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A Systems Engineering Approach to Equipment Qualification in Health Care

Dermot Hale

Submitted for the degree of Doctor of Philosophy to the National University of Ireland, Galway

Research Supervisor: Enda F. Fallon
Senior Lecturer in Industrial Engineering

Date Submitted: August 2015

Volume: 1 of 2
'To copy is too risky, because you don’t understand why you are doing it,

To adapt, and not adopt, is the way'

- Dr. W. Edwards Deming
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Declaration

I hereby declare that, except where duly acknowledged, the work presented in this thesis is my own, and that it has not been submitted in full or partial fulfilment of the requirement for any other award in the National University of Ireland or any other University.

______________________________
Dermot Hale
Abstract

Equipment Qualification is a formal quality assurance process in manufacturing which establishes confidence that specified equipment is ‘ready for its intended use’. This thesis, in drawing parallels between requirements of manufacturing equipment and medical equipment, hypothesises that the protocols, practices and tools of Equipment Qualification can be adapted for application in healthcare.

In manufacturing, where the quality of output is of critical concern, the scope of Equipment Qualification is limited to building confidence that the equipment can produce product to specification. In healthcare, where patient safety is the critical concern, the identification and control of potential causes of adverse events is of central importance in establishing confidence that the equipment is ‘ready for its intended use’.

This thesis details the development of an Equipment Qualification framework for healthcare to guide healthcare practitioners in best practice tools, techniques and considerations for the identification and control of potential causes of adverse events. The Equipment Qualification framework presented in this thesis synthesises existing knowledge in the domains of risk management, quality, safety, reliability, maintenance, calibration, human factors engineering and lean methods with empirical findings of benchmarking case studies in manufacturing companies and requirements analysis case studies and questionnaire in healthcare.

A systems engineering approach is adopted to manage the complexity of the Equipment Qualification process. The framework, consisting of a model written in the systems engineering modelling language IDEFØ and supporting qualification template protocols, was verified and validated via a novel expert review process.
Acknowledgements

First and foremost I would like to thank my supervisor Enda Fallon. As a part-time student I had thought arranging meetings would be difficult. Enda, though, regularly met with me out of working hours, frequently inviting me over to his home. I would also like to thank Enda’s family and his wife, Anne, for always welcoming me despite the often late hours we worked. Enda always went the extra mile in his dedication to this work, for which I am very grateful.

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Professor Emeritus John Sheil, supervisor of my M.Eng.Sc., has also been a major influence on my academic career. John continued to give exceptional guidance, support and input for this project long into his retirement; I always left a meeting with John feeling motivated and enthusiastic about the project.

This work could not have been carried out without the assistance of the fieldwork participants, and although they will remain anonymous, their contributions are greatly appreciated. I would also like to thank the staff of Smithstown Light Engineering, particularly Gerard, Brian and Pat for their support of this work and helping me to consistently improve my engineering knowledge and skills.

I would like to thank my family for their consistent support throughout all my education and from whom I learned to work hard and do my best. Also to the FitzGerals in Ballyhahill, a big thank you for your support and encouragement.

Finally, and most importantly, a very special thanks to the very special Christine, who was always supportive as my girlfriend, fiancée and wife over the course of this work.
Published Work

The following is a list of papers published based on, or associated with, the work of this thesis:


Chapter One: Introduction

1.1 Introduction

Medical equipment is an essential resource in healthcare systems. Prior to clinical use, medical equipment manufacturers must demonstrate compliance with strict regulations in the design and manufacture of the equipment (WHO, 2013) in order to build confidence that the equipment can be utilised in a safe, effective and efficient manner.

Adverse events, however, continue to occur in the use of medical equipment. The Institute of Mechanical Engineers (IME) report that, in 2013 in the UK, 13,642 incidents related to faulty medical equipment were reported to the Medicines and Healthcare products Regulatory Agency (MHRA); leading to 309 deaths and 4,955 people sustaining serious injury (IME, 2015). In Ireland, the Health Service Executive (HSE) risk committee state that there is no reason to believe that the Irish healthcare system would be very different to the findings of international reports, adding that a study to quantify the exact number of adverse events happening in Irish hospitals is planned, with results expected in 2016 (Mudiwa, 2015).

While the immediate causes of adverse events involving medical equipment have been described as related to either failure of the equipment (Dhillon, 2000) or use error (Cooper et al., 2007, Money et al., 2011), Amoore and Ingram (2002) found that adverse incidents involving medical equipment are typically multifactorial in origin, with latent factors\(^1\), faults, errors, and mistakes aligning together\(^2\). Latent factors in particular have been identified as root causes of adverse events (Flewelling et al., 2014).

---

\(^1\) The term ‘latent’ describes a quality or state that exists but is not yet developed or manifest. In relation to analysis of adverse events, latent factors are defined as those aspects of the system predisposing threat or error (Helmerich, 2000).

\(^2\) Reason’s Swiss cheese model, which is based on this multifactorial nature of system accidents, has become the dominant paradigm for analysing medical errors and patient safety incidents (Perneger, 2005).
Chapter One: Introduction

It is evident, therefore, that the identification of latent risk factors, prior to the clinical use of medical equipment, can mitigate the risk of adverse events occurring. Currently in healthcare, acceptance testing ensures the facility has received the equipment that was specified in the purchase agreement and commissioning establishes base line measurements for future quality control checks (Fontenot et al., 2014). Existing acceptance testing and commissioning tasks address concerns within the scope of ‘failure of the equipment’. This thesis seeks to develop the current scope of activities through developing a framework, considering both ‘failure of the device’ and ‘use error’, to guide healthcare practitioners in identifying latent factors at the acceptance testing stage of medical equipment.

Healthcare facilities also strive for efficient and effective use of resources. As medical equipment is a key resource in the healthcare system, setting the foundation for excellence at the equipment acceptance testing stage can ensure that the equipment and its work environment are ready to maximise productivity.

If it is accepted that a framework to guide healthcare practitioners in identifying latent risk factors and implementing best practice in maximising potential for productivity can support practitioners to make healthcare safer and more efficient then the following question is raised; how can best practice be achieved? In order to answer this question, best practice must be identified and a mechanism for systematically capturing this best practice must be achieved.
Chapter One: Introduction

1.2 A Systems Engineering Approach

Systems engineering in healthcare consists of the scientific study and application of methods to improve the value of healthcare delivery. The objective is to use methods, tools and techniques of disciplines that are different to the traditional medical and biological related disciplines in order to improve the processes that support healthcare delivery (Fowler et al., 2011). Aslaksen (2012) notes that systems engineering does not add any technical knowledge that is not already present, if the process is done correctly the outcome will be the same, regardless of whether or not a systems engineering approach has been used. Aslaksen further argues that the value of systems engineering, similar to formal quality systems, is in providing a methodology for ensuring that the engineering is done correctly through reducing the variance of the engineering process.

The National Academy of Engineering (NAE) and Institute of Medicine (IOM) publication ‘Building a Better Delivery System, A New Engineering/Health Care Partnership’ advocated the widespread application of systems engineering tools to improve health care delivery, arguing that although drawing direct parallels between other economic sectors and healthcare can be problematic, many functions common to both have been significantly improved in other sectors through engineering analysis (Reid et al., 2005). Systems engineering has been applied successfully in many aspects of healthcare, with authors stating that the value of adopting of a systems approach in healthcare is fewer risks to patients, greater efficiencies and a reduction in costs for healthcare facilities (Vockley, 2013, Padula et al., 2014, Clark et al., 2014).
1.3 Identifying Best Practice in Acceptance Testing

Equipment acceptance testing is a function which is common to both manufacturing and healthcare. At first glance the parallels between healthcare and manufacturing equipment may not be obvious; manufacturing may be seen as an industry that deals with the simple process of making inanimate objects. Healthcare, on the other hand, deals with complex processes for the treatment of injury and disease. If viewed from a systems engineering perspective, however, healthcare can be seen to have much in common with the manufacturing industry. In both domains inputs are converted to outputs through the use of the equipment. In healthcare this process aims to add value to the input, i.e. improving the health of the patient. In manufacturing the process also aims to add value to the input, through enhancing the form or function of the part.

Manufacturing, in regulated industries, has developed systematic practices, protocols and tools for equipment acceptance testing, described by the term Equipment Qualification (Webster et al., 2005). The purpose of Equipment Qualification is to demonstrate, through documented evidence, that the equipment is ‘ready for its intended use’ (Broad et al., 2006). In Equipment Qualification, value is represented by a measure of risk; as risk decreases, value created increases. The practices, protocols and tools of Equipment Qualification in manufacturing represent an opportunity to adapt best practice methods for acceptance testing of medical equipment in healthcare.
1.4 Research Question & Objectives

Cognisant that the practices, protocols and tools of Equipment Qualification in manufacturing represent an opportunity to adapt best practice methods for acceptance testing of medical equipment in healthcare, the following research question is addressed in this thesis:

‘How can the protocols, practices and tools of Equipment Qualification be developed and modified for application in healthcare?’

In order to answer this question the research aims to develop a best practice based Equipment Qualification framework for the qualification of medical equipment in healthcare. In systematically assessing that the equipment is ready for its intended use, confidence can be established that the equipment will perform as required as within the healthcare delivery system.

In order to answer the research question the following objectives were identified:

1. To explore, through a review of the literature, best practice in supporting disciplines to Equipment Qualification
2. To benchmark, through case studies, best practice methods used in manufacturing industries for Equipment Qualification.
3. To determine the identified and unidentified³ requirements of key stakeholders of activities within the scope of Equipment Qualification activities in healthcare.
4. Informed by the results of 1 to 3 above, to develop a framework to assist healthcare providers in applying best practice methods in the qualification of medical equipment.

³ Unidentified requirements are those requirements that are present but have not been consciously realised (Bates et al., 2003)
Chapter One: Introduction

1.5 Scope of the Study

The Equipment Qualification framework will be developed for medical equipment in healthcare. Medical equipment may be seen as a subdivision within the scope of medical devices. The WHO define medical equipment as medical devices requiring calibration, maintenance, repair, user training and decommissioning (WHO, 2011). Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment (WHO, 2015). Examples of medical equipment within the scope of the study include linear accelerators, dialysis equipment, ultrasound equipment and MRI scanners. Examples of medical devices outside the scope of the study include surgical instruments and implants, stents and all single use medical devices.

Given the diversity of products within the scope of the research, the framework will not attempt to give technology-specific guidance for any particular equipment; in the case of linear accelerators, for example, the framework will not specify tests for evaluating beam performance. It will be the responsibility of local personnel to seek-out/select specific tasks/tests, such as those to determine beam performance, under the structure of the framework presented in this thesis.

1.6 Expected Contribution to Knowledge

The fundamental expectation of a PhD thesis is that the thesis demonstrates originality and an evident contribution to knowledge. Phillips and Pugh (2010), based on interviews with PhD students, supervisors and examiners identify nine instances in which research can be considered to be original and contribute to knowledge:

- Carrying out empirical work that hasn’t been done before

---

Additional discussion of the semantics of the terms ‘medical device’ and ‘medical equipment’ is presented in Section 2.2.
Chapter One: Introduction

- Making a synthesis that hasn’t been made before
- Using already known material, but with a new interpretation
- Trying out something that has previously only been done in other countries
- Taking a particular technique and applying it in a new area
- Bringing new evidence to bear on an old issue
- Being cross-disciplinary and using different methodologies
- Looking at areas that people in the discipline haven’t looked at before
- Adding to knowledge in a way that hasn’t been done before.

Phillips and Pugh (2010) also report the established criteria of Francis (1976) for showing that research is original and a contribution to knowledge has been achieved:

- Setting down a major piece of new information in writing for the first time
- Continuing a previously original piece of work
- Carrying out original work designed by the supervisor
- Providing a single original technique, observation or result in an otherwise unoriginal but competent piece of research
- Having many original ideas, methods and interpretations all performed by others under the direction of the postgraduate
- Showing originality in testing somebody else’s idea.

The primary contribution to knowledge sought in this thesis is the synthesis of existing knowledge and tools with empirical findings of the fieldwork to develop an original framework for Equipment Qualification in healthcare. Further discussion on the means by which contributions to knowledge have been realised in this thesis is presented in Section 10.2, which details each of the criteria of Phillips and Pugh (2010) and Francis (1976).
Chapter One: Introduction

1.7 Thesis Structure

This thesis is structured as follows:

**Chapter 1** outlines the rationale for the research, its aims and objectives, and briefly outlines the research approach adopted. Chapter 1 also defines the scope of the study and provides a short discussion on the primary contribution to knowledge sought in the thesis.

Chapters two, three, four and five contain reviews of the pertinent literature. **Chapter 2** provides an overview of the regulations which govern the medical device lifecycle while also exploring approaches to medical device management in healthcare. A particular emphasis on the Irish healthcare system is provided. **Chapter 3** discusses systems engineering at a macro level before proceeding to a review of existing systems engineering approaches in healthcare. This chapter provides the reader with a frame of reference, through understanding challenges and opportunities for the proposed Equipment Qualification framework. **Chapter 4** contains a detailed description of the Equipment Qualification process and the related method of Process Validation. The Equipment Qualification process is shown to be a function of the discipline of systems engineering. The scope of usage of Equipment Qualification in the quality/safety critical manufacturing industries of aerospace, automotive, medical device and pharmaceutical manufacturing is explored. In **Chapter 5** the disciplines which support the qualification of medical equipment are presented and discussed with the objective of identifying best practice tools, methods and considerations which can be adapted for use in the qualification of medical equipment in healthcare.

**Chapter 6** details the fieldwork and data collection methods employed. It describes the rationale for using both case study and questionnaire methods and it describes the criteria and methods for selecting and accessing Key Informants in the domains of manufacturing and healthcare.
Chapter One: Introduction

Chapter 7 presents the results of the field work undertaken. Best practice, as found through case studies, in Equipment Qualification in medical device, pharmaceutical and combination product manufacturing is presented along with current and recommended future practices for healthcare, informed by key healthcare stakeholders.

Building on a synthesis of the key findings from the literature review and outcomes from the work reported in chapter seven, Chapter 8 presents a framework for Equipment Qualification in healthcare.

Subsequently, Chapter 9 presents the verification and validation of the framework. Challenges evident in the literature regarding the verification and validation of systems engineering frameworks are discussed. In order to overcome the demonstrated challenges a custom verification and validation method for systems engineering frameworks was developed and applied.

Finally, Chapter 10 provides a conclusion to the research undertaken. An overview of the work completed is provided, together with a summary of significant findings. Limitations of the research and recommendations for future research are also discussed.
Chapter Two: Literature Review – Medical Device Regulation & Management
2.1 Introduction

A critical prerequisite for healthcare providers in providing safe and effective patient care is the quality of the medical devices supplied by medical device manufacturers. After delivery of the medical device, the medical device management system implemented by the healthcare organisation must ensure that the medical device is managed to ensure the initial and ongoing effectiveness and safety of the medical device.

In the following sections, international medical device regulatory systems will be discussed in terms of requirements for medical device manufacturers. Following this review of the regulatory landscape, approaches to managing medical equipment will be discussed, with a particular emphasis on extracting requirements and best practice that can/must be integrated into the Equipment Qualification framework.

2.2 Medical Device/Equipment Definitions

The EU Medical Devices Directive 93/42/EEC defines a medical device as follows:

"Medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means” (European Commission, 1993).

The term “medical devices” includes medical equipment (MHRA, 2007). Medical equipment can be interpreted as including a wide range of instruments, equipment, machinery or apparatus used for medical and para-medical purposes. The Irish Medicine Board state that medical equipment includes such devices as diagnostic imaging equipment, life support equipment, infusion pumps, endoscopes, nebulisers, laboratory analysers and point of care IVDs which are used for the treatment, management and diagnosis of patients in hospitals (Irish Medicines Board, 2006). Medical equipment includes the entire range of mechanical, electrical and electronic devices used, directly or indirectly, for the delivery of health care while excluding single use devices such as guidewires and stents and orthopaedic implants.

2.3 Medical Device Regulation

Globally there are many agencies that regulate medical devices for their respective jurisdictions. For example, in Japan the Pharmaceutical Affairs Law (PAL) and Ministerial Ordinance #169 issued by the Ministry of Health, Labour and Welfare (MHLW) specify the requirements for the quality management system of medical device manufacturers. In Australia, the device must be included in the Australian Register of Therapeutic Goods (ARTG) which is regulated by the Australian Therapeutic Goods Administration. Health Canada is the agency that regulates medical devices in Canada. Medical device manufacturers who want to sell their devices in the United States must comply with 21 CFR Part 820 of US law. In Europe, obtaining regulatory approval to sell medical devices involves securing CE marking for the product.
Regulatory agencies issue standards that provide ‘best practice’ guidance from pre-design to post-end-of-life, for medical devices. Standards can be described as vertical or horizontal, depending on how broad they are. A vertical standard is specific to a device, and a horizontal standard applies to a wide range of devices. While there are numerous international regulatory agencies, for Irish organisations the United States FDA Quality System Regulation (QSR) and the European medical device directives are of most relevance (Hale and Sheil, 2010). There are three primary European medical device directives, each of which has been transposed into Irish law by way of Statutory Instrument:

- S.I. No. 304 of 2001 transposed Directive 98/79/EC concerning In-vitro Diagnostic Medical Devices (IVDs)

The Health Products Regulatory Authority (HPRA)\(^5\) is the Competent Authority for medical devices in Ireland. The HPRA has responsibility under legislation to ensure that manufacturers of medical devices and the medical devices they place on the market meet the requirements of the relevant medical device directives for the protection of the patient, user and others involved in the use of medical devices.

### 2.3.1 Medical Device Conformity Assessment

Before a medical device can be sold within Europe, there must be a CE Mark visible on the device itself or on the packaging. The CE mark is a legally binding statement by the manufacturer that their product has met all of the requirements of the Medical Devices Directive (MDD 93/42/EEC), In Vitro

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\(^5\) Formerly known as Irish Medicines Board (IMB), the HPRA was established in July 2014 with the role of protecting and enhancing public and animal health by regulating medicines, medical devices and other health products.
Chapter Two: Medical Device Regulation & Management

Diagnostic Device Directive (IVD 98/79/EC) or the Active Implantable Medical Device Directive (AIMD 90/385/EEC), where applicable.

The classification of medical devices in the European Union is outlined in Annex IX of the Council Directive 2007/47/EC. Classification is based on the medical device design complexity, its usage characteristics, and its potential to cause harm if misused. The key characteristics considered are duration of contact of the device with the patient, degree of invasiveness, whether or not the device is active and the part of the body affected. There are four classes, ranging from low risk to high risk, as shown in Table 2.1

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Risk Level</th>
<th>Examples of Devices</th>
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<tr>
<td>I</td>
<td>Low Risk</td>
<td>Bandages, tongue depressors.</td>
</tr>
<tr>
<td>IIa</td>
<td>Medium Risk</td>
<td>Electrocardiographs, ultrasonic diagnostic equipment.</td>
</tr>
<tr>
<td>IIb</td>
<td>Higher Risk</td>
<td>Incubators, linear accelerators, Lung ventilators.</td>
</tr>
<tr>
<td>III</td>
<td>Highest Risk</td>
<td>Cardiovascular catheters, Prosthetic heart valves, Total hip, knee and shoulder joint replacements systems</td>
</tr>
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Table 2.1: Medical Device Classification

The CE mark conformity assessment procedures as directed by the Medical Device Directive 2007/47/EC are dependent on this classification system.

Class I
The manufacturer is responsible for ensuring that his product complies with the relevant directive and must draw up a written statement to this effect (self-declaration). Additionally manufacturers of sterile products and devices with a
measuring function must apply to a Notified Body\(^6\) for certification of the aspects of manufacture relating to sterility or metrology. Once the manufacturer is satisfied that the product meet all the relevant essential requirements, the device can then be CE marked and placed on the market (MHRA, 2008).

**Class IIa**

As for Class I, the manufacturer declares conformity with the provisions of the directive and regulations and ensures that products comply with relevant essential requirements. However, for Class IIa products, this declaration must be backed up in all cases with conformity assessment by a Notified Body. This assessment may, at the manufacturer’s choice, consist of one of the following:

i. Examination and testing of each product or homogenous batch of products

ii. Audit of the production quality assurance system elements of ISO 13485 (excluding design)

iii. Audit of final inspection and testing elements of ISO 13485 (excluding design & manufacture)

iv. Audit of the full ISO 13485 quality assurance system

**Class IIb**

A Notified Body must carry out either an audit of the full quality assurance system (ISO 13485), or a type-examination plus one of the three options given in items i - iii above for Class IIa.

**Class III**

Class III controls are similar to those for Class IIb devices but additionally require the manufacturer to submit the design dossier to the Notified Body for approval.

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\(^6\) Notified Bodies are designated by the Competent Authority to carry out conformity assessment of medical devices. In Ireland, the National Standards Authority of Ireland (NSAI) has been approved as a Notified Body by the HPRA.
2.3.2 Medical Device Incident Reporting

In both the EU medical device directives and FDA regulations mechanisms are provided to identify and monitor significant adverse events involving medical devices. The EU Medical Devices Directive (MDD) operates a vigilance system as a process of notification and evaluation of adverse incidents involving medical devices. The directive requires medical device manufacturers to report certain types of incidents to the national Competent Authority. The HPRA as the competent authority for Ireland is obliged to manage a reporting system for adverse incidents associated with the use of medical devices in Ireland. The FDA operates a similar Medical Device Reporting (MDR) mechanism.

Medical device incident reporting systems are intended to protect the health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated and to correct product problems. During acceptance testing of medical devices in healthcare it is important to be cognisant of the incident reporting systems. Any deviation from expected results or hazards identified may need to be reported to the relevant authority.

2.4 Medical Device Management in Healthcare

Medical device management programs are established in hospitals to provide safe and reliable operation of medical equipment and promote effective utilisation through defining procedures and policies to manage activities related to medical equipment, from their selection and acquisition to decommission (Stiefel, 2009).

The World Health Organisation (WHO) recognises the importance of medical device management in contributing to the provision of quality health care. A ‘cradle to grave’ consideration of the management process is recommended, beginning with understanding the needs of the country, region, community or facility and ending with decommissioning (WHO, 2014). Healthcare providers
have implemented medical device management programs at international level (TJC, 2014), national level (MHRA, 2014a, HSE, 2010a) and at organisational level.

In the following sections the primary international, national and facility level documents will be discussed with particular emphasis on the aspects of the documents related to acceptance testing of medical equipment.

2.4.1 Joint Commission

The Joint Commission is an international, independent non-profit organisation responsible for the accreditation and certification of health care organisations. The stated mission of the Joint Commission is to continuously improve health care for the public by evaluating health care organisations and inspiring them to excel in providing safe and effective care of the highest quality and value.

The Joint Commission’s Environment of Care standards (Joint Commission, 2007) require healthcare facilities to have documented and implemented management plans for each of seven elements: safety, security, hazardous materials and waste, emergency management, fire safety, equipment, and utility systems. The Joint Commission standard EC.01.01.01 acknowledges that risks are inherent in the equipment and materials necessary to provide care. The standard recommends that the best way to manage these risks is through a systematic approach that involves the pre-emptive evaluation of the harm that could occur in the use of medical equipment. Furthermore the standard advocates the use of high level management plans, which address the scope and objectives of risk assessment and management, to help the hospital manage risks.

Sections EC.02.04.01 and EC.02.04.03 of the Environment of Care standards are particularly relevant to the management of medical equipment. Standard EC.02.04.01 concerns the management of medical equipment risks and includes the following elements of performance (EPs):
The hospital maintains either a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use and equipment incident history.

The hospital evaluates new types of equipment before initial use to determine whether they should be included in the inventory.

The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers’ recommendations or with strategies of an alternative equipment maintenance (AEM) program.

The hospital’s activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers’ recommendations:

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining be in accordance with the manufacturers’ recommendations, or otherwise establishes more stringent maintenance requirements
- Medical laser devices
- Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)
- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies

A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternate manner that includes the following:

- How the equipment is used, including the seriousness and prevalence of harm during normal use
- Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm
- Availability of alternative or back-up equipment in the event the equipment fails or malfunctions
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- Incident history of identical or similar equipment
- Maintenance requirements of the equipment

EC.02.04.03 concerns the inspection, testing and maintenance of medical equipment and includes the following elements of performance (EPs):

- Before initial use of medical equipment the organisation performs safety, operational and functional checks.
- The organisation documents all activities in the inspection, testing and maintenance of specified equipment.

2.4.2 ANSI/AAMI EQ56

ANSI/AAMI EQ56:2013 Recommended Practice for a Medical Equipment Management Program is a document which specifies criteria for a management program designed to minimise risks associated with medical equipment and to help ensure that a medical device is used safely and effectively. EQ56 was developed by the clinical engineering community, who saw the need to develop a document to provide a detailed set of guidelines that would help hospitals understand the elements of an equipment management program from the perspective of equipment management experts. EQ56 aims to complement the Joint Commission standards by expanding on some of the details that define an effective equipment management plan (Hertz, 2004).

EQ56 details procedures and practices under the categories of leadership, inventory, equipment safety, inspection and planned maintenance program, repair program and resources. EQ56, like the Joint Commission standards, does not prescribe specific actions. Instead, EQ56 recommends practices for consideration in developing an equipment management plan, it is the responsibility of healthcare facilities to utilise the recommendations to meet their own unique challenges. As noted by Hertz (2004) hospitals support different patient populations, have different mixes of equipment and have access to different levels of resources. Therefore, EQ56 does not mandate a
single level of activity for each hospital. Instead, the philosophy of EQ56 is best summarised as; “Say what you do, and then do what you say” (Hertz, 2004).

Policies for receiving a new device are covered in Section 5.2.2 Acceptance Testing, which requires that as new equipment arrives in the hospital, it must be acceptance tested to show that is in proper working condition before it is used on patients. While this section emphasises the importance of communication between stakeholders, the guidance provided for acceptance testing activities is limited.

**2.4.3 UK Medicines and Healthcare Products Regulatory Agency**

The Medicines and Healthcare Products Regulatory Agency (MHRA) is an executive agency of the United Kingdom (UK) Department of Health which is responsible for regulating all medicines and medical devices in the UK (MHRA, 2014b). The MHRA document ‘Managing Medical Devices: Guidance for Healthcare and Social Services Organisations’ outlines a systematic approach to the acquisition, deployment, maintenance, repair and disposal of medical devices. The document is intended primarily for people in hospital and community based organisations that are responsible for the management of reusable medical devices, to help them set up and develop systems that promote the use of medical devices for safe and effective health care (MHRA, 2014a).

Managing Medical Devices details guidance under the categories of systems of management, appropriate acquisition and selection of devices, clinical investigations involving non-CE marked medical devices, receiving a new device, training, instructions for use, maintenance and repair, decontamination, decommissioning and disposal of devices. Section 5 of the Managing Medical Devices document, which concerns receiving a new device, advises that simple checks on delivery can save time and avoid trouble; finding out that a device is broken or inappropriate only when someone tries to use it for the first time can delay or interrupt treatment and invalidate warranties (MHRA, 2014a). The
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document recommends that healthcare organisations should keep records of delivery inspection and any safety or functional tests for the following reasons:

- Health and safety inspectors require records to be available
- A defence in a negligence case based on good device management can only be effective if records are available for the device involved
- Recording the individual device or batch details on a validated and secure database means it can subsequently be traced for maintenance or for a manufacturer’s recall/field correction

The MHRA advocate risk assessment before first use for devices manufactured outside the scope of the medical devices regulations (e.g. in house manufactured products), devices which have, or may have, been used before and devices within the scope of the medical devices regulations which are not CE marked (e.g., devices custom made for a named patient). While it is recommended that risk assessment may mean local testing and the issue of a local safety certificate to confirm that the device is safe and effective, the document does not give guidance on tools or techniques appropriate for this risk assessment.

The Managing Medical Devices document provides guidance on what checks and tests should cover delivery checks and safety and calibration checks\(^7\), and the skills required to carry them out. This guidance is presented in Table 2.2 for delivery checks and Table 2.3 for safety and calibration checks.

---

\(^7\) The MHRA advise that these checks will be dependent on device type.
<table>
<thead>
<tr>
<th><strong>Paperwork / database</strong></th>
<th><strong>Delivery check</strong></th>
<th><strong>Knowledge required</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Is the device compatible with specification set out in the purchase order?</td>
<td>Familiarity with:</td>
</tr>
<tr>
<td></td>
<td>• Have the user, repair and maintenance information, compliance and</td>
<td>• Ordering system</td>
</tr>
<tr>
<td></td>
<td>calibration certificates, as well as test results been included, where relevant?</td>
<td>• Inventory system</td>
</tr>
<tr>
<td></td>
<td>• Add device details, asset number and serial number on to device management</td>
<td>• Names and appearances of common</td>
</tr>
<tr>
<td></td>
<td>records.</td>
<td>medical devices</td>
</tr>
<tr>
<td></td>
<td>• Does the device (or any component part or accessory) need decontaminating</td>
<td>• Medical device documentation</td>
</tr>
<tr>
<td></td>
<td>before first use?</td>
<td>(Instructions for Use, certificates etc.)</td>
</tr>
<tr>
<td></td>
<td>• Are the instructions for use appropriate?</td>
<td>• Serial numbers and model identification</td>
</tr>
<tr>
<td></td>
<td>• Does the device require validation?</td>
<td>codes</td>
</tr>
<tr>
<td></td>
<td>• Are the Decontamination instructions appropriate?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Visual inspection</strong></th>
<th><strong>Delivery check</strong></th>
<th><strong>Knowledge required</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Is the outer packaging intact and undamaged?</td>
<td>• Knowledge of areas to check for damage</td>
</tr>
<tr>
<td></td>
<td>• Is there any damage apparent to the device on inspection?</td>
<td>• Familiarity with the appearance of product</td>
</tr>
<tr>
<td></td>
<td>• Is there an appropriate: expiry date, CE marking, Notified Body</td>
<td>in good condition and common defects</td>
</tr>
<tr>
<td></td>
<td>number, electrical class, lot number, quantity in pack, storage</td>
<td>• Knowledge of medical devices and their use</td>
</tr>
<tr>
<td></td>
<td>information for unopened pack etc.?</td>
<td>• Knowledge of electrical class symbols.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Configuration</strong></th>
<th><strong>Delivery check</strong></th>
<th><strong>Knowledge required</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Configure the medical device in such a way as to ensure compatibility</td>
<td>• Knowledge and understanding of the</td>
</tr>
<tr>
<td></td>
<td>with all other equivalent medical devices in the healthcare organisation</td>
<td>medical device and its clinical application</td>
</tr>
<tr>
<td></td>
<td>and with its clinical requirements.</td>
<td>• Knowledge and understanding of the impact</td>
</tr>
<tr>
<td></td>
<td>• Where this is a new medical device discuss with and get agreement</td>
<td>of configuration changes on clinical care</td>
</tr>
<tr>
<td></td>
<td>from the responsible clinical manager/director as to how the device(s)</td>
<td>• Knowledge of how to configure this</td>
</tr>
<tr>
<td></td>
<td>should be configured, documenting the decision with reasons, where appropriate.</td>
<td>particular device.</td>
</tr>
</tbody>
</table>

Table 2.2: MHRA Basic guidance on delivery checks
<table>
<thead>
<tr>
<th></th>
<th>Safety and calibration checks</th>
<th>Knowledge required</th>
</tr>
</thead>
</table>
| **Functional check**<br>Note: This may require more extensive checks by specialist staff for complex or specialist device. | • Does the device function in line with the manufacturer’s information?  
• Are accessories/parts included and compatible?  
• Do indicators and displays function correctly in line with the manufacturer’s information when powered up?*  
• When powered up, does the device start when it should and do the dials and switches do what they say?* | • For some devices, the skills required will be little more than basic training to allow the manufacturer’s information to be followed.  
• In cases where the manufacturer’s instructions specify specialist assembly or manipulation, familiarity with the functions of the device and its components and accessories is required. |
| **Electrical check**<br>(basic safety)  | • Are the mains leads, plugs and other connectors undamaged?  
• Are the mains plugs compatible with the sockets used in the UK (BS 1363/A)?  
• Mains adapters should not be used on medical devices. | • Training in visual electrical safety inspection techniques. |
| **Calibration and measurement** | Where appropriate, use test device to check:  
• Accuracy of physiological measurements  
• Dose delivery*  
• Energy delivery*  
• Accuracy of other outputs*  
*only for active devices | • Tests should be carried out by an adequately trained and appropriately qualified person. |

*Table 2.3: MHRA Basic guidance on safety and calibration checks*
2.4.4 Health Service Executive

The Medical Devices/Equipment Management Policy (Incorporating the Medical Devices Management Standard) was developed by the Health Service Executive (HSE) in Ireland to ensure compliance with requirements of legislation and guidance from the European Union (EU), the Health Information and Quality Authority (HIQA) the Irish Medicines Board, the Health and Safety Authority (HSA), the National Standards Authority of Ireland (NSAI) and the Electro-Technical Council of Ireland (ETCI) (HSE, 2010a). The overall objective of the Medical Devices/Equipment Management Policy is to provide an organisation wide framework for the management of Medical Devices/Equipment and to ensure that the highest standards of device safety, risk management and financial efficiency are realised in the management of the device (HSE, 2010a).

