Master in Engineering and Industrial Management

Organization and management of maintenance indexed to risk factors in healthcare environment

Project report for graduation degree of Master of Science in Engineering and Industrial Management

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"The mind that opens to a new idea, never returns to its original size."

Albert Einstein

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This dissertation/project is dedicated to my mother

for her love, endless support

and encouragement.

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Abstract

Currently, in a similar way to the policies adopted by the organizations, the hospitals lay an enormous effort in the search of the maximum efficiency of the organizational flows. This results in the improvement of the provided services and patient safety, taking into account the profitability of the physical resources and economic conditions. To achieve these goals, it is necessary not only to increase the efficiency of medical equipment throughout their life cycle, but also to prevent the risks associated with their handling, with emphasis on patient safety. The concepts of maintenance management and risk assessment have been evolving towards the adequacy of the policies most adapted to the nature of the facilities and equipment, whether by economic, functional or other classification. The concept of risk in a hospital environment is very diverse. There are physical, chemical, biological and psychosocial risks. Although all risks are important for the safety and well-being of patients, this dissertation/project focuses mainly on biological risks (infections due to viruses, fungi, bacteria and parasites), and physical risks with a special focus on electrical risk. These risks can be partially indexed to the organization and management of the maintenance of hospital facilities and equipment, as this can help to prevent risks; However, with a good evaluation and management of these, maintenance costs can be reduced and unexpected interventions can be avoided. In this context, this article analyzes the main electrical and biological risks, in order to establish a cause-effect relationship with the maintenance policies carried out by the institutions.

Keywords: Maintenance management; Risk Assessment and Management; Medical equipment; Quality; Maintenance Plans; Electrical risk; Nosocomial infection.

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Resumo

Atualmente, de forma semelhante às políticas adotadas nas organizações, os hospitais colocam um enorme esforço na procura da obtenção da máxima eficiência dos fluxos organizacionais, traduzindo-se na melhoria dos serviços prestados e na segurança dos pacientes, tendo em vista a rentabilização dos recursos físicos e económicos existentes. Para atingir tais objetivos torna-se necessário, não só o aumento da eficiência dos equipamentos médicos ao longo do seu ciclo de vida, como também a prevenção dos riscos associados ao seu manuseamento, com ênfase na segurança dos pacientes. Os conceitos de gestão da manutenção e avaliação do risco têm vindo a evoluir no sentido da adequação das políticas mais adaptadas à natureza das instalações e equipamentos, seja por classificação económica, funcional, ou outra. O conceito de risco em meio hospitalar é muito diverso, traduzindo-se em risco físico, químico, biológico e psicossocial. Embora todos os riscos sejam importantes para a segurança e bem-estar dos pacientes, esta dissertação/projeto incide essencialmente nos riscos biológicos (infeções devido a vírus, fungos, bactérias e parasitas), e nos riscos físicos, com especial enfoque no risco elétrico. Estes riscos podem indexar-se parcialmente à organização e gestão da manutenção das instalações e equipamentos hospitalares, pois esta pode ajudar a prevenir riscos; porém, havendo uma boa avaliação e gestão destes, podem reduzir-se custos de manutenção e evitar intervenções inesperadas. Neste âmbito, este documento efetua uma análise aos principais riscos elétricos e biológicos, com o intuito de estabelecer uma relação de causa-efeito com as políticas de manutenção levadas a efeito pelas instituições.

Palavras-chave: Gestão de manutenção; Avaliação e Gestão de Risco; Equipamentos médicos; Qualidade; Planos de Manutenção; risco elétrico; infeção nosocomial.

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List of Acronyms

AAMI - Association for the Advancement of Medical Instrumentation
ACCE - American College of Clinical Engineers
ACH - Air Change per Hour
AHA - American Hospital Association
AIA - American Institute Of Architects
ASHE - American Society for Healthcare Engineering
BMET - Biomedical Equipment Technician
BMT - Bone Marrow Transplant
CBA - Cost–benefit Analysis
CCHSA - Canadian Council on Health Services Accreditation
CDC - Centers for Disease control and Prevention
CE - Clinical Engineering
CED - Clinic Engineering Department
CM - Corrective Maintenance
CMMS – Computerized Maintenance Manage System
CMS - Centers for Medicare & Medicaid
CSA - Canadian Standards Association
CSE - Clinical Systems Engineering
DGS - Direcção-Geral da Saúde (National Health Entity)
EMR - Electronic Medical Record
EPA - Environmental Protection Agency
ESU - Electrosurgical Unit
EU - European Union
FDA - Food and Drug Administration
FMEA - Failure Mode and Effect Analysis
GDP - Gross Domestic Product
HAI - Hospital-Associated Infections
HEPA – High-Efficiency Particulate Air
HVAC – Heating Ventilation and Air Conditioning
IAQ - Indoor Air Quality
ICP - Infection Control Practitioners
ICRA - Infection Control Risk Assessment
ICU - Intensive Care Units
IMS - Intelligent Maintenance Systems
INE, IP – Instituto Nacional de Estatística, Instituto Público
IPOFG, EPE - Instituto Português de Oncologia de Coimbra Francisco Gentil, Entidade Pública Empresarial
ISO – International Organization of Standardization
IT – Information Technologies
LT – Logistic Time
MIDS - Medical Information Data System
MRI – Magnetic Resonance Imeging
MRSA - Methicillin-resistant Staphylococcus Aureus
MS - Ministry of Health (Ministério da Saúde
MTF - Swedish Society for Medical Engineering and Medical Physics

NADCA - National Air Duct Cleaning Association
NI - Nosocomial infection
OECD - Organization for Economic Co-operation and Development
OEM – Original Equipment Manufacturer
OHS - Occupational Health and Safety
PM – Preventive Maintenance
PPCIRA - Programa de Prevenção e Controlo de Infeção e Resistência aos Antimicrobianos (Program for Prevention and Control of Infection and Resistance to Antimicrobials)
QMS – Quality Management System
RM – Risk management
RT – Repair Time
SIE – Serviço de Instalações e Equipamentos (Service of Facilities and Equipment)
TPN/Lusa – The Portuguese News / Lusa News Agency
U.S. – United States
U.S.A. – United States of America
UK - United Kingdom
UPMC – University of Pittsburg Medical Center
WHO - World Health Organization

1. Introduction

1.1. Scenario

In 1985, Eduardo Caetano refer that the Portuguese people have no sensitivity for technical equipment maintenance, with special focus on health equipment, preferring to spend billions to invest in buildings and equipment, less than 1/20 of this value for their annual maintenance (Caetano, 1985).

In 1997, José Torres Farinha mentioned in his book that sometimes hospitals are built, the equipment is installed, putted into operation, and only at the end the maintenance service is activated (Farinha J. T., 1997).

Since then, the outlook on hospital maintenance has been changing, because the hospitals have become buildings of extreme complexity. However, the attitude in Portugal is still somewhat bleak, not only by ignorance, but also by the lack of interest of the top managers/administrators, whom sometimes still see maintenance as a service of secondary importance and a source of expenses that translate a necessary evil. For years, maintenance has been treated as a dirty, boring and often overlooked job. It is very important to get the best productivity from a company's equipment, but maintenance was not recognized as a part of the operation that produces revenue.

Also, hospital infections in Portugal remain stubbornly high and the results of the campaigns against hospital infections are "less than nothing" as described by Elaine Pina about antimicrobial resistance and infection control. Between 2009, when Portugal joined the global campaign against infections, and 2012, the hospital infection rate went from 11.03% to 11.50% (TPN/Lusa, 2016), which means that implementation of hospital infection control activities may been carried out in an irregular way.

The influence of maintenance on equipment and facilities is essential and decisive in its functioning, and reflected in the quality of provided services, and patient safety. It should be noted that the organization and maintenance management can, not only, have economic repercussions, but also the ability to exercise a great psychological effect on patients. Currently, the maintenance of a hospital and risk prevention requires an optimized management and effective activities planning to meet the technological complexity, the legislative requirements, the standards of comfort and required quality and environmental issues.

Against this context, the author finds a need for a change of mentality, understanding the importance of maintenance managing and risk preventing as a vehicle for efficiency and

improvement of hospitals, not only by reducing costs and increasing equipment availability, but also the important role against hospital infections. It is not enough just to have the financial, human and material resources, to achieve the desired results.

In an age in which challenges, the traditional management based on improvisation, this document deals with the concept of the organization and hospital maintenance management transversely to buildings, special facilities and all technical assets and existing systems, with the objective of creating a model that allows to add value to IPOFG, EPE (Instituto Português de Oncologia de Coimbra Francisco Gentil, Entidade Pública Empresarial). Although this project has been developed within the IPOFG, EPE, it is highlighted that all the concepts, techniques and procedures used, can be extrapolated to any other hospital.

This introductory chapter will make a brief description of the maintenance evolution, the existing definition and types of maintenance, its legal framework, the evolution of maintenance as a discipline of hospital engineering and finally the structure of the document.

1.2. Brief history of maintenance

The mechanization associated to the Industrial Revolution of the last century has highlighted the need to regularly repair the machines, however, these repairs were left to the operators themselves (Farinha J. M., 2011).

From the 1st World War, and after the implementation of the first production lines, the manufacturing units began to establish minimum standards of production. As a result of the increase of production, it was necessary to create specialized teams that could make repairs in the machines in the shortest time possible. In result, it was created the need for the implementation of what, nowadays, is called Corrective Maintenance (CM).

After the 2nd World War, with the need to streamline the increasing production, companies began to worry not only to correct the flaws, but also to prevent it from happening, emerging a new concept of maintenance, today called Preventive Maintenance (PM) (Tavares, 2005).

The term "maintenance" has its remote origin in the vocabulary; however only at the beginning of the 50's the term was introduced in industry (Monchy, 1989).

With the spread of computers and the sophistication of measure and protection instruments in the 70’s, the Maintenance Engineering started to develop more sophisticated criteria, beginning to make the planning and control of maintenance through the use of computer tools, with the purpose of developing, implementing and analyzing the results of maintenance services. At that time, the growing concern in determining the appropriate period to perform

preventive maintenance, based on historical data of assets, led to the emergence of a new concept, the engineering reliability, since at the time there was no knowledge about equipment failure patterns.

In the late 70's and early 80's, with the advent of microelectronics, the devices have become more complex, possessing large quantities of electronic components subject to damage, so it is no longer possible in many cases to establish preventive methods maintenance depending on the age of the asset. With the development of digital high-precision instruments, it has become possible at low cost, making early diagnosis of faults by measuring operating parameters. Thus is born another concept, Predictive Maintenance, which was limited to applications where it was technically feasible and economically interesting, normally associated to higher risk sectors, such as aviation and nuclear power plants (Parodi-Herz, 2008).

1.3. The “maintenance” function

Like a personal health care insurance, maintenance can be considered the heath care of our manufacturing machines and equipment. By writing that "maintenance is the medicine of machines", Monchy makes a practical analogy between "human health" and "health machine", comparing the human aspects of birth, longevity, good health and death, to the machine, respectively, into operation, durability, reliability and deactivation (Monchy, 1989).

Maintenance is required to effectively reduce waste and run an efficient, continuous manufacturing operation, business, or service operation. The cost of regular maintenance can be very small when compared with the cost of a major breakdown at which time there is no production.

Almost all definitions, official or not, tend to set the maintenance function as a guarantee of the equipment availability. It is a set of actions to ensure the proper functioning of equipment and facilities, ensuring that they are intervened in time right and correctly, in accordance with the legal and technical requirements in order to avoid the loss or reduction of productivity and, if this happens, the operating conditions must be restored as soon as possible, at an optimal cost.

The standard NP EN 13306: 2007 provides a brief definition of maintenance, in line with an asset management policy, which is reflected by a ″combination of all technical activities, administrative and management during the life cycle of an asset, designed to keep it or replace it in a state where it can perform its required function.".

So, we can say the main purpose of regular maintenance is to ensure that all equipment required for production is operating at maximum efficiency at all times. Through short daily

inspections, cleaning, lubricating, and adjustments, minor problems can be detected and corrected before they become a major problem that can shut down a production line. A good maintenance program requires company-wide participation and support by everyone ranging from the top executive to the shop floor personnel.

About the management philosophy, the maintenance can be classified mainly into three types:

- Corrective maintenance (CM): It is performed after a malfunction or failure occurred due an internal cause (a broke bearing, ...) or external (bad operation, ...).
- Preventive maintenance (PM): It is performed in order to avoid malfunctions or failures and it can be systematic (performed at predefined intervals cycles, hours, kilometers, etc.) or conditioned (determined from symptoms verified by visual inspection).
- Predictive maintenance: It is performed based on the monitoring of the health of the equipment, like the modification of a condition or performance parameter, using data collected through vibration analysis sensors, ultrasound, etc.

Also within the philosophy of the types of maintenance, and according to a recent view of continuous improvement, it is relevant to add the term "improvement" as a maintenance style to improve the performance of the equipment, that is, to identify changes that would improve the way of working. The latter concept follows a new trend of asset management procedures called Normative Maintenance.

The literature about maintenance has established some numbers on the advantages of preventive maintenance against corrective maintenance (Cabral, 2013):

- A well maintained equipment lasts 30% to 40% more than a poorly maintained;
- Studies show that the implementation of preventive maintenance induces energy consumption savings of 5% to 11%;
- In corrective maintenance, about 20% of the parts are lost;
- Preventive maintenance significantly reduces downtimes and increases the efficiency of the equipment;
- The corrective work costs 3 to 4 times more than preventive;
- To change from a traditional organization style, to a best level organization can take between 3 to 5 years.

1.4. Maintenance of tomorrow

With modern computing and information technologies, more products and machines are equipped with sensors on critical parts of machines to warn of potential failures long before they may fail so they can be corrected before they stop production.

Intelligent Maintenance Systems (IMS) predict and forecast equipment performance so "near-zero breakdown" status is possible. Near-zero downtime focuses on machine performance techniques to minimize failures. Data comes from two sources: sensors (mounted on the machines) and the entire enterprise system (including quality data, past history and trending). By looking at data from these sources (current and historical), it can predict future performance.

The long-term view on intelligent maintenance is that we can use any means – including embedded (software) and remote technologies - to monitor equipment performance. Then, if wear starts to occur, there is enough time to service the item before failure. A machine can self-assess its health and trigger its own service request as needed. If this model works, then we will have a product that can manage its own service performance and its own warranty-based contracts. It also can alert us on ways to keep it running in a high-performance manner.

World-class companies already have taken a game-changing approach, implementing a new service business model to change maintenance systems into smart service and asset management solutions. They reduce downtime and provide the ability to look ahead at the quality of products before they ship by closely watching equipment performance and machine wear. Rather than reactive maintenance - "Fail and Fix" - companies can indeed move to "Predict and Prevent" maintenance.

1.5. Maintenance management

For many years, the absence of a Maintenance Management System caused the deterioration of equipment that make up the set of assets of organizations since, for most companies, the only practiced maintenance was corrective. With increasing automation and the resulting increase in the number of breakdowns, companies soon realized that the frequent production downtimes or frequent 'bottlenecks' in maintenance services provided, caused a decrease in product/service quality, consequently increasing costs and reducing competitiveness and, in some cases, this led to potential loss of customers. The philosophy of corrective maintenance is no longer satisfactory. The maintenance concept evolved from simple repair of the fault to another, more recent concept, in which interventions are planned in order to avoid breakdowns – preventive maintenance (Correia, 2013).

Understanding the adequate type of maintenance for each organization is a key success factor. Nowadays, it is known that successful companies increasingly adopt proactive maintenance techniques and practice maintenance engineering. In practice, it can be said that an organization that carries out corrective maintenance, but is gradually including preventive

and predictive maintenance tasks, will quickly be carrying out maintenance engineering, and consequently, maintenance management.

The NP EN 13306 standards:2001 defines maintenance management as all management activities that determine the objectives, the strategy and the responsibilities relating to the maintenance and implement them by means such as planning, control and supervision of maintenance and improvement methods in the organization, including economic aspects.

In a context of broad view with in accordance with a terologic approach of maintenance management formulated by José Torres Farinha (Farinha J. M., 2011), it turns out that this has a high number of aspects associated, including: operational investigation, information management, engineering, reliability, invoicing, general and cost accounting, inventory and parts management, and quality.

Based on this interdisciplinary maintenance is expected to understand the maintenance management as a planning, as defined by José Paulo Saraiva Cabral (Cabral, 2013).

1.6. Legal Framework

About maintenance, recently has been significant activity to standardize concepts and terminologies, by creating European standards that allow progressively replace the current rules and practices used in different countries.

This project focuses only on NP 4483 standards:2009 (maintenance management) and ISO 31000:2013 (risk management); however, it is necessary to know other existing rules about the subject under consideration, including:

- Maintenance terminology of the NP EN 13306:2007 (CEN, 2001) - Defines the basic terms and concepts used in maintenance. It is a basic document on how to speak and understand the language associated to maintenance tasks;

- Standard maintenance indicators NP EN 15341:2009 (CEN, 2007) - Defines the concept of indicator and refer the most significant management indicators with a simple language formulations that can be understood by everyone;

- Standard maintenance contracts NP EN 13269:2007 (CEN, 2006) - Defines a structure for the development of a maintenance contract through a checklist of aspects that should be referenced;

- Standard maintenance documentation NP EN 13460:2009 (CEN, 2001) - Defines the set of documentation that must be present in a maintenance management system and specifies the requirements for each of these documents;

- Standard for the implementation of maintenance management system NP 4483:2009 - Portuguese standard developed based on the standards referred to above, which specifies the requirements for a maintenance management system where an organization needs to demonstrate its ability to, consciously, provide a service that meets the client's objectives and the legal and regulatory requirements;

- ISO 31000:2009 series – They are international standard for risk management. It has no certification purpose, but it is a tool that can bring huge benefits to organizations using their guidelines applied to a wide range of activities, including strategies, decisions, operations, processes, functions, projects, products, services and assets.

1.7. Clinical Engineering

The origins of clinical engineering can be found in the increasing concerns for patient safety that arose in the 1960's because of the proliferation of clinical equipment in the medical arena. The functions of clinical engineers were at that time mainly focused on repair of equipment and carrying out routine electrical safety inspections. As equipment became more complex and grew in number, it became obvious that electrical safety failures represented only a small part of the overall safety problem. Investigators of accidents found that the users of clinical equipment did not completely understand its operation and most of the instruments were not properly maintained. Furthermore, they found that many devices did not perform as specified by the manufacturer. As clinical engineers entered the hospital environment, they took care of these problems, developing routine programs for integral safety and performance inspections. These actions made hospitals consider clinical engineering departments as a tool to provide the hospital with solutions to safety problems. The clinical engineers of today play a multifaceted role in the clinical environment, as the result of their continuous and growing involvement with the management of clinical equipment. They regularly interact with the clinical staff, the administrators of the hospital, vendors and manufacturers, the clinical engineers at other healthcare institutions and regulatory agencies (Lozano-Nieto, 1999).

To explain clinical engineering for a person who is not familiar with the profession may be not so difficult. It can be said that it is the engineer who works in the healthcare service or in a hospital. However, explaining to this same person what are the activities of the clinical engineer and his/her role in the healthcare system may be a bit more complex matter and quite complicated to be described in a single phrase.

Over the years, a number of organizations have attempted to provide an appropriate definition, for example (Bronzino, 2003):

- The AHA defines a clinical engineer as: "a person who adapts, maintains, and improves the safe use of equipment and instruments in the hospital".
- The American College of Clinical Engineering defines a clinical engineer as: "a professional who supports and advances patient care by applying engineering and managerial skills to health care technology".
- The definition that the Association for the Advancement of Medical Instrumentation (AAMI) originally applied to board certified practitioners describes a clinical engineer as: "a professional who brings to health care facilities a level of education, experience, and accomplishment which will enable him to responsibly, effectively, and safety manage and interface with medical devices, instruments, and systems and the user thereof during patient care...".
- For the purpose of certification, the Board of Examiners for Clinical Engineering Certification considers a clinical engineer to be: "an engineer whose professional focus is on patient-device interfacing; one who applies engineering principles in managing medical systems and devices in the patient setting".
- The Journal of Clinical Engineering has defined the distinction between a biomedical engineer and a clinical engineer by suggesting that the biomedical engineer: "applies a wide spectrum of engineering level knowledge and principles to the understanding, modification or control of human or animal biological systems".
- Finally, in the book "Management of Medical Technology," a clinical engineer was defined as: "an engineer who has graduated from an accredited academic program in engineering or who is licensed as a professional engineer or engineer-in-training and is engaged in the application of scientific and technological knowledge developed through engineering education and subsequent professional experience within the health care environment in support of clinical activities".

It is important to emphasize that one of the major features of these definitions is the clinical environment on each country.

Clinical Engineering has been rapidly growing in the last 15 years both in "industrialized" and in "developing" countries. The degree of its diffusion, however, varies from country to country as it is linked to the needs of health care area on each country. The issue has been extensively discussed in books and scientific journals, for example by Barry Feinberg, Cesar Caceres, Joseph Bronzino, John Webster, Albert Cook, as well as within the World Health Organisation (WHO).

For example, in the United States, the original needs for its creation was basically patient safety. The clinical engineering model developed over there has a lot to do with risk and

financial management, as well as contract management and internal operations, and is the Biomedical Equipment Technician (BMET) who develops the medical/hospital equipment maintenance. They even produced several guidelines on such subjects that are helping clinical engineers all over the world. In other world regions, such as Latin America, clinical engineering was developed basically to manage the maintenance of medical equipment.

Hence, clinical engineers are seen as the person who either do the medical/hospital equipment maintenance and/or manage it. In fact, clinical engineering in these regions was originated basically due to the need of lowering the prices charged by external companies (service or vendors), to make repair and, sometimes, preventive maintenance. This is today the stigma carried by the majority of clinical engineers, mainly the ones who are frightened to stand up and present their skills to perform other tasks to the hospital administration.

Going to Japan, clinical engineers not only develop the maintenance of complex equipment but also work as an active health staff member during specific medical procedures. Such activity involves a direct participation, with doctors and nurses, on surgeries such as cardiac valve implants, cardiac catheterization, blood purifications, and several others. Their participation are not as a standby person waiting to solve some operational difficulty but actually are a member of the surgical team dealing and handling with the equipment, accessories, and even the part to be implanted in the patient.

Another example of the development of different clinical engineering models is in the European continent, where some countries use clinical engineers to monitor and manage external maintenance service companies, while in other countries most hospitals have their own clinical engineering group but developing different tasks. A German clinical engineer is quite dedicated to risk programs; in United Kingdom, there are clinical engineering groups dealing with rehabilitation developments as well as medical equipment maintenance. Some UK groups includes services for the Ministry of Health regarding testing and conformity with standard (Calil, 2016).

1.8. Maintenance as a discipline of clinical engineering

The literature suggests that clinical engineering was born in January 1972 in the city of St. Louis, when creating the course in medical equipment maintenance. The course last for 12 weeks, and was taught by the United States Armed Forces. Later, in the city of Denver, Colorado, it was created in the army a maintenance school for medical equipment.

In the 60’s and 70’s, with the evolution and growing share of technology in hospitals (creation of ultrasound, chemical blood analyzers and tomography), the health care costs began to increase. It was estimated that 50% of the increase in health care costs in the United

States, 1965-1974, was directly or indirectly linked to medical technology. In this period, the equipment purchased by hospitals did not carry out instructions for use or repair, resulting in a huge gap between technological knowledge and its implementation. The maintenance began to represent an alternative that allowed reduction of costs with technology in hospitals. In the late 60's and early 70's, unproven speculation, that there would be about 1200 deaths per year due to electric shocks related to medical equipment, led the Food and Drug Administration (FDA) to try to find a legislative solution to the certification of medical equipment.

In 1976, it was approved a document which required medical equipment manufacturers to submit the equipment for approval by the FDA, before being put on the market, in order to ensure safety and effectiveness. This measure resulted in the need to hire about 300 biomedical and electrical engineers to the FDA offices and gradually engineers were occupying those spaces in hospitals and health institutions, where its engineering expertise could ensure effective implementation and secure new health technologies. In the 70's, Cesar Caceres, along with Thomas Hargest created the term "clinical engineer". Thomas Hargest was known as the first certified clinical engineer of history. They defined clinical engineer as hospital equipment manager, through repairing, operators training, safety and performance definition, and technical specifications for a good purchase. In his point of view, a clinical engineer was a maintenance manager.

From the 80's, the clinical engineer is no longer considered just a maintenance manager of biomedical equipment, and becoming an element that could have active participation in technology transfer. In the 90's, the American College of Clinical Engineers (ACCE), expanded the range of action of clinical engineering, creating a more realistic definition of clinical engineer who emphasized the administrative part of management and technology assessment (Ramirez & Calil, 2000).

The maintenance has become a part of the clinical engineering, however, it is important to know that is probably also the most important item.

Clinical engineering profession, from its start, has undergone a huge identity crisis face administrators, doctors and nurses who, for lack of technical knowledge of the equipment, did not give due respect, cooperation and acceptance (Goodman, 1991).

Today, it is clearly apparent that the increasing electronic equipment park in hospitals, some with very complex operating principles, and the emergence of new technologies, made indispensable the presence of specialized professionals to advise, from a technical point of view, the medical staff, the management of all these new technologies related to health services; however, in some Portuguese hospitals, clinical engineering is still trying to win some space.

1.9. Document structure

This document is divided in five main chapters, before the appendixes and bibliography:

- Introduction;
- State of the art;
- IPOFG, EPE facilities;
- Contributions;
- Conclusions and further developments.

In the introduction chapter (chapter 1) is made an approach to the history of maintenance, maintenance of today and tomorrow, and maintenance as a discipline of clinical engineering.

The state of the art (chapter 2) can be divided in two parts: The first part gives us a general approach of what is being done around the world about clinical engineering and risk management, and the second part indexes the subject of nosocomial infection (hospital acquired infection) and electrical hazards, to the maintenance management.

The IPOFG,EPE facilities (chapter 3) is intended to give the lectures the dimensional idea of the hospital, as well as what is done in this case of study.

In the contributions (chapter 4) are given some procedures that can help the hospital in managing maintenance in order to prevent risk hazards.

Finally in conclusions and further developments, is made an analysis of what is missing in this document, what should be done in the future and how the hospital accepted this challenge.

