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An audit of lead aprons used in operating theatres at three academic hospitals in Johannesburg

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AN AUDIT OF LEAD APRONS USED IN OPERATING THEATRES AT THREE ACADEMIC HOSPITALS IN JOHANNESBURG

Dr A J Cohen

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree

of

Master of Medicine in Anaesthesia

Johannesburg, 2016

Declaration

I, Anthony Cohen declare that this thesis is my own work.

It is submitted for the admission to the degree of Master of Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Signature

Signed at: University of the Witwatersrand, Johannesburg

On this date:

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Abstract

Background: Occupational radiation exposure to anaesthetists is increasing as a growing number of procedures requiring anaesthetic care are performed using radiological imaging. The primary modality of protection during these procedures are lead aprons. The aprons used in the three hospitals audited in this study were anecdotally thought to be in poor condition, with accompanying serious effects for the wearers. In a review of the literature no studies could be identified which measured the radiation exposure to anaesthetists in South Africa, nor to assess the adequacy of the protective garments worn in South African operating theatres. Although radiation exposure to anaesthetists has been described as low in the international literature, this assumes functional protective shielding.

Objectives: The objectives of this study were to identify and describe pre-existing apron maintenance protocols, describe the apron populations in terms of demographic data (age, lead equivalence, manufacturer, design) and describe the aprons' physical condition (cleanliness, holes, fasteners). The aprons' internal, radiation attenuating structure was assessed by X-ray and additional radiation transmitted as a result of defects was calculated. The aprons were then assessed for adequacy in terms of national guidelines and international literature.

Methods: The research design was that of a descriptive, prospective, contextual study, assessing the adequacy of lead aprons used in operating theatres at three hospitals affiliated with the University of the Witwatersrand in Johannesburg. Descriptive data was collected by the researcher. The aprons were X-rayed by qualified radiographers under standard conditions and the resulting images were assessed by a qualified radiologist. The additional radiation exposure was then calculated by the researcher using Microsoft Excel™ 2013.

At each hospital, every apron identified as being used in the main operating theatre complex was included in this study.

Results: A total of 87 aprons were investigated across the three hospitals. Of these 45/87 (52%) were found to be unsafe for use in operating theatres due to inadequate lead equivalence as defined by South African law. A subset of 18/87 (21%) aprons had defects identified by X-ray severe enough to render them inadequate for use.

Conclusion: The majority of aprons investigated were inadequate for use by anaesthetists in operating theatres. Insufficient quality control, poor handling by the wearers and vague government guidelines were all implicated as causative for the high failure rate.

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List of abbreviations

ALARA	As Low As Reasonably Achievable
CHBAH	Chris Hani Baragwanath Academic Hospital
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
Gy	Gray
HJH	Helen Joseph Hospital
ICRP	International Commission on Radiological Protection
keV	Kiloelectrovolts
LET	Linear energy transfer
mmPb	Millimetres lead
Sv	Sievert
wt	Tissue weighting factor

Chapter One
Overview of the study

1.1 Introduction

This chapter serves to introduce an overview of the study. The background, problem statement, aim, objectives, research definitions, demarcation of the study field, ethical considerations, research methodology, the significance of the study, validity and reliability and an outline of the report are included. These topics will be presented in greater detail in subsequent chapters.

1.2 Background to the study

Radiation exposure to anaesthetists in operating theatres is an ongoing concern in hospitals across the world (1, 2). Anaesthetists' exposure to ionising radiation is increasing as more specialties begin to use fluoroscopy in theatre and as anaesthetists become involved in more procedures requiring imaging outside of theatre (1-5). This increased exposure to radiation places the anaesthetist at increased risk of harm in a dose dependent fashion (6).

Radiation exposure in excess of the prescribed safe limits can have deleterious effects, including cataractogenesis (7), malignancy (8, 9), and even activation of HIV type I replication (10). These risks are magnified if the protective measures employed in theatre are not part of a regular maintenance routine (11, 12).

The literature describes two broad approaches for protecting medical staff in these environments: a fixed barrier and protective garments. These methods rely on the use of lead or lead equivalents to attenuate the amount of radiation reaching the staff, and in some settings a combination of fixed barrier and protective garment is used. (4, 6) Due to the practical requirements for an anaesthetist to move freely in theatre, protective garments are used more commonly than fixed barriers. At the hospitals involved in this study, lead aprons are the only available option in operating theatres.

Much work has been done to evaluate the safety of anaesthetists who work in environments where radiological studies are performed (1, 4, 5, 13). Although the consensus from these studies is that radiation exposure to anaesthetists is below recommended limits, all of the above studies conceded that this is only true if protective

garments are used. There is evidence that even with protective garments pregnant anaesthetists may be exposed to unsafe levels of radiation (5).

In 2001, Lambert and McKeon (11) first described criteria for evaluating and, if necessary, rejecting lead aprons. Subsequently their work has been adopted as the de facto standard and is cited in multiple government and departmental guidelines worldwide (14-16). Criteria for removal from service are based on radiological imaging of the aprons and extrapolation of projected additional radiation exposure, as a result of observed defects (12). Furthermore it is recommended that aprons are reviewed on an annual basis in order to ensure optimal safety (12, 14-18).

The projected maximum life span of a lead apron is 10 years (11, 12). This is a best-case scenario and is dependent on regular cleaning and correct usage and storage of the apron. The aprons are subject to damage from both regular wear and tear as well as damage from mishandling and incorrect washing (19). Even minor errors, such as folding or dropping the apron can cause sharp bends in the protective material rendering it defective (11, 20).

A review of the international literature revealed that high rates of rejection of aprons were experienced when inspections were first initiated, 17,9 to 100% (12, 21), but subsequently the rate dropped to 3 to 4% per annum (12). This was attributed to longstanding wear and tear which had previously not been checked for, followed by a slower rate of damage to new garments once the defunct items had been removed from service.

No South African literature was identified on the topic of protective garments, nor any literature on the exposure of South African anaesthetists to radiation. A study was conducted to establish the exposure to South African surgeons in theatre, and although the sample size was small, it showed that in some instances the exposure was above the recommended doses (22). These harmful effects may be magnified if the protective garments are inadequately shielding the wearers.

1.3 Problem statement

The lead aprons used in the operating theatres at the University of the Witwatersrand affiliated academic hospitals i.e. Charlotte Maxeke Johannesburg Academic Hospital (CMJAH); Chris Hani Baragwanath Academic Hospital (CHBAH); and Helen Joseph Hospital (HJH), were perceived to be in poor condition. Large numbers of these aprons had outward signs of deterioration e.g. worn Velcro replaced by adhesive tape, faded exteriors, and even gross defects. Anecdotally these garments were known to be handled poorly and contrary to suggested guidelines, as reported by hospital employees.

Due to these concerns, it was possible that many of the lead aprons used in these hospitals were no longer in safe working order and that anaesthetists and other medical staff may have been unwittingly exposed to dangerous levels of ionising radiation.

1.4 Aim

The aim of this study was to audit the lead aprons worn by anaesthetists in operating theatres at selected academic hospitals affiliated with the University of the Witwatersrand and to assess their adequacy according to the criteria established by Stam (12).

1.5 Objectives

The objectives of this study were to:

- describe the lead apron maintenance protocol at each hospital
- describe the lead aprons available at each of the hospitals in terms of: number, age, manufacturer, identifying mark, lead equivalency, and design (single versus double layer)
- perform a visual inspection of the aprons to describe external condition (cleanliness, holes, fasteners, blood)
- perform an X-ray examination of all the available aprons in order to describe the size, number and location of defects in the lead lining
- assess the aprons' adequacy for protecting healthcare workers.

1.6 Demarcation of study field

The research was conducted at CMJAH, CHBAH, and HJH, in their respective theatre complexes. CMJAH and CHBAH are central hospitals, and HJH is a regional hospital. All three are affiliated to the University of the Witwatersrand, and are referral centres for smaller hospitals and clinics, and at times, each other.

In all three hospitals the operating theatres are functioning 24 hours a day and lead aprons are worn whenever imaging is to be used.

1.7 Research definitions

The following definitions were used in this study.

Protective garments: any form of wearable shielding designed to protect the wearer from ionising radiation. This includes but is not limited to: lead aprons, thyroid shields, protective eye wear, and gloves.

Lead apron: a protective garment available in various configurations, designed to shield the wearer from the neck line down to the knees.

Ionising radiation: a form of radiation, produced by X-ray machines, capable of causing harm to the human body. For the purpose of this study “radiation” will be used to mean “ionising radiation” unless otherwise explicitly stated.

Inadequate lead apron: an apron was deemed inadequate using Stam’s (12) rejection criteria. If the defect in the material allowed an additional dose of radiation greater than or equal to 0,22 mSv i.e approximately 1% of the annual limit.

This additional dose of 0,22 mSv is based on the ALARA principle i.e. that radiation should be “As Low As Reasonably Achievable” considering practicalities encountered in the operating room environment. The measured rate of deterioration once a defect appears in an apron is also taken into account. The values obtained for rejection criteria match with other practices while providing an easy framework with which to assess damage. Stam’s criteria do not produce unacceptably high rates of rejection but do ensure a safe margin of error.

Additionally a lead apron was deemed inadequate if it was of a lead equivalent less than that prescribed for use in operating theatres by law (17).

Visible tears: refers specifically to defects in the outermost layer of material of the aprons.

1.8 Ethical considerations

Approval to conduct this study was obtained from the relevant authorities of the University of the Witwatersrand. An ethics waiver was obtained from the Human Ethics Committee of the University of the Witwatersrand (Appendix A) as no humans were involved in this study. The data collected will be stored for 6 years.

This study did not involve any drug or therapeutic management, and was conducted by adhering to the South African Good Clinical Practice guidelines (23) and the Declaration of Helsinki (24).

1.9 Research methodology

1.9.1 Study design

The research design was that of a descriptive, prospective, contextual study, assessing the adequacy of lead aprons used in operating theatres at CMJAH, CHBAH, and HJH.

1.9.2 Study population

The study population comprised the lead aprons in the operating theatres at the three hospitals.

1.9.3 Study sample

Sample Size

All of the lead aprons in the operating theatres were included. Thus the sample size was 87 aprons.

Sampling method and inclusion and exclusion criteria

All lead aprons in the main theatre complex at each hospital were included in this study.

1.9.4 Data collection procedures

At each hospital the individual responsible for maintenance of the lead aprons in the operating theatres was identified, and asked for details regarding the existing maintenance protocol.

Each hospital was visited at a time when as few lead aprons as possible were in use, in order to facilitate their inspection without disrupting planned or emergency surgeries. Lead aprons were assigned a unique identifying number for identification purposes. The aprons were inspected and these findings were recorded on a data collection sheet.

Each apron was X-rayed by one radiographer at each hospital under standardised conditions and a digital X-ray film of each investigation was stored. These films were then reviewed by a qualified radiologist. The radiological criteria for rejection were based on published guidelines (11, 12), using the size of radiographically identified defects in the aprons.

1.9.5 Data collection sheet

Two data collection sheets were used (Appendix A). Data collection sheet 1 was devised to record the demographics of the aprons being investigated. Data collection sheet 2 captured information about the maintenance protocols. The data was collected by the researcher personally, and entered into a Microsoft Excel™ 2013 spreadsheet.

1.10 Data analysis

The statistical program Statistica 12.5 was used for data analysis. Frequencies and percentages were used to summarise categorical data. Normally distributed data was

described using means and standard deviations, and that not normally distributed, was described using medians and interquartile ranges.

1.11 Significance of the study

No literature could be identified on the exposure of South African anaesthetists to ionising radiation. Although international studies have shown low exposure rates to anaesthetists in the past (13, 25), there does seem to be a trend of increasing exposure rates in the literature in recent years (3-5).

As a precursor to any studies evaluating South African anaesthetists' occupational exposure to radiation, it must first be determined if the aprons are in good working order.

Anecdotally the lead aprons used by anaesthetists at the hospitals in question were in poor condition, some with gross defects, and thought to be older than their 10 year maximum lifespan. In order to achieve the low exposure rates described in the literature, all of the anaesthetists wore functioning lead aprons. One can not necessarily extrapolate this data to our setting as the South African working environment may be different to that internationally and importantly it was not known if the lead aprons were in fact attenuating the radiation effectively.

The methodology employed may be transferable to other institutions, and may provide a framework for further action in other hospitals in South Africa. The results of this study may therefore contribute to a safer working environment.

1.12 Validity and reliability

Measures were taken to ensure the validity and reliability of this study.

1.13 Outline of report

The report will be discussed as follows:

Chapter 1:	Overview of the study
Chapter 2:	Literature Review
Chapter 3:	Research design and methodology
Chapter 4:	Results and discussion
Chapter 5:	Summary, limitations, recommendations, and conclusion

1.14 Summary

This chapter provided an introduction and overview of the study. The literature review follows in Chapter 2.

Chapter Two
Literature review

2.1 Introduction

This chapter will review the literature surrounding the medical use of radiation. In the first section an overview of ionising radiation is provided. The next section contains a review of safety guidelines for medical personnel followed by a description of the dangers associated with ionising radiation exposure. Following this is a look at radiation exposure to anaesthetists and then a review of the literature surrounding protective garments in operating theatres and the care and quality control thereof.

2.2 Ionising radiation

The electromagnetic spectrum can be broadly divided into two categories: ionising and nonionising radiation. Nonionising radiation includes, but is not limited to: visible light, radio waves, ultrasound and magnetic resonance imaging. It is generally considered safe, as it lacks sufficient energy to disrupt electrons. Conversely, ionising radiation is so named as it is capable of removing an orbital electron from matter and thus can affect the tissues through which it passes. Examples of ionising radiation include X-rays and gamma rays, as well as the products of radioactive decay processes: alpha (α) and beta (β) particles. (26, 27)

Ionising radiation is able to affect tissues by means of an energy transfer. This is termed Linear Energy Transfer (LET) and is measured in kiloelectrovolts (keV) per micrometre (µm) of tissue. The ionising radiation used in medical procedures (X-rays and gamma-rays) have relatively low LET as compared with that of products created by nuclear fission. (2)

Radiation dosage is quantified using the SI unit Gray (Gy). One Gy is defined as the absorption of one joule of energy, in the form of ionising radiation, per kilogram of matter. In order to compare different sources of radiation in different scenarios various definitions are used. The effective dose is a measure of cancer risk to a whole organism due to ionising radiation delivered non-uniformly to a part or parts of a body. It takes into account both the type of radiation and the nature of each organ being irradiated. (28) The equivalent dose is measured in Sievert (Sv), it has the same dimensions as the Gy and is a measure of potential damage to human tissue. It takes into account the energy of a

radiation type relative to gamma rays, by means of a weighting factor (29). For X-ray radiation the weighting factor is 1, thus 1 Sv is equal to 1 Gy. (30, 31)

The effects of ionising radiation can be classified as direct or indirect. High LET radiation predominantly has direct effects, meaning that atoms or molecules in the tissue are directly ionised or excited, leading to a chain of events causing damage. (2)

Low LET radiation acts by predominantly indirect effects. The radiation generates high energy electrons which collide with other molecules and form free radicals. It is these free radicals which then disrupt cell DNA. Cells which replicate at the highest rate are the most susceptible to this form of radiation. This damage results in one of the three following outcomes: complete recovery; inability to repair the damage leading to apoptosis of the cell; or inaccurate repair of DNA causing genetic abnormalities. (2, 30, 32)

2.3 Radiation exposure guidelines

In 2007 the International Commission on Radiological Protection (ICRP) published ICRP Publication 103 which contains updated recommendations for maximum radiation exposure in medical staff (33).

The 2007 guidelines recommend that occupational workers receive a maximum effective dose of 20 mSv per year, averaged over five years, with no more than 50 mSv in any one year (33). Furthermore, the equivalent dose radiation limit to the skin, hands and feet was prescribed as 500 mSv each. In 2011 the ICRP released new guidelines regarding exposure to the eye. The new guidelines reduced the equivalent dose limit for the lens of the eye from 150 mSv to 20 mSv per year, averaged over 5 years, with no year exceeding 50 mSv (34). This downward reduction in acceptable dose was due to new information coming to light and advancements in the medical knowledge surrounding the susceptibility of the eye to ionising radiation (35, 36). The South African Department of Health has subsequently adopted these guidelines (37). For pregnant women a maximum equivalent dose of 2 mSv to the abdomen is allowed with a foetal dose limit of 1 mSv (37-39).

The guidelines for members of the general public are much lower i.e. 1 mSv per year effective dose (total body); an equivalent dose of 1 mSv per year to the lens of the eye; and 50 mSv equivalent dose per year to the skin. (17, 33, 37, 38)

A distinction is made between “occupational exposure” and “radiation workers”, the former encompassing anyone who is exposed to radiation in the course of their daily work and the latter being, “any person who is potentially exposed to radiation as a result of his/her occupation to more than three tenths of the occupational dose limit” (37). Radiation workers need to have their exposure continuously monitored whereas the occupationally

exposed do not necessarily require monitoring (40). This creates a grey area into which anaesthetists fall. Internationally it has been shown that anaesthetists do not require continuous monitoring as their exposure is low and less than the three tenths rule (4, 13). At this time no research could be identified on South African anaesthetists and their exposure to radiation in operating theatres.

The South African guidelines state that “all full time theatre personnel must be monitored…” except in cases where the expected exposure is “very low”, in which case “the requirement for the monitoring of workers must be determined individually.” (40) Thus although monitoring of anaesthetists is not strictly prescribed, individual hospitals may find it prudent to do so, especially in the absence of any data about exposure in the South African context.

The ICRP also advocates that radiation be kept “as low as reasonably achievable”, or simply ALARA. The ALARA principle is based on the concept that there is no known safe threshold for the stochastic effects of radiation and that all exposure should be minimised. (27)

In order to minimise radiation exposure the ICRP recommends proper facility design and surgical planning (33). Intra-operatively three variables dictate the anaesthetist’s exposure to radiation: time, distance, and shielding (3, 4, 6, 16, 30, 31, 41). The basic principle being that if one can minimise exposure time, maximise distance from the source and make use of adequate shielding, then radiation will be minimised.

Exposure time in operating theatres or other environments where anaesthetists may be expected to work is usually dependant on the skill and experience of the operator performing the procedure and the complexity of the procedure being performed (3, 4). Cumulative dose to an anaesthetist is dependent on the number of cases or procedures requiring fluoroscopy over a given time period. Thus exposure time is often not a variable an anaesthetist has control over. Additionally exposure time for anaesthetists is increasing in general. Katz (4) found that mean exposure time doubled after the introduction of an electrophysiology laboratory in their facility.