The policy argues that the use of a standards based approach can ensure safe, efficient and high quality management of all medical devices. The objective of the policy, for HSE facilities, is stated as follows:

“There is a system in place which ensures that all risks associated with acquisition and use of Medical Devices and Equipment are minimised.”

The standard details 26 supporting criteria describing a ‘system of internal control’(HSE, 2010b). In regard to the goals of this thesis the most relevant criteria are items 4, 6, 7, 8, 9, 12, 18, 21, 22 and 24. Criterion 4 states that Service Areas have a responsibility to identify and develop procedures to support all elements of the lifecycle; notably including the installation of new medical devices and equipment.

Criterion 6 requires that all medical device developments, modifications and trials are conducted in accordance with relevant legislation and guidance. Risk assessment and the application of best practice in the appraisal of the device is particularly important for such devices as the original manufacturer’s liability will
be limited and liability may be partly or wholly transferred to the organisation or person making the modifications if the device is implicated in an adverse incident (HSE, 2010b).

Criterion 7 requires that delivery and pre-use checks are carried out on all newly delivered Medical Devices/Equipment. The standard states that it is the responsibility of clinical engineering to ensure that new equipment is subjected to an acceptance test procedure. Performance, safety, commissioning and the training of staff to support the end-users should be part of the acceptance test procedure. Delivery checks should include that checking that the correct product, complete with usage and maintenance information and any relevant accessories, has been supplied and ensuring that devices have been delivered in good condition. When a piece of equipment needs to be installed, there should be a procedure for commissioning the installation, which has been agreed with the supplier and the organisation responsible for carrying it out. Criterion 7 also identifies the delivery and pre-use stage of the medical device lifecycle as the appropriate phase to set in place procedures for the management of training needs, planned preventative maintenance, technical support of users and risk assessment. Requirements for risk assessment mirror those of the MHRA Managing Medical Devices document as shown in Table 2.4.

<table>
<thead>
<tr>
<th>Category of Devices Requiring Risk Assessment</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical devices manufactured outside the scope of the Medical Devices Regulations.</td>
<td>Purchased by an individual outside EU.</td>
</tr>
<tr>
<td></td>
<td>In-house manufacture.</td>
</tr>
<tr>
<td>Equipment which has, or may have, been used before.</td>
<td>Bought second-hand.</td>
</tr>
<tr>
<td></td>
<td>Lent by another responsible organisation.</td>
</tr>
<tr>
<td></td>
<td>Equipment reissued to second or subsequent users.</td>
</tr>
<tr>
<td>Devices within scope of Medical Devices Regulations, but not CE marked.</td>
<td>Custom-made for a named patient.</td>
</tr>
<tr>
<td></td>
<td>Under clinical investigation.</td>
</tr>
</tbody>
</table>

Table 2.4: HSE Policy for Risk Assessment of Medical Devices
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Criterion 8 requires that all newly delivered medical devices/equipment are properly stored after acceptance, stating that at a minimum, all medical devices in equipment stores, pools and libraries should be subjected to performance and quality assurance tests prior to reissue. Criterion 9 states the manufacturer is responsible for issuing clear and accurate instructions and that any shortcomings in the instructions should be reported to the relevant authority as an adverse incident.

Criterion 12 requires that all medical equipment is properly maintained and repaired; stating that preventative maintenance schedules should be based on the manufacturer’s recommendations and managed by the Clinical Engineering department as otherwise the provider will carry increased liability in any subsequent litigation. The standard also lists criteria for planned preventative maintenance of Medical Devices/Equipment as detailed in Table 2.5.
<table>
<thead>
<tr>
<th>Heading</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service interval</td>
<td>Should be based on the manufacturer’s recommendation, taking into account how much the equipment will be used.</td>
</tr>
</tbody>
</table>
| Initial inspection       | • Is the device clean?  
• Does it need decontaminating?  
• Note settings of controls.  
• Inspect each element in line with manufacturer’s instructions.                                                                                           |
| Parts replaced           | • Note each item/part to be replaced.  
• Record each items/part replaced, including details of source manufacturer and method of fitting.                                                                                                      |
| Calibration              | • Establish if any element/part requires calibration or re-calibration.  
• Calibrate in line with the manufacturer’s instructions.                                                                                                                                                    |
| Performance and safety checks | Carry out performance tests against the manufacturer’s specifications before and after maintenance.                                                                                                           |
| Decontamination          | Is Decontamination Certificate completed?                                                                                                                                                                |
| Return-to-use            | • Input all details on individual equipment record in the maintenance database.  
• Check the device has its accessories, where appropriate, and is properly assembled.  
• Return controls either to zero or to the settings noted at initial inspection.  
• Stick on a dated ‘JUST SERVICED’ label, and a note of any alterations in control settings.                                                                 |
Medical devices are seen as high risk and therefore must have management systems in place.

- Are staff-related occupational safety, health and welfare risks identified, assessed and managed and are arrangements in place to ensure the management of occupational health, safety and welfare?
- Are environmental and fire safety risks identified, assessed and managed and are arrangements in place to ensure that environmental and fire risks are minimised through meeting legislative and mandatory requirements?

Criterion 21 and 22 concern training, requiring that all end users and technical supervisors must be trained in the safe operation of medical devices/equipment.

The standard states that where relevant, training should cover:

- Any limitations on the use of the device
- How to fit accessories and to be aware of how they may increase or limit the use of the device
- How to use any controls appropriately
- The meaning of any displays, indicators, alarms etc., and how to respond to them
- Requirements for maintenance and decontamination, including cleaning
- How to recognise when the device is not working properly and know what to do about it
- Understanding the known pitfalls in the use of the device, including those identified in safety advice from the IMB, manufacturers and other relevant bodies
- Understanding the importance of reporting device-related adverse incidents to the IMB.

Criterion 24 reflects the central purpose of this thesis where it states a requirement that healthcare organisations should participate in benchmarking its management of medical devices/equipment.
2.4.5 Health Products Regulatory Authority

The Health Products Regulatory Authority\(^8\) (HPRA) is an Irish state agency whose role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products. In relation to the management of medical devices in healthcare the HPRA has published the following Medical Device Safety Notices:

- SN2003(08) Equipment Management: Guidance for the Maintenance and Timely Replacement of Medical Equipment
- SN2003(09) Equipment Management: Some basic Principles of Equipment Management
- SN2006(03) The Procurement and Commissioning of Medical Equipment in Hospitals
- SN2007(06) Medical Devices Recommended by Healthcare Institutions for use in a Community Setting

SN2003(08) Equipment Management: Guidance for the Maintenance and Timely Replacement of Medical Equipment was issued as a guide for those responsible for purchasing, installation, commissioning, scheduled maintenance and repair of medical devices in hospitals to address the issue that continued use of equipment that has surpassed its recommended life span may result in undesirable effects. This Safety Notice argues that the factors that have the greatest impact on device safety are training and maintenance and therefore, provides guidance on both these issues. In relation to the scope of Equipment Qualification the Safety Notice recommends the following actions before initial use of a device:

- Conduct an acceptance test

\(^8\) Formerly known as Irish Medicines Board (IMB), the change in name to HPRA was made in July 2014 to better reflect the broad remit and regulatory functions of the agency. The HPRA have not rebranded previously released documents, therefore pre-July 2014 documents are referred to as IMB documents
Check leads, probes, ancillary pipework are in good order and properly installed
• Check reassembly if the device had been dismantled
• Conduct relevant functional and calibration checks, noting results
• Check setting and controls
• Check storage equipment
• Document all the above information on a device inventory record

SN2003(09) Equipment Management: Some Basic Principles of Equipment Management was issued to the same target audience as SN2003(08), with the broad aim of addressing the issue that poor equipment management in organisations that use medical devices can result in undesirable effects e.g. adverse incidents or near misses or delayed implementation of corrective actions. SN2003(09) lists a number of key considerations for medical device management including recommendations that acceptance checks should be carried out on all newly delivered medical devices. No further detail is given on the content or methods for acceptance testing.

SN2006(03) The Procurement and Commissioning of Medical Equipment in Hospitals provides guidance on policies and procedures for the purchase and commissioning of medical devices within an effective medical equipment management system. Given that serious problems can arise over the operational lifetime of medical equipment SN2006(03) recommends that healthcare institutions consider the implementation of a comprehensive management system for the purchase and commissioning of medical equipment to include:
• A mechanism for linking with existing medical equipment to ensure compatibility/consistency in the equipment used throughout the hospital
• A system to ensure that installation and operational qualification are addressed
• A medical device acceptance process
The Safety Notice warns that inadequate attention to detail at the purchasing and commissioning stage can result in safety implications at a later date, such issues as inadequate facilities and incompatibility with existing medical devices or consumables. The Safety Notice represents the flow of key activities for the purchase and commissioning of medical equipment as shown in Figure 2.1.
SN2006(03) is a significant document with regard to the scope of this thesis as it is the only healthcare standard or guidance document in the literature which recommends Installation and Operational Qualification. In Annex 1: Good Practice Guidelines SN2006(03) states that once the specific medical equipment has been chosen installation and operational qualification protocols should be prepared and agreed by the facility stakeholders and the manufacturer prior to the acceptance and commissioning of the medical equipment.

SN2006(03) describes installation qualification as being used to verify that the medical equipment is installed according to manufacturer’s recommendations. It is recommended that the manufacturer or suppliers representative should visit the site to ensure that the environmental conditions are suitable for the installation and operation of the medical equipment based on product specifications. SN2006(03) also lists a number of considerations for assessment as part of an IQ:

- Access e.g. door and lifts
- Physical connections
- Storage of ancillaries
- Power supply
- Ventilation
- Humidity and temperature
- Electrical Safety
- Radiation protection
- Space planning
- System Configuration
  - Interfacing of the medical device with a patient management system and/or other medical devices
- Waste disposal
- Disinfection room
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Operational Qualification, according to SN2006(03), is conducted to ensure that the medical equipment operates as intended by the manufacturer and in accordance with the product specifications. Unlike for IQ, there are no considerations given for OQ activities. SN2006(03) also mentions Performance Qualification in the narrative, stating that the user should arrange for the medical equipment to be tested independent of the manufacturers testing to ensure that the medical equipment achieves the performance claims specified by the manufacturer. However, no further detail is given.

SN2007(06) Medical Devices Recommended by Healthcare Institutions for use in a Community Setting is a Safety Notice aimed at those responsible for prescribing, distributing or placing medical devices for use in the community and is therefore outside the scope of this thesis.

2.4.6 Irish Healthcare Stakeholder Bodies

In this section the publications of stakeholders in Irish healthcare will be analysed for regulations and guidance in the field of medical equipment management.

The Commission on Patient Safety and Quality
The Commission on Patient Safety and Quality Assurance was established by the Irish Government in January 2007 to develop clear and practical recommendations which would ensure the safety of patients and the delivery of high quality health and personal social services (Madden, 2008). The Commission published its report in Building a Culture of Patient Safety (2008). The report opens with the statement that patient safety and quality are at the heart of the delivery of healthcare. The report’s recommendations provide direction on how to build a patient safety culture and recognise the importance of standards for quality and safety in this process. Effective medical device management is recommended in guidance on the themes of risk management and physical environment and resources.
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The Building a Culture of Patient Safety (2008) report also references the UK Bristol Report (Teasdale, 2002) which states that an approach to safety based on designing safer systems and equipment should be encouraged. Vincent’s Framework\(^9\) for Analysing Risk and Safety is discussed and shown to demonstrate how inadequate equipment appraisal is a latent failure in the healthcare system. No specific detail is given, however, on potential approaches to medical equipment appraisal.

**Health Information and Quality Authority (HIQA)**

The Health Information and Quality Authority (HIQA), established in May 2007 by the Health Act 2007, is responsible for driving improvements in the quality and safety of healthcare on behalf of patients through developing standards, monitoring compliance with standards and carrying out investigations where there are reasonable grounds to do so (HIQA, 2014).

The National Standards for Safer Better Healthcare document (HIQA, 2012) was developed by HIQA to provide a roadmap for improving the quality, safety and reliability of healthcare and is centred on the following dimensions of quality:

- **Person-Centred Care and Support**
  - How services place the service user at the centre of their delivery of care. This includes the concepts of access, equity and protection of rights.

- **Effective Care and Support**
  - How services deliver best achievable outcomes for service users in the context of that service, reflecting best available evidence and information. This includes the concepts of service design and sustainability.

- **Safe Care and Support**
  - How services avoid, prevent and minimise harm to service users and learn from when things go wrong.

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\(^9\) Vincent’s framework is discussed in Section 3.4.2 of this thesis
Better Health and Wellbeing

How services identify and take opportunities to support service users in increasing control over improving their own health and wellbeing.

The need for management of medical devices/equipment is recognised primarily within the theme ‘Safe Care and Support’ where Standard 3.1 states that service providers must protect service users from the risk of harm associated with the design and delivery of healthcare services. The standard advises systematic identification of aspects of the delivery of care associated with possible increased risk of harm to service users and structured arrangements to minimise these risks. Management and use of medical devices and equipment is listed as one such aspect of delivery of care. The standard further states that safe and effective management of medical devices and other equipment should be in accordance with legislative requirements, national policy, national guidelines where they exist, and best available national and international evidence (HIQA, 2012).

Health and Safety Authority (HSA)

The Health and Safety Authority (HSA) was established under the Safety, Health and Welfare at Work Act, 1989 and reports to the Minister for Jobs, Enterprise and Innovation. The HSA is the national statutory body with responsibility for ensuring that workers and those affected by work activity are protected from work related injury and ill-health through enforcing occupational health and safety law, promoting accident prevention and providing information and advice (HSA, 2014a).

In 2006 the HSA published a guidance document for the healthcare sector, ‘How to develop and implement a Safety and Health Management System’ (HSA, 2006), which outlined the key elements of a safety and health management system and described the steps to implementing and developing such a system in the healthcare sector. Section 2.5 of the guidance document ‘Implementation
and Operation’ contains the most relevant guidance in terms of this thesis; detailing responsibilities, management of the implementation process, changing attitudes and behaviour, hazard identification and the risk assessment process.

Under responsibilities the document states that accidents, ill-health and incidents are seldom random events, they generally arise from failures of control and involve multiple contributory elements. The document argues that while the immediate cause of an adverse event may be a human or technical failure, they usually arise from organisational failings which are the responsibility of management. It advises therefore that management should ensure that all their decisions reflect their safety, health and welfare intentions.

The identification of hazards is seen as an essential first step in the control of safety and health risks and should involve a critical appraisal of all activities to take account of hazards to employees and others (e.g. service users, visitors, members of the public, and contractors). Consideration should be given to hazards arising from routine and non-routine operations (HSA, 2006). The document focuses on hazards related to manual handling, slips, trips and falls and injuries due to violence as these have been reported as the three main accident types in healthcare (HSA, 2006).

In term of risk assessment, the HSA document states that a written risk assessment should be carried out to examine what could cause harm so that employers can weigh up whether they have taken enough precautions or should do more to prevent harm. The document advises that there are various qualitative and quantitative methods for carrying out risk assessment; the organisation should choose which one suits its activities most appropriately. The risk assessment should be reviewed to ensure it is valid when new equipment or technology is introduced.

When risks have been analysed and assessed, risk assessors can make decisions about workplace precautions. All final decisions about risk-control methods must
take the relevant legal requirements into account, as they establish minimum levels of risk prevention or control. In formatting control measures, appropriate consideration needs to be given to the Principles of Prevention, which detail a hierarchy of control measures to be used as outlined in Schedule 3 of the Safety, Health and Welfare at Work Act 2005. In relation to the management of medical equipment these include:

- Avoidance of risks
- Evaluation of unavoidable risks
- Combating of risks at source
- Adaptation of work to the individual, especially as regards the design of places of work, the choice of work equipment, and the choice of systems of work, with a view, in particular, to alleviating monotonous work and work at a predetermined work rate and to reducing their effect on health
- Adaptation of the place of work to technical progress
- Replacement of dangerous articles, substances, or systems of work by non-dangerous or less dangerous articles, substances, or systems of work
- Giving priority to collective protective measures over individual protective measures
- Development of an adequate prevention policy in relation to safety, health and welfare at work, which takes account of technology, organisation of work, working conditions, social factors, and the influence of factors related to the working environment
- Giving appropriate training, instruction and supervision to employees

In guidance material for work equipment in healthcare published (HSA, 2014b), the HSA advise that new medical products should be CE marked, come with a Declaration of Conformity and be supplied with user instructions written in English. The HSA provide substantial guidance on considerations which should be observed to ensure that medical equipment is safe and does not present a risk to those who come into contact with it. In terms of the appraisal of equipment before being put into service the following must be considered:
• Use equipment only for the operations and under the conditions for which it is appropriate
• Ensure the compatibility of items of equipment which are used together e.g. patient slings and hoists, beds and bedrails
• Develop a planned preventative maintenance programme to ensure equipment is kept in good repair.
• Ensure workers who carry out repairs, modifications, maintenance and servicing are competent.
• Keep records of maintenance checks, examinations, testing and servicing.
• Advise staff to check all items of equipment before use (i.e. a simple visual check) and only to use equipment that is safe. Where equipment is unsafe it must be taken out of service and sent for repair or replaced as required.
• CE marking is applicable to many products placed on the market; ensure that items purchased are CE marked where applicable. Note that CE marking is not a guarantee of quality but an indication by the manufacturer that the product complies with relevant EU Directives.
• Obtain the instructions/user manual and ensure employees have access to it where necessary for their work.
• Power cables can become damaged if not properly routed or equipment is moved while plugged in, as may be the case with electrically operated beds, hoists etc. Measures must be taken to reduce the likelihood and consequences of damage to cables in line with manufacturer’s instructions.
• Make employees aware of any health and safety risks associated with work equipment. Provide information, instructions and training to staff where required for the safe operation of equipment.
• Where guards or other protection devices are required to ensure the safe operation of equipment they must be in place before use.
• Where necessary, post warning notices and safe operating procedures alongside machines to remind operators and others of the dangers they impose and safe work practices.

**National Standards Authority of Ireland (NSAI)**

The National Standards Authority of Ireland (NSAI) is Ireland’s official standards body, who operate under the National Standards Authority of Ireland Act (1996) and are accountable to the Minister for Jobs, Enterprise and Innovation. The NSAI are the national certification authority for CE Marking of medical devices and provide a certification service to enable businesses to demonstrate that goods and services conform to applicable standards. The NSAI may have a direct interaction with healthcare facilities pursuing formal certification to an ISO quality, environmental and/or health and safety management system. Also the NSAI as a certification authority may be responsible for the CE marking of medical devices developed within the facility.

**Electro-Technical Council of Ireland (ETCI)**

The Electro-Technical Council of Ireland Limited (ETCI) is a voluntary body of nineteen organisations representative of all aspects of electro-technology in the Republic of Ireland. Formally constituted in 1972, the Council is the national body responsible for the harmonisation of standards in the electro-technical field in collaboration with the National Standards Authority of Ireland (NSAI) (ETCI, 2014). The primary roles of the ETCI are in electro-technical standardisation and the promotion of electrical safety.

Technical Committee 10 (TC 10) of the ETCI is responsible for the standardisation of electrical equipment used in medical practice. ETCI TC 10 safeguards the patient and users of electrical medical equipment by ensuring safe and effective standards for electrical medical equipment. ETCI TC 10 serves:

• Manufacturers in designing and assembling safe medical electrical equipment and systems
Chapter Two: Medical Device Regulation & Management

- Manufacturers, test houses and regulatory authorities in assessing compliance with requirements set forth in relevant international standards
- Health care professionals in managing the risks associated with use of these products (ETCI, 2013)

ET101:2008 National Rules for Electrical Installations is the governing document for electrical safety in Ireland, within this document Section 710 specifies requirements for medical installations. ET101:2008 is for use by electrical professionals. The guidance document ET218:2011 Electricity in the Medical Workplace: An Educational Guide for Users of Electrical Equipment in Medical Practice was published by the ETCI to give an overview of electricity and its use in the medical workplace setting. This document describes best practice in protection against electric shock and management of electrical systems; it can be used as a reference by healthcare stakeholders when installing new electrical medical equipment.

2.4.7 International Healthcare Providers

Medical equipment management systems and policies specific to the initial testing and evaluation of medical devices, have been developed at an organisational level in countries worldwide. Examples are the ‘Management of Medical Equipment/Medical Devices Policy’ of the Tameside Hospital in the UK, the ‘Initial Testing and Evaluation’ policy of the Duke University Health System in the USA and the ‘Biomedical Equipment – testing, labelling and tagging’ policy directive of the South Eastern Sydney Illawarra Area Health Service (SESIH) in Australia.

In terms of the acceptance testing of medical devices, Tameside Hospital focuses on administrative responsibilities and entering the device into an equipment management database. Risk assessment activities are limited to equipment that has been purchased outside of the EU, purchased second hand or custom made
devices. The Tameside Hospital policy states that assembly of the device and performance checks must be performed in line with manufacturers recommendations to ensure the accuracy of the device prior to clinical use (Tameside Hospital NHS Foundation Trust, 2011).

The ‘Initial Testing and Evaluation’ policy of the Duke University Health System in the USA (Duke University Health System, 2013) is a document whose aim is to ensure that all clinical equipment is inspected prior to its initial use and identified for inclusion/exclusion in the equipment management program. The clinical engineering department must ensure that the new equipment is inspected for:

1. Presence of all accessories required for proper operation.
3. Proper operation of the equipment as specified in the performance specifications in the manufacturer’s service literature.
4. Clinical alarm functionality and audibility.
5. Passage of electrical safety requirements as specified by applicable agencies.
6. Inclusion into, or exclusion from, the Equipment Management Program.
7. Compliance on labeling of equipment, to ensure that the equipment has been “evaluated for safety and suitability for intended use” by a nationally recognized testing laboratory as required by local laws.

If equipment passes all required inspections the clinical engineering technician will affix a Clinical Equipment Inspection sticker in a visible location on the device.

The ‘Biomedical Equipment – testing, labelling and tagging’ policy directive of the South Eastern Sydney Illawarra Area Health Service (SESIH) in Australia (SESIH, 2006) establishes the process for safety and functional testing of biomedical equipment within SESIH. This policy provides direction on acceptance testing, which the policy states usually consists of electrical safety and full functional
testing of the device. The policy lists a number of considerations for risk
minimisation for the safe, correct use of medical equipment which is intended to
be read in close consultation with the appropriate operators’ manual for specific
instructions and warnings for the device. The relevant considerations for initial
evaluation of medical equipment include:

- Close consultation with operators manual regarding specific safety
  hazards should be undertaken prior to use of any medical item
- Inspect the equipment and mains cable for damage prior to use
- Ensure all cables are placed so that they cannot incur damage during use
- Ensure all cables are placed so they do not cause a trip hazard
- Ensure locks associated with suspended equipment heads operate
correctly
- Assess weight and position of equipment and use appropriate manual
  handling guidelines for moving or lifting
- Position equipment to ensure adequate ventilation and protection
  against ingress of contaminants

The guidance and direction given in the Tameside, Duke and SESIH documents is
representative of the nature of policies of other international organisational level
policies, with an emphasis on electrical and functional safety and acceptance
testing to manufacturers’ recommendations.

2.5 Discussion

Understanding the regulation of medical devices is an important consideration in
developing a framework for Equipment Qualification in healthcare as it is
through the regulatory process that characteristics of safety and quality are
assessed by the manufacturer and third parties. The presence of a CE mark on
medical equipment assures the healthcare user that the appropriate procedures
have been adhered to in evaluating the design and controlling the manufacture
of the equipment.
The management of medical equipment in healthcare is controlled by individual hospital management. Guidance is available from international and national bodies. The Joint Commission’s Environment of Care standards and ANSI/AAMI EQ56 are useful international references for developing a macro level medical equipment management plan. The UK MHRA and the Irish HSE provide some detail on safety checks for receiving a new device. The IMB Safety Notice SN2003(08) Equipment Management: Guidance for the Maintenance and Timely Replacement of Medical Equipment is the sole guidance document which recommends the use of Equipment Qualification, though without providing explicit detail on how this may be achieved.

It is evident that guidance documents recommend the adoption of activities to pre-emptively assure the safety of medical equipment. However, the guidance for such activities is underdeveloped. An opportunity is evident, therefore, to develop comprehensive guidance for healthcare, building on the safety recommendations provided to include a wider assessment of factors that are relevant to the safe and effective use of medical equipment and the demonstration of compliance with regulatory requirements.
Chapter Three: Literature Review – Systems Engineering
Chapter Three: Systems Engineering

3.1 Introduction

The term ‘system’ has been defined by the International Electrotechnical Commission (IEC) (1998) as a:

‘set of elements which interact according to a design, where an element of a system can be another system, called a subsystem, which may be a controlling system or a controlled system and may include hardware, software and human interaction’.

Inherent within this definition is an understanding of the inter-connectivity of elements of an overall system, the varying dynamics of relationships between elements and, importantly, recognition of the role of the human in a system. Eberhardt Rechtin, in a definition that has been adopted by the International Council of Systems Engineering (INCOSE), states that a system is a:

‘construct or collection of different elements that together produce results not obtainable by the elements alone. The elements, or parts, can include people, hardware, software, facilities, policies, and documents; that is, all things required to produce systems-level results. The results include system level qualities, properties, characteristics, functions, behaviour and performance. The value added by the system as a whole, beyond that contributed independently by the parts, is primarily created by the relationship among the parts; that is, how they are interconnected’ (Rechtin, 2000).

The term ‘systems engineering’ dates back to the work of the Bell Telephone Laboratories in the 1940s (Buede, 2000). Systems engineering takes the concept of a system and applies a systematic and methodical approach to affecting its inputs, processes and/or outputs (Blanchard, 2004). Systems engineering is seen by many authors as being synonymous with the discipline of Industrial Engineering (Kopach-Konrad et al., 2007). Kossiakoff et al. (2011) emphasise the
importance of using a rigorous, structured and systematic approach to system development and the iterative nature of systems engineering in promoting continuous improvement.

There has been broad paradigm shifts in the interpretation of systems engineering, reflecting an evolution from a ‘classical’ view to an ‘expanded’ view. Classical definitions of systems engineering arose in the 1960s and 1970s, and are still widely in use today (Rhodes and Hastings, 2004). The classical definitions are fairly similar in nature, having design as a single core focus, with some variation regarding reference to it as a practice, process, method, or approach (Rhodes and Hastings, 2004). An example of a definition taking the classical view of systems engineering is:

‘Systems engineering is the process of selecting and synthesising the application of the appropriate scientific and technical knowledge to translate system requirements into system design and subsequently to produce the composite of equipment, skills, and techniques that can be effectively employed as a coherent whole to achieve some stated goal or purpose’ (Chase, 1974).

The expanded view considers systems engineering beyond the translation of requirements to design as a single core focus (Rhodes and Hastings, 2004). There are many varied definitions which reflect this expanded view.

‘A methodical, disciplined approach for the design, realisation, technical management, operations, and retirement of a system’ (NASA, 1997).
‘An engineering discipline whose responsibility is creating and executing an interdisciplinary process to ensure that the customer and stakeholder’s needs are satisfied in a high quality, trustworthy, cost efficient and schedule compliant manner throughout a system’s entire life cycle’ (INCOSE, 2006).
Chapter Three: Systems Engineering

‘The art and science of creating a product or service, based on phased efforts that involve definition, design, development, production and maintenance activities. The resulting product or service is functional, reliable, of high quality, and trustworthy and has been developed within time and cost constraints’ (Sage and Rouse, 2009).


While the themes of interdisciplinary, iteration, sociotechnical views, and totality are common within these definitions, a general consensus does not exist on what, specifically, systems engineering is and how it should be applied. This lack of a standard definition and understanding has been described by Brill (1994) as a ‘semantics jungle’, while Rhodes and Hastings (2004) argue that debate on the semantics of systems engineering has been ongoing for several decades without conclusion.

Each individual definition given in the literature tends to reflect the application domain of the authors. Cognisant of this ‘a la carte’ approach to the adoption of a definition of systems engineering for specific application domains, the following definition given by the International Council on Systems Engineering (INCOSE, 1998) is considered the best fit for clarifying the purpose of adopting a systems engineering approach in tackling the research question of this thesis:

‘An interdisciplinary approach and means to enable the realisation of successful systems’

Further supporting the adoption of a systems engineering approach is that systems engineering has been shown to be an appropriate methodology for the
inclusion of users requirements, demands and perceptions to understand how each element can be included in system development (Storey, 2006).

As a means of clearing a path through the ‘semantics jungle’ identified by Brill, the discipline of systems engineering utilises ontology engineering. An ontology is the formal representations of a set of concepts within a domain and the relationships between those concepts (Sreenivasan, 2010). Ontologies are required to assist interested parties in understanding the broad and multifaceted nature of the discipline of systems engineering (Sarder and Ferreira, 2007). Ontology engineering is the set of tasks related to the development of ontologies for a particular domain (Pouchard et al., 2000). The following sections will explore and discuss systems engineering ontologies through an analysis of prominent system engineering standards, processes and terminology.

3.2 Systems Engineering Process Development Methods

The literature presents numerous models which describe different methods for the systems engineering process. As similarly seen in the varying definitions of systems engineering, these methods tend to reflect the application domain of the authors. In reviewing these methods it is important, therefore, to be cognisant that, as advised by Blanchard (2004), that the systems engineering process should be ‘tailored’ to the individual system or program requirement.

3.2.1 Systems Engineering Standards

According to Sage and Rouse (2009) there are hundreds of thousands of specifications and standards from which the systems engineer can select when designing a system. Of these industry and government generally use ISO/IEC 15288 or EIA 632 to identify the fundamental processes and requirements necessary for a systems engineering program (Sage and Rouse, 2009).
ISO/IEC 15288

ISO/IEC 15288: Systems and software engineering - System life cycle processes approach aims to provide a ‘common process framework to improve communication and co-operation among the parties that create, utilise and manage modern systems in order that they can work in an integrated, coherent fashion’ (ISO/IEC 15288, 2008). This standard is referenced in the INCOSE Systems Engineering Handbook.

ISO/IEC 15288 lists 23 processes that cover the breadth of systems engineering and places them into the following categories:

- **Technical Processes**
  - Technical processes include stakeholder requirements definition, requirements analysis, architectural design, implementation, integration, verification, transition, validation, operation, maintenance, and disposal.

- **Project Processes**
  - Project processes include planning, assessment, control, decision-making, risk management, configuration management, and information management.

- **Enterprise Processes**
  - Enterprise processes include enterprise management, investment management, system life cycle processes management, resource management, and quality management.

- **Agreement Processes**
  - Agreement Processes address acquisition and supply.

Cook (2004), commenting on the ISO/IEC 15288 system life cycle model processes, stated that systems engineering can be considered a meta-discipline that coordinates and interacts with other related disciplines.
ANSI/EIA 632

The EIA 632 standard was developed by the Systems Engineering Committee of the Electronic Industries Alliance (EIA) and released in 1998. The standard is regarded as a ‘top tier’ standard for the processes essential to engineering a system. It is intended that the standard can help develop second and third tier standards that define specific practices related to certain disciplines (e.g., systems engineering, electrical engineering, software engineering) and industry domains (e.g., aircraft, automotive, pharmaceutical, building construction, and highway construction) (Martin, 2000). EIA 632 describes the following hierarchy of processes for engineering a system:

- **Acquisition and Supply**
  - Supply Process
  - Acquisition Process

- **Technical Management**
  - Planning Process
  - Assessment Process
  - Control Process

- **System Design**
  - Requirements definition process
  - Solution definition process

- **Product Realization**
  - Implementation process
  - Transition to Use process

- **Technical Evaluation**
  - System Analysis Process
  - Requirements Validation Process
  - System Verification Process
  - End Products Validation Process

EIA 632 views the systems engineering process as a comprehensive, iterative and recursive problem solving process. It transforms needs and requirements into a
set of system descriptions, generates information for decision-makers, and provides input for the next level of development (Leonard, 1999).

