FOR EACH EXAMINATION AND COMPARISON WITH OTHER STUDIES

Figure 4.8: Comparison of Mean KAP (Gy.cm^2) values for each examination at both Facilities A and B.

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From Figure 4.8, the mean KAP values at both Facilities for each examination were compared. Hysterosalpingography examination recorded the lowest mean KAP values of 4.49 $Gy.cm^2$ and 3.48 $Gy.cm^2$ for Facilities A and B, as compared to urethrogram and barium swallow examinations. The Barium swallow examinations for this research work recorded the highest mean KAP values of 10.43 $Gy.cm^2$ and 9.60 $Gy.cm^2$ for for Facilities A and B respectively.

The differences in KAP values between the two Facilities were attributed to the complexity of the procedures, screening time, number of images taken and the techniques used at each Facility. At Facility B the pulsing mode was employed, which reduced the fluoroscopy screening time resulting in a lower dose as compared to a continuous fluoroscopy used in Facility A.

Figure 4.9: Comparison of mean KAP ($Gy.cm^2$) values for HSG Examination at Facilities A and B with other studies.

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From Figure 4.9, the mean KAP values at Facilities A and B were compared with other studies for hysterosalpingography examination.

The mean KAP values for Facilities A and B were higher than that of Wambani et al., 2014 and the study done by Gyasi, 2013. Facility A was higher than that of Wambani et al., 2014 and Gyasi, 2013 by a factor of 1.55 and 2.11 respectively. For Facility B the mean KAP values were higher than Kenyatta Hospital and Gyasi by a factor of 1.2 and 1.6 respectively (Gyasi, 2013 and Wambani et al., 2014). This could be due to differences in the techniques and protocols used during the execution of the procedure.

Figure 4.10: Comparison of the mean KAP values at Facilities A and B with estimated mean value from Gyekye et al, 2009 and Gyasi, 2013 for Urethrogram examination.

From figure 4.10, the mean KAP values of Facilities A and B have been compared with other studies. The mean KAP value obtained at Facilities A and B for this research work was higher than that of the study done by Gyekye et al., 2009 and Gyasi, 2013. For Facility A, mean KAP values are higher than that of Gyekye et al., 2009 and Gyasi, 2013 by a factor of 1.55 and 3.43. Facility B the mean KAP values are higher than that of Gyekye et al., 2009 and Gyasi, 2013 by a factor of 1.42 and 3.16 respectively. The variations in the mean KAP values could be attributed to the difference in protocols and techniques used in performing the examination.

Figure 4.11: Comparison of the mean KAP values at Facilities A and B with estimated mean value from Gyekye et al and that of Gyasi for Barium swallow examination.

From Figure 4.11, the mean KAP value recorded at Facility A is higher than that of Facility B by a factor of 1.1.

The mean value recorded at Facility A is higher than of Facility B by a factor of 1.03. Both mean KAP values recorded in this research study at both Facilities A and B were lower than the mean KAP value estimated by Gyekye et al., 2009 by a factor of 1.58 and 1.75 respectively. The mean KAP value estimated by Gyasi, 2013 was lower than that Facilities A and B by a factor of 1.35 and 1.2 respectively. From Figure 4.9, Gyekye at al., 2009 recorded the highest value whiles Gyasi, 2013 recorded the lowest value. This could have been as a result of different clinical protocols and techniques used at these different Facilities. Patient dose is mainly dependent on the procedure, equipment used and user experience (Boix, 2011; Mahesh, 2001).

4.6 MEAN FLUOROSCOPY SCREENING TIME FOR EACH EXAMINATION

Figure 4.12: Comparison of mean Fluoroscopy Screening Time per examination at
Facilities A and B.