Distance from the exposure source is also essential in determining radiation dose. The dose is described by the inverse square rule: the intensity of the beam is inversely proportional to the square of its distance from the source ($1/d^2$) i.e. doubling the distance reduces the exposure to one quarter (16). Therefore the further anaesthetists are from the source of radiation the less radiation they will be exposed to. Modern hospitals may have facilities to monitor a patient from the control room (41, 42). While this is advisable, in reality an anaesthetist may need to be near the patient in order to administer a safe

anaesthetic or may be in a location outside of theatre with cramped conditions, necessitating close proximity to the radiation source (3, 4).

The third variable is shielding. Anaesthetists cannot always rely on time or distance to protect themselves. Shielding is therefore of paramount importance. The South African Department of Health, Directorate of Radiation Control accepted the guidelines put forth by the ICRP in 1990 (17, 18). These state: “any person within 1m of an X-ray source or patient when the machine is operated at 100 kV, should wear a protective apron of at least 0.35 mm lead or lead equivalency. Other staff in theatre should wear at least 0.25 mm lead or equivalent aprons for protection.” The South African Department of Health further recommends that occupational workers should be provided with “leaded gloves, eye protection (leaded glasses), thyroid shields and/or portable shields.” (17, 43)

2.4 Dangers of ionising radiation exposure

The effects of ionising radiation exposure are well documented, with many studies conducted in different populations; data have been collected from workers in the nuclear industry (44), nuclear bomb blast exposed populations (45, 46), patients and various medical staff (3, 6, 47, 48). The type of damage which results from excessive radiation depends on both the dose delivered and the temporal relationship to the exposure. Effects can be defined as somatic i.e. occurring in the individual exposed; or genetic i.e. occurring in the offspring of exposed individuals due to mutations inherited from an exposed parent (2). Heritable, or genetic effects of radiation have not, however, been demonstrated in human cohorts (49, 50). Despite initial concerns about effects on the offspring of survivors of nuclear bomb blasts, no evidence has been found for any radiation induced genetic diseases (51, 52).

Somatic effects can be further subdivided into acute and chronic. Acute effects are normally associated with exposure to a high dose of radiation in a relatively short time interval. High doses are likely to cause cell death, and if a large enough area of tissue is affected can lead to organ dysfunction. Lower doses tend to rather result in complete repair and recovery, or DNA mutation. (2, 32)

The resultant damage can be categorised into two final subsets: dose-dependent, known as deterministic and non-dose-dependent known as stochastic. Deterministic effects have known thresholds above which the manifestations can be expected to increase in severity and frequency and below which no effect is expected (53). Stochastic effects have no lower limit or threshold and include carcinogenesis. This is the major health concern at

doses less than 100 mSv (53). Carcinogenesis can occur with minimal exposure. This is because only a single mutation is necessary for cancer development (2, 47).

Good epidemiological evidence exists for cancer risk at acute radiation exposures greater than 50 mSv and chronic exposures greater than 100 mSv. Reasonable evidence exists that these limits may be even lower. Medical procedures typically generate doses in the range of 3 to 30 mSv. (47) Below these doses it becomes impractical to use epidemiological studies to predict risk, as the number of participants required for acceptable statistical power and precision, grows very large (see Figure 2.1).

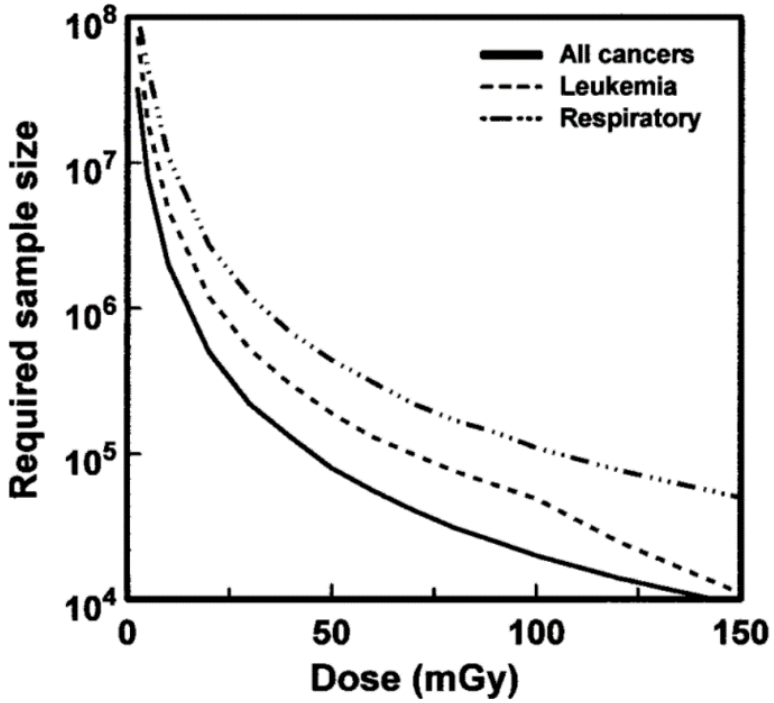


Figure 2.1 Size of a cohort exposed to different radiation doses, which would be required to detect significant increases in cancer mortality in that cohort, assuming lifetime follow-up (54)

In order to extrapolate data from lower rates of exposure a model must be used. Various models have been proposed but the “linear non-threshold” model is currently thought to be the most accurate:

> Although other dose–response relationships for the mutagenic and carcinogenic effects of low-level radiation cannot be excluded, no alternate dose–response relationship appears to be more plausible than the linear non-threshold model on the basis of present scientific knowledge (55).

“Linear” refers to the proportional effects of radiation when extrapolating below levels for which data exists, “non-threshold” refers to the absence of a lower limit, i.e. there is no

limit below which it can be assumed that the effects are zero. Interestingly, a study by Derby et al. (56) investigated coronary disease in breast cancer patients who had received radiation. The authors found “incidental exposure… increased the rate of major coronary events by 7.4% per gray, with no apparent threshold” thus confirming the model.

The impact of acute exposure can be described relative to the dose and sensitivity of the cell type, as defined by the “Law of Bergonie and Tribondeau” (57, 58). These turn of the century scientists proposed that tissue radio-sensitivity was a function of the metabolic state of the tissue.

The law is as follows:

- “stem cells are the most radio-sensitive cells
- the younger the tissue or organ, the more sensitive
- older cells are relatively more resistant to radiation
- radio-sensitivity increases as metabolic activity increases
- radio-sensitivity increases as cellular proliferation rate increases (57).”

This law allows one to understand and predict the relative radio-sensitivity of various tissues and organs. Bone marrow, reproductive cells, lymphoid tissue, thyroid and gastrointestinal cells are at greatest risk, whereas bone and cartilage can be said to be relatively radio-resistant (30). Developing foetuses are at very high risk and extra measures are recommended to protect them from radiation exposure (59).

Acute exposure, particularly to high LET radiation, affects the body in a relatively predictable, dose related fashion. Collectively these effects are known as “Acute Radiation Syndrome” (Table 2.1) (60). These effects range from mild haematopoietic changes in blood count (0.05 Gy total body radiation) to central nervous system failure with apnoea, cardiovascular collapse and death (>20 Gy) (2). Acute radiation syndrome has four stages:

- The prodrome, occurring after an effective dose of 1 Gy or more, involves gastro-intestinal and haematological symptoms. The length and severity of the prodrome is determined by the exposure dose.
- The latent period, during which no symptoms are evident, can last from hours to weeks depending on the dose received.
- The manifest stage can affect all organ systems, if the dose is non-lethal recovery may take up to six months, during which time, exposed individuals may have gastrointestinal, haematopoietic, central nervous system and/or cardiovascular symptoms.

- The final stage is either recovery or death. This is largely dependent on the dose received and the degree of medical assistance provided. (31)

Table 2.1 Variation in presentation of acute radiation syndrome with increasing radiation dose (2).

Exposure dose (Gy) total body radiation	**Effect**
< 0.05	Nil immediately quantifiable effects.
0.05 – 0.5	Change in blood cell counts.
0.5 – 1.5	Likely gastrointestinal effects including nausea, vomiting, fatigue, and loss of appetite.
1.5 – 10	Gastrointestinal symptoms appear immediately. Severe changes in blood cell counts. 1.5 Gy is known as the death threshold, death will occur in the most sensitive individuals. 3 to 5 Gy 50% mortality within 60 days without intensive medical support. Death is due to bone marrow suppression. Bone marrow transplant required to survive.
10 – 20	100% mortality within 2 weeks due to gastrointestinal failure.
> 20	Death due to CNS failure.

Low LET radiation such as from X-rays and fluoroscopy, as would be encountered by anaesthetists in operating theatres, can also result in severe disability, although the energy is lower, a high dose is still dangerous (53). The most common of these effects are described in the discussion below. The radiation exposure values which follow represent exposure to a particular organ and are *equivalent* doses and so appear very high in comparison to doses in Table 2.1, which are *effective* or total body doses.

The skin is the first barrier to radiation and is therefore commonly affected. Erythema may be the only visible effect at doses of 2 to 5 Gy. Desquamation, telangiectasia and atrophy occur at doses above 10 Gy and chronic permanent ulceration above 15 Gy. (53, 61) This can be of concern for patients (27), and anaesthetists performing pain procedures in close proximity to the X-ray beam (62).

Radiation exposure leads to cataract formation (7, 36). The likelihood of its occurrence and the degree of opacity is proportional to the dose received. Similarly the latent period is proportional to the dose received, thus higher doses result in cataract formation earlier

than chronic low dose exposure. (53) Previous estimates suggested a threshold of 2 to 5 Gy depending on the duration of the exposure (7). Subsequently these estimates have been reduced greatly, and may not even have a lower limit (53). This is in keeping with a linear non-threshold model and is what led to the new ICRP guidelines for exposure to the eye, which are much lower than previous guidelines (34).

Reproductive organs are affected by radiation which can lead to reduced fertility or infertility. The male reproductive system is more sensitive than the female. In males, temporary infertility occurs after acute doses of 500 mGy and permanent sterility can occur above 6 Gy. Cumulative doses of 20 to 50 mGy per week can result in permanent sterility if total dose exceeds 2,5 to 3 Gy. In females the dose required to cause infertility is age dependent. Younger women are more radio-resistant with 10 Gy causing sterility before puberty versus 2 to 3 Gy in women over the age of 40. (53)

As noted previously, the haematopoietic and lymphatic systems are amongst the most radio-sensitive in the body (30). The time from radiation exposure to the onset of haematological changes is related to the life span of the affected cells. Lymphocytopaenia may occur within hours whereas granulocytopaenia and thrombocytopaenia occur over days. Depletion of red cells occurs over weeks owing to their relatively longer life span. These responses can be seen after acute doses of as little as 0,5 to 1 Gy. (53)

Immune function can be compromised after either acute, 1,5 Gy, or chronic, 0,3 to 0,5 Gy per year, exposure. The changes in the cellular immunity are as a result of the paucity of immune cells from the effects on the haematopoietic and lymphatic systems. Evidence suggests there may be an effect on inflammatory responses as well. (53) In vitro studies (10) have also shown that ionising radiation can up regulate the replication of HIV I, which is similar to the effects of other DNA damaging agents on the replication of the virus.

Chronic radiation presents in a similar manner to chronic inflammation: local effects like ulceration, stenosis, fibrosis and atrophy are common (2, 6, 27, 30). Furthermore, following an acute exposure or even acute radiation syndrome, an exposed individual may still be at risk of long term complications such as carcinogenesis (31). Acute or chronic leukaemias and solid tumours are all possible (2, 48).

Radiogenic cancers are indistinguishable from those due to other causes, and are characterised by a latent period. Generally the time from exposure to presentation of the tumour is 7 to 10 years for blood based tumours and 20 to 30 years for solid tumours. The risk of carcinogenesis is related to the dose received and the tissue affected. (53)

2.5 Radiation exposure to anaesthetists

The greatest source of occupational exposure to anaesthetists, and doctors in general, is fluoroscopy (63). Increasingly anaesthetists are being involved in patient treatment involving fluoroscopy both in and out of the operating theatre (2-5, 64). Some anaesthetists also perform fluoroscopic guided procedures for pain, placing them at even greater risk for occupational radiation exposure (65).

Studies into the dose and effects of radiation on anaesthetists have been performed intermittently since at least 1965, when Trachtenberg et al (66) described exposure during "radium implantation procedures". In more recent years interest in the subject has been rekindled as anaesthetists found themselves exposed to ever increasing use of imaging technologies (1, 3-5, 13, 25, 67).

Study designs have varied, but all involved the use of some form of "dosimeter" to measure radiation. A dosimeter is a device containing radiation sensitive material. It is available in different sizes, and is worn on people or placed on objects. The dosimeter stores dose information about ionising radiation which can be read off at a later time. (68) Niklason et al (69) described a technique for using two dosimeters to estimate the effective total body dose when a protective apron is worn, with one worn below the apron at waist level and one outside the apron at the level of the collar. Most of the studies reviewed used this methodology.

Overwhelmingly the international studies reviewed showed that if using standard protective garments, the occupational radiation exposure to anaesthetists is very low or even negligible (1, 3-5, 13, 25). In all of the studies the anaesthetists wore lead protective aprons, and in all but two of the studies (1, 13), the anaesthetists wore lead thyroid shields as well. Henderson et al (25) described one anaesthetist who wore two lead aprons simultaneously and a thyroid shield, and moved more than three metres from the exposure source in every case. He received the lowest exposure despite being in operating theatres using fluoroscopy for some of the longest hours when compared to other participants in the study.

Although the studies mostly found low exposures overall, Durack et al (5) made special mention of individuals in the study who were outliers. In their study, one anaesthetist received a collar (thyroid) dose of 7,08 mSv in one month which raised "concern", and they strongly recommended that all anaesthetists wear thyroid collars. Further, they noted that although the overall exposure was within safe limits, it was far above the limit for pregnant women (5, 39). Ismail (1, 3), conducted two similar studies to assess exposure to anaesthetists in operating theatres. These studies took place in the same institution

approximately four years apart. In the first study none of the anaesthetists ever wore thyroid shields (1), yet by the time of the second study, hospital guidelines had changed and all the anaesthetists wore thyroid shields routinely (3).

Of interest, two of the earliest studies, Henderson (25) in 1994 and McGowan (13) in 1996, recorded the lowest exposure. Henderson found the dose to be “negligible”, whereas in McGowan’s study the dose was below the detection limit and “effectively zero”. In contrast, the later studies (1, 3-5), from 2005 onwards found significant albeit safe radiation exposure. Although it is not possible to attribute this perceived rise in exposure dose to any one cause, it does seem to suggest a trend of increasing risk to anaesthetists. Katz (4) found that the mean radiation exposure to anaesthetists doubled after the introduction of an electrophysiology laboratory, but in one individual it increased more than 18 fold.

Several studies were identified which produced different results, especially with regard to the eyes (42, 67, 70, 71). One was designed to assess the exposure to nurse anaesthetists during ureteroscopic procedures under fluoroscopy (67). This study simply attached a dosimeter to the anaesthetic machine and recorded the results. Although it was a poorer reflection of real world experience than other studies, the authors concluded that potentially dangerous doses of radiation were possible if anaesthetic staff were not wearing adequate protection Of note, at the time this study was published the extrapolated exposure to the eyes was deemed within safe limits, but today the same dose would be regarded as dangerous (34).

In another study Anastasian et al. (70) found that exposure to anaesthetists’ eyes during interventional procedures was six times greater than for non-interventional procedures and three-fold greater than that of the radiologist performing the procedure. The authors concluded that some anaesthetists may have ocular doses similar to the radiologists and that protective eyewear should be worn.

No studies related to anaesthetists’ exposure in South Africa could be identified. A study of South African surgeons’ exposure, showed that at times the radiation dose was higher than the safe limits set forth by the Department of Health (22). In this particular study this was attributed to improper placement of the X-ray tube i.e. an operator error, with the operator in this instance being the surgeons themselves.

This lone South African study highlights the need for further research in the South African context. Although the international studies have shown that radiation exposure to anaesthetists is low, this is not necessarily the case in our setting. The South African Department of Health has stipulated that the operator of a c-arm (mobile fluoroscopy) unit

“must be a radiographer or radiologist” (37), in the South African public hospitals this is not always the case. Similarly the Department of Health recommends that fluoroscopy equipment be checked three-monthly (72), this too is thought to not always be adhered to.

With the South African reality in mind, it is apparent that relying on international findings may not be appropriate. It is not possible to make direct comparisons of outcomes if international institutions are performing daily checks of their X-ray equipment (25, 73), whereas no clear timetable is thought to be adhered to in some of the hospitals in the public health sector in South Africa. In all of the studies reviewed (1, 3-5, 13, 25, 41, 67, 70), the integral role of protective garments is emphasised in great detail and yet anecdotally in the South African public hospitals these garments are, in some instances, never reviewed.

2.6 Protective garments in operating theatre

A multitude of protective shielding devices and garments are available to protect anaesthetists from ionising radiation. A brief overview will be provided below with emphasis placed on lead aprons.

Shielding from ionising radiation is achieved by means of a barrier, either fixed or wearable, which contains a material able to absorb radiation to a high degree (6, 31). The percentage of radiation which is able to pass through this barrier is known as the transmission factor and is expressed as a fraction, the lower the transmission the better the barrier (12). Lead is often used for this purpose as it has relatively high absorbancy allowing it to be made into protective garments which can be worn e.g. 0,5 mm lead (mmPb) absorbs gamma rays to the same extent as 3 mm of concrete (6).

The entire body is at risk of radiation exposure in an operating theatre. Different modes of protection are available for the different organs. The eyes, face and head, the thyroid, the gonads, the hands and the thoracic and abdominal cavities can all be protected depending on the anaesthetists’ requirements and the form of protection employed (6, 17, 18). The South African Department of Health guidelines state that:

> Only persons whose presence is necessary shall be in the theatre during exposures. All such persons shall be protected (e.g., provided with leaded aprons, leaded gloves, eye protection (leaded glasses), thyroid shields and/or portable shields. (17)

In current practice, only lead aprons are provided in the main operating theatres at the hospitals in this study. Thyroid shields and/or protective glasses are available in neuro-

interventional suites or occasionally are worn by doctors who have purchased their own privately.