3.2.2 Systems Engineering Vee Model

The Vee Model is a systems engineering process model that originated from software development (Limbourg, 2009). The Vee model is used to visualise the system engineering focus, particularly during the concept and development stages. The model highlights the need to define verification plans during requirements development, the need for continuous validation with stakeholders and the importance of continuous risk and opportunity assessment (INCOSE, 1998).

Figure 3.1 depicts the Vee meta-model, as presented by INCOSE, wherein time and system maturity proceed from left to right. The left side of the Vee depicts the evolving baseline from user requirements agreement to identification of a system concept to definition of systems components that will comprise the final product. The right of the Vee depicts the realisation of the system and the verification of the final system achieving stakeholder requirements.

Figure Removed for Copyright Reasons

Figure 3.1: INCOSE Vee Meta-Model
Chapter Three: Systems Engineering

The Vee meta-model has been widely tailored for specific industries and applications such as laboratory information management systems, software testing, and analytical chemistry (Tracy and Nash, 2002, Lucas, 2003, Burgess, 2000).

3.3 Systems Engineering Terminology

The ‘semantics jungle’ identified by Brill (1994) remains a significant challenge in systems development due to a lack of semantic heterogeneity in the definitions of systems engineering structures (Foster et al., 2014). It is common in the literature to find terms such as reference architecture, reference framework, architectural framework and system architecture, with terms often used with similar or largely overlapping meanings (Camarinha-Matos and Afsarmanesh, 2008). The terms most frequently used to describe systems engineering constructs are architectures and frameworks.

The international standard ISO/IEC/IEEE 42010 Systems and Software Engineering — Architecture Description defines a system architecture as the ‘fundamental concepts or properties of a system in its environment embodied in its elements, relationships, and in the principles of its design and evolution’ (ISO/IEC/IEEE, 2011). Castro et al. (2002) describe system architecture as ‘a relatively small, intellectually manageable model of system structure, which describes how system components work together’. Maier and Rechtin (2000) define system architecture as ‘the structure - in terms of components, connections, and constraints - of a product, process, or element’. System architectures can be described through a range of format or media, including document-centric, model-based and repository-based approaches (ISO/IEC/IEEE, 2011).

Camarinha-Matos and Afsarmanesh (2008) view a framework as an ‘envelope’ that might include a number of models, collections of templates, procedures and methods, rules, and even tools (e.g. modelling languages). Alter (2000) states
that a framework summarises the elements a business professional should look at when analysing an existing or potential system in an organisation. In the context of business process reengineering (BPR), Reijers and Liman Mansar (2005), state that a framework is not a model of a process, it is rather an explicit set of ideas which exist to help practitioners in thinking about the business process, choosing best practice by identifying and showing the relationship between topics.

For the purposes of this thesis the term framework is deemed the most appropriate description of the research output, as it implies the inclusion of models, templates, procedures and methods which are used to help practitioners identifying topics that should be considered in choosing best practice the Equipment Qualification of medical equipment in healthcare.

### 3.3.1 Framework Development in Systems Engineering

Traditionally, large projects have employed document-based systems engineering approaches, characterised by the generation of textual specifications and design documents, in hard-copy or electronic file format, that are then exchanged between customers, users, developers, and testers. These documents and drawings represent the systems requirements and the design information (Friedenthal et al., 2011). Rashed et al. (2011) argue that in document based approaches completeness, consistency, and relationships between requirements, design, engineering analysis and test information are difficult to assess since this information is spread across several documents.

In addressing the challenges of document based approaches system developers utilise models in developing frameworks. A model is defined by INCOSE (1998) as a representation of an artefact or activity intended to explain the behaviour of some aspects of the artefact or activity. In quality assurance a model is defined as a standardised or selected set of quality system requirements combined to satisfy the quality assurance needs of a given situation (ISO 8402, 1994). Voland
Chapter Three: Systems Engineering

(2004) defines models as purposeful representations of a process, object or system which are used when a system or process is too complex, too large or insufficiently understood to implement without further evaluation. Voland (2004) further explains that models are abstractions that are used to interpret relationships and interdependencies among system components and variables that may not be recognised without the use of the model. Trochim et al. (2006) describe systems modelling as ‘a methodological tradition that involves the use of formal models or simulations as explicit aids to increase our understanding of complex systems and improve the effectiveness of our actions within them’.

A range of modeling languages has been developed to depict system models in specific domains. In enterprise modelling Integrated Enterprise Modeling (IEM), Design & Engineering Methodology for Organisations (DEMO), Dynamic Enterprise Modeling (DEM) and Enterprise Modelling Methodology/Open Distributed Processing (EMM/ODP) are widely used. In business process modelling Business Process Model and Notation (BPMN), Extended Business Modeling Language (xBML), Cognition Enhanced Natural language Information Analysis Method (CogNIAM) and Unified Modeling Language (UML) are prevalent. In functional modelling the most common languages are the Function Flow Block Diagram (FFBD), Data Flow Diagram (DFD), N2 (N-Squared) Chart, IDEFØ Diagram, Use Case, Sequence Diagram, Enhanced Function Flow Block Diagram, and Behavior Diagram (BD) (Long, 2002).

The widely used general-purpose modelling languages such as SysML and the IDEF family of modelling languages facilitate the documentation and specification of a range of system requirements. In the following sections both SysML and the IDEF family of modelling languages will be discussed in detail.

3.3.2 Systems Modeling Language (SysML)

The Systems Modeling Language (SysML) is a general-purpose graphical modeling language for specifying, analysing, designing, and verifying complex
systems (Dickerson, 2011). SysML can be used for systems that may include hardware, software, information, personnel, procedures and facilities (Vanderperren and Dehaene, 2005). SysML is an extension of the software focused Unified Modeling Language (UML) (Weilkiens, 2011) which aims to replace the wide range of modeling languages and techniques currently used for complex system development (David et al., 2010). SysML can represent many different system aspects, including:

- Structural composition, interconnection, and classification
- Function-based, message-based, and state-based behaviour
- Constraints on the physical and performance properties
- Allocations between behaviour, structure, and constraints
- Requirements and their relationship to other requirements, design elements, and test cases (Friedenthal et al., 2011)

As illustrated in Figure 3.2 there are nine different types of diagrams in SysML; package diagram, requirement diagram, activity diagram, sequence diagram, state machine diagram, use case diagram, block definition diagram, internal block diagram and parametric diagram.

![Figure 3.2: SysML Diagrams](image-url)
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The package diagram represents the organization of a model in terms of packages that contain model elements. The requirement diagram represents text-based requirements and their relationship with other requirements, design elements, and test cases to support requirements traceability. The activity diagram represents behaviour in terms of the order in which actions execute based on the availability of their inputs, outputs, and control, and how the actions transform the inputs to outputs. The sequence diagram represents behaviour in terms of a sequence of messages exchanged between systems, or between parts of systems. The state machine diagram represents behaviour of an entity in terms of its transitions between states triggered by events. The use case diagram represents functionality in terms of how a system is used by external entities to accomplish a set of goals. Block definition diagram represents structural elements called blocks, and their composition and classification. Internal block diagram represents interconnection and interfaces between the parts of a block. Parametric diagram represents constraints on property values used to support engineering analysis (Friedenthal et al., 2011).

SysML is intended to help specify and develop systems and specify their components that can then be designed using other domain-specific languages such as UML for software design and three-dimensional geometric modeling for hardware design (Friedenthal et al., 2011). Consequently, SysML is most beneficial for use in modelling the development of hardware/software integrated systems such as product design (Wölk and Shea, 2009, Follmer et al., 2010), nuclear automation (Pihlanko et al., 2013) and embedded electronic software in automobiles (Boulanger, 2008).

SysML has also attracted criticism in the literature, however. Herzog et al. (2005) argue that while the language has facilitated improved interaction between software and systems engineers, there is still a long way to go until a there is integrated tool and infrastructure support available for all engineering disciplines within organisations developing complex technical systems.
3.3.2 The IDEF Family of Modelling Languages

During the 1970s, the US Air Force Program for Integrated Computer Aided Manufacturing (ICAM) sought to increase manufacturing productivity through systematic application of computer technology. The ICAM program identified the need for better analysis and communication techniques for people involved in improving manufacturing productivity. As a result, the ICAM program developed a series of modelling methodologies, based on the then well-established Structured Analysis and Design Technique (SADT) graphical modelling method (Marca and McGowan, 1987), known as the ICAM Definition (IDEF) methods\(^\text{10}\), which include:

a) IDEF\(\Phi\), used to produce a function model.
   A function model is a structured representation of the functions within a system or subject area.

b) IDEF1, used to produce an information model.
   An information model represents the structure and semantics of information within a system or subject area.

c) IDEF2, used to produce a dynamics model.
   A dynamics model represents the behaviour of a system or subject area as it varies over time (IEEE, 1998).

IDEF\(\Phi\) has been the most widely adopted method, used as the function modelling method of choice in a large number of military and non-military organisations in both North America and Europe (IEEE, 1998).

In the IDEF family of languages, a model is a representation of a set of components of a system or subject area. The model is developed for understanding, analysis, improvement or replacement of the system. The model

\(^{10}\) There are sixteen types of IDEF modelling methods, applicable to a broad range of enterprise improvement and integration strategies (e.g., concurrent engineering, total quality management, business reengineering) (IEEE, 1998).
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describes what a system does, what controls it, what things it works on, what means it uses to perform its functions and what it produces (NIST, 1993).

In general, IDEF modelling methods are used to regiment analysis processes, such as defining as-is process models (Ling, 2005). According to Hanrahan (1995) “IDEF modelling methods facilitate an enterprise to develop a basis for process improvement projects and builds groundwork in defining information necessities”. In providing a systematic method for defining information necessities the IDEF family of languages provide an effective system representation structure. IDEFØ has particular interest for this thesis due its applicability in function modelling.

**IDEFØ Function Modelling Method**

The IDEFØ function modelling method is designed to model the decisions, actions and activities of an organisation or a system. The NIST describe IDEFØ as “an engineering technique for performing and managing needs analysis, benefit analysis, requirements definitions, functional analysis, system design, maintenance, and baselines for continuous improvement” (NIST, 1993). IDEFØ includes both a graphical modelling language and a comprehensive methodology for developing models.

IDEFØ models provide a ‘blueprint’ of functions and their interfaces that must be captured and understood in order to make systems engineering decisions that are logical, affordable, integratable and achievable. The IDEFØ model reflects how system functions interrelate and operate just as the blueprint of a product reflects how the different pieces of a product fit together (NIST, 1993).

An IDEFØ model is composed of a hierarchical series of diagrams that gradually display increasing levels of detail describing functions and their interfaces within the context of a system. IDEFØ models illustrate what functions the system performs, what constraints the functions have, what is needed for functions, and what input and output are meaningful in performing those functions (Mayer et
There are three types of diagrams: graphic, text, and glossary. The graphic diagrams contain boxes, arrows, and box/arrow interconnections which reflect associated relationships. Boxes represent each major function of the subject being modelled. These functions are broken down or decomposed into more detailed diagrams, until the subject is described at a level necessary to support the goals of a particular project. The top-level diagram (A-0) in the model provides the most general or abstract description of the subject represented by the model. The text and glossary diagrams provide additional information in support of graphic diagrams (NIST, 1993).

An important concept in the IDEFØ method is the abstraction from time, as the IDEFØ diagrams show activation of activities, rather than flow sequences (Kelly, 2011).

Figure 3.3 is a graphic representation of the A-0 context diagram for an activity, illustrating how IDEFØ is used to depict activities, inputs, outputs, controls, and mechanisms (ICOMs).

The elements of ICOMs are as defined as follows:

- Inputs are data or objects that are consumed or transformed by an activity.
- Outputs are data or objects that are the direct result of an activity.
Controls are data or objects that specify conditions that must exist for an activity to produce correct outputs.

Mechanisms (or resources/tools) support the successful completion of an activity, but are not changed in any way by the activity.

In healthcare, IDEFØ has been used to simplify communication between medical experts and non-medical experts (Cempel and Dąbal, 2014).

3.4 Systems Engineering in Healthcare

Healthcare delivery is a complex system. Effken (2002) describes health care as a complex dynamic sociotechnical system. Sociotechnical systems constitute three major elements; a technological subsystem, a personnel subsystem and a work system\(^{11}\). These three elements interact with each other and a fourth element, the relevant aspects of the external environment, on which the work system is dependent for its survival and success (Hendrick, 2007).

Carayon et al. (2011) contend that due to the great complexity inherent in health care, it is important to adopt a systems approach aimed at identifying the multiple system elements, their interactions and their impact on quality of care, as well as understanding the key adaptive role of people in the system. Systems engineering provides an approach for healthcare that involves anticipating ineffective processes and designing interventions to overcome such shortcomings (Padula et al., 2014).

The primary systems engineering models and frameworks used in macro level analyses in healthcare are Reasons Swiss Cheese Model, Vincent’s Framework, Haddon Matrix, Donabedian’s Structure, Process, Outcome (SPO) Model and the Systems Engineering Initiative for Patient Safety (SEIPS) model. In the following

---

\(^{11}\) The work system is comprised of the organisations structure and processes
sections each will be discussed, cognisant of how each approach may inform the development of an Equipment Qualification framework for healthcare.

3.4.1 Reason’s Swiss Cheese Model

Reason’s Swiss cheese model, depicted in Figure 3.4, is based on the multifactorial nature of system accidents and has become the dominant paradigm for analysing medical errors and patient safety incidents (Perneger, 2005). In this model an analogy is drawn between the layers of ‘defence’ in healthcare processes and slices of Swiss cheese, the holes in the Swiss cheese represent opportunities for a process to fail. An error or failure may allow a problem to pass through a hole in one layer, but in the next layer the holes are in different places, and the problem should be caught. For a catastrophic failure to occur, the holes need to align for each step in the process allowing all defences to be defeated and resulting in a failure.

Figure Removed for Copyright Reasons

Figure 3.4: Reason's Swiss Cheese Model (Reason, 2000)

The model is formed on the concept of two distinct types of errors/failures; latent and active. Latent errors develop from the decisions made by designers, builders, procedure writers and top level management and can lie dormant within a system for many years. Active failures are the unsafe acts committed by people who are in direct contact with the system and often take the form of
slips, lapses, mistakes and procedural violations (Reason, 2000). Reason argues that the existence of ‘holes’ within each defence layer does not normally cause a bad outcome, but an incident occurs when the holes line up to permit a trajectory of accident opportunity. The Equipment Qualification framework can provide an opportunity to identify some of these holes through addressing latent errors and potential causes of active errors.

### 3.4.2 Vincent’s Framework

Building upon Reason’s Swiss Cheese Model, Vincent (2011) published a model of organisational accident causation within patient safety. In this model seven categories of factors are identified which influence clinical practice:

1. Institutional factors
2. Management and organisational factors
3. Work environment
4. Team factors
5. Individual staff factors
6. Task factors
7. Patient factors

Figure 3.5 depicts Vincent’s framework. In this framework the accident sequence is shown to begin (from the left) with the negative consequences of organisational processes, such as planning, scheduling, forecasting, design, maintenance, strategy and policy. The created latent conditions are transmitted along various organisational and departmental pathways to the workplace (the operating theatre, the ward, etc.), where they create the local conditions that promote the commission of errors and violations (e.g. high workload or poor human equipment interfaces) (Vincent, 2011).
Vincent (2011) argues that the model presents the people at the sharp end as the inheritors rather than as the instigators of an accident sequence.

Table 3.1 presents Vincent’s taxonomy for classifying the error producing conditions and organisational factors which affect clinical practice. This taxonomy is a particularly useful for reference when risk assessment of medical equipment and its use environment is being conducted.
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Characteristics</td>
<td>Clinical condition (complexity and seriousness)</td>
</tr>
<tr>
<td></td>
<td>Language and communication</td>
</tr>
<tr>
<td></td>
<td>Personality and social factors</td>
</tr>
<tr>
<td>Task and Technology factors</td>
<td>Task design and clarity of structure</td>
</tr>
<tr>
<td></td>
<td>Availability and use of protocols</td>
</tr>
<tr>
<td></td>
<td>Availability and accuracy of test results</td>
</tr>
<tr>
<td></td>
<td>Decision making aids</td>
</tr>
<tr>
<td>Individual (staff) factors</td>
<td>Knowledge and skills</td>
</tr>
<tr>
<td></td>
<td>Competence</td>
</tr>
<tr>
<td></td>
<td>Physical and mental health</td>
</tr>
<tr>
<td>Team Factors</td>
<td>Verbal communication</td>
</tr>
<tr>
<td></td>
<td>Written communication</td>
</tr>
<tr>
<td></td>
<td>Supervision and seeking help</td>
</tr>
<tr>
<td></td>
<td>Team leadership</td>
</tr>
<tr>
<td>Work Environment factors</td>
<td>Staffing levels and skills mix</td>
</tr>
<tr>
<td></td>
<td>Workload and shift patterns</td>
</tr>
<tr>
<td></td>
<td>Design, availability and maintenance of equipment</td>
</tr>
<tr>
<td></td>
<td>Administrative and managerial support</td>
</tr>
<tr>
<td></td>
<td>Physical environment</td>
</tr>
<tr>
<td>Organisation and Management factors</td>
<td>Financial resources and organisational structure</td>
</tr>
<tr>
<td></td>
<td>Organisational structure</td>
</tr>
<tr>
<td></td>
<td>Policy, standards and goals</td>
</tr>
<tr>
<td></td>
<td>Safety culture and priorities</td>
</tr>
<tr>
<td>Institutional Context factors</td>
<td>Economic and regulatory context</td>
</tr>
<tr>
<td></td>
<td>National health service executive</td>
</tr>
<tr>
<td></td>
<td>Links with external organisations</td>
</tr>
</tbody>
</table>

Table 3.1: Vincent’s Taxonomy
3.4.3 Haddon Matrix

The Haddon matrix (or Haddon model) is a method to address injury prevention systematically, analysing injuries in terms of causal factors and contributing factors, rather than just using a descriptive approach (Marcinko, 2011). Applications of the model have included road safety (Murray et al., 2014), risk assessment of sharps injury in emergency departments (Ganczak et al., 2007) and analysis of causes of medical error (Brasel et al., 2000). Table 3.2 below demonstrates an application of the Haddon Matrix in addressing the problem of injuries to children falling on playgrounds.
<table>
<thead>
<tr>
<th></th>
<th><strong>Host</strong> (children on the playground)</th>
<th><strong>Agent/vehicle</strong> (specific playground equipment and devices)</th>
<th><strong>Physical environment</strong> (overall playground design)</th>
<th><strong>Social environment</strong> (community norms, policies, rules)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-event</strong> (before the fall)</td>
<td>Teach children to follow safety rules on the playground (e.g., no crowding on the climbing equipment)</td>
<td>Construct equipment with tacky grips, sized to children’s hands, to reduce the risk of hands slipping</td>
<td>Build sliding boards into hillsides so children do not have to climb to heights</td>
<td>Foster social norms that encourage adults to help maintain orderly play on the playground</td>
</tr>
<tr>
<td><strong>Event</strong> (during the fall and time of impact)</td>
<td>Teach children to fall in ways that reduce injury</td>
<td>Reduce the number of protrusions on equipment so falling children do not hit sharp components</td>
<td>Ensure the presence of resilient surfacing</td>
<td>Organize community-watch systems to monitor playground safety (e.g., maintaining surfacing)</td>
</tr>
<tr>
<td><strong>Post-event</strong> (after the child is injured by the fall)</td>
<td>Teach children how to summon help when injuries occur (e.g., using emergency call boxes)</td>
<td>Avoid equipment in which children can fall into areas not easily reached by rescue personnel</td>
<td>Provide benches for supervisors that afford good visibility of all playground areas to facilitate noticing when children are injured</td>
<td>Ensure funding for adequate emergency personnel appropriately equipped to deal with paediatric emergencies</td>
</tr>
</tbody>
</table>

Table 3.2: Application of Haddon’s Matrix to Children Falling on Playgrounds (Runyan, 2003)
This application can be seen as broadly analogous to preventing adverse events in the use of medical equipment in healthcare settings. The pre-event actions can be seen as addressing latent errors in the system. The event can be seen as the initiation of pre-defined response plans for when an adverse event is occurring and the post-event as the feedback loop to ensure that the learnings from the adverse event can be disseminated elsewhere. Conceptually, the model may be applied to the use of medical equipment in healthcare settings as per Table 3.3.

<table>
<thead>
<tr>
<th></th>
<th><strong>Host</strong> (healthcare stakeholders)</th>
<th><strong>Agent</strong> (medical equipment)</th>
<th><strong>Physical environment</strong> (Use environment of medical equipment)</th>
<th><strong>Social environment</strong> (community norms, policies, rules)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-adverse event</strong></td>
<td>Ensure competence of staff to perform required functions</td>
<td>Assess usability of medical equipment</td>
<td>Assess the use environment of medical equipment</td>
<td>Foster work practices that encourage best practice</td>
</tr>
<tr>
<td><strong>Adverse Event Occurrence</strong></td>
<td>Initiate response procedure</td>
<td>Ensure that fail to safety alarms are activated</td>
<td>Ensure the suitability of the use environment to contain the adverse event</td>
<td>Implement preventative maintenance and calibration programs</td>
</tr>
<tr>
<td><strong>Post-adverse event</strong></td>
<td>Ensure patient/healthcare stakeholders can recover from adverse event condition</td>
<td>Ensure equipment can recover from adverse event condition</td>
<td>Implement poka-yoke techniques to identify adverse events</td>
<td>Ensure learnings are disseminated to relevant stakeholders</td>
</tr>
</tbody>
</table>

**Table 3.3: Conceptual Application of Haddon’s Matrix to use of Medical Equipment in Healthcare**

While this model is overly simplistic in terms of the goal of this thesis, the concept of addressing adverse events in terms of host, agent/vehicle, physical environment and social environment is a useful paradigm to carry forward to the framework development stage.
3.4.4 The Donabedian Model

The Donabedian Model is a conceptual model that provides a framework for examining health services and evaluating quality of care (McDonald et al., 2007). The model is built on the constructs of Structures, Processes and Outcomes. Donabedian (1988) explains that Structure describes the context in which care is delivered, including hospital buildings, staff, financing, and equipment, Process denotes the transactions between patients and providers throughout the delivery of healthcare and Outcomes refers to the effects of healthcare on the health status of patients and populations, including the patients satisfaction with the care received. In Figure 3.6, below, Chelluri (2008) graphically represents the Donabedian Model as a quality improvement initiative applied in a critical care setting:

The theory of the Donabedian model is that good structure provides a foundation for good process, which in turn increases the probability of a good outcome. This theory supports a central argument of this thesis; that medical equipment which has been verified as ready for its intended use supports good patient outcomes.

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12 Activities in ensuring medical equipment is ready for its intended use fall within the scope of Structure in Donabedian’s model
3.4.5 Systems Engineering Initiative for Patient Safety Model

The Systems Engineering Initiative for Patient Safety (SEIPS) model is a systems engineering approach to patient safety, anchored within the industrial engineering subspecialty of human factors, which provides a framework for understanding the structures, processes and outcomes in health care and their relationships (Carayon et al., 2006).

Carayon et al. (2006) argue that the SEIPS model goes further than Reason’s, Vincent’s and Haddon’s models by showing how the design of the healthcare system components and their interactions can contribute to acceptable or unacceptable processes.

Figure 3.7: Systems Engineering Initiative for Patient Safety (SEIPS) model

As shown in Figure 3.7 the model considers five components of the work system which are inter-related; person, tasks, tools and technologies and the physical environment. This work system shapes the work processes and subsequent outcomes. Elements\(^{13}\) of each component of the work system are listed in Table 3.4.

\(^{13}\) Carayon et al. (2006) note this is not an exhaustive list of elements, but should be considered as examples
## Chapter Three: Systems Engineering

<table>
<thead>
<tr>
<th>Components</th>
<th>Elements (examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Person</strong></td>
<td>Education, skills and knowledge</td>
</tr>
<tr>
<td></td>
<td>Motivation and needs</td>
</tr>
<tr>
<td></td>
<td>Physical characteristics</td>
</tr>
<tr>
<td></td>
<td>Psychological characteristics</td>
</tr>
<tr>
<td><strong>Organisation</strong></td>
<td>Teamwork</td>
</tr>
<tr>
<td></td>
<td>Coordination, collaboration and communication</td>
</tr>
<tr>
<td></td>
<td>Organisational culture and patient safety culture</td>
</tr>
<tr>
<td></td>
<td>Work schedules</td>
</tr>
<tr>
<td></td>
<td>Social relationships</td>
</tr>
<tr>
<td></td>
<td>Supervisory and management style</td>
</tr>
<tr>
<td></td>
<td>Performance evaluation, rewards and incentives</td>
</tr>
<tr>
<td><strong>Technologies and tools</strong></td>
<td>Various information technologies (electronic health record, computerized provider order, entry and bar coding)</td>
</tr>
<tr>
<td></td>
<td>Medical devices</td>
</tr>
<tr>
<td></td>
<td>Other technologies and tools</td>
</tr>
<tr>
<td></td>
<td>Human factors characteristics of technologies and tools</td>
</tr>
<tr>
<td><strong>Tasks</strong></td>
<td>Variety of tasks</td>
</tr>
<tr>
<td></td>
<td>Job content, challenge and utilization of skills</td>
</tr>
<tr>
<td></td>
<td>Autonomy, job control and participation</td>
</tr>
<tr>
<td></td>
<td>Job demands (e.g. workload, time pressure, cognitive load)</td>
</tr>
<tr>
<td><strong>Environment</strong></td>
<td>Layout</td>
</tr>
<tr>
<td></td>
<td>Noise</td>
</tr>
<tr>
<td></td>
<td>Lighting</td>
</tr>
<tr>
<td></td>
<td>Temperature, humidity and air quality</td>
</tr>
<tr>
<td></td>
<td>Work station design</td>
</tr>
<tr>
<td><strong>Process</strong></td>
<td>Care processes</td>
</tr>
<tr>
<td></td>
<td>Other processes: information flow, purchasing, maintenance, cleaning</td>
</tr>
<tr>
<td></td>
<td>Process improvement activities</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>Job satisfaction and other attitudes</td>
</tr>
<tr>
<td></td>
<td>Job stress and burnout</td>
</tr>
<tr>
<td></td>
<td>Employee safety and health</td>
</tr>
<tr>
<td></td>
<td>Turnover</td>
</tr>
<tr>
<td></td>
<td>Organisational health (e.g. profitability)</td>
</tr>
<tr>
<td><strong>Patient outcomes</strong></td>
<td>Patient safety</td>
</tr>
<tr>
<td></td>
<td>Quality of care</td>
</tr>
</tbody>
</table>

*Table 3.4 Components and elements of the SEIPS Model*
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Holden et al. (2013) introduced an extended SEIPS model, named SEIPS 2.0. The most significant change between SEIPS and SEIPS 2.0 is the incorporation of an additional three concepts into the original model; configuration, engagement and adaptation. The concept of configuration highlights the dynamic, hierarchical and interactive properties of sociotechnical systems, making it possible to depict how health-related performance is shaped at ‘a moment in time’. Engagement conveys that various individuals and teams can perform health-related activities separately and collaboratively. Adaptation is introduced as a feedback mechanism that explains how dynamic systems evolve in planned and unplanned ways (Holden et al., 2013).

Of particular interest to this thesis is the view of the role of technology and tools in the SEIPS model, which are demonstrated to operate within a work system which has a direct relationship with patient safety, quality of care and employee and organisational outcomes.

3.4.6 Areas of Application of Systems Engineering Principles

The National Academy of Engineering (NAE) and Institute of Medicine (IOM) report ‘Building a Better Delivery System, A New Engineering/Health Care Partnership’ sparked interest in a systems approach to healthcare and the utilisation of systems engineering principles in a range of areas of application such as patient flow (Hall, 2006), infection control (Muder et al., 2008), patient safety in radiotherapy (Rivera and Karsh, 2008) and surgical robotics (Gomes, 2011).

Chadwick (2011) utilised a systems engineering approach in developing a method for human error and system failure analysis in healthcare called Systems and Error Analysis Bundle for Health Care (SEABH). The SEABH method uses and builds upon aspects of the following methods:

- IDEFØ
- Failure Mode and Effects Analysis (FMEA)
Chapter Three: Systems Engineering

- Cognitive Reliability and Error Analysis Method (CREAM)
- Health Care Failure Mode and Effects Analysis (HFMEA)
- Irish HSE Risk Assessment Tool

IDEFØ has been also used as a project management tool in the simulation modelling and analysis process in emergency evacuation from a hospital (Cempel and Dąbal, 2014). Mutic et al. (2010) utilised IDEFØ in the system mapping of radiotherapy. Mutic et al. (2010) state that the healthcare industry is a demanding environment for process mapping tools and languages due to the complexity of operations, the fact that most healthcare professionals are unfamiliar with systems approaches to process management, and the well-known time constraints confronting the industry. Mutic et al. (2010) argue that for a tool to be broadly accepted in the healthcare industry it must be easy to learn and logical in its formulation. IDEFØ is shown by Mutic et al. (2010) to meet these requirements and that the language can be used by healthcare professionals to model their clinical operations.

In a review paper on how systems engineering can improve healthcare technology Vockley (2013) argues that a systems perspective is applicable throughout the entire lifecycle of the medical equipment. Vockley (2013) quotes Kathleen Whanger, quality assurance manager at Teleflex Arrow International who argues that healthcare can learn from other industries; “Other industries have worked out different ways of making sure that pieces connected together actually work together as intended, while minimising unintended consequences”. This notion of benchmarking other industries is a central tenet of the fieldwork of this thesis.

3.5 Discussion

This thesis adopts a systems engineering approach to Equipment Qualification as a method for managing the complexity of the Equipment Qualification process and ensuring that a standard, best practice based approach is available to guide
Chapter Three: Systems Engineering

healthcare stakeholders. The aim of this chapter, therefore, was to introduce systems engineering and its terminologies, methods and languages. Examining systems engineering at a macro level, it is evident that there is a wide range of definitions and methods used, analogous to an ‘a la carte’ approach in that authors tend to choose definitions and methods that best fit their needs. It is ironic that a systematic approach is clearly lacking in systems engineering.

This chapter also explores the scope of existing systems engineering methods in healthcare, examining how the proposed Equipment Qualification framework can be informed by understanding the scope and approaches of existing models and methods. The application of systems engineering in healthcare has been shown to be challenging as healthcare is a complex, fragmented and dynamic sociotechnical system. Existing macro level system engineering approaches demonstrate error pathways that can lead to adverse events, highlighting the need to address latent and active failures in healthcare processes and the wide range of influencing factors for patient safety. Existing micro level system engineering approaches in healthcare demonstrate the successful use of the IDEFØ method for describing and assessing healthcare processes.

It is evident that adopting a systems engineering approach in developing an Equipment Qualification framework for healthcare will require the selection of definitions, tools and methods which meet the needs of the domain of application. The IDEFØ method was shown to provide both a graphical modelling language and a comprehensive methodology for developing functional models. As the scope of IDEFØ best fits the goals of this thesis, it is the IDEFØ method that will be employed to provide a systems engineering approach to the development of an Equipment Qualification framework for healthcare.
Chapter Four: Literature Review – Process Validation & Equipment Qualification
4.1 Introduction

The World Health Organisation define Process Validation (PV) as establishing documented evidence which provides a high degree of assurance that a planned process will consistently perform according to the intended specified outcomes (WHO, 1997). The United States Food and Drug Administration defines the term Process Validation as follows; ‘Process Validation is establishing documented evidence which provide a high degree of assurance that specific processes will consistently produce products meeting predetermined specifications and quality characteristics’ (FDA, 1996). Validation studies are performed for analytical tests, equipment, facility systems such as air, water, steam, and for processes such as the manufacturing processes, cleaning, sterilisation, sterile filling, lyophilisation, etc. (WHO, 1997). ISO/IEC 17025 describes validation as ‘the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled’ (ISO/IEC 17025, 2005).

Equipment Qualification (EQ) is a formal quality assurance process that establishes confidence that specified equipment is ready for its intended use. Validation and qualification are components of the same concept, and are often used synonymously, though there is a distinct difference; qualification can be viewed as the generation of evidence that equipment is ready for its intended use while validation is documenting that the use of the equipment will result in output meeting its predetermined specifications. Qualification can be utilised as part of the wider validation process (WHO, 2006b). Taking as an example the manufacturing process of injection moulding; there will be separate qualification protocols for the injection moulding machine as an equipment item and validation protocols for the injection moulding process. The reader will note here the use of the term qualification for machine related activities and validation for process related activities.