In the next chapter, is presented the state of the art in clinical engineering with also the most relevant facts in Portugal.

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2. State of the art

2.1. Demographic aging, a burden on the society

The impact of demographic aging in the most developed countries, caused by consistent low birth rates and higher life expectancy, is likely to be of major significance in the coming decades. At present, 17.4% of all Europeans are aged 65 and older. In 2020, the share of those over age 65 will rise to 28% (COM – European Commission, 2012). For example, in Ireland, where the highest share of young people in the total population in 2012 was observed to be 21.6%, the proportion of the population aged over 65 years is expected to increase from 11% to 15% by 2021.

In Sweden, the most dramatic change will occur from the age of 80, where the number of persons will increase by 50% over the next 15 years. The share of older persons in the total population will increase significantly even in other European countries in the coming decades.

In Portugal, between 1970 and 2014, the proportion of the young population decreased by 14% from 28.5% of the total population in 1970 to 14.4% in 2014. In turn, the relative weight of the old population increased by 11% from 9.7% in 1970 to 20.3% in 2014 (INE, I.P , 2015).

In the world, the proportion of people aged over 60 years of age increased from 9.2% in 1990 to 11.7% in 2013, and is expected to continue to increasing, reaching 21.1% in 2050 (INE, I.P , 2015). This will lead to an increased burden on the society to provide for the healthcare expenditure required by the aging population.

Many of the elderly persons will be relatively healthy a large number of years, but there will also be a number of persons with multiple disorders. Many of these elderly persons will know more about their disorders and also more about the possibilities that there is to cure or relieve the illnesses or disorders. These persons probably will want to be treated at their homes or other places outside the hospitals, which will need new technologies and new ways of nursing. It is important to understand the demographic aging, in order to give the best clinical engineering experience to the healthcare structures.

2.2. Clinical engineering over Europe

Clinical engineering has a long tradition in North America, Australia, and in the Nordic countries. Most of the reporting departments had been functioning for more than 30 years. (Pallikarakis & Glouhova, 2004).

The healthcare structure and delivery systems in European countries are today different from country to country. There are differences in how the systems are financed and how they are organized. The differences depend not only on differences in recourses, economical, or material, but also on culture, demography, and geography. Nowadays, the number of doctors and nurses has increased and the average number of practicing doctors per 1000 population in Europe is 3.4 ranging from 2.2 to 6.2, according to the Organization for Economic Co-operation and Development (OECD) statistics, (OECD, 2014). The basic financing of the healthcare system in Europe is through taxes and it is the dominating financing type in the Nordic countries. Most hospitals are owned and run by the society. However, some of the public hospitals are run as corporations, but the sole owner is the society. There are also some private companies running hospitals and healthcare centers.

In 2012, European Union (EU) member states used in average 8.7% of their Gross Domestic Production (GDP) to health spending. This is 1.4% more than in 2000 (OECD, 2014). All the Nordic countries spend more than the average in Europe, with Denmark on the top with 11.0% expenditure. The other countries use between 9.6% to 9.0% of their GDP. The Baltic countries had lower expenditures compared to the European average reaching 6.1% in average (OECD, 2014). Portugal increased from 8.3% in 2000 to 9.9% in 2009 and after started decreasing to 9.0% in 2014 (OECD, 2014).

Retrospectively, we can see that the different technological innovations have clearly changed the methods for diagnosis and therapy. The development of medical imaging systems is a good example of how technological development has changed and improved the diagnostics.

Today the clinical engineers at most Nordic hospitals support the radiologists when purchasing the systems, they work with installation of these systems together with the manufacturers' staff, and they are also responsible for the technical operation of these systems and how the systems communicate with other systems. The increase of the usage of medical equipment shows how technology has become more and more important for delivery of healthcare and how its importance is growing steadily. Therefore, it is essential the idea that the healthcare organizations in Europe need a medical equipment management program, like we see in USA, Australia, and Canada. This program is important to assure that medical equipment is appropriate to the clinical needs and that it functions effectively and safely.

The aim of the clinical engineering work is to provide the hospitals and other healthcare providers with engineering support, know-how and technology management, which is based on knowledge, competence, and experience, so that the patients can be diagnosed and treated cost-effectively in the best possible way. In Portugal sometimes is difficult to reach this goals because the Service of Facilities and Equipment (SIE - Serviço de Instalações e

Equipamentos) doesn't have enough workers, and most of them are not qualified for clinical engineering.

Overall technology management in Nordic hospitals was the primary application of clinical engineering in Europe and it had the focus on the safe and efficient use of medical devices so that the patients could be diagnosed and treated in a best possible way. This means that clinical engineers ensured that appropriate, efficacious, and cost-effective equipment's were available at the hospitals to meet the demands of quality in patient care. The Clinic Engineering Departments (CED) in these countries are following the idea of Joseph Bronzino "The development and implementation of a comprehensive technology management program requires a systematic approach. Such programs must embrace not only the technical aspects of maintaining medical equipment, but also the development of policies concerning equipment acquisition, acceptance, training, use, replacement and disposition. In essence, the primary goal of any technology management program is to ensure that the most cost-effective methods for the safe and effective operation of medical equipment are utilized" (Teriö, 2016).

At the beginning, many CED had problems to identify their role in healthcare organization and were not able to establish goals for their operations, because it was not clear what role they had. The main idea is to have an operation that is patient oriented, a statement that almost the whole medical world uses today. This means that CED will be responsible for the management of the medical equipment so that the clinic has access to the specified services, device functionality, and material, and pursue an active safety work to prevent adverse events with the equipment caused by technical reasons. It also means that the CED will facilitate education, research, innovation, and development in medical technology. CED must have close cooperation with the manufacturers and vendors and they must deliver services with a good quality. The strategies to achieve these purposes could then be, for example, to support the patient flow through maintaining the clinic's medical equipment. Clinical engineers should also have a good control over the everyday work and a good dialogue with the clinics about the needs of development. It is also necessary to have a partnership with the vendors and an effective quality management system that will secure the unanimous way of working. For the hospital management, it is important that CED will contribute to build up an internal technical expertise that the hospital can take advantage of when developing new control systems for management of larger medical equipment, entities or when investigating technical problems. All strategies must be harmonized with the core values of the hospital and be in line with the hospital's goals and strategies. The latest technology always needs a large investment in both equipment and competences. Therefore, carefully prepared planning of technology investments can reduce the running costs and costs for maintenance most evidently. (Teriö, 2016).

PM and CM maintenance, including calibration of medical devices are basic activities in the process of device management. When the equipment is purchased, there is also a discussion

of who is going to carry out the maintenance activities. In the Nordic countries, it is often a mixture between in-house and vendor services. The decision, who is doing the different maintenance tasks and to what extension, depends on the recourses and the costs. It is also possible to renegotiate the agreements when the situation has changed.

Technology management requires an accurate inventory to keep track on the detailed information on the medical devices and systems. It should also be possible to monitor equipment performance, reliability, and cost-effectiveness, as well as to assist decision making in equipment acquisition and technology assessment. The inventory system should provide a comprehensive, expandable, and easy-to-use database of protocols for the performance of quality control, preventive and corrective maintenance, electrical safety, calibration, and acceptance tests of medical device. Since CED has to perform continuous monitoring and evaluation of its performance in order to identify probable problems and measure its contribution to the quality of patient care, the system should also monitor and measures a set of quality and cost indicators, allowing a continuous overview of the departments performance in terms of productivity, effectiveness, and efficiency.

Nowadays, medical information systems are connected directly to medical devices in order to retrieve physiological data or to control the function of the medical devices. Information Technologies (IT) systems and software used in healthcare have obtained more crucial importance for the treatment and care of an individual patient. Integration of medical devices and IT, and the use of the devices in networks have made it necessary to study the integration of the two areas. The Swedish Society for Medical Engineering and Medical Physics (MTF) has conducted a project with the aim to improve patient safety through clarification of responsibilities for work with medical devices integrated with IT systems that are used to collect physiological data for diagnosis and/or treatment of a patient and transfer this data through a network to a server/database (MTF, 2008). This system was called MIDS, as acronym of Medical Information Data System, and its use increases the requirements for higher competence in the persons who handle these systems and it is also necessary to develop the cooperation between clinical engineers and IT engineers. In many of the Swedish Counties, IT and CE are already in close cooperation or belong to the same organization. Medical Informatics, CED, IT, and biotechnology will be integrated more and more in a common organization to support the development of healthcare (Teriö, 2016).

2.3. Maintenance cost comparison in UK

Maintenance can represent a significant portion of the cost in asset intensive organizations, as breakdowns have an impact on the capacity, quality and cost of operation. However, the formulation of a maintenance strategy depends on a number of factors, including the cost of down time, reliability characteristics and redundancy of assets. Consequently, the balance between Preventive Maintenance (PM) and Corrective Maintenance (CM) for minimizing

costs varies between organizations and assets. Nevertheless, there are some rules of thumb on the balance between PM and CM, such as the 80/20 rule. Studies on the relationship between PM and CM in practice are rare, but based on a case study made of rail infrastructure historical data carried out in 2016 to determine the shares of PM and CM, together with a Cost–Benefit Analysis (CBA) to assess the value of PM, we can conclude that the benefit of PM is positive (Stenstrom, Norrbin, Parida, & Kumar, 2016).

While studies on PM to CM costs are lacking, a common rule of thumb for evaluating performance says one should aim for a PM to CM share of 80/20 in general. To analyze the cost comparison between preventive and corrective maintenance in a rail infrastructure, Christer Stenström, Per Norrbin, Aditya Parida and Uday Kumar, formuled some equations for assigning costs to maintenance inspections, repair of potential failures, repair of functional failures and service/production loss. PM and CM data are associated with both direct and indirect costs. Direct costs are those for materials and labour, and indirect costs are everything else. Common operation and maintenance data are: maintenance times (administrative time, Logistic Time (LT) and Active Repair Time (RT), delays, failures, remedies, causes and item information. To calculate the cost of CM, important data on costs are considered to be: service/production loss, Logistic Time (LT), RT and materials. It was assumed that notice of a failure is provided at zero cost. In the study, the authors realized that PM represents, more or less, between 10% and 30% of the total maintenance cost, and the study indicated also that the railway sections with the lowest total maintenance cost, have the highest share of PM (Wireman, 2003).

2.4. Economic evaluation of implementing a service of Clinical Engineering in Brazil

As Clinical Engineering is an important area for health care facilities, capable of applying engineering and management techniques to improve health technologies. It was made a study in a Brazilian hospital, that reports the economic impacts of the application of clinical engineering management techniques. The study was made in General Hospital of the Federal University of Uberlândia, a large Brazilian public hospital, which is also a reference for high complexity medical procedures. The discussion was supported by a quantitative documentary research, which took into account not only the economic aspects, but also the quality of the service provided. The survey was based on reports and administrative documents from 2001 to 2010, related to human resources, service and quality indicators, costs of parts and contracts. Among the findings, it was observed a reduction of approximately 20% in corrective maintenance and their stabilization over time, even as the technological park of the institution increased. As for the overall amount of cost with contracts, there was a reduction of approximately 65% during the period. The savings generated by the Clinical Engineering Service, for the institution, were about R$ 2 million (555918.33€) in 2010. The cumulative savings over the period of 2001 to 2010 were about R$ 7.6 million (1.877.744€). Based on

those results, it can be concluded that the Clinical Engineering Service provided a significant reduction in costs for the institution, by means of setting and training its own team, reducing costs and a better planning of maintenance. Those results demonstrate the importance of a Clinical Engineering Service for best managing costs and technologies in hospitals, whether public or private (Souza, Milagre, & Soares, 2012). The results of the paper showed the importance and advantages of the creation of a CED in a hospital in order to improve health technologies and reduce maintenance costs.

2.5. Outsource or In-House: A complex equation

Outsourcing of services can offer remunerations to healthcare facilities, however, before senior leadership can give outsourcing a green light, they must consider some variables: reasons why to outsource, obstacles to outsourcing, best practices of outsourcing, and implications to hospital management (Roberts, Henderson, Olive, & Obaka, 2013). One of the apparent benefits relates to reduced operating expenses that an experienced vendor brings. It can eliminate the need to hire in-house resources; therefore, labor costs and operational costs can be minimized to a great extent. No longer is needed to invest in and train highly specialized biomedical technicians. The hired vendor will handle all resourcing needs by tapping into their pool of highly skilled, trained and certified technicians. Facilities can pay for expert service on a needed basis. It is no longer need to invest in recruiting and training expensive resources for your business. An important aspect to this is being able to find hidden costs, saving through standardization, and using a strategic approach to servicing medical equipment. An independent firm that specializes in asset management will be able to easily oversee the enormous scope of work involved with a comprehensive medical equipment maintenance program. This certainly includes overseeing the sheer volume of contracts associated with managing, maintaining, and eventually repairing all of the sophisticated medical equipment housed in your medical facility.

As medical devices continue to grow more and more sophisticated with every passing day, having skilled biomed service technicians becomes even more paramount. Sometimes it can be cost-prohibitive to expect an in-house program to compete with the staffing, training and education needed to handle a large assortment of very sophisticated equipment located throughout a hospital. An in-house technician may be able to do a sufficient job to a certain degree but they lack the remote capabilities, advanced training, and access to an increasingly skilled hierarchy of technicians. Outsourcing medical equipment repair services to a qualified third party can provide all of the above mentioned benefits, but it will be always necessary a good coordination between the outsourced companies and the maintenance team of the hospitals. The importance as one considers the possibility of outsourcing responsibilities is to contemplate if a competitive market for the use of outsourced services exists. A company that provides these services can often capitalize on acquiring services at multiple hospitals in a region. The buying power of volume purchases and incentives can provide a strong marketing

advantage against both independent hospitals and competitors in the marketplace. Engineering management requires an understanding of mechanical and electrical machinery. It is important to understand how to perform maintenance on the machinery, functions, and optimization for efficient operation and resulting lower operating costs. It is critically important to have trained and properly qualified operators on staff to maintain and operate the machinery (Young, 2002). Identification of the tasks is very important in understanding how the hospital best can use the services of the outsourcing company. Hospitals must remain aware that the outsourcing company's motivation to complete the service is profit. The maintenance management team should be able to identify plan, collect history and monitor the outsource company during the interventions. A general scheme of this tasks is presented in the next picture:

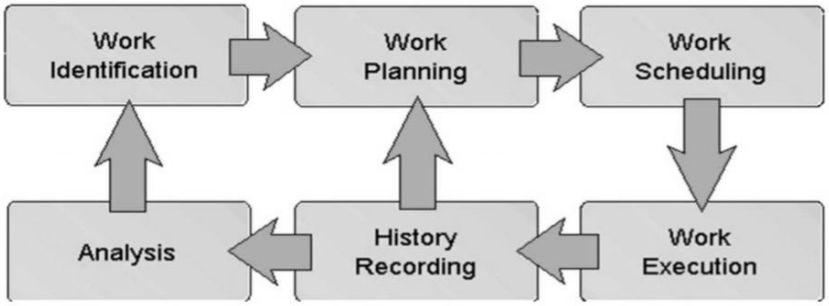

Figure 1- Task Development and Evaluation Process (Dunn, 2015)

To decide whether to outsource some or all of their biomedical services in a Hospital, there is no one-size-fits-all answer. George Gyurtsak, director, biomedical services, Community Health Systems, is becoming rather an expert at insourcing, converting biomedical service departments from those that use outsourcing models to those that bring services in-house. In fact, the 208 affiliated hospitals (in 29 states) in which the Franklin, Tenn-based hospital company owns, leases, or operates, about 190 have in-house biomedical departments. The majority of these 190 departments have been converted to an in-house operation in just the past 6 years.

Recently there was a massive shift from outsourcing to in-house. Considering the size of Community Health Systems, it isn't surprising that it has decided to take the in-house servicing option. "There's a size where it always makes sense to outsource and a size where it never makes sense," says David Hargraves, vice president of clinical supply chain, and vice president operations at BioTronics Inc. BioTronics (formed in the early 1980's) is a subsidiary of the University of Pittsburgh Medical Center (UPMC), and as such is the clinical engineering services provider for UPMC. It also provides equipment management and clinical engineering services to a number of other hospitals in the region. "The fact is, the smaller the healthcare facility in terms of the number of beds, pieces of equipment, and FTE (Full-Time Employees) in the clinical engineering department, the more likely service is

going to be outsourced", Hargraves says. "In the case of UPMC and BioTronics, we have over 145 employees, so there is almost no scenario in which we would outsource that business, because we are large enough, and have the capacity, the cross-training, the redundancy, and the ability to float technicians among facilities, so we can achieve a much lower cost-to-service ratio". On the other hand, if a facility has a biomedical services department with two or three employees, it's unlikely to spend thousands of dollars to get one of them trained to maintain and service a computed tomography scanner. That's precisely the kind of situation that Izabella Gieras, director of clinical technology at Huntington Memorial Hospital in Pasadena, faces in her department. The size and competency of her staff will determine her department's ability to maintain and service specific pieces of equipment or maintain it through service contacts. "If we have just one MRI (Magnetic Resonance Imaging) - and that's what we have at Huntington (which is a 625-bed, nonprofit, regional medical center) - we're obviously not going to train one person to be an MRI specialist to maintain that one machine," Gieras says.

And there are other variables as well, such as accessibility to training, the cost of the training, the age of the equipment in question, and its service history, she says: "So we'll take all of those different variables into consideration before deciding whether we can take a piece of equipment in-house, or it's better to take a service contract". According to Ramy Boghdadi, director of consulting at Siemens Healthcare, Malvern, Pa, the first thing organizations need to consider is not necessarily the question of insourcing versus outsourcing, but how they can effectively "life cycle manage" their equipment. "You have this installed base of invested assets," Boghdadi points out. "So how do you get the maximum utilization, productivity, and longevity of those investments, and what's the appropriate time to turn them over?" The point is that "biomedical departments should be an integral part of an organization's life cycle management and capital planning process," he says. "Because if (an organization) looks at biomed as just a break/fix part of the organization, and just a cost center, then it doesn't really have the vision and insight to truly maximize those programs and departments, and it might make sense to outsource services in those organizations". If, however, an organization "is really interested in developing an in-house program and committing to it", Boghdadi says, "I believe there would be quantifiable return on investment associated with it". And the organization will have to look at issues like staffing, competencies, and training, as well as issues related to dispatching, part sourcing, and standardization, "which are a big part of cost containment". In addition, with a high-performing in-house program, a hospital should see increased satisfaction among users in areas like cardiology or radiology. And if done correctly, this program should be a very strategic component in the organization's efforts to the maximum utilization out of its investments. There are going to be challenges involved with going in-house as well, Boghdadi adds. For example, it will take time and resources to find and train people who are competent enough to maintain and service an organization's biomedical equipment. And departments will have to make sure they have staffing redundancies so that in the case of vacation or illness, they have qualified personnel available

to service any piece of equipment. There's also the problem of attrition because will be invest in training these individuals with the risk that they are going to leave and go elsewhere. Ultimately, Boghdadi adds, a "hybrid" model (a combination of insourcing and outsourcing) makes sense for a lot of organizations in that it provides the best way to get the advantages of bringing things in-house, while mitigating the risks involved. The advantages with the in-house model are that "you have resources that are right there at your fingertips", he says. "So you have better response time and reduced down time, and you don't have to depend as much on third parties or OEM to service an asset. Bud DeGraff, general manager of diagnostic and clinical services for GE Healthcare, Waukesha, Wis, agrees that when it comes to the in-house/outsourcing question, "there probably isn't a one-size-fits-all solution. Hargraves says that staff training can be a tricky issue. "Most manufacturers provide it, but what does it cost?" he asks. "What is its availability, and do they train you the exact same way they train their own technicians?" At the end, training is critical because biomedical departments have to pay attention to the professionalism and quality of repair. It's one of the best defenses against being outsourced. And, if an organization is going to outsource, it can't assume that just because a company has a good trade name that the specific people they are going to put have been properly trained and have the right degree of professionalism. Hargraves recounts a situation in which he had a discussion with a potential client for whom the reason for transitioning a Community Health System facility to an in-house servicing and maintenance model varies case by case, Gyurtsak says. Often it's simply a situation where a contract affecting one or more hospitals is coming to an end. So, to make a decision on what is the most efficient and cost-effective way to go, we would typically do an analysis and compare the costs of doing things in-house versus outsourcing, with the added benefit of having more management control over the program. In other cases, it could be a situation where there are service-related issues that warrant bringing a program in-house, Gyurtsak says, or it could simply be a decision that the program could be more cost-efficient by bringing things in-house. Of course, there are situations in which it makes sense to go in the other direction (from in-house to outsourcing). "You may have a very small facility in a very remote location where you really won't have the opportunity to share resources", Gyurtsak says. "In that kind of scenario, you may want to look for a vendor that can provide you with 1, 2, or 3 days of service at a lower overall cost" (Bassett, 2014).

2.6. Standardizing the clinical engineering

There is intrinsic value in standardizing technology to the extent practicable. Vendors, models, characteristics of similar equipment types, and service responsibilities can be standardized. The standardization can be within the products and services offered by a specific vendor, or include characteristics (e.g., communication bus) and services (e.g., guaranteed availability of loaner units across different vendors, service providers, and clinical areas of use) (Dyro J. , 2004).

In 2010 it was published a paper where 8 authors from 5 countries (France, Spain, Italy, USA and Gemany), showed the benefits of standardizing the use of whole slide images in digital pathology (Daniel, et al., 2010). The goal of integrating the healthcare enterprise initiative was to specify how data standards should be implemented to make systems integration more efficient and less expensive for specific health care use cases. It was their hope that the work would lead to greater adoption of standards within medical community, allowing for a proliferation of systems that will be able to seamlessly interoperate, similar to the experience in the field of Radiology, where imaging equipment and information systems from multiple vendors routinely work together, providing a rich environment for clinical imaging activities.

In 2011, the Clinical Systems Engineering (CSE) Department at Kaiser Permanente Northern California accepted the challenge of standardize the patient-monitoring clinical engineering processes of 41 hospitals of Berkley, CA, by incorporating high-quality, cost-effective clinical technologies into a sprawling, multihospital healthcare system, while still addressing unexpected medical technology needs through the year. This multidisciplinary team composed by 13 CSE engineers, has developed a strategy enabling it to blend immediate needs with long-term strategy by doing equipment replacement planning, implementation, and management. This engineers were skilled of multiple workflows in different fields, so that made them a very flexible team. Acosta, one of the Northern California Clinical System Engineering (CSE) team, said that one of the keys to reducing cost is developing a standardized model, which is why the environment is moving towards a regional standard. With a shift from paper to electronic records, the challenge faced by the CSE team was how to implement the new technology while attending the day-to-day responsibilities. The challenge was not just creating software with new features, and replacing old existing equipment, but the accompanying policies, guidance, regulations with new safety features, etc., with only a few team members that in addition had many other responsibilities. The solution to manage so many hospitals, offices and clinics was the meticulous organization and great teamwork, meant that they would have to maintain a map of all locations, and set up a regional simulation where workflow could be analyzed and optimized, so they could look to the multiple workflows, turning them into one, and applying that workflow across the region. Meanwhile, the team also had to manage to address emergent medical technology needs that arose during implementation period, by meeting with new customers first, then vendors, then trials, then data collection, and finally making a choice. In addition, the CSE team had nondisclosure agreements with top vendors at least annually to discuss new technology. Clinical technology planning, acquisition, and implementation services were all based on a data-driven, multidisciplinary approach, for developing the medical equipment management database and obtaining customer feedback, so that team members were able to access data such as equipment-to-patient use ratios, equipment service history, and equipment life expectancy. With the standardization of the patient-monitoring system, for example, the CSE team collected data in several areas to be able to develop an effective solution. In the end the Kaiser Permanente saw a successful deployment of its new KP Health Connect

system, effective data integration, as well as the smooth integration of high quality, cost effective clinical technologies into Northern California region hospitals. Nowadays, the Clinical Technology Committee provides budget proposals to the leadership and publishes a plan annually that allows the team to coordinate the acquisition, upgrade, and replacement of clinical technologies for each area (Hatva, 2012).

2.7. A clinical engineer's approach to respond to regulatory changes in USA

The United States is a global leader in healthcare. Their academic institutions, healthcare professionals and service providers are internationally known and admired. Yet, despite this, Americans die sooner than citizens of many other nations. In most recent years, U.S. health care spending has grown faster than the economy. By 2020, health care expenditures are projected to reach 20 percent of the nation's Gross Domestic Product (GDP). By 2030, people over 65 will make up 20 percent of our population, with the fastest growing group over age 85. As greater numbers of Americans lead longer lives, the cost of care will continue to rise. Health disparities are a persistent challenge for the U.S health care system, and high rates of preventable diseases among racial and ethnic minorities add to growing health care expenditures. It is known that when a population is healthier, costs are lower, and societies can invest resources in other priorities such as education, infrastructure, and defense. The Centers for Medicare & Medicaid (CMS) have the mission of strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost, and, they are focused on measurably improving care and population health by transforming the U.S. health care system into an integrated, standardized and accountable delivery system that continuously improves care, reduces unnecessary costs, prevents illness and disease progression, and promotes health defense (CMS, 2013).

As the U.S. Department of Health & Human, Centers for Medicare & Medicaid (CMS), requires that hospitals must maintain adequate facilities for their services and hospital facilities, supplier, and equipment are maintained to ensure an acceptable level of safety and quality, in December of 2013, the CMS and, subsequently the Joint Commission on Accreditation of Healthcare Organizations, made some regulatory changes in the hospital equipment maintenance requirements and proceedings.

In response to this regulatory changes, most U.S. hospital-based Healthcare Technology Management (HTM) program had three options for consideration when determining how best prepare for these chances:

1) They could "do nothing", if they believe that their existing program was already in full compliance;

2) They could "make minor modifications" to their existing policies, inspection and maintenance procedures and equipment risk based assessment programs based upon deficiencies they determined to exist;
3) They could "perform an extensive review and assessment (full makeover)" of all their medical equipment management plan and make changes where needed.