Fixed, semi-fixed, and portable shields take many different forms. Shields can be suspended from the ceiling, fixed to the floor, on wheels, attached to the bottom of the operating table, or attached to a pivoting arm from the ceiling. These shields are able to protect the entire body. (6) Typically the shields are composed of acrylic or glass with the equivalent of 0,5 mm lead within them. These barriers are very effective at blocking radiation and are more comfortable than the traditional lead aprons which are often heavy, but suffer from the drawback of having limited mobility. Shields of this manner are generally not subjected to the same wear and tear as wearable garments and thus have longer lifespans. (6)

After several studies found increased risk for cataract development in medical personnel in 2010 and 2011 (35, 36, 70), and the ICRP reduced the safe limit for eye exposure in 2011 (34), eye protection has come under greater scrutiny. It remains the focus of ongoing research (42, 71). Some authors now believe that there may be no lower threshold for cataract development (53).

Eye protection is available in several forms:

- regular leaded glasses (prescription lenses available), with or without side shields
- leaded glasses that fit over prescription glasses
- a leaded clip-on shield for prescription glasses
- a full face shield, which also provides protection from splashes. (6)

Depending on the form chosen, radiation can be reduced by 5 to 25 times (74).

Thyroid shields are available as either a “built in” solution, where it is part of a lead apron, or as a stand-alone garment worn around the neck (6, 15). The thyroid is one of the most radio-sensitive tissues in the body (5, 33). There is a 6% increased lifetime risk of fatal cancer after 1 Sv of ionising radiation exposure (6, 75). Furthermore, the effective dose to the body is twofold higher if thyroid protection is not worn. This is because the thyroid shield protects all the underlying tissues, including skin, bone marrow, vertebrae, and oesophagus (74). Therefore thyroid shields are regarded as one of the most important shielding devices, second only to lead aprons, and worn routinely by anaesthetists in most of the studies reviewed (3-5, 25).

Hands warrant protection because they are exposed to radiation either by being directly in the beam such as during pain procedures or they may be exposed to back scatter (6). Radio-protective gloves or “gauntlets” have been developed that can attenuate the dose

received by 15 to 30% however some controversy surrounds their use. Some models of fluoroscopy machine are able to automatically increase the kilovolts supplied if they detect an impedance, thus if an operator leaves his gloved hands in the exposed field, the dose may be increased and the benefit from the gloves negated. (6, 76)

Another concern is that while the gloves may offer some protection to the hands they increase the amount of back scatter to other organs (77). Furthermore, these gloves are often thicker than normal gloves, reducing the wearer's dexterity and touch sensation and may produce a hazard to the environment if not discarded appropriately. This has led some authors to advocate the use of time and distance rather than shielding as the most appropriate technique for protecting the hands (77).

Lead aprons are used to protect the thoracic and abdominal cavities (6). The aprons are constructed from lead impregnated vinyl or rubber and are described in terms of their shielding abilities equivalent to a thickness of lead in millimetres. Modern lead free, or lead-composite aprons are also available. Typically the garments have a nylon outer layer. (11, 20, 78)

Lead aprons are available in a variety of designs. Some cover the front and back with the sides exposed, some cover only the front. Some aprons are "wrap-around" allowing for full protection in the front, back and sides with a double or overlapping layer in the front. Due to weight constraints some aprons have been divided into vest and skirt combinations, allowing up to 70 % of the weight to be carried on the hips and helping to alleviate back pain. (6, 19) Most of these designs are available in various lead equivalencies, the most common being 0,25 mm, 0,35 mm and 0,5 mm, if these aprons are employed in double layers then 0,7 mm and 1,0 mm are also available configurations (12). South African guidelines dictate that any person who shall be within one metre of the X-ray source or patient must wear 0,35 mm lead equivalent shielding and all others must wear at least 0,25 mm lead equivalent shielding (17, 18). Table 2.2 illustrates the advantages of increasing lead equivalence.

Table 2.2 Transmission values for aprons of different lead equivalences. (12)

Lead equivalence (mmPb)	**Transmission**
0,25	0,19
0,35	0,10
0,50	0,038
0,70	0,010
1,00	0,0014

Thus it can be seen that a properly functioning lead apron can drastically reduce exposure dose. In order to maintain aprons functioning at this level, strict codes of practice must be enforced to care for these garments and regular testing must be performed (6, 20).

In recent years, lighter aprons have become available on the market. These aprons are either “lead free” or made up of “composite” materials (6). In an attempt to make aprons that are more ergonomic and more comfortable for the wearer, the lead is replaced or mixed with other high atomic numbered elements. The lead substitutes are lighter-weight leading to improved comfort. These aprons are defined in terms of lead equivalency, even if they contain no lead in order to provide a familiar, easy to use categorisation system. Some doubt exists as to whether the manufacturers stated lead equivalency is truly equal to the original lead aprons, but further investigation is needed in this regard. (78)

The maintenance of lead aprons must be multi-faceted. An important aspect of the care is staff education. Oyar et al (21), found that personnel were “not aware of the importance of preservation and storage conditions, and for this reason they do not heed the rules for using, preserving and cleaning aprons.” Lead aprons are very easily damaged, merely folding an apron is enough to permanently damage it in such a way as to render it ineffective. Doing so causes sharp bends in the vinyl which lead to cracks that are permeable to the radiation. (11, 20) Lead aprons should not be laid on a flat surface, and must always be hung up by the shoulder or on approved apron hangers (79).

Another important aspect of maintenance is the cleaning of these aprons. Daily cleaning is recommended, using a soft bristle brush and water to remove any residue. Bleach should be avoided and the aprons should never be laundered or dry cleaned. (6, 79) A properly cared for apron can last up to 10 years (11, 15). This is however only if it is used, stored and cleaned as described, if this is not the case then the efficacy diminishes prematurely, potentially placing the wearer at risk (21).

The cornerstone of radiation safety in theatre is good quality control (6, 80). Owing to the relatively fragile nature of lead aprons it is important to assess them for damage on a regular basis (11, 81). The South African Department of Health requires that lead aprons must be verified to be free of defects via a visual and manual check monthly, and a radiographic/fluoroscopic test at least annually with defective items withdrawn from use (18). Similar guidelines exist in other countries (82). The guidelines, although reasonable in terms of frequency, do not specify criteria with which to judge the adequacy of the aprons.

For many years this left institutions to establish their own criteria, often arbitrarily, and in some cases aprons were discarded for only superficial cosmetic damage (11), or

conceivably were being kept in service longer than was safe to do so. In 2001, Lambert and McKeon (11), first described criteria for rejection of lead aprons. These authors borrowed an idea from the nuclear industry which had not been used previously in medical arenas. Using the ALARA principle they were able to define “reasonable” as “a dollar amount spent to avert a given dose”. From this practice, a mathematical model was created which produced criteria for rejecting lead aprons from clinical service based on the area of the defects in millimetres squared detected either radiographically or fluoroscopically. In addition these criteria could be modified based on the sensitivity of the organs over which the defects were situated. (11)

Lambert and McKeon (11) proposed that aprons be imaged, either with X-rays or fluoroscopy and the size of any defects measured. It was recommended that an apron be discarded if a defect of 15 mm^2 or greater was detected. If the defect was clearly not over a critical organ, such as the gonads, then a less stringent 670 mm^2 was recommended as grounds for removal. Not over a critical organ was defined as “along the seam, in overlapped areas, or on the back of the lead apron.” (11)

These recommendations were the first scientifically derived guidelines for assessing the adequacy of lead aprons. In 2002, Michel and Zorn (20), built on the ideas proposed by Lambert and McKeon (11) and suggested a more thorough procedure for the annual inspection of aprons. They recommended not only radiographic examination of the aprons but also a physical inspection for “tears, perforations and thinning creases”. These defects as well as those found radiographically were grounds for removal of the aprons from service, unless they could be repaired or were found to be safe by a “qualified individual”. (20)

Stam and Pillay (12), further developed these guidelines. As recently as 2008 they introduced the concept of “additional dose”. This is the dose that an individual would be exposed to as a result of the defect in the lead apron, as described by Lambert and McKeon (11). They then went on to say that although the original criteria describe a defect with an area in millimetres squared, in practice the defects are often tears with a length measured in millimetres. These authors derived an equation to convert the length of a tear into an area so that it could be used in the original equation by Lambert and McKeon (11). They further modified the equation to take into account lead aprons of double layers (wrap-around), the results of which are in Table 2.3. Stam and Pillay (12) also derived rejection criteria for aprons exposed to radiation from oblique angles and not simply antero-posterior.

Table 2.3 Maximum tolerable tear length (mm) for an exposure of 100mSv. (12)

Rejection Criteria		Lead Equivalence (mmPb)		
		0.25	**0,35**	**0,5**
Type of Apron	**Body Area**	**Maximum Length of Defect (mm)**		
Single	Whole Body	59	56	54
	Gonads	19	18	17
	Thyroid	19	18	18
Double	Whole Body	135	175	27
	Gonads	44	56	87

Although Lambert and McKeon (11) had recognized the importance of defects over the gonads versus the rest of the body, Stam and Pillay (12) refined the idea for practical screening purposes. They defined an area on the lead apron, “independent of the physical differences between wearers” to be defined as the “gonad area” with everything outside of this area defined as “whole body”. The gonad area measures 30 x 35 cm and is measured 40 cm from the neck-line of the lead apron. Although this area is considerably larger than the gonads themselves it provides a margin of safety as well as practicality for assessing exposure.

In 2012 Oyar (21), described an audit of the lead aprons used in their facility. Aprons were described in terms of their age, manufacturer, design, lead equivalence, and outward appearance and cleanliness. Each apron was then assessed radiographically and a measure of their radiation absorption was performed. Of the 85 aprons reviewed 72 were found to be unfit for service based on radiographic criteria alone. Only two of the rejected aprons were greater than six years old and 50 of the rejected aprons were less than three years old.

In addition to radiographical imaging of the aprons Oyar (21) also used dosimeters to assess the amount of radiation that was penetrating through the lead aprons. They compared these findings with brand new “control” aprons as well as known transmission values for the appropriate lead equivalencies of the aprons in question. Using this technique it was found that all of the aprons allowed significantly higher transmission of radiation than was acceptable. (21) This highlights the difference between using a derived equation to predict additional radiation exposure and actual measurement of radiation permeability.

Ultimately all 85 of the aprons reviewed were removed from service based on either radiographic or other criteria. The authors found no relationship between the aprons' appearances and their radiation permeability. They noted that two "brand new, very clean" 0,5 mm lead equivalent aprons when examined radiographically had holes and cracks so large that the aprons had actually been destroyed. Furthermore no significant relationship was found between the total number of users or the period during which the aprons were used, and the radiation permeability. (21)

Despite the increased specificity of measuring the permeability of the aprons directly, imaging is still the only method recommended in various governmental guidelines around the world, including Canada (15) Australia (14) and South Africa (18). This is presumably due to the extra cost, time, and technical skill necessary to use more advanced techniques.

2.7 Summary

The protection of medical staff from ionising radiation is a broad topic. It encompasses the dangers of radiation and the need for protection, the protective methods available, and the checks to ensure that the protection is adequate. An overview of the literature surrounding these topics has been provided above. Collectively this provides a clear rationale for undertaking an audit of the lead aprons used in the three hospitals studied. The chapter which follows will outline in detail the methodology employed to conduct the study.

Chapter Three
Research design and methodology

3.1 Introduction

This chapter describes the research methodology in depth. Study design, study population, sample size, description of data collection procedures and statistical analysis will be discussed.

3.2 Aim

The aim of this study was to audit the lead aprons worn by anaesthetists in operating theatres at selected academic hospitals affiliated with the University of the Witwatersrand and to assess their adequacy according to the criteria established by Stam (12).

3.3 Objectives

The objectives of this study were to:

- describe the lead apron maintenance protocol at each hospital
- describe the lead aprons available at each of the hospitals in terms of: number, age, manufacturer, identifying mark, lead equivalency, and design (single versus double layer)
- perform a visual inspection of the aprons to describe external condition (cleanliness, holes, fasteners, blood)
- perform an X-ray examination of all the available aprons in order to describe the size, number and location of defects in the lead lining
- assess the aprons' adequacy for protecting healthcare workers

3.4 Problem statement

The lead aprons used in the operating theatres at the University of the Witwatersrand affiliated academic hospitals i.e. Charlotte Maxeke Johannesburg Academic Hospital (CMJAH); Chris Hani Baragwanath Academic Hospital (CHBAH); and Helen Joseph Hospital (HJH), were perceived to be in poor condition. Large numbers of these aprons had outward signs of deterioration e.g. worn Velcro replaced by adhesive tape, faded

exteriors, and even gross defects. Anecdotally these garments were known to be handled poorly and contrary to suggested guidelines, as reported by hospital employees.

Due to these concerns, it was possible that many of the lead aprons used in these hospitals were no longer in safe working order and that anaesthetists and other medical staff may have been unwittingly exposed to dangerous levels of ionising radiation.

3.5 Ethical considerations

Approval to conduct this study was obtained from the Postgraduate Committee of the University of the Witwatersrand, and an ethics waiver was obtained from the Human Research Ethics Committee of the University of the Witwatersrand (both in Appendix B) as no humans were involved in this study. Approval was also requested from the Chief Executive Officer (CEO) of CMJAH, and HJH, and the Medical Advisory Committee at CHBAH (Appendix C). The Head of the relevant radiology departments, and the matrons in charge of the theatre complexes were informed of this study.

Data collected will be stored securely for 6 years following completion of the study.

Aprons that were identified as not adequate for safe use, were brought to the attention of the relevant responsible parties. This allowed the aprons to be removed from service so as not to further endanger staff at the hospitals involved.

This study did not involve any drug or therapeutic management, and was conducted by adhering to the South African Good Clinical Practice guidelines (23) and the Declaration of Helsinki (24).

3.6 Research methodology

3.6.1 Study design

The research design was that of a descriptive, prospective, contextual study, assessing the adequacy of lead aprons used in operating theatres, at CMJAH, CHBAH, and HJH.

A descriptive study describes the characteristics of the sample being studied. In this form of study, variables are not manipulated by the researcher. (83) This study made use of radiography, and a physical inspection to describe the quality and adequacy of lead aprons used in operating theatres.

A prospective study design is one where the variables are measured during the time the study takes place (83). By taking physical measurements, the variables in this study fulfilled these criteria.

This study is deemed contextual as it took place in a specific location or area (84).

3.6.2 Study population

Each of the three hospitals have lead aprons to protect healthcare workers from radiation. In each operating theatre that uses fluoroscopy there is a minimum of one scrub sister, a floor nurse, a surgeon, and an anaesthetist. In some cases there may be additional nursing staff, one or more surgical assistants, a representative from a company supplying medical equipment, and one or more anaesthetic assistants. Each one of these people require a lead apron. In addition there may be more than one operating theatre requiring aprons at the same time.

The three hospitals each had a pool of lead aprons which all of the operating theatre staff shared, 87 in total. All of these aprons were assessed.

3.6.3 Study sample

Sample size

The aim of this study was to assess the lead aprons in use in the CMJAH, CHBAH, and HJH operating theatres, thus the sample size was 87 aprons. Ethically all of the aprons needed to be included. In its lifetime each apron is exposed to different wearers and conditions, Oyar (21) found no significant correlation between outward appearance, age of the apron, or number of users of the aprons and the efficacy of the apron to attenuate radiation. It was therefore imperative to include all of the aprons. Similar studies (12, 21) have found a 17,9 to 100%, rate of rejection when first embarking on lead apron inspection programs.

Sampling method and inclusion and exclusion criteria

All lead aprons in the main theatre complex at each hospital were included in this study.

3.6.4 Data collection sheet

Two data collection sheets were used in this study (Appendix A). Data collection sheet 1 was devised to record the demographics of the aprons being investigated.

Identifying information was collected under the following headings:

- date of inspection, date of last inspection
- apron identification number (as designated for this study)
- hospital
- manufacturer

- lead equivalence
- design
- age of the apron.

The physical appearance of the aprons was documented as follows:

- presence of pre-existing identifying number or similar
- cleanliness of the apron
- presence of blood on the apron
- presence of visible tears
- condition of fasteners or Velcro.

The radiological findings:

- number, size, and location of cracks (linear defects)
- number, size, and location of holes (irregular defects)

Data collection sheet 2 recorded information about the maintenance protocols at the hospitals. Information collected included:

- presence of a cleaning protocol
- description of cleaning protocol
- presence of a radiological inspection protocol
- content of radiological inspection protocol: methodology, frequency, rejection criteria

The data was collected by the researcher personally, and entered into a Microsoft Excel™ 2013 spreadsheet.

3.6.5 Data collection procedures

Initially at each hospital the individual responsible for maintenance of the lead aprons in the operating theatres was identified and asked for details regarding the existing maintenance protocol. This was reported on Data collection sheet 2.

Each hospital was visited on separate days, this was done at a time when as few lead aprons as possible were in use, in order to facilitate their inspection without disrupting planned or emergency surgeries. CMJAH and HJH were visited on Wednesday afternoons, as due to academic responsibilities, this is a time when only emergency surgeries are performed. CHBAH was visited on a Sunday morning for similar reasons.

Lead aprons were collected from each theatre and were assigned a unique identifying number for reference and identification purposes. The aprons were inspected in a hanging position. The aprons were then described in terms of their distinguishing features. These findings were recorded on Data collection sheet 1. The aprons were also photographed for later reference. The cleanliness of the aprons, although subjective, was assessed by only one person, the researcher, which ensured consistency in the assessment.

Each apron was X-rayed by one radiographer at each hospital under standardised conditions i.e. 100 kV, 320 mA, 63 ms, at a distance of 110 cm, and a digital X-ray film of each investigation was stored. These films were then reviewed by a qualified radiologist. Two separate tables were used to collect the information from the X-ray examination of the aprons. One to record the number, size and location of linear cracks, and another to record the number, size and location of holes. These tables were found on Data collection sheet 1.

The radiological criteria for rejection (Appendix D) were based on published guidelines (11, 12), using the size of radiographically identified defects in the aprons. Lambert et al. (11) and Stam et al. (12) derived mathematical formulae to reject aprons based on the size of the defects found and the lead equivalence of the apron. These formulae were programmed into a Microsoft Excel™ 2013 spreadsheet, and used by the researcher to calculate the additional dose of radiation that would reach wearers of the aprons.

3.7 Data analysis

The statistical program Statistica 12.5 was used for data analysis. Frequencies and percentages were used to summarise categorical data. Normally distributed data was described using means and standard deviations, and that not normally distributed, was described using medians and interquartile ranges.

3.8 Validity and reliability

When developing a research study design it is important to be cognisant of the formal evaluation of measurement error. Measurements are assessed in terms of reliability and validity (85). Reliability is the degree of similarity of the information obtained when the measurement or test is repeated on the same subject or the same group. Validity is the degree of accuracy with which a measure actually quantifies what it is meant to measure. (85)

The validity and reliability of this study was ensured by adhering strictly to the guidelines for rejection of lead aprons as described by Stam (12).