In the context of the objectives of this thesis, developing a framework for the qualification of medical equipment in healthcare, it is important to distinguish
between process validation and equipment qualification. The inherent complexity of healthcare processes and in particular the wide variation in inputs (patient diseases, injuries etc.) and treatment modes required renders healthcare processes extremely difficult to validate. It will however be possible to qualify the medical equipment. For this reason the focus of this thesis will be on Equipment Qualification.

4.2 Process Validation / Equipment Qualification in Manufacturing

Process Validation is a well-established practice within the safety critical industries of aerospace, automotive, pharmaceutical and medical device manufacturing. In the following sections the requirements and guidance for Process Validation, and where available Equipment Qualification, will be analysed to determine which industries present the greatest opportunity for detailed investigation of Equipment Qualification practices.

4.2.1 Aerospace

Aerospace Quality Standard AS/EN 9100 is an ISO standard which outlines the specific requirements for the application of ISO 9001 Quality Management Systems to aerospace production (AS/EN 9100, 2009). Within this standard the validation of a process is required by Section 7.5.2:

> The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable,
> a) defined criteria for review and approval of the processes,
> b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records, and
e) revalidation.

The US regulatory body, Federal Aviation Administration (FAA), in its Guidelines to Minimize Manufacturing Induced Anomalies in Critical Rotating Parts document, defines process validation as “a procedure in which it is demonstrated that the manufacturing process delivers parts and product consistent with the form, fit and function required by the design of the part to meet its Service Life” (FAA, 2006). According to the FAA, two approaches to Process Validation are used within the aerospace manufacturing industry:

- Part Specific Process Validation (PSPV)
- Generic Manufacturing Process Validation (GMPV)

In PSPV, a part is evaluated against its design requirements and subsequent production is controlled to deliver product consistent with the evaluation (FAA, 2006). In GMPV, the manufacturing methods that are identified as being sensitive and necessitating a high level of control in the manufacturing process to meet the design requirements are controlled by specifications and/or validated parameter limits. The GMPV ensures that any product manufactured within the parameter window will meet the design requirements (FAA, 2006).

The FAA demonstrates the routes to Process Validation and the issues that require consideration through the illustrative example presented in Table 4.1 (FAA, 2006).
# Table 4.1: Illustrative Route to Process Validation is Aerospace

<table>
<thead>
<tr>
<th>Step</th>
<th>Who</th>
<th>Activity</th>
<th>How/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Engine Designer</td>
<td>Identify parts which must maintain a high level of integrity to avoid hazardous engine effects and designate them as critical, flight safety part or life controlled part.</td>
<td>FMEA of the engine leads to part classification. The critical nature of the part should be conveyed to all parties concerned with manufacturing the part.</td>
</tr>
<tr>
<td>2</td>
<td>Validation Team</td>
<td>Review all part features and identify the features made by Sensitive Manufacturing Processes.</td>
<td>PFMEA or other disciplined method should be used to help identify Sensitive Manufacturing Processes.</td>
</tr>
<tr>
<td>3</td>
<td>Validation Team</td>
<td>Validate the Manufacturing Process for those features identified in step 2.</td>
<td>The Process Validation can be a combination of PSPV and GMPV</td>
</tr>
<tr>
<td>3.1</td>
<td>Manufacturing Engineer</td>
<td>PSPV: Define manufacturing process</td>
<td>Based on validated manufacturing methods</td>
</tr>
<tr>
<td>3.2</td>
<td>Validation Team</td>
<td>Establish fatigue capacity</td>
<td>Investigate the fatigue behaviour or parameter limits including consideration of the most adverse combinations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GMPV: Define parameter limits</td>
<td>By fatigue test using part, sub-element or specimen which captures material, Surface Condition and geometry, Or Metallurgical evaluation where experience defines an acceptable material Surface Condition Or A combination of the above.</td>
</tr>
<tr>
<td>3.3</td>
<td>Validation Team</td>
<td>Declare service life within established fatigue capability using Approved Lifing Method.</td>
<td>Confirm the fatigue life determined in 3.2 is consistent with the Approved Lifing Method.</td>
</tr>
<tr>
<td>3.4</td>
<td>Validation Team</td>
<td>Manufacturing Process is defined for the part</td>
<td>Specification or validated parameter limits defined</td>
</tr>
<tr>
<td>4</td>
<td>Manufacturing Engineer</td>
<td>Capture the Manufacturing Process into the Manufacturing Control Plan (MCP)</td>
<td>The MCP defines all the steps &amp; methods for manufacturing Critical Rotating Parts.</td>
</tr>
</tbody>
</table>
Chapter Four: Process Validation & Equipment Qualification

It is evident from aerospace standards and guidance that the focus of process validation is on process analysis and control, with pre-emptive appraisal of equipment not explicitly required. The practice of Equipment Qualification is not formalised in aerospace practices.

While on the topic of aerospace practices the procedure for the release to service of new aircraft is also worth investigating, to determine if practices can be adopted for the release to service of new medical equipment. The release of new aircraft to service, in the European Union, is governed by the European Aviation Safety Agency (EASA). The process begins with EASA approving the design requirements of the new aircraft and issuing a Type Certificate, at this stage the aircraft is subject to a range of stress tests of materials and components and undergoes formal flight testing.

Having established that the design of the aircraft is acceptable, it is then necessary to certify that each specific serial number aircraft produced by the manufacturer meets the certification requirements of the Type Certificate. This process is conducted by the national aviation authority of the state in which the aircraft is registered, in Ireland this is the Irish Aviation Authority, and results in the issuing of a Certificate of Airworthiness. Applications for a Certificate of Airworthiness must include a statement of conformity from the manufacturer to state the aircraft was manufactured to design requirements, a weight and balance report with a loading schedule and the flight manual. According to the IAA, the issuing of a Certificate of Airworthiness is usually a straight forward process (IAA, 2014).

It is evident that the procedure for the release to service of new aircraft is heavily dependent on testing done at the design stages. This parallels the process for medical equipment where the equipment design is verified through the CE marking and/or FDA 510k process. In terms of the goals of this thesis, however, there are no evident tools or practices that may be utilised in the Equipment Qualification framework.
4.2.2 Automotive

ISO/TS 16949 is an ISO standard which outlines the specific requirements for the application of ISO 9001 to automotive production and relevant service part organisations (ISO/TS 16949, 2009). Validation for processes for production and service provision is captured in Section 7.5.2 and mirrors AS/EN 9100 requirements.

The Automotive Industry Action Group (AIAG) is a not-for-profit association which publishes standards and guidance for the automotive industry. These documents have become the de-facto standard that must be complied with by all major automotive manufacturers (Regalado, 2010). The AIAG released an implementation guide for ISO/TS 16949 in 2003, this document details the requirement for inspection of production parts for process validation but does not formalise pre-emptive appraisal of equipment. Automotive manufacturing, therefore, does not present practices for Equipment Qualification.

4.2.4 Medical Devices

ISO 13485 is the sector specific quality management standard for the medical device industry, which like AS/EN 9100 is based on ISO 9001 with standard validation requirements presented in Section 7.5.2. Unlike AS/EN 9100 supplemental requirements are present in Section 7.5.2 of ISO 13485. The supplemental requirements relate to an organisation's obligation to validate sterilisation processes for medical devices and a requirement that if a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer.

In the ISO 13485 guidance document, ISO/TR 14969, information is presented to aid medical device manufacturers in the development, implementation and maintenance of quality management systems to meet the requirements of ISO
Chapter Four: Process Validation & Equipment Qualification

13485. In meeting the requirements of Section 7.5.2 of ISO 13485 the guidance document states that process validation can be considered to consist of four phases:

a. Review and approval of equipment specifications
b. Initial qualification of the equipment used and provision of necessary services, i.e. installation qualification (IQ)
c. Demonstration that the process will produce acceptable results and establishment of limits (worst case) of the process parameters, i.e. operational qualification (OQ)
d. Establishment of long-term process stability, i.e. performance qualification (PQ)

ISO/TR 14969 further states that process validation planning should include, but not be limited to, the following considerations:

- the accuracy and variability of the process parameters, including the settings of the equipment used
- the skill, capability and knowledge of operators to conform to quality requirements
- the adequacy of control of all process, including environmental parameters
- the qualification of processes and equipment, as appropriate
- the acceptance criteria and the process for handling process performance that does not meet these criteria
- the circumstances that require process revalidation.

The guidance document lists control charts, capability studies, designed experiments, tolerance analysis, robust design methods, failure modes and effects analysis (FMEA), sampling plans and mistake-proofing as examples of tools that may be used in process validation.
Chapter Four: Process Validation & Equipment Qualification

In terms of the installation of medical devices the guidance document states that if a medical device must be assembled or installed at the user’s site, instruction should be provided by the manufacturer to guide correct assembly, installation, testing and/or calibrations. The document notes that special attention should be paid to ensuring the correct installation of safety control mechanisms and safety control circuits (ISO/TR 14969, 2004).

It is evident from the prominent industry guidance document ISO/TR 14969 and backed up in the literature (Dixon et al., 2006), that Equipment Qualification is well established in medical device manufacturing.

4.2.3 Pharmaceutical

In pharmaceutical manufacturing the European Union EudraLex regulations and United States Food and Drug Administration (FDA) Code of Federal Regulations Title 21 govern manufacture of medicinal products for EU and United States markets respectively. Validation and qualification activities are within the scope of Volume 4 of EudraLex and Part 211 of the US CFR; both concerning current Good Manufacturing Practice (cGMP). The FDA describe cGMP as a method to develop systems which assure proper design, monitoring, and control of manufacturing processes and facilities while EudraLex views cGMP as the element of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use.

EudraLex

In EudraLex the requirements for validation/qualification are captured in Annex 15: Qualification and Validation. Annex 15 describes minimum requirements for Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) phases. Design Qualification is seen as an optional stage where the compliance of a design with cGMP is demonstrated and documented. Installation Qualification is required for
new or modified facilities, systems and equipment. IQ should include, but not be limited to the following:

a. Installation of equipment, piping, services and instrumentation checked to current engineering drawings and specifications;

b. Collection and collation of supplier operating and working instructions and maintenance requirements;

c. Calibration requirements;

d. Verification of materials of construction.

Operational Qualification should follow Installation Qualification. OQ should include, but not be limited to the following:

a. Tests that have been developed from knowledge of processes, systems and equipment;

b. Tests to include a condition or a set of conditions encompassing upper and lower operating limits, sometimes referred to as “worst case” conditions.

Annex 15 further states that the completion of a successful OQ should allow the finalisation of calibration, operating and cleaning procedures, operator training and preventative maintenance requirements. It should permit a formal ‘release’ of the facilities, systems and equipment.

Performance Qualification (PQ) should follow successful completion of Installation Qualification and Operational Qualification. PQ should include, but not be limited to the following:

a. Tests, using production materials, qualified substitutes or simulated product, that have been developed from knowledge of the process and the facilities, systems or equipment;

b. Tests to include a condition or set of conditions encompassing upper and lower operating limits.
Annex 15 further notes that although PQ is described as a separate activity, it may be appropriate, in some cases, to perform it in conjunction with OQ. For established facilities, equipment and systems Annex 15 states that evidence should be available to support and verify the operating parameters and limits for the critical variables of the operating equipment. Additionally, the calibration, cleaning, preventative maintenance, operating procedures and operator training procedures and records should be documented.

Annex 15 describes three categories of validation; prospective, concurrent and retrospective, which are defined by the stage of the product lifecycle during which the validation is performed. Prospective validation describes validations that are completed prior to the distribution and sale of product, this is the most desirable type of validation. Concurrent validation describes validation conducted during routine production, while retrospective validation is completed on processes that have been in use for some time.

Irrespective of the type of validation conducted it is a requirement that the facilities, systems and equipment used are qualified prior to execution of the validation effort. Furthermore, facilities, systems, equipment and processes should be periodically evaluated to verify that they are still operating in a valid manner.

**FDA CFR**

In the United States Process Validation for drugs (finished pharmaceuticals and components) is within the remit of the Food and Drug Association (FDA). FDA regulations are described in current good manufacturing practice (cGMP) for finished pharmaceuticals. Currently there is no explicit requirement for Equipment Qualification or Process Validation within cGMP. Interestingly, in 1996 the FDA drafted a Subpart L to 21 CFR Part 211 titled ‘Validation’ which included the following requirements:

*The manufacturer shall validate all drug product manufacturing processes …’*
The manufacturer shall design or select equipment and processes to ensure that product specifications are consistently achieved. The manufacturer’s determination of equipment suitability shall include testing to verify that the equipment is operating satisfactorily.’

In 2007 the proposed addition of Subpart L was, however, withdrawn “in light of more recent scientific and technical advances and evolving quality systems and risk management concepts” (FDA, 2007). The FDA noted that comments from the public on Subpart L indicated that the new section on validation, as proposed, did not provide the intended clarification on the subject.

While explicit requirements for Equipment Qualification and/or Process Validation have not been imposed, the FDA has released a Process Validation principles and practices guidance document (FDA, 2011) to aid in the development of cGMP practices. In this guidance document qualification of the facility, utilities and equipment is described as a pre-requisite of subsequent process validation and continued process verification.

It is evident, particularly in EU regulations, that Equipment Qualification is well established in pharmaceutical manufacturing.

4.3 The Equipment Qualification Process

It has been shown that the process of Equipment Qualification in manufacturing is established in the medical device and pharmaceutical industries. Typically the EQ process consists of three stages of qualification: Installation Qualification (IQ),
Operational Qualification (OQ) and Performance Qualification (PQ). Some authors add a preliminary qualification stage known as Design Qualification (DQ), most frequently however the elements of a DQ phase are incorporated in prerequisites to the equipment qualification process (Bedson and Sargent, 1996).

In the following sections each phase of Equipment Qualification will be detailed from the perspective of the application domains of medical device manufacturing through GHTF\textsuperscript{14} guidance (GHTF, 2004), pharmaceutical manufacturing through ISPE guidance (ISPE, 2011) and healthcare facilities through IMB guidance (IMB, 2006). The applicability of systems engineering in the equipment qualification process will also be detailed and discussed.

4.3.1 Qualification Prerequisites

As a means of planning for equipment selection and qualification a broad range of user needs documents may be created; including user requirements specifications, operational specification and functional specification documents. User Requirements Specifications (URS) should describe, overall, what users want from the equipment. The operational specifications should describe the intended use of the equipment, key performance features of the equipment and ranges over which the equipment is required to operate\textsuperscript{15}. The functional specifications should take into account the overall requirements of the equipment including the operational specifications and other factors relating to its use; for instance technical, environmental and safety precautions which may

---

\textsuperscript{14} The Global Harmonisation Task Force (GHTF) was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Its purpose was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade. In 2012 the GHTF disbanded. The International Medical Device Regulators’ Forum (IMDRF), a voluntary group of medical device regulators from around the world, is currently building on the work of the GHTF.

\textsuperscript{15} The generation of these requirements fall within the field of Health Technology Assessment and is outside the scope of this thesis.
not form part of CE certification and documentation (protocols for IQ, OP and PQ, model SOPs, etc.) (Papadoyannis and Samanidou, 2005).

Factory Acceptance Testing (FAT) is equipment testing that is performed at the site of the vendor to ensure the equipment has the required functionality; it is often performed before purchasing. Site Acceptance Testing (SAT) describes testing performed on site to ensure the equipment works as intended. Some companies perform a SAT before validation activities, while others incorporate this testing into their IQ/OQ testing.

Once the required device has been procured and shipped to the healthcare facility, frequently the next step is to commission the device. The WHO define commissioning as the setting up, adjustment and testing of equipment or a system to ensure that it meets all the requirements, as specified in the user requirement specification, and capacities as specified by the designer or developer. The WHO further state that commissioning is carried out before qualification and validation (WHO, 2006a). Commissioning, when it is performed, can support the qualification process.

### 4.3.2 Installation Qualification

In medical device manufacturing, Installation Qualification (IQ) is defined as establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer’s approved specification and that the recommendations of the supplier of the equipment are suitably considered. In pharmaceutical manufacturing, the ISPE define IQ as the documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer’s recommendations. The IMB state that Installation Qualification is used to verify that the medical equipment is installed according to the manufacturer’s recommendations.
Chapter Four: Process Validation & Equipment Qualification

Installation Qualification consists primarily of static checks. Bennett and Cole (2003) list a number of checks that may be performed for the purposes of IQ:

- **System completion**: Check that the system is mechanically complete and all critical punch list items have been cleared.
- **Security / Utility Connections**: Check that the correct connection of utilities has been made and tested where required.
- **Documentation Inventory**: Check that all necessary supporting documentation such as specifications, operation and maintenance manuals are available and have been reviewed and approved.
- **Equipment Inventory**: Check that installed equipment name plate data complies with specification and record serial numbers.
- **Materials Qualification**: Check that, where appropriate, contact part materials, surface finishes and lubricants are in accordance with the specification.
- **Main equipment features**: Check that each main component is in accordance with the construction drawing, check critical specifications such as filter grade, perform any static checks required prior to start up, such as checking lubricant levels, drive belt tension and torque settings.
- **Instrument calibration**: Check that all critical instruments have been calibrated and that the calibration is traceable to national standards.
- **Spares and maintenance**: Check that adequate spares provision has been made and maintenance requirements have been considered.

Verification that an IQ task has been successfully completed can be accomplished by visual inspection, or by a measuring device. The method of determination should be denoted accordingly in the protocol. It is important that each participant in the execution of the IQ has the education, training and experience that supports their competency to perform the required task (Stephon, 2013a). Installation Qualification must be completed before Operational Qualification can commence (Sherman, 1998).
4.3.3 Operational Qualification

In medical device manufacturing, the GHTF define Operational Qualification as establishing by objective evidence process control limits and action levels which result in product that meets all predetermined requirement. The ISPE define OQ as the documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges. In the IMB guidance document (IMB, 2006) it is stated that Operational Qualification is conducted to ensure that the medical equipment operates as intended by the manufacturer and in accordance with the product specifications.

While Installation Qualification is primarily static checks, Operational Qualification is primarily dynamic checks. OQ usually includes verification of equipment parameters, such as speed, RPM, power consumption, and cycle duration. In addition, OQ involves testing and verifying that all sensors, switches, control devices, logic circuits, gauges, system diagrams, and safety controllers are calibrated and operating correctly (Stephon, 2013b).

Determining which equipment functions are to be evaluated during OQ is an important step. (Stephon, 2013b) advises that consideration should be provided as to the function of the system as a whole, followed by which specific equipment attributes control those functions. (DeCaris et al., 2007) recommend a risk based approach to Operational Qualification, in particular focusing on the use of Failure Modes and Effects Analysis.

The OQ should challenge the machine parameters to demonstrate the robustness of the equipment, i.e. that the equipment can operate satisfactorily under ‘worst-case’ conditions. The GHTF state that the challenge should include the range of conditions as defined by operators’ practices and procedures (GHTF, 2004). Typically a challenge test will involve operating the equipment at maximum and minimum settings for variable parameters and/or testing capability of the equipment to accommodate ‘worst-case’ inputs.
Chapter Four: Process Validation & Equipment Qualification

The GHTF list the following Operational Qualification considerations:

- Process control limits (time, temperature, setup conditions, etc.)
- Software parameters
- Raw material specifications
- Process operating procedures
- Material handling requirements
- Process change control
- Training
- Short term stability and capability of the process, (latitude studies or control charts)
- Potential failure modes, action levels and worst-case conditions (Failure Mode and Effects Analysis, Fault Tree Analysis)
- The use of statistically valid techniques such as screening experiments to establish key process parameters and statistically designed experiments to optimise the process can be used during this phase.

4.3.4 Performance Qualification

The GHTF define Performance Qualification as establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements. The ISPE state that PQ is the documented verification that the facilities, systems and equipment, as connected together, can perform effectively and reproducibly, based on the approved process method and product specification. The IMB advise that the user of medical equipment should arrange for the medical equipment to be tested independent of the manufacturers testing as part of the PQ procedure to ensure that the medical equipment achieves the performance claims specified by the manufacturer.

Before PQ can commence both IQ and OQ must be complete, with any deviations satisfactorily resolved and documented. There may be a significant
time lapse between the OQ and PQ phases, and as a result, consideration must be given to whether any control and monitoring instrumentation needs to be recalibrated. De Claire (2003) advises recalibration of critical instrumentation under the site calibration procedures to guarantee correct calibration prior to commencing PQ.

As PQ evaluates the equipment’s performance under actual use conditions it is advantageous to have knowledgeable and trained personnel that are familiar with the equipment, involved in creating and approving the PQ protocol (Stephon, 2013a).

The GHTF list the following Performance Qualification considerations:

- Actual product and process parameters and procedures established in OQ
- Acceptability of the product
- Assurance of process capability as established in OQ
- Process repeatability, long term process stability

The GHTF further advise that process and product data should be analysed to determine what the normal range of variation is for the process output as understanding the normal variation of the output is crucial in determining whether a process is operating in a state of control and is capable of consistently producing the specified output.

4.4 Systems Engineering Vee Model in Equipment Qualification

The International Society for Pharmaceutical Engineering, in its publication ‘GAMP: Good Automated Manufacturing Practice, Supplier Guide for Validation of Automated Systems in Pharmaceutical Manufacture’ present an adaption of the systems engineering Vee modell for automated pharmaceutical manufacturing equipment validation. The GAMP document was developed to

16 As discussed in Section 4.4
'help suppliers of automated systems to the pharmaceutical industry to ensure that systems are developed with quality build-in and to provide documentary evidence that their systems meet the agreed specifications’ (ISPE, 1995).

As illustrated by the process development validation Vee model in Figure 4.1, the three qualification phases of IQ, OQ and PQ relate to specifications for the system that must be prepared before the system is built. A formal design qualification is a notable absentee from this model; instead the expected contents of a design qualification phase are captured in the left hand wing of the Vee model.

The GAMP document is seen as an excellent document for process validation and is an example of why manufacturing process validation is reasonably well understood (Alexander and Clarkson, 2000a). Indeed, for these reasons the GAMP Vee model has also been widely adopted by medical device manufacturers (Mccaffrey et al., 2004).
4.5 Qualification / Validation Protocols

A protocol describes the details of the planned activities and tests for IQ, OQ and PQ phases. Protocols may include background information, explain the rationale for and the objective of the study, give a full description of the procedures to be followed, set out the parameters to be measured, describe how the results will be analysed and provide pre-determined acceptance criteria for drawing conclusions. Validation protocols are important in ensuring that documented evidence is recorded which demonstrates that an equipment item, a system, a process or a method can consistently perform at a specified level (WHO, 1997).

The procedure for using EQ/PV protocols is as follows:

1. Develop protocol
2. Approve protocol
3. Execute protocol instructions
4. Resolve any deviations encountered

While protocols must be written to meet the needs of each specific equipment/process, template protocols are often used to provide direction on the structure and content of the protocol (Cloud, 1999).

4.6 Discussion

Equipment Qualification (EQ), a component of Process Validation, is a formal quality assurance process that establishes confidence that specified equipment is ready for its intended use.

Equipment Qualification has been shown to be formalised in medical device and pharmaceutical manufacturing only. Process validation activities in aerospace and automotive manufacturing is limited to proving that process output will meet predetermined specifications, without the need for supporting EQ activities.
Chapter Four: Process Validation & Equipment Qualification

The Equipment Qualification methods of medical device and pharmaceutical manufacturing are, therefore, of greatest relevance in answering the research question of this thesis.
Chapter Five: Literature Review – Supporting Disciplines to Equipment Qualification
5.1 Introduction

As demonstrated in Chapter One, medical equipment in healthcare is generally considered ‘ready for its intended use’ once the functionality of the equipment has been verified and basic safety checks and administrative tasks completed, activities which are undertaken within the scope of well-established programs of commissioning and acceptance testing activities (Sharma, 2007, Cheng et al., 2003, Koller et al., 2006). However, this scope of activities has been shown to be limited, there is an opportunity to also assess latent hazards in terms of the potential for failure of the device and the potential for users making mistakes with the device, while also setting the foundation for a productive work environment.

Risk Management underpins all efforts in identifying and mitigating latent hazards. The disciplines of quality, safety\(^\text{17}\), reliability, maintenance and calibration are tightly coupled with failure of the device while users making mistakes is tightly coupled with the disciplines of quality, safety and human factors engineering. The tools and techniques of lean are most closely associated with the goal of maximising productivity. Table 5.1 displays this relationship between the components of ready and the supporting disciplines for each.

\(^\text{17}\) Interestingly, the HSE publication ‘Towards Excellence in Clinical Governance – A Framework for Integrated Quality, Safety and Risk Management across HSE Service Providers’ states that the terms ‘quality, safety and risk management’ and ‘quality and risk management’ can be regarded as synonymous (HSE, 2009). This view of the overlapping relationship between quality, safety and risk is also evident in the wider literature (Arah and Klazinga, 2004, Auerbach et al., 2007, Brennan et al., 2005).
<table>
<thead>
<tr>
<th>Component of Ready</th>
<th>Supporting Disciplines</th>
</tr>
</thead>
</table>
| Potential for failure of the device minimised          | Quality  
Safety  
Reliability  
Maintenance  
Calibration  
Risk Management |
| Potential for users making mistakes minimised          | Quality  
Safety  
Human Factors Engineering  
Risk Management |
| Potential for productivity maximised                   | Lean                                                |

**Table 5.1: Components of Ready and Supporting Disciplines**

In presenting and discussing the literature this thesis will be cognisant of the tight coupling evident between the goals of each supporting discipline. While each area will be presented in separate sections, reflecting traditional approaches, the reader should be aware that each paradigm/tool discussed will be considered as a potential method of establishing confidence that the equipment is *ready for its intended use*. For example, actions taken to improve housekeeping in the work area of the device may simultaneously improve safety, quality and productivity. Therefore, in order to answer the research question of this thesis no demarcation between the objectives of the supporting disciplines is required or sought.
Chapter Five: Supporting Disciplines to Equipment Qualification

5.2 Risk Management

The international standard ISO 14971 Medical Devices – Application of Risk Management to Medical Devices (ISO 14971, 2007) is the definitive source of guidance and direction for risk management in relation to medical devices. While ISO 14971 was developed specifically for medical device and medical system manufacturers it can be used by healthcare industries as informative guidance in developing and maintaining a risk management system and process.

ISO 14971 provides a framework within which experience, insight and judgment are applied systematically to manage the risks associated with the use of medical devices. The standard specifies a process to identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks and monitor the effectiveness of that control. ISO 14971 uses established principles of risk management for managing risks, primarily of risks to the patient, but also to the operator, other persons, other equipment and the environment (ISO 14971, 2007).

ISO 14971 defines risk management as the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk. The standard states that the concept of risk has two components:

a) the probability of occurrence of harm;

b) the consequences of that harm, that is, how severe it might be.

The standard notes that the concepts of risk management are particularly important in relation to medical devices because of the variety of stakeholders including medical practitioners, the organisations providing health care, governments, industry, patients and members of the public. All stakeholders need to understand that the use of a medical device entails some degree of risk; the acceptability of the risk to a stakeholder is influenced by the stakeholder’s perception of the risk.
ISO 14971 describes three primary phases of the risk management process; risk analysis, risk evaluation\(^{18}\) and risk control. Depending on the specific life-cycle phase of the medical equipment, individual elements of the risk management process can have varying emphasis; in the following sections those elements relevant to the scope of this thesis will be discussed.

### 5.2.1 Risk Analysis

Risk analysis considers firstly the intended use and identification of characteristics related to the safety of the medical device, secondly the identification of hazards and finally the estimation of the risk(s) for each hazardous situation. Annex C of ISO 14971 contains questions that can be used to identify medical device characteristics that could impact on safety to aid in developing a complete picture of where the hazards can be found, Annex E lists potential hazards. For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data, which may include:

- a) Published standards
- b) Scientific technical data
- c) Field data from similar medical devices already in use, including published reported incidents
- d) Usability tests employing typical users
- e) Clinical evidence
- f) Results of appropriate investigations
- g) Expert opinion
- h) External quality assessment schemes

It is important to consider every reasonably foreseeable sequence or combination of events that could result in a hazardous situation.

---

\(^{18}\) Risk Analysis and Risk Evaluation together constitute Risk Assessment
Annex G of the Standard provides guidance on available techniques for risk analysis, noting that the techniques can be complementary and it might be necessary to use more than one of them. The techniques described are:

- Preliminary Hazard Analysis (PHA)
- Fault Tree Analysis (FTA)
- Failure Mode and Effects Analysis (FMEA) and Failure Mode, Effects and Criticality Analysis (FMECA)
- Hazard and Operability Study (HAZOP)
- Hazard Analysis and Critical Control Point (HACCP)

**Preliminary Hazard Analysis (PHA)**

Preliminary Hazard Analysis (PHA) is a technique that is used early in the development process to identify the hazards, hazardous situations, and events that can cause harm when few of the details of the medical device design are known (ISO 14971, 2007); this technique therefore is not suited for use in healthcare settings where finalised medical device designs are being evaluated.

**Fault Tree Analysis (FTA)**

Fault Tree Analysis (FTA) is an analytical technique used to find all credible ways in which a system can fail (Haney et al., 1989). The fault tree is a graphic model of all the parallel and sequential combinations of faults that result in a predefined undesired event, it predicts the logical interrelationships of basic events that lead to or result in a predefined undesired event (Gertman and Blackman, 1994). FTA is especially useful early in the development stages of safety engineering for the identification and prioritisation of hazards and hazardous situations as well as for analysing adverse events (ISO 14971, 2007). As with PHA, this risk assessment technique is not suited to evaluating medical equipment in healthcare where finalised medical device designs are being evaluated.
Chapter Five: Supporting Disciplines to Equipment Qualification

Failure Mode and Effects Analysis (FMEA) Methods

The international standard IEC 60812 Analysis Techniques for System Reliability – Procedure For Failure Mode And Effects Analysis (FMEA) (IEC, 2006) describes FMEA as a systematic procedure for the analysis of a system to identify the potential failure modes, their causes and effects on system performance. IEC 60812 states that the procedural steps needed to perform an analysis are as follows:

a. Decide whether FMEA or FMECA is required
b. Define system boundaries for analysis
c. Understand system requirements and function
d. Define failure/success criteria
e. Determine each item’s failure modes and their failure effects and record these
f. Summarise each failure effect
g. Report findings

FMEA can be applied at all stages of the equipment lifecycle from design (Design FMEA), to the manufacturing and assembling of equipment (Process FMEA) and the use or misuse of the product by the end user (Application FMEA).

An FMEA worksheet captures the details of the analysis in a tabularised manner. In the worksheet the severity (S) of the effect of failure, the probability of occurrence (O) of the cause of failure and the probability of detection (D) of the failure by current controls are rated out of 10. A Risk Priority Number (RPN) can then be calculated by the multiplication of $S \times O \times D$. The RPN provides a measure of criticality of failure modes, allowing for identification and prioritisation of countermeasures. Typically, if the RPN falls within a pre-determined range, corrective action may be recommended or required to reduce the risk. Table 5.2 depicts two lines of a theoretical FMEA worksheet for demonstrative purposes.
IEC 60812 states that Failure Mode, Effects and Criticality Analysis (FMECA) is an extension to the FMEA to include a means of ranking the severity of the failure modes to allow prioritization of countermeasures. FMECA expands on FMEA to include the following additional steps:

a. Determine system failure severity classes
b. Establish item’s failure mode severity
c. Determine item’s failure mode and effect frequencies
d. Determine failure mode frequencies
e. Draw up criticality matrix for item failure modes
f. Summarize the criticality of failure effects from the criticality matrix
g. Draw up criticality matrix for system failure effects
h. Report findings at all levels of analysis.