The option one is a bit risky, but the cost of full compliance may initially prohibit many healthcare organizations from jumping right into making changes that may be required, especially if it relates, for example, the requirement that all the medical devices must have maintenance done "by the book". McLaren Health Cares' Clinical Engineering Services took an aggressive proactive approach in how it is going about demonstrating CMS compliance, which started by performing a gap analysis evaluating 28 indicators identified in the CMS document, to apply a new program in the 12 member hospitals of McLaren Health Care. Once again the challenge requires development and implementation of a standardized corporate clinical engineering program across all member hospitals. David M. Dickey, the corporate director of the McLaren Health Clinical Engineering Services, started by reading the CMS Regulation over and over to start capturing the key components of the regulation into a usable format, that led to the development of a simple table, for use in determining how well their medical equipment management program complied. The document was distributed to all of their program managers over the 12 hospitals, and for each CMS program requirement, they just had to see if the hospital was complying, and if so how it was demonstrated or documented.

As they are using a risk scoring model to justify the elimination of unnecessary Preventive Maintenance (PM), the results were not too far off the mark, especially as related to their current equipment scoring approach used to determining which device types do not benefit from having a scheduled inspection.

Evaluating safety and effectiveness of the alternative equipment management program it is stated that the hospital has policies and procedures which address the effectiveness, and when evaluating the effectiveness of the program, it is expected that the hospital addresses factors including, but not limited to:

- Verifying how incidents of equipment malfunction are identified (usually by a corrective maintenance or repair work order);
- Verifying how incidents of equipment malfunction are investigated (usually by the service staff troubleshooting the failed device and finding the faulty component).

It is also needed to document how the malfunction was investigated as well as, whether the malfunction could have been prevented. They concluded that each hospital should develop and implement a medical equipment management program that includes, at a minimum, the following components:

a) Processes implemented to manage the effective, safe and reliable operation of medical equipment;
b) Processes for selecting and acquiring medical equipment;
c) Requirement for all equipment users to be properly trained on the safe use of devices;
d) Procedures for identifying, evaluating and creating an inventory of equipment, based, minimally, on equipment function, risk and incident history;
e) Procedures for developing inspection scheduled and maintenance strategies for all equipment on the inventory, in order to achieve effective, safe and reliable operation of equipment on the inventory;
f) Processes for monitoring and acting on equipment hazard notices and recall;
g) Processes for monitoring and reporting incidents in which a medical device is suspected or attributed to the death, serious injury or serious illness of any individual;
h) Processes for identifying and implementing emergency procedures that address actions to be taken when equipment fails; how to perform emergency interventions when equipment fails; and how to obtain repair services;
i) Documentation requirements of performance and safety testing of all equipment covered by the medical equipment management plan;
j) Documentation procedures of inspection and maintenance of equipment used for life support that is consistent with identified maintenance strategies to minimize clinical and physical risk;
k) Documentation procedures of inspection and maintenance of equipment used for non-life support that is consistent with identified maintenance strategies to minimize clinical and physical risk;
l) Documentation of performance tests on all sterilizers;
m) Documentation of chemical and biological testing of water used in renal dialysis, if applicable;
n) Requirement for an annual program review to include measurement of effectiveness of all aspects of the Medical Equipment Management Program.

2.8. Medical device calibration

Calibration is a comparison between a known measurement (the standard) and the measurement using your instrument. The accuracy of all measuring devices degrade over time. This is typically caused by normal wear and tear. However, changes in accuracy can also be caused by electric or mechanical shock or a hazardous manufacturing environment (e.x., oils, metal chips, etc.). Depending on the type of the instrument and the environment in which it is being used, it may degrade very quickly or over a long period of time. The bottom line is that calibration improves the accuracy of the measuring device and accurate measuring devices improve product quality. Usually, the health care facilities have proceedings to calibrate the most important medical devices like tomographs where the calibrations are made by the manufactures or according to manufactures guidelines. Although some devices are

calibrated and audited, some small devices like the ones used to measure blood pressure, glycaemia, and others, sometimes are not calibrated neither its conformity is audited.

Calibration of measuring instruments has two objectives: checking the accuracy of the instrument and it determining the traceability of the measurement. In practice, calibration also includes repair of the device if it is out of calibration. A report is provided by the calibration expert, which shows the error in measurements with the measuring device before and after the calibration. Calibration is an essential component of every Quality Management System (QMS). It generally states that manufacturers have to ensure that "...all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results". Further, it also requires medical device manufacturers to have procedures in place for calibrating, inspecting, checking and maintaining equipment. As for calibration requirements in particular, the FDA's medical device calibration requirements require medical device companies to have procedures in place that specifically offer directions and limits with regard to precision and accuracy.

The AHA made a scientific statement where they wrote some recommendations for blood pressure measurements (AHA - American Heart Association, 2005). In that document they provide a standardized set of recommendations that, if followed, should lead to accurate estimation of blood pressure. They recognize that many committees and organizations have published recommendations and that, in practice, blood pressure measurement remains suboptimal. In view of the consequences of inaccurate measurement, including both the risks of overtreatment and undertreatment, it is the opinion of the committee that regulatory agencies should establish standards to ensure the use of validated devices, routine calibration of equipment, and the training and retraining of manual observers. Because the use of automated devices does not eliminate all major sources of human error, the training of observers should be required even when automated devices are used. It is widely recommended that sphygmomanometers are maintained and calibrated regularly to ensure that the pressure scale remains accurate to within the European Standard specification of +/-3 mmHg. In primary care, however, such checks are reported to be only rarely performed (Coleman, Steel, Asworth, Vowler, & Shennan, 2005). In a study published in 2005 in Blood Pressure Monitoring journal, 279 sphygmomanometers were calibrated using an accurate electronic reference pressure sensor. The key finding of the study was that 17.9% (50 out of 279) of all surveyed devices gave errors exceeding the +/-3 mmHg threshold. Of these, 53.2% (33 out of 62) of aneroid devices (without mercury – usually more portable) were found to be reading in error by more than +/-3 mmHg compared with 7.8% (16 out of 217) of the combined population of mercury and automated devices (Coleman, Steel, Asworth, Vowler, & Shennan, 2005). Dr. Hiremath, a kidney specialist at Ottawa Hospital in Canada says: “We want to empower patients, but we also want to make sure the measurements are accurate”. Dr. Hiremath says the finding emerged from a program to teach people with

kidney disease on how to use home blood pressure monitoring. Untreated or inadequately treated high blood pressure is the main cause of kidney disease today, and contributes to its complications. Starting in 2011, people with kidney disease were asked to bring their home blood pressure monitoring equipment to the kidney clinic at Ottawa Hospital to have it checked for accuracy against a standard office device. It was impressive how inaccurate some of the machines were", Dr. Hiremath says. "They were sometimes 15 or 20 mmHg off". Dr. Hiremath and his colleagues pulled together blood pressure records for 210 clinic patients. For 30% of them, the systolic pressure (the first number of a blood pressure reading) was 5 mmHg or more different from the office reference measurement. The diastolic pressure (second number) was similarly inaccurate (Pendick, 2014).

2.9. ISO 31000:2009

The requirements for effective Risk Management (RM) have grown during the recent years. As a response to these emerging needs, a substantial growth and development has been seen in the risk management industry. However, the diversity of different actors in the field of risk management has been a source for much confusion and ambiguity with regard to mutual RM practices and the use of terminology. The attempts to harmonize risk management practices have been actualized in a number of risk management standards, latest of which is ISO 31000, that claims to be a standard for managing all risk everywhere.

The ISO 31000:2009 *Risk management - principles and guidelines*, was published in November 2009, by the International Organization for Standardization (ISO). The purpose of this standard is to offer generic guidelines for establishing a risk management framework, in context of which management of risk is applied, and it is intended to be transversally applicable for organizations of every industry, size and type.

Looking of what the new standard is describing, the document is divided in 5 clauses:

- Clause 1 - *Scope*: Defines the scope as generic risk management and says the standard contains principles and guidelines;
- Clause 2 - *Terms and definitions*: Provides definitions of 29 terms used in the standard, all sourced from another ISO document, a glossary of risk management terms called ISO Guide 73:2009;
- Clause 3 - *Principles*: Lists 11 principles for risk management, each with a paragraph of explanation;
- Clause 4 - *Framework*: Describes a cyclical process for developing risk management within an organization;
- Clause 5 - *Process*: Describes a cyclical process for managing particular risks.

To better understand the scope of this standard, the document shows in a scheme the relation between the tree last clauses, principles, framework and process, presented in the Figure 2.

These were developed through a consensus-driven process over four years and involving the input of hundreds of risk management professionals around the world. The new standard supports a new, simple way of thinking about risk and risk management and is intended to begin the process of resolving the many inconsistencies and ambiguities that exist between many different approaches and definitions.

As an abstract topic like risk management is far harder to write clearly, definitions are sometimes vague, and consequently, hard to understand. Some literature refers that ISO 31000:2009 is disappointing. In a paper called "ISO 31000:2009 - The New International Standard on Risk Management" (Leitch, 2010), Matthew Leitch wrote that the document is unclear, leads to illogical decisions if followed, it is impossible to comply with, and is not mathematically based.

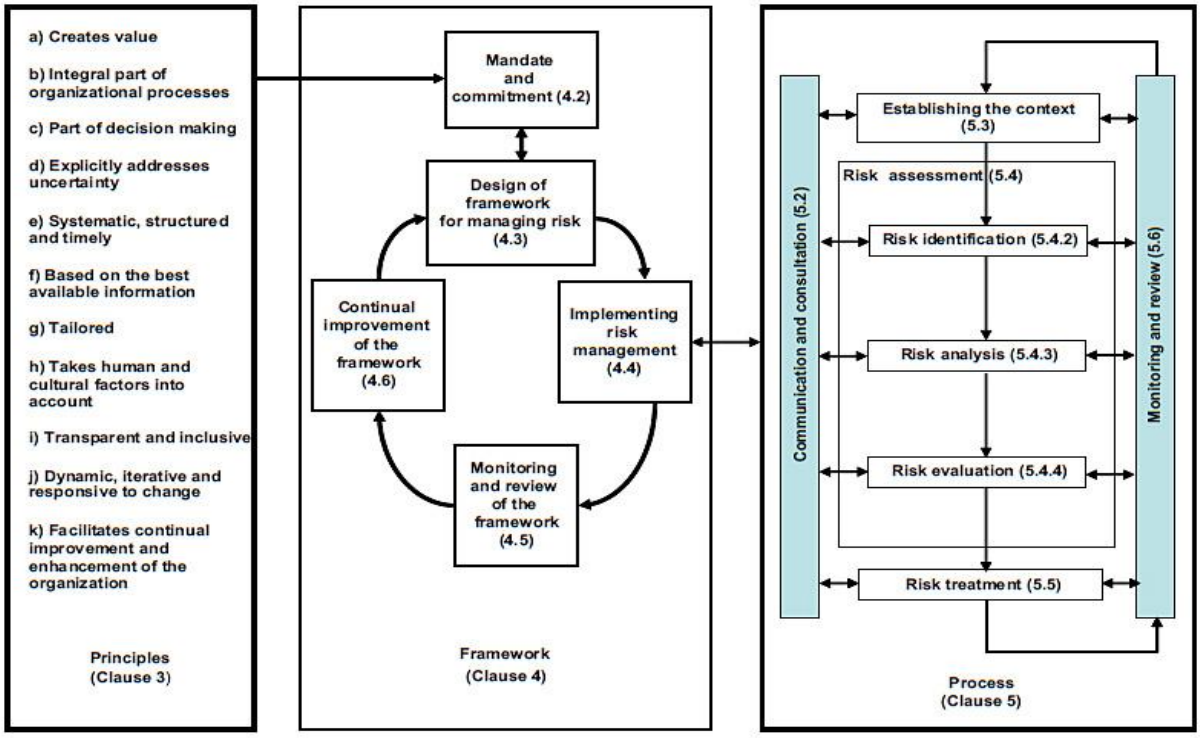

Figure 2- ISO 31000 Principles, Framework and Process

Although this standard is not easily accepted by everyone, the fact is that we can note a positive feedback in all the entities that follow this standard, and even the new standard for asset management (ISO 55000:2014) that interlocks with ISO 31000 in the risk management aspects. ISO 31000:2009 has also introduced some important and more pertinent terms to the risk management standard and hence helps in better orchestration and implementation of the process across the organization to yield benefits whilst at the same time controlling the costs and the overall optimization of resources.

As risk management is a process that is under-pinned by a set of principles, it needs to be supported by a structure that is appropriate to the organization and its external environment or context. A successful risk management initiative should be proportionate to the level of risk in the healthcare organization (as related to the size, nature and complexity), aligned with other corporate activities, comprehensive in its scope, embedded into routine activities and dynamic by being responsive to changing circumstances.

This standard is also "not intended for the purposes of certification. People are more likely to say that their approach to risk management is "based on" the standard than compliant with it".

2.10. Aplying Risk Management to Medical Devices

Performance Assurance (PA) is an integral component of clinical engineering, and is responsible for establishing a standardized method to determine, manage, implement and document medical equipment periodic inspection activities, and establishes a process to verify that medical equipment operate optimally and reliably; performs within specified limits and complies with safety requirements. This ensures equipment availability for continued patient care and enhanced patient safety. Over the years there has been increasing the recognition that PA program implementation is a risk management issue; however, there was no general consensus on the risk categories and the inclusion criteria. For that reason, the Clinical Engineering (CE) community has made concerted efforts to define appropriate risk factors and develop quantitative risk models for efficient data processing and improved PA program operational decision making. In 2008 Tidimogo Gaamangwe, Augustina Krivoy and Petr Kresta, have published a paper, (Gaamangwe, Krivoy , & Krest, 2008), where they present a framework for linking the PA program to the overall risk management decision-making process, as well as proposing new risk categories and appropriate risk contributing factors that will assist in defining the appropriate risk assessment technique. The management of medical devices entails a number of essential components, including technology assessment, acquisition, inventory control, repair service, in-service education, PA, and others. The PA program, in some cases referred to as Preventive Maintenance (PM), deals with device operation, performance, and safety. It is important to know that PA program is much more than preventive maintenance, and it should regard as a specific subcomponent or activity of the PA program.

As the PA program is defined as "a planned and scheduled method of performing inspections for performance verification, preventive maintenance, and safety testing", the authors followed the equation described by M. Ridgway (Ridway, 2001) with slightly different terminology defined as: $PA = PV + PM + ST$, where PV (Performance Verification) entails testing according to a written procedure to ensure that equipment is performing within specified performance limits and PM is a planned periodic procedure for cleaning, lubricating, adjusting, and replacing components whose failure may impair equipment

function. ST (Safety Testing) in this context is performed to verify that equipment is in compliance with electrical safety requirements. In the last years it has been a tremendous shift in PA philosophy, from do it all, to do as less as possible. As the pendulum swings to less PA and the concept gains acceptance, the question of how to select devices for inclusion in a PA program arises. The understanding that a PA program is developed and implemented for risk management is fundamental for clinical engineering departments. The basis of a PA program is risk management, which has two components: risk financing, which deals with insurance, and risk control, which deals with controlling losses. Risk control is defined as any conscious action (or decision not to act) that reduces the frequency, severity, or unpredictability of accidental loss. Therefore, PA is implemented for risk control and this aspect is recognized by Canadian Council on Health Services Accreditation (CCHSA), Canadian Standards Association (CSA), the Canadian Medical and Biological Engineering Society's Clinical Engineering Standards of Practice and the Joint Commission in United States. General risk management principles are addressed in some documents of the CSA and Association for the Advancement of Medical Instrumentation (AAMI). Because there is a lot of information to take into account: technical, regulatory, stake holder interest, etc., not only during the risk identification and assessment process, but throughout the whole process, it is important to understand that efficient risk management requires a risk management team. By owning and using medical devices, the enterprises faces a number of risks, but it still no consensus about the categories of risk. Some literature like (Fennigkoh & Smith, 1989), (Wang & Levenson, 2000), (Collins JT, 2001) and (J., 2000) have identified three categories as the main risks: function risk, physical risk (emanating from clinical application of the equipment), and maintenance requirement (level of maintenance inspection requirement). These risks are used by a large number of clinical engineering departments, but they are limited to devices, patient and user safety.

In the paper published by Tidimogo Gaamangwe, Agustina Krivoy and Petr Kresta, (Gaamangwe, Krivoy , & Krest, 2008) it was proposed new enterprise-level risk categories that are linked to ownership and use of medical devices: financial risk, legal liability, patient and staff safety. These new categories are broader than the previously used (function risk, physical risk, and maintenance requirement), and the definitions of previous categories suggest that they fall within the new proposed risk categories, as the use of equipment in any of the function categories has safety, legal, and financial implications for the enterprise.

In addition, the risks emanating from clinical application as defined above also have implications on safety, legal liability, and financial risk. Also, maintenance requirement, means that if inspections are not performed, the consequences for the enterprise could be one or all of the following: compromised patient and staff safety, increased legal liability, and financial risk. Therefore, the previously defined risk categories are covered within the new categories. By addressing risks from the enterprise perspective it is easier to see how actual device risks link to the broader risk categories. The newly identified risk categories emanate

from a number of contributing factors, some of which are inherent to the equipment design, some of which are related to the equipment use, and some of which are regulatory, as illustrated in the next figure (Gaamangwe, Krivoy , & Krest, 2008) e:

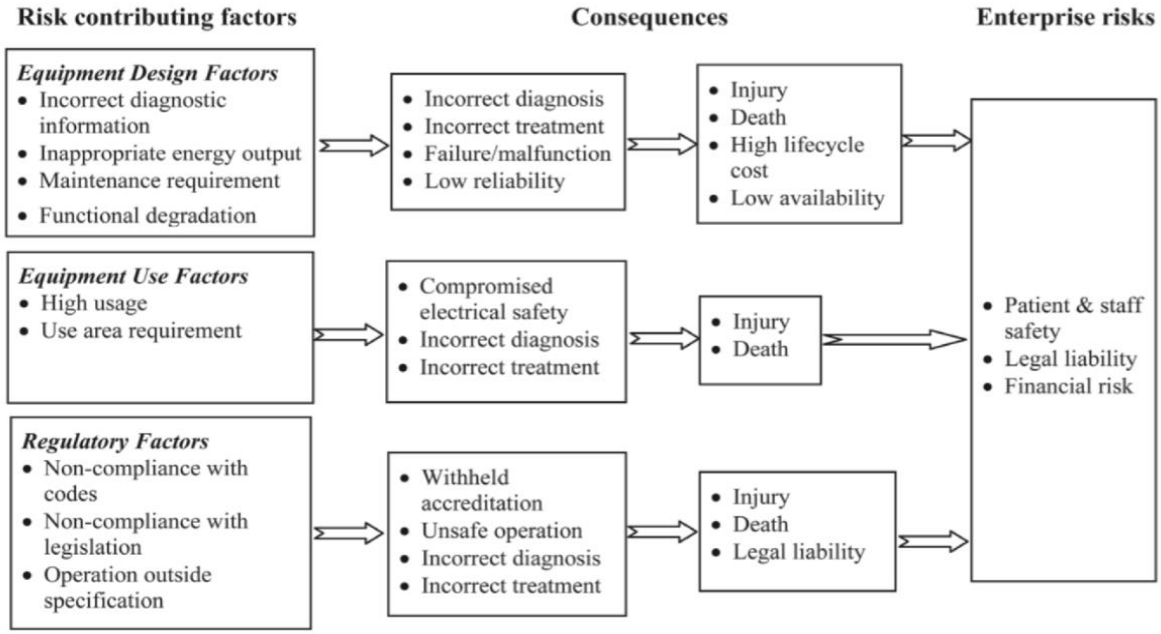

Figure 3-Illustration of how risk categories emanate from risk contributing factors (Gaamangwe, Krivoy , & Krest, 2008)

Risk analysis and evaluation allows the organization to estimate the probability and severity of risk and to evaluate the acceptability of risk. There are various risk assessment techniques, but most statistical techniques, such as probability and regression analysis, require data to be able to make an objective decision. The use of the appropriate technique depends not only on the availability of data but also on the type of data. In risk assessment (risk analysis and evaluation) is defined the delineation process for separating the inventory into two subsets: devices that need to be in the PA program (need regular inspection because they pose unacceptable risk to the organization) and devices that do not need regular inspections (excluded from PA). It is necessary to define the appropriate and acceptable inclusion criteria, which determines the size of each subset. While reliability engineering methods are used in some industries for identifying possible device failures, the type of analysis involved is normally quite complex and time consuming, as these methods include Life Cycle Cost (LCC), Failure Mode and Effect Analysis (FMEA), Mean Time Before Failure (MTBF), and other analysis techniques. Not all these analysis techniques are appropriate for all the devices, so they are not generally used in PA programs. Due to the difficulty of applying these strategies to a large and complex inventory of medical devices, there has been concerted effort in clinical/biomedical engineering to develop alternate appropriate inclusion criteria.

Since risk-contributing factors are the cause of risk categories, any changes in the risk-contributing factors or quantities derived from them would cause changes to the risk categories defined above. Therefore, risk-contributing factors or quantities derived from them can be used as indicators for risk or inclusion criteria parameters, and the inclusion criteria parameters provide the specification against which risk can be assessed and the specification will determine the types of data required for the risk assessment. In this case, where the proposed inclusion criteria parameters are derived from risk-contributing factors, the information required for risk assessment would be available in any healthcare enterprise, with or without historical data. This is important because there are no constraints placed on PA implementation by historical data and retrospective data from monitoring the program can be used for reassessing risk. Risk control measures are specific actions or activities intended to reduce the frequency and/or severity of loss. In the risk management decision-making process, before any decision is made on a specific action to control any identified risk, a broad strategy question: whether the risk can be avoided, prevented, or reduced, is usually asked. This process is important because there may be no need for the enterprise to devise any elaborate specific activities, e.g., if the best strategy is to transfer the risk to another part. Choosing the right strategy to use depends on the problem at hand. This is important information because the knowledge of the appropriate control strategy narrows risk control options or measures to be considered. From a risk control point of view, the subcomponents of PA, are actually risk control measures. Usually the activities or detail of inspection undertaken under any of the above risk control measures are sometimes based on manufacturer procedures/protocols or protocols developed in-house, depending on a number of factors, such as whether the devices are specialized, the number of devices in the inventory, etc. Besides deciding on the activities, it is important to decide on the frequency of activities, i.e., inspection frequency. The inspection frequency is often based on information from a number of factors, such as manufacturer recommendation, facility experience, recalls/alerts, repair, and incidents. Monitoring is an important part of risk control to ensure that the measures are effective in achieving the desired outcomes and to adapt the program whenever necessary.

2.11. Hospitals of the future

Human lives weigh in the balance every day in hospitals. For hospital patients and their families, the hospital experience is often a central point in their life: where their child was born, their beloved died, where they received life-saving treatment, rejuvenating therapy or care to overcome an episode of illness. Despite the impact of globalization and "disaggregation," hospitals have a mission to fulfill to society. With the coming squeeze on health care pricing and increased competition, hospitals will need to adapt. They will have to learn to do more with less by squeezing out inefficiencies in care delivery. Hospitals will have to reduce their costs in order to achieve equilibrium in the ratio of payments received to costs expended (The Joint Commission, 2008).

While there are many possible issues to discuss relating to medicines of the future, from the point of view of science, the most important one is the further development of knowledge and biomedical engineering. In the short-term, the development that is already bringing new technology advances to medical equipment is a revolution in the use of robotics and medical telemetry. The range of robots already developed include master/slave robots intended for applications in radiosurgery, that are able to self-assemble inside the human body. They include nano robots that are able to navigate the human body to facilitate diagnosis and surgical treatment, that was unimaginable just 20 years ago. Today these interventions are minimally invasive, high-precision, safe and fast. Undoubtedly, the next generation of robots will be even more precise, allowing diagnosis, procedure and rehabilitation to become even more efficient, further increasing the life expectancy of the population. Medicine will have new challenges, not only because of the emergence of new diseases, but also due to the problems of looking after an ageing population. Our increasingly ageing population will generate increased clinical demands to look after an increasing number of patients with chronic conditions (Embry , 2013). Environmental factors such as natural light, color and the ability to commune with nature, are very important, and hospitals must change to become more enjoyable and less depressive (Teriö, 2016).

Telemetry clinics are currently starting doing remote surgeries, however it is important to note that any medical or surgical intervention directed by remote specialists will imply a high cost. It will be a facility that will allow interventions directed by medical specialists, without the need for the patient to travel to the specialist, who could be anywhere in the world. There are concepts in the design of clinics and hospitals which will lead to good solutions, always taking into account their "connectivity", alone and as part of a larger complex. The explosive demand for clinical services resulted in the creation of large hospital complexes whose attention focused on different medical specialties. Sometimes these buildings are confusing, hard to navigate, and contain a high concentration of public and patients. They can also be cold buildings, with many people all searching for a solution to their very individual problems. Currently, these mega-hospitals have a laborious administrative process which can result in reaction times that are not always consistent with what is expected by patients and often many visits to the hospital are required to achieve the desired objective.

The new hospital of the future will have highly efficient diagnosis and treatment units, supported by state-of-the-art digital imaging equipment, which directly corresponds to surgery. The majority of hospitals will offer non-invasive surgery offering a significant reduction in in-patient numbers. Surgery will be reserved for the most complex cases. It must be emphasized that the "Hospital of the Future", will not be an industrial assembly line, and instead, it will offer a logical clinical sequence, where patients will follow through a "life line". They will enter through a reception area and after a process of diagnosis, treatment and recovery, they will emerge, fully recovered, at the other end. Integrating the patient's friends

and family and providing areas for relaxation and recreation are important. Patients will progress from a state of illness to recovery in a welcoming environment, where the trauma of interventions is minimized. All of these factors need to be incorporated into the new design of clinical habitat. Waste management needs to be properly controlled, and we need to look at using clean energy as well as looking at more energy efficient environment options. Important to understand that all of these changes will not eliminate the need for clinical engineering support services, which should be located in close proximity to provide all the necessary services and resources (Embry , 2013).

The Joint Commission published in 2008 a document where they explain the guiding principles for the development of the hospital of the future. It has some general guidelines to help the healthcare entities to improve their facilities and services, following what leads to the future of clinical engineering. The physical design of the hospital has significant implications for the ability of the hospital to meet its goals for care that is safe, patient-centered, clinically effective and collaboratively delivered. It also represents the physical manifestation of the hospital's commitment to environmental health and sustainability. There are a lot to be done until we reach this hospitals of the future, but in the meantime, hospitals must do their part to reduce error and waste, and increase efficiencies as a mean of improving safety and containing costs.