The X-rays were taken in a licensed unit using a calibrated X-ray machine, and by a single radiographer at each hospital. Standardised parameters were used for every image obtained. The images were reviewed by a qualified radiologist.

3.9 Summary

The discussion in this chapter provides a description of the methodology used to conduct this study. The following chapter details the data collected, an analysis thereof and a discussion of the results of the study.

Chapter Four
Results and discussion

4.1 Introduction

In this chapter the results and discussion are presented. The objectives are re-iterated to provide context for the data:

- describe the lead apron maintenance protocol at each hospital
- describe the lead aprons available at each of the hospitals in terms of: number, age, manufacturer, identifying mark, lead equivalency, and design (single versus double layer)
- perform a visual inspection of the aprons to describe external condition (cleanliness, holes, fasteners, blood)
- perform an X-ray examination of all the available aprons in order to describe the size, number and location of defects in the lead lining
- assess the aprons' adequacy for protecting healthcare workers

4.2 Sample realisation

As per ethical necessitation, all of the aprons used in the main operating theatres at the three hospitals were included in the study. This was achieved by collecting data when no elective procedures were being performed. The researcher investigated all the available aprons not in use (physical inspection and radiography) and then substituted them for those in use. Where this was not possible, the remaining aprons were assessed on subsequent visits.

A total of 87 aprons were identified across the three hospitals. No aprons were excluded.

4.3 Results

In this section percentages are rounded to the nearest whole number.

4.3.1 Objective: describe the lead apron maintenance protocol at each hospital

No formal maintenance protocols existed at any of the three hospitals. Informal "protocols" at each hospital differed. The maintenance is divided into two distinct domains: daily care for the aprons and regular radiological assessment of the aprons. The daily care is

performed by the theatre staff who wear the aprons and the radiological assessments by the Quality Assessment Radiographers at the respective hospitals.

CMJAH performs six-monthly, and if necessary more regular, fluoroscopic investigations of the available aprons and defective aprons are removed from circulation regularly. The location of cracks is marked on the outside of the apron and consideration is made as to whether the defect is on the front or back of the apron. At CMJAH the lead aprons that had been investigated most recently (12 out of 35, 34%) were labeled as such.

CHBAH had not examined the theatre aprons fluoroscopically in the memory of the radiographer responsible. None of the theatre aprons had identifying numbers on them at the time of this study.

HJH performs three-monthly visual inspections of their aprons for visible cracks and tears. Suspicious aprons are then X-rayed. Aprons with no defects or small defects in the periphery are returned to the circulation. If the cracks are deemed major then they are removed. Screening of the entire apron population is performed 2 yearly.

These results are summarised in Table 4.1

Table 4.1 Lead apron maintenance protocols

Maintenance	Hospital		
	CMJAH	CHBAH	HJH
Daily maintenance			
Formal protocol	No	No	No
Frequency of cleaning	Unknown	Unknown	Unknown
Radiographic maintenance			
Formal protocol	No	No	No
Frequency of Radiological inspection	6 monthly	Erratic	3-24 monthly
Factors evaluated	Presence of holes; location (front or back); evidence of holes from previous examination	Presence of holes	Presence of holes; size of holes (“small or large”); location (central or peripheral)

4.3.2 Objective: describe the lead aprons available at each of the hospitals in terms of: number, age, manufacturer, identifying mark, lead equivalency, and design (single versus double layer)

The two largest hospitals had the most lead aprons, 35 at CMJAH and 36 at CHBAH. HJH, a smaller hospital, had 16 aprons in use in the theatre complex.

At CMJAH, 18 out of 35 aprons had the date of purchase visible on the apron. At CHBAH a single apron bore the date of its purchase. No information was available to determine the age of the aprons at HJH. The average age of the 19 aprons with dates, was 4.26 years (SD = 1,12 years). The newest was 1.5 years old and the oldest was 7.65 years old.

Several distinct manufacturers/suppliers had provided aprons to the hospitals. These are described in Table 4.2.

Table 4.2 Description of apron manufacturers

Manufacturer	Hospital			
	CMJAH n (%)	CHBAH n (%)	HJH n (%)	Total n (%)
Med Mac Services	6 (17)	5 (14)	1 (6)	12 (14)
Radshield	19 (54)	30 (83)	3 (19)	52 (60)
Burlington Medical Supplies			1 (6)	1 (1)
Unknown	10 (29)	1 (3)	11 (69)	22 (25)
Total	**35**	**36**	**16**	**87**

Identifying marks, such as apron numbers, were found on 17/35 (49%) of the Aprons at CMJAH, none of the aprons at CHBAH, and 12/16 (75%) of the aprons at HJH. In total 58/87 (67%) aprons did not have identifying marks of any description.

The different designs available at each hospital paralleled the multitudes of suppliers. HJH, had the highest number of distinct designs, in keeping with the high number of manufacturers. For 22/87 (25%) of the aprons, the manufacturer and lead equivalence were unidentifiable. CMJAH had the highest number of aprons of unknown lead equivalence (29%) as even some of the aprons from known manufacturers could not have their lead equivalence determined. Across the three hospitals 25/87 (29%) of the aprons were of unknown lead equivalence. An additional 20/87 (23%) were of known lead equivalence less than 0.35 mmPb. HJH is the only hospital to have an apron of 0.7 mmPb equivalent, the highest amount of protection available at any of the hospitals tested in this study. This is described in Table 4.3.

Table 4.3 Description of apron design and lead equivalence at the three hospitals.

Design and lead equivalence (mmPb)	Hospital			
	CMJAH n (%)	CHBAH n (%)	HJH n (%)	Total n (%)
Front and back	**35 (100)**	**14 (39)**	**8 (50)**	**57 (66)**
0.25	2 (6)	13 (36)	1 (6)	16 (18)
0.35	19 (54)		2 (13)	21 (24)
0.5	1 (3)			1 (1)
Unknown	13 (37)	1 (3)	5 (31)	19 (22)
Front only		**18 (50)**	**6 (38)**	**24 (28)**
0.25		4 (11)		4 (5)
0.5		14 (39)		14 (16)
Unknown			6 (38)	6 (7)
Wrap-around (double layered)		**4 (11)**	**2 (12)**	**6 (7)**
0.5		4 (11)	1 (2)	5 (6)
0.7			1 (2)	1 (1)
Total	**35**	**36**	**16**	**87**

The combination of age, manufacturer and lead equivalency of the garments was only documented for 19/87 (22%) aprons.

4.3.3 Objective: perform a visual inspection of the aprons to describe external condition (cleanliness, holes, fasteners, blood)

The visual inspection of the aprons assessed four variables: The general state of cleanliness of the apron; the absence or presence of macroscopic blood; the functionality of the various fasteners and the absence or presence of visible tears/defects.

HJH had the highest number of dirty aprons while CMJAH had the cleanest overall. Blood stained aprons followed a similar pattern. These values are presented in Table 4.4.

Table 4.4 Physical attributes of the aprons at the three hospitals

Attribute	Hospital			
	CMJAH n (%)	CHBAH n (%)	HJH n (%)	Total n (%)
Cleanliness				
Clean	21 (60)	9 (25)	2 (13)	32 (37)
Moderately dirty	10 (29)	18 (50)	4 (25)	32(37)
Dirty	4 (11)	9 (25)	10 (63)	23 (26)
Blood				
No	32 (91)	25 (70)	12 (75)	69 (79)
Yes	3 (9)	11 (30)	4 (25)	18 (21)
Tears				
No	24 (69)	31 (86)	9 (56)	64 (74)
Yes	11 (31)	5 (14)	7 (44)	23 (26)
Fasteners				
Broken	12 (34)	6 (17)	3 (19)	21 (24)
Functional	23 (66)	30 (83)	13 (81)	66 (76)

4.3.4 Objective: perform an X-ray examination of all the available aprons in order to describe the size, number and location of defects in the lead lining.

The distribution of the defects found in the lead lining was non-uniform. Defects were detected in 52/87 (60%) of the aprons. The most defects described in a single apron was 31. The majority of the defects (92%) were linear tears as opposed to areas/holes. Almost half the defects (44%) were found in the gonadal regions. This is presented in Table 4.5. Only the aprons with defects are listed.

Table 4.5 Number and location of defects identified by X-ray

Apron No.	No. of defects				Additional radiation from defects (mSv)
	Linear Tear		Holes		
	Gonadal	Non-gonadal	Gonadal	Non-gonadal	
CMJAH					
CMJAH (2)			1		0.001
CMJAH (3)	2			1	0.139
CMJAH (5)	1		1		0.146
CMJAH (6)		1			0.005
CMJAH (12)		1			0.011
CMJAH (14)		1			0.006
CMJAH (16)			1		0.026
CMJAH (17)		2			0.004
CMJAH (18)	1				0.008
CMJAH (22)	1		1		0.040
CMJAH (23)	3	4		1	0.541
CMJAH (24)	14	11			1.198
CMJAH (25)		1			0.006
CMJAH (28)	2				3.036
CMJAH (32)		2			0.002
CHBAH					
CHBAH (2)	13	5			2.869
CHBAH (3)	2	12		1	0.316
CHBAH (4)		3			0.001
CHBAH (9)		1			0.012
CHBAH (10)		2			0.004
CHBAH (11)	1	1			0.082
CHBAH (12)	3	1			0.095
CHBAH (13)	1	1			0.060
CHBAH (14)	2				0.046
CHBAH (18)	1	2			0.224
CHBAH (19)			1		3.498
CHBAH (20)		2			0.001
CHBAH (22)		2			0.001
CHBAH (23)		1			0.007
CHBAH (24)	1				0.057
CHBAH (25)	2	1			0.034
CHBAH (26)	1	4			0.022
CHBAH (27)	3	6			0.160
CHBAH (28)		2			0.005
CHBAH (29)		2			0.107
CHBAH (30)	3	3			142.476
CHBAH (31)	1	6			0.247
CHBAH (34)		2			0.006
CHBAH (36)		4			0.073

Table 4.5 Number and location of defects identified by X-ray (continued)

Apron No.	Defects				Additional radiation from defects (mSv)
	Linear Tear		Holes		
	Gonadal	Non-gonadal	Gonadal	Non-gonadal	
HJH					
HJH (1)	16		3	1	136.677
HJH (2)	2	14		1	1.381
HJH (3)	1		1	1	1.156
HJH (4)	4	1			0.460
HJH (5)			1		34.982
HJH (8)		10			0.124
HJH (10)			1	1	1.489
HJH (11)	4	1			0.249
HJH (12)	14	14	2	1	103.926
HJH (13)		1			0.025
HJH (14)	2	4			0.160
HJH (15)	2	1			2.452
HJH (16)	5	1			0.024

Although it was not included as an objective in this study, and the study was not specifically powered for this interpretation, a statistical analysis was performed. A statistically significant relationship was found by performing a Fisher's Exact test on the presence of visible tears and the radiological adequacy of the aprons (p=0,0005) (Table 4.6). Eighty-nine percent of the aprons with no visible tears were found to be radiologically adequate.

Table 4.6 Visible defects and radiological findings

Visible Defects	Radiological Finding	
	Safe	Unsafe
Yes	12	11
No	57	7

p=0,0005

4.3.5 Objective: assess the aprons' adequacy for protecting healthcare workers.

It was found that 18 of the 87 (21%) aprons were no longer safe due to defects allowing excessive radiation exposure i.e. greater than 0,22 mSv. CMJAH had 9% unsafe aprons (3/35). CHBAH had 17% unsafe aprons (6/36) and, HJH had 57% unsafe aprons (9/16). The results of the X-ray examination are shown in Figure 4.1.

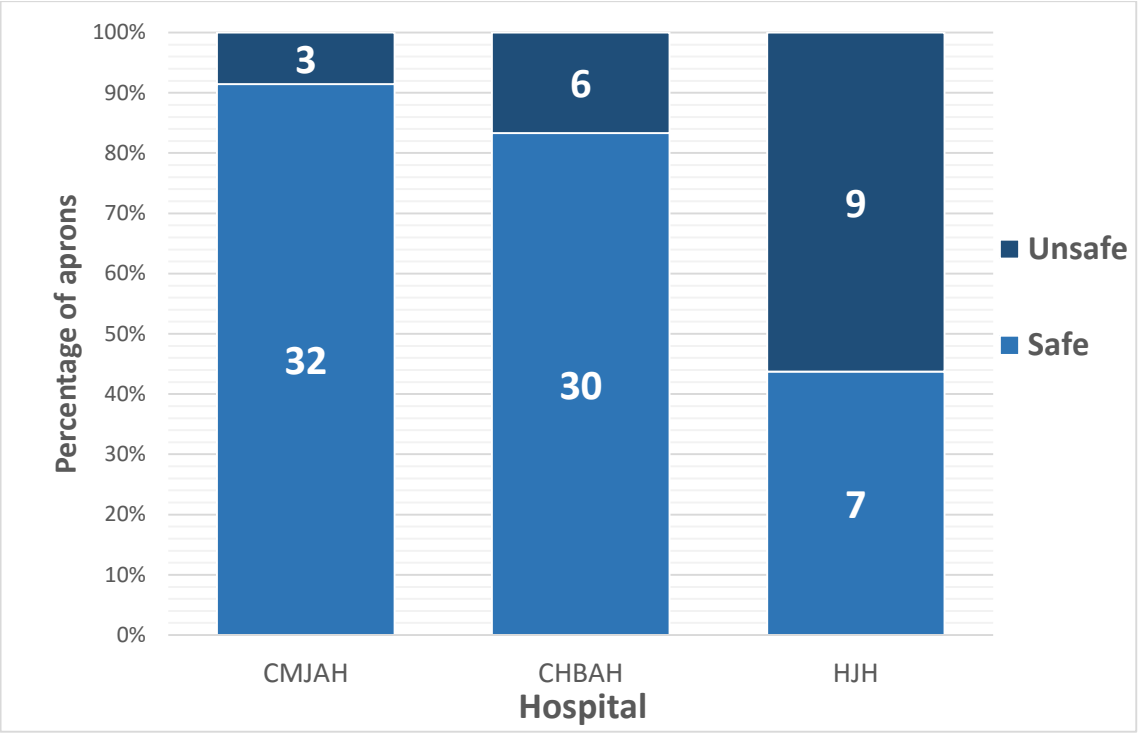


Figure 4.1 Radiological apron findings by hospital.

In addition to the radiological defects detected, aprons were deemed inadequate for use if they were of a lead equivalence of less than 0,35 mmPb. Aprons of unknown lead equivalence were included in this group. In total, 45/87 (52%) of the aprons investigated were found to be unsafe due to inadequate lead equivalence. All 18 radiologically unsafe aprons were also of inadequate lead equivalence and therefore the total number of inadequate aprons was 45. This is shown in Table 4.7.

Table 4.7 Adequacy of aprons by radiological findings and lead equivalence

Adequacy Criteria	Hospital			
	CMJAH n(%)	CHBAH n(%)	HJH n(%)	Total n(%)
Adequate lead equivalence	**20 (57)**	**18 (50)**	**4 (25)**	**42 (48)**
Inadequate lead Equivalence	**15 (43)**	**18 (50)**	**12 (75)**	**45 (52)**
Radiologically safe	12 (34)	12 (33)	3 (19)	27 (31)
Radiologically unsafe	3 (9)	6 (17)	9 (56)	18 (21)
Total	**35**	**36**	**16**	**87**

The median additional exposure transmitted by the lead aprons that were removed from service was 1,44 mSv, (IQR = 0,48-3,38). Five of the aprons were found to be completely destroyed, to the extent that wearing one of them offered negligible protection. The additional radiation for each of the aprons that failed the radiological testing is presented in Figure 4.2.

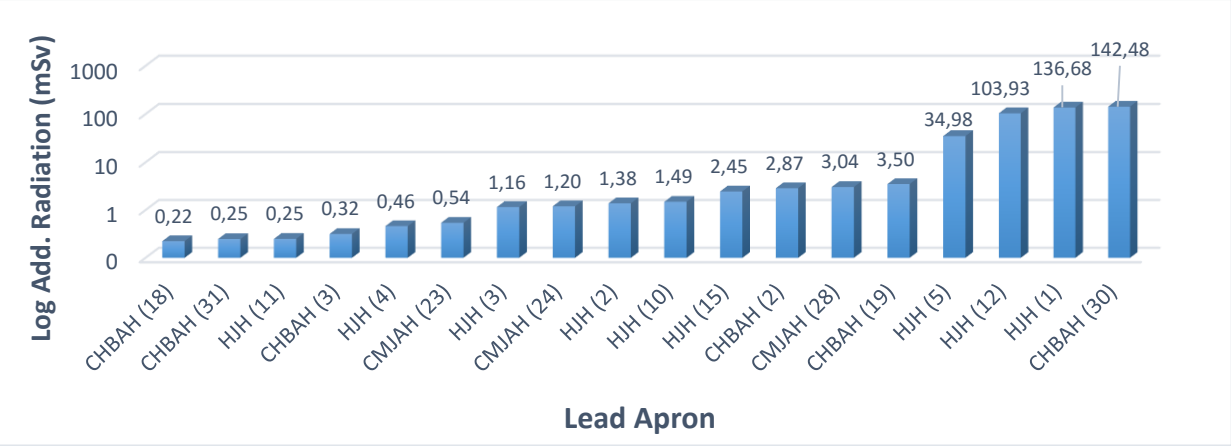


Figure 4.2 Additional radiation exposure in mSv for each apron that failed by radiological criteria

4.4 Discussion

The purpose of this study was to audit the protective garments worn by anaesthetic staff at the three hospitals investigated and to assess the aprons' adequacy and safety. Although the focus of the study was to evaluate the radiation to which anaesthetists are routinely exposed in theatre, the implications of the results are far reaching and of importance to a wide number of medical professionals. The lead aprons worn by the anaesthetists are from a shared pool and indeed the surgeons and nursing staff who wear them are often at greater risk than the anaesthetists, due to their proximity to the radiation source (5, 13, 67).

Specifically, the amount of *additional* radiation the wearer of a damaged apron would be exposed to, was measured. This additional dose was calculated by imaging the aprons, measuring any observed defects and extrapolating the amount of radiation that would be transmitted through these defects. The methods used are internationally recognised (14, 15).

By documenting several easily measurable variables in addition to the radiological adequacy of the aprons, the researcher hoped to provide context for the results as well as identify aspects of apron maintenance that could be improved if in fact any existed. This would possibly result in better care of lead aprons and therefore better protection of medical professionals in the future.