From Figure4.12, a comparison of the fluoroscopy screening time for each examination
type at Facilities A and B was recorded. From the figure above, Barium swallow
examinations at both Facilities recorded the highest mean screening time values of 1.2
minutes and 0.94 minutes respectively. Urethrogram examinations recorded the second
highest values of screening time of 0.61 minutes and 0.55 minutes respectively.
Hysterosalpingography examinations at both facilities recorded the lowest values of 0.43
minutes and 0.41 minutes respectively. It was therefore noted that the complexity of the
fluoroscopy examination type results in an increase in the screening time used to complete
the procedure.

4.7 NUMBER OF IMAGES PER EXAMINATION

Figure 4.13: Number of images per examination at Facilities A and B.

From Figure 4.13 the number of images taken per examination was higher in Barium swallow examination at both facilities. At facility A, the number of images taken for barium swallow was higher by a factor of 2.2 and 3.7 for urethrogram and HSG examinations respectively. At facility B, it was higher by a factor of 2 and 2.5 for urethrogram and HSG examinations respectively. This is because Barium swallow examination consists of a detailed examination of the esophagus. A lot of images were taken to visualize the esophagus and stomach. Urethrogram examination recorded the second highest number of fluoroscopy images at both facilities which recorded about five images per examination. Hysterosalpingograpy examination recorded the least number for both facilities which also recorded three to four images per examination. The difference

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in the number of images taken for a particular examination at Facilities A and B, could be as a result of the technique used by the radiographers and the radiologist's request needed in order to make sure that the images are entirely satisfactory for the clinical diagnosis.

4.8   DISTRIBUTION   OF   FLUOROSCOPY   SCREENING   TIME   PER EXAMINATION

Figure 4.14: Comparison of the number of patients for fluoroscopy screening time for Hysterosalpingography examination at Facilities A and B.

Comparison of the number of patients for fluoroscopy screening time for Hysterosalpingography examination was also conducted as depicted in figure 4.14. The

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highest patient distribution of the screening time for HSG examination for both Facilities was between 0.2-0.4 (minutes), which is the mean fluoroscopy screening time required to complete an HSG examination. The second highest time was between 0-0.2 (minutes) and 0.4-0.6 (minutes) which other studies (Gyasi, 2013) have suggested as a good screening time to complete an HSG examination depending on the complexity of the procedure.

Figure 4.15: Comparison of the number of patients for fluoroscopy screening time for Barium Swallow examination at Facilities A and B.

From figure 4.15; A comparison of the number of patients for fluoroscopy screening time for barium swallow examination at both Facilities was done. The highest patient distribution for the fluoroscopy screening time for barium examinations at Facilities A

and B was between 1.0-1.5 (minutes) and 0.5-1.0 (minutes) respectively. This research study recorded lower fluoroscopy screening time of 0-1.5 (minutes) for barium swallow examination as compared to the screening time reported by Gyasi, 2013. This could be due to the technique used and experience of the radiographer.

Figure 4.16: Comparison of the number of patients for fluoroscopy screening time for Urethrogram examination at Facilities A and B.

Figure 4.16 shows a comparison of the number of patients for fluoroscopy screening time for Urethrogram examination at both Facilities. The highest frequency distribution for the screening time for Urethrogram examination at Facilities A and B was between 0.3-0.6 (minutes). The second highest frequency distribution was between 0.6-0.9 (minutes).

4.9 PROPOSING THE DIAGNOSTIC REFERENCE LEVELS (DRLS)

Details of the descriptive statistics from the surveyed examinations are presented in Figures 4.17 and 4.18. The mean and local DRLs for each fluoroscopy examination and fluoroscopy screening time were calculated for each facility and a comparative study was also done to compare KAP values and fluoroscopy screening time across the fluoroscopy facilities and other studies done in other countries. The individual facilities are denoted by the alphabets A and B in order to avoid mentioning facility names for confidentiality and anonymity purposes.