Between the guiding principles for the development of the hospital of the Future are (The Joint Commission, 2008):

- Encourage the alignment of hospital measurement and payment systems to meet quality and efficiency-related goals;
- Apply process improvement tools to improve efficiency and reduce costs;
- Use digital technology to support patient-centered hospital care and extend that care beyond the hospital walls;
- Use robust process improvement tools to improve quality and safety, and support achievement of patient-centered care;
- Educate health professionals to deliver team-based care and promote teamwork in the hospital environment;
- Establish reliable authorities to provide technology assessment and investment guidance for hospitals;
- Incorporate evidence-based design principles that improve patient safety, including single rooms, decentralized nursing stations and noise-reducing materials, in hospital construction;
- Address high-level priorities, such as infection control and emergency preparedness, in hospital design, construction and maintenance;

- Include clinicians, and other hospital staff in the design process to maximize opportunities to improve staff work flow and patient safety, and create patient-centered environments;
- Design flexibility into the building to allow for better adaption to the rapid cycle of innovation in medicine and technology;
- Incorporate "green" principles in hospital design and construction.

2.12. A few aspects about nosocomial infection

Nosocomial infections (NI) present a widespread problem in today's healthcare environment: between 4% and 10% of hospitalized patients acquiring an infection annually in the UK (Schabrun & Lucy, 2006) and between 16% and 22% in the USA (Monteiro, 1993). In developed countries, anywhere from 5 to 10% of patients admitted to acute care hospitals acquire an infection which was not present or incubating on admission. The attack rate for developing countries can exceed 25%. Because of the illnesses, deaths, and added costs related to nosocomial infections, the field of infection control has grown in importance over the last 30 years (Wenzel, Bearman, Brewer, & Butzler, 2008). Although nosocomial infections have been well cataloged and are fairly well understood, traditional solutions have failed to completely eliminate the problem. Even the most modern hospitals find themselves stymied by the persistence of these pathogens in hospital wards and operating rooms. The degree to which most of these infections are airborne is not known, but a growing body of evidence indicates that airborne transmission plays a role in many hospital-acquired infections (Kowalski W. , 2012). A recent study to estimate the negative burden of health-care-associated infections in Europe shows that the risk of hospital infection outweighs the risk of human immunodeficiency virus, influenza and tuberculosis infection together. The World Health Organization also estimates that hospital infections affect one in 20 patients (Cassini, et al., 2016).

A clean environment plays an important role in the prevention of Hospital-Associated Infections (HAI). Many factors, including the design of patient care areas, operating rooms, air quality, water supply and the laundry, can significantly influence the transmission of infections (World Health Organization (WHO), 2004). According to the World Health Organization (WHO), nosocomial infections are defined as infections acquired in the hospital or other medical facilities, for a patient who was admitted for other health reasons and, at time of entry infection was not present or in state of incubation. WHO also includes contracted infections during hospital stay, but that appeared after the patient is back home, and occupational infections that occur with staff within the hospitals. These infections are not a recent problem. It was around 1960 when UK and US started to create the first committees for surveillance and control of hospital infection. However, nowadays it presents as a serious issue, not only due to the associated morbidity and mortality but also due to the economic burden on hospitals. The increased susceptibility of patients and the increased resistance to

antibiotics by bacterial agents are important factors in the present situation. Among the different nosocomial pathogens, Methicillin-Resistant *Staphylococcus aureus* and *Clostridium difficile* are two of the most distressing for hospitals worldwide. Knowledge of their epidemiology, pathological and clinical particularities and treatment are fundamental in the observation and control of these infections, and that's why a multidisciplinary team with knowledge in the different areas is fundamental.

Nosocomial infections are transmitted in hospitals through three main environmental routes air, surface contact and water, and careful consideration of environmental routes for transmission of infection can help reducing nosocomial infection rates.

2.13. Water supply as a source of infection

Although numerous hospital sources can cause nosocomial outbreaks, possibly the most overlooked, important, and controllable source of nosocomial pathogens is hospital water.
Water is used in vast quantities in health-care premises. Many aquatic microorganisms can survive and flourish in water with minimal nutrients and can be transferred to vulnerable hospital patients in direct (e.g., inhalation, ingestion, surface absorption) and indirect ways (e.g., by instruments and utensils) (Emmerson, 2001). Many outbreaks of infection occur through lack of prevention measures and ignorance of the source and transmission of opportunistic pathogens. Waterborne microorganisms proliferate in moist environments and aqueous solutions, especially under warm temperature conditions and presence of a source of nutrition. Waterborne infections spread through direct contact (e.g., for hydrotherapy and showers), ingestion of contaminated water, indirect contact, and inhalation of aerosols dispersed from water sources. Designing the water supply system to minimize stagnation and back flow as well as provide temperature control to prevent growth of bacteria is an important aspect of preventing contamination through the water supply (Sehulster & Chinn, 2003). The next picture is a schematic representation of the transmission of waterborne pathogens in hospitals.

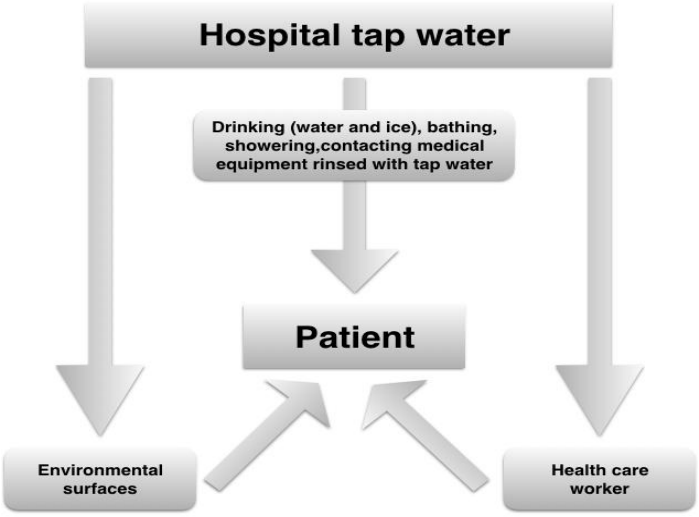

Figure 4-Schematic representation of the transmission of waterborne pathogens in the hospitals. Adapted from Anaissie (Anaissie, Penzak, & Dignani, 2002)

The ability of microbes to survive in hospital water tanks was described more than 30 years ago, and in United States it is estimated around 1400 deaths each year as a result of waterborne nosocomial pneumonias caused by *Pseudomonas aeruginosa* alone. Of all the water-related pathogens, *Legionella pneumophila* is most likely to be recognized by health care workers as a cause of nosocomial infection, however the acquisition of this infection in hospital, is similar to that of other water organisms. Although recommendations for preventing *legionelosis* have become standard knowledge in medical textbooks, nosocomial waterborne infections by other microbes have been largely ignored despite their high morbidity and mortality rates.

Another waterborne pathogen are the bacteria, and nosocomial infections caused by this pathogen have been associated to serious morbidity and even mortality and include *bacteremias*, *tracheobronchitis*, pneumonias, sinusitis, urinary tract infections, meningitis, wound infections, peritonitis, ocular infections and others. As nosocomial *aspergillosis* (fungi) continues to occur despite the air filtration, it suggests that may be other hospital sources of spores. Fungi can inhabit water distribution systems, including those of hospitals, and consequently cause infections. Over the years some fungi have been recovered from hospital water systems. Even not been reported waterborne infections by viruses, in fact several of these pathogens were also found in hospital water supplies (Anaissie, Penzak, & Dignani, 2002).

Legionellae are naturally distributed in aquatic environments, growing best at temperatures of 25°C to 42°C. Colonization is increased by water stagnation and sediment buildup as a result of alterations in the plumbing of the complex distribution systems often found in hospital hot-water systems. Cooling towers are often implicated in hospital and community outbreaks, so, wet cooling towers (if used) and cooling water systems should be regularly maintained,

cleaned, and disinfected. How systems become seeded with *Legionella* is unclear, but these organisms can colonize certain types of water fittings, pipework, and materials. Actions that reduce the risk of infection include removing dead legs, avoiding washers and gaskets made of natural rubber (nutrient source), replacing heavily scaled faucets and showerheads, and avoiding shock absorbers and pipe materials not made of copper or plastic. Conditions that affect the proliferation of legionellae include sludge, scale, rust, algae, and organic particulates thought to provide nutrients for growth. Infection can be minimized by good engineering practices supplemented by heat, disinfectants, and biocides (Emmerson, 2001).

Microorganisms tend to settle on surfaces of tanks and pipes where they circulate, forming biofilms. The primary cause of diminished water quality is the buildup of biofilm and the corrosion of distribution lines and tank surfaces resulting from poor design or aging of distribution systems and water stagnation. The increased water demand during summer or when construction activity increases flow through stagnant pipelines, dislodge organisms from biofilms and release them into the water supply. Patient exposure to waterborne microorganism in the hospital occurs while showering, bathing, drinking water or ice, and through contact with contaminated medical equipment rinsed with tap water. The source of organisms includes hospital water tanks, faucet tap water and showers, and even small quantities of organisms in water can cause infection. For example, the Centers for Disease Control and Prevention (CDC) of Atlanta (US), developed recommendations for the prevention of nosocomial pneumonia and *legionellosis* that include routine maintenance of the hospital water supply system, the use of sterile water in immunodepressed patients, and also recommends avoiding shower, using sponge baths instead. Additionally, showers maintenance must be done by removing their heads for cleaning and disinfecting with a 1/100 solution of chlorine (Piteira, 2007).

Hydrotherapy has become popular in many hospitals, but the physical structure of hydrotherapy pools, their high water and air temperatures, and intermittently intensive use by diverse groups of patients and staff produce potentially hazardous conditions. The pool should be designed to allow water to circulate through a filter and for the addition of a suitable disinfectant (often hypochlorite) in appropriate amounts with a mechanism for adjusting the pH (appropriate range 7.2 to 7.8). Pools should be cleaned regularly, have some water replaced weekly, and be emptied annually (Emmerson, 2001).

The health care facility should provide safe water. If it has water storage tanks, they should be cleaned regularly and the quality of water should be sampled periodically to check for bacterial contamination.

2.14. Air as a source of infection

There is a strong and sufficient evidence of a relation between ventilation and control of airflow directions in buildings and the transmission and spread of infectious diseases (Nielsen, Li, Buus, & Winther, 2010). Since 1990's, improvements in ventilation techniques and isolation procedures have been commonly credited with the decline in nosocomial transmission of tuberculosis and other airborne diseases; however, little effort has been made to study the risk of isolation patients acquiring secondary infections from contaminated air migrating into negatively pressurized isolation rooms from adjacent spaces (Mousavi & Grosskopf, 2015). The most dangerous hospital acquired infections pathogens are those that have the potential to spread by the airborne route (Kowalski W. J., 2006). Influenza virus, rhinovirus, adenovirus, and other pathogenic microorganisms resistant to conventional treatments can cause diseases such as tuberculosis; varicella-zoster and rubella (Piteira, 2007). A list of airborne nosocomial pathogens can be seen in Table 3 of appendix. Many of these pathogens, such as Methicillin-resistant *Staphylococcus Aureus* (MRSA), are now called "superbugs" because they are virtually invincible to standard drug treatments. Favorable indoor environments tend to self-perpetuate these agents, adding to the concern by infection control specialists everywhere. Maintenance of environmental controls is critical and staff should be educated and trained accordingly. With the advent of sealed high-rise buildings and forced ventilation, expensive negative pressure rooms have been introduced to house patients with infections thought likely to be transmitted by aerosol. To ensure sufficient dilution of the bacterial load around an infected patient, room air should be changed between 10 to 12 times every hour. Actual room air changes in negative pressure rooms often fall below this level because of poor plant and maintenance (Eames, Tang, Li, & Wilson, 2009).

Vulnerable patient populations are exposed to a variety of airborne infectious pathogens (Table 3 of appendix). Airborne pathogens are transmitted in three main ways:

1) When an environmental reservoir of a pathogen (i.e., soil, water, dust, decaying organic matter) is disturbed, fungal spores (e.g., *Aspergillus*) may be released into the air and make their way into the hospital environment.
2) Microorganisms can also be transmitted directly from person to person in the form droplets in the air. When droplets are produced during a cough or sneeze, a cloud of infectious particles is released into the air, resulting in potential exposure of susceptible persons within three feet of the source person.
3) Other infectious diseases such as tuberculosis are transmitted via residuals of droplets that remain indefinitely suspended in the air and can be transported over long distances. The microorganisms in the droplet residuals persist in dry cool conditions with little or no exposure of light or direct radiation. Susceptible individuals who come in contact with high concentrations of the microorganism may get infected.

Airborne pathogens such as *Aspergillus* survive well in the air, dust, and moisture present in healthcare facilities and are usually released into the air during site construction and renovation.

Bacteria are the largest single cause of nosocomial infections. Almost all of these bacterial cells are less than 5 microns in size and, if aerosolized, may remain suspended in air for prolonged periods. This array of bacteria consists of both communicable and noncontagious bacteria, many of which are endogenous commensals and opportunistic pathogens. The next picture graphically illustrates the array of airborne nosocomial bacteria by aerodynamic logmean diameter shown in relative size, as indicated.

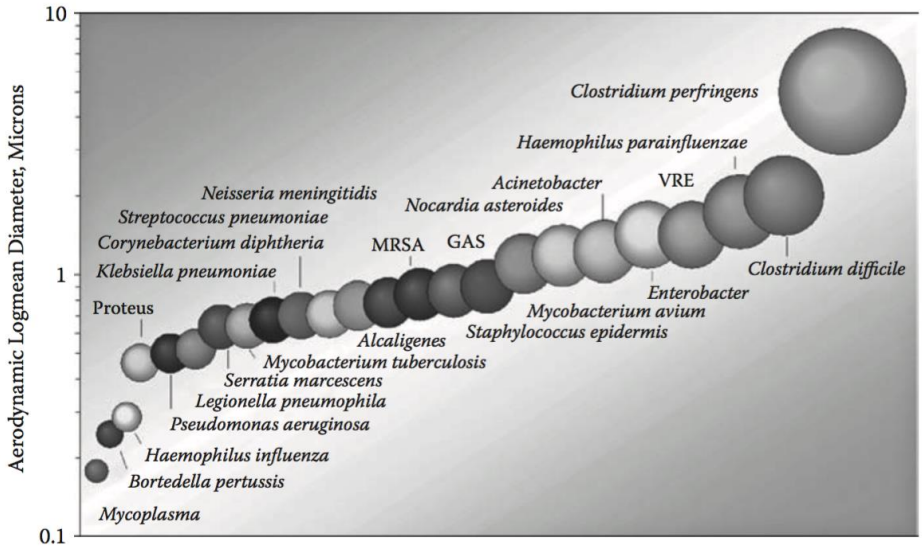

Figure 5-Relative size of airborne nosocomial bacteria based on aerodynamic logmean diameter (Kowalski W. , 2012). Volume of spheres are proportional to diameters

All viruses are pathogens and there are no truly endogenous viruses, but viruses may be communicable or no-communicable, and humans are the ultimate reservoir for most of them. The next picture illustrates the distribution of viruses by aerodynamic logmean diameter and these are shown in relative size, as indicated. All viruses in this size range may become aerosolized and remain suspended in air almost indefinitely.

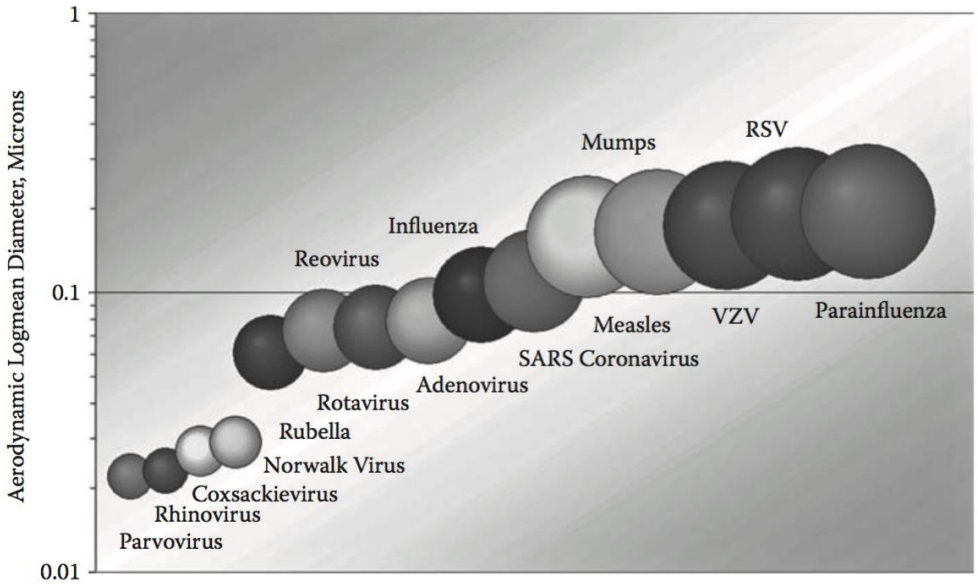

Figure 6- Relative size of airborne nosocomial viruses based on aerodynamic logmean diameter (Kowalski W. , 2012). Volume of spheres are proportional to logmean diameters

A wide variety of fungi are potentially airborne by virtue of their spores and are often present in outdoor and indoor air samples. Although most fungi are harmless to healthy humans, they can cause severe infections in the immunocompromised. All fungal spores may become aerosolized and remain suspended in air for prolonged periods. Almost all fungi are considered no-communicable, although they are ubiquitous in the environment and routinely contaminate homes, furnishings, and clothes. The next picture graphically illustrates the relative size of airborne nosocomial fungi based on aerodynamic logmean diameter.

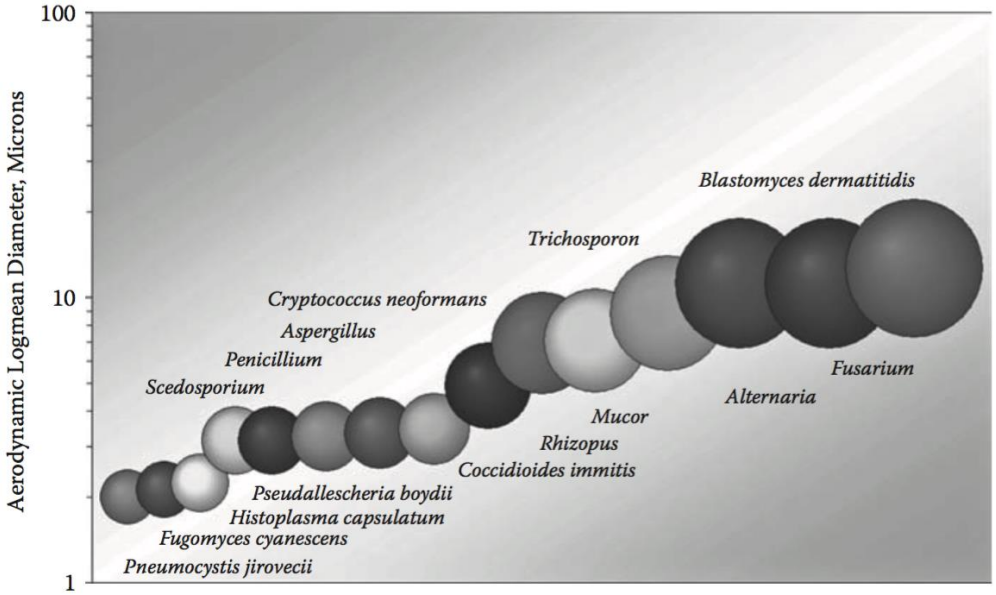

Figure 7- Relative size of airborne nosocomial fungi based on aerodynamic logmean diameter (Kowalski W. , 2012). Volume of spheres are proportional to logmean diameters

Many incidents and outbreaks of nosocomial infection have been linked to malfunctions and contamination of the ventilation system in hospital. Several studies have identified the type of air filter, direction of airflow and air pressure, air changes per hour in room, humidity, and ventilation-system cleaning and maintenance as factors related to air quality and infection rates. Accumulation of dust and moisture within HVAC systems increases the risk for the spread of environmental fungi, viruses and bacteria. HEPA filters are highly effective in preventing airborne infections from entering the hospital environment. Other than providing good quality air and ensuring adequate ventilation in patient-care areas, instituting effective prevention and control measures during construction and renovation is critical. Effective measures include using portable HEPA filters, installing barriers between the patient-care and construction areas, using negative air pressure in construction/renovation areas relative to patient-care spaces, and sealing patient windows (Joseph, 2006), (Eames, Tang, Li, & Wilson, 2009).

In 2001, Moritz, Peters, Nipko and Ruden (Moritz, Peters, Nipki, & Ruden, 2001) have studied the ability of medium efficiency air filters to retain airborne outdoor microorganisms in two HVAC systems. The filters reduced bacteria levels by approximately 70% and mold spores by over 80%. However, when humidity exceeded 80%, a proliferation of bacteria on air filters resulted in a subsequent release into the filtered air.

Ventilation systems should be designed and maintained to minimize microbial contamination. The air conditioning filters should be cleaned periodically and fans that can spread airborne pathogens should be avoided in high-risk areas. High-risk areas such as operating rooms, critical care units and transplant units require special ventilation systems. Filtration systems (air handling units) designed to provide clean air should have high efficiency particulate air (HEPA) filters in high-risk areas. Unidirectional laminar airflow systems should be available in appropriate areas in the hospital construction. Ultra clean air is valuable in some types of cardiac surgery/neurosurgery/implant surgery theatres and transplant units (World Health Organization (WHO), 2004).

For the operating room, the critical parameters for air quality include:

- Frequent maintenance/validation of efficacy of filters (in accordance with manufacturer's requirements);
- Pressure gradient across the filter bed and in the operation theatre;
- Air changes per hour (minimum 15 air changes per hour);
- Temperature should be maintained between 20°C and 22°C and humidity between 30% and 60% to inhibit bacterial multiplication;
- General areas should be well ventilated if they are not air-conditioned.

Negative air pressure vented to the air is recommended for contaminated areas and is required also for isolation of patients with infections spread by the airborne rout (World Health Organization (WHO), 2004).

2.15. Surface: Contact pathways of infectious pathogens

Although infection caused by airborne transmission poses a major safety problem, most infections are now acquired in the hospital via the contact pathway. Microbiologically contaminated surfaces can be reservoirs of pathogens. For example, the methicillin-resistant *Staphylococcus aureus* (MRSA) can survive on surfaces or skin scales for up to 80 days and spores of *Clostridium difficile* may last even longer (Eames, Tang, Li, & Wilson, 2009). The importance of assiduous hand washing by healthcare workers, accordingly, cannot be overemphasized for reducing hospital-acquired infections. While most infections are not directly transmitted to patients from environmental surfaces, these surfaces come in contact with the hands of caregivers frequently. Regular cleaning and disinfection of environmental surfaces as appropriate is critical for controlling surface contact transmission of infections (Joseph, 2006).

Environmental surfaces that are likely to get contaminated by pathogens can be divided into two groups: those with frequent hand contact (such as surfaces of medical equipment and high-touch housekeeping surfaces such as doorknobs, bedrails, light switches, wall areas around the toilet in the patient room, and edges of privacy curtains), and those with minimal hand contact (e.g., floors and ceilings). The number and type of organisms present on the surface depends upon the number of people present in the environment, the amount of moisture, the amount of activity, the presence of material capable of supporting bacterial growth, the rate at which organisms suspended in the air are removed (ventilation), and the type of surface and orientation (horizontal or vertical) (Collins, 1988).

High-contact surfaces in patient-care areas need to be cleaned and disinfected more frequently than minimal contact surfaces. Typically, the infection-control specialists in the organization use a risk-assessment approach to identify high-touch surfaces and then coordinate an appropriate cleaning and disinfecting strategy and schedule with the housekeeping staff (Joseph, 2006).

Transmission of infections in health care facilities can be prevented and controlled through the application of basic infection control precautions. Standard precautions can be: hand washing and antisepsis (hand hygiene); use of personal protective equipment when handling blood, body substances, excretions and secretions; appropriate handling of patient care equipment and soiled linen; environmental cleaning and spills-management; and appropriate handling of waste. Using personal protective equipment provides a physical barrier between micro-organisms and the wearer. It offers protection by helping to prevent micro-organisms

from contaminating hands, eyes, clothing, hair and shoes. Important to see the protective equipment as not just safety for the user but also for the patient. Sometimes physicians touch the monitors with the infected gloves, contaminating the equipment, and in the next shift the physicians start by testing the equipment without gloves, and just put the gloves to start the chirurgical act. Personal protective equipment can be gloves; protective eye wear (goggles); mask; apron; gown; boots/shoe covers; and cap/hair cover. Routine cleaning is important to ensure a clean and dust-free hospital environment. There are usually many micro-organisms present in "visible dirt", and routine cleaning helps to eliminate this dirt. Administrative and office areas with no patient contact require normal domestic cleaning. Most patient care areas should be cleaned by wet mopping. Dry sweeping is not recommended. The use of a neutral detergent solution improves the quality of cleaning. Hot water (80°C) is a useful and effective environmental cleaner.

Hospital waste is also a potential reservoir of pathogenic micro-organisms and requires appropriate, safe and reliable handling. Although the risk of acquiring disease from infectious waste is relatively low, all hospitals should develop a waste management program. The program should be jointly designed and coordinated by the infection control unit, the hospital engineering staff, and municipal authorities (Joseph, 2006).

All surfaces of the instrument/equipment must be cleaned taking care to reach all channels and bores of the instrument. If instruments are being washed manually the following procedure should be followed (World Health Organization (WHO), 2004):

- Wear personal protective equipment (plastic apron, thick rubber gloves, eye protection, surgical mask and/or face shield);
- Remove any gross soiling on the instrument by rinsing in tepid water (15-18 degrees);
- Take instrument apart – fully and immerse all parts in warm water with a biodegradable, non-corrosive, nonabrasive, low foaming and free rinsing detergent or use an enzymatic cleaner if necessary;
- Ensure all visible soil is removed from the instrument – follow manufacturers' instructions;
- Rinse in hot water (unless contraindicated);
- Dry the instrument either in a drying cabinet, or hand dry with clean lint-free cloth;
- Inspect to ensure the instrument is clean.