The radiological findings in this study were of great importance. It was found that 18 (21%) of the aprons were no longer fit for use due to excessive internal damage (Figure E.1, Appendix E). This means that theatre staff had a 1 in 5 chance of wearing a defective

apron. Some of the aprons were so damaged as to offer no protection whatsoever. Each apron that failed due to radiological findings also failed due to unknown or inadequate lead equivalence. Inadequate lead equivalence is conceptually the same as damaged aprons as both allow excessive radiation to be transmitted to the wearer.

The lead equivalence of a “lead” apron is what confers its protection. Higher lead equivalency offers greater protection. This variable showed heterogeneity between and within the different hospitals. If the lead equivalence is unknown additional complications arise:

When calculating the additional exposure as a result of defects in the lead-attenuating lining of the garments, the transmission for that lead equivalence (Table 2.2) is taken into consideration (11, 12). For reasons of safety, if the lead equivalence of a garment is unknown when performing these calculations, it must be assumed that the garment is of a lead equivalence with the lowest threshold for failure (0,5 mmPb for single layer aprons and 0,25 + 0,25 mmPb for double layer aprons). This may cause unnecessary removal of acceptable aprons if they are indeed of other lead equivalents, however it prevents potentially dangerous exposure to the wearer.

Additionally, the South African Department of Health guidelines (17) stipulate that any personnel who will be within one metre of either the X-ray source or the patient shall wear a lead apron of at least 0,35 mmPb. If the lead equivalence of the apron is unknown it must be assumed to be less than 0,35 mmPb, or risk exposing the wearer to excessive radiation. These aprons are therefore unsuitable for use by the anaesthetists, surgeons, and scrub sisters. In addition the floor nurses may also fall into this category and so these aprons are unfit for use by most, if not all of the operating theatre staff.

In this study 25/87 (29%) of the aprons were of unknown lead equivalence. An additional 20/87 (23%) were of known lead equivalence less than 0.35 mmPb. All 18 of the aprons found to be unsafe for use by radiological criteria fell into one of these two groups. Thus 45/87 (52%) of the aprons were found to be inadequate for use in theatre by anaesthetists and the majority of the theatre staff. Of note all the aprons known to be of lead equivalence 0,35 mmPb or greater were also found to be radiologically intact.

Although the failure rate at all three hospitals was above the 3 to 4% per annum described by Stam and Pillay (12) for institutions performing annual quality control assessments, it was not uniform. CMJAH, CHBAH, and HJH had failure rates of 9%, 17%, and 56% respectively on radiological criteria. This increased to 43%, 50%, and 75% respectively when lead equivalence was taken into account. These figures are in line with hospitals embarking on maintenance inspections for the first time (12, 21). Although no formal

protocols existed at these hospitals, all had some form of maintenance program in place at the time of this study.

The potential effects of this cannot be overstated. Each time a medical professional donned one of these inadequate aprons they were exposing themselves to excessive doses of radiation and significantly increasing their risk of skin changes, haematological and immune dysfunction, cancer, infertility and the myriad deleterious effects described more fully in Chapter 2 of this research report. Some of these effects are potentially fatal.

Several possible explanations exist for the high failure rate of the aprons and insight can be gained by evaluating the results of the other objectives in this study.

The adequacy of the aprons is intimately linked to the maintenance and quality control procedures at the respective hospitals. None of the three hospitals had written protocols but there were informal “protocols” which were being followed with varying degrees of success. The high failure rate of the lead aprons by radiological criteria highlights the inadequacy of the current maintenance programs in these hospitals and may be applicable to other hospitals as well.

The daily maintenance did not have a formal identifiable protocol that was being followed and it was the impression of the researcher that very little, if any, daily care was being performed. This was borne out by the findings that only 32/87 (37%) of the aprons were found to be “clean” and 18/87 (21%) were found to have visible blood.

Where the aprons were routinely inspected by the radiography departments it was done so fluoroscopically, in real-time, in a vacant operating theatre or in the X-ray department. No images were stored. None of the three hospitals had clear criteria for the removal of lead aprons from service and instead relied on the discretion of the radiographer performing the quality control checks.

The South African Department of Health Guidelines For the Protection of Personnel in Theatre (17) state that “…protective clothing should bear an identifying mark and should be examined at yearly intervals. Defective items should be withdrawn from use.” These guidelines do not stipulate how to inspect the aprons or what criteria to use to withdraw the aprons, thus at least partially explaining the protocols at the three hospitals. In comparison this study used guidelines set forth in the international literature (11, 12). Notably, 58/87 (67%) aprons did not have an “identifying mark” as required by law.

The Department of Health Guidelines regarding protective clothing in theatre (17) are not being adhered to in respect of lead equivalence or identifying the aprons, furthermore the testing is not stringent or regular enough. None of the hospitals assessed all of their

aprons in any one sitting. None had complete records of their apron population to ensure that those aprons omitted were screened at the next investigation. It is possible that lead aprons favoured by the theatre staff (for reasons of weight, cleanliness, comfort or perceived superiority) could be excluded from testing in consecutive screenings. Thus, damaged aprons could remain in circulation for longer than the duration between scheduled checks, and evade the minimum yearly screening prescribed by The Department of Health.

The wear and tear on the aprons between routine screenings may be excessive as compared with international settings and may contribute to the high radiological failure rate achieved in this study. The physical appearance of the aprons (cleanliness and blood, and visible defects and fastener functionality) are a surrogate for how well the theatre staff look after the aprons. While the radiography department is responsible for routine screening of the aprons to ensure that defective or unsafe aprons are removed from circulation, the daily care is the responsibility of those who wear the aprons and the theatre staff in general. It is logical that the better the aprons are cared for on a daily basis, the fewer aprons will be defective at annual or semi-annual screenings.
Oyar et al (21) described very poor storage conditions for the aprons they investigated, and found 100% of the aprons to be unsafe for use.

There is documentation both in the form of data collected in this study, and in the form of photographs taken by the researcher, that the aprons are not cared for properly by the theatre staff in between inspections. At all three hospitals aprons were found discarded over stretchers or chairs or even on the floor; instead of on the appropriate hangers (Figure E.2, Appendix E). The presence of visible defects or dysfunctional fasteners are likely to be as a result of poor handling of the aprons by the wearers, often manifested after completing a case and then not hanging the aprons up correctly.

Visible cracks are defined as defects in the outer cosmetic lining of the aprons. This layer does not attenuate radiation and serves merely as a shell for the protective, inner lining. It is thought that the cracks develop in areas of repeated stress or strain and it follows that if the outer layer has been damaged in this way then the inner layer has probably been exposed to the same stressors. Michel and Zorn (20) recommended the removal of lead aprons from service on the basis of cosmetic damage alone due to the likelihood of underlying defects. These recommendations were not followed in this study as the protective lead layer was investigated directly using X-rays, and because of the additional costs the hospitals would incur in an already resource constrained setting.

Despite this seemingly logical association between outward appearance and radiological integrity Oyar et al. (21) found that two aprons described as “brand new, very clean and in good condition in terms of appearance” had defects so large as to render them destroyed. Similarly in this study some of the aprons which were found to be destroyed on X-ray, showed minimal exterior damage. Of the 18 aprons found to be internally destroyed, 7 (39%) did not have any visible defects. Conversely 12 of the 69 remaining aprons (17%) did have visible defects but were found to be radiologically safe. This is illustrated in Table 4.7 and Figure E.3 (Appendix E).

If the lead aprons are not hung correctly, on the appropriate hangers and racks, they are prone to excessive strain from the weight of the absorbent materials and can break or tear at weak points (11, 20, 79). Of note, many of the visible tears identified were at the shoulder where both a buckle and a Velcro strip are intended to support the weight of the apron. Conceivably these tears are from misuse or disregard of this mechanism (Figure E.4, Appendix E).

The apron populations at the three hospitals were inhomogeneous in all measured characteristics. This reflects the constant turnover inherent in the populations i.e. as the garments become damaged, they are replaced by newer, different models, perhaps representing a cheaper supplier or a change in legislature or medical knowledge, or a combination of these factors.

A large number of aprons had no identifying features in terms of either manufacturer, age or lead equivalency. All three of these variables were known in only 19/87 (22%) of the aprons. This raises several questions about their quality, and fitness for service.

Of initial concern is the number of unidentifiable suppliers. It is known that government procurement contracts are awarded predominantly (80 to 90%) on cost (86). This means that contracts are often awarded to the cheapest supplier and anecdotally it is thought that some of these products are of inferior quality. Glaze et al. (87) found that a small but significant number (<5%) of new aprons had defects on delivery, warranting return to manufacturer. Oyar et al. (21) found that 100% of the aprons in their hospital had unacceptably high radiation permeability i.e. they were not attenuating radiation by the amount expected, and were not safe for use. Similarly Muir et al. (88) and Finnerty et al (78) found that radiation permeability was not as advertised for many aprons. If the supplier of the aprons is not known then the quality of the apron must be questioned. The radiation permeability was not measured in this study due to the added complexity involved and the restraint on resources it would impose.

The design of the aprons showed wide variation. The different designs encountered included front only aprons, aprons with protection on the front and the back, and aprons that wrap-around the wearer thus protecting all sides of the body with a double layer of protection in the front. Concurrently all these designs existed in various lead equivalences. The South African Department of Health guidelines recommend that individuals who move around the theatre during the procedure should wear wrap-around lead aprons (17). This is a recommendation only and not a strict stipulation. Anaesthetists are probably the best example of professionals who move around during the procedure, however only 6 of the 87 aprons (7%) were of a wrap-around design. It follows then that the majority of the time anaesthetists are not wearing optimum protection as described by the Department of Health.

It was possible to ascertain the age of only 22% of the aprons. Oyar et al. (21) found no significant relationship between the time the aprons had been in use and the radiation permeability. In this study all of the aprons with a known date of purchase were found to be in satisfactory condition radiologically. Of these the oldest apron was 7,65 years old, with an additional radiation of 0.026mSv. This serves as an example of the longevity possible when proper maintenance is adhered to.

Although not explicitly stated as an objective in this study it was found that none of the operating theatres audited had either thyroid shields or protective eyewear. This is in direct contravention of the government guidelines for radiation protection in theatre, which state:

> Only persons whose presence is necessary shall be in the theatre during exposures. All such persons shall be protected (e.g., provided with leaded aprons, leaded gloves, eye protection (leaded glasses), thyroid shields and/or portable shields). (17)

The operating theatres where very high radiation exposure was expected, such as those used for vascular and neuro-interventional procedures, did supply thyroid shields but no protective eye-wear.

The mathematical formulae described in Appendix D and conceived by Stam and Pillay (12) make use of a “tissue weighting factor” (wt) for the gonadal region, as specified by the ICRP (33). The tissue weighting factor and the surface area of the gonads result in a smaller allowable tear over these organs before the maximum additional exposure is reached. Very similar figures (wt=0,05 for thyroid vs. 0,08 for gonads) would be used to assess the safety of thyroid shields as, like the gonads the thyroid is an extremely radio-sensitive organ (5, 33). Protecting the thyroid is therefore as important as protecting the

gonads. The effective dose to the body is twofold higher if thyroid protection is not worn. This is because the thyroid shield protects all the underlying tissues (74). Thyroid shields are therefore as important as the lead aprons yet were not found in a single one of the theatres audited in this study.

4.5 Summary

In this chapter the results were presented followed by a discussion thereof.

Chapter Five
Study summary, limitations, recommendations and conclusion

5.1 Introduction

In this chapter a summary of the study is presented, followed by the limitations, recommendations and the conclusion.

5.2 Study summary

This study audited the protective lead aprons used at three academic hospitals in Johannesburg. It looked specifically at the aprons that would be worn by anaesthetists and therefore was confined to those aprons found in the main operating theatre complex in each hospital. The theatre maintenance routines were documented as well as various physical attributes of the aprons. Most importantly, the aprons themselves were evaluated radiologically to quantify any additional radiation the wearer would be exposed to. This allowed for the removal of all aprons that were deemed unsafe for use.

In order to evaluate the maintenance protocols and the integrity of the aprons, commonly used international guidelines as well as the relevant South African Department of Health guidelines were followed (11, 12, 17, 18, 20, 33).

With the aid of X-rays, 87 aprons were investigated in this study. The sample comprised of every lead apron in use in the hospitals' main operating theatres and multiple sessions were required to prevent any aprons being excluded. The subjective findings such as degree of cleanliness were assessed by one individual (the researcher) in order to maximise consistency. The X-ray images were interpreted by a specialist radiologist to ensure accuracy.

Ultimately it was found that 52% of the aprons in the operating theatres were not fit for use. While this finding obviously implicates quality control processes at the respective hospitals, the other findings of the study suggest that the health professionals who wear the aprons are also partially responsible. Finally it appears that the South African

Government guidelines lack sufficient clarity and guidance to be implemented in a consistent and therefore safe manner.

In addition to the main objectives of the study it became apparent that additional protection from radiation in the form of thyroid shields and eye protection was not provided in the general operating theatres. This was in contravention to the Department of Health guidelines (17), as well as the majority of the literature reviewed on radiation exposure to anaesthetists (3-5, 25), where thyroid shields were worn routinely although eyewear was not. The combination of defective aprons identified in this study and the lack of other routine mandatory shielding likely places the anaesthetists and other theatre staff at great risk.

5.3 Limitations

Several limitations apply to this study and should be considered when assessing the findings of the audit. Due to the contextual nature of the study it is uncertain to what extent the study findings can be generalised to other hospitals.

Protective aprons in high exposure areas such as the angiography suite, CT and cardiac catheterisation laboratories were not included in this investigation.

Although every possible precaution was taken to ensure that all the theatre aprons were included in the study, the possibility exists that some were not assessed. As none of the three hospitals had an inventory of the aprons in their theatre complex, it is not possible to know if additional aprons exist.

5.4 Recommendations

5.4.1 Recommendations for clinical practice

The results of this study necessitate a change of maintenance program at the three hospitals investigated. Written protocols should be created for all aspects of apron care including daily storage and cleaning, and radiological assessment.

It is recommended that the respective radiography departments adopt the criteria suggested by Stam and Pillay (12). While this is more time consuming than the current screening regimens, it adds far greater precision to the decision making process and would only need to be done once or twice a year.

The images from screening the aprons would need to be saved for later review, but only those images where defects were identified, therefore not every image would need to be reviewed, and thus the additional time/labour required is likely to be minimal.

Accurate, updated records of the apron populations need to be kept in apron registers. In this study 13 aprons needed to be removed from the operating theatres as their lead equivalence was unknown, despite the aprons being intact and otherwise fit for service. Complete records of the apron population may have prevented this. The apron registers should indicate the apron number, manufacturer, lead equivalence, date of purchase, date of last inspection, presence and location of any defects. Each individual apron must be clearly marked with an identifying number. This would ensure that no aprons are excluded from screening. Over time it may also allow the most cost affordable manufacturers to be identified as trends may emerge. Small acceptable cracks could be more closely monitored to determine if they are enlarging. Stam and Pillay found an average increase in defect length of 270% over a 10 month follow up period (12).

It is recommended that any new aprons which are purchased are of at least 0,35mmPb and of a wrap-around design.

It is recommended that theatre staff receive additional information and inservice training on the care of protective garments as they are the ones most likely to be causing the defects. They should also be informed of the law surrounding radiation protection in theatre so as to better protect themselves.

5.4.2 Recommendations for further research

The results of this audit lead to the removal of more than half of the aprons investigated. Therefore similar audits should be undertaken in other hospitals. Furthermore very little research has been done on the exposure of South African theatre staff to radiation. As our working conditions may differ significantly from those in other countries it is recommended that exposure of medical professionals be investigated.

A further study should repeat this investigation in the areas of the hospital not assessed thus far e.g. angiography suite and CT scanner.

Another domain that may be of interest is to assess whether the lead aprons found in the South African operating theatres actually attenuate radiation by the amount advertised, as studies have found this to not always be the case (21, 88).

5.5 Practice changes following the completion of the study

The relevant individuals and departments at the three hospitals were informed of the findings of this study in writing. The list of inadequate aprons at the respective hospitals was attached as well as a brief summary of the findings and reasons for finding the

aprons inadequate. Garments that had gross defects identified at the time of screening were removed from service immediately and not returned to the theatre pool. Additional aprons identified as inadequate after interpreting the X-ray films were removed from service as a result of the written notification. An example of the written notification is provided in Appendix F.

5.6 Conclusion

Fifty two percent of the protective garments worn in the operating theatres investigated in this study were found to be inadequate. The high failure rate is thought to be multifactorial and the radiography departments, theatre staff and Department of Health guidelines are all at least partially responsible.

The effects of using the damaged aprons may be far reaching and include severe morbidity and even mortality but are not easily quantifiable. The importance of this will only grow as the amount of radiography assisted procedures increases in the future.

Recommendations have been made according to international and South African guidelines as how best to improve the safety for all theatre staff in the future.