Tables 4.2 and 4.3 represent 75th percentiles of the KAP values for a particular examination and the fluoroscopy screening time from the facilities surveyed. The 75th percentiles imply that 75 percent of the examinations surveyed operate at or below the dose values presented for all the categories of examination surveyed. These values represent values with which fluoroscopy practices in these facilities can be compared to and with recommended standards survey from other countries. Examinations with dose values mainly within the remaining 25th percentile for a particular examination are considered as unusually high doses, which should be considered for downward review in order to achieve optimization.

Figure 4.17: Comparison of local diagnostic reference levels (LDRLs) for examination
types at Facilities A and B.

Figure 4.17 shows the values of local diagnostic reference levels for this study compared
to each other. From the figure above, Hysterosalpingography examinations recorded the
lowest DRL values followed by urethrogram and barium swallow examinations
respectively. At facility A and B, DRLs for HSG examinations were lower than barium
and urethrogram examinations by a factor of 2.0 and 1.2, 2.8 and 1.5 respectively. The
relatively high calculated DRL values recorded for barium swallow can be attributed to
the prolonged fluoroscopic screening time and complexity of the examination.

Figure 4.18: Comparison of diagnostic reference levels (DRLs) of fluoroscopy screening time per examination at Facilities A and B.

From figure 4.18, a comparison of DRLs for the fluoroscopy screening time per examination at both facilities was done. The recorded results of screening times for the different examination types indicated that hysterosalpingography examinations have shorter screening time than Barium swallow and urethrogram examinations. At facility A, the screening time were shorter for HSG examinations by a factor of 2.3 and 1.2 for barium swallow and urethrogram examinations respectively. At facility B, it was lower by a factor of 2.4 and 1.4 for barium swallow and urethrogram examinations respectively. Higher DRL screening time values recorded for the Barium swallow studies can be attributed to

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the complexity of the examination since other studies has shown that the screening time of the fluoroscopy procedure is proportional to its complexity.

4.9.1 COMPARISON OF LOCAL DIAGNOSTIC REFERENCE LEVELS (LDRLS) WITH OTHER STUDIES

Table 4.2: Comparison of diagnostic reference levels (DRLs) of KAP values for Hysterosalpingography and barium swallow examinations for this study with Kenya and UK study.

Examination	DRL ($Gy.cm^2$)			
	Facility A	Facility B	Wambani et al, 2014 Kenya Study	Hart et al,2012 UK Study
HSG	6.0	4.1	3.0	2.0
Barium Swallow	12.1	11.5	9.0	7.5
Urethrogram	7.0	6.50	_	_

From Table 4.2, A comparison of DRLs of KAP values for hysterosalpingography, barium swallow and urethrogram examinations for this study with other studies was done. LDRLs values obtained at Facilities A and B for the three examinations are almost close to the values from the other studies. However, the DRL values at Kenyatta National Hospital (Wambani et al., 2014) and DRLs of UK (Hart et al., 2012) have lower values as compared to the values of this study. Wambani et al., 2014 value obtained was lower than facilities A and B by a factor of 2 and 1.4 for HSG examination respectively. Hart et al., DRL value was also lower than this study by a factor of 3 and 2.1. For Urethrogram

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examination, there was no available data for comparison. The high DRL KAP values 12.1 Gy.cm^2 and 11.5 Gy.cm^2 recorded for this research study indicates that the fluoroscopy examinations were performed with higher doses, resulting in high DRLs for the KAP values. The fluoroscopy examinations in this study compared to IDRLs indicates the need for proper training in, as well as the use of optimized imaging techniques and protocols. The similar trends in results for KAP values in this study also suggest the likelihood for standardization of anatomical-related imaging techniques and protocols. Standardization of protocols should be established to outline the number of images acquired per examination to a complete procedure by a radiologist.

Table 4.3: Comparison of diagnostic reference levels (DRLs) for Fluoroscopy Screening Time for Hysterosalpingography, Barium swallow and Urethrogram examinations for this study with Kenyatta National Hospital and UK study.