2.16. Healthcare equipment as a source of nosocomial infection

The high financial and individual costs associated with Nosocomial Infections (NI) make the identification of sources of infection, and the development of adequate cleaning protocols, a necessity in all areas of healthcare (Schabrun & Lucy, 2006). NI are frequently caused by environmental organisms and have been linked to a wide variety of contaminated hospital

equipment, suggesting that the risk of NI following contact with equipment is high. Despite the increasing prevalence of NI, current research indicates that up to one-third of infections acquired in the healthcare setting could be prevented by thorough handwashing and adequate cleaning and maintenance of equipment. Equipment used in the non-critical setting is less likely to have standard cleaning protocols than equipment used in the critical setting, making it more likely to carry large numbers of micro-organisms. In addition, several studies into the contamination of stethoscopes have reported infrequent cleaning of equipment, with one study reporting that 45% of practitioners cleaned their stethoscope once a year or never, and a further 35% cleaned their stethoscope monthly. These low levels of cleaning are likely to contribute to the incidence of NI, making the development of quick and effective cleaning protocols integral to reducing the spread of infection. S. Schabrun and L. Chipchase (Schabrun & Lucy, 2006) published a paper where they made a systematic review over published and unpublished studies between 1972 and 2004. The included studies reported that 86.8% of all sampled equipment was contaminated. They could conclude that healthcare equipment is a significant source of NI and high levels of contamination are present on a wide range of healthcare equipment.

2.17. Cleaning, disinfection and sterilization

Prior to any reprocessing to achieve disinfection or sterility all instruments and equipment must be cleaned. If not cleaned properly, organic matter may prevent the disinfectant or sterilant from having contact with the instrument/equipment and may also bind and inactivate the chemical activity of the disinfectant. If an instrument/equipment is unable to be cleaned then it is unable to be sterilized or disinfected (World Health Organization (WHO), 2004).

There are four main methods used for cleaning of instruments and equipment (World Health Organization (WHO), 2004):

1) Manual cleaning: All surfaces of the instrument/equipment must be cleaned taking care to reach all channels and bores of the instrument.
2) Enzymatic cleaners: Used for optical fiber instruments and accessories, and other items that are difficult to clean. These products are hazardous and care should be taken when in contact with them.
3) Ultrasonic cleaners and automated washers: Ultrasonic cleaners and automated washers are recommended for cleaning basic instruments that can withstand this process. These cleaners must be compliant with national guidelines and standards, and must be used according to the manufacturer's instructions. Ultrasonic cleaners do not disinfect the instruments. By causing high frequency, high-energy sound waves to hit the instrument/equipment, the soiling matter drops off the instrument, or becomes easy to remove during the rinsing process. These cleaners are not appropriate for use on cannulated instruments (they cannot clean inside the instrument), plastic materials, two or more different metals, or some glass instruments, syringes and lenses.

4) Disinfection: Removes micro-organisms without complete sterilization. Disinfection is used to destroy organisms present on delicate or heat-sensitive instruments which cannot be sterilized or when single use items are not available. Disinfection is not a sterilizing process and must not be used as a convenient substitute for sterilization. Thermal disinfection is not appropriate for instruments that will be used in critical sites as these instruments must be sterile.

Various methods of sterilization are available for hospitals: steam sterilization, dry heat sterilization, gas sterilization using ethylene oxide, formaldehyde or vapor-phase hydrogen peroxide. Ionizing radiation is another method which is mainly used for industrial sterilization of single-use items. All items to be sterilized should be wrapped or packed to avoid recontamination after the sterilization process. Monitoring the sterilization process is an essential quality assessment procedure for infection control. Physical monitoring is the observation of sterilizer functioning (e.g., temperature, pressure, time). Any deviation from the expected readings should alert the operator to potential problems. Chemical monitoring describes color or physical change indicators that monitor exposure to sterilizing agents or conditions. Biological monitoring (e.g., using *Bacillus stearothermophilus* spores for steam sterilizers) is the most important check on sterilizer and should be performed at least weekly (Joseph, 2006).

2.18. Causes of Fungal Related Infections

Patients in health care facilities are exposed to airborne fungal spores that are derived from indoor sources and outdoor sources. *Aspergillosis* in high-risk immunosuppressed patients has been associated with indoor environmental reservoirs from sources including bird droppings in the air ducts supplying high-risk patient areas, contaminated fireproofing material, damp timber and plaster (especially particle board) and potted indoor plants. Protective environment rooms and strict management procedures are generally used to reduce the risk of infection from these sources. The outdoor environment is by far the largest reservoir of fungal spores. Building supply air systems must be designed, installed and maintained in such a way as to control the number of fungal spores delivered to an occupied space. Correctly fitted and maintained high efficiency deep bed filters will remove 90–95% of spores at 2–3.5μm. Building works are a recognized source of *Aspergillus sp* related to nosocomial infections. The Health Canada publication *Construction-related Nosocomial Infections for Hospitalized Patients: Decreasing the Risk of Aspergillus, Legionella and Other Infections*, cites 25 outbreaks of nosocomial *Aspergillus sp* infections over a twenty-year period resulting in 106 deaths. These deaths were either suspected or confirmed as being caused by construction activity.

2.19. Construction, renovation, repairs and maintenance as a source of infection

Construction, renovation, and maintenance activities have become common in health care facilities to support continuous change and advances in the delivery of medical care. Since 1947, numerous published reports have linked construction and renovation activities in hospitals to outbreaks of *Aspergillosis* which have had fatal outcomes to multiple patients hazards (Atrache, 2008). These activities in hospitals and other health care facilities can cause dust containing fungal spores and water aerosols containing Legionella bacteria to become airborne and can cause serious or fatal infections to patients near the project area. For most healthy individuals, environmental exposure to etiological agents results in no adverse effects, but immunocompromised patients are left susceptible to inadvertent exposures to opportunistic bacteria, fungi and viruses during construction. Opening a "Pandora's box" during constructions, renovations and maintenance can unleash unintended consequences; it is therefore imperative that a thorough, multi-disciplinary approach establishes an infection control plan that is stated clearly and put firmly in place, allowing healthcare construction projects to move forward with confidence that patient safety is the first specification (Clair & Colatrella, 2013). The first general standards for healthcare construction were published in 1947 and evidence has continued to grow to support "clean" design and construction. The American Institute of Architects (AIA) publishes guidelines for hospital design and construction, and regulators like the Joint Commission, the federal government and some states require hospitals and others health care facilities to design, construct and renovate according to the AIA guidelines.

The First Edition of the AIA guidelines for Health Care Construction was distributed in 1987 and has since evolved to include infection control standards. The Association for Professionals in Infection Control and Epidemiology released the report "The Role of Infection Control during Construction in Health Care Facilities" followed by American Society for Healthcare Engineering (ASHE) posting the first Infection Control Risk Assessment (ICRA) Matrix as a strategic tool to protect vulnerable patients and staff. These guidelines have given birth to a body of research that encompasses the impact that the hospital environment has on patient and staff safety and includes the investigation of adverse events, root cause analysis and has resulted in reporting systems to track infection rates (Clair & Colatrella, 2013).

Construction practices disseminate bacteria and filamentous fungi. Of the nosocomial infections, the vast majority are due to filamentous fungi, and the organisms that most frequently cause construction-related infections are *Aspergillus fumigatus* and *Aspergillus flavus. Aspergillus* is a species of fungus that ubiquitous in soil, decaying vegetation, household dust, and building material. *Aspergillus* is transmitted by small spores that become suspended in the air and can survive for prolonged periods (Hardy & Haas, 2008).

A formal approach to risk management should be part of all construction, renovation and maintenance activities within a healthcare facility. Lack of planning, risk identification and risk control practices to abate airborne contaminants during construction can lead to serious environmental contamination within a healthcare facility. Cross education between infection control and engineering should be encouraged, in order to enable better lines of communication between clinical and engineering staff. Clinical staff seem to speak a different language to engineering staff. Often important facts are missed due to this. Clinical staff must be educated in the basics of the building process as well. Risk identification is likely to be the most difficult stage of the risk management process. It is generally more difficult to identify patient safety issues that can create an adverse event than it is to devise systems to overcome the adverse event once it is identified. The aim is to improve the overall outcome of the project by reducing the risks (Clair & Colatrella, 2013).

The Health Canada and the Canadian Standards Association (CSA) have issued extensive guidelines for the conduct of construction or maintenance activities near patients or other high risk areas, in order to control the risk. The CSA Guideline Z317.13-03 "Infection Control during Construction or Renovation of Health Care Facilities" and Health Canada's document titled, "Construction-related Nosocomial infections in Health Care Facilities", classified the construction work into four activity types: A, B, C and D (table 1 on the appendix) and four risk groups (1,2,3 &4). The combination of the activity type and risk group determines which Preventive Measure class: I, II, III or IV (table 2 of the appendix) is to be followed. Preventive measures have been shown to be effective in health care facilities, decreasing the incidence of construction/renovation related fungal infections. They are cost-effective because the patients safety will be maintained and litigation cases prevented (Atrache, 2008).

2.20. The AIA guidelines for construction

According to AIA guidelines, construction projects can be divided into the preconstruction, construction, and post construction periods, and each one has specific tasks that must be completed to ensure safety of patients in the area.

Preconstruction start with the design phase. The AIA guidelines refer that design and planning for renovation and new construction projects shall require consultation from infection control and safety personnel, as early involvement in the conceptual phase helps ascertain the risks to susceptible patients and disruption of essential patient services. The involvement of the infection control professional helps to ensure that space and equipment essential to infection prevention is not overlooked in the design. An essential part of the preconstruction phase is developing the Infection Control Risk Assessment (ICRA), that takes into consideration the type of construction or renovation being done, the amount of time

the project will take, and the area of the facility in which the project will be done. The focus of infection control during construction is on containing dust and moisture. It is important to document what types of barriers will be needed, what protection is required for elevators that will be used, and what type of cleanup is required. The ICRA should delineate the routes that construction workers will take getting to and from the project site, the protective clothing or actions required (such as requirements that workers vacuum themselves with HEPA filter vacuum system to remove dust), and the routes for materials and debris. All infection-prevention and environmental-safety measures should be documented before the project is sent out for bid. Before construction or renovation, all construction personnel should be educated about the potential risks to patients and the rationale and strategies for infection prevention during the project. The education includes information regarding the pathogen *Aspergillus* and its transmission, the type of barriers used to contain the dust, and airflow considerations for maintaining negative pressure in the construction area. Construction workers must be informed of the routes they should use to enter and exit the construction area, and how to get needed tools and material to the site (Hardy & Haas, 2008).

Facility design and planning also should ensure (World Health Organization (WHO), 2004):

- adequate safe water supply;
- appropriate cleaning practices;
- adequate floor space for beds;
- adequate interbed space;
- adequate handwashing facilities;
- adequate ventilation for isolation rooms and high-risk areas like operation theatres, transplant units, intensive care areas, etc.;
- adequate isolation facilities for airborne, droplet, contact isolation and protective environment;
- regulation of traffic flow to minimize exposure of high-risk patients and facilitate patient transport;
- measures to prevent exposure of patients to fungal spores during renovations;
- precautions to control rodents, pests and other vectors; and
- appropriate waste management facilities and practices.

Before beginning construction, patient supplies and equipment must be removed from the construction area. Any equipment that cannot be moved should be sealed tightly in plastic, and barriers must be erected around essentially all construction or renovation areas. The operating room is considered one of the highest risk areas because of the invasive nature of surgical procedures and the underlying health issues of the population served. The barriers may include a plastic dust abatement curtain before construction of the rigid barrier; sealing and taping all joint edges, including the top and bottom; extending the barrier from floor to ceiling; and fitting or sealing any temporary doors connecting the construction zone to the adjacent area. An entry vestibule for changing clothes and storing tools is needed for larger

jobs. Special ventilation is required during construction. Under normal conditions, operating rooms are maintained under positive pressure with air introduced at the ceiling and exhausted near the floor. This means that air flows from the operating room toward the corridors and adjacent areas. During construction, the air within the construction area must be contained. Fans should be turned off before opening ductwork and adjacent areas should be evaluated to ensure there are no hidden wall or ceiling penetrations. When preparing for construction, one of the first steps is to isolate the ventilation system in the area. Air exhaust from the construction site should be directed outside via a window with no recirculation into the building. The construction site must be under negative pressure with respect to surrounding areas. The construction personnel or the facilities department should maintain and monitor the negative pressure and the results should be documented. Always, elevators, entrances, and exits for construction workers must be designated and clearly marked, and patients may not be transported on the same elevator with construction material and debris. If traffic patterns are not easily altered to meet these requirements, then construction personnel may need to work during off-hours or weekends. If infection control requirements still cannot be met, the area may need to be relocated or closed temporarily. Any decision to relocate or temporarily close should be made by the multidisciplinary planning team. Construction workers should be provided with disposable jump suits, head and shoe covers. Protective clothing should be removed before exiting the work area. Tools and equipment should be damp-wiped before being transported from the work area. In cases where workers don't wear protective clothing, an HEPA-filtered vacuum should be used to remove dust from clothing before leaving the construction site. The construction area should be maintained in a clean manner by contractors and swept or HEPA-vacuumed daily or more frequently as needed. The construction site must be frequently monitored to ensure compliance with the ICRA and maintenance of appropriate air pressure. The use of a checklist can provide a way to ensure that all aspects of the site are monitored. Some facilities have a designated person who monitors construction sites and oversees the infection control and safety aspects of construction projects. Throughout the construction or renovation project, the facilities or maintenance department should monitor and evaluate the air-pressure differentials and humidity within the construction zone (negative pressure) and the adjacent operating room (positive pressure) to ensure that the ventilation system is functioning properly. Any concerns identified should be brought to the attention of project manager or, if required, to the multidisciplinary team (Hardy & Haas, 2008).

Before the construction area can be returned to full service or patient occupancy, the multidisciplinary team should walk through and inspect the area. A cleanup agreement is established in the early planning phase. This agreement delineates who is responsible for the various aspects of cleanup and final cleaning after removal of barriers. The facilities department restores appropriate air condition and heating equipment, and cleans or replaces filters. In the operating room, and before it can be occupied, an environmental air sampling is conducted to evaluate for potential sources of airborne fungal spores.

2.21. Infection control programme

The responsible health authority should develop a national (or regional) programme to support hospitals in reducing the risk of health-care-associated or nosocomial infections. Health administrators should be oriented towards the importance of the infection control programme. Health care workers should be equipped with requisite knowledge, skills and attitudes for good infection control practices (World Health Organization (WHO), 2004).

The important components of the infection control programme are (World Health Organization (WHO), 2004):

- Basic measures for infection control, i.e. standard and additional precautions;
- Education and training of healthcare workers;
- Protection of healthcare workers, e.g. immunization; identification of hazards and minimizing risks;
- Routine practices essential to infection control such as aseptic techniques, use of single use devices, reprocessing of instruments and equipment, antibiotic usage, management of blood/body fluid exposure, handling and use of blood and blood products, sound management of medical waste;
- Effective work practices and procedures, such as environmental management practices including management of hospital/clinical waste, support services (e.g., food, linen), use of therapeutic devices;
- Surveillance;
- Incident monitoring;
- Outbreak investigation;
- Infection control in specific situations;
- Research. In addition to implementing basic measures for infection control, healthcare facilities should prioritize their infection control needs and design their programmes accordingly.

Risk prevention for patients and staff is a concern of everyone in the facility, and must be supported by the administration. An infection control committee should provide a forum for multidisciplinary input, cooperation and information sharing. This committee should include wide representation from all relevant departments. An infection control team is responsible for the day-to-day activities of the infection control programme. Healthcare establishments must have access to specialists in infection control, epidemiology, and infectious disease, including physicians and infection control practitioners. In some countries, these professionals are specialized teams working for a hospital or a group of health care establishments; they may be administratively part of another unit (e.g. a microbiology laboratory, medical or nursing administration, public health services). The optimal structure

will vary with the type, needs, and resources of the facility (World Health Organization (WHO), 2004).

2.22. Heating, ventilation, and air conditioning (HVAC)

The design of the HVAC airside systems plays an important role for achieving the optimum air quality beside the optimum comfort level. Codes and guidelines specify temperature range criteria in some hospital areas as a measure for infection control as well as comfort. Local temperature distributions greatly affect occupant comfort and perception of the environment. Temperature should be controlled by change of supply temperature without any airflow control; the temperature difference between warm and cool regions should be minimized to decrease airflow drift. Efficient air distribution is needed to create homogenous domain without large difference in the temperature distribution. Three basic filtration stages are usually incorporated namely: Primary filter, second stage filter (the high efficiency particulate bag filter) and a third stage filter which is the high efficiency particulate filter located at the air supply outlets. Air Change per Hour (ACH) plays an important role to provide a free contamination place. The negative pressure is obtained by supplying less air to the area than is exhausted from it. This induces a flow of air into the area around the perimeters of doors and prevents an outward airflow. The operating room offers an example of an opposite condition. This room, which requires air that is free of contamination, must be positively pressurized relative to adjoining rooms or corridors to prevent any airflow from these relatively highly contaminated areas. In general, outlets supplying air to sensitive ultraclean areas and highly contaminated areas should be located on the ceiling or on sidewalls closing to ceiling, figure 8, with perimeter or several exhaust inlets near the floor. The bottoms of return or exhaust openings should be at least 0.075*m* above the floor (Khalil, 2005).

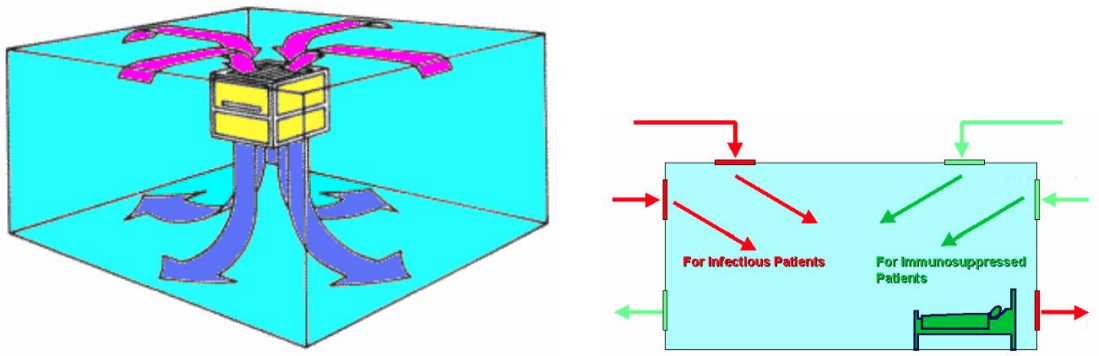

Figure 8- Airflow Movement in Rooms (Khalil, 2005)

In the isolation rooms for infectious patients, the patient bed should be located close to the extract ports. The infectious isolation rooms should be maintained at negative pressure. The immunosuppressed patient's bed should be located in the side of supplied air, or close to the supply outlets, figure 9.

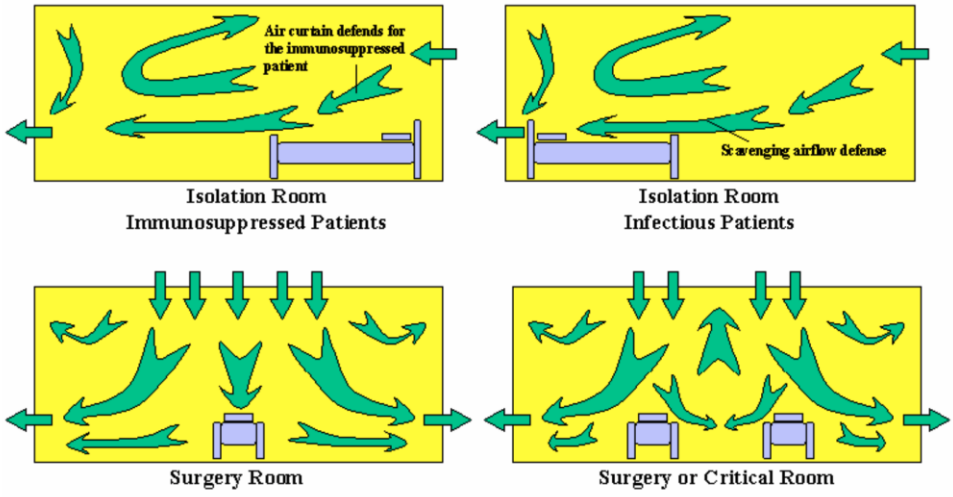

Figure 9- Airflow Configurations for Critical Areas (Khalil, 2005)

The air is not just a medium but it can be regarded as a guard in the critical health applications. The proper direction of the airflow increases the possibilities of successful infection prevention from healthcare facilities.

Engineering control methods include building ventilation, use of HEPA and other air cleaning methods, use of air disinfection methods, etc. The general purpose of ventilation in buildings is to provide healthy air for breathing by both diluting the pollutants originating in the building and removing the pollutants from it. The effectiveness of ventilation is also known for controlling airborne diseases in single enclosed spaces.

Building ventilation (both natural and mechanical ventilation) has three basic elements:

1) Ventilation rate, i.e. the amount of outdoor air that is provided into the space, and the quality of the outdoor air should be considered;
2) Airflow direction, i.e. the overall airflow direction in a building, which should be from clean zones to dirty zones;
3) Air distribution or airflow pattern, i.e. the external air should be delivered to each part of the space in an efficient manner and the airborne pollutants generated in each part of the space should also be removed in an efficient manner.

Hence, there are two basic physical principles behind the roles of ventilation in infection control. The first is through dilution of airborne pathogens, and the second is the control of movement of airborne pathogens from one space to another. In theory, if a disease can be shown to be airborne, the importance of ventilation becomes obvious. However, the relative importance of building ventilation as compared to quarantine, vaccine, use of masks, etc. is difficult to determine. The ventilation requirements are also difficult to define and other transmission routes may coexist with the airborne route (Eames, Tang, Li, & Wilson, 2009).

Hospitals also save energy and money by optimizing HVAC performance. Effective, energy-efficient technologies and practices reduce HVAC-related energy costs while enhancing infection control. The U.S. Department of Energy's Hospital Energy Alliance developed a sheet to assist hospital facility managers and operators in using energy-efficient Heating, Ventilation, and Air Conditioning (HVAC) technologies and practices. They wrote that some hospitals may need to expand their HVAC system or make major renovations to achieve better performance. Simply improving components of an existing system can accomplish much. Hospitals should schedule and perform regular maintenance on key HVAC components to identify opportunities for energy-efficiency improvements and upgrades, like (U.S. Department of Energy's Hospital Energy Alliance, 2011) describes:

Fans:

- For non-critical spaces with lower ventilation requirements (such as medical-office floors), switch to a variable air volume system by installing variable frequency drives on all motors. Unlike constant air volume systems, variable systems modulate air flow based on the demands of the space being served, reducing power use in fans by as much as 50 percent;
- Appropriately size fans coincide with optimal efficiency points on fan curves based on actual pressure drop and flow rate;
- Upgrade to energy-efficient motors. A NEMA-rated premium efficiency motor is 2 to 9 percent more efficient than a pre-EPAct 2005 standard motor and 1 to 3 percent more efficient than newer standard motors.

Coils and Filters:

- Perform consistent operations and maintenance functions to minimize pressure drops across the coils and filters; simply keeping the coils and filters clean can dramatically improve the efficiency of the entire HVAC system;
- Consider adding a coil bypass on both the heating and cooling coils. When the coil is not in operation, a bypass damper will open, allowing for the air to pass through with a substantially lower pressure drop. This can reduce fan energy significantly;
- Increase the filter cross-sectional area (angled filter bags, pleated filters) to provide more energy-efficient filtration.

Dampers and Ducts:

- Verify proper damper operation regularly. Clean and repair (or replace) dampers as needed.

Controls:

- Calibrate, check, and adjust thermostats to accurately heat and cool different building zones;

- Correct any HVAC systems that are in conflict by heating and cooling an area simultaneously;
- Reduce HVAC use when areas are unoccupied or in low use (and therefore are subject to lower indoor air-quality and temperature requirements). This can be done by employing energy-efficient scheduling-including setbacks, weekend settings, optimal start-stop settings, and temperature resets based on outside conditions. Such settings are particularly valuable in operating rooms because operating rooms do not need to constantly maintain the extreme temperatures required during surgery.

The overall Indoor Air Quality (IAQ) benefits of routine duct cleaning on Heating, Ventilating, and Air Conditioning (HVAC) systems continue to be reviewed and researched. Despite more than two decades of research, there is still not enough evidence to draw solid conclusions about duct cleaning benefits on IAQ, occupant health, HVAC system performance, or energy savings, according to a 2010 review of scientific studies on duct cleaning. The review did find clear evidence that ductwork can be contaminated with dust and can act as a reservoir for microbial growth under normal operating conditions. Yet, even when duct cleaning was extremely efficient at removing contaminants within ducts, the effectiveness of reducing indoor air pollutants was highly variable, and, in many cases, post-cleaning levels of contaminants were higher than pre-cleaning levels (National Institutes of Health, 2015).

Although the value of routine duct cleaning remains questionable, the U.S. Environmental Protection Agency (EPA) and industrial hygienists agree that duct cleaning (or, in some cases, duct replacement) is appropriate in the following circumstances (National Institutes of Health, 2015):

- Permanent or persistent water damage in ducts;
- Slime or microbial growth observed in ducts;
- Debris build-up in ducts that restricts airflow;
- Dust discharging from supply diffusers;
- Offensive odors originating in ductwork or HVAC components.

Prevention of duct contamination is a key for avoiding problems. It is important to follow these recommendations to avoid the need for costly duct cleaning (National Institutes of Health, 2015). A highlight of these recommendations is the following:

- Perform routine preventive maintenance on HVAC systems, by complying with manufacturer schedules for changing HVAC filters, cleaning coils, and other components;
- During building renovation, seal ductwork to prevent construction dust and debris from entering the HVAC system;
- Maintain good housekeeping in occupied spaces;

- Ensure that air intakes are located away from contaminant sources;
- Consider routine inspections of ductwork. The National Air Duct Cleaning Association (NADCA)'s standard, recommends that HVAC systems be visually inspected for cleanliness at regular intervals, depending on building use. For healthcare facilities, the standard recommends annual inspections of air handling units and supply/return ductwork.