Healthcare Failure Mode and Effects Analysis (HFMEA) is an adaption of the FMEA method for healthcare. HFMEA is based upon five steps:

1. Define the high-risk or high-vulnerability area as the HFMEA topic
2. Assemble the multidisciplinary team making certain to include a subject matter expert, advisor, and leader
3. Create and confirm a process flow diagram to visually depict the steps of the process
4. Analyse the possible or potential failure modes for each of the graphically identified sub-processes and determine the severity and probability of each potential failure using the Hazard Scoring Matrix

5. Develop action and outcome measures for each failure mode

HFMEA streamlines the hazard analysis steps found in the traditional Failure Mode and Effect Analysis (FMEA) process by combining the detectability and criticality steps of the traditional FMEA into an algorithm presented as a Decision Tree. It also replaces calculation of the risk priority number (RPN) with a hazard score that is read directly from the HFMEA Hazard Matrix Table (Patail, 2004). Practitioners of HFMEA, however, have reported difficulties with the method, related to using the flowchart, identifying failure modes, determining corrective measures, using the hazard scoring system and the time required to complete studies (Chadwick et al., 2012).

The family of FMEA methods have limitations as each generally deals with individual, independent failure modes and the effect of these failure modes on the system. FMEA is consequently deemed unsuitable for consideration of dependent failures or failures resulting from a sequence of events (IEC, 2006).

**Hazard and Operability Study (HAZOP)**

HAZOP is a systematic technique for identifying hazards and operability problems which is based on a theory that assumes accidents are caused by deviations from the design or operating intentions (ISO 14971, 2007). While originally developed for the chemical industry, ISO 14971 states that HAZOP can be applied to the functionality of medical equipment or to a process used in the manufacture or maintenance of the equipment (e.g., sterilisation).

The international standard IEC 61882 Hazard and operability studies (HAZOP studies) – Application Guide (IEC, 2001) argues that the primary benefit of HAZOP is that the knowledge obtained by identifying potential hazards and operability problems in a structured and systematic manner is of great assistance
in determining appropriate remedial measures. HAZOP studies consist of four basic sequential steps, shown in Figure 5.1.

In the HAZOP examination process the system being studied is divided into parts based on complexity. IEC 61882 recommends that the HAZOP team examines each part for deviation from the design intent which can lead to undesirable consequences. The identification of deviations from the design intent is achieved by a questioning process using predetermined "guide words". The role of the guide word is to stimulate imaginative thinking, to focus the study and elicit ideas and discussion, thereby maximising the chances of study completeness. IEC 61882 notes that a range of guide words can be used to facilitate brainstorming for identification of potential deviation and lists the basic guide words and their meanings as shown in Table 5.3.
### Guide Word Table

<table>
<thead>
<tr>
<th>Guide Word</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO OR NOT</td>
<td>Complete negation of the design intent</td>
</tr>
<tr>
<td>MORE</td>
<td>Quantitative increase</td>
</tr>
<tr>
<td>LESS</td>
<td>Quantitative decrease</td>
</tr>
<tr>
<td>AS WELL AS</td>
<td>Qualitative modification/increase</td>
</tr>
<tr>
<td>PART OF</td>
<td>Qualitative modification/decrease</td>
</tr>
<tr>
<td>REVERSE</td>
<td>Logical opposite of the design intent</td>
</tr>
<tr>
<td>OTHER THAN</td>
<td>Complete substitution</td>
</tr>
</tbody>
</table>

**Table 5.3: IEC 61882 Basic Guide Words & Meanings in HAZOP Studies**

Each of the guide words is applied to the selected element (and to each of its characteristics as relevant) to obtain a specific interpretation. When a deviation has a credible cause and the design is not considered acceptable, a recommendation for change or for further study is made. Table 5.4 depicts two lines of a theoretical HAZOP worksheet for demonstrative purposes.

<table>
<thead>
<tr>
<th>Guide Word</th>
<th>Element</th>
<th>Deviation</th>
<th>Possible Causes</th>
<th>Consequences</th>
<th>Safeguards</th>
<th>Actions Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>Gas Supply</td>
<td>No gas supply</td>
<td>Supply tank is empty</td>
<td>Patient Injury</td>
<td>Low gas</td>
<td>Verify low gas alarm is functioning</td>
</tr>
<tr>
<td>MORE</td>
<td>Gas Supply</td>
<td>More gas supply</td>
<td>Regulator malfunction</td>
<td>Patient Injury</td>
<td>High gas alarm</td>
<td>Verify low gas alarm is functioning</td>
</tr>
</tbody>
</table>

**Table 5.4: Sample HAZOP Worksheet**

The limitations of HAZOP, however, reflect those identified in FMEA as it generally deals with individual, independent failure modes.
Hazard Analysis and Critical Control Point (HACCP)

Originally developed by NASA to prevent food poisoning of astronauts, HACCP is a systematic approach to the identification, evaluation and control of hazards based on a set of principles and defined terms. The core curriculum of HACCP consists of the following seven principles:

1. Conduct hazard analysis and identify preventive measures
2. Determine the critical control points (CCPs)
3. Establish critical limits
4. Monitor each CCP
5. Establish corrective actions
6. Establish verification procedures
7. Establish record-keeping and documentation procedures

An effective HACCP system focuses on the continuing control and monitoring (HACCP principles 2, 3 and 4) of the identified hazards. A manufacturer demonstrates the effectiveness of established control measure(s) (HACCP principles 5 and 6) through process mapping, process hazard analysis and establishing a critical control plan (HACCP principle 7).

Applied to medical devices, HACCP is used for the control and monitoring of causes of product hazards originating in processes, particularly manufacturing processes (ISO 14971, 2007). HACCP, however, is not designed for the preemptive evaluation of latent hazards and is therefore deemed unsuitable to the scope of interest of this thesis.

Structured What If Technique (SWIFT)

The Structured What-If Technique (SWIFT) is a systematic, team-orientated technique for risk identification (Borek et al., 2013). SWIFT can be used on a stand-alone basis, or as part of a staged approach to make more efficient use of bottom-up methods like FMEA (Card et al., 2012a). SWIFT is a facilitated brainstorming group activity, which extracts expertise from a multidisciplinary
team of experts. While there is no single standard approach to SWIFT, (Borek et al., 2013) suggest the following approach:

- A team is brought together under the direction of a facilitator. The team should comprise individuals who are experienced in the systems/process being analysed
- Define and agree on the systems/processes and scope of the study
- Discuss known risks and hazards, previous experience and incidents, known and existing controls and safeguards, and regulatory requirements and constraints
- The facilitator uses prompts to initiate discussion with in the group:
  - What if….?
  - Could someone or something.....?
  - Has anyone ever....?
- Summarise the risks and consider what controls are in place
- Confirm the description of the risk, and its causes, frequency, consequences and any safeguards
- Consider if the controls are effective;
  - If not, consider risk treatment tasks and define potential controls. Further ‘What if....?’ Questions are asked to identify other risks.
- The facilitator uses the prompts to monitor discussions and suggest additional issues and scenarios for discussion
- Rank the actions created by prioritizing them; use a qualitative or semi-quantitative risk assessment method, taking into account the existing controls/safeguards and their effectiveness

In adapting SWIFT to healthcare (Card et al., 2012a) recommend the following guidewords for the facilitator to consider:

- Wrong: Person or people
  - Examples: Wrong patient surgery, Referral to the wrong specialist, Treatment delivered by staff suffering from fatigue
- Wrong: Place, location, site, or environment
The primary advantage of SWIFT is that the method creates a detailed and auditable record of the hazards identification process and is less time consuming than other systematic techniques such as FMEA (Ilias Maragakis et al., 2009). Indeed, Card et al. (2012a) state that a SWIFT risk assessment can be conducted in as little as one third of the time required for a HFMEA based approach and that healthcare workers have found SWIFT to be easy to learn, easy to use and credible.
5.2.2 Risk Evaluation

Risk evaluation is conducted to decide if risk reduction activities are required. In order to make this decision criteria relating to the acceptability of identified risks must be established. While ISO 14971 does not specify acceptable/unacceptable risk, it does list methods of determining acceptable risk including the following:

- Using applicable standards that specify requirements which, if implemented, will indicate achievement of acceptability concerning particular kinds of medical devices or particular risks;
- Comparing levels of risk evident from medical devices already in use;
- Evaluating clinical study data, especially for new technology or new intended uses taking into account the state of the art\textsuperscript{19} and available information such as technology and practice existing at the time of design.

Risk evaluation can be quantitative or qualitative. ISO 14971 describes an N-by-M matrix (N levels of probability and M levels of severity) as a typical qualitative approach used to describe the probabilities and severities of the risk associated with each hazards. Probability is typically rated as high (likely to happen, often, frequent), medium (can happen, but not frequently) and low (unlikely to happen, rare, remote). Severity is typically rated as significant (death or loss of function or structure), moderate (reversible or minor injury) or negligible (will not cause injury or will injure slightly). Using the probability (N) as rows and the severity (M) of the harm as columns, a risk matrix can be produced. The estimated risks populate the appropriate cells, for which combinations of probability of harm and severity of harm are predetermined as either acceptable or unacceptable. A sample 3 x 3 matrix is shown in Table 5.5.

\textsuperscript{19} “State of the art” is used here to mean what is currently and generally accepted as good practice.
The N-by-M approach can also be utilised with semi-quantitative and/or user defined scales where probability and severity is known to be within an estimated range (such as an order of magnitude). For example the probability scale may range from $< 10^{-6}$ to $> 10^{-3}$ and severity might range from negligible impact (inconvenience or temporary discomfort to patient/stakeholder) to catastrophic (results in death).

### 5.2.3 Risk Control

For each hazardous situation where it has been determined that risk must be reduced, risk control options must be identified and implemented and residual risk\(^{20}\) evaluated. Risk control options should be implemented in the following priority:

1. Inherent safety by design
2. Protective measures in the manufacturing process or medical device
3. Information for safety

After all risk control measures have been implemented and verified, the residual risk posed by the medical device is assessed using the risk acceptability criteria. If

\(^{20}\) Residual risk is the risk remaining after risk control measures have been taken.
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the overall residual risk is not deemed acceptable, it must be determined if the medical benefits of the intended use outweigh the overall residual risk, this decision may be assisted by a review of relevant data and literature.

ISO 14971 also mandates an assessment of the risks arising from control measures and the completeness of risk control. Of particular interest to healthcare facilities is the requirement in Section 9 of ISO 14971 which states that manufacturers shall establish, document and maintain a system to collect and review information about the medical device or similar devices in the production and the post-production phases. The manufacturer must consider the mechanisms by which information generated by the operator, the user, or those accountable for the installation, use and maintenance of the medical device is collected and processed.

5.3 Quality

The concept of quality is an elusive one. Many quality gurus have attempted to define quality. Juran et al. (1974) define quality as fitness for use while Crosby (1979) states quality means conformance to requirements. Feigenbaum (1951) argues that whether the quality of the product is good or not depends on two customer conditions; the actual use and the selling price of the product. The International Organisation for Standardization (ISO) defines quality as the degree to which a set of inherent characteristics fulfills requirements (ISO 9000, 2005). In the healthcare domain, the Institute of Medicine (Institute of Medicine, 2001) have defined quality as follows:

"Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."

Quality Management is a term for a system of quality awareness, control and continuous improvement. ISO 9000 defines a quality management system as a
management system to direct and control an organisation with regard to quality (ISO 9000, 2005). Quality Management has evolved from a focus on inspection after manufacture/service delivery (quality control) to building quality into products and processes to achieve ‘right first time’ results (quality assurance). The goal of a quality management system is to ensure product safety and efficacy and customer satisfaction.

Health practices and policy in much of the developed world is increasingly concerned with assessing and improving the quality of health care (Davies et al., 2000). According to Gowen III et al. (2006) healthcare organisations have adopted quality management programs with the particular goal of preventing error-related patient safety adverse. Gowen III et al. (2006) list customer satisfaction evaluation, employee quality teams, statistical process control, competitive benchmarking, and supply chain management as the most common quality management practices utilised by healthcare organisations.

McLaughlin and Kaluzny (2006) state that all quality initiatives usually involve a common set of characteristics, which include the following:

- A link to key elements of the organisation’s strategic plan
- A quality council made up of the institution’s top leadership
- Training programs for personnel
- Mechanisms for selecting improvement opportunities
- Formation of process improvement teams
- Staff support for process analysis and redesign
- Personnel policies that motivate and support staff participation in process improvement
- Application of the most current and rigorous techniques of the scientific method and statistical process control.
5.3.1 Total Quality Management

Total Quality Management (TQM) is a term used to describe a management approach to quality improvement. The American Society for Quality view TQM as a management approach to long-term success through customer satisfaction based on all members of an organisation participating in improving processes, products, services and the culture in which they work. The methods for implementing this approach are found in the teachings of quality leaders as Philip B. Crosby, W. Edwards Deming, Armand V. Feigenbaum, Kaoru Ishikawa and Joseph M. Juran.

Joseph M. Juran describes TQM as the building of quality into products and process and making quality a concern and responsibility for everyone in the organisation (Juran, 1992). Oakland (2003) models the key characteristics of TQM as depicted in Figure 5.2:

![Figure Removed for Copyright Reasons](image)

**Figure 5.2: TQM Model**

Dhillon (2000) illustrates seven important elements of TQM in medical device manufacturing, as shown in Figure 5.3.
While TQM has a heavy emphasis on intangible elements of product/service provision, statistical methods and techniques are seen as a critical success factor. Traditionally TQM primarily uses the following tools:

1. Histograms 
2. Ishikawa Diagrams 
3. Check Sheets 
4. Pareto Charts 
5. Flow Charts 
6. Control charts 
7. Scatter Diagrams

TQM is not limited, however, to these basic quality tools, all currently available quality and statistical techniques can be used as part of the TQM toolkit (Dahlgaard et al., 1998).

5.3.2 Continuous Quality Improvement

In healthcare the paradigm of quality has been designated many different terms. Currently, authors in the literature tend to describe Continuous Quality Improvement (CQI) as the template for quality improvement initiatives. CQI is viewed as the evolution of Total Quality Management (TQM) as TQM was applied to health care administrative and clinical processes (Sollecito et al., 2011). Continuous Quality Improvement (CQI) is defined as a structured organisational process for involving personnel in planning and executing a continuous flow of improvements to provide quality healthcare that meets or exceeds expectations (McLaughlin and Kaluzny, 2004).
Together with these distinguishing characteristics, CQI is usually composed of philosophical, structural and healthcare specific elements (Sollecito et al., 2011). Philosophical elements include a strategic and customer focus, emphasis on a systems view, evidence based analysis and continuous improvement. Structural elements include process improvement teams, organisational leadership, the use of quality tools and statistical analysis and benchmarking. Healthcare specific elements are detailed as those concerning evidence-based medicine and the medical staff governance process. The use of risk-adjusted outcome measures, cost-effectiveness analysis and use of quality assurance data and techniques and risk management are also referred to as healthcare specific elements (McLaughlin and Kaluzny, 2006), though it may be argued that these concerns are universal.

5.3.3 Six Sigma

Six Sigma is the prevalent approach to quality improvement employed in the manufacturing industry (de Mast, 2007). Six Sigma is viewed by many authors in the literature as a methodology within TQM (Klefsjö et al., 2001). Pande and Holpp (2002) define Six Sigma a disciplined method of using extremely rigorous data gathering and statistical analysis to pinpoint sources of errors and ways of eliminating them. According to Caulcutt (2001), Six Sigma is a fact-based, data-driven philosophy of quality improvement that values defect prevention over defect detection. It drives customer satisfaction and bottom-line results by reducing variation and waste, thereby promoting a competitive advantage. Six Sigma is also used as a measure of an organisation’s performance; Six Sigma quality performance, when accounting for the generally accepted 1.5 sigma shift, is reported as no more than 3.4 defects per million opportunities.

21 (Sollecito et al., 2011) specify in particular the seven basic tools of quality; Cause-and-effect diagram, Control chart, Histogram, Pareto chart, Scatter diagram and regression analysis.
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The Six Sigma methodology employs a systematic approach to quality improvement projects through the DMAIC cycle. The DMAIC project methodology has five phases; Define, Measure, Analyse, Improve, Control. At each phase of the DMAIC cycle, Six Sigma practitioners utilise applicable tools. Six Sigma practitioners are described using a martial arts style grading system of Yellow Belts, Green Belts, Black Belts and Master Black Belts. Each grade represents a demonstrated level of competency in the use of the Six Sigma methodology and toolkit.

The benefits of implementing a Six Sigma program in manufacturing have been well documented. The Irish Medical Device Association (IMDA) has recognised the importance of Six Sigma to continuous improvement in the manufacture of medical devices by incorporating Six Sigma training into its Manufacturing Excellence Skill-Net programme. The Irish government report on the skills needs of the Irish medical devices sector highlights Six Sigma as a key aspect of building operational excellence (Forfás, 2008).

Six Sigma uses approximately 140 statistical tools and concepts to effectively define, measure, analyse, improve and control variation (Bendell, 2006). Table 5.6 lists the primary Six Sigma tools, with a brief description of each, and a rating of the applicability of the tool for the Equipment Qualification of medical equipment in healthcare. Tools which have a high applicability rating will be discussed in further detail.
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### Overall Equipment Effectiveness

**Description:** Overall equipment effectiveness (OEE) is used to monitor equipment effectiveness by measuring equipment availability, performance, and product quality of the equipment ([Voehl et al., 2013](#)).

**Applicability Rating:** Low

**Rationale:** Macro level tool process control tool

### Hypothesis Testing

**Description:** Hypothesis testing is a statistical procedure that allows researchers to use sample data to draw inferences about the population of interest ([Gravetter and Wallnau, 2013](#)).

**Applicability Rating:** Low

**Rationale:** Macro level tool process improvement tool

### Capability Analysis

**Description:** Capability analysis studies the ability of the process to produce products within the specification limits. It provides information about the noise level of the system when there is no out-of-control condition ([Peck et al., 1998](#)).

**Applicability Rating:** High

**Rationale:** Value Add activity for Equipment Qualification

### Measurement Systems Analysis

**Description:** Measurement system analysis (MSA) is an experimental and mathematical method of determining how much the variation within the measurement process contributes to overall process variability ([Bucher, 2007](#)).

**Applicability Rating:** Low

**Rationale:** Process control tool

### Design of Experiments

**Description:** Design of experiments is a statistical technique used to study multiple variables simultaneously ([Roy, 2001](#)).

**Applicability Rating:** Low

**Rationale:** Process improvement tool

### Statistical Process Control

**Description:** Statistical Process Control is a statistical technique used to monitor the natural variability of a process ([Yu, 2007](#)).

**Applicability Rating:** Low

**Rationale:** Process control tool

<table>
<thead>
<tr>
<th>Tool</th>
<th>Description</th>
<th>Applicability Rating</th>
<th>Applicability Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Equipment Effectiveness</td>
<td>Overall equipment effectiveness (OEE) is used to monitor equipment effectiveness by measuring equipment availability, performance, and product quality of the equipment (<a href="#">Voehl et al., 2013</a>).</td>
<td>Low</td>
<td>Macro level tool process control tool</td>
</tr>
<tr>
<td>Hypothesis Testing</td>
<td>Hypothesis testing is a statistical procedure that allows researchers to use sample data to draw inferences about the population of interest (<a href="#">Gravetter and Wallnau, 2013</a>).</td>
<td>Low</td>
<td>Macro level tool process improvement tool</td>
</tr>
<tr>
<td>Capability Analysis</td>
<td>Capability analysis studies the ability of the process to produce products within the specification limits. It provides information about the noise level of the system when there is no out-of-control condition (<a href="#">Peck et al., 1998</a>).</td>
<td>High</td>
<td>Value Add activity for Equipment Qualification</td>
</tr>
<tr>
<td>Measurement Systems Analysis</td>
<td>Measurement system analysis (MSA) is an experimental and mathematical method of determining how much the variation within the measurement process contributes to overall process variability (<a href="#">Bucher, 2007</a>).</td>
<td>Low</td>
<td>Process control tool</td>
</tr>
<tr>
<td>Design of Experiments</td>
<td>Design of experiments is a statistical technique used to study multiple variables simultaneously (<a href="#">Roy, 2001</a>).</td>
<td>Low</td>
<td>Process improvement tool</td>
</tr>
<tr>
<td>Statistical Process Control</td>
<td>Statistical Process Control is a statistical technique used to monitor the natural variability of a process (<a href="#">Yu, 2007</a>).</td>
<td>Low</td>
<td>Process control tool</td>
</tr>
</tbody>
</table>

**Table 5.6: Rating of Applicability of Six Sigma Tools for Equipment Qualification**
Capability Analysis

Capability Analysis is a method for understanding and predicting the effect of variation through comparing an output data distribution with specified tolerances. This comparison is reported as capability indices. The most commonly used process capability indices are:

\[
C_p = \frac{USL - LSL}{6\sigma} \quad \text{and} \quad C_{pk} = \min \left( \frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma} \right)
\]

Where \(\mu\) is the process average, \(\sigma\) is the process standard deviation, USL is upper specification limit and LSL is lower specification limit. (Juran et al., 1974) proposed the \(C_p\) index. It considers the ratio of the engineering tolerance to the natural tolerance and reflects only the process precision. The \(C_{pk}\) index proposed by (Kane, 1986) considers both the process precision and the process accuracy. Typically a \(C_p\) and \(C_{pk}\) of > 1.33 is required to ensure confidence in meeting tolerances in routine use (Sharma and Kharub, 2014).

Process capability refers to a range of indices that measure the ability of a process to deliver the customer’s requirements (Brook, 2010). Process Capability will consider all inputs to the process, including personnel, tools, work methods and the equipment. Process Capability studies can support Equipment Qualification in determining the capability of the medical equipment to produce consistent results.

5.4 Safety and Reliability

In broad terms, safety is ‘the freedom from unacceptable risk of physical injury or of damage to the health of people, either directly or indirectly as a result of damage to property or to the environment’ (Adams et al., 2003). Reliability is the probability that an item will function satisfactorily over a period of time under given conditions (Evans, 2003). Reliability refers to the frequency of occurrence of a failure in a component or system.
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For medical equipment reliability considerations can be categorised as relating to the equipment or to the human. Equipment reliability engineering utilises risk assessment prior to equipment design, design for reliability and reliability testing such as accelerated life testing. The Weibull distribution can be used to develop statistical information such as Mean Time to Failure (MTTF). The reliability design and testing function will be the responsibility of the medical device manufacturers and therefore can be deemed outside the scope of Equipment Qualification activities. Considerations relating to the human in reliability engineering are discussed in detail in Section 5.6 Human Factors Engineering.

Reliability and safety are inter-related. If it is accepted that all failures in medical equipment will induce either active or latent errors then reliability can be considered a component of safety; where safety is a combination of reliability and the degree of consequences of failure. Efforts to improve safety are inherently complementary to improving reliability. It is the broad scope of safety, therefore, that will be explored in relation to supporting Equipment Qualification.

5.4.1 ALARP Principle

Safety is tightly coupled with the tools and practices of risk management. In addition to the ISO 14971 tools and techniques outlined earlier, safety practitioners commonly adopt the As Low As Reasonably Practicable (ALARP) Principle when deciding whether it is better to accept, remove, reduce or handle a risk. As shown in Figure 5.4 ALARP categorises risks into three regions; Broadly Acceptable, Intolerable and the ALARP Region.
Risks in the Broadly Acceptable region are tolerated and do not require any further action. Risks in the Unacceptable region are intolerable and must be removed or reduced to make them tolerable or acceptable. Risks in the ALARP Region are tolerable if their reduction is impracticable or the cost is grossly disproportionate to the improvement gained.

5.4.2 Legislative Safety Requirements

The health, safety and welfare of employees in Ireland is governed by national legislation, much of which is derived from European Framework Directive 89/391/EEC. The primary piece of legislation governing the duties of employers to keep their workforce safe and healthy is the Safety, Health and Welfare at Work Act, 2005. There are also a significant number of regulations that apply to places of work within Ireland which provide more explicit detail of safety requirements. The most significant regulation is the Safety, Health and Welfare at Work (General Application) Regulations, 2007 - 2012 which contains many of the provisions that apply to healthcare facilities.
The Safety, Health and Welfare at Work Act, 2005 requires employers to prepare a Safety Statement which must include a written record of the hazard analysis/risk assessment carried out. The Act requires that the risk assessment in individual workplaces/workstations must be undertaken with subsequent action to eliminate or reduce the risk where appropriate. When performing a risk assessment, the employer is guided by the following General Principles of Prevention outlined in Schedule 3 of the Act:

1. The avoidance of risks
2. The evaluation of unavoidable risks
3. The combating of risks at source
4. The adaptation of work to the individual, especially as regards the design of places of work, the choice of work equipment and the choice of systems of work.
5. The adaptation of the place of work to technical progress.
6. The replacement of dangerous articles, substances or systems of work by safe or less dangerous articles, substances or systems of work.
7. The giving of priority to collective protective measures over individual protective measures.
8. The development of an adequate prevention policy in relation to safety, health and welfare at work, which takes account of technology, organization of work, working conditions, social factors and the influence of factors related to the working environment.
9. The giving of appropriate training and instructions to employees.
10. The avoidance of risks.

The Safety, Health and Welfare at Work (General Application) Regulations, 2007 - 2012 specify requirements for specific topics such as electricity, sensitive risk groups (young persons, pregnant employees, shift workers) and pressure systems. Part 2 Chapter 2 of the regulations concerns the use of work equipment and is of particular interest to the scope of this thesis. The duties of the employer under this section concentrate on ensuring that the equipment design, installation and working environment is conducive to the ongoing safety of the
equipment. Where the safety of work equipment depends on the installation conditions the regulations state that the employer must ensure an initial inspection is carried out after installation is completed and before it is first put into service. Inspection must also be carried out after assembly at any new site or in any new location to verify that the work equipment is installed correctly and is operating properly.

5.4.3 Safety Systems

In healthcare the term ‘patient safety’ has become synonymous with safety. While patient safety is a critical consideration of equipment qualification, attention must also be given to the safety of equipment users and the environment. It is the domain of systems safety which best encapsulates the safety requirements of Equipment Qualification.

System safety is a proven engineering discipline that is applied during system development to identify and mitigate hazards, and in so doing eliminate or reduce the risk of potential mishaps and accidents (Ericson, 2005). The concept of safety systems stems from the logic of system functions and of preventing errors before they happen (Moriarty, 1990). Safety systems design is concerned with the identification, evaluation, elimination and control of hazards and risks through analysis, design and management practices (O’Connor et al., 2012). System safety deals with systems as a whole rather than with subsystems or components. In system safety, safety is treated as an emergent property that arises at the system level when components are operating together. According to Leveson and Diaz-Herrera (1995) the core principles of safety systems are:

- emphasis on designed-in safety, not just added as after-thought
- analysis of the system as a whole as opposed to subsystems or constituent elements
- taking a larger view of hazards than just failures, including the prospective analysis of systems to facilitate a culture of continuous improvement
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- emphasis on analysis instead of exclusively relying on past experience
- emphasis on qualitative techniques as opposed to quantitative techniques

**Functional Safety**

Functional safety is the part of the overall safety of a system, or piece of equipment, that depends on the system or equipment operating correctly in response to its inputs, including the safe management of likely operator errors, hardware failures and environmental changes. Functional safety relies on active systems, such as limit switches rather than passive systems such as fire resistant materials. The objective of functional safety is freedom from unacceptable risk of physical injury or damage to the health of people either directly or indirectly (through damage to property or to the environment) (Lee and Ahn, 2014).

IEC 61508 (2010) is an international standard for functional safety of electrical and/or electronic and/or programmable electronic (E/E/PE) safety related systems. IEC 61508 notes that neither safety nor functional safety can be determined without considering the system as a whole and the environment with which they interact. IEC 61508-1 adopts a structured systematic approach to specifying the development lifecycle model for safety-relates systems, as shown in Figure 5.6. IEC 61508-1 describes in detail the objectives and requirements to successfully complete each individual lifecycle stage. Of particular interest to the scope of this thesis is Step 7: Overall Safety Validation planning, Step 8: Overall Installation & Commissioning Planning, Step 12: Overall Installation & Commissioning and Step 13: Overall Safety Validation.

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22While IEC 61508 addresses in detail the realisation of safety related Electrical/Electronic/Programmable Electronic (E/E/PE) technology, the lifecycle presented can be applied generically to other safety systems.
IEC 61508-1 advises that the planning sections (Steps 7 & 8) should be considered in the context of the other risk reduction measures. The safety validation planning phase prescribes requirements for measures, techniques and procedures that will be used for confirming that the allocation of safety functions has been carried out correctly. The safety validation plan must describe timeframes, the required environment and responsible persons for the validation, pass and fail criteria, the technical strategy for the validation (for example analytical methods, statistical tests, etc.) and specification of the modes of operation to be tested (start-up, automatic, manual, shut-down, reasonably
foreseeable abnormal conditions etc.). The installation and commissioning planning stage prescribes requirements for the installation and commissioning of the equipment in a controlled manner, to ensure that the required functional safety is achieved. The installation and commissioning plans must detail schedules, responsibilities and procedures for each stage.

Step 12: The overall installation and commissioning phase requires that information related to the installation/commissioning activities and resolution of failures and incompatibilities must be documented. The information required in Step 13: overall safety validation is follows:

- documentation in chronological form of the validation activities
- the version of the specification for the overall safety requirements being used
- the safety function being validated (by test or by analysis)
- tools and equipment used, along with calibration data
- the results of the validation activities
- configuration identification of the item under test, the procedures applied and the test environment
- discrepancies between expected and actual results.

IEC 61508 states that when discrepancies occur an analysis should be made to decide whether to continue the safety validation or issue a change request and return to an earlier part of the validation.

**Environmental Safety**

In industry, health and safety departments are increasingly assuming environmental responsibilities in order to minimise the adverse effects that result from normal operating conditions and to prevent incidents or accidents that might result from abnormal operating conditions, in essence these activities represent the management of the safety of the environment.
ISO 14001 is the international standard for environmental management systems. The standard is based on the Shewhart concept of Plan, Do, Check, Act (PDCA). The goal of ISO 14001 is to provide for any organisation, irrespective of its activities, size or location, a framework with which to address its environmental issues (Cascio et al., 1996). ISO 14001 was updated in 2015 to consist of seven primary elements: Context of the Organisation, Leadership, Planning, Support, Operation, Performance Evaluation and Improvement. The standard gives emphasis to risk management and a lifecycle perspective. Of particular interest to the scope of Equipment Qualification activities are the aspect/impact evaluation and operational planning and control.

ISO 14001 defines environmental aspects as the elements of an organisation's activities or products or services that interacts or can interact with the environment. Environmental impacts are defined as the changes to the environment, whether adverse or beneficial, wholly or partially resulting from an organisation's environmental aspects. Based on the aspects/impacts evaluation, operational planning and control may be required depending on compliance obligations and the risk associated with the aspect/impact. Annex A of ISO 14001 recommends the following control methods:

- a. Designing a process in such a way to prevent error and ensure consistent results
- b. Using technology to control processes and prevent adverse results (i.e., engineered controls)
- c. Using competent personnel to assure desired results
- d. Performing the process in a specified way (i.e. standardised procedure)
- e. Monitoring or measuring the process to check the results
- f. Determining the use and amount of documented information necessary.

This hierarchy of control mirrors the General Principles of Prevention outlined in Schedule 3 of the Safety, Health and Welfare at Work Act, 2005 and is an important concept for consideration in Equipment Qualification.
5.5 Maintenance & Calibration

Maintenance is defined as the combination of all technical and associated administrative actions intended to retain an item in, or restore it to, a state in which it can perform its required function (Parida and Kumar, 2006). According to Nakajima (1988) there have been four main periods of maintenance management:

1. Reactive (breakdown) maintenance (prior to 1950) where the emphasis was on fixing failures when they occurred.
2. Preventive maintenance (1950s) where the emphasis changed to determining the best methods to prevent failure and to reduce repair time through periodic inspections and repair of the equipment.
3. Productive maintenance (1960s) introduced maintainability improvement where equipment was modified to prevent breakdowns and facilitate ease of maintenance.
4. Total productive maintenance (1970s) which is designed to maximise equipment effectiveness. TPM is discussed in detail under lean methods in Section 5.7.

Calibration is defined by the Irish National Accreditation Board (INAB) as a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards (INAB, 2014). Calibration ensures that values displayed by the equipment for a given parameter are accurate for its intended use. The intended use will dictate the tolerance allowable in the calibration.

For medical equipment in healthcare, the equipment manufacturer will generally specify the parameters that require calibration (if required) and will suggest calibration intervals for these. It is the responsibility of the healthcare organisation to implement and manage a calibration schedule to ensure these
activities are completed. Calibration is well established in existing commissioning and acceptance testing activities in healthcare (Willson et al., 2013), the Equipment Qualification process therefore can leverage existing practices in this area.