EXAMINATION	DRLs (Fluoroscopy Screening Time (minutes))			
	Facility A	Facility B	Wambani et al, 2014 Kenya Study	Hart et al, 2012 Uk Study
HSG	0.60	0.50	2.10	0.70
Barium Swallow	1.40	1.20	2.6	2.1
Urethrogram	0.70	0.70	_	_

The DRLs values for fluoroscopy screening time for Hysterosalpingography, Barium swallow and Urethrogram examinations for this research work were compared with

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Kenyatta National Hospital (Wambani et al., 2014) and UK study (Hart et al., 2012). It was observed that, the DRL values for the HSG examination screening time for this study, was lower compared with that of Kenyatta National Hospital (Wambani et al., 2014) but close to that of UK study (Hart et al., 2012). The Kenyatta National Hospital had a higher value than that of Facilities A and B by a factor of 3.5 and 4.2 respectively. For Barium swallow examinations, facilities A and B recorded lower values compared to Kenyatta hospital (Wambani et al., 2014) and UK studies (Hart et al., 2012) by a factor of 2 and 1.5, 2.3 and 1.75 respectively. Moreover, due to the unavailability of screening time for Urethrogram examination from other studies used, comparison was not done.

4.10 NORMALISATION OF KAP VALUES TO PROPOSED DRL

Figure 4.19: Normalized DRLs for HSG examination KAP Values at Facilities A & B

Figure 4.19 shows the deviations of KAP values from the proposed DRL for HSG examinations at facilities A and B. It was observed that most of the KAP values were below the DRLs for both facilities which accounts for about 75% of the total KAP values. This indicates that, there was optimization to some extent during the execution of the procedures. The standard error of HSG examination KAP values from the proposed DRLs for facility A and B were found to be 0.23 and 0.22 respectively.

Figure 4.20: Normalized DRLs for Barium Swallow examination KAP Values at Facilities
A & B

Figure 4.20 shows the deviations of KAP values from the proposed DRL for Barium
Swallow examinations at Facilities A and B. It was observed that most of the KAP values
were below the DRLs for both facilities which accounted for about 79% of the total KAP
values. Indicating that there was optimization to some extent during the procedures. The
standard errors for Barium Swallow examination KAP values from the proposed DRLs
for Facilities A and B were found to be 0.89 and 0.58 respectively.

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Figure 4.21: Normalized DRLs for Urethrogram Examination KAP Values at Facilities A
        & B

Figure 4.21 shows the deviations of KAP values from the proposed DRL for Urethrogram examinations at Facilities A and B. It was observed at Facility A that about 71% of the total number of values were found below the proposed DRL whiles 76% of values from Facility B were found above it. Since at Facility B values were above the proposed DRL, there is a more crucial need to investigate whether small changes could be made to the imaging protocols selected for an examination in order to reduce values of radiation dose quantities whilst still providing the required clinical information (Ng et al., 2014). The standard errors for Urethrogram examination KAP values from the proposed DRLs for Facilities A and B were found to be 0.35 and 0.28 respectively.

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

5.0 INTRODUCTION

Chapter five provides the conclusions and recommendations for the two facilities considered in this research work.

5.1 CONCLUSIONS

This research work provided the frequency of fluoroscopy examinations and the typical values of the related dose quantities, surveyed in two facilities in the Greater Accra of Ghana. The fluoroscopy examinations are description of the current practice in these facilities, hence the proposed diagnostic reference levels estimated could serve as a guideline before the establishment of a regional or national DRL. Mean values were calculated and the corresponding LDRLs were established in terms of KAP, screening time and number of images taken for each examination was based on the 75th percentile dose values from the survey for the most commonly performed fluoroscopy examinations. Appropriate inter-comparison studies were done with International values to confirm whether these facilities in Ghana were meeting international standards. From the analysis of the results, the number of Hysterosalpingography examinations (HSG) was more than the rest of the examinations in all the facilities studied. It accounted for about 55.86 % and 53.62% of the total number of 111 and 138 patient data at facilities A and B respectively. There was a percentage distribution switch in the number of patients between urethrogram examination and barium swallow examination in the two facilities. HSG examinations