2.23. Maintenance to prevent infection control

As written before in an indirect way, the maintenance departments purpose is to provide a hygienic environment through systematic inspection and preventive maintenance of all equipment, establishing routines for emergency repairs, and by proper care of the entire physical structure (Okabayashi, 2009).

Based on the Hilo Hospital policy, the maintenance services should:

1. Maintain and inspect all equipment as well as provide emergency repairs of all essential equipment;

2. Implement a prompt, reliable system of notification of defects in equipment as well as structures, and availability of repair capabilities;

3. Certify safe status of physical plant and equipment through Environment of Care Rounds, Building Maintenance Program, and Utility/Equipment/Infection Control Risk Assessments;

4. Plan and make recommendations in the development of the physical facility;

5. For the air conditioning system:
    a) Regularly inspect the air conditioning, heating, electrical, refrigerating and plumbing systems;
    b) Replace air-handling filters semi-annually or according to the manufactures or environment needs. Check and service air filtration system on a regularly scheduled basis;
    c) Maintain heating and cooling systems at optimal temperatures and humidity at all times;
    d) Clean air conditioning coils and drip pans on a regular schedule;
    e) Clean and sterilize humidification equipment regularly to avoid contamination of the air conditioning systems;

f) Monitor the handling of wall regulators, the cleaning of central vacuum suction traps and the disposition of exhaust air intake of the ventilation system.

6. For the ventilation system:
    a) Air intakes and outlets:
        - Discharge and exhaust air opening and re-circulating air intakes are located at least 7.62*cm* above floor;
        - When located less than 2.13*m* above the floor, inlet and outlet opening should be protected by a grill or screen with opening not larger than 1.27*cm* mesh;
        - All air supplies to sensitive areas such as surgery, delivery room, nurseries, etc. are delivered at or near the ceiling;
        - At least two exhaust outlets are used in all operating rooms and delivery rooms;
        - This air is supplied from the outside; all air is exhausted directly into outdoors and no recirculation occur within the areas;
        - Annual air balance testing for isolation rooms, operating room, decontamination and autopsy for negative and positive pressure. Report to be submitted to the Infection Control Committee.

    b) Air filters on air condition units:
        - Clean or replace unit filters when the resistance to air flow has increased to two times the original resistance or when the manufacturer recommends it. If filters are the automatic liquid adhesive type, sludge should be quarterly removed from the liquid adhesive reservoir;
        - Disposable filters should never be cleaned and reused;
        - Central type filters are changed semi-annually throughout the hospital.

    c) Ventilation and Anesthetizing Locations:
        - When properly filtered, 80% of the air may be re-circulated with no more contamination than if 100% outdoor air is filtered in the same manner;
        - Positive air pressure relative to the air pressure of adjoining areas shall be maintained in the anesthetizing locations, thus eliminating infiltration of contaminated air;
        - Ventilation systems shall incorporate HEPA filters with an efficiency of not less than 90%;
        - 50% to 60% humidity controls airborne bacteria;
        - Degrees Celsius, humidity (%):
            - Operating Room – 21-24 degrees/50-60%;

- Delivery – 21-24 degrees/50-60%;
- Recovery – 23.8 degrees/50-60%;
- Nursery – 23.8-26.6 degrees/50%;
- Intensive Care – 21-26.6 degrees/50-60%.

d) Piped-In Gases:
   - Oxygen, nitrous oxide, or other flammable gas systems are installed and operated in compliance with the standards;
   - Preventive maintenance and annual testing by contract vendor to ensure compliance.

e) Water Supply System:
   - Water supply lines must be checked regularly for cracks, leaks, rust, and potential blockage of debris;
   - Chlorination procedures must be instituted at once whenever repairs are done to the water supply lines;
   - Vacuum breakers must be installed in water supply lines and must be routinely checked to ensure proper function;
   - Distilled water equipment must also be checked routinely in order to ensure its integrity;
   - Hand washing facilities must be kept in good working order;
   - Water supply is obtained from the public water supply system. Water samples are taken and test on a regular basis from the hospital water system by the Department of Water Supply. Copies of this test will be forwarded to Medical Center and kept on file;
   - Hospital water supply is not connected with other piping system that could allow contamination;
   - A reserve source of portable water will be available through arrangements with Civil Defense for the contracting of water hauling tankers.

f) Plumbing:
   - In accordance with plumbing codes, air gaps must be installed in liquid plumbing and must be regularly checked for cracks, leaks or blockage and repaired immediately if there are any detectable defects;
   - Drains in areas such as surgery and delivery room are not connected with other units;
   - Aerators shall not be installed on faucets;
   - Ice machines should be thoroughly cleaned quarterly and Housekeeping Department to clean exterior monthly.

g) Food Service Equipment:
   - Proper temperatures must be maintained for food serving units using refrigeration or hot service elements. These must be checked on a regularly scheduled or as needed basis;
   - Cleanliness and proper functioning of food preparation and food serving equipment must be maintained at all times;
   - Refrigerators must be equipped with thermometers and must be checked routinely or as needed to keep them in good working order so that proper temperatures are maintained at all times.

h) Housekeeping Equipment:
   - The Maintenance Department is responsible for repairing and maintaining all housekeeping equipment in a state of readiness in order that housekeeping personnel may perform their duties adequately.

i) Environmental Items:
   - Ceilings, walls, floors, windows and doors should be inspected regularly and kept in good repair at all times in order to maintain a clean and safe environment. Any openings or breaks in the walls, foundations, window frames, etc. shall be repaired immediately in order to preserve a clean environment. Acoustical surfaces for walls or ceiling are not used for surgery, kitchens, obstetrical units, nurseries and treatment rooms where cleaning problems are most important;
   - Rodents and all other pests must be controlled or control supervised by the Maintenance Department. Non-patient areas shall be treated as needed with appropriate approved insecticide. In patient rooms, insecticides shall be used for a definite and specific problem only, selecting the lowest possible level of toxicity.

j) Waste Management:
   - Waste for disposal should be properly handled and appropriate safety precautions observed during handling of wastes for disposal;
   - Appropriate equipment or barriers such as gloves, rubber apron, and face shield should be used when handling contaminated and infectious waste;
   - Waste should be properly contained in appropriate bags for disposal at the landfill (county rubbish dump);
   - Waste must be transported to the appropriate collection area for disposal;

- Bags of waste must be retained in watertight receptacles of impervious materials with tight-fitting closures that will protect the contents from files, insects, rates and other animals;
- Infectious waste such as culture plates, tubes, used syringes, needles, sharps, pathological wastes shall be properly processed by autoclaving before transport to the landfill;
- Autoclave infectious waste shall be appropriately bagged for transport and disposal to the landfill;
- Infectious waste must be properly bagged or labeled (red bag and/or universal label for biohazard);
- Liquid waste is to be discarded into appropriate clinical sink for disposal into the sewer system;
- Disposable receptacle used to retain liquid waste is to be properly discarded.

In order to safeguard patients, visitor, and hospital personnel from direct or indirect transmission of infectious agents while maintaining equipment located within rooms or areas occupied by the patients in isolation, certain general rules and specific procedures must be observed:

a) There must be full cooperation by all concerned to carry out a safe isolation Procedure;
b) All requests coming from these units to the Maintenance Department should be marked "Isolation" so that maintenance personnel will be made aware;
c) Maintenance personnel should check with nursing personnel before entering the Isolation room;
d) Maintenance personnel should observe isolation technique according to the patient's condition (see card on the door);
e) These employees should always wash hands thoroughly with soap and water prior to entering or leaving the isolation unit;
f) Used personal protective equipment must be discarded in the appropriate receptacle;
g) These employees should not spend any more time within an isolation unit than is necessary to complete the job;
h) Only tools and repair parts that are to be used should be taken into an isolation unit (leave all excess tools outside the unit).

For handling of tools and test equipment by maintenance personnel, general rules and specific procedures must be observed:

a) Tools and test equipment introduced into patient care areas must be clean;
b) Tools and test equipment taken into an isolation unit must be placed upon a clean cloth or clean paper towels in order to protect them from contamination;

c) An appropriate method of disinfection for tools and test equipment must be established and used consistently in order to avoid cross-contamination. Consult with the Infection Control Committee for guidelines;
d) In extreme cases, some testing equipment may be sent to Central Service for sterilization after properly coordinating such a request with the supervisor for Central Service;
e) Equipment sent for repair or servicing from an isolation room should be thoroughly cleaned and disinfected by unit personnel before sending;
f) Maintenance personnel should repair equipment on site whenever possible. In these instances, equipment should be cleaned, disinfected and removed from the isolation by nursing personnel before the repair.

For standards of appearance and personal hygiene, general rules must be observed:

a) All clothing should be kept clean, in good repair and maintained in such a manner as to ensure a neat and presentable appearance;
b) All maintenance personnel should observe acceptable standards of personal hygiene and cleanliness;
c) Maintenance personnel should comply with the appropriate dress regulation and Policies established within each clinical area, the wearing of mask, cap and gown in the operating rooms, delivery rooms, newborn nurseries and isolation rooms in accordance with infection control policies;
d) Clothing, shoes, heavy boots and coveralls should be changed when they become so soiled with contaminated wastes.

2.24. Electrical safety

In the hospital environment of the sixties, electricity came to be used more often on, in and around patients to a degree beyond conception only a few years previously. It was early in 1961 that there appeared the first news that "microshock" (small electric currents applied to a conductor near the heart) was happening in the medical field. In 1969, 1200 patients were being accidentally electrocuted in U.S. hospitals each year, and the concept of microshock suddenly became publicized. During the 1970's, several proposals and regulations were introduced to manage this suspected problem in hospitals. In 1971, the National Fire Protection Association published a recommended standard to help hospital engineers understand the principles of electrical safety and coordinate a program of medical equipment electrical testing in their facilities. In 1970, the AAMI (Association for the Advancement of Medical Instrumentation) published a first draft standard for electrical leakage current standards that was adopted as an American national standard in 1978. Probably the most dramatic proposal was the Joint Commission on the Accreditation of Hospitals (now the Joint Commission on the Accreditation of Healthcare Organizations – JCAHO) 1976 recommendation that hospitals maintain equipment control programs to provide for electrical

safety training, create a documented preventive maintenance program, and perform semi-annual safety and performance equipment inspections and annual inspections of electrical receptacles. Today, health care institutions in the United States support clinical engineering programs that provide ongoing electrical safety and performance testing as well as preventive maintenance and repair of medical equipment. Typically, these programs use the most recent editions of NFPA 70, NFPA 99, NFPA 101, AAMI Recommended Standards, and Joint Commission accreditation manuals for their reference standards (BAPCO).

2.25. Electrical hazards

While being essential to the functioning of hospital activities, electricity is the most discrete form of energy. Incorrect use of this may cause irrecoverable damage or even death. Electrical accidents happen usually by recklessness, ignorance or negligence. Because people do not know how to deal with electrical hazards, electrical installations are not in good condition, or simply because the risk is underestimated. Electrical accidents can result in fire, burns or shock.

Many medical devices are used for diagnostic procedures and therapeutic using invasive techniques which leave patients deprived of their natural electrical protection, the skin, making them more vulnerable to electric currents that even low intensity, can become fatal (Maciel & Rodrigues, 2009).

The lack of power, even for moments, can endanger the health of patients, or even compromise the success of therapy or diagnosis (Castellari, 2013). Common electrical disturbances can also cause malfunction of sensitive medical equipment, and used in vulnerable patients, this malfunction can easily result in serious injury. Patient safety is the main reason for trying to minimize the malfunction of medical equipment and its consequences. In addition to the safety aspects, the malfunction of the equipment can result in patient discomfort or even wrong diagnoses (Baggini, Buratti, & Granziero).

Most surgeons are unaware of what they do not know. In many cases, what has been done in the past may not be safe, as it may be placing patients at unnecessary risk from the energy settings chosen, devices used, and operative approach. There are approximately 40000 burns by electrical surgical devices every year in United States. During laparoscopy, 70% of these burns may go undetected. A survey of the American College of Surgeons showed that 18% of surgeons reported an insulation failure or capacitive coupling injury, and 54% of surgeons knew of a colleague who faced an electrical injury. Most injuries are minor and result in minimal injury, but several of these are significant, disabling, and completely preventable (Jones, Brunt, Feldman, Mikami, Robinson, & Jones, 2015).

Some physiological effects caused by electricity are: muscle contraction, heart fibrillation, burns, blood electrolysis and organ damage (Maciel & Rodrigues, 2009). The electric shock is influenced by several parameters, such as impedance (resistance) of the body, the frequency of the current, the duration of the shock and the current density through the body. In hospital, electric shocks can be divided into macro-shocks (direct and greater intensity) and micro-shocks (indirect and less intense). The macro shocks are caused by contact with the outer body part, may cause danger both to the patients as to all other hospital workers. The microshock is caused within the body of the patient due to invasive procedures applied to the heart area through catheters or electrodes. It is a miniscule current, in the range between 50 and 100*mA* which can be dangerous if applied to the heart via a central venous line when it can cause ventricular fibrillation (figure 10).

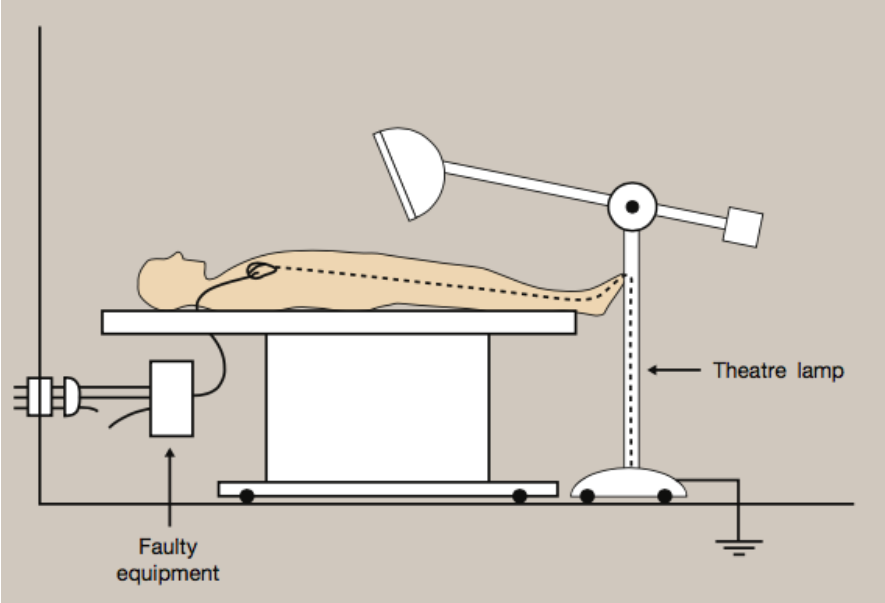

Figure 10- Example of risk of microshock (JH,2016)

Some of the main causes of electrical accidents in hospitals are enhanced simply problems in power cables (eg. damaged isolation). The electric shock is produced by current, not voltage that a person is exposed; It is the intensity of the current transmitted through the body which determines the intensity of a shock. The severity of damage is proportional, not only to the intensity of current flowing through the body, but also the current density in the transition zone (Tooley, 2007). The human body acts as a resistance to current flow. An average adult has a resistance between two hands about 1000*ohms* (Ω) with wet skin and 10^6 Ω with dry skin. The resistance depends on the body weight and moisture content. The perception threshold for an average adult is about 2 milliamps (mA) sufficient to produce a slight tingling pain. Between 20*mA* and 30*mA* cause muscle contractions. A current of 50*mA* is enough to cause pain, fainting and fatigue. From 100*mA* ventricular fibrillation can occur and, consequently, cardiac arrest (Hopps, 1968), although there literature considers that

current between 10*mA* and 20*mA* crossing the heart it's enough to induce fibrillation (Sabo, 1976).

In a magnetic resonance imaging suite, the powerful changing electromagnetic fields can induce currents in objects in contact with the patient. This can lead to interference affecting the electrocardiograph and pulse oximeter, but more seriously they may cause local heating and skin burns too. There have been case reports of the finger on which the pulse oximeter was attached being lost due to severe burns (Hasher & Palmer, 2013).

As general measures, regular maintenance of electrical equipment must be done. It is important to make sure that the patient does not come in contact with earthed objects is important, and the use of antistatic shoes. As specific measures it is important the maintenance of equipotential bonding systems to guarantee that different equipment are all connected to the same potential. If equipment in close proximity has a different potential, then current can flow from the equipment with higher voltage to that with a lower voltage if a person is in contact with the equipment completes the circuit. It can be also used circuit breakers, and isolated or floating circuits where patients are not connected directly to earth via electrodes so current cannot reach the patient if contact with a live supply occurs. This is achieved by the use of an isolating transformer (figure 11).

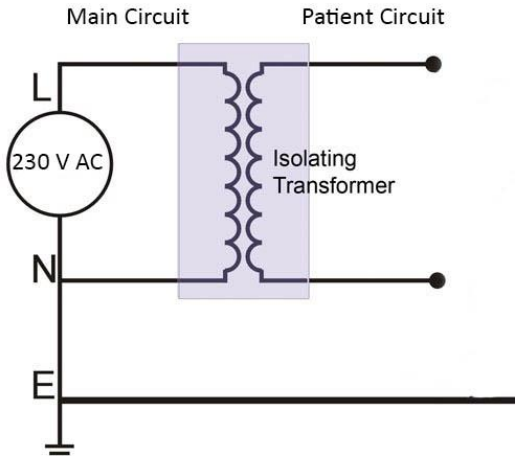

Figure 11- Isolated or floating circuit example

2.26. Leakage currents, grounding and isolation impedances

Electrical measurements in the circuitry of electronic equipment frequently reveal current flows through inductive, capacitive or resistive paths, between components such as transformers or capacitors, and the metal chassis or case. These unintentional currents are termed leakage currents and are extremely difficult to eliminate. For a current to flow there must be a continuous circuit. Leakage currents complete their circuit by flowing to ground when the equipment is powered by conventional electrical service with one wire grounded

where it enters the building (figure 12).

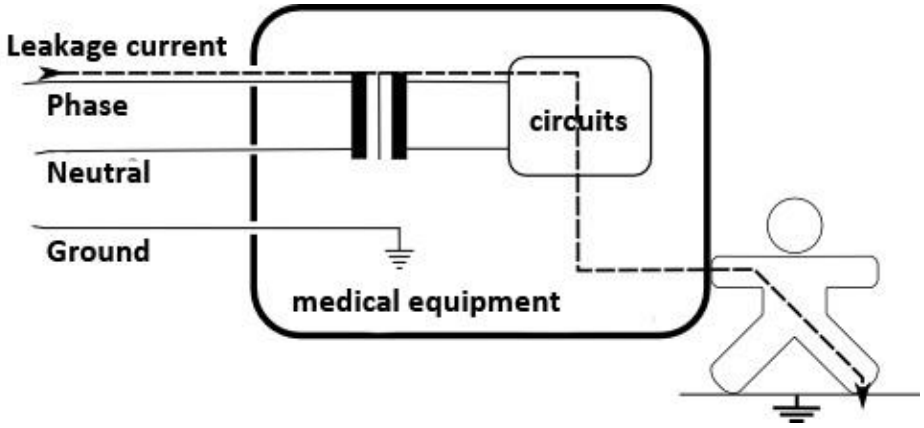

Figure 12- Example of leakage current

The leakage currents are usually quite small as they are limited by high impedances (Hopps, 1968). Leakage current is one of the most stringent, yet telling, parameters of possible danger to patients or caregivers. It does not need much electric current flowing through the human body to cause harm. This is especially true for patients with weakened immune systems. The potential risk is why measurement of leakage current in electrical medical products is so critical (Einser, Brown, & Modi, 2004). It becomes apparent that effective grounding of the case or chassis of monitoring equipment eliminates undesirable current in the patient circuit. It has also been stated that a hazard may exist when one piece of equipment is grounded and another is not. Also, if multiple pieces of equipment connected to the patient have their cases ungrounded, leakage currents may flow between them, through the patient. In practice, it is difficult to avoid grounds, particularly in the operating room where it is common to practice the grounding the patient for electrostatic protection. Also, when we use multiple ground points in a room, we have no guarantee that they are all at the same potential (Hopps, 1968). In hospitals, many devices have leakage currents higher than those expected to exist between the equipment and patients. These small leakage currents are enough to induce micro-shocks and cause fibrillation if the patients are by some way in contact with the ground. To avoid damage caused by leakage currents, the equipment must be properly grounded. There are on the market numerous ground testing equipment for checking the safety of electrical installations. In fact, grounding's purpose is a lot more than providing a common point of reference. It is the key to safety and protection of personnel, equipment and facilities. When considering protection of personnel, equipment and facilities against electrical hazards there is a need to consider both grounding and overcurrent protection and how they relate, as they go hand to hand. A facility's electrical protection systems are intended to: protect personnel from electrocution and fire; protect equipment and facility from failure and fire; protect electrical circuit from cable failures (Pfeiffer, 2001). Medical equipment manufacturers have to comply with an international standard called IEC 60601-1. It describes the maximum leakage currents allowed and classifies methods of electrical protection and the degree of protection (Tooley, 2007).

In operating theaters and in any group of medical locations where medical devices are used in intra-cardiac surgery, surgical operations, or where the patient is subjected to vital treatment, the power supply is an essential condition for appliances and medical devices, from which are dependent the lives of patients. In this context, isolated power systems are used to ensure continuity of service for the medical activities, even when a first leakage to earth occur. In these systems, the neutral is isolated or earthed through appropriate impedance and the metal masses are attached to a grounding system that is shared or separate from that which the neutral may be connected. In the case of a first ground leakage, the circuit breaker is not involved, since the current is limited by the high impedance isolation. A low isolation resistance value indicates a loss of earth due to a fault. This first ground fault must be eliminated, since a second will cause the action of protective devices (thermal magnetic circuit breakers), causing an interruption in power supply (ABB Group, 2015).

2.27. Electrosurgery equipment

Monopolar electrosurgical energy is the most commonly used energy source during laparotomic and laparoscopic surgery. The clinical application of monopolar energy is not without risk. Monopolar electrosurgical energy was introduced into surgical practice at the turn of the 20th century and alternate site burns during laparotomic application were the most common complication for the first half century (i.e., ground point burns and dispersive electrode burns) (Odell, 2013).

If direct current or high frequency alternating current passes through the body, heating effects and ultimately burns will occur. This is the effect intentionally created when electrosurgical generators are used to cut tissue and coagulate fluids. The lack of knowledge in the handling electrosurgery equipment can cause also microshock. To use this technology, basic knowledge of electricity is fundamental (Way & Hinrichs, 2000). Electrosurgery equipment is also the major cause of fires and explosions in the operating rooms. In monopolar systems, the return electrode placement is critical to minimize the risk of burn or undesired current flows through the patient's body (figure 13).

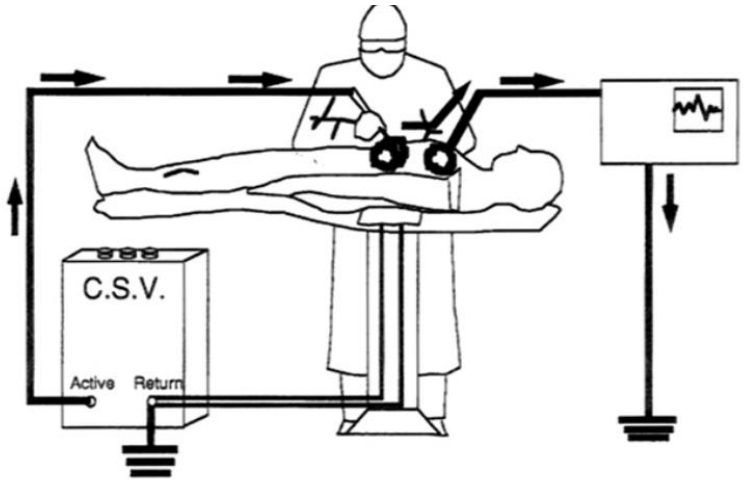

Figure 13 – Example of microshock when the current returns through the monitor equipment instead the return electrode.

If the return electrode is too small, the current concentration is higher and consequently heater. If the return electrode is isolated from the body, higher the risk of injury. Therefore, the return electrode must be placed in perfect contact with muscular tissue and well vascularized areas, avoiding the areas of adipose tissue, bone prominences and thick skin like the plantar area (Wang & Advincula, 2007). In cases where the dispersive plate is far from the active electrode's active zone, aside of the current tends to return to the monitoring electrodes, and due to the reduced area of these electrodes, the likelihood of burns is high (figure 13). In addition to the improper use of the return electrode, there are three additional risks related to monopolar electrosurgery systems, namely accidental contact of the active electrode with metallic elements of other equipment, failure of the insulation around the active electrode (the current in the patient's body may flow through other unwanted / unintended paths), or the danger of capacitive coupling (when two active conductors are separated by an insulation, an electrostatic field is created, that at a given time the current of a conductor will be transmitted to the other conductor, if the insulation capacity is exceeded) (Wang & Advincula, 2007). This latter phenomenon, although not common, is important because of the possibility of induction of undesirable electrical currents in patients (Kadavil & Palmer, 2013).

Resistive coupling occurs when the body comes in direct contact with a source of electricity and earth (such as touching a live wire or socket by accident). Sources of electricity can be either due to machine malfunction or leakage currents. Leakage current occurs when a piece of equipment attached to the patient is at a higher potential than earth, or two different earth potentials exist in equipment to which the patient is attached. Even a small amount of current (microshock) can be dangerous when applied to the heart. Capacitive coupling is the transfer of electrosurgical energy to adjacent conductive material through intact insulation of the laparoscopic instrument. No defect or fault is required for capacitive coupling to occur. Capacitive coupling may occur with new disposable instruments and reusable devices and

may transfer a percentage of the energy displayed on the Electrosurgical Unit (ESU) to non-target tissue or adjacent instrument(s). Direct coupling occurs when the exposed active electrode accidentally comes in contact with another metal instrument or object within the surgical field and results in the total energy displayed on the ESU being transferred to that device. The two most common devices for the occurrence of direct coupling are the laparoscope and a cold metal irrigation/suction tube. Great care should be taken to not allow the exposed active electrode tip to arc or to come into contact with adjacent instruments (Odell, 2013).