References

1. Ismail S, Khan FA, Sultan N, Naqvi M. Radiation Exposure of Trainee Anaesthetists. Anaesthesia. 2006;61(1):9-14.
2. Taylor J, Chandramohan M, Simpson KH. Radiation Safety for Anaesthetists. Continuing Education in Anaesthesia, Critical Care & Pain. (2013) 13 (2): 59-62
3. Ismail S, Khan F, Sultan N, Naqvi M. Radiation Exposure to Anaesthetists During Interventional Radiology. Anaesthesia. 2010 Jan;65(1):54-60. PubMed PMID: 19922509. Epub 2009/11/20. eng.
4. Katz JD. Radiation Exposure to Anesthesia Personnel: The Impact of an Electrophysiology Laboratory. Anesthesia and Analgesia. 2005 Dec;101(6):1725-6. PubMed PMID: 16301249. Epub 2005/11/23. eng.
5. Durack DP, Gardner AI, Trang A. Radiation Exposure During Anaesthetic Practice. Anaesthesia & Intensive Care. 2006;34(2):216-7. PubMed PMID: 24309175.
6. Dewar C. Occupational Radiation Safety. Radiologic Technology. 2013 May-Jun;84(5):467-89. PubMed PMID: 23687243. Epub 2013/05/21. eng.
7. Ainsbury EA, Bouffler SD, Dorr W, Graw J, Muirhead CR, Edwards AA, et al. Radiation Cataractogenesis: A Review of Recent Studies. Radiation Research. 2009 Jul;172(1):1-9. PubMed PMID: 19580502. Epub 2009/07/08. eng.
8. Sont WN, Zielinski JM, Ashmore JP, Jiang H, Krewski D, Fair ME, et al. First Analysis of Cancer Incidence and Occupational Radiation Exposure Based on the National Dose Registry of Canada. American Journal of Epidemiology. 2001 Feb 15;153(4):309-18. PubMed PMID: 11207146. Epub 2001/02/24. eng.
9. Wingren G, Hallquist A, Hardell L. Diagnostic X-Ray Exposure and Female Papillary Thyroid Cancer: A Pooled Analysis of Two Swedish Studies. European Journal of Cancer Prevention : The Official Journal of The European Cancer Prevention Organisation (ECP). 1997 Dec;6(6):550-6. PubMed PMID: 9496457. Epub 1998/03/13. eng.
10. Faure E. X-Rays-Induced Secretion of Cellular Factor(S) That Enhance(S) Hiv-1 Promoter Transcription in Various Non-Irradiated Transfected Cell Lines. Cellular and Molecular Biology (Noisy-le-Grand, France). 1998 Dec;44(8):1275-92. PubMed PMID: 9874515. Epub 1999/01/05. eng.
11. Lambert K, McKeon T. Inspection of Lead Aprons: Criteria for Rejection. Health Physics. 2001 May;80(5 Suppl):S67-9. PubMed PMID: 11316086. Epub 2001/04/24. eng.
12. Stam W, Pillay M. Inspection of Lead Aprons: A Practical Rejection Model. Health Physics. 2008 Aug;95 Suppl 2:S133-6. PubMed PMID: 18617796. Epub 2008/07/22. eng.
13. McGowan C, Heaton B, Stephenson RN. Occupational X-Ray Exposure of Anaesthetists. British Journal of Anaesthesia. 1996 Jun;76(6):868-9. PubMed PMID: 8679364. Epub 1996/06/01. eng.
14. Department of Health Victoria Australia. Testing Lead Aprons Used in Diagnostic Radiology Departments Melbourne, Australia 2011 [accessed 7 July 2013]. Available from: http://www.health.vic.gov.au/radiation/publications.htm.
15. Phillip B, Duran EB. Rejection criteria for defects in lead apparel used for radiation protection of X-ray workers. Vancouver: BC Centre for Disease Control; 2003 Mar 1 [accessed 9 Feb 2015]; 8 p. Available from: http://www.bccdc.ca/NR/rdonlyres/A5EB891B-7BC4-442D-A6ED-864438FAF9EF/0/RejectionCriteriaforLeadApparel.pdf

16. Health Physics Office Stanford Hospital and Clinics. Radiation Protection Guidance for Hospital Staff Palo Alto, CA 2012 [accessed 7 June 2013]. Available from: http://web.stanford.edu/dept/EHS/prod/researchlab/radlaser/.

17. Directorate: Radiation Control. Guidelines: Radiation Protection of Personnel in Theatre: Department of Health South Africa; 2011 [accessed 7 June 2013]. Available from: http://sites.google.com/site/radiationcontroldoh/.

18. Directorate: Radiation Control. Guidelines: Protective Clothing: Department of Health South Africa; 2009 [accessed 7 June 2013]. Available from: http://sites.google.com/site/radiationcontroldoh/.

19. International Atomic Energy Agency. Iaea Training Course on Radiation Protection for Doctors (Non-Radiologists, Non-Cardiologists) Using Fluoroscopy: How Do I Reduce My Radiation Risk? [accessed 29 May 2013]. Available from: https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/Non-radiologistsNon-cardiologists.htm

20. Michel R, Zorn MJ. Implementation of an X-Ray Radiation Protective Equipment Inspection Program. Health Physics. 2002 Feb;82(2 Suppl):S51-3. PubMed PMID: 11797906. Epub 2002/01/19. eng.

21. Oyar O, Kislalioglu A. How Protective Are the Lead Aprons We Use against Ionizing Radiation? Diagnostic and Interventional Radiology (Ankara, Turkey). 2012 Mar-Apr;18(2):147-52. PubMed PMID: 22020951. Epub 2011/10/25. eng.

22. Van Der Merwe B. Radiation Dose to Surgeons in Theatre. SAJS. 2012 May 2012;50(2): 26-9.

23. Department of Health. Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Pretoria, South Africa: Department of Health; 2006.

24. WMA. World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects 2008. [accessed 29 May 2013] Available from: http://wma.net/e/policy/b3.htm.

25. Henderson KH, Lu JK, Strauss KJ, Treves ST, Rockoff MA. Radiation Exposure of Anesthesiologists. Journal of Clinical Anesthesia. 1994 Jan-Feb;6(1):37-41. PubMed PMID: 8142097. Epub 1994/01/01. eng.

26. World Health Organization. What Is Ionizing Radiation? 2013 [accessed 3 June 2013]. Available from: http://www.who.int/ionizing_radiation/about/what_is_ir/en/index.html.

27. MEMBERS WC, Hirshfeld JW, Balter S, Brinker JA, Kern MJ, Klein LW, et al. ACCF/AHA/HRS/SCAI Clinical Competence Statement on Physician Knowledge to Optimize Patient Safety and Image Quality in Fluoroscopically Guided Invasive Cardiovascular Procedures: A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training. Circulation. 2005 February 1, 2005;111(4):511-32.

28. Stabin M. Radiation Basics - Radiation Quantities and Units Health Physics Society, [accessed 5 June 2013]. Available from: http://www.hps.org/publicinformation/ate/q1252.html.

29. Canadian Nuclear Safety Commission. Radiation Doses [accessed 5 June 2013]. Available from: http://cnsc-ccsn.gc.ca/eng/readingroom/radiation/radiation_doses.cfm#3.

30. Phillips G, Monaghan WP. Radiation Safety for Anesthesia Providers. AANA Journal. 2011;79(3):257-67. PubMed PMID: 60913316.

31. Colangelo JE, Johnston J, Killion JB, Wright DL. Radiation Biology and Protection. Radiologic Technology. 2009 May-Jun;80(5):421-41. PubMed PMID: 19457846. Epub 2009/05/22. eng.

32. International Atomic Energy Agency. Biological Effects of Ionizing Radiation at Molecular and Cellular Levels [accessed 3 June 2013]. Available from: http://www.pub.iaea.org/MTCD/publications/PDF/eprmedt/Day_2/Day_2-6a.pps

33. International Commission on Radiological Protection. Recommendations of the International Commission on Radiological Protection, ICRP Publication 103. Ann ICRP 2007. p. 1-332. Pergamon Press, Oxford, United Kingdom

34. International Commission on Radiological Protection. Statement on Tissue Reactions, ICRP Publication 118. Ann ICRP 2011. p. 1-2. Pergamon Press, Oxford, United Kingdom

35. Ciraj-Bjelac O, Rehani MM, Sim KH, Liew HB, Vano E, Kleiman NJ. Risk for Radiation-Induced Cataract for Staff in Interventional Cardiology: Is There Reason for Concern? Catheterization and Cardiovascular Interventions: Official Journal of the Society for Cardiac Angiography & Interventions. 2010 Nov 15;76(6):826-34. PubMed PMID: 20549683. Epub 2010/06/16. eng.

36. Vano E, Kleiman NJ, Duran A, Rehani MM, Echeverri D, Cabrera M. Radiation Cataract Risk in Interventional Cardiology Personnel. Radiation Research. 2010 Oct;174(4):490-5. PubMed PMID: 20726724. Epub 2010/08/24. eng.

37. Directorate: Radiation Control. Code of Practice for Users of Medical X-Ray Equipment: Department of Health South Africa; 2011 [accessed 7 June 2015]. Available from: http://sites.google.com/site/radiationcontroldoh/.

38. Directorate: Radiation Control. Ionizing Radiation Dose Limits and Annual Limits on Intake of Radioactive Material: Department of Health South Africa; 2001 [accessed 6 June 2013]. Available from: http://sites.google.com/site/radiationcontroldoh/.

39. Directorate: Radiation Control. Guidelines: Management of Pregnant Radiographers and Other Staff Members: Department of Health South Africa; 2009 [accessed 6 June 2013]. Available from: http://sites.google.com/site/radiationcontroldoh/.

40. Directorate: Radiation Control. Guidelines: Monitoring of Radiation Workers in Theatre: Department of Health South Africa; 2011 [accessed 6 June 2013]. Available from: http://sites.google.com/site/radiationcontroldoh/.

41. Hayman MW, Paleologos MS, Kam PC. Interventional Neuroradiological Procedures-a Review for Anaesthetists. Anaesthesia and Intensive Care. 2013 Mar;41(2):184-201. PubMed PMID: 23530785. Epub 2013/03/28. eng.

42. Kong Y, Struelens L, Vanhavere F, Vargas CS, Schoonjans W, Zhuo WH. Influence of Standing Positions and Beam Projections on Effective Dose and Eye Lens Dose of Anaesthetists in Interventional Procedures. Radiation Protection Dosimetry. 2015 Feb;163(2):181-7. PubMed PMID: 24795393. Epub 2014/05/06. eng.

43. International Commission on Radiological Protection. Radiological Protection of the Worker in Medicine and Dentistry. A Report of a Task Group of Committee 3 of the International Commission on Radiological Protection. Annals of the ICRP. 1989;20(3):1-83. PubMed PMID: 2633671. Epub 1989/01/01. eng.

44. Kendall GM, Muirhead CR, MacGibbon BH, O'Hagan JA, Conquest AJ, Goodill AA, et al. Mortality and Occupational Exposure to Radiation: First Analysis of the National Registry for Radiation Workers. BMJ (Clinical research ed). 1992 Jan 25;304(6821):220-5. PubMed PMID: 1739796. Pubmed Central PMCID: PMC1881453. Epub 1992/01/25. eng.

45. Mettler FA, Jr., Gus'kova AK, Gusev I. Health Effects in Those with Acute Radiation Sickness from the Chernobyl Accident. Health Physics. 2007 Nov;93(5):462-9. PubMed PMID: 18049222. Epub 2007/12/01. eng.

46. Simon SL, Bouville A, Land CE, Beck HL. Radiation Doses and Cancer Risks in the Marshall Islands Associated with Exposure to Radioactive Fallout from Bikini and Enewetak Nuclear

Weapons Tests: Summary. Health Physics. 2010 Aug;99(2):105-23. PubMed PMID: 20622547. Epub 2010/07/14. eng.

47. Brenner DJ, Doll R, Goodhead DT, Hall EJ, Land CE, Little JB, et al. Cancer Risks Attributable to Low Doses of Ionizing Radiation: Assessing What We Really Know. Proceedings of the National Academy of Sciences. 2003 November 25, 2003;100(24):13761-6.

48. Ron E. Ionizing Radiation and Cancer Risk: Evidence from Epidemiology. Radiation Research. 1998 Nov;150(5 Suppl):S30-41. PubMed PMID: 9806607. Epub 1998/11/07. eng.

49. International Commission on Radiological Protection. Risk Estimation of Multifactorial Diseases. ICRP Publication 83. Ann. ICRP 1999. p. 3-4. Pergamon Press. Oxford United, Kingdom

50. International Commission on Radiological Protection. Biological Effects after Prenatal Irradiation (Embryo and Fetus). ICRP Publication 90. Ann. ICRP 2003. p. 1-2. Pergamon Press. Oxford, United Kingdom

51. Morgan WF. Non-Targeted and Delayed Effects of Exposure to Ionizing Radiation: Ii. Radiation-Induced Genomic Instability and Bystander Effects in Vivo, Clastogenic Factors and Transgenerational Effects. Radiation Research. 2003 May;159(5):581-96. PubMed PMID: 12710869. Epub 2003/04/25. eng.

52. Satoh C, Takahashi N, Asakawa J, Kodaira M, Kuick R, Hanash SM, et al. Genetic Analysis of Children of Atomic Bomb Survivors. Environmental Health Perspectives. 1996 May;104 Suppl 3:511-9. PubMed PMID: 8781374. Pubmed Central PMCID: PMC1469615. Epub 1996/05/01. eng.

53. Mettler FA. Medical Effects and Risks of Exposure to Ionising Radiation. Journal of Radiological Protection: Official Journal of the Society for Radiological Protection. 2012 Mar;32(1):N9-N13. PubMed PMID: 22395124. Epub 2012/03/08. eng.

54. Committee on an Assessment of CDC Radiation Studies National Research Council. Radiation Dose Reconstruction for Epidemiologic Uses: The National Academies Press; 1995.

55. National Council on Radiation Protection and Measurements. Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation. Bethesda: NCRP, 2001 Contract No.: 136.

56. Darby SC, Ewertz M, McGale P, Bennet AM, Blom-Goldman U, Brønnum D, et al. Risk of Ischemic Heart Disease in Women after Radiotherapy for Breast Cancer. New England Journal of Medicine. 2013;368(11):987-98. PubMed PMID: 23484825.

57. Bergonié J, Tribondeau L. Interpretation of Some Results of Radiotherapy and an Attempt at Determining a Logical Technique of Treatment / De Quelques Resultats De La Radiotherapie Et Essai De Fixation D'une Technique Rationnelle. Radiation Research. 1959 1959/10/01;11(4):587-8.

58. Bergonié J. Interpretation De Quelques Résultats De La Radiotherapie Et Essai De Fixation D'une Technique Rationnelle. Comptes Rendus Hebdomadaires de l'Academie des Sciences. 1906:983-5.

59. De Santis M, Di Gianantonio E, Straface G, Cavaliere AF, Caruso A, Schiavon F, et al. Ionizing Radiations in Pregnancy and Teratogenesis: A Review of Literature. Reproductive Toxicology (Elmsford, NY). 2005 Sep-Oct;20(3):323-9. PubMed PMID: 15925481. Epub 2005/06/01. eng.

60. Grammaticos P, Giannoula E, Fountos GP. Acute Radiation Syndrome and Chronic Radiation Syndrome. Hellenic Journal of Nuclear Medicine. 2013 Jan-Apr;16(1):56-9. PubMed PMID: 23570025. Epub 2013/04/10. eng.

61. Balter S, Hopewell JW, Miller DL, Wagner LK, Zelefsky MJ. Fluoroscopically Guided Interventional Procedures: A Review of Radiation Effects on Patients' Skin and Hair. Radiology. 2010 February 1, 2010;254(2):326-41.

62. Wagner LK, Eifel PJ, Geise RA. Potential Biological Effects Following High X-Ray Dose Interventional Procedures. Journal of Vascular and Interventional Radiology : JVIR. 1994 Jan-Feb;5(1):71-84. PubMed PMID: 8136601. Epub 1994/01/01. eng.

63. Charles M. Unscear Report 2000: Sources and Effects of Ionizing Radiation. United Nations Scientific Comittee on the Effects of Atomic Radiation. Journal of Radiological Protection: Official Journal of the Society for Radiological Protection. 2001 Mar;21(1):83-6. PubMed PMID: 11281539. Epub 2001/04/03. eng.

64. Shook DC, Gross W. Offsite Anesthesiology in the Cardiac Catheterization Lab. Current Opinion in Anaesthesiology. 2007 Aug;20(4):352-8. PubMed PMID: 17620845. Epub 2007/07/11. eng.

65. Jung CH, Ryu JS, Baek SW, Oh JH, Woo NS, Kim HK, et al. Radiation Exposure of the Hand and Chest During C-Arm Fluoroscopy-Guided Procedures. The Korean Journal of Pain. 2013 Jan;26(1):51-6. PubMed PMID: 23342208. Pubmed Central PMCID: PMC3546211. Epub 2013/01/24. eng.

66. Trachtenberg HA, Slater EM. Anesthetists' Exposure to Radiation During Radium Implantation Procedures. JAMA : the Journal of the American Medical Association. 1965 Mar 1;191:763-4. PubMed PMID: 14245527. Epub 1965/03/01. eng.

67. Otto LK, Davidson S. Radiation Exposure of Certified Registered Nurse Anesthetists During Ureteroscopic Procedures Using Fluoroscopy. AANA J. 1999 Feb;67(1):53-8. PubMed PMID: 10488277. Epub 1999/09/17. eng.

68. University of California Irvine. Dosimetry 2010 [accessed 19 June 2013]. Available from: http://www.ehs.uci.edu/programs/radiation/radfaq.html.

69. Niklason LT, Marx MV, Chan HP. The Estimation of Occupational Effective Dose in Diagnostic Radiology with Two Dosimeters. Health Physics. 1994 Dec;67(6):611-5. PubMed PMID: 7960781. Epub 1994/12/01. eng.

70. Anastasian ZH, Strozyk D, Meyers PM, Wang S, Berman MF. Radiation Exposure of the Anesthesiologist in the Neurointerventional Suite. Anesthesiology. 2011 Mar;114(3):512-20. PubMed PMID: 21285864. Epub 2011/02/03. eng.

71. Arii T, Uchino S, Kubo Y, Kiyama S, Uezono S. Radiation Exposure to Anaesthetists During Endovascular Procedures. Anaesthesia. 2015 Jan;70(1):47-50. PubMed PMID: 25267714. Epub 2014/10/01. eng.

72. Directorate: Radiation Control. Guidelines Regarding Organizational Requirements for Authority Holders and Their Appointed Radiation Protection Officers in Respect of Group Iv Hazardous Substances: Department of Health South Africa; 2000 [accessed 6 June 2013]. Available from: http://sites.google.com/site/radiationcontroldoh/.

73. Judkins MP. Guidelines for Radiation Protection in the Cardiac Catheterization Laboratory. Catheterization and Cardiovascular Diagnosis. 1984;10(1):87-92. PubMed PMID: 6713537. Epub 1984/01/01. eng.

74. Thornton RH, Dauer LT, Altamirano JP, Alvarado KJ, St Germain J, Solomon SB. Comparing Strategies for Operator Eye Protection in the Interventional Radiology Suite. Journal of Vascular and Interventional Radiology : JVIR. 2010 Nov;21(11):1703-7. PubMed PMID: 20920841. Epub 2010/10/06. eng.

75. Naidu LS, Singhal S, Preece DE, Vohrah A, Loft DE. Radiation Exposure to Personnel Performing Endoscopic Retrograde Cholangiopancreatography. Postgraduate Medical

Journal. 2005 Oct;81(960):660-2. PubMed PMID: 16210465. Pubmed Central PMCID: PMC1743365. Epub 2005/10/08. eng.

76. International Atomic Energy Agency. Staff Radiation Protection 2013 [accessed 20 June 2013]. Available from: https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/4_InterventionalRadiology/fluoroscopy-operating-theatres/fluoroscopy-staff-protection.htm.