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also presented lower KAP LDRL values of 6.0 Gy.cm^2, 4.1 Gy.cm^2 and screening time of 0.6 minutes, 0.5 minutes for facilities A and B respectively. This was due to the less complexity of the procedures followed by urethrogram examinations. Barium swallow examination however recorded higher LDRL values compared to HSG and Urethrogram examinations. It was higher by a factor of 2, 1.7 and 2.8, 1.8 at facilities A and B respectively. There was a slight variation of values observed across facilities and was attributed mainly to difference in protocols and techniques used in the two facilities. Similarly reported LDRLs values obtained at facilities A and B for the three examinations are almost close to the values from the other studies. However it was noted that the DRL values at Kenyatta National Hospital and DRL, UK have lower values as compared to the values of this research work. Kenyatta National hospital was lower than this study by a factor of 2 and 1.4 while UK study was lower than a factor of 3 and 2.1 at facilities A and B respectively.

Generally, factors that affect patient doses for fluoroscopy examinations could be attributed to the radiological technique, the screening time and the number of images taken during the procedure. Hence, radiographers and radiologists should use optimized technique factors to strengthen the protection of patients by minimizing the screening time used and also minimizing the number of images taken during a fluoroscopy procedure. Again, this work suggests standardization of protocols across facilities as a means to increase optimization of doses due to observed variations in KAP values, screening time values and number of images taken for the same type of examination.

5.2 RECOMMENDATIONS

5.2.1 Hospital Authorities

- It is imperative to note that meeting the DRL does not always mean that good practice is performed. Quality control should also be maintained even when the DRL is not exceeded.

- There is need to organize training programmes for the staff of the radiology departments on the significance and application of DRLs in the optimization of fluoroscopic procedures.

- Should ensure that LDRLs are set for all the fluoroscopic examinations in the facility. Also implement measures of compliance of the LDRLs. This may result in optimization of all the fluoroscopic procedures.

5.2.2 Regulatory Authorities

- This research work suggests the need for a regional and national survey of fluoroscopic procedures to be conducted to have a better view of practices and level of optimization at the radiology facilities in Ghana.

- The medical professional bodies such as the Ghana Society for Medical Physics, Medical and Dental Council and Ghana Society of Radiographers in collaboration with the Nuclear Regulatory Authority, Ghana should ensure the establishment of DRLs and incorporate same into the regulatory control programmes in Ghana.

- Implement strict measures to ensure compliance by registrants and licencees.

5.2.3 Research Community

It is recommended that, further work should be conducted in the remaining facilities with fluoroscopy systems and to include more complex examinations such as myelogram and retrogram pyelograghy, with the ultimate goal to establish a NDRLs to promote dose management in the country.

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APPENDIX I- INTRODUCTORY LETTER

DEPARTMENT OF MEDICAL PHYSICS
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University of Ghana – Atomic

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SNAS/MPHY/ADMIN/16
Your Ref:

Date: 12th Dec. 2017

The Chair

Ethical Review Board

KORLE – BU TEACHING HOSPITAL

ACCRA.

INTRODUCTORY LETTER MISS JOAN OTOO

I am pleased to introduce to you **Miss Joan Otoo**, a second year Masters student of the Department of Medical Physics, School of Nuclear And Allied Sciences (SNAS), University of Ghana. He is about to undertake her research study(thesis) titled **Establishing diagnostic reference levels for fluoroscopy Procedures in Ghana**, which would require collection of data from the department of Radiology, Korle-Bu Teaching Hospital.

Miss Joan Otoo has successfully presented her research proposal before the Thesis Supervisory and Examinations Committee of SNAS and approval has been granted her to proceed the study.