2.28. In Portugal

In Portugal, there has been significant improvements in measures of population health status and in health care outcomes. For example, the rates of perinatal and infant mortality went from being the worst in Europe during the 1980's and 1990's to among the best in 2003.

Despite this, however, there remain some significant challenges, particularly in the areas of morbidity. There are critical gaps in health information in Portugal that may limit the potential to develop health system policies and strategy on the basis of sound evidence. There were limited data on measures of safety and health and it is difficult to assess and monitor the extent of socioeconomic inequalities in health. The gaps in health information also limit the capacity to support transparency and accountability through the public reporting of results (WHO, 2010). Nowadays, it is still difficult to identify the role of SIE in the Portuguese hospitals and sometimes they are not able to establish goals for their operations, because it is not clear what role they have.

The Portuguese healthcare system has not undergone any major changes on the financing side since the early 1990's, despite the steady growth of public health expenditure. On the other hand, many measures have been adopted to improve the performance of the health system, including Public–Private Partnerships (PPP) for new hospitals, a change in NHS hospital management structures, pharmaceutical reforms, the reorganization of primary care and the creation of long-term care networks. Some of these measures have faced opposition from the local population, namely those related to the closure of health care facilities. There is an overall awareness, and concern, about the rise in health care expenditure in Portugal. Most of the reforms that have come into effect have done so too recently to measure any effects at present. All these reforms were just administrative, not bringing any value for clinic engineering.

Portuguese healthcare systems have various forms of organization, changing the mode of how providers are paid, relative weight of public and private sectors, and how the sector is funded. The Portuguese National Health Service (Serviço Nacional de Saúde - SNS) over the

years has become a heavy and bureaucratic machine in terms of its organization and management (Macedo & Macedo, 2005).

All residents in Portugal have access to health care provided by the SNS, financed mainly through taxation. Health care delivery is based on both public and private providers. Public provision is predominant in primary care and hospital care.

In 2016, a study coordinated by former minister Correia de Campos, says that the SNS is afraid of the technology due to increased costs and not being sure to be compensated. The study also reports that its uncomfortable relationship with innovation must be overcome, (Almeida, Alves, Mendes, Perelman, Lobão, & Sousa).

In general, maintenance done in Portuguese hospitals is insufficient or even non-existent. It is limited basically to clean and replacement of filters of certain units of the systems. When there are critical issues affecting the hospital functions so that they cannot continue, emergency repairs are carried out, sometimes at high prices, both at the economic level and even at the cost of loss of life (patients who lose their lives due to nosocomial infections, caused by lack of maintenance). A major concern is related to engineering problems and infection control during construction, demolition, maintenance and repair of hospital facilities. Often, after a surgery in which all clinical staff are involved and gave the maximum of their scientific, technical knowledge and all the professional dedication to the patient, the operation that had been a success in the clinical aspect, is complicated after a few days of hospitalization (Piteira, 2007).

In addition to the health problems that lead patients to be hospitalized, nosocomial infections may complicate the clinical situation which led to admissions, increasing the length of hospital stay. This is reflected not only in increased costs and reduced availability of the hospital, but also to prolong the suffering of patients or even cause their death.

2.29. Nosocomial infections in Portugal

The incidence of fungal hospital-acquired infection has increased substantially over the past two decades in parallel with medical technological advances. Nosocomial infection is a major concern in patients, but the magnitude of the problem remains poorly defined. Additional epidemiologic studies in pediatric patients in non-outbreak settings are necessary to better understand the scope of the problem to improve a better control on risk factors of nosocomial infection.

Data from Portugal are scarce, non-published and obtained from small surveys or studies conducted on specific groups of patients or limited to only nosocomial infections caused by bacteria.

From January of 1998 to March 2000, during 27 months it was made a study at the main Lisbon Children's Hospital, D. Estefânia Hospital. During the 27 months of the study nosocomial fungal infection was identified in 63 children with a total of 67 reported episodes, since one patient had four different episodes and one another had two. These episodes are considered new cases because they were spaced more than one month. In seven cases death was associated with nosocomial fungal infection, accounting for 10.4% (7/67) of lethality. Nosocomial fungal infections occurred in all wards, but the highest incidence occurred in the Intensive Care Units (ICU).

In the national survey of infection prevalence accomplished in March 2009 by the National Program for Infection Control within the campaign of the World Health Organization "Simple Practices Save Lifes" there were studied 21459 patients from 144 hospitals, whereby seen a prevalence of 11.03% in nosocomial infections (Pina, Ferreira, Marques, & Matos, 2010).

In 2012, the hospital infection rate in Portugal was almost double of the European average. The Portuguese health units use more antibiotics and greater amounts of disinfectant than other countries, but our hospital infection rate in 2012 was substantially higher than the average of the European Union (EU). In Portugal, one in ten patients contracted last year an infection in health facilities (10.6%), when the global prevalence rate of nosocomial infections was 6.1%. In December of 2015, legionella was detected in the old plumbing system of a health care center in Vila Real de Santo António, a city in the south of Portugal. Although the regional delegate of health for the Algarve, Ana Cristina Guerreiro, informed that the fact didn't result in risk for the patients, but some rooms and areas had to be closed, affecting the normal operation of the health center with financial consequences for the government (Público, 2015). Everyday we find news like this in the Portuguese media. A study from the pharmaceutical industry affirm that in Portugal there is no sense of national determination for a problem that continues to reveal a frightening dimension (Almeida, Alves, Mendes, Perelman, Lobão, & Sousa).

The results of a survey done by the national health entity, Direcção Geral da Saúde (DGS), in 2012, indicate that the average consumption of antiseptic alcoholic solution was 52.9 liters per thousand days of internment in Portugal, while the average in Europe was up by 36.6 liters, and the percentage of patients taking antibiotics was also higher (45.4% against 35.8%). On the contrary, the DGS report highlights the low number of infection control nurses and almost total absence of medical assistance in infection control committees in Portuguese hospitals. Analyzing numbers from previous surveys made in Portugal (nosocomial infection rate of 8.4% in 2003 and 9.8% in 2009), it seems that the situation is getting worse. The coordinator of the National Program for Prevention, Infection Control and Antimicrobial Resistance, José Artur Paiva (co-author of the DGS survey) refer that to get

out of this vicious cycle involves some key interventions: strengthen compliance with hand hygiene, the proper use of gloves and compliance with the rules of hygiene and disinfection of frequently used surfaces (such as countertops and computer keyboards); to end the use of prophylaxis for more than 24 hours after surgery and limit therapeutic for seven to eight days, except in exceptional cases; create the figure of a kind of counselor, a professional with "high know-how", which, when perspective the use of antibiotics that create many resistances, discuss and validate the option with the teams (Campos, 2013). After we realize what is being done around the world to prevent the hospital acquired infection, it is easy to think that Portugal have a lot steps to climb.

2.30. Cost of infections in a Portuguese health care facility

The hospital infections acquired during health care provoke morbidity, mortality and high costs. Every year, billions of euros are spent in the development of new drugs for the treatment of infections when, in fact multidrug resistance of microorganisms can be prevented by applying a correct policy on the use of antimicrobials and correct maintenance.

When treating a patient with a hospital-acquired infection usually are spent three times the amount that the institution would make available to solve the problem of ordinary patient. A case study was made to show the "*evaluation of the costs associated to hospital infections*" in patients of some internment specialties at the Centro Hospitalar Cova da Beira. To accomplish this objective, the empirical study was based on a Case-Control study. It was used the comparative method that involved the evaluation of costs associated to resources used by 77 infected patients (Cases) and 77 non-infected patients (Controls). The results showed that infected patients had 2.4 plus time of hospital stay than non-infected patients and the mean global costs of hospital stay per service are two times higher in the infected patients. Also, in infected patients the costs with antibiotics were 2.5 times higher, the costs with microbiologic cultures were 9 times higher, the costs with clinic pathology exams were 2 times higher, and the costs with imagological exams were 2 times higher than the costs for patients that did acquire infection. The conclusions of the study highlighted the necessity of defining strategies of intervention for rationalizing the use of antibiotics and engaging health care professionals for change of behavior and adoption of best practices (Martins, Franco, & Duarte, 2007).

2.31. Hospital acquired infection prevention – A practical guide

Based on World Health Organization guidelines, the Portuguese ministry of health (Ministério da Saúde - MS) have created a practical guide with the basic guidelines to be followed by the healthcare facilities. In this document, it doesn't show just the role of the doctor, the microbiologist, the hospital pharmacist, the nurse, the central sterilization service, or the infection control team, but also show the role of the installation service and equipment.

The installation and equipment service is responsible for (Ministério da Saúde, 2002):

- Collaborate with hotelier's services, nursing or any other service in the equipment selection, and ensure the rapid identification and prompt correction of any defects;
- Inspect and make preventive maintenance of the plumbing, the heating and cooling system, electrical installation and air conditioning / air renewal; It should be kept records of these activities and the maintenance shall be made known to the responsible service;
- Develop procedures to ensure emergency repairs to essential services;
- Ensuring environmental safety outside the hospital, e.g., waste disposal, water sources.

Additional special features include (Ministério da Saúde, 2002):

- Participate in the choice of equipment, if their maintenance involves technical assistance;
- Regularly inspect, clean and replace the filters of all ventilation equipment and humidifiers;
- Test sterilizers (temperature, pressure, vacuum, registration system) and ensure their regular maintenance (cleaning of the inner chambers, emptying the tubes);
- Monitoring of refrigerators registration thermometers, warehouses pharmacy, laboratory, blood bank and kitchens;
- Regularly inspect all surfaces - walls, floors, ceilings - to ensure it remains smooth and washable;
- Repair any opening or crack in partition walls or window frames;
- Ensure the maintenance of hydrotherapy equipment or other specific equipment;
- Notify the ICC of any expected disruption in services such as plumbing or air conditioning / air exchange.

The document also refers the importance of an Infection Control Committee, that provides a forum for cooperation and multidisciplinary participation and sharing of information. This committee should include a broad representation of other relevant areas: i.e., administration, doctors, other health professionals, Clinical Microbiology, Pharmacy, Supply, Installation, Service and Equipment, Hoteliers Services, Department of Education. The committee should report directly to the board or to the medical directorate in order to ensure the visibility and effectiveness of the program.

In an emergency (if an outbreak), this committee should be able to meet promptly. The commission has the following functions (Ministério da Saúde, 2002):

- Review and approve an annual program of activities for the epidemiological surveillance and prevention;

- Epidemiological surveillance review data and identify areas of intervention;
- Assessing and promoting the improvement of practices, at all levels, to provide health care;
- Ensure adequate training for professionals in infection control and safety;
- Review the risks associated with new technologies and monitor the risk of infection;
- New devices and products before the approval of its use;
- Review and provide data for the investigation of outbreaks;
- Communicate and collaborate with other hospital committees with common objectives.

As Portuguese hospitals doesn't have a clinical engineering department, maintenance is made by the Installation and Equipment Service, and it is important for this department to have active voice in the Infection Control Committee, in order to understand the relation between maintenance/construction/repair and the rate of hospital acquired infection.

A good maintenance program of all mechanical equipment and air conditioning systems can (Piteira, 2007):

- Ensure the normal operation within the specifications of the manufacturers;
- Reduce early deterioration of all equipment and system;
- Decrease the cost of repairs and energy consumption;
- Provide better indoor air quality;
- In case of surging legal problems caused by indoor air quality, maintenance record data are the true test of all the efforts made by the responsible to maintain healthy environmental conditions for all occupants.

On the other hand, the lack of an effective maintenance program (Piteira, 2007):

- Is the biggest cause of problems related to indoor air quality;
- Entails higher urgent repair costs;
- Prevents the immediate diagnosis to resolve issues related to indoor air quality, for lack of sufficient knowledge about the condition of the equipment and the system, and the lack of maintenance records that indicate what could possibly have failed.

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3. The Portuguese institute of Oncology Francisco Gentil, EPE.

3.1 General objectives

This part of the document aims the Portuguese Institute of Oncology Francisco Gentil analysis, related to the maintenance and risk prevention, in order to give some positive contributions. The hospital is a state-run cancer hospital and research organization from Portugal. The I.P.O. has autonomous regional branches in Lisbon, Porto and Coimbra, but the scope of this project only cares about the hospital of Coimbra.

However, the main objective of this project is to extrapolate the contributions for any Portuguese hospital or, in a broader vision, for any hospital in any place over the world.

3.2 Facilities

The hospital occupies a 35155 m^2 area divided into 23,603 m^2 of Private Area (PA - hospital area: operating rooms, offices, etc.) and 1552 m^2 Dependent Area (DA - garages, warehouses, etc.).

The hospital comprises seven buildings characterized as follows:

Oncology

FLOOR	PA (m2)	DA (m2)	DIVISIONS
3	856		40
2	856		32
1	976		41
0	1431		69
-1	478	1019	58
TOTAL	4597	1019	240

Table 1 – Oncology area by floor

Surgery

FLOOR	PA (m2)	DA (m2)	DIVISIONS
3	946		40
2	992	356	32
1	992	550	41

0	1058	66	69
TOTAL	3988	972	182

Table 2 – Surgery area by floor

Radiotherapy

FLOOR	PA (m2)	DA (m2)	DIVISIONS
3		284	5
2	772		49
1	1057		47
0	1819		72
TOTAL	3648	284	173

Table 3 – Radiotherapy area by floor

Ambulatory

FLOOR	PA (m2)	DA (m2)	DIVISIONS
4		193	
3	1568		48
2	1568		63
1	1568		63
0	2290		46
-1		2832	
-2		2884	
TOTAL	6994	5909	220

Table 4 – Ambulatory area by floor

Patients Hotel

FLOOR	PA (m2)	DA (m2)	DIVISIONS
3	1024		56
2	1024		55
1	950		25
0	1134		53
-1		1836	24
-2		1532	
TOTAL	4132	3368	213

Table 5 – Patients Hotel area by floor

Eco-point

FLOOR	PA (m2)	DA (m2)	DIVISÕES
1	170		7

Table 6 – Eco-point area

Transformer substation

PISO	ABP (m2)	ABD (m2)	DIVISÕES
1	74		4

Table 7 – Transformer substation area

The construction/renovation of facilities are made with the support of Service of Facilities and Equipment (SIE), Infection Prevention Service and Risk Prevention Service.

3.3 Equipment

3.3.1 General equipment:

In order to enable heating of water for use in heating of buildings and equipment, there are three boilers (water heating systems). To produce cold water to be used for air cooling, products and equipment as required, the IPO has 10 chillers (water cooling systems) serving buildings as follows: five to radiotherapy, three to surgery, two for ambulatory, oncology and patient's hotel, and one chiller with heat pump for the pharmacy.

The Heating, Ventilation and Air Conditioning (HVAC) is composed by 25 ATU (air treatment units), 500 fun coils (small units of air-handling terminal), 30 air extraction fans, and 20 splits (air conditioning unit - inner and outer equipment). The maintenance of all this equipment is made by technicians of two outsourced companies, and there are no maintenance plans.

The hospital has an emergency generator of 810 KVA to serve the entire hospital in case of power failure. The generator supplies the hospital in case of emergency, except HVAC systems. Maintenance is also outsourced and performed annually in accordance with the manufacture maintenance plan. The emergency generator is tested every week.

The hospital has a stock of spare parts of high-wear components. There are spare parts from 2004 that have not been used because it was not necessary (bearings, valves, power units, pumps, etc.). Sometimes it is necessary to stop the machines to make the corrective maintenance. Sometimes weekends are used to do the maintenance in order to minimize the hospital disturbance.

The precedent problems signify that the hospital needs to evaluate its spare parts management policy and its interrelation with the maintenance management policy.

3.3.2 Biomedical equipment:

Some important biomedical equipment is inventoried and available in a maintenance management software application inside service of facilities and equipment (SIE). The maintenance periods are being inserted according to the instructions of each manufacturer. The software application can warn maintenance requirements to the hospital technician who will call the outsource company responsible for that equipment maintenance/repair. In each intervention is created a work order and a report of maintenance/repair. The history of interventions began to be created just about six months ago. It is possible to check all the history of interventions of each equipment and export to other platforms.

For example, in a linear accelerator was collected that its being done preventive maintenance every two months. However, we can see that it has sometimes more than five failures with external intervention between each preventive maintenance act. The two months are, in fact, in accordance with the manufacture's schedule for a standard operation time, but maybe, the operation time of the equipment in the hospital is higher. This means that maybe the maintenance needs to be adapted to the real time of operation.

The time series forecasting or other methods for prediction, may be used to evaluate carefully the equipment's history with the objective to aid defining the best time between interventions according to functioning variable interval or and real time that maximizes the equipment's availability.

3.3.3 Critical equipment:

Due to the high number of failures, some equipment like the linear accelerators in the radiotherapy building are considered critical. When it fails, the department technician of the radiotherapy calls directly to the manufacturer to attend the problem. When solved the company leaves the building and latter sends the bill. The payment order is made by the

radiotherapy department and does not include the SIE. SIE will receive a communication of what was done just to include in the new software database. This is made just to keep an historical data about maintenance in this specific equipment. Also the decision of acquiring this specific equipment's, as well as, what equipment to acquire is made in the departments, not in the SIE. A complete inventory of this equipment is maintained by the financial department. The studies of what equipment best suits the department needs and facilities are made by the the supplier of the equipment.

The precedent situation must be corrected, and analysed carefully, namely having into account the followings aspects:

- To define the Terms of References by the SIE and the Service responsible for the equipment;
- To oblige the maintenance supplier to till a detailed work order in order to create a rigorous historic of maintenance interventions;
- To evaluate the maintenance historic by adequate tools, as above referred, in order to adequate the time between interventions according to the equipment reliability.

3.4 Relevant Services

3.4.1 Service of Facilities and Equipment (SIE)

The Service of Facilities and Equipment (Serviço de Instalações e Equipamento) is responsible for maintenance of electricity, carpentry, metal work, painting, plumbing, construction and air conditioning and is composed by 16 persons:

- Director – 1 person;
- Warehouse – 1 person;
- Management of equipment - 1 person;
- Secretary desk - 2 persons;
- Electricity - 4 persons;
- Carpentry - 2 persons;
- Metal work - 1 person;
- Painting - 1 person;
- Plumbing - 1 person;
- Construction - 1 person;
- Thermal power plant - 1 person.

The department uses contracts in paper to manage maintenance. Now, they have just begun to shift from paper to an IT software, so it is too early to speak about history of failures and/or malfunction. Costs of malfunctions are never calculated. When the failures happen that turns down equipment and consequently the service for some time. In this case the hospital turns to private entities to ensure the service. The cost of this stop usually is not estimated. This type of management does not permit to evaluate the indirect costs of maintenance what is a management weakness.

From the electricity technicians, just one works directly for the hospital. The services report the faults to the SIE or place their needs in a safety report. The SIE's electricity department every year opens plugs and checks electrical boards. The electrical transformation station (PT) is maintained every year and the state of the electric central panel is verified through a thermographic image. Since the hospital does not have a thermographic camera, this is done by an external company. The equipotentiality is measured several times per year. All operating rooms have insolation transformers. When there is a fault in the system, an SIE technician is called to check. However, the electrical maintenance/repair of the operating rooms is carried out by an outsource company twice a week. The maintenance of electrosurgery equipment is performed by an external entity as well. Regarding the electrical part, when a service has a problem, it contacts the SIE. In case of external company competence, SIE contacts the outsourced company. When the SIE is not operating, the services contact directly the responsible outsourced company and communicate latter to the SIE. The payments are always validated by the SIE. All works of electricity are documented in a worksheet that is latter registered in the system.

The hospital tries to ensure that the employees of the external entities have the necessary electrical qualification to carry out the tasks, however this is rather complex task, since the employees of these companies will rotate frequently. Usually before any technician makes any intervention, it contacts the responsible nurse of the area in order to know the specifications of the operating area. The worksheet is subsequently prepared by the two services. SIE is able to access all worksheets, however each service only accesses its own worksheets.

The last two points shows that there is a lot to do to increase quality management, namely in the following points:

- The equipment's faults communication and control;
- The quality of outsourcing suppliers:

This last aspect can be solved in a great extension if the hospital requires exclusively maintenance suppliers certified by NP4492:2010 (Requirements for the provision of maintenance services).

3.4.2 Infection prevention service (local coordinator group of PPCIRA)

Nosocomial infection prevention team consists of a local group coordinating the Prevention and Infection Control and Antimicrobial Resistance Program (Programa de Prevenção e Controlo de Infeção e Resistência aos Antimicrobianos - PPCIRA) a DGS program created nationally by the *Despacho n.º 2902/2013, of 22 of February*. Its overall objective is characterized by reducing infection rate associated with health care, hospital and community, as well as the rate of microorganisms with antimicrobial resistance and the continuous monitoring of hospital infection, antibiotic consumption and the incidence of multi-resistant microorganisms.

There is only one isolation room which can be used for both positive and negative pressures, depending on the needs of the hospital. The ventilation flow and bed position are not changed according to the needs. In a near future, it will be created two more isolation rooms.

The cleaning staff are from an outsource company, but they are full-time in the hospital. The hospital provides training to all employees in order to adapt them to specific conditions according to hospital needs. Whenever the hospital changes the provider cleaning services company, the employees remain the same. The hospital policy obliges to keep the staff that were properly trained. The hygiene plan is accredited by CHKS that is a provider of leading healthcare intelligence and quality improvement services, Developing solutions for healthcare organizations since 1989. Every three years the hygiene plans are reviewed and adjusted to the new hospital conditions. Because of the specification, the operating rooms are cleaned by internal workers, and not by the cleaning company.

The hospital is in the process of acquiring a device that measures the cleanliness of a surface, then it will be possible to measure the cleanliness and know it its being effective or not.

Equipment of high risk are sterilized, with medium risk are disinfected, and equipment with low risk are just washed and properly cleaned.

The gastroenterology services passed temporarily to a hospital area that had been a bar. In a perspective of integration of services, infection committee was called to verify if the new location is able to receive the gastroenterology service and which cleaning precautions will need to be taken before the service comes into operation.

The infection rate in the IPO is relatively lower than the European average, since the hospital does not have emergency services open to community, and does not have intensive care units. The IPOFG.EPE, has only one insulation room. Liquid tumors (eg. leukemia) are not treated in the hospital, so it also does not deal with highly immunosuppressed patients. The hospital

also has no cooling towers, which normally constitutes a major focus of nosocomial infections.

The calibration of medical equipment is outsourced by competent entities. The departments send the equipment to SIE to calibrate which in turn send to external entities to make the property calibration. The portable blood pressure meters (sphygmomanometers) or portable blood glucose, in some offices are not calibrated or audited. The recommendation to disinfect stethoscopes after use on each patient is also unaudited.

The sterilization section at the present is situated in an underground floor, and works with just one zone of ventilation.

HEPA filters are replaced in the insulation room when any patient leaves.

There are no hydrotherapy baths. The entire water system has return, that means the water is always in circulation, only being stagnant at the end of the pipes. It is performed preventive maintenance to the ends of the pipes. The shower heads and water dispersion valves are dipped in hipoxcloridric solutions each 6 months. The water from the tank that feeds the fire extinguishing system is also treated.

3.4.3 Risk prevention service

In Portuguese reality, usually the time between the panning, the work beginning, and end of the construction or renovation, can takes several years. When the work is over, it is already outdated. This is one more reason to be aware for the possibility of risk hazards. In the hospital, both infection commission and risk assignments are made in a part-time regime, accumulating with the normal tasks of their elements. This complicates the work of this commissions, reason why it is important the multidisciplinary work and organization. The IPO is one of the few hospitals in Portugal that has the Risk Management Committee, that is composed of a multidisciplinary team represented by the following elements:

- Director of Occupational Health Services;
- Director of Information Systems Management Service;
- Director of Facilities and Equipment Services;
- Responsible for the Board of Directors of General Risk Management;
- Responsible for the Council of Hospital Safety Administration Fire;
- Responsible for the Board of Directors of Clinical Risk Management;
- Responsible for the Board of Directors of Homeland Security;
- Responsible for the Board of Directors of Radiation Protection;
- Responsible for the Board of Directors of Hospital Waste Management;

- Responsible for the Board of Directors of Emergency Clinic.

Housed in a vision of commitment and quality, the hospital corporate governance integrates the concepts of rationality, efficiency, effectiveness, co-responsibility, sustainability and excellence. Clinical governance is carried out through the interaction of the following working groups/committees:

- Committee on Quality and Patient Safety;
- infection Commission (GCL-PPCIRA);
- Commission of Pharmacy and Therapeutics;
- Ethics Committee;
- Transfusion Committee;
- Risk Management Committee;
- Group Training, Clinical Research and Innovation;
- High Management Team
- Group of Clinical Audit;
- Group Healing;
- Group Falls Prevention;
- Group for the Improvement of Quality of Service;
- Group for the Prophylaxis of Venous Thromboembolism;
- Working Group for the Study of Alternatives to Blood Components

Also make part of the clinical governance the multidisciplinary teams of the following pathologies:

- Breast;
- Digestive;
- Head and neck;
- Bone and Soft Tissue;
- Dermatology;
- Endocrinology;
- Lung;
- Gynecology;
- Urology;
- Central Nervous System;
- Neuroendocrine tumors;
- Hematology;

In the last building renovations, an organizational LEAN thinking perspective was applied, through the placement of guidelines of different colors in the various facilities and services. This maximize efficiency by not allowing patients to get lost. The core idea is to maximize customer value while minimizing waste, creating more value for customers with fewer resources. As lean organization understands customer value and focuses its key processes to continuously increase it, there are a lot to be done before really entering a LEAN thinking approach. The ultimate goal will be to provide perfect value to the customer through a perfect value creation process that has zero waste. To accomplish this, lean thinking changes the focus of management from optimizing separate technologies, assets, and vertical departments to optimizing the flow of products and services through entire value streams that flow horizontally across technologies, assets, and departments to customers.