77. Wagner LK, Mulhern OR. Radiation-Attenuating Surgical Gloves: Effects of Scatter and Secondary Electron Production. Radiology. 1996 Jul;200(1):45-8. PubMed PMID: 8657942. Epub 1996/07/01. eng.

78. Finnerty M, Brennan PC. Protective Aprons in Imaging Departments: Manufacturer Stated Lead Equivalence Values Require Validation. European Radiology. 2005 Jul;15(7):1477-84. PubMed PMID: 15789212. Epub 2005/03/25. eng.

79. Radiology Compliance Branch. The Use and Care of Radiology Protective Equipment Raleigh: North Carolina Department of Health and Human Services; 2011 [accessed 15 June 2013]. Available from: http://www.ncradiation.net.

80. International Commission on Radiological Protection. General Principles for the Radiation Protection of Workers. Annals of the ICRP. 1997;27(1):1-60. PubMed PMID: 9247684. Epub 1997/01/01. eng.

81. Christodoulou EG, Goodsitt MM, Larson SC, Darner KL, Satti J, Chan HP. Evaluation of the Transmitted Exposure through Lead Equivalent Aprons Used in a Radiology Department, Including the Contribution from Backscatter. Medical Physics. 2003 Jun;30(6):1033-8. PubMed PMID: 12852526. Epub 2003/07/11. eng.

82. Joint Commission on Accrediation of Healthcare Organizations. Accreditation Manual for Hospitals, Environment of Care Chicago 2001 [accessed 6 June 2013]. Available from: http://www.jointcommission.org/.

83. Brink H. Fundementals of Research Methodology for Health Care Professionals Second ed. Cape Town: Juta; 2006.

84. Burns N, Grove S. Understanding Qualitative Research Design. 6 ed. Henderson L, editor. Missouri, USA: Saunders Elsiever; 2009.

85. Katzenellenbogen J, Joubert G, Abdool Karim S. Epidemiology: A Manual for South Africa. South Africa: Oxford University Press; 2002.

86. Government Communications Information System Department. Tender Procedures: Department of Health; [accessed 4 June 2015]. Available from: www.gcis.gov.za/content/about-us/procurement/procedure.

87. Glaze S, LeBlanc AD, Bushong SC. Defects in New Protective Aprons. Radiology. 1984 Jul;152(1):217-8. PubMed PMID: 6729117. Epub 1984/07/01. eng.

88. Muir S, McLeod R, Dove R. Light-Weight Lead Aprons--Light on Weight, Protection or Labelling Accuracy? Australasian physical & engineering sciences in medicine / supported by the Australasian College of Physical Scientists in Medicine and the Australasian Association of Physical Sciences in Medicine. 2005 Jun;28(2):128-30. PubMed PMID: 16060320. Epub 2005/08/03. eng.

Appendices

Appendix A – Data collection sheets

Data Collection Sheet 1 **(pg. 1)**

Date of inspection:

Date of last inspection: **Unknown:**

Apron identification number:

Hospital: CHBAH CMJAH HJH

Manufacturer: **Unknown:**

Lead equivalence: 0,25mmPb 0,35mmPb 0,5mmPb
Unknown

Design: Front only Front and back no sides Wrap-around

Age: **years** **Unknown**

Physical Appearance:

Presence of Identifying Number: Yes if yes, number No

Cleanliness: Clean Moderately dirty Dirty

Blood: Yes No

Visible tears: Yes No

Fasteners: Functional Broken

X-ray results (pg. 2)

Linear Cracks

Number	Size (mm)	Location
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Holes

Number	Size (mm^2)	Location
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Data Collection Sheet 2

Hospital: CHBAH ☐ CMJAH ☐ HJH ☐

Formal protocol for daily cleaning: Yes ☐ No ☐

If yes, describe the protocol: _____

_____

_____

_____

_____

Formal protocol for apron maintenance and screening: Yes ☐

No ☐

Who is responsible for maintaining the aprons?: _____

_____

How often is maintenance performed?:_____

_____

How are the aprons inspected?: _____

_____

_____

What are the criteria for removing an apron?: _____

_____

_____

_____

Appendix B – Approval from the University

Approval to conduct the study from Postgraduate Committee of the University of the Witwatersrand

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
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Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

09 January 2015
Person No: 0405168V
PAG

Dr AJ Cohen
P O Box 1157
Gallo Manor
2052
South Africa

Dear Dr Cohen

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *An audit of lead aprons used in operating theatres at three academic hospitals in Johannesburg.* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Ethics waiver for the study from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand

University
of the Witwatersrand,
Johannesburg

Human Research Ethics Committee (Medical)
(formerly Committee for Research on Human Subjects (Medical)

Secretariat: Research Office, Room SH10005, 10th floor, Senate House • Telephone: +27 11 717-1234 • Fax: +27 11 339-5708
Private Bag 3, Wits 2050, South Africa

Ref: W-CJ-130719-1 19/07/2013

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: **Dr A J Cohen.**

Project title: **An audit of lead aprons used in operating theatres at three academic hospitals in Johannesburg.**

Reason: This is an audit of the integrity of lead aprons used in operating theatres. No human participants are involved. Written permission to do the study is required from the CEOs of the participating hospitals. Copies of this permission must be lodged with the ethics secretariat before the study is started.

UNIVERSITY OF THE WITWATERSRAND
PROF PE CLEATON-JONES
HREC (MEDICAL)
2013 -07- 19
JOHANNESBURG

Professor Peter Cleaton-Jones
Chair: Human Research Ethics Committee (Medical)

copy: Anisa Keshav, Zanele Ndlovu, Wits Research Office

Appendix C – Approval from hospitals

Approval to conduct the study from the CEO of CMJAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries: Mrs. Lefentse Mapaisa
Office of the Clinical Executives
Tel: (011)488-3710
Fax: (011)488-3947
02 February 2015

Dr. Anthony Cohen
Registrar
Department of Anaesthesiology
University of the Witwatersrand

Dear Dr. Cohen

RE: **An audit of lead aprons used in operating theatres at three academic hospitals in Johannesburg**

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported / ~~not supported~~

Dr. M.I. Mofokeng
Director: Clinical Services
DATE: 2/2/2015

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 03/02/2015

Approval to conduct the study from the Medical Advisory Committee of CHBAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 15 August 2014

TITLE OF PROJECT: An audit of lead aprons used in operating theatres at three academic hospitals in Johannesburg

UNIVERSITY: Witwatersrand

Principal Investigator: AJ Cohen

Department: Anaesthesiology

Supervisor (If relevant): H Perrie and J Wagner

Permission Head Department (where research conducted): Yes

Date of start of proposed study: Aug 2014
Date of completion of data collection: Dec 2015

he Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- An ethics waiver having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

Recommended
(On behalf of the MAC)
Date: 15 August 2014

Approved/Not Approved
Hospital Management
Date: 20/08/14

Approval to conduct the study from the CEO of HJH

health and social development
Department Health and Social Development
GAUTENG PROVINCE

PERMISION FOR RESEARCH

DATE: 01/07/2014

NAME OF RESEARCH WORKER: DR A. COHEN

CONTACT DETAILS OF RESEARCH (INCLUDE ALTERNATE RESEARCHER):
DR COHEN 072 480 3315
DR Janine Wagner 082 933 7194.

TITLE OF RESEARCH PROJECT AN AUDIT OF LEAD APRONS USED IN OPERATING THEATRES AT THREE Academic HOSPITALS

OBJECTIVES OF STUDY (Briefly or include a protocol):
TO ASSESS THE ADEQUACY OF LEAD APRONS WORN BY Theatre Staff. - Protocol attached.

METHODOLOGY (Briefly or include a protocol): X-Ray Aprons to assess for defects, Protocol attached.

THE APPROVAL BY THE SUPERINTENDENT IS STRICTLY ON THE BASIS OF THE FOLLOWING:

(i) CONFIDENTIALITY OF PATIENTS MAINTAINED: NO Pts involved
(ii) NO COSTS TO THE HOSPITAL: Costs to researcher - see attached letter from head of Radiology
(iii) APPROVAL OF HEAD OF DEPARTMENT: Approved by Post Graduate Comitee
(iv) APPROVAL BY ETHICS COMMITTEE OF UNIVERSITY: Ethics Waiver - Attached.

SUPERINTENDENT PERMISION

Signature: [signature] Date: 4/7/2014

SUBJECT TO ANY RESTRICTIONS: Financial impact on hospital budget.

Helen Joseph Hospital
Perth Road
Tel: 011 489 1011

Private Bag X47
Auckland Park
2006

Appendix D – Derivation of the criteria used to reject inadequate lead aprons as proposed by Stam. (12)

The effective dose for a lead apron with a defect of area "*a"* is given by equation 1:

$$E_{tot}(a) = w_t \times H \times T \times \left(1 - \frac{a}{A}\right) + w_t \times H \times \left(\frac{a}{A}\right) \qquad \textbf{(Eqn 1)}$$

Where "w_t" is the tissue weighting factor, "H" is the unshielded equivalent dose exposing an effective area "A" with a transmission "T".
In practice, defects appear as tears with a length "L" rather than an area "a". Therefore equation 1 is derived for a tear with a length "L" (Fig D.1)

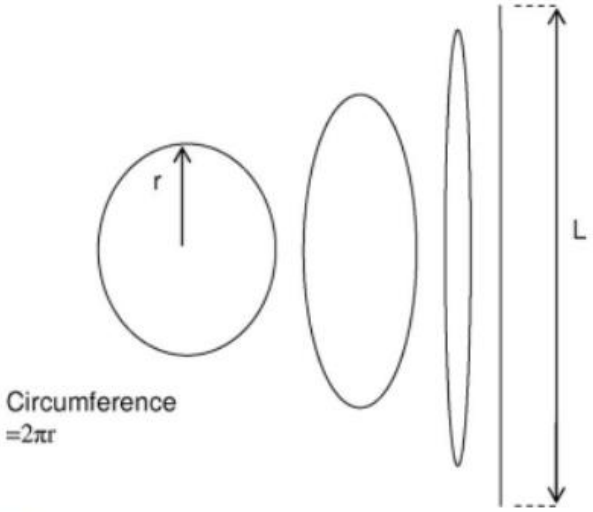


Figure D.1 Conversion from linear tear to area of defect

To convert from a linear tear of length "L" to area "a", i.e., circle with a maximum area a (= πr^2) with circumference 2L = 2 πr**,** equation 2 is derived where the radius is substituted for the length:

$$E_{add}(L) = w_t \times H \times \frac{(L^2/\pi)}{A}(1 - T) \qquad \textbf{(Eqn 2)}$$

The value for transmission "T" is related to the lead equivalence of the apron and is provided in Table 2.2 reproduced here for completeness.

Table 2.2 Transmission values for aprons of different lead equivalences. (12)

Lead equivalence (mmPb)	Transmission
0,25	0,19
0,35	0,10
0,50	0,038
0,70	0,010
1,00	0,0014

Stam (12) defines the rejection criteria as “the maximum additional dose that is just tolerable, i.e… 0,22 mSv.” Using this dose and either equation 1 or 2 (for an area or a tear respectively), the maximum tolerable defect size for lead aprons of various lead equivalences can be calculated.

Appendix E - Figures

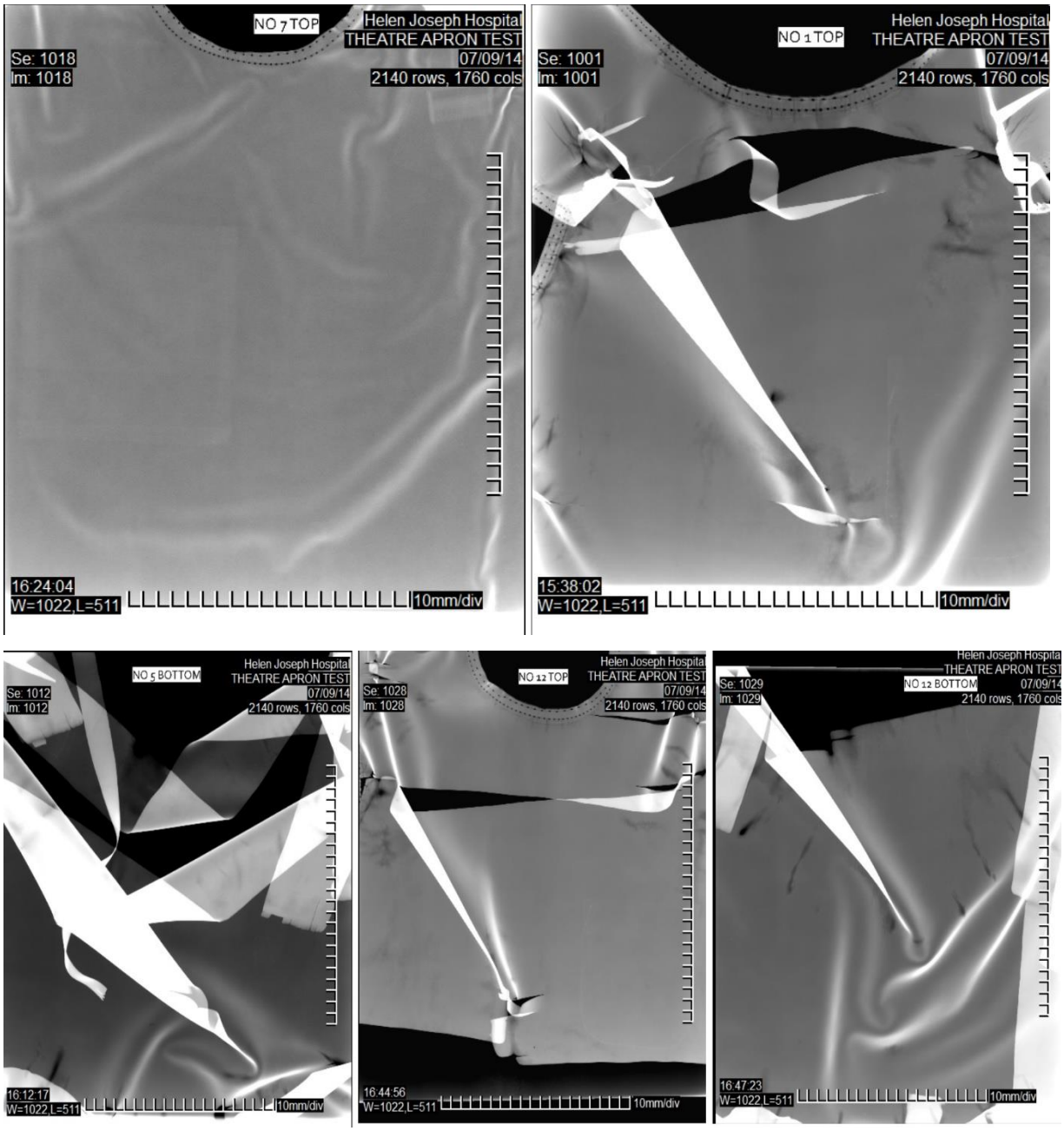


Figure E.1 X-ray images from HJH. Top left an intact apron, top right a defective apron removed from service. The black areas represent holes, the white areas occur where the lead attenuating layer has folded on itself. The neck lines are clearly visible on each apron as a semicircular black hole at the top of the images, the apron on the right has numerous additional black areas where the defects are present. The apron on the right allowed an additional dose of 136,6 mSv to the wearer. Bottom images, three destroyed aprons removed from service.



Figure E.2 Examples of the poor storage conditions as identified by the researcher. From left to right: an apron at HJH hung on the correct rack, but in a manner likely to cause damage and contrary to prescribed guidelines; two aprons at CMJAH draped over orthopaedic equipment; an apron at CHBAH draped over a trolley; and an apron crumpled on the floor.



Figure E.3 Top right: a photo of an apron at CHBAH shows a relatively intact exterior but the X-ray of the same apron (top left) reveals that all the radiation attenuating material has in fact collapsed at the bottom of the apron and no protection is afforded over the chest. The bottom image depicts an apron from CMJAH with large visible defect, which was found to be radiologically intact (safe).



Figure E.4 Four different aprons are depicted. Clockwise from the top: an apron from CHBAH with broken shoulder mechanism repaired with adhesive tape; an apron from HJH with the same arrangement at the shoulder; an apron from CMJAH illustrating a broken buckle mechanism; and lastly an apron from CMJAH illustrating a defective Velcro mechanism.

Appendix F – Sample of letter to hospitals discussing results

WITS UNIVERSITY

DEPARTMENT OF ANAESTHESIOLOGY
UNIVERSITY OF THE WITWATERSRAND,
JOHANNESBURG
Tel.(011)933-9334/5 / Fax (011)933-1843

FACULTY OF HEALTH SCIENCES

20 July 2015

Dear Madam,

Re: Anaesthesiology MMed "An audit of lead aprons used in operating theatres at three academic hospitals in Johannesburg"

With the written permission of the hospital CEO (attached) an audit was undertaken of the lead aprons worn by the theatre staff in your institution. This audit was performed as part of an MMed (Anaes) and the results have been described formally in a research report.

The purpose of this audit was not to assign blame or point fingers at any parties involved but merely to assess the aprons adequacy for protecting the wearers, and to compare the findings with similar investigations performed elsewhere.

Briefly, the aprons were inspected to describe their external appearance and then X-rayed to look for any defects in the lead lining. These defects were then assessed by a specialist radiologist, and the aprons' fitness for ongoing use was calculated according to internationally recognised criteria (attached). The aprons were also assessed in terms of the Department of Health Directorate of Radiation Control Guidelines for the Protection of Personnel in Theatre (attached). The relevant theatre and radiography staff were also interviewed to ascertain the current quality control procedures.

The staff at your hospital were extremely polite and helpful with all aspects of the study and I am very grateful to them.

I am writing this letter in order to formally inform you of the results of the audit so that inadequate aprons may be removed from the theatre complex if this has not already been done.

Across three hospitals, Charlotte Maxeke Johannesburg Academic Hospital; Chris Hani Baragwanath Academic Hospital; and Helen Joseph Hospital 87 aprons were investigated, and 45 (52%) were found to be inadequate.

At CMJAH 35 aprons were identified in the main theatre complex, and were numbered in permanent marker on the front shoulder (left or right).

Fifteen of these aprons are not fit for use in theatre.

Three of them have large defects identified on X-ray making them unsafe. They should be removed from service. They are aprons 24, 25 and 29.

The additional aprons that are inadequate for use are either of lead equivalence less than 0.35 mmPb or could not have the lead equivalence determined. The Department of Health states that:

"Any person required standing within 1 metre of the X-ray tube or patient shall wear a protective apron of at least 0.35 mm lead equivalence, eye protection (leaded glasses) and thyroid protection."