It will be appreciated if she will be given the necessary assistance to obtain the needed ethical clearance for her study.

Counting on your favorable response.

Thank you.

Sincerely,

Dr. Francis Hasford

Head

HEAD OF DEPARTMENT
MEDICAL PHYSICS
SCHOOL OF NUCLEAR & ALLIED SCIENCES
UNIVERSITY OF GHANA
ATOMIC CAMPUS

APPENDIX II- INTRODUCTORY LETTER AND

APPROVAL

RADIOLOGICAL AND MEDICAL SCIENCES RESEARCH INSTITUTE

In case of reply, number and date of this letter should be quoted.
Our Ref.: RAMS/LRR/SF.70/C/52

Your Ref.:.....................................

Telephone: + 233 289 542 201
Fax: + 233 302 400 807
email: ramsri.gaec@gmail.com
website: www.gaecgh.org

Ghana Atomic Energy Commission
P.O. Box LG 80
Legon – Accra

Date: 8th March, 2018

The Head
Imaging Department
Ridge Hospital,

Dear Sir,

INTRODUCTORY LETTER - MS JOANA OTOO

I am pleased to introduce to you Ms Joana Otoo, who is an MPhil student of the Department of Medical Physics, School of Nuclear and Allied Sciences, University of Ghana. The topic of her thesis work is Establishment of Diagnostic Reference Levels for Fluoroscopy Examinations in Ghana. As part of her research work, Ms Joana Otoo will collect data on patient dose during a fluoroscopy examination, which would require prospective data collection from the Department of Imaging.

I write on behalf of Ms Joana Otoo, to kindly request for permission for access to your facility and to give the necessary assistance to obtain the needed information for her research work.

I thank you in advance for your anticipated positive response.

Yours faithfully,

Prof. Mary Boadu
Director
(Supervisor)

. No objection
. Please proceed with research.

12/3/2018

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APPENDIX III- ETHICAL APPROVAL

In case of reply the number
And the date of this
Letter should be quoted
My Ref. No. KBTH/MD/G3/18
Your Ref. No...........................

KORLE BU TEACHING HOSPITAL
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26ᵗʰ April, 2018

JOANA OTOO
DEPT. OF MEDICAL PHYSICS
SCHOOL OF NUCLEAR AND ALLIED SCIENCES
UNIVERSITY OF GHANA, LEGON

**ESTABLISHING DIAGNOSTIC REFERENCE LEVELS FOR FLUOROSCOPY PROCEDURES
IN GREATER ACCRA REGION AT THE KORLE BU TEACHING HOSPITAL**

KBTH-IRB /00090/2017

Investigator: Joana Otoo

The Korle Bu Teaching Hospital Institutional Review Board (KBTH IRB) reviewed and granted approval to the study entitled "Establishing diagnostic reference levels for fluoroscopy procedures in Greater Accra Region"

Please note that the Board requires you to submit a final review report on completion of this study to the KBTH-IRB.

Kindly, note that, any modification/amendment to the approved study protocol without approval from KBTH-IRB renders this certificate invalid.

Please report all serious adverse events related to this study to KBTH-IRB within seven days verbally and fourteen days in writing.

This IRB approval is valid till 30ᵗʰ July, 2019. You are to submit annual report for continuing review.

Sincere regards,

OKYERE BOATENG (MR)
CHAIR (KBTH-IRB)

Cc: The Chief Executive Officer
        Korle Bu Teaching Hospital

        The Director of Medical Affairs
        Korle Bu Teaching Hospital

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APPENDIX IV: PATIENT DATA COLLECTION SHEET

NAME OF INSTITUTION…………………………………………………………………..

EQUIPMENT MANUFACTURER………………………………………………………….

MODEL NUMBER…………………………………………………………………………...

SERIAL NUMBER…………………………………………………………………………..

PATIENT IDENTIFICATION NUMBER………………………….....................................