The cleaning contracts are analyzed by the Risk Management Committee. It is specified frequency and the degree of cleaning of different locations / equipment. Waste with risk of infection is separated and treated outsourced by a specialized company. The sterilization service is equipment with ultrasound and autoclave devices. All constructions/renovations are analyzed by both infection and risk committee. In areas of care are not allowed conventional vacuum cleaners. The hospital has a HEPA vacuum cleaner.

There are risk reports on the intranet for workers to fill out and send to the Risk Management Committee. It can even be sent anonymously. After the implementation of Risk Analysis, an intranet platform was developed for the workers. This platform is like a social network, a place where the workers can interact. The platform is only associated with non-clinical risk, ie, the risk associated with the worker. The clinical risk associated with the patient is not contemplated. Each worker has an account on the platform. When they login the platform will indicate their location, their functions, associated risks and preventive measures by each function. This platform is still in an embryonic state, not being fully operational. The platform has about 900 registered workers, all of whom are part of the hospital staff. Whenever a worker suffers an accident at work, the information changes the severity index and automatically adapts the information showed on the platform. Training in the training room will be replaced by b-learning training tools to facilitate access to education without disruption to services. For each function there is an online b-learning training. The platform also intends to create a mechanism of accountability. If there is a guarantee that the worker knows what to do and the correct procedures in order to avoid the risks, he is more easily held accountable. For each work hazard an accident form is created. This form includes a field for workers to indicate the resting hours. It is important to know if the fail is connected to worker's level of fatigue.

The annual activity report of the risk management committee only covers the activities carried out by all services. Each service reports the accidents that occurred. The report does

not have any improvement measures, which are written in the minutes of the meeting of the Risk Management Committee. There is also a plan of actions and a plan of activities.

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4. Contributions

Along the last chapters it were pointed contributions for solutions of the problems identified. In this chapter there will synthesized some more contributions that may be used not only by IPOFG, but for any Portuguese hospital or, in a more general vision, for any hospital around the world.

The aim of the clinical engineering work is to provide the hospitals and other healthcare providers with engineering support, know-how and technology management, which is based on knowledge, competence, and experience, so that the patients can be diagnosed and treated cost-effectively in the best possible way, according to the science state-of-the-art. Following the policy of The Joint Commission for the hospitals of the future, there are a lot to be done, but in the meantime, hospitals must do their part to reduce error and waste, and increase efficiencies as a means for improving safety and containing costs.

The IPOFG needs to continue addressing high-level priorities, such as infection control and emergency preparedness, in hospital design, construction and maintenance. Once the SIE is consulted when constructions/renovations are needed, it would be good to design a person who monitors the construction site and oversees the infection control and safety aspects of construction projects.

Although the SIE of IPOFG has been working to follow the hospital evolution, it is hard to reach this goals with just two engineers (a chief of department and a technician). As seen by the SIE staff, it is more orientated to maintenance of the facilities than of medical equipment. At the moment it is also almost impossible for SIE to support radiotherapy department when purchasing the systems, working with installation of these systems together with the manufacturer's staff, or being responsible for the technical operation of these systems, like in the Nordic Countries. However, like the USA, Australia and Canada models that Europe healthcare organizations are being followed in the last years, it will be essential the idea of an effective medical equipment management program. This program is important to assure that medical equipment is appropriate to the clinical needs and that it functions effectively and safely. It should embrace not only the technical aspects of maintaining medical equipment, but also the development of policies concerning equipment acquisition, acceptance, training, use, replacement and disposition, including at minimum the following components:

a) Processes implemented to manage the effective, safe and reliable operation of medical equipment;
b) Processes for selecting and acquiring medical equipment;
c) Requirement for all equipment users to be properly trained on the safe use of devices;

d) Procedures for identifying, evaluating and creating an inventory of equipment, based, minimally, on equipment function, risk and incident history;
e) Procedures for developing inspection scheduled and maintenance strategies for all equipment on the inventory, in order to achieve effective, safe and reliable operation of equipment on the inventory;
f) Processes for monitoring and acting on equipment hazard notices and recall;
g) Processes for monitoring and reporting incidents in which a medical device is suspected or attributed to the death, serious injury or serious illness of any individual;
h) Processes for identifying and implementing emergency procedures that address actions to be taken when equipment fails, how to perform emergency interventions when equipment fails, and how to obtain repair services;
i) Documentation requirements of performance and safety testing for all equipment covered by the medical equipment management plan;
j) Documentation procedures of inspection and maintenance of equipment used for life support that is consistent with identified maintenance strategies to minimize clinical and physical risk;
k) Documentation procedures of inspection and maintenance of equipment used for non-life support that is consistent with identified maintenance strategies to minimize clinical and physical risk;
l) Documentation of performance tests on all sterilizers;
m) Documentation of chemical and biological testing of water used in renal dialysis, if applicable;
n) Requirement for an annual program review to include measurement of effectiveness of all aspects of the Medical Equipment Management Program;
o) Implementation of Standard ISO 31000:2009 (Risk Management);
p) Implementation of Standard ISO 55000:2014 (Asset Management);
q) Implementation of KPI and a *Balanced Scorecard*;
r) Implementation of an Enterprise Asset Management.

As the program is very comprehensive, some of this subjects are not concern exclusively of the SIE, requiring a good cooperation between this department, the infection control and risk control groups. Also permanent communication between the SIE, and radiotherapy department, for example, will be very important. These two departments should work closely and not each one as their own. As sometimes is difficult to identify the role of each department, it is also necessary to define clearly the role of each one have and how they can interact.

A great goal to reach what in being done in Europe would be the SIE to be responsible for the management of the medical equipment, as well as facilitating education, research, and innovation, and having a close cooperation with the manufacturers and vendors. This would pursue an active safety work to prevent adverse events with the equipment caused by

technical reasons, and guarantying that vendors and external maintenance technicians deliver services with good quality. To start, SIE can contribute to build up an internal technical expertise that the hospital can take advantage when developing new control systems for management of larger medical equipment, entities or when investigating technical problems. Because the use of automated devices does not eliminate all major sources of human error, the training of observers should be required even when automated devices are used. All strategies must harmonize with the core values of the hospital and be in line with the hospital's goals and strategies.

The latest technology always needs a large investment in both equipment and competence. Therefore, carefully prepared planning of technology investments can reduce the running costs and costs for maintenance most evidently. It cannot be forgotten that the goal is not having the capability of dealing everything with in-house staff but to manage assets according to the state-of-the-art. It is to continue carrying the maintenance activities with a mixture between in-house and vendor services, but being capable of managing and controlling all the activities. The decision, who will do the different maintenance tasks and to what extension, will depend on the recourses and the costs, and it is also possible to renegotiate the agreements when the situation change. At this moment it is too early to talk about having an accurate inventory to keep track on the detailed information on the medical devices and systems, but it is important to start thinking in inventory based on equipment function, risk and incident history. SIE should assist decision making in equipment acquisition and technology assessment, in order to guarantee a standardization of communication protocols to be able in the future, to monitor equipment performance, reliability, and cost-effectiveness.

The inventory system should provide a comprehensive, expandable, and easy-to-use database of protocols for the performance of quality control, preventive and corrective maintenance, electrical safety, calibration, and acceptance tests of medical device. SIE should guaranty the continuous monitoring and evaluation of equipment performance, in order to identify probable problems and measures that contribute to the quality of patient care. The system database should also monitor and measures a set of quality and cost indicators, allowing SIE to have a continuous overview of the departments performance in terms of productivity, effectiveness, and efficiency. There are studies that demonstrate a good performance should aim for a PM to CM share of 80/20. As the SIE just recently start to collect the medical equipment data, it is too early also to check witch is the relation between PM and CM at the moment, but is a good indicator to start collecting for future analysis. Also with historic will be possible to better manage spare parts, in order avoid having unnecessary spare parts.

About the electric maintenance (3.2.2.1), it is important to ensure the qualification of the technicians. It's advisable to ensure to follow up of maintenance/repairs made by external companies. It is risky when some electrical circuits are dependent on outside companies for

which we do not know if their technicians have the necessary qualifications. As the energy systems have been evolving, it is important that the electrical technicians can follow this evolution. About this question, in the mentioned chapter it was given the respective contribution.

Related to critical equipment (3.2.1.3), once SIE is starting to see that some equipment are having several fails between the PM (i.e. linear accelerators), it will be good to search the datasheets for the standard operating time. In alternative, can be asked to manufacturers witch was the operating time used to estimate the preventive maintenance acts of each critic equipment. If the operating time used by standard is inferior to the real operating time in the hospital, contact the manufacturer in order to establish a new regime of maintenance acts.

In a near future, it would be interesting the implementation of an asset management vision postulated in ISO 55000/1/2, particularly on the subject of equipment lifecycle. The behavior of the most important assets and more expensive, would be accompanied in order to estimate its lifecycle and the best time to disable and replace by new equipment.

Related to the Infection Preventive Service (3.2.2.2), it can be made a study for the possibility of adapting the position of beds to the ventilation flow according to this document or other relevant studies. Before the construction of the new two rooms, pre-plan is necessary in order to adapt the ventilation structure to the future needs. Educate the staff to properly use the new equipment to measure the cleanliness and use it to educate the cleaning staff. They should be warned about what surfaces are not being property cleaned. SIE should make public to the hospital the importance of calibrating also the small monitor equipment, and also check for witch entities are certified to calibrate that equipment. It is widely recommended that sphygmomanometers are maintained and calibrated regularly to ensure that pressure scale remains within the standard. There is no way of obligate physicists to disinfect their own stethoscopes, and it is not easy to audit also. The idea of disinfecting stethoscopes after the use on each patient should be spread, in order to change the mentality. The critical areas such as sterilization or humid areas as kitchens, should not be underground. Underground facilities tend to have more humidity and consequently increases the multiplication of pathogenic agents. This services must be located above the level of implementation. The humidity in the ducts near the filters can be monitored in order to prevent the multiplication of pathogens in the filter itself, which can then easily be thrown by the flow of ventilation.

Related to the Risk Prevention Service (3.2.2.3), as risk management it is a process that is under-pinned by a set of principles, it needs to be supported by a structure that is appropriate to the hospital and its external environment or context. Reinforce the multidisciplinary team, not just with the chief of departments, but also with other workers who can help in their knowledge areas. Establish good communication routes between the members, for example meeting periodically to discuss the critical subjects. What, when, where, and by whom should

be done must be documented in each session, and confirm in the next session. It is entirely pertinent to include clinical risk in the platform, since both may have a cause-and-effect relationship. A medication error (clinical risk) may be due to a non-clinical risk such as stress or fatigue of the worker.

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5. Conclusions and future developments

The risk management and maintenance management in Portuguese hospitals and healthcare units is still not developed compared with other countries like U.S., Canada, Australia and Nordic Countries, with consequences for patients and other users of the hospital environment. The topics and examples used in this document were intended to show a little about state of the art, as well to raise awareness of a change of mentality to make these medical structures more efficient, secure, and economically sustainable. Compliance with these provisions implies the existence of a competent and proactive maintenance service in order to guarantee the safety of patients and other users of hospitals and health facilities. Step by step hospitals can start to change their "modus operandi" and become better facilities.

This dissertation/project made a first approach to the cause-effect relationship between maintenance management and risk management, and opened several doors to very pertinent issues that should be further developed. Because the dissertation/project relies on data whose nature reverses a high degree of criticality and hence confidentiality, it becomes difficult to perceive actual infection rates, as well as the causes of hospital accidents. Electrical hazards, as well as other types of hazards, have yet to be more explored. Each risk at the hospital level triggers a universe of options to study. It is necessary that these issues continue to be explored and addressed, not only comprehensively as this document does, but also at a more specific detail level.

The hospital (IPOFG.EPE.) was receptive to the work developed along this months, as well to some of the improvement proposals. In order to continue the academic contributions to the hospital's environment, it was accepted another master's project, for the next year, that will give continuity to this one. Despite the lack of human resources with technical know-how, the hospital is opened to try to cooperate as far as possible with the necessary change of mentality to accomplish the goals of efficiency of the organizational flows.

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6. Appendix

Table 1

Types of Construction Activity	
Type A	Inspection and non-invasive activities: These include, but are not limited to, activities that require removal of ceiling tiles for visual inspection (limited to 1 tile per 50 square feet), painting (but not sanding), wall covering, electrical trim work, minor plumbing (disrupts water supply to a localized patient care area [e.g. 1 room] for less than 15 minutes), and other maintenance activities that do not generate dust or require cutting of walls or access to ceilings other than for visual inspection.
Type B	Small scale, short duration activities that create minimal dust. These include, but are not limited to, activities that require access to chase spaces, cutting of walls or ceilings where dust migration can be controlled for the installation/repairs of minor electrical work, ventilation components, telephone wires or computer cables, and sanding of walls for painting or wall covering to *only repair* small patches. It also includes plumbing that requires disruption to the water supply of more than one patient care area (e.g. > 2 rooms) for less than 30 minutes.
Type C	Any work that generates a moderate to high level of dust or requires demolition or removal of any fixed building components or assemblies (e.g. counter tops, cupboards, sinks). These include, but are not limited to, activities that require sanding of walls for painting or wall covering, removal of floor-coverings, ceiling tiles and casework, new wall construction, minor duct work or electrical work above ceilings, major cabling activities, and any activity that *cannot be completed* within a single work shift. It also includes plumbing that requires disruption to the water supply of more than one patient care area (e.g. > 2 rooms) for more than 30 minutes but less than 1 hour.
Type D	Major demolition, construction and renovation projects. These include, but are not limited to, activities that involve heavy demolition or removal of a complete cabling system and new construction requiring consecutive work shifts to complete. It also includes plumbing that results in disruption to the water supply of more than one patient care area (e.g. > 2 rooms) for more than 1 hour.

Table 2

Specifications for Infection Prevention and Control Measures

Class I

Engineer/Maintenance Staff & Contractors

a) Construction/Renovation Activities

- Immediately replace tiles displaced for visual inspection;
- Vacuum work area.

b) Plumbing Activities

- Schedule water interruptions during low activity (e.g. evenings if at all possible);
- Flush water lines prior to reuse;
- Observe for discoloured water;
- Ensure water temperature meets the standards set by the health care facility;
- Ensuregasketsanditemsmadeofmaterialsthatsupportthegrowthof*Legionella*arenotbeing used;
- Ensure faucet aerators are not installed or used;
- Maintain as dry an environment as possible and report any water leaks that occur to walls and substructures;

Environmental Services

a) Plumbing Activities

- Report discoloured water and water leaks to maintenance and ICP.

Medical/Nursing Staff

a) Construction/Renovation Activities (Risk reduction)

- Minimize patients' exposure to construction/renovation area.

b) Plumbing Activities

- Report discoloured water and water leaks to maintenance and ICP.

Class II

Engineer/Maintenance Staff & Contractors

a) Construction/Renovation Activities

1) Dust Control

- Execute work by methods that minimize dust generation from construction or renovation activities:
  - wet mop and/or vacuum as necessary.
- Provide active means to minimize dust generation and migration into the atmosphere
  - use drop sheets to control dust;
  - control dust by water misting work surfaces while cutting – seal windows and unused doors with duct tape;
  - seal air vents in construction/renovation area;
  - place dust mat at entrance to and exit from work areas;

2) Ventilation

- Disable the ventilation system in the construction/renovation area until the project is

complete;
- Monitor need to change and/or clean filters in construction or renovation area;

3) Debris Removal & Cleanup
- Contain debris in covered containers or cover with a moistened sheet before transporting for disposal.

b) Plumbing Activities
- Avoid collection tanks and long pipes that allow water to stagnate;
- Consider hyperchlorinating or superheating stagnant potable water (especially if Legionella is already present in potable water supply).

Environmental Services
a) Construction/Renovation Activities
Dust Control
- Wet mop and vacuum area with a HEPA filtered vacuum as needed and when work is complete;
- Wipe horizontal work surfaces with a disinfectant.

Medical/Nursing Staff
a) Construction/Renovation Activities
Risk Reduction
- Identify high risk patients who may need to be temporarily moved away from the construction zone;
- Ensure that patient care equipment and supplies are protected from dust exposure.

Class III

Engineer/Maintenance Staff & Contractors
a) Construction/Renovation Activities

1) Risk Reduction
- EnsurethatICPconsultationhasbeencompletedandinfectionpreventionandcontrolmeasures have been approved

2) Dust Control
- Erect an impermeable dust barrier from true ceiling (includes area above false ceilings) to the floor consisting of 2 layers of 6 mil polyethylene or Sheetrock;
- Ensure that windows, doors, plumbing penetrations, electrical outlets and intake and exhausts vents are properly sealed with plastic and duct taped within construction/renovation area;
- Vacuum air ducts and spaces above ceilings if necessary;
- Ensure that construction workers wear protective clothing that is removed each time they leave the construction site before going into patient care areas;
- Do not remove dust barrier until the project is complete and the area has been cleaned;
- thoroughly and inspected;
- Remove dust barrier carefully to minimize spreading dust and other debris particles associated with the construction project.

3) Ventilation

- MaintainnegativepressurewithinconstructionzonebyusingportableHEPAequippedair filtration units;
- Ensure air is exhausted directly outside and away from intake vents or filtered through a HEPA filter before being recirculated;
- Ensure ventilation system is functioning properly and is cleaned if contaminated by soil or dust after construction or renovation project is complete.

4) Debris Removal & Cleanup

- Remove debris at the end of the work day;
- Erect an external chute if the construction is not taking place on ground level;
- Vacuum work area with HEPA filtered vacuums daily or more frequently if needed.

b) Plumbing Activities

- Flushwaterlinesatconstructionorrenovationsiteandadjacentpatientcareareasbeforepatients are readmitted.

Environmental Services

a) Construction/Renovation Activities

- Increase frequency of cleaning in areas adjacent to the construction zone while the project is under way;
- In collaboration with ICP ensure that construction zone is thoroughly cleaned when work is complete.

Infection Prevention and Control Personnel

a) Construction/Renovation Activities

1) Risk Reduction

- Move high risk patients who are in or adjacent to the construction area;
- In collaboration with environmental services ensure that construction zone is thoroughly cleaned when work is completed;
- Inspect dust barriers.

2) Traffic Control

- In collaboration with the facility project manager designate a traffic pattern for construction workers that avoids patient care areas and a traffic pattern for clean or sterile supplies and equipment that avoids the construction area.

b) Plumbing Activities

• Consider hyperchlorinating or superheating stagnant potable water (especially if *Legionella* is already present in potable water supply)

Medical/Nursing Staff

a) Construction/Renovation Activities

Risk Reduction

- Move high risk patients who are in or adjacent to the construction area;
- Ensure that patients do not go near the construction area.

b) Plumbing Activities

- Consider hyperchlorinating or superheating stagnant potable water (especially if Legionella is already present in potable water supply).

Medical/Nursing Staff

a) Construction/Renovation Activities

Risk Reduction

- Move high risk patients who are in or adjacent to the construction area;
- Ensure that patients do not go near the construction area;
- In collaboration with environmental services ensure that construction zone is thoroughly cleaned when work is completed;
- Inspect dust barriers.

Class IV

Engineer/Maintenance Staff & Contractors

a) Construction/Renovation Activities

1) Dust Control

- Before starting the construction project erect an impermeable dust barrier that also has an anteroom;
- Place a walk-off mat outside the anteroom in patient care areas and inside the anteroom to trap dust from the workers' shoes, equipment and debris that leaves the construction zone;
- Ensure that construction workers leave the construction zone through the anteroom so they can be vacuumed with a HEPA filtered vacuum cleaner before leaving the work site; or that they wear cloth or paper coveralls that are removed each time they leave the work site;
- Direct all personnel entering the construction zone to wear shoe covers;
- Ensure that construction workers change the shoe covers each time they leave the work site;
- Repair holes in walls within 8 hours or seal them temporarily.

2) Ventilation

- Ensure negative pressure is maintained within the anteroom and construction zone;
- Ensure ventilation systems are working properly in adjacent areas;
- Review ventilation system requirements in the construction area with ICP to ensure system is appropriate and is functioning properly.

3) Evaluation

- Review infection control measures with other members of the planning team or delegate to evaluate their effectiveness and identify problems at the end of the construction project.

b) Plumbing Activities

- If there are concerns about Legionella, consider hyperchlorinating stagnant potable water or superheating and flushing all distal sites before restoring or repressurizing the water system.

Environmental Services

a) Construction/Renovation Activities

Evaluation

- Review infection prevention and control measures with other members of the planning team or delegate to evaluate their effectiveness and identify problems at the end of the construction project.

Infection Prevention and Control Personnel

a) Construction/Renovation Activities

1) Risk Reduction

- Regularly visit the construction site to ensure that preventive measures are being followed. Wear coveralls and shoe covers when visiting the site.

2) Evaluation

- Review infection control measures with other members of the planning team or delegate to evaluate their effectiveness and identify problems at the end of the construction project.

b) Plumbing Activities

- If there are concerns about *Legionella,* consider hyperchlorinating stagnant potable water or superheating and flushing all distal sites before restoring or repressurizing the water system.

Medical/Nursing Staff

Staff are not allowed to visit the construction site.

a) Construction/Renovation Activities

Evaluation

- Review infection control measures with other members of the planning team or delegate to evaluate their effectiveness and identify problems at the end of the construction project.

b) Plumbing Activities

- Consider using another source of potable water for patients who are at greatest risk until potable water has been cleared for signs of *Legionella* after major plumbing installation/repairs.

Table 3: Airborne Nosocomial Pathogens (Kowalski W. , 2012)

Microbe	Type	Size (µm)	Source	BSL	Category 1	2	3	4	5	6	7	Airborne Class
Acinetobacter	Bacteria	1.225	E	RG 2	X			X		X	X	2
Adenovirus	Virus	0.079	H	RG 2	X	X			X	X		2
Alcaligenes	Bacteria	0.775	HE	RG 2	X							2
Alternaria alternata	Fungi	11.225	E	RG 1				X	X			2
Aspergillus	Fungi	3.354	E	RG 2	X	X	X	X	X			1
Blastomyces dermatitidis	Fungi	12.649	E	RG 2	X				X			2
Bordetella pertussis	Bacteria	0.245	H	RG 2	X						X	1
Clostridium difficile	Bacteria	2	H	RG 2		X			X	X	X	1
Clostridium perfringens	Bacteria	5	HE	RG 2		X					X	2
Coccidioides immitis	Fungi	3.464	E	RG 3	X				X			2
Coronavirus (SARS)	Virus	0.11	H	RG 2	X						X	1
Corynebacterium diphtheriae	Bacteria	0.698	H	RG 2	X					X		2
Coxsackievirus	Virus	0.027	H	RG 2	X						X	2
Cryptococcus neoformans	Fungi	4.899	E	RG 2	X				X			2
Enterobacter	Bacteria	1.414	HE	RG 1	X		X	X	X	X		2
Enterococcus (VRE)	Bacteria	1.414	H	RG 1-2	X		X	X	X	X	X	2
Fugomyces cyanescens	Fungi	2.12	E	RG 1					X			2
Fusarium	Fungi	11.225	E	RG 1				X	X			2
Haemophilus influenzae	Bacteria	0.285	H	RG 2	X					X	X	2
Haemophilus parainfluenzae	Bacteria	1.732	H	RG 2	X							2
Histoplasma capsulatum	Fungi	2.236	E	RG 3	X	X			X			1
Influenza A virus	Virus	0.098	H	RG 2	X				X	X	X	1
Klebsiella pneumoniae	Bacteria	0.671	HE	RG 2	X		X	X	X	X		2
Legionella pneumophila	Bacteria	0.52	E	RG 2	X						X	1
Measles virus	Virus	0.158	H	RG 2	X					X		1
Mucor	Fungi	7.071	E	RG 1	X			X				2
Mumps virus	Virus	0.164	H	RG 2	X							1
Mycobacterium avium	Bacteria	1.118	E	RG 2					X			2

Table 3 (continued): Airborne Nosocomial Pathogens (Kowalski W. , 2012)

Microbe	Type	Size (µm)	Source	BSL	Category 1	2	3	4	5	6	7	Airborne Class
Mycobacterium tuberculosis	Bacteria	0.637	H	RG 3	X	X			X	X	X	1
Mycoplasma	Bacteria	0.177	H	RG 2	X					X	X	2
Neisseria meningitidis	Bacteria	0.775	H	RG 2						X		2
Nocardia asteroides	Bacteria	1.118	E	RG 2	X							2
Norwalk virus	Virus	0.029	E	RG 2		X					X	1
Parainfluenza virus	Virus	0.194	H	RG 2	X					X	X	2
Parvovirus B19	Virus	0.022	H	RG 2						X		2
Penicillium	Fungi	3.262	E	RG 2					X			2
Pneumocystis jirovecii	Fungi	2	HE	RG 1	X				X			2
Proteus mirabilis	Bacteria	0.494	H	RG 2	X		X	X		X		2
Pseudallescheria boydii	Fungi	3.162	E	RG 1					X			2
Pseudomonas aeruginosa	Bacteria	0.494	E	RG 1	X	X	X	X	X	X		1
Reovirus	Virus	0.075	H	RG 2						X		2
Respiratory syncytial virus (RSV)	Virus	0.19	H	RG 2	X				X	X	X	1
Rhinovirus	Virus	0.023	H	RG 2	X						X	2
Rhizopus	Fungi	6.928	E	RG 2	X			X				2
Rotavirus	Virus	0.073	H	RG 2					X	X	X	2
Rubella virus	Virus	0.061	H	RG 2	X							1
Scedosporium	Fungi	3.162	E	RG 1					X			2
Serratia marcescens	Bacteria	0.632	E	RG 1	X		X	X	X	X		2
Staphylococcus aureus (MRSA)	Bacteria	0.866	H	RG 2	X	X	X	X	X	X	X	1
Staphylococcus epidermis	Bacteria	0.866	H	RG 1			X	X		X		2
Streptococcus pneumoniae	Bacteria	0.707	H	RG 2	X	X			X	X	X	2
Streptococcus pyogenes	Bacteria	0.894	H	RG 2	X	X		X			X	1
Trichosporon	Fungi	8.775	E	RG 3					X			2
Varicella-zoster virus (VZV)	Virus	0.173	H	RG 2	X				X	X		1

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