The surgeon, anaesthetist, scrub sister and floor nurse are almost always within 1 metre of the X-ray source or patient and therefore this stipulation applies to virtually all theatre staff.

Because these aprons are of a lower or unknown lead equivalence they should be removed from theatre. They may be of use elsewhere in the hospital depending on the relevant codes. The apron numbers are: 1; 2; 3; 5; 14; 19; 26; 27; 28; 30; 33; 34.

It is recommended that new aprons purchased for theatre are at least 0,35 mmPb equivalent and if possible of a wrap-around design.

Additionally it is recommended that all aprons are entered into an "apron register". This should include:

- Date of purchase
- Manufacturer
- Lead equivalence
- Apron number
- Date of last inspection
- Location, size, description of any worrying defects

All aprons should be investigated at least annually and an effort should be made to ensure no aprons are excluded from the annual inspection.

The decision to remove damaged aprons from use should be based on the same criteria used in this audit, and attached to this letter. A written formal protocol should be devised and implemented, including daily cleaning by the theatre staff. The Department of Health currently does not specify the grounds for removal of damaged aprons and this may lead to excessive costs or dangerous exposure if a scientific method of assessment is not used.

It is strongly recommended that thyroid shields are provided as routine in all theatres where fluoroscopy is used. This is the international standard and stipulated by the Department of Health. The effective dose to the body is twofold higher if thyroid protection is not worn. This is because the thyroid shield protects all the underlying tissues, including skin, bone marrow, vertebrae, and oesophagus.

Finally in-service training of theatre staff about the dangers of radiation, how to protect themselves and how to look after the aprons should be instituted. Much of the damage to the aprons can be attributed to the wearers' improper use and care of the aprons.

If you have any queries please feel free to contact the authors of this research report using the contact details listed below.

Sincerely,

Dr A. Cohen MBBCh (Wits) DA (SA)
Registrar
Dept. of Anaesthesiology University of the Witwatersrand

Email: cohen.ant@gmail.com

Prof. A. C. Lundgren MBChB, FFA(SA) PhD
Chief Specialist and Head
Dept. of Anaesthesiology University of the Witwatersrand

Email: chris.lundgren@wits.ac.za



DEPARTMENT OF HEALTH

DIRECTORATE: RADIATION CONTROL



GUIDELINES

RADIATION PROTECTION OF PERSONNEL IN THEATRE

The principles as stated in the document "Policy: Monitoring of radiation workers in a theatre" are also valid for personnel in theatre. The Department is further guided by the NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS as stated in NCRP Report No. 102 regarding the following aspects:

3.7.4 (h) "Only persons whose presence is necessary *shall* be in the theatre during exposures. All such persons *shall* be protected (e.g., provided with leaded aprons, leaded gloves, eye protection (leaded glasses), thyroid shields and/or portable shields). "

(j) "The operator *shall* stand behind a barrier if possible and *shall* observe the patient during radiographic exposures."

(q) "People who must move around the room during the procedure *should* wear a wraparound protective garment."

(aa) "When possible, the specialist and all other personnel required in the room *should* step back from the table and behind portable shields during fluoroscopy and serial radiography procedures.

Comment: This action can decrease the exposure of the specialist and other personnel by a factor of three or more."

(cc) "All personnel not required in the room *shall* leave the room during serial radiographic exposures."

It can thus be stressed that all full time personnel in the theatre must be monitored and that eye protection (leaded glasses) shall be added to the list in paragraph (h). The Department accepted the recommendations of the ICRP 57 (Radiological Protection of the Worker in Medicine and Dentistry) regarding protective aprons and gloves, namely

"If workers cannot remain in the protected area when the X-ray machine is operated, they shall wear a **protective apron** of at least **0.25 mm lead equivalent**. As far as reasonably practicable they should occupy areas of the room where the levels of radiation exposure are low.

Any person required standing within 1 metre of the X-ray tube or patient shall wear a protective apron of at least **0.35 mm lead equivalence,** eye protection (leaded glasses) **and thyroid protection**. **Protective gloves** should be of at least **0.35 mm lead equivalence**. All such protective clothing should bear an identifying mark and should be examined at yearly intervals. Defective items should be withdrawn from use.

---------- ooOOoo ----------

Operational Topic

Optimal protection by lead aprons against ionizing radiation requires adequate quantitative models for determining their efficacy.

Inspection of Lead Aprons: A Practical Rejection Model

*W. Stam and M. Pillay**

Abstract: *As a sequel to the article by Ken Lambert and Tara McKeon, we propose a model by which defects in lead aprons may easily be evaluated on a routine basis. The model is applicable to lead aprons of various lead equivalent thicknesses. As recommended rejection criteria, we have used the concept of additional dose that an individual might receive due to defects in the lead (Pb) apron. The model has been implemented as an annual quality check in a large medical facility. In this article we consider only dose-related rejection criteria, since financial aspects related to ALARA have already been addressed in the abovementioned article. Health Phys. 95(Supplement 2):S133–S136; 2008*

Key words: *operational topics; occupational safety; dose; medical radiation*

INTRODUCTION

In order to keep the radiation dose received by hospital personnel under normal working conditions as low as reasonably achievable (ALARA), lead aprons and thyroid shields are provided as valuable aids. Intensive use of these accessories could lead to age-related or poor-handling defects often giving rise to multiple tears across the entire apron. Without routine control these lead aprons will, with time, contribute significantly to the radiation burden of the wearer.

However, local defects may not necessarily lead to gross changes in the radiation dose received by the wearer. For this reason the location and size of defects are important in evaluating whether a lead apron will need replacing or whether it will require more frequent control. It is recommended to submit lead aprons for inspection at least once a year. In order to quantify any defect detected, we need to know both the size of the defects and their location. In the quantification of a defect we also need to know the lead equivalence of the apron. Finally, the type of lead apron, e.g., single or double layer, is important.

In this article we describe a method by which uniform rejection criteria can be achieved taking the above factors into consideration. We also include criteria for the defects in thyroid lead shielding.

MATERIALS AND METHODS

Additional dose

As a measure of the dose one will receive due to a tear in the Pb apron, we introduce the term "additional dose." The additional dose is defined as the dose that the wearer receives above that which is normally expected for a given transmission and when a tear in the lead apron exceeds a given limiting value. To achieve this limiting value we assume that the additional dose is linearly related to the size of the tear in the apron. The additional dose is, therefore, the dose which will be received above that which will normally be expected if there was no defect.

The effective dose for a lead apron with a defect with an area a is given by eqn 1:

$$E_{\text{tot}}(a) = w_t \times H \times T \times \left(1 - \frac{a}{A}\right) + w_t \times H \times \left(\frac{a}{A}\right), \quad (1)$$

where w_t = the weight factor for tissue, and $H = H(5)$ the unshielded equivalent dose exposing an effective area A with a transmission T (Lambert and McKeon 2001).

In practice, defects appear as tears with a length L rather then an area a. Therefore, eqn (1) is derived for a tear with a length L (Fig. 1).

To convert from a linear tear of length (L) to area (a), i.e., circle with a maximum area a ($=\pi r^2$) with circumference equal to $2L = 2\pi r$, we get eqn (2) where the radius is substituted for the length:

* *Medical Center Haaglanden, Departments of Nuclear Medicine and Radiation Hygiene, Lijnbaan 32, 2512 VA, The Hague, Netherlands.*



Marrimuthoo Pillay is head of Radiation Hygiene and Clinical Physicist Nuclear Medicine at the Medical Center, The Hague. He graduated from the University of London and later completed the Dutch registration in nuclear medicine through the University of Groningen. He is currently liaison officer for the NEA/OECD Nuclear Databank for the Netherlands. His email is m.pillay@mchaaglanden.nl.

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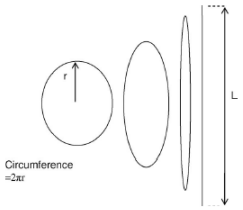


Figure 1. Conversion from linear tear to area of defect.

$$E_{\text{add}}(L) = w_t \times H \times \frac{(L^2/\pi)}{A}(1 - T). \quad (2)$$

Note that eqn (2) can only be used for protective clothing with a single layer of protective material. For lead aprons which overlap (partially) with double layers of protective material, eqn (3) is derived:

$$E_{\text{add}}(L) = w_t \times H \times \frac{(L^2/\pi)}{A}(T_s - T_d), \quad (3)$$

where T_s is the transmission of a single layer, and T_d is the transmission of double layers of protective material. Eqn (3) is only to be used on parts with double layers of protective material.

Differentiation in lead equivalence

The transmission of protective clothing is dependent on the incident energy of the photons and the thickness of the protective material. The thickness is expressed in lead equivalences (mmPb), and these values usually apply at a photon energy of around 100 keV.

When the transmission factors of the different lead equivalences are known, it is easy to take these into account. The common lead equivalences for protective clothing are 0.25, 0.35, and 0.50 mmPb. In Table 1 the corresponding transmission factors are given. Note that the transmission for thicknesses 0.70 and 1.00 are included where a double layer of protective material is present for 0.35 and 0.50 mmPb. Because of its low contribution, build-up is not taken into account (ICRP 1982a).

Table 1. Obtained transmission values for aprons of different lead equivalences.

d (mmPb)	Transmissie T (−)
0.25	0.19
0.35	0.10
0.50	0.038
0.70	0.010
1.00	0.0014

Rejection criteria

The rejection criteria are based on the additional effective dose that is applicable on each type of protective clothing and for all lead equivalences. In defining general rejection criteria, it becomes possible to determine, using eqns (2) and (3), the maximum tolerable tear length under the different circumstances.

To establish such rejection criteria we begin with the annual lower limit, e.g., of 2 mSv, i.e., 10% of the annual legal limit of 20 mSv. On the basis of 2 mSv per annum, the maximum tear length will exceed the dimensions of the protective clothing. We therefore introduce the additional dose constraint equivalent to one third of this annual limit producing a more acceptable rejection length. However, this produces rejection tear lengths for double layer Pb aprons of greater than 1 meter, since a small tear can quickly result in a larger defect due to the inherent weight of the Pb apron, decreasing the criteria results to a smaller value for the maximum tear length of the lead apron so that rejection will take place earlier. Empirically a further reduction by a factor 3 establishes realistic and practical rejection criteria (ICRP 1982b).

So finally the rejection criteria are established as indicated in eqn (4):

$$E_{(\text{add.reject})} = 1/3 \times 1/3 \times 2\ \text{mSv} = 0.22\ \text{mSv}. \quad (4)$$

Hence, the rejection criteria may be defined as follows: *The rejection is equal to the maximum additional effective dose that is just tolerable, i.e., exceeds a third squared of one-tenth of the annual lower limit—in this case 2 × (1/3)² = 0.22 mSv.*

Definition areas—whole body, gonads and thyroid

From a radiation protection point of view, as well as for psychological reasons, the gonads deserve extra attention (ICRP 2003). It may, therefore, be useful to define an area on the lead apron that is independent of the physical differences between wearers, which has a predetermined location on the lead apron. The applied dimensions for the gonads area amount to 30 × 35 cm² measured 40 cm from the neck-line of the lead apron. The irradiated area is considerably larger than the area of the gonads (22 cm²). Parts of the lead apron outside this area are considered as the "whole body" area.

The differences in tissue weight factor and irradiated organ area, 4,000 cm² for whole body, result in a smaller maximum tear length for the gonads. For thyroid protection an organ area of 22 cm² is applied (Fig. 2).

Correction for exposure geometry—double layers

Lead aprons will primarily be exposed anteriorly. However,

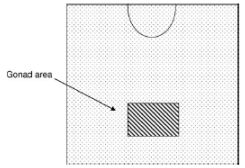


Figure 2. Lead apron showing gonad location.

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different activities will mean that lead aprons may also be exposed laterally or posteriorly, depending on the work environment. Double layered lead aprons are constructed such that the overlap takes place in the anterior position so that the anterior aspect will be protected with a double layer of lead. However, the back and on both left and right sides there will be just one layer of protective material, so that eqn (3) is applicable for the front side.

However, the risk of exposure posteriorly or laterally is much smaller than from the front. In the event that the wearer spends a significant amount of time exposed in a posterior or lateral aspect, correction factors have been introduced such that the posterior exposure time was taken as 10% and lateral exposure as 30% of the total time of the anterior exposure.

This means that doses in these directions may be corrected as 10/3× and 10×, respectively, in comparison with anterior-posterior (AP) exposure. This results in higher maximum tolerable tear length [factor $\sqrt{(10/3)}$ and $\sqrt{10}$].

Partial doses

To calculate the total additional dose caused by multiple defects, it would be incorrect to sum the lengths and to finally calculate the additional dose. For each defect the additional dose has to be determined separately and, finally, these partial doses summed as in eqn 5:

$$E_{\text{additional,Total}} = \sum_{tear=i} E_i. \quad (5)$$

DISCUSSION

Results

In the calculations it is assumed that a lead apron is exposed to an unshielded dose equivalent of 100 mSv (Lambert and McKeon 2001). This is equal to five times the limit for a radiological worker. Because the radiological worker is wearing a lead apron, the unshielded dose equivalent the apron is exposed to is allowed to be five times higher (in case of a 0.25 mmPb apron with $T = 0.2$) resulting in a rejection criterion of 0.22 mSv.

In Table 2 the maximum tolerable tear lengths are shown in relation to the type of protective clothing, the lead equivalence of the material, and the defined area. In addition, the maximum tolerable tear length is given in posterior-anterior (PA) (10%) and lateral (LAT) (30% and 75%) directions for lead aprons that are (partially) provided with a double layer of protective material (0.50 mmPb per layer).

The results for double layered lead aprons show that the maximum tolerable length increases with increasing lead equivalence. A declaration for this is that $(T_s - T_d)$ (3) approaches zero for higher lead equivalences. The maximum tolerable length decreases with increasing lead equivalence, because $(1 - T)$ (2) ultimately approaches unity.

The results for double layered protective clothing AP direction applied to the whole body vary from 13.5 to 27 cm. These high values can be explained by the fact that there is still another layer of material so that the contribution of a tear is considerably reduced.

However, in practice, it seems that employees who are aware of such defects may have psychological reasons for not wanting to use the lead apron. Besides, the fit and comfort of the protective clothing will suffer under such circumstances, which could influence the overall radiation reduction.

Practical considerations

As a general rule, lead aprons in medical facilities are inspected once a year. We have introduced an additional inspection half-yearly for lead aprons that show marginal defects not yet exceeding our rejection criteria. To demonstrate the rate at which small defects progress, a 10 month follow-up of 8 lead aprons with small defects not exceeding our rejection criteria were found to have an average increase in tears of greater than 270% (from 1.2 cm in 2006 to 3.3 cm in 2007).

In our facility, 96 lead aprons were inspected by the method described of which three (3.1%) were found to have defects producing unacceptable additional doses of 0.62 mSv and 0.79 mSv, respectively. In 2005, when lead apron inspection was first introduced as a standard procedure using previous practices, 12 out of 67 lead aprons were rejected (i.e., 17.9%). We attribute this high rejection rate to the fact that lead aprons were not previously inspected and may have had defects long before inspections were introduced.

Figures from another medical facility of equal size to our own and using subjective rejection criteria indicate that they reject about 4.1% (6 out 145) of lead aprons per annum.

Considering these numbers, we can safely argue that the proposed rejection criteria do not lead to excessive rejection, but that the rejected numbers might even become lower as control becomes more enshrined in the quality assurance program.

In our facility, lead aprons have a lifespan of around 8 y. Considering that lead aprons cost around $600, an annual budget of about $1,800-$2,400 could be sufficient for the replacements. Finally, in the process of quality assurance, it is important to pay special attention to the handling and storage of lead aprons. Poor handling and storage could adversely affect the balance between economy and safety.

Table 2. Maximum tolerable tear length (cm) $H = 100$ mSv.

Type of apron	Definition area	Lead equivalence (mmPb) 0.25	0.35 AC = 0.22 mSv	0.50
Rejection criterion		Max. length of defect (cm)		
Double AP	Whole body	13.5	17.5	27.0
	Gonads	4.4	5.6	8.7
Single	Whole body	5.9	5.6	5.4
	Gonads	1.9	1.8	1.7
	Thyroid	1.9	1.8	1.8
Double	PA (10%)			17.0
	LAT (30%)			9.8
	LAT (75%)			6.2

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CONCLUSION

The method described above gives unique rejection criteria that can be applied to different types of radiation protective clothing and different lead equivalences. The obtained rejection criteria are based on an additional effective dose of 0.22 mSv. On this basis it is possible to determine the maximum tear length. Taking into account the radiation sensitivity of the gonads and a separate thyroid shield, three specific areas are defined, namely "whole body," "gonads," and "thyroid." For each of these specific areas, the maximum realistic tear length is obtained.

The obtained results vary from 1.8 cm for the thyroid to 5.9 cm for the whole body for single layered material and from 4.4 cm for the gonads to 27.0 cm for whole body for double layered material.

Furthermore, the possibility is given to make a correction for geometry of exposure. This applies only to double layered clothing. For the AP direction the exposure is set on 100%. For LAT and/or PA the exposure is dependent on the activities. When the exposure is set on 30% and 70% for LAT and 10% for PA, the corresponding maximum lengths are 17.0, 9.8, and 6.2 cm, respectively.

All the obtained values for the maximum tolerable length of defects match with present day rejection practice making the described method a good and practical guide for periodical inspections of radiation protective clothing such as lead aprons.

With this method the ALARA principle is applied in many ways (as seen in the calculations where it is assumed that a defect is exposed as a circle area). In practice, this is the worst case approach. Further, it is assumed that the radiological worker will be exposed to the yearly limit. In good practice, this will seldom occur. Finally, the rejection criteria are based on the lower limit for radiological workers (2 mSv), which results in a smaller maximum tolerable tear. The determined additional effective dose is, therefore, an over-estimation of the actually received additional dose.

REFERENCES

International Commission on Radiological Protection. Protection from ionising radiation from external sources used in medicine. Oxford: Pergamon Press; ICRP Publication 33; Ann ICRP 9(1); 1982a.

International Commission on Radiological Protection. General principles of monitoring for radiation protection of workers. Oxford: Pergamon Press; ICRP Publication 35; Ann ICRP 9(4); 1982b.

International Commission on Radiological Protection. Relative biological effectiveness (RBE), quality factor (Q), and radiation weighting factor (wR). Oxford: Pergamon Press; ICRP Publication 92; Ann ICRP 33(4); 2003.

Lambert K, McKeon T. Inspection of lead aprons: criteria of rejection. Health Phys 80(Suppl 2):S67–S69; 2001.

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