### 5.6 Human Factors Engineering

Human Factors Engineering (HFE) is the development of tools that facilitate making the human interaction with systems one that reduces error, increases productivity, enhances safety, and enhances comfort (Wickens et al., 2004). HFE might also be called human factors, ergonomics, human engineering, usability engineering, or human–computer interaction (HCI) (ANSI/AAMI, 2009).

Human Factors Engineering is increasingly accepted as a powerful approach to improve patient safety through technology management (Lau et al., 2008). Rich (2008) states that, in healthcare, the objective of human factors is to improve human performance with medical products, including medical devices, and to reduce the likelihood of error or injury, thus improving patient and workplace safety. The FDA have adopted the view put forward by Rich (2008) and have included this paper in their articles on device safety (FDA, 2014).

The International Ergonomics Association recognises physical, cognitive and organisational considerations as the domains of specialisation within the discipline of human factors/ergonomics. Physical ergonomics is concerned with human anatomy, and some of the anthropometric, physiological and biomechanical characteristics as they relate to physical activity. Relevant topics include working postures, materials handling, repetitive movements, work related musculoskeletal disorders, workplace layout, safety and health (IEA, 2015).

Cognitive ergonomics is concerned with mental processes, such as perception, memory, reasoning, and motor response, as they affect interactions among
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humans and other elements of a system. The relevant topics include mental workload, decision-making, skilled performance, human-computer interaction, human reliability, work stress and training as these may relate to human-system design (IEA, 2015).

Organisational ergonomics is concerned with the optimisation of sociotechnical systems, including their organisational structures, policies, and processes. The relevant topics include communication, crew resource management, work design, design of working times, teamwork, participatory design, community ergonomics, cooperative work, new work paradigms, organisational culture, virtual organisations, telework and quality management (IEA, 2015).

In developing an Equipment Qualification framework for healthcare it is important to be cognisant of physical and cognitive ergonomics, in particular assessing usability testing which considers both physical and cognitive ergonomics related to the medical equipment.

5.6.1 Usability

One of the most often cited definitions of usability is that of ISO 9241-11 Ergonomic requirements for office work with visual display terminals (VDTs) - Part 11: Guidance on usability (ISO 9241-11, 1998). In this standard usability is defined as 'The effectiveness, efficiency, and satisfaction with which specified users achieve specified goals in particular environments'. The components of the definition are explained as follows:

- **Effectiveness**: The accuracy and completeness with which specified users can achieve specified goals in particular environments.
- **Efficiency**: The resources expended in relation to the accuracy and completeness of goals achieved.
- **Satisfaction**: The comfort and the acceptability of the work system to its users and other people affected by its use.
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Inherent in this definition is the notion that a successful outcome of the system is a function of usability. This view however has been challenged in the literature. According to Grudin (1992) usefulness is a measure of how well a technical system can achieve a desired goal. Usefulness can then be divided into two aspects: utility and usability. Utility depends on whether the functionality of the technical system can perform what is required, while usability depends on how well the user can use that functionality. For example, in the case of a drilling machine, utility refers to the drill’s capacity to make holes, whereas usability describes how well the user can handle the drill while it bores holes.

The difference between usability and utility is an important consideration when evaluating medical devices. Bligård (2007) states that in the case of medical devices that utility is the medical function of the equipment, such as how well a blood-pressure gauge measures blood pressure or how well a scalpel cuts while usability is how well the medical personnel can use the equipment’s medical functionality, such as whether a nurse can understand what the blood-pressure gauge displays or whether the scalpel fits in a surgeon’s hand.

IEC 62366

IEC 62366: Medical Devices – Application of Usability Engineering to Medical Devices is a process-based standard that aims to help manufacturers of medical devices ‘design in’ usability and ‘design out’ usage errors. The standard specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors (IEC 62366, 2007).

IEC 62366 adopts a risk based approach, stating that if the usability engineering process has been complied with and the acceptance criteria documented in the usability validation plan have been met, then the residual risks, as defined in ISO 14971: Medical devices - Application of risk management to medical devices, associated with usability of a medical device are presumed to be acceptable, unless there is objective evidence to the contrary.

The standard describes a Usability Engineering Process with nine stages:

1. **State Application Specification**
   
   The most important characteristics relating to the use of the device (such as the intended medical purpose, patient population, the intended user profile, conditions of use, the device’s operating principle etc.) are stated.

2. **Identify Frequently Used Functions**
   
   Frequently used functions are of particular importance as there is an increased probability of use errors.

3. **Identification of hazards and hazardous situations related to usability**
   
   The standard directs the reader to ISO 14971 to assist in an identification of characteristics of the device which could impact safety.

4. **Identify Primary Operating Functions**
   
   The primary functions are those functions that relate directly to the safety of the device and also include the frequently used functions identified earlier. The annex recommends functional analysis techniques that can be used in this stage.
5. **Develop Usability Specification**
   The usability specification must provide testable requirements for usability verification, describe use scenarios and create testable usability goals.

6. **Prepare the usability validation plan**
   The usability validation plan describes how the usability of the device's primary operating functions will be validated and specifies success criteria. It also defines the test users and the test use scenarios.

7. **Design and implement the user interface**
   At this stage, the user interface is designed utilising usability engineering methods and techniques. It is important to note that the term "interface" applies to all parts of the device a user interacts with, not just to a visual display or touch screen.

8. **Verify the user interface design**
   At this stage, the design is verified against its usability specification and redesigned as necessary.

9. **Validate the usability of the medical device**
   In the final stage, the device is validated to ensure that user’s goals have been met. This validation needs to be carried out under actual or simulated conditions. Validation should be conducted by people not directly involved in the design of the user interface.

In support of the usability engineering process IEC 62366 presents a number of detailed annexes along with useful worked examples. Of particular interest are the recommended methods and techniques for the usability engineering process. In Appendix I a summary table describing and assessing the advantages and limitations of each tool is presented.

**ANSI/AAMI HE75**

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recommend that HE75 can also benefit clinical and bioengineering teams in institutional care settings. HE 75 is seen a useful resource for both human factors professionals and for engineers who might know only a little about human factors engineering as it gives specific advice on design principles. Rather than scouring the HFE literature, engineers can look up the design principles in HE 75 (Patterson et al., 2010). As examples, North and Patterson (2010) state that the Workstations and Anthropometry and Biomechanics sections of HE75 can be used as a guide for workstation layouts and that usability considerations found in the General Principles and Usability testing sections provide purchasing staff with key questions for vendors regarding their usability validation and testing that should accompany the design of any medical device or system.

HE75 categorises usability tests as either formative or summative. Formative usability testing is performed early, using simulations and early working prototypes; it is intended to explore whether usability objectives are attainable, but does not have strict acceptance criteria. Summative usability testing is performed late in design as part of a formal verification and validation (ANSI/AAMI, 2009). It is evident therefore that the scope of summative testing most appropriately reflects the usability evaluation needs of healthcare providers.

HE75 states that in usability tests, representatives of the intended user population interact with one or more device models, prototypes, or production units to assess ease of learning, ease of use, effectiveness and efficiency of use, memorability, safety, and/or user appeal. Based on this generic view of usability testing the HE75 standard gives guidance on good usability testing design. Central to this guidance are recommendations for the content of the usability test plan. HE75:2009 states that the usability test plan should describe the following:

i. Purpose of the usability test.

ii. The setting for the test; e.g. laboratory, clinical setting etc.
iii. Participants; should be representative of the users most likely to use the device.

iv. Prototypes and simulations.

v. Methodology or test protocol; the method description in a usability testing plan, its actual protocol, and the subsequent report are much like the methodology section of any scientific report. The usability test plan should describe the usability study methodology and related test protocols in enough detail that another researcher or designer could replicate the study.

vi. Tasks; the usability test plan should describe the tasks that subjects will be asked to perform and should specify the order in which the tasks will be presented.

a. Task-analysis studies should be performed to identify the usability test tasks. Task analysis is done by means of contextual inquiry techniques of systematic observation and data collection to create task flows, use cases, and typical usage scenarios, among many other outcomes.

b. The tasks selected for usability testing should include the most critical safety-related tasks. Analytical usability inspection methods such as cognitive walk-throughs are recommended for comprehensively evaluating all user tasks.

vii. Usability Objectives; The main reason for specifying usability objectives (also known as usability requirements, usability goals, performance goals, or human factors requirements) is to define metrics that can be applied during usability testing to provide quantitative test acceptance criteria.

viii. Data Collection; Data collection can take many forms, from simple paper-based logging forms and stopwatches, to computer logging software and video recording, to systems that track dynamic eye movements. The form of data collection depends on the stage of development, the criticality of the device, and the development project’s budget and schedule constraints.
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ix. Data Analysis; Data Analysis should be mostly quantitative for summative usability testing against usability objectives with quantitative acceptance criteria.

x. Reporting; Usability testing results should be reported according to accepted practices for writing scientific reports, especially in the case of summative usability tests with formal acceptance criteria.

HE75 also refers to usability inspection methods; i.e. analytical methods that are complementary to empirical measures of usability. These methods are:

i. Cognitive Walk-throughs
   Cognitive walk-throughs involve a structured review of user requirements for the performance of a sequence of predefined tasks.

ii. Expert Reviews
   Expert reviews are evaluations of device usability by HFE specialists to identify design strengths and weaknesses and to recommend improvements.

iii. Heuristic Reviews
   In a heuristic review, clinical or HFE experts evaluate a device or system by assessing how it conforms to well established user-interface design rules or heuristic guidelines. A heuristic review is a more formal process than an expert review and requires multiple experts who develop a consensus opinion about design characteristics.
5.7 Lean

The concept of lean can be traced to the Toyota Production System (TPS) (Sohal and Egglestone, 1994), a manufacturing philosophy pioneered by the Japanese engineer Taiichi Ohno. “All we are doing is looking at the time from the moment the customer gives to an order to the point when we collect the cash. And we are reducing that time line by removing the non-value-added wastes” is how Taiichi Ohno explained the TPS (Liker, 2004). According to Black (2008), Ohno identified the following seven types of waste:

- **Waste of Overproduction:**
  Producing items without an order or producing items not in a timely manner (e.g. too early or too late). Ohno considered overproduction to be the fundamental waste as it causes most of the other wastes (Liker, 2004).

- **Waste of Time:**
  Delays coming from people, processes, or Work-in-Progress (WIP), inventory sitting inactive while waiting for instructions, information, raw materials, or any other resources. Wasteful waiting ties up capital, increases the risk of obsolescence or damage, and often requires additional handling and movement of goods (Choudhary et al., 2012).

- **Waste of Transportation:**
  The movement of raw material, WIP or finished goods, sometimes over long distances, between process steps or into and out of storage (Liker, 2004).

- **Waste of Processing:**
  Adding unnecessary features that are not value adding. Poor process design can lead to producing higher quality products or services than a customer needs or is willing to pay for (Choudhary et al., 2012).

- **Waste of Inventory:**
  Excess inventory causes longer lead-times since every item has to wait in inventory until every preceding item has been processed. Furthermore,
inventory has to be stored and transported, which is costly and may damage the products. Inventory also hides issues such as an unlevelled production line (Liker, 2004)

- **Waste of Motion:**
  Unnecessary movement of people, product, or equipment which does not add value to a product. For example, workers walking back and forth from the work area to the supply area, moving around unneeded equipment, or performing redundant motions can be completely eliminated or automated to speed up the process (Choudhary et al., 2012).

- **Waste of Making Defective Products:**
  Parts that need to be reworked or repaired require additional handling, delays, and effort (Liker, 2004).

These seven wastes can be further described through the 3M’s of the Japanese terms muda, mura and muri. Muda is a general term for waste (Chalice, 2007). Mura is unevenness in an operation (e.g. an uneven work pace in an operation which causes operators to hurry and then wait) (Marchwinski and Shook, 2003). Muri is all the unreasonable work that management imposes on workers and machines because of poor organisation, such as carrying heavy weights, moving things around, dangerous tasks and working significantly faster than usual. It is pushing a person or a machine beyond its natural limits (Asefeso, 2012). In the context of healthcare, muri is a particularly important concept to be cognisant of.

The concept of lean became global after the publication of the international bestseller “The Machine that Changed the World” by Womack, Jones, and Roos (Womack et al., 1990). In this book Womack et al. (1990) describe five Lean principles which emphasises creating a Lean Enterprise rather than just Lean Manufacturing. Figure 5.6 gives a graphical representation of these five principles.
The first principle is to identify and specify the value that is being created within the company, requiring the identification of the customers and the customer’s needs. Womack et al. (1990) stress that customers define value by what they are willing to pay for a given product or service. The second principle is the Value Stream; A value stream describes all processes and steps needed to produce a product or service (Rother and Shook, 2003). The third principle is Flow; Through flow, according to Womack et al. (1990), services and goods can be processed more efficiently and accurately with less Work in Progress (WIP).

The fourth principle is to implement a pull rather than push system. A pull system produces only products or services when demanded by a customer. In an ideal state, production time is so short that the actual production of a product or service will start only when a customer order is received. In this case, no finished goods inventory will exist (Womack et al., 1990). Lastly, the fifth principle is a merciless drive for perfection which triggers the process of continuously improving the current state (Womack et al., 1990).
5.7.1 Lean Tools

The lean philosophy utilises over 100 tools to assist in the identification and elimination of waste (Pavnaskar et al., 2003). Lean practitioners, therefore, must understand and utilise those tools which are applicable to their specific requirements. Table 5.7 lists the primary lean tools, with a brief description of each, and a rating of the applicability of the tool for the Equipment Qualification of medical equipment in healthcare. Tools which have a high applicability rating are discussed in further detail.
<table>
<thead>
<tr>
<th>Tool</th>
<th>Description</th>
<th>Applicability Rating</th>
<th>Applicability Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Work</td>
<td>The standardisation of best practices for activities which can used as a base for improvement (Dennis, 2007)</td>
<td>High</td>
<td>Value Add activity for Equipment Qualification</td>
</tr>
<tr>
<td>Value Stream Mapping</td>
<td>A flow diagram method for visualising and analysing a current process to identify improvement opportunities (Lasa et al., 2008)</td>
<td>Low</td>
<td>Macro level process improvement tool</td>
</tr>
<tr>
<td>Total Productive Maintenance</td>
<td>A maintenance programme which seeks to engage employees at all levels and functions in an organisation in order to maximize the overall effectiveness of equipment (Nakamura, 2008)</td>
<td>High</td>
<td>Value Add activity for Equipment Qualification</td>
</tr>
<tr>
<td>Heijunka</td>
<td>The levelling of workload and production over a defined period in order to achieve constant flow of mixed parts and to minimize the peaks and valleys in the workload (Jones, 2006)</td>
<td>Low</td>
<td>Macro level tool process control tool</td>
</tr>
<tr>
<td>Poka-Yoke</td>
<td>An error proofing method with high reliability, which is designed for specific work place conditions (Shimbun, 1988)</td>
<td>Low</td>
<td>Equipment design stage tool</td>
</tr>
<tr>
<td>Jidoka</td>
<td>Building quality into the process through people and machine mechanisms to detect abnormal conditions, thus preventing defective parts passing to the next process and determining and eliminating the root cause (Baudin, 2007)</td>
<td>Low</td>
<td>Macro level tool process improvement tool</td>
</tr>
<tr>
<td>5S Housekeeping</td>
<td>5S is a business system for organising and managing operations, it creates a work environment that is disciplined, clean and well-ordered (Chapman, 2005)</td>
<td>High</td>
<td>Value Add activity for Equipment Qualification</td>
</tr>
<tr>
<td>Just in time</td>
<td>Producing goods at the right time and the right quantity to meet customer demand (Monden, 2011)</td>
<td>Low</td>
<td>Macro level tool process control tool</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Tool</th>
<th>Description</th>
<th>Applicability Rating</th>
<th>Applicability Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andon</td>
<td>A method which allows everyone working on the production line to stop the production if defect is detected (Liker and Morgan, 2006)</td>
<td>Low</td>
<td>Macro level tool process control tool</td>
</tr>
<tr>
<td>Kanban</td>
<td>Kanban is a pull signal, controlling work in process inventory (Berkley, 1992)</td>
<td>Low</td>
<td>Macro level tool process control tool</td>
</tr>
<tr>
<td>Kaizen</td>
<td>Kaizen is the extent to which employees contribute to the company’s development through suggestions aimed at elimination of all kinds of waste (Manos, 2007)</td>
<td>Low</td>
<td>Macro level tool process improvement tool</td>
</tr>
<tr>
<td>Visual Management</td>
<td>Methods used to display value added information to relevant staff (Mastroianni and Abdelhamid, 2003)</td>
<td>Low</td>
<td>Macro level tool process control tool</td>
</tr>
<tr>
<td>One Piece Flow</td>
<td>One piece flow from one process to another without WIP inventory between the processes (Sekine et al., 1991)</td>
<td>Low</td>
<td>Macro level tool process control tool</td>
</tr>
<tr>
<td>SMED</td>
<td>SMED stands for Single Minute Exchange of Dies and is a method for set-up time reduction (McIntosh et al., 2000)</td>
<td>Low</td>
<td>Macro level tool process improvement tool</td>
</tr>
<tr>
<td>Quality Function Deployment</td>
<td>An overall concept that provides a means of translating customer requirements into the appropriate technical requirements for each stage of product development and production (Sullivan, 1986)</td>
<td>Low</td>
<td>Equipment design stage tool</td>
</tr>
</tbody>
</table>

Table 5.7: Rating of Applicability of Lean Tools for Equipment Qualification
Standard Work

Standard work, in the context of healthcare, has been defined as ‘the current one best way to safely complete an activity with the proper outcome and the highest quality’ (Graban, 2011). In manufacturing Standard Operating Procedures (SOP) ensure consistency and predictability of inputs, processes and outputs. In hospitals standardised procedures typically are used for hand washing and hygiene, labelling of patient specimens, labelling of medications and methods for using equipment (Graban, 2011).

At the installation stage of fixed installed medical equipment for healthcare, activities should include a verification that SOPs are in place for maintenance, calibration and operating equipment. The process and responsibilities for the installation of the equipment could also be standardised to ensure that all best practice activities have been considered before the equipment is handed over to medical staff for clinical use.

Total Productive Maintenance

The Japan Institute of Plant Engineers (JIPE) developed Total Productive Maintenance (TPM) and defined TPM as a system of maintenance covering the entire life of the equipment in every division, including planning, manufacturing, maintenance, and all other divisions, involving everyone from the top executives to the shop floor workers and promoting productive maintenance through morale-building management and small group activities in an effort to maximize equipment efficiency (Nakajima, 1988).

Nakajima (1988) defined TPM through five key elements:

1. TPM aims to maximize equipment effectiveness.
2. TPM establishes a thorough system of Preventive Maintenance for the equipment’s entire life span.
3. TPM is cross-functional, implemented by various departments (engineering, operators, maintenance and managers).
4. TPM involves every single employee.
TPM is based on the promotion of Preventive Maintenance through the motivation of management and autonomous Small Group Activity.

TPM also contributes to a positive safety culture through management incentive, management commitment, participation of management and workers, communication, education and training, working conditions and procedures, morale and job satisfaction, and attitude and risk perception (Loi, 2001). Blanc (1993) defines six principles for TPM:

1. Improvement of product and process quality through zero mentality
2. Elimination of the six big losses:
   a. **Breakdown failures**: Losses due to sporadic and function-reducing machine failures
   b. **Setups and adjustments**: Shutdown losses accompanying setup changeovers and adjustments
   c. **Idling and minor stoppages**: Losses due to idling or stoppage resulting from transient problems
   d. **Reduced speed**: Losses arising from disparities between actual operating speeds and speeds specified in equipment design
   e. **Quality defects and rework**: Losses due to defects and rework
   f. **Start-up and reduced yield**: Losses incurred in the interval between production start-up and stable production.
3. Development of a clean, safe, well organised, and visually controlled workplace.
5. Development of equipment management systems (predictive maintenance, OEE tracking, preventive maintenance) which enhance TPM implementation and development.
6. Increase skill levels of operators and maintenance personnel and begin to transfer more equipment ownership to operators.

Total Productive Maintenance is applied through a twelve step process, based on the work of (Nakajima, 1988). Robinson and Ginder (1995) recommend that
changes in the order of the steps proposed by Nakajima are required to suit western-style organisations. The 12-steps of these two models are summarized in Table 5.8 below.

<table>
<thead>
<tr>
<th>Step</th>
<th>Japanese Approach</th>
<th>Western Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Announce top management decision to introduce TPM</td>
<td>Launch education campaign to introduce TPM</td>
</tr>
<tr>
<td>2</td>
<td>Launch education campaign to introduce TPM</td>
<td>Create an organisational structure to promote TPM</td>
</tr>
<tr>
<td>3</td>
<td>Create an organisational structure to promote TPM</td>
<td>Announce top management decision to introduce TPM</td>
</tr>
<tr>
<td>4</td>
<td>Establish basic TPM policies and goals</td>
<td>Establish basic TPM policies and goals</td>
</tr>
<tr>
<td>5</td>
<td>Formulate master plan for TPM development</td>
<td>Formulate master plan for TPM development</td>
</tr>
<tr>
<td>6</td>
<td>Kick-off TPM</td>
<td>Kick-off TPM</td>
</tr>
<tr>
<td>7</td>
<td>Improve effectiveness of each piece of equipment</td>
<td>Improve effectiveness of each piece of equipment</td>
</tr>
<tr>
<td>8</td>
<td>Develop an autonomous maintenance program</td>
<td>Develop an autonomous maintenance program</td>
</tr>
<tr>
<td>9</td>
<td>Develop a scheduled maintenance program for the maintenance department</td>
<td>Develop a scheduled maintenance program for the maintenance department</td>
</tr>
<tr>
<td>10</td>
<td>Conduct training to improve operation and maintenance skills</td>
<td>Conduct training to improve operation and maintenance skills</td>
</tr>
<tr>
<td>11</td>
<td>Develop early equipment management program</td>
<td>Develop early equipment management program</td>
</tr>
<tr>
<td>12</td>
<td>Perfect TPM implementation and raise TPM levels</td>
<td>Perfect TPM implementation and raise TPM levels</td>
</tr>
</tbody>
</table>

Table 5.8: Approaches to TPM
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The implementation of TPM could be instigated at the installation stage of medical equipment in hospitals to facilitate a ‘born lean’ approach. Prior to, and during commissioning of the equipment an education campaign could be launched through internal correspondence and awareness posters/talks. The appointment of a TPM champion and the support of management would satisfy steps 2 & 3. The basic policies and goals and the TPM master plan would be created to suit the working environment, it may be expected to defines roles and responsibilities for maintenance, cleaning and defect reporting and include expected results and rationale for adopting TPM. An organised event or ‘TPM Day’ could be established to formally kick off TPM efforts. Improving the effectiveness of equipment may be achieved through expert review of the equipment and/or application of statistical techniques such as Design of Experiments and Response Surface Methodology.

An autonomous maintenance program can be achieved through setting standards for cleanliness and maintenance parameters and the methods used to achieve these standards. Visual aids such as equipment nameplates, operating range displays on gauges and photographs of the desired state of cleanliness can be used with regular inspection checklists to verify the required conditions are sustained. A formal maintenance schedule should be in place, which records dates and personnel who completed maintenance activities.

Training is of particular importance in a healthcare setting; operators of equipment should be capable and confident in the use of the equipment and receive initial and refresher training when required. Equipment performance metrics should be used be utilised to enable early management of the equipment. Step 12, Perfect TPM implementation and raise TPM levels, is the ultimate target to be accomplished.
5S Housekeeping

5S is a method of workplace organisation and standardisation. The 5S’s ‘Sort, Set in Order, Shine, Standardise, and Sustain’ are rough translations from the original Japanese terms ‘Seiri, Seiton, Seiso, Seiketsu, and Shitsuke’.

1. **Sort – (Seiri)**
   The first S focuses on eliminating unnecessary items from the workplace. An effective visual method to identify these unneeded items is called ‘red tagging’ where a red tag is placed on all items deemed unnecessary to the area. If an item is not claimed by another employee within a set time frame it is removed to external storage.

2. **Set in Order (Seiton)**
   Set in Order is the second S and focuses on efficient and effective storage methods. The emphasis of this step is on ensuring ‘A place for everything and everything in its place’. Methods used include outlining work areas and locations, shadow boards and modular shelving and cabinets.

3. **Shine: (Seiso)**
   After the unnecessary items have been removed from the workstation and a set location has been decided for the remaining items, the next step is to thoroughly clean the work area. The Shine step also helps create ownership in the equipment and facility.

4. **Standardize: (Seiketsu)**
   To standardise the 5S efforts a decision must be made on how work functions will be performed, and then an effort must be made to keep them regulated.

5. **Sustain: (Shitsuke)**
   Sustain highlights the importance of establishing a method to monitor and report 5S adherence and progress. Sustain is regarded as the hardest S to implement and achieve.

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23 It is common to find different titles for each S (e.g. Shine is often called Sweep)
5S has been shown to increase moral, create positive impressions for customers (patients) and employees have reported a more positive perception of their work environment (Karim et al., 2012). 5S is also seen as the foundation for lean practices through creating an atmosphere in which change is embraced (Esain et al., 2008).

In a healthcare environment 5S can be expected to contribute the following benefits:

- Reduced workplace accidents, in particular slips, trips and falls, as a result of a cleaner, tidier environment (Chapman, 2005).
- Improved employee morale improving from working in a more organised workplace (Gapp et al., 2008).
- Better inventory management would ensure that the appropriate supplies, instruments and equipment will be readily available thus reducing throughput times and increasing customer satisfaction (Furterer, 2014). Required documentation and information could also be managed through 5S.
- Visitors to the hospital will see a more organised environment, which should lend itself to an improved public perception of the hospital.
- 5S helps reduce changeover times between procedures/patients (Johnson et al., 2007).

5.8 Discussion

In this chapter the supporting disciplines to Equipment Qualification which facilitate fulfilling the goals of minimising the potential for failure of the device, minimising the potential for users making mistakes with the device and with maximising the potential for productivity in the use of the device were explored. The disciplines of quality, safety, equipment reliability, maintenance and calibration were shown to be tightly coupled with failure of the device while users making mistakes was shown to be tightly coupled with the disciplines of
quality, safety and human factors engineering. Lean tools and techniques were described as being closely associated with the goal of maximising productivity. Risk management was described as underpinning all efforts in identifying and mitigating latent hazards. Indeed, in Equipment Qualification, value may be seen as a function of risk; as risk decreases, value created increases.

In exploring risk management it was shown that risk analysis tools such as FMEA & HAZOP are useful in identification of single point independent failure modes. However, the latent errors and potential pathways for adverse events that must be addressed during Equipment Qualification in healthcare are more complex than independent failure modes. It cannot be expected, therefore, that FMEA and/or HAZOP when used in isolation, will constitute a thorough risk assessment to capture the full extent of complexities in the use of medical equipment in healthcare. The Structured What-If Technique (SWIFT) provides the most comprehensive method to pre-emptively capture the potential for latent factors, faults, errors, and mistakes in the use of medical equipment in healthcare.

The capability analysis tool of Six Sigma, within the scope of quality initiatives, has been shown to be a potential value add tool for Equipment Qualification. The discipline of quality has contributed philosophical considerations for the development of an Equipment Qualification framework for healthcare; particularly in ensuring cognisance of the systematic approach recommended for quality initiatives. Due to the overlapping relationship between quality, safety and risk (Arah and Klazinga, 2004, Auerbach et al., 2007, Brennan et al., 2005) it may also be expected that contributions of other disciplines can be synthesised to improve quality.

Safety and reliability were shown to be inter-related, where efforts to improve safety are inherently complementary to improving the reliability of the medical

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24 While adverse incidents involving medical equipment are often ascribed to human factors, including users' inexperience, they are typically multifactorial in origin, with latent factors, faults, errors, and mistakes aligning together (Amoore and Ingram, 2002)
Chapter Five: Supporting Disciplines to Equipment Qualification

equipment. The As Low As Reasonably Practicable (ALARP) is an important concept for Equipment Qualification practitioners to be aware of when assessing the safety of medical equipment. Environmental safety was discussed in terms of an aspects/impacts evaluation as recommended by ISO 14001.

Maintenance and calibration were introduced, with an acknowledgement that the well-established maintenance and calibration practices of commissioning and acceptance testing in healthcare can be leveraged by the Equipment Qualification framework.

Human Factors Engineering was discussed primarily through analysing standards and tools for assessing usability of medical equipment in the use environment. It is evident that the emphasis of the medical device usability standards is on processes for the manufacturer of the medical device, particularly in design and development lifecycle phases. In terms of extracting guidance on which usability engineering methods can be utilised in the Equipment Qualification framework it is evident that the scope of IEC 62366 is more aligned with formative usability testing, presenting named techniques within formal requirements for manufacturers while HE 75 gives more detail and guidance in conducting summative usability tests. HE 75, therefore, may be seen as the ‘go to’ reference guide for healthcare practitioners in developing and executing summative usability tests.

The discipline of Lean supports Equipment Qualification as lean and Equipment Qualification share a common goal of delivering value and customer satisfaction. Equipment Qualification provides an opportunity to verify the implementation of lean methods, particularly standard work, TPM and 5S in the healthcare environment. Utilising lean techniques at an early stage ensures that the equipment and surrounding workspace can facilitate a productive work environment and that programs for the ongoing management of the workspace are implemented. Furthermore, the visual nature of lean tools will ensure that all personnel within the workspace will have clear instruction on expected
Chapter Five: Supporting Disciplines to Equipment Qualification

standards that must be adhered to, standards that are based on best practice and are auditable. While healthcare facilities must be particularly cognisant of the lean concept of muri, as overburdened personnel are more likely to make mistakes, ultimately the implementation of lean tools should create time for healthcare practitioners as equipment, information and instruments will be more readily available when needed.

In this chapter the supporting disciplines to Equipment Qualification were analysed in detail to extract the most relevant tools, methods and considerations for the development of the Equipment Qualification framework. Table 5.9 builds on Table 5.1 as presented earlier, providing specific supporting tools, techniques and considerations relevant to Equipment Qualification.

<table>
<thead>
<tr>
<th>Component of Ready</th>
<th>Supporting Disciplines</th>
<th>Tools/Techniques/Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential for productivity maximised</td>
<td>Lean</td>
<td>5S Total Productive Maintenance Standard Work</td>
</tr>
</tbody>
</table>

Table 5.9: Components of Ready, Supporting Disciplines and Associated Tools/Techniques/Considerations
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6.1 Introduction

This chapter presents the rationale for the research design and the methods used for establishing the validity of the research design in developing an Equipment Qualification framework for healthcare.

6.2 The Research Design

Research designs are the plans and procedures for research that span the decisions from broad assumptions to detailed methods of data collection and analysis (Creswell, 2003). Yin (2009) describes research design as the “logic that links the data to be collected (and the conclusions to be drawn) to the initial research questions of the study”. Accordingly, the research design of this study begins with a reiteration of the research question and objectives:

‘How can the protocols, practices and tools of Equipment Qualification be developed and modified for application in healthcare?’

In order to answer the research question the following objectives were identified:

1. To explore, through a review of the literature, best practice in supporting disciplines to Equipment Qualification
2. To benchmark, through case studies, best practice methods used in manufacturing industries for Equipment Qualification.
3. To determine the identified and unidentified requirements of key stakeholders of activities within the scope of Equipment Qualification activities in healthcare.
4. Informed by the results of 1 to 3 above, to develop a framework to assist healthcare providers in applying best practice methods in the qualification of medical equipment.
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In developing a valid research design to answer the research question it is imperative that the study is cognisant of the fundamental theories of research. Checkland and Holwell (1998) state that there are three elements necessary to describe any piece of research; a framework of ideas, a methodology and an area of concern.

The framework of ideas (F) in which the knowledge about the area of concern is expressed includes current theories, bodies of knowledge and heuristics as documented in the literature as well as tacit knowledge. The methodology (M) incorporates methods, tools and techniques in a manner appropriate to the discipline that uses them to investigate the area of concern. The Area of Concern (A) might be a particular problem in a discipline (area of study), a real-world problem situation, or a system of interest (Checkland and Holwell, 1998).

Checkland and Holwell (1998) describe this FMA approach as the basic framework for all intellectual work. Figure 6.1, below, illustrates the relationship between these three elements and how undertaking the methodology creates new knowledge about all three elements.

Figure Removed for Copyright Reasons

Figure 6.1: FMA Approach to Research (Checkland and Holwell, 1998)
Chapter Six: Methodology

In the context of tackling the research question in terms of the FMA framework, each element is addressed as follows:

- The framework of ideas concerns the exploration of the theories, standards and techniques explored in the literature review.
- The methodology is addressed in this chapter.
- The area of concern is the development of an Equipment Qualification framework for medical equipment in healthcare.