PATIENT EXPOSURE INFORMATION

AGE OF PATIENT	PATIENT SEX	TYPE OF EXAMINATION	KAP MEASUREMENTS	SCREENING TIME	NUMBER OF IMAGES

APPENDIX V- PATIENT DOSE DATA FROM PARTICIPATING FACILITIES

E 1: HYSTEROSALPINGOGRAPHY EXAMINATIONS AT FACILITIES A & B

FACILTY B				FACILITY A			
Ages of patients	KAP (μGym^2)	Screening Time	Number of Images	Ages of patients	KAP (μGym^2)	Screening Time	Number of Images
23	63.4	0.1	1	19	189.16	0.2	2
24	95.4	0.1	2	21	206.49	0.2	2
25	102.4	0.1	2	21	214.09	0.2	2
25	135.9	0.1	2	23	215.26	0.2	4
25	158.5	0.1	2	23	224.15	0.2	2
26	158.7	0.2	2	25	228.66	0.2	2
26	165.8	0.2	2	26	241.77	0.2	2
27	168.7	0.2	2	27	245.06	0.2	2
27	168.9	0.2	2	27	247.06	0.2	4
28	170	0.2	2	28	258.52	0.2	2
28	173.5	0.2	2	28	266.99	0.2	2
28	179.2	0.2	2	28	287.62	0.2	2
28	194.6	0.2	2	28	287.7	0.2	2
28	199.4	0.2	2	28	296.33	0.2	2
28	201.7	0.2	2	30	310.61	0.2	2
29	210.5	0.2	2	30	310.87	0.3	3
29	227.8	0.2	2	30	311.44	0.3	2
29	228.6	0.2	2	30	311.9	0.3	2
29	233.9	0.3	3	31	317.27	0.3	3
29	234.1	0.3	3	31	318.82	0.3	4
29	234.6	0.3	3	32	326.59	0.3	3
29	239.6	0.3	3	32	330.23	0.3	2
29	244.5	0.3	3	32	334.25	0.3	2
30	247.4	0.3	3	32	334.56	0.3	2
30	250.5	0.3	3	32	343.58	0.3	2
31	255.9	0.3	3	33	347.18	0.3	2
32	258.1	0.3	3	33	353.72	0.3	2
32	263.1	0.3	3	33	354.4	0.3	2
32	272.1	0.3	4	34	354.75	0.3	3
33	272.9	0.3	4	34	367.24	0.3	4
34	279.3	0.3	4	34	381.61	0.4	3
34	281	0.3	4	34	438.56	0.4	3
34	281.7	0.3	4	34	444.08	0.4	2
34	282.8	0.3	4	35	457.22	0.4	2
34	284.6	0.3	4	35	459.88	0.4	2
34	284.6	0.3	4	35	473.36	0.4	2
34	286.2	0.4	4	35	495.24	0.4	3
35	292.3	0.4	4	35	495.69	0.4	3
35	298.6	0.4	4	35	498.06	0.5	3
35	300.3	0.4	4	36	533.96	0.5	5
35	318.3	0.4	4	36	535.47	0.5	5
35	325.8	0.4	4	36	542.33	0.5	3