Creswell (2003) states that, in identifying a suitable research design, the research must give consideration to:

i. the research audience,
ii. the problem at hand, and
iii. the researcher’s background.

While the research audience of this work is broad; encompassing all parties interested in the application of systems engineering in healthcare, the primary research audience is the stakeholders in healthcare who are tasked with ensuring that medical equipment is ready for its intended use. Accordingly, the research will be designed primarily to meet the needs of this cohort. The problem at hand is captured in the research question and objectives. Finally, Creswell (2003) stresses the need for researchers to consider their own personal training and experiences in identifying a suitable research design. Appendix II contains the authors Curriculum Vitae, highlighting the author’s academic and professional experience in Equipment Qualification and its supporting disciplines.

Creswell (2003), in refining the work of Crotty (1998), presents three questions which are central to the design of research:

1. What knowledge claims are being made by the researcher (including a theoretical perspective)?
2. What strategies of inquiry will inform the procedures?
3. What methods of data collection and analysis will be used?
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In the following sections paradigms of knowledge claims (Section 6.2.1), strategies of inquiry (Section 6.2.2) and data collection methods (Section 6.2.3) will be explored and discussed, cognisant of Creswell’s criteria for identifying a suitable research design.

6.2.1 Knowledge Claims

The knowledge claims of research provide the philosophical context in which the research is grounded and framed. Stating a knowledge claim means that researchers start a project with certain assumptions about how they will learn and what they will learn during their inquiry (Creswell, 2003). Philosophically, researchers make claims about what is knowledge (ontology), how we know about it (epistemology), what values go into it (axiology), how we write about it (rhetoric), and the processes for studying it (methodology) (Creswell, 1994).

There is much debate in the literature on the philosophical underpinnings of research. Pedersen et al. (2000) and Seepersad et al. (2005) propose two opposing views; the Foundationalist/Reductionist/Formalist View and the Relativistic/Holistic/Social View, while Creswell (2003) suggests that four separate knowledge schools exist; Postpositivism, Advocacy/Participatory, Constructivism and Pragmatism.

The Foundationalist/Reductionist/Formalist views of knowledge are based on the beliefs that knowledge exists only in binary terms i.e. right or wrong, true or false answers, that the formal accuracy of new knowledge is the primary concern rather than practical use and that quantification of results is the only correct measure of knowledge (Pedersen et al., 2000, Seepersad et al., 2005). Evidently the Foundationalist/Reductionist/Formalist does not lend itself towards facilitating a research topic whose goal is the development of a best practice framework in a complex system.
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In contrast, the Relativistic/Holistic/Social view is better suited to open ended problems such as design and analysis methods where no definitive answer exists and many possible solutions for the same problem can be identified based on objective and subjective sources. In the Relativistic/Holistic/Social view the acceptance of new knowledge is dependent on a socially justified belief in the new knowledge, the usefulness of the new knowledge with respect to its intended purpose and the requirement that the knowledge can be applied by a suitably qualified user in the domain in which the knowledge is applied (Pedersen et al., 2000, Seepersad et al., 2005). In terms of the goals of this research the Relativistic/Holistic/Social view provides a fitting philosophical stance.

While the Relativistic/Holistic/Social view is a research epistemology which appropriately captures the essence of this work, its applicability is not necessarily exclusive as will be shown in a review of Creswell’s view of knowledge. Creswell’s (2003) four schools of knowledge can be summarised as follows:

- **Postpositivism:**
  - Determination
  - Reductionism
  - Empirical observation and measurement
  - Theory verification

- **Constructivism:**
  - Understanding
  - Multiple participant meanings
  - Social and historical construction
  - Theory generation

- **Advocacy/Participatory:**
  - Political
  - Empowerment issue-orientated
  - Collaborative
  - Change-orientated
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- **Pragmatism:**
  - Consequences of actions
  - Problem-centred
  - Pluralistic
  - Real-world practice orientated

Postpositivism, sometimes referred to as the ‘scientific method’, is a school of knowledge where an individual begins with a theory, collects data that either supports or refutes the theory, and then makes necessary revisions before additional tests are conducted (Creswell, 2003). Postpositivism strongly reflects the Foundationalist/Reductionist/Formalist views of knowledge, and does not capture the essence of this research.

Constructivism has been described by Von Glasersfeld (1989) as ‘a theory of knowledge with roots in philosophy, psychology and cybernetics’. In constructivism the researcher’s intent is to interpret the views of others. Rather than starting with a theory (as in Postpositivism), inquirers generate or inductively develop a theory or pattern of meaning (Creswell, 2003). Crotty (1998) argues that constructivism is always social, arising in and out of interaction with the human community. For the purposes of this research, while elements of constructivism may be present in the interaction with research stakeholders, as a philosophical stance it does not comprehensively frame the research.

Paradigms within the Advocacy/Participatory school arose from a belief that the underlying assumptions of existing approaches did not satisfy the research demands for studying unique, marginalised groups or did not adequately address issues of social justice (Creswell, 2003). As research within this school of knowledge is intertwined with politics and political agenda, it is deemed unsuitable for this research.
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Patton (1988) states that pragmatism concerns applications and solutions to problems, i.e. ‘what works’. Pragmatism advocates the use of all available methods for analysing the research problem and finding solutions (Erlandsson, 2011), an approach which also reflects the multidisciplinary nature of systems engineering. Pragmatism can utilise both quantitative and qualitative methods of research (Creswell, 2003). As with the Relativistic/Holistic/Social view, the Pragmatic school of thought is a strong fit as a philosophical frame of reference for this research. The Pragmatic school of thought is, arguably, more tightly specified than the Relativistic/Holistic/Social view and therefore provides a more comprehensive grounding in philosophy for this work.

6.2.2 Strategies of Inquiry

At a fundamental level, the theoretical stance of a research methodology can be classified in two broad strategies; quantitative and qualitative methods (Patton, 1988). Quantitative research is ‘Explaining phenomena by collecting numerical data that are analysed using mathematically based methods (in particular statistics)’ (Aliaga and Gunderson, 1999). Quantitative research, as an objective approach, creates and tests hypotheses and is often referred to as the scientific method. Creswell (2003) identifies two primary strategies of inquiry associated with the quantitative approach:

- **Experiments** include true experiments, with the random assignment of subjects to treatment conditions, as well as quasi-experiments that use nonrandomized designs (Keppel, 1991). Included within quasi-experiments are single-subject designs.

- **Surveys** include cross-sectional and longitudinal studies using questionnaires or structured interviews for data collection, with the intent of generalising from a sample to a population (Babbie, 1990).

Qualitative research, on the other hand, is a subjective approach which emphasises the exploration of topics of interest in a complex situation which cannot always be easily quantified. A qualitative researcher according to Polit
and Beck (2012) begins with a broad topic area and focuses on an area where investigation is warranted. According to Denzin and Lincoln (2000) qualitative research;

- Provides an in-depth interpretative understanding of the research objectives
- Works relatively well with a very small sample
- Allows for interactive research which enables a more in-depth exploration of the issue
- Allows for flexibility in the analysis required
- Enables a greater insight through consistent analysis integration of the views of various respondents

Creswell (1998) identifies five traditions of qualitative research:

- Biography: Exploring the life of an individual
- Phenomenology: Understanding the essence of experiences about a phenomenon
- Grounded Theory: Developing a theory grounded in data from the field
- Ethnography: Describing and interpreting a cultural and social group
- Case Study: Developing an in-depth analysis of a single case or multiple cases

Lee (1999) states that there are five major data collection methods used by qualitative researchers; focus groups, case studies, interviews, observation and analysing documents and audio-visual data.

While traditionally research was classified as either quantitative or qualitative, researchers commonly now use mixed-methods approaches. Associated with the pragmatic school of thought, mixed-method researchers are first and foremost concerned with the problem at hand and not philosophical arguments about what constitutes ‘valid’ research (Lupton, 2007). The central premise of mixed-method research is that a combination of quantitative and qualitative
approaches provides a better understanding of research problems, than either approach alone (Creswell et al., 2003).

Individual researchers are free to choose the methods, techniques and procedures of research that best meet their needs and purposes (Creswell, 2003). In this thesis the researcher takes a pragmatic position where the research question is central and the methods used are those which best meet the needs and purposes of the research question. The selected fieldwork methods are described in the following sections following a discussion of the participant recruitment guiding principles for each stage of the fieldwork.

6.3 Participant Recruitment Guiding Principles

A common objective of each phase of the fieldwork is the access to, and extraction of information from research stakeholders. In order to ensure academic rigour in the collection of this information, it is important to follow best practice in the identification and selection of participants for interview and access to information.

A stakeholder in systems engineering can be defined as an “interested party having a right, share or claim in a system or in its possession of characteristics that meet that party's needs and/or expectations”. In this definition stakeholders include, but are not limited to, users, supporters, developers, producers, trainers, maintainers, disposers, purchaser and supplier organisations, regulatory bodies and members of society (ISO/IEC 15288, 2008). Sommerville and Kotonya (1998) further state that in the domain of systems engineering categories of stakeholder include end-users, managers and others involved in the organisational processes influenced by the system, engineers responsible for system development and maintenance, customers of the organisation who will use the system to provide a service, external bodies such as regulators and domain experts.
Newman et al. (1995) suggest that stakeholders can be categorised as those who will use the system directly or indirectly, and those who will be involved in developing the system. Sharp et al. (1999) note that the set of stakeholders in the knowledge acquisition process and the set of stakeholders in the use of a system are not necessarily identical; they are likely to vary in membership, and for those members in common, the type and level of stake they have is likely to vary. Table 6.2, identifies the stakeholders in this research.

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Stakeholder Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Clinical Engineers</td>
<td>Direct Users</td>
</tr>
<tr>
<td>Health Medical Physicists</td>
<td>Direct Users</td>
</tr>
<tr>
<td>Medical Device Suppliers</td>
<td>Indirect Users</td>
</tr>
<tr>
<td>Patients</td>
<td>Indirect Users</td>
</tr>
<tr>
<td>Healthcare Professionals: Doctors, nurses etc.</td>
<td>Indirect Users</td>
</tr>
<tr>
<td>Medical Device Manufacturing Senior Validation/Quality Engineers</td>
<td>Equipment Qualification Expert</td>
</tr>
<tr>
<td>Pharmaceutical Manufacturing Senior Validation/Quality Engineers</td>
<td>Equipment Qualification Expert</td>
</tr>
</tbody>
</table>

Table 6.2: Research Stakeholders

Accessing the appropriate stakeholders is a critical aspect in ensuring the quality of data collection. In simple stratified random sampling a list of individuals who fit in each category would be constructed, and from these strata participants would be chosen at random. Such an approach, however, is more consistent with research whose intention is to generalise results to a wider population. In this research study, the goal is to create a framework based on best practice. Therefore in order to extract existing best practice methods, and user requirements, there is a need to adopt a more purposive sampling method.
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Purposive sampling is a non-probability sampling approach in which the sample units are chosen because they have particular features or characteristics which will enable detailed exploration and understanding of the central themes and topics which the researcher wishes to study (Lewis and Ritchie, 2003).

Within each stakeholder group there will be a wide variation in knowledge and experience of individuals. A Key Informant is an expert who is most knowledgeable of the organisation or issue of interest (Lavrakas, 2008). Each phase of the fieldwork must be cognisant of the selection of Key Informants to ensure that the individual providing information for the research has access to and can provide accurate, comprehensive and best practice information. For the fieldwork of this research Key Informants were identified and approached to facilitate case studies and participate in interviews, consistent with a purposive sampling approach.

The Key Informants involved in this research were selected through professional contacts and based on their willingness to participate and agreement to provide access to the required individuals and support documentation. The Key Informants were contacted informally initially to determine their interest in participating and where co-operation was forthcoming a formal letter of invitation to participate was sent to the Key Informant (Appendix III).
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6.4 Fieldwork Phase I: Benchmarking Case Studies

Phase I involves process benchmarking of industries in which the Equipment Qualification framework is utilised and which face similar challenges to healthcare regarding the use of equipment.

6.4.1 Benchmarking

Benchmarking is a way of helping organisations to compare themselves against others in order to learn from them. It provides a proven mechanism to help identify and prioritise areas for improvement within a business in an objective manner (Keegan and O'Kelly, 2004). Benchmarking is a widely used research method for developing and improving an organisation’s practices and strategies. According to Bhutta and Huq (1999) the essence of benchmarking is the process of identifying the highest standards of excellence for products, services, or processes, commonly called ‘best practices’, and then making the improvements necessary to reach those standards.

According to Czarnecki and Cznarnecki (1999), benchmarking as a tool creates value by focusing the organisation on key performance gaps, bringing in ideas from other organisations, identifying opportunities, establishing new standards of performance and making better decisions based on a wider knowledge. In addition, benchmarking for better practices enables an organisation to ‘sell’ ideas that may not otherwise be approved by management.

Benchmarking has been demonstrated to be effective in improving performance of specific types of medical equipment (Wang et al., 2006b, Wang et al., 2006a, Mullally and Frize, 2008). Indeed, Bergman (1994) while investigated the use of benchmarking in improving clinical quality recommended benchmarking as a means for finding opportunities for process improvements in hospitals.
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Elmuti and Kathawala (1997) specify four types of benchmarking, namely internal benchmarking, competitive benchmarking, functional benchmarking and process (generic) benchmarking.

Internal benchmarking involves making comparisons with other parts of the same organisation, e.g. other departments or companies within the same group (Bendell et al., 1993). In internal benchmarking, similar internal functions serve as pilot sites for conducting benchmarking (Camp and Tweet, 1994). The main advantage of internal benchmarking is that it minimises problems of access and data confidentiality (Neely et al., 2005). However, the primary disadvantage of internal benchmarking is that the target process may fall short of what is actually ‘best practice’ in the industry (Southard and Parente, 2007).

Competitive benchmarking entails measuring an organisation’s functions, processes, activities, products or services against those of its competitors (De Jager, 1999). Competitive benchmarking is considered the most difficult form of benchmarking as target companies are usually not interested in helping the benchmarking team (Boxwell, 1994).

Functional benchmarking is the comparison of processes or functions against those of non-competitor companies within the same industry or technological area (Andersen and Pettersen, 1996).

Process benchmarking (also referred to as generic benchmarking) is considered the most advanced form of benchmarking. It entails the comparison of business functions and processes that are the same regardless of industry (Margherita and Klein, 2007). Process benchmarking requires a broad conceptualisation of the entire process and a careful understanding of procedures (Finch and Luebbe, 1995). Although it is thought to be extremely effective, it is difficult to implement (Dantas and Giovinazzi, 2002). One objective of this thesis is to identify best practice methods for Equipment Qualification in manufacturing industries. As
this can be accomplished via process benchmarking, the process benchmarking approach was chosen as a research method for this particular study.

In performing a benchmarking study it is important to be cognisant of potential concerns and misconceptions of the process. Benchmarking is sometimes seen as merely replication and copying of other organisations practices. However, to be successful benchmarking requires an ability to understand, modify and adapt methods and practices that, while effective in one particular circumstance, may not necessarily transfer successfully to another application (Keegan and O'Kelly, 2004). As stated by Dr. W.E. Deming 'To copy is too risky, because you don’t understand why you are doing it, To ADAPT, and not adopt, is the way’.

6.4.2 Case Studies

Case studies were identified as one of the five traditions of qualitative research. Creswell (2008) describes case studies as those in which the researcher explores, in depth, a programme, an event, an activity, a process, or one or more individuals. Yin (2008) provides more specific boundaries for case study research, stating that a case study is an empirical inquiry that;

i. investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident

ii. copes with the technically distinctive situation in which there will be many more variables of interest than data points.

Yin (2008) further identifies the following four categories of case studies:

- **Exploratory case studies**: An exploratory case study researcher explores a phenomenon where the phenomenon being studied has no clear, single set of outcomes. In an exploratory case study, the collection of data occurs before theories or specific research questions are formulated.
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- **Descriptive case studies:** A descriptive case study method describes the characteristics of a phenomenon. Descriptive case studies require theory to guide the collection of data.
- **Illustrative case studies:** Illustrative case studies illustrate certain phenomena in a descriptive mode.
- **Explanatory case studies:** An explanatory case study may not only describe the phenomena, but also explain why or how the phenomenon being studied is happening.

Stake (1995) identifies three further categories:

- **Intrinsic** - when the researcher has an interest in the case
- **Instrumental** - when the case is used to understand more than what is obvious to the observer
- **Collective** - when a group of cases is studied.

The case study design employed for this research is best described as a combination of exploratory and descriptive. The case studies are exploratory in that the scope of characteristics of interest of the case studies is not finite and are descriptive in that a key objective of the case studies is to describe current practice, where the literature review provides guidance on characteristics of interest. The case studies display each of Stake’s characteristics; intrinsic – in that the researcher has both an academic and professional interest in the case studies, instrumental – in that experts in each domain will form a significant part of the data collection phases and collective – in that there are three studies conducted in Phase I and two in Phase II.

**6.4.3 Case Studies Validity and Reliability**

Case study research, as a has been labeled by some academic circles as ‘soft research’ (Leite and Marks, 2005). The perceived limitations of case studies are based on the following criticisms; a lack of rigour (Seuring, 2005), inadequate
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foundation for scientific generalisation (Simons, 1996, Tellis, 1997) and that case studies are considered too long and difficult to conduct (Yin, 2008).

While the case studies of this thesis will not be used as a foundation for scientific generalisation there is a need to address the limitations identified by Seuring and Yin. This will be achieved through the development of a formal case study protocol. Tellis (1997) states that it is the development of a formal case study protocol that provides the reliability that is required of all research, while Yin (2009) asserted that the development of the rules and procedures contained in the protocol enhance the reliability of case study research. Yin (2009) advises the protocol should include the following sections:

- An overview of the case study project
- Field procedures
- Case study questions
- A guide for the case study report

Lubbe (2004) reflects the views of Tellis (1997) and Yin (2009) in stating that a case study protocol is a primary tactic in increasing the reliability of the case study procedure. Lubbe suggests that the field procedure should also include defining who should be interviewed, gaining access to the right people\(^{25}\), having adequate resources available such as time, paper, media storage etc., making a schedule of the required data collection activities and outlining the research objectives and interview schedule.

Further supporting the use of case studies in answering the research question of this thesis Lubbe (2004) advises that from a research strategy point of view, the case study methodology is a way of establishing valid and reliable information which add to the accumulated knowledge of the processes by which an organisation functions.

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\(^{25}\) The rigour associated with the identification of the ‘right people’ is captured in Section 6.3 Participant Recruitment Guiding Principles
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6.4.4 Case Studies Selection

When using a case study approach, it is important to choose cases that are interesting, relevant, and are clearly defined operationally (Yin, 2003). As introduced in Chapter One, this research aims to assess how the well-developed practices, protocols and tools of Equipment Qualification in manufacturing can be transferred, developed and modified for application in healthcare. It is imperative, therefore, that the company, personnel and nature of equipment explored in the case studies reflect the complexity of requirements of healthcare.

In the case of the medical device industry, manufacturing ranges from simple operations such as soldering and manual assembly in producing devices such as guidewires and pumps to the operation of highly complex CNC manufacturing equipment producing safety critical implants and life supporting devices. It is companies who operate in the high complexity (of manufacturing equipment) / high criticality (of manufacturing output) manufacturing space who are of most interest to this study. Similarly for combination product and pharmaceutical manufacturing, the companies, personnel and equipment selected for the case study must high complexity/high criticality manufacturing systems.

6.4.5 Pilot Test of Benchmarking Case Studies Protocol

Prior to the data collection case studies being conducted the case study protocols were examined through a pilot case study. Yin (2009) advises that a pilot case study helps to refine data collection plans with respect to both the content of the data and the procedures to be followed. Kvale (2008) further adds that a pilot test assists the researcher in determining if there are flaws, limitations, or other weaknesses within the research instrument design and will allow the researcher to make necessary revisions prior to the implementation of the study.
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As noted by Turner (2010), the pilot test should be conducted with participants that have similar interests as those that will participate in the implemented study, i.e. the pilot study must be representative of medical device, pharmaceutical and combination product manufacturing companies.

Smithstown Light Engineering, a precision manufacturing subcontractor, was chosen for the pilot as manufacturing practices in this company must meet the requirements of medical device, pharmaceutical and combination product customers. Smithstown Light Engineering manufactures components of medical devices and moulds and tooling for pharmaceutical companies. Smithstown Light Engineering are ISO 9001 (quality management), ISO 13485 (medical device quality management), ISO 14001 (environmental management) and ISO 17025 (calibration laboratory) certified. As a Quality & Validation Engineer in Smithstown Light Engineering the author has a full understanding of the demands on the company with regard to quality assurance in general, and Equipment Qualification in particular, and also has unlimited access to the company’s EQ documentation and the EQ documentation of several multinational corporations26.

The Quality Manager of Smithstown Light Engineering was identified, cognisant of the participant recruitment guiding principles in Section 6.3, as the Key Informant for the Equipment Qualification methods in the company. In an initial meeting the Quality Manager was briefed on the goals of the research and the purpose of the benchmarking case studies. In reviewing the data collection protocol (Appendix V) the Quality Manager was satisfied that the ‘Overview of the Fieldwork’ document was comprehensive in the information provided and that the ‘Field Procedures’ were appropriate to the objectives of the case studies.

26 For confidentiality reasons these companies, or their documents, cannot be detailed in this thesis.
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In terms of the case study questions the evaluation was cognisant of the pilot testing criteria proposed by Fowler (1995):

i. Is the instrument (the case study questions) easy to read as worded?
   ii. Do respondents understand the question in a consistent way?
   iii. Can the question be accurately answered?

In this section the Quality Manager advised that the terminology of Equipment Qualification and Process Validation should be addressed verbally at the start of the case study to ensure that informants are aware of the scope of this research. Regarding the questions of the case study the Quality Manager was satisfied that each fulfilled criteria i, ii and iii above.
6.5 Fieldwork Phase II: Requirements Analysis Case Studies

Phase II of the fieldwork explores current activities undertaken in hospitals from when medical equipment is delivered to when the first patient interacts with the equipment. It aims to extract identified requirements and recommendations for tools, methods and considerations for inclusion in the proposed framework.

6.5.1 Requirements Analysis

In order to develop useful and usable systems, user needs must be first understood and then represented in user requirements (Sutcliffe, 2012). In systems engineering terminology, this process is known as requirements engineering. Requirements engineering encompasses all activities concerned with eliciting, analysing, documenting, validating and managing system requirements (Sommerville and Kotonya, 1998). Requirements analysis is an early stage in the requirements engineering process. Requirements analysis is used to develop functional and performance requirements, i.e. how stakeholder requirements are translated into a set of requirements that define what the system must do and how well it must perform (Darrin and Barth, 2011).

Some examples of requirements analysis techniques include interviews, questionnaires, literature reviews, brainstorming, prototyping and ergonomics laboratory research (Samaras and Horst, 2005). The NIST standard for IDEFØ (NIST, 1993) specifies data collection methods that can be employed when analysing or designing a system. The standard advises that one might do the following:

- Read existing documents, using each table of contents and index to locate needed information
- Observe the system in operation, if it already exists
- Survey a large group of people, through questionnaires or other such means
- Talk to one or more experts who possess the desired knowledge
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- Use whatever is already known by the author
- Guess or invent a hypothetical description, and ask readers to help bring it closer to reality

Of all these methods, the NIST consider face-to-face interaction with an expert to be the most important data collection method. Interviews, in particular, are recommended to gather information from an individual who possesses an expertise considered important to the analytical effort (NIST, 1993).

6.5.2 Case Studies Selection

As was described for the manufacturing case studies, it is important to choose cases that are interesting, relevant, and are clearly defined operationally (Yin, 2003). For the requirements analysis case study it is important to select a healthcare facility that utilises a broad range of medical equipment and aims to adopt best practice in medical equipment management.

In hospitals the management of medical equipment is, with the exception of radiation based equipment, the responsibility of the discipline of clinical engineering. The management of medical equipment which utilises radiation, radiology and radiotherapy, is the responsibility of the discipline of medical physics. While medical physics and clinical engineering are very similar disciplines without sharp or distinct boundaries27 (Van der Putten, 2010) most hospitals tend to have separate clinical engineering and medical physics staff. Therefore, in order to be comprehensive in requirements analysis it is critical to conduct case studies in both disciplines.

The Key Informant required for each case study stage of the requirements analysis process is the person responsible for the introduction of medical equipment.

27 Van der Putten et al. (2012) further argues that the professions of Medical Physics and Clinical Engineering should be combined into a single profession; “Clinical Science and Technology”
equipment into the healthcare system. The Key Informant must have extensive experience, in a range of different types of medical equipment, in the activities that are undertaken from when the medical equipment is delivered to when a patient interacts with it for the first time.

6.5.3 Pilot Test of Requirements Analysis Case Studies Protocol

Prior to the healthcare case studies being conducted the case study protocols (Appendix VI) were examined through a pilot case study. The pilot study was completed taking into account the recommendations of Yin (2009), Kvale (2008) and Turner (2010) as discussed in Section 6.3.3 on the pilot study of the manufacturing industries case studies.

As noted by Turner (2010), the pilot test should be conducted with participants that have similar interests as those that will participate in the implemented study, i.e. the pilot study must be representative of activities undertaken in hospitals from when medical equipment is delivered to the hospital to when the first patient interacts with the equipment. A multinational medical device manufacturing company\(^{28}\) who is responsible for commissioning of medical equipment in healthcare facilities was chosen for the pilot as the practices in this company reflect those of the clinical engineering and medical physics functions in the hospital. The Field Service Engineer role was identified, cognisant of the participant recruitment guiding principles in Section 6.3, as the Key Informant for the company. The Field Service Engineer is responsible for installation of medical equipment in healthcare facilities as well as meeting the maintenance and repair needs of the equipment. Throughout these activities the Field Service Engineer works closely with clinical engineering staff in hospitals.

In an initial meeting the Field Service Engineer was briefed on the goals of the research and the purpose of the healthcare case studies. In reviewing the case

\(^{28}\) Anonymity was requested with respect to both company and the Key Informant
study protocol the Field Service Engineer was satisfied that the ‘Overview of the Fieldwork’ document was comprehensive in the information provided and that the ‘Field Procedures’ were appropriate to the objectives of the case studies.

In terms of the case study questions the evaluation was cognisant of the pilot testing criteria proposed by Fowler (1995):

   i. Is the instrument (the case study questions) easy to read as worded?
   ii. Do respondents understand the question in a consistent way?
   iii. Can the question be accurately answered?

In this section the Field Service Engineer advised that the phrase ‘acceptance testing’ is used in clinical engineering as an umbrella term to cover all activities relating to preparation for use and initial appraisal, while in radiotherapy the scope of acceptance testing is more limited. The Field Service Engineer also recommended that the term ‘environmental’ was clarified as relating to prevention of pollution rather than the internal use environment of the equipment. For the remainder of the questions of the case study the Field Service Engineer was satisfied that each fulfilled criteria i, ii and iii above.
6.6 Fieldwork Phase III: Requirements Analysis Self-Completion Questionnaire

Phase III of the fieldwork extracts identified requirements and recommendations for tools, methods and considerations for inclusion in the proposed framework from healthcare stakeholders through the use of a self-completion questionnaire. This section describes the population of interest of the questionnaire and the methods employed to access this population.

6.6.1 Self-Completion Questionnaire

As defined by Bryman (2008), a self-completion questionnaire is a survey instrument in which ‘respondents answer questions by completing the questionnaire themselves’. The use of a self-completion questionnaire as a survey instrument facilitates collection of data from a large population in an economical manner (Oppenheim, 1992). The design of the questionnaire is of key importance to extracting the required data from respondents, influencing the response rate and subsequently facilitating the analysis of data to inform the research output (Kelley et al., 2003, Bryman, 2012).

6.6.2 Self-Completion Questionnaire Validity and Reliability

In order to ensure the development of a valid and reliable questionnaire the following five step design and validation process suggested by Frazer and Lawley (2001) was followed:

- Step 1: Determine the required information and from whom it should be sought.
- Step 2: Determine the interview method and the lengths of the questionnaire.
- Step 3: Prepare the draft questionnaire
- Step 4: Pre-test and revise the questionnaire
- Step 5: Assess the validity of the questionnaire
Chapter Six: Methodology

Step 1: Determine the required information and from whom it should be sought.
The required information to be gained from the questionnaire is derived from the research question and objectives and seeks to extract the respondents’ requirements and recommendations for tools, methods and considerations for inclusion in the proposed framework.

Step 2: Determine the interview method and the lengths of the questionnaire.
Once the researcher has decided what information is required, the next step is to choose an appropriate type of questionnaire (mail, personally administered, telephone or online) (Frazer and Lawley, 2001). Feedback during the requirements analysis case studies fieldwork suggested that a self-completion questionnaire would be the most efficient method of potential respondents. It was also suggested that an online questionnaire, which would take no longer than 10-15 minutes to complete, would be most effective in terms of cost of administering the survey and maximising response rates from busy professionals. Surveymonke…

Step 3: Prepare the draft questionnaire
This step has four elements; question content, question wording, response format and questionnaire structure and layout. The question content was determined by the information needs in step one. Question wording was considered in ensuring that each question in the questionnaire is linked to the research question and objectives and must be asked clearly in a simple way without ambiguity, bias or the use of jargon/technical language, particularly language related to Equipment Qualification as this term would not be familiar to many healthcare professionals.
Chapter Six: Methodology

The third element is the response format. The requirements analysis questionnaire utilised open, closed and Likert scale questions. Open ended questions allow greatest opportunity for the respondent to add personal comments; this is an important consideration in exploratory research. For close ended questions, the respondent is asked to select an answer from a specified list provided by the researcher. Closed ended questions are popular in survey research as they provide greater uniformity of responses and are more easily processed (Babbie, 1990). When responding to a Likert scale questionnaire item, respondents specify their level of agreement to a statement or question. Oppenheim (1992) recommends a continuum of five response statements for Likert scales, e.g. ranging from 'strongly agree' to 'strongly disagree'.

Finally, in this step the structure and layout of the questionnaire was determined. A well-structured questionnaire will motivate the respondents to complete it. The questionnaire opens with a brief introduction to provide clear and simple instructions with the following questions ordered in a logical manner. A clean and clear appearance is also important, which is established by the SurveyMonkey program.

*Step 4: Pre-test and revise the questionnaire*

The pre-test questionnaire or pilot study helps the researcher to reveal any uncertainty in the questionnaire design and aids in measuring the length of time required for completing the questionnaire (Oppenheim, 1992).

The questionnaire was initially sent electronically to three PhD students in NUI, Galway for feedback. Subsequently the questionnaire was sent electronically to three Equipment Qualification experts in medical device manufacturing. Finally, the questionnaire was reviewed by healthcare experts following the clinical engineering and medical physics case studies. The results of piloting are shown in Table 6.1.
### Table 6.1: Questionnaire Pilot Feedback

<table>
<thead>
<tr>
<th>Reviewer Group</th>
<th>Feedback</th>
</tr>
</thead>
<tbody>
<tr>
<td>PhD Students</td>
<td>• Suggested naming research supervisors on welcome page&lt;br&gt;• Suggested inclusion of NUI Galway logo&lt;br&gt;• Clarified the privacy statement on the welcome page&lt;br&gt;• Suggested closing question ‘Do you have any other comments, questions or concerns?’</td>
</tr>
<tr>
<td>Equipment Qualification Industry Experts</td>
<td>• Suggested open question after each Likert scale to capture any additional information respondents may have.&lt;br&gt;• Suggested following question ‘Are you aware of any recurring causes for setbacks/delays/non-conformances or other problems during acceptance testing activities’</td>
</tr>
<tr>
<td>Healthcare Experts</td>
<td>• Clarified description of scope of acceptance testing activities on welcome page&lt;br&gt;• Clarified ‘Environment’ in Question 4 as relating to prevention of pollution</td>
</tr>
</tbody>
</table>

**Step 5: Assess the validity of the questionnaire**

Reliability and validity are concerned with establishing the quality of research. Frazer and Lawley (2001) state that a questionnaire is valid if it measures what it is supposed to measure and it is reliable if the responses are consistent and stable. Fink (2003) states that there are three types of validity in relation to survey; content, face and criterion. Content validity refers to the extent to which a measure thoroughly and appropriately assesses the skills or characteristics it is intended to measure. The content of the questionnaire has been established through a thorough literature review, analysis of the objectives of the research, the findings of the preceding fieldwork phases and a pilot study. Face validity refers to how a measure appears on the surface; does it ask all the needed questions and use appropriate language? (Fink, 2003). To address face validity a pilot study of the questionnaire was conducted.
Reliability of survey results may be affected by social desirability bias. Respondents may try to portray themselves or their organisation in a more favourable light. The effect of this bias, however, is minimal as responses are anonymous with respect to both individuals and organisations. It is also important to be cognisant, when analysing the questionnaire data, of potential bias which is inherent and unavoidable in Likert scales; respondents may avoid using extreme response categories (central tendency bias) or agree with statements as presented (acquiescence bias).

6.6.3 Population of Interest and Distribution Methods

The target population of this questionnaire is all clinical engineers and medical physicists in both public and private healthcare facilities in Ireland. This population, however, poses methodological difficulties due to the ‘hidden’ nature of the population, in the sense that there is no source data to quantify the parameters of the target population. While details of the population of healthcare facilities in Ireland are available, individual facilities do not list personnel employed or job roles.

Probability samples, or random samples, are those in which every element has a known, nonzero chance of selection and the elements are selected through a random procedure (Czaja and Blair, 1996). Ideally, this method should be used for the purpose of selecting participants for the questionnaire. However, as the individuals could not be identified the sampling frame could not be established and therefore random sampling was ruled out.

To access the target population of this research a non-probability sample design was required. A non-probability sample is a sample for which there is no guarantee that all eligible units have an equal chance of being included. Its main disadvantage is that it is vulnerable to selection bias. Non probability sampling is however appropriate for use in many questionnaires (Fink, 2003).
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Purposive sampling is a non-probability sampling approach in which the sample units are chosen because they have particular features or characteristics which will enable detailed exploration and understanding of the central themes and puzzles which the researcher wishes to study (Lewis and Ritchie, 2003). Snowball sampling is a non-probability sampling approach which relies on previously identified members of a group to identify other members of the population. As newly identified members name others, the sample snowballs. This technique is used when a population listing is unavailable and cannot be compiled (Fink, 2003).

Purposive sampling and snowball sampling were the non-probability sampling methods employed to reach members of the target population. The method of distributing the questionnaire was to request the professional organisations for clinical engineering and medical physics in Ireland to distribute the questionnaire to its members. Respondents were also approached directly through LinkedIn, an online business network. Respondents contacted through LinkedIn were asked to distribute the questionnaire to colleagues in clinical engineering and medical physics.

Appendix IV contains the finalised questionnaire and introductory note, as presented electronically via SurveyMonkey, to respondents. Unfortunately the response rate to the questionnaire is unknown as due to the sampling limitations it is unknown how many individuals were invited to complete the questionnaire.
6.7 Summary

The fieldwork of this thesis utilises a mixed methods approach, pragmatic and exploratory in nature, shaped by the research question and objectives and conducted in three phases as follows:

**Phase I: Benchmarking Case Studies**

| Medical Device Manufacturing | Combination Product Manufacturing | Pharmaceutical Manufacturing |

**Phase II: Requirements Analysis Case Studies**

| Clinical Engineering Case Study | Medical Physics Case Study |

**Phase III: Requirements Analysis Questionnaire**

| Healthcare Stakeholders Questionnaire |

*Figure 6.2: Fieldwork Overview*

Phase I involves process benchmarking of medical device, pharmaceutical and combination device manufacturing companies in which Equipment Qualification is utilised in complex manufacturing processes.

Phase II of the fieldwork explores current activities undertaken in hospitals from when medical equipment is delivered to when the first patient interacts with the equipment. It also aims to extract identified requirements and recommendations for tools, methods and considerations for inclusion in the proposed framework. The research during this phase will also be cognisant of stakeholders unidentified...
requirements, i.e. those requirements that are present but have not been consciously realised (Bates et al., 2003).

Phase III of the fieldwork aims to obtain views on the strengths and weaknesses of current acceptance testing activities and to extract identified requirements and recommendations for tools, methods and considerations for inclusion in the proposed Equipment Qualification framework from clinical engineers and medical physicists. As in Phase II, the research during this phase will also be cognisant of respondents’ unidentified requirements.

The research design employed in this thesis takes cognisance of ensuring the validity and reliability of the research methods. In adhering to best practice in developing research methods, confidence can be established that the findings of the fieldwork will inform the development of the Equipment Qualification framework accurately and comprehensively. This approach represents step 1 of a two-step approach to the validation of the developed Equipment Qualification framework:

1. Validation of the Research Methods
2. Validation of the Research Output

The validation of the developed framework and the methodological approach adopted for this validation is discussed separately in Chapter Nine.
Chapter Seven: Fieldwork Results and Analysis

7.1 Introduction

This chapter presents, in chronological order, the findings from the fieldwork carried out in this study. The chapter begins by presenting the findings from Phase I: Benchmarking Case Studies, which involved process benchmarking of medical device, pharmaceutical and combination device manufacturing industries. Subsequently, the findings of Phase II are presented, exploring current activities undertaken in hospitals from when medical equipment is delivered to when the first patient interacts with the equipment and extracting, from healthcare stakeholders, identified requirements and recommendations for tools, methods and considerations for inclusion in the Equipment Qualification framework. Building on the healthcare case studies, the findings of Phase III of the fieldwork are presented which detail the results of a national survey of clinical engineers and medical physicists.

7.2 Phase I: Benchmarking Case Studies

The objective of the benchmarking case studies was to understand best practice in the qualification of equipment in medical device, pharmaceutical and combination product manufacturing. In these manufacturing industries, as in healthcare, it is essential that stakeholders are confident in the capability of equipment to meet intended requirements. Within these industries Equipment Qualification is well established as a method of pre-emptively evaluating equipment. The best practices discovered in this phase will be integrated, and developed where appropriate, into a best practice framework for healthcare. Data collection for each case study was managed as per the Benchmarking Case Study Protocol in Appendix V.
7.2.2 Medical Device Manufacturing Case Study

‘MedDev Company’, the medical device manufacturing company on which this case study is based, is located in the west of Ireland and is an Irish-owned company. The company employs approximately 50 people in the design, manufacture, marketing and sales of a number of specialty Class II medical device drug delivery systems, offering high quality, high efficiency and easy to use products. As an advanced medical device manufacturer the technical expertise and manufacturing process required to manufacture the companies patented products is vastly more complicated than that required for traditional products in the market.

The products of MedDev Company are distributed primarily throughout Europe, USA, Asia and Australia, with additional market development in Africa, India and Mexico. MedDev Company has a distinguished history of awards in recognition of its product and operational excellence; in the year preceding this case study the company won a major ‘company of the year’ award for Irish medical device manufacturers. This award gives a high level confidence that the information extracted from this case study will be of best practice standard.

MedDev Company has a successful Food and Drug Administration (FDA) audit history and has been successfully audited to the medical device quality standard ISO 13485. Although the company does not have an externally certified environmental or health and safety management system, it does aim to adopt best practice and has an Environmental Health & Safety (EHS) policy in place.

In conducting this case study a number of techniques were used; interviews, observations and examination of the company’s Equipment Qualification/Process Validation (EQ/PV) and related systems; including a review of Standard Operating Procedures (SOPs), protocol templates and executed protocols. The IDEFØ standard recommends talking to “one or more experts who possess the desired knowledge”, therefore the Key Informant for this case study
was the person with overall responsibility for the EQ/PV function in the company, in MedDev Company this person is the Senior Manufacturing Engineer.

**Understanding the EQ/PV Process in MedDev Company**

MedDev Company operate a systematic and standardised approach to the introduction of new products to the manufacturing system, of which the EQ/PV process is a key function. Figure 7.1 demonstrates the stages in this new product introduction:

![MedDev Company New Product Introduction Flowchart](image)

*Figure 7.1: MedDev Company New Product Introduction Flowchart*

New product concepts are designed and finalised by the design department, with input from manufacturing to ensure best practice in Design for Manufacturing
Once a finalised drawing is released to the manufacturing department the first step is to map the required manufacturing process flow. From this the manufacturing risks are analysed using the pFMEA tool. Once risks have been identified, risk mitigation can be planned. Risk mitigation can involve 100% inspection of critical features to ensure the part has been manufactured to specification, this method however is time consuming and costly. The alternative is to validate the process.

The validation process begins with a Master Validation Plan (MVP) which describes the process flow and outlines the validation requirements for each step. The MVP is peer reviewed and approved by a cross functional team of internal stakeholders in the process. These validation requirements will be integrated into the Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) protocols to produce a validation program specific to the product in question. Once a validation has been successfully executed a Standard Operating Procedure (SOP) for manufacturing can be written based on the results of the validation.

A ‘case by case’ approach is used each time EQ/PV is required, as the specific requirements will be driven by the pFMEA. MedDev Company has a robust internal documented system for defining the procedure for conducting EQ/PV and has templates of the required forms and protocols which can be developed for each specific case.

The Key Informant of MedDev Company views the manufacturing equipment as ‘ready for its intended use’ when the potential causes of the machine not producing parts to specification have been identified in the pFMEA, the MVP has been peer reviewed and approved, the validation either completed (or a justification documented where validation will not be completed), and the SOP has been released and approved.
Chapter Seven: Fieldwork Results and Analysis

**EQ/PV Prerequisites**

The primary prerequisite to the EQ/PV process is the risk assessment, i.e. the pFMEA. Any further prerequisites required are, as seen with the entire EQ/PV process, specific to each individual process and risk driven through the pFMEA. User Requirement Specifications (URS) are created where custom built equipment will be used, with subsequent validation protocols written to challenge the requirements stated in the URS. Supplier Evaluation is a managed on an ongoing basis external to the EQ/PV process. Factory Acceptance Testing is outside the validation requirements of the MedDev Company and is not seen as a current concern. In developing EQ/PV protocols, validation engineers can take guidance from the internal process validation procedure and the IQ/OQ/PQ protocol templates.

**IQ/OQ/PQ Protocols**

MedDev Company utilises template protocols for IQ, OQ and PQ. These protocols contain the generic checks, tests and verifications required for each process/equipment. Specific protocol requirements for each unique process/equipment will be additional to these requirements.

In developing the Installation Qualification MedDev Company will refer to the process validation procedure, the applicable pFMEA(s), the applicable MVP(s) and the IQ protocol template. The IQ protocol template firstly requires verification that the equipment has been CE marked, has been installed correctly and that all utilities are correctly rated. Functional testing, alarms and limit testing, data connection testing and utility failure testing are all conducted and documented as part of the IQ. Verification that a maintenance program has been established and training conducted is also required. The calibration system operates externally to the EQ/PV process, at IQ stage the verification is to ensure that the equipment has been calibrated. Environmental considerations are not formally addressed in the IQ or in any related system. While Ergonomics/Human Factors and Health & Safety requirements are not specified in the EQ/PV process, the Health & Safety Manager is a required signatory of the peer review approval
process. This process ensures that the Health & Safety Manager is aware of the proposed manufacturing system and can update the external Health & Safety system accordingly.

In writing the Operational Qualification protocol the MedDev Company will again refer to the process validation procedure, the applicable pFMEA(s), the applicable MVP(s) and in this instance the OQ protocol template. The OQ is used to determine the operating windows/tolerances for process parameters which will achieve a capable process. To achieve this process capability indices are calculated for parts produced at the upper and lower limits of the operating window, the acceptance criteria is a Cpk of greater than 1.33. Process characterisation and optimisation is generally completed using Design of Experiments in the process development phase. Testing of alarms and limits, data connections, verification of training requirements and verification that supporting processes such as equipment cleaning and adjustment can be performed are generally not required, though such verification would be included in the OQ if deemed necessary through the pFMEA.

The focus of Performance Qualification is in determining the consistency of output of the equipment/process at nominal equipment/process parameter settings. In writing the PQ protocol MedDev Company will again refer to the process validation procedure, the applicable pFMEA(s), the applicable MVP(s), the PQ protocol template and the internal statistical procedure. There is a particular emphasis on ensuring that sample sizes used in the PQ are statistically significant to ensure that the reported capability indices accurately reflect the capability of the equipment/process.

On completion and approval of the validation reports the process is deemed to be in a validated state. At this stage any changes to the process or equipment must go through a formal change control process which will again be peer reviewed. Changes may be due to process optimisation development work, to address problems encountered in production or to address new risks that have
been identified through the pFMEA. The development of manufacturing processes, and consequently validation requirements, is an iterative process that is ongoing for the lifespan of the equipment and/or process.

Macro Level Questions
The Key Informant of MedDev Company was asked to appraise the Equipment Qualification process in terms of providing an effective framework for addressing quality, maintenance, calibration, reliability and safety considerations. Regarding quality, the Key Informant viewed the testing and subsequent confidence obtained in the ability of the equipment/process output to meet required product specifications/tolerances as the central benefit of the EQ/PV process. Maintenance and calibration considerations were deemed to be adequately captured through verifying that a Preventative Maintenance (PM) program and calibration schedule had been put in place, that training had been carried out and that requirements for spare parts had been addressed. Reliability considerations were captured through the PM program, any further reliability issues are managed through the companies Corrective Action Preventative Action (CAPA) system. While health and safety requirements are not explicitly detailed in the protocols, the verification of the CE approval and the health and safety manager peer review approval are deemed by MedDev Company to adequately capture health and safety requirements.

Reflecting on which are the key elements of the EQ process the Key Informant argues that each piece of equipment will have unique key EQ elements depending on the use of the equipment for each particular product, these key elements will be driven by the pFMEA. In terms of specific techniques used in the EQ process, FMEA has been shown to be the driver of EQ activities. Other advanced techniques such as HAZOP, Total Productive Maintenance, Reliability Centred Maintenance and Human Reliability Analysis methods are not incorporated into the EQ process.
Chapter Seven: Fieldwork Results and Analysis

Closing Questions

In considering how the equipment qualification process could be improved the Key Informant advocated a lean approach to the process, particularly in terms of the quantity and nature of checks and tests to be performed. The Key Informant stated that the inclusion of individual EQ requirements should always be risk based and that each test/check should add value in creating confidence that the equipment is ready for its intended use.

The final question of the case study related to seeking the Key Informant’s opinion on how healthcare could best utilise and benefit from an Equipment Qualification framework. In answering this question the Key Informant recalled a situation he had observed in a hospital where medical equipment was not functioning correctly, he was surprised to note the lack of response to the issue where the healthcare staff did not escalate the issue to have it resolved. The Key Informant argued that if this medical equipment had been qualified through the EQ process there would have been a PM and calibration program in place which may have prevented or identified the problem. Furthermore the EQ process creates ownership of the maintenance and calibration functions, with records and identification of responsible stakeholders which would have ensured that the healthcare staff could have quickly escalated the issue to be resolved.

Key Findings of MedDev Company Case Study

The purpose of this case study was to explore the approach adopted by a medical device manufacturer to the equipment qualification/process validation function and to extract best practice from this sector. The key findings of this case study were as follows:

- EQ/PV activities are risk driven
- An emphasis on quality assurance
- Ergonomics/Human Factors, Safety and Environment considerations are managed through separate systems
- Template IQ/OQ/PQ protocols facilitate systematic approach
MedDev Company develops the EQ/PV requirements based on the outcomes of pFMEA risk assessment activities. This risk-based approach to validation has been advocated by many authors for varying applications, including medical device design (Alexander and Clarkson, 2000b), medical device software (Lincoln, 2011), medical device manufacturing (Justiniano and Gopalaswamy, 2004), pharmaceutical manufacturing (DeCaris et al., 2007, Agalloco and Carleton, 2013) and packaging (Christiansen and Jensen, 2009).

It is apparent that Quality Assurance is the primary purpose of the EQ/PV process in MedDev Company, with Ergonomics/Human Factors, Safety and Environment considerations managed through separate systems. While this approach is in accordance with process validation guidance of the Global Harmonisation Task Force (GHTF, 2004) and meets medical device manufacturing regulatory requirements there is an opportunity for integration of additional systems through the EQ/PV process.

Finally, the importance of robust documentation for EQ/PV activities is strongly evident throughout the case study. Template protocols provide guidance for validation engineers and facilitate a systematic approach to protocol development and execution. A comprehensive documented system provides clear evidence of work completed which can be audited by third parties such as the FDA or NSAI. Furthermore, ownership of functions such as maintenance and calibration will be clearly defined and the peer review approval process ensures that a cross functional team have unanimously agreed that the validation activities are appropriate for each individual process/equipment.
7.2.3 Combination Products Manufacturing Case Study

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. ‘Combo Company’, the combination product manufacturing company on which this case study is based is a US owned multinational. Combo Company manufactures, distributes and services a diverse range of industry-leading product lines in three segments: medical devices, pharmaceuticals and medical supplies; the facility in which this case study was conducted manufactures respiratory care products for ventilation and airway management.

Combo Company has markets in 140 countries worldwide, employs more than 41,000 employees in over 65 countries, and has manufacturing facilities in 16 different countries. In Ireland, Combo Company has five facilities throughout the country employing 1,400 people. The Irish manufacturing facilities of Combo Company have a distinguished history of awards in recognition of its operational excellence, most notably achieving the Shingo Bronze Medallion award in 2013 for enterprise excellence. This prestigious award gives a high level confidence that the information extracted from this case study will be of best practice standard.

‘Combo Company’ has a successful Food and Drug Administration (FDA) audit history and has been successfully audited to the medical device quality standard ISO 13485 and environmental management standard ISO 14001. Although the company does not have an externally certified health and safety management system, it does aim to adopt best practice and has a Health & Safety policy in place.

In conducting this case study the approach to the MedDev Company case study was replicated; diagnostic techniques employed included interviews, observations and examination of the company’s EQ/PV and related systems, including a review of Standard Operating Procedures (SOPs), protocol templates
Chapter Seven: Fieldwork Results and Analysis

and executed protocols. The Key Informant and facilitator of this case study was the person with overall responsibility for the EQ/PV function in the company, in Combo Company this person is the Senior Quality Engineer (Validation).

**Understanding the EQ/PV Process in Combo Company**

The validation system examined in this case study was the validation of a test stand system. Test stand system validation is required in Combo Company due to the high complexity of equipment, where the output of processes cannot be inspected/verified using standard testing methods thus necessitating custom testing. Test stand systems consist of both hardware and software subsystems and are used to verify the functionality of combination product manufacturing equipment and finished combination products. Figure 7.2 shows the development lifecycle of a test stand system with validation procedures mapped (in yellow) to the appropriate stages:
Chapter Seven: Fieldwork Results and Analysis

Figure 7.2: Combo Company Test Stand Development Flowchart
Chapter Seven: Fieldwork Results and Analysis

As shown in Figure 7.2 the manufacturing test specifications consist of both hardware and software requirements and are based on the product specifications. The manufacturing test specification\(^{29}\) dictates the unit testing requirements, and from the unit testing requirements the EQ/PV protocols can be developed. Once the protocols have been developed and approved the IQ and OQ are executed during the system testing stage. PQ is executed during the acceptance testing phase. After the validation has been successfully completed the test stand system can be implemented, with any subsequent changes to the test system evaluated through the change control procedure.

As each test stand system is built to meet the unique demands of each product a ‘case by case’ approach is used each time EQ/PV is required. Similar to MedDev Company, Combo Company has a robust internal documented system for defining the procedure for conducting EQ/PV. In addition to the manufacturing test specification, Combo Company utilise a validation checklist to develop EQ/PV protocols. The validation checklist lists considerations for the IQ, OQ and PQ protocols which may be included as relevant to each unique case, the detail of the considerations will be discussed in the IQ, OQ and PQ sections later.

Document controlled templates are available for the test stand requirements document, test stand design document, test stand requirements trace matrix, validation checklist, installation qualification protocol, operational qualification protocol and performance qualification protocol. Each document and protocol requires cross-functional peer review and authorisation.

The Key Informant of Combo Company views the equipment as ‘ready for its intended use’ when the IQ, OQ and PQ have been peer reviewed, approved and successfully executed. The Key Informant further noted that while equipment physically could be used it is not ‘ready’ until all the requirements of the EQ/PV

\(^{29}\) The manufacturing test specification is analogous to User Requirement Specification (URS).
have been met, and in particular that preventative maintenance and calibration systems are in place.

**EQ/PV Prerequisites**

The primary prerequisite to the EQ/PV process is the manufacturing test specification. Risk assessment is conducted using the FMEA tool and is a live document that will be updated as new risks become apparent, the EQ/PV process is used as a control measure for a number of failure modes. Supplier Evaluation is a managed on an ongoing basis external to the EQ/PV process; general requirements are that supplies are sourced from recognised reliable manufacturers. Factory Acceptance Tests (FAT) may be conducted on more complex fixtures or subcomponents of equipment before they are integrated into Combo Company’s manufacturing system; requirements for a FAT however are the exception rather than the norm.

**IQ/OQ/PQ Protocols**

As described earlier Combo Company initially develop the manufacturing test specification based on the product specification. This manufacturing test specification dictates the requirements for specific details of the EQ/PV protocols. Considerations that are generic to all EQ/PV projects are detailed in the validation checklist; these considerations are optional and act as prompts in developing protocol requirements. The requirements of the protocols are then transferred into EQ/PV datasheets which are completed by the relevant validation stakeholder.

In developing the **Installation Qualification** protocol Combo Company will refer to the process validation procedure, the applicable FMEA(s), the manufacturing test specification and the validation checklist. The validation checklist contains the following generic IQ considerations:

- Voltage and Frequency Requirements
- Air Requirements
- Oxygen Requirements
Chapter Seven: Fieldwork Results and Analysis

- Equipment Calibration
- Preventative Maintenance
- Spare Parts List
- Application Software Installation
- Computer Network Connection
- ESD Assessment
- Health and Safety Review/Audit
- Equipment CE mark Review
- Environmental Operating Requirements
- Line Layout Drawing
- Fixture Assessment

The IQ protocol reviewed in the case study for the test stand system opens with the Global Harmonisation Task Force definition of Installation Qualification; ‘Establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer’s approved specification and that the recommendations of the supplier of the equipment are suitably considered’. The IQ requirements begin with verification that manufacturing test specifications have been generated and approved for release. The next section concerns utilities, with verification required that air, electricity and network requirements have been satisfied. Environmental Operating Requirements are verified to ensure that the temperature and humidity in the workplace meet pre-defined conditions. A preventative maintenance schedule and spare parts list are required. Equipment calibration requirements detail the instrument to be calibrated, calibration ID, calibration due date, confirmation that the instrument is within (or outside) its calibration schedule and a requirement for recording the calibration certificate. A software installation check verifies the program files are located in pre-specified drive locations.

Hardware operational checks are also required, including verification of functionality of emergency stops, power switches and pneumatics. Finally the protocol states that where acceptance criteria have not being met the deviation
shall be reviewed and investigated to determine root cause, and if deemed a non-conformance, the IQ shall cease, CAPA determination shall be made and documented prior to recommencement or repeat of the IQ.

Environmental considerations are not listed in the validation checklist and do not form part of the IQ protocol; a separate ISO 14001 certified environmental management system is used to control environmental aspects and impacts. Health & Safety is addressed in the validation checklist, along with CE mark review. These, however, are optional considerations and will not always form part of the IQ protocol. Ergonomics/Human Factors considerations or requirements do not feature in the EQ/PV system of Combo Company.

In developing the **Operational Qualification**, Combo Company will refer to the process validation procedure, the applicable FMEA(s), the manufacturing test specification and the validation checklist. The validation checklist contains the following generic OQ considerations:

- FMEA
- Software Code Review
- Training
- Functional Testing
- Process Verification (Gage R&R, Cpk)
- Statistical Analysis

The OQ protocol reviewed in the case study for the test stand system opens with the Global Harmonisation Task Force definition of Operational Qualification; ‘Establishing by objective evidence process control limits and action levels which result in product that meets all predetermined requirements.’ The OQ protocol for the test stand system firstly requires that an FMEA is completed and documented. Secondly, a peer review of the test software must be completed and the software must be revision controlled. Functional testing is required after software verification. The next stage of the OQ protocol requires the use of the
statistical tool Process Capability Analysis to report on data from a sample of product. It is noted that for critical to quality parameters the Cpk is required to be greater than 1.33. Finally the protocol states that where acceptance criteria have not being met the deviation shall be reviewed and investigated to determine root cause, and if deemed a non-conformance, the OQ shall cease, CAPA determination shall be made and documented and if necessary, elements of the IQ shall be rerun, prior to recommencement or rerun of the OQ.

Absent from the OQ requirements are testing of alarms and limits, data connections and verification that supporting processes can be performed. The Key Informant did note however that such issues can be included if deemed necessary by the validation engineer. Process characterisation and optimisation is generally completed using Design of Experiments in the product design and/or process development phase.

In developing the **Performance Qualification** Combo Company will refer to the process validation procedure, the applicable FMEA(s), the manufacturing test specification and the validation checklist. The validation checklist contains the following generic PQ considerations:

- Sample Build
- Device History Record (DHR) Copies
- Statistical Analysis
- Operator Training Confirmation
- Operator Training Record
- Process Verification (Gage R&R, Cpk)

The PQ protocol reviewed in the case study for the test stand system opens with the Global Harmonisation Task Force definition of Performance Qualification; ‘Establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements.’ The PQ protocol for the test stand system requires that 30
products must be tested using the test stand by operators trained to the Standard Operating Procedure. A Cpk of 1.33 or greater is again required for critical to quality parameters. The Key Informant noted that process development work can be leveraged in the PQ as evidence of process capability.

The status of the qualified equipment and validated process upon final completion and peer review approval of the validation documentation mirrors that of MedDev Company; i.e. that any changes to the process or equipment, which may be due to process optimisation development work or to address problems encountered in production or to address new risks that have been identified through the FMEA, must go through a formal change control process which will again be peer reviewed. The development of manufacturing processes, and consequently validation requirements, is an iterative process that is ongoing for the lifespan of the equipment and/or process.

**Macro Level Questions**

The Key Informant of Combo Company was asked to appraise the equipment qualification process in terms of providing an effective framework for addressing quality, maintenance/calibration, reliability and safety considerations. Regarding quality, the Key Informant was hesitant in being fully reliant on the EQ process to guarantee quality over time. Notably, the Key Informant explained that EQ evaluates a ‘snapshot in time’ which may be a ‘one hit wonder’ unless the appropriate programs, such as maintenance and calibration, are in place to maintain the qualified state of the equipment. Following from the statement on the importance of an ongoing maintenance system the Key Informant agreed that the EQ process provides a suitable framework for ensuring that a maintenance program has been created and ownership of the maintenance function has been assigned to the relevant personnel, the Key Informant again reiterated the importance of not using equipment which is outside its maintenance/calibration schedule.
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In terms of reliability, the Key Informant viewed the EQ process as providing a useful framework for verifying that the equipment has the ability to perform its required function. Verification of maintaining this ability over time is a function of the ongoing quality control, maintenance and calibration systems. As was seen in MedDev Company, health and safety requirements are not explicitly detailed in the protocols. The Key Informant did, however, stress the potential usefulness of including health and safety checks and tests during the EQ process as the baseline standards could be set at this stage which subsequently can be audited as part of ongoing health and safety reviews.

In considering the key elements of the EQ process the Key Informant reiterates the importance of including requirements for maintenance and calibration programs in generic EQ protocols. The verification of the environmental operating conditions, such as temperature and humidity, and utility supplies, such as air and water, is also regarded as of high importance as the Key Informant argues that failures in these conditions are likely to cause equipment/system failures.

Closing Questions

In addressing potential methods to improve the Equipment Qualification process, the Key Informant of Combo Company focused on potential software solutions to make the EQ process more efficient. In particular the Key Informant would value software which could automate the generation of EQ protocols and maintenance and calibration software which could provide a log of activities completed and automatically email/alert relevant stakeholders when an activity is due.

The final question of the case study related to seeking the Key Informant’s opinion on how healthcare could best utilise and benefit from the Equipment Qualification framework. In reflecting on this question the Key Informant emphasised his belief that healthcare could benefit greatly from a formal EQ system. In particular the Key Informant viewed the EQ requirements for ownership of maintenance and calibration systems, and subsequent improving
communication between frontline and support staff in reacting to adverse equipment conditions, as being of central importance. Interestingly, this emphasis on allocation of responsibility for ongoing programs at the EQ stage reiterates the views of the Key Informant of MedDev Company on how healthcare can best utilise the EQ process.

**Key Findings of Combo Company Case Study**

The purpose of this case study was to explore the approach adopted by a pharmaceutical manufacturer to the equipment qualification/process validation function and to extract best practice from this sector. The key findings of this case study were as follows:

- EQ/PV system of Combo Company broadly comparable to the EQ/PV system of MedDev Company
  - Similar requirements for IQ, OQ and PQ stages
  - An emphasis on Quality Assurance
  - Template protocols
  - Documentation and peer review creates responsibility and ownership
  - Ergonomics/Human Factors, Safety and Environment considerations are managed through separate systems.
- EQ/PV activities are driven by product requirements
- EQ/PV regarded as a snapshot in time – (need for ongoing control systems)

Throughout the case study of Combo Company it was apparent that the EQ/PV system employed broadly replicated that of MedDev Company. In both sectors the EQ/PV system is heavily biased towards Quality Assurance and establishing confidence in the ability of the equipment to produce a desired output within the production process, whereas Ergonomics/Human Factors, Safety and Environment considerations are managed through separate systems. While this approach has been shown, through both companies successful FDA and ISO audit history, to be effective in meeting regulatory needs there is an evident
opportunity to merge Quality Assurance considerations with Ergonomics/Human Factors, Safety and Environment considerations at the EQ stage. In doing so the organisation will realise a more holistic approach to introducing new equipment and stakeholders of each consideration can more fully appreciate the impact of their responsibilities on the wider organisational system.

A further aspect of the EQ/PV process that was identified and highlighted by the Key Informants in both MedDev Company and Combo Company is the importance of peer review of protocols and the documentation of all activities. The peer review process ensures that signatories have reviewed the protocols and deem the contents and requirements of the protocol to be appropriate to the goals of the specific EQ/PV application. Formal documentation of all activities completed, including results achieved and identification of the individual responsible for the activity, facilitates a comprehensive history of the EQ/PV which acts a reference for future production and is auditable internally and by third parties.

In contrast to MedDev Company, who advocated a risk driven approach to generating EQ/PV requirements, in Combo Company EQ/PV activities are driven by product requirements. While risk assessment, through the use of the FMEA tool, does have a role in EQ/PV, in Combo Company the product requirements and subsequent manufacturing test specifications are the primary drivers of protocol requirements.
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7.2.4 Pharmaceutical Manufacturing Case Study

‘Pharma Company’, the pharmaceutical manufacturing company on which this case study is based is a US owned multinational. ‘Pharma Company’ is a global manufacturer of injectable pharmaceutical products serving a variety of niche markets, with expertise in a broad range of therapeutic applications such as cardiology, urology, anaesthesiology, viscosupplementation, cosmetic dermatology and anti-histamines. Pharma Company has markets in 150 countries and employs more than 22,000 employees worldwide.

In Ireland, Pharma Company has two facilities, employing 900 people. The primary products of the Irish manufacturing facilities are filled vials and prefilled syringes. ‘Pharma Company’ has a successful Food and Drug Administration (FDA) and Healthcare Products Regulatory Authority (HPRA) audit history and has been successfully certified to the medical device quality standard ISO 13485. Although the company does not have an externally certified environmental or health and safety management system, it does aim to adopt best practice and has environmental and health & safety policies in place.

In conducting this case study the approach to the MedDev and Combo Company case studies was replicated; diagnostic techniques employed included interviews, observations and examination of the company’s EQ/PV and related systems, including a review of Standard Operating Procedures (SOPs), protocol templates and executed protocols. In Pharma Company two Key Informants facilitated the case study; the Director of Quality who has overall responsibility for the EQ/PV function in the company and the Validation manager who is directly responsible for management of the EQ/PV system in the company and reports to the Director of Quality.

Understanding the EQ/PV Process in Pharma Company

The validation system considered in this case study was the manufacturing process, and associated qualified equipment and facilities, for filled vials and
prefilled syringes. The validation system adopts a risk based approach, is procedure driven and is controlled at a macro level by the facilities Master Validation Plan (MVP). The MVP outlines the principles involved in process validation, facility and utility qualification and validation, equipment qualification, cleaning validation and software validation.

Pharma Company place particular emphasis on comprehensive equipment and process planning activities as manufacturing equipment is primarily custom made for the company’s specific purposes. Pharma Company’s approach to the EQ/PV process can be depicted as per the following flowchart:