35	329	0.4	4	37	552.18	0.5	2
35	329.9	0.4	4	38	554.7	0.5	2
35	336.2	0.4	4	38	592.21	0.5	2
35	341.5	0.4	4	38	601.82	0.5	2
35	359.1	0.4	4	38	603.08	0.6	2
36	359.5	0.4	4	39	608.58	0.6	3
36	362.7	0.4	4	40	618.75	0.6	4
37	365.1	0.4	4	40	619.82	0.6	3
37	367.4	0.4	5	40	625.54	0.6	4
37	370.7	0.4	5	40	625.74	0.6	2
38	375.3	0.4	5	41	627.77	0.6	3
38	376.5	0.5	5	41	630.37	0.7	4
38	376.8	0.5	5	42	684.45	0.7	2
38	401.9	0.5	6	43	707.94	0.7	4
39	434	0.5	6	44	709.12	0.8	3
39	457.3	0.5	6	45	710.52	0.8	3
39	457.6	0.6	6	45	733.56	0.9	2
40	470.4	0.6	6	46	788.89	0.9	4
40	504.7	0.6	6	48	801.66	1.1	3
40	508	0.6	6	54	989.89	1.3	2
40	511.8	0.6	6				
41	525.3	0.6	6				
41	526.3	0.6	6				
42	548.9	0.7	6				
42	579.8	0.7	6				
42	588	0.7	6				
43	664.2	0.7	6				
44	695.4	0.7	6				
46	726.5	0.9	6				
47	966.01	1.2	6				
47	977.2	1.2	6				
47	1035.1	1.3	8				

E 2: BARIUM SWALLOW EXAMINATION AT FACIKLITIES A AND B

FACILITY B				
Ages of Patients	Gender of Patients	KAP (μGym^2)	Screening Time	Number of Images
23	M	527.8	0.8	8
25	M	573.4	0.5	8
27	M	598.1	0.8	8
33	F	655.1	0.8	9
34	M	784.3	0.7	8
34	M	843.1	0.8	9
35	M	948.3	0.8	10
40	F	1015.5	1	10
42	F	1064.9	1.2	12
45	M	1104.2	1.2	10
52	M	1172.1	1.3	10
54	F	1180.6	1.3	10
64	M	1262.5	1.4	12
64	M	1432.8	1.6	12
65	F	1527.8	0.8	10
66	M	601.5	0.5	8
66	M	1085	0.8	12
71	F	786.3	0.8	10
83	M	1070.1	0.9	12
90	M	865.2	1	10
94	M	1032.7	0.7	12
95	M	1003.2	0.9	12

FACILITY A				
Ages of patients	Gender of Patients	KAP (μGym^2)	Screening Time	Number of Images
27	F	598.72	0.8	8
33	F	663.29	0.9	9
33	M	758.33	0.9	9
40	F	873.46	1	10
50	M	944.3	1.1	10
50	F	974.3	1.2	10
57	M	1098.04	1.3	10
59	F	1142.82	1.3	11
61	F	1211.03	1.4	12
65	M	1222.8	1.4	12
79	F	1334.74	1.5	14
83	M	1695.97	1.6	14

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E 3: URETHROGRAM EXAMINATIONS AT FACILITIES A AND B

FACILTY B					FACILITY A			
Ages of patients	KAP (μGym^2)	Screening Time	Number of Images		Ages of patients	KAP (μGym^2)	Screening Time	Number of Images
25	396.76	0.4	4		25	297.44	0.3	5
29	458.14	0.5	4		28	354.09	0.3	4
31	683.83	0.6	6		30	375.09	0.4	4
32	524.8	0.6	6		32	388.18	0.4	5
35	387.66	0.4	4		33	395.67	0.4	5
36	734.92	0.8	8		34	437.67	0.4	4
37	638.66	0.7	6		34	445.96	0.4	5
37	354.07	0.4	4		37	448.33	0.5	5
39	541.43	0.5	6		39	451.34	0.5	5
43	642.89	0.5	6		43	457.66	0.5	4
48	448.64	0.8	4		43	475.91	0.5	4
48	377.18	0.4	4		48	476.28	0.5	5
60	410.6	0.5	4		50	481.41	0.5	5
65	608.22	0.7	6		52	518.04	0.5	3
71	475.88	0.4	4		56	560.91	0.6	9
72	484.22	0.4	4		60	602.07	0.6	4
75	437.76	0.7	4		60	624.98	0.6	4
					65	665.62	0.7	4
					66	668.24	0.7	3
					70	682.05	0.7	5
					73	689.57	0.7	5
					73	739.21	1.2	5
					74	942.02	1.2	4
					74	993.26	1.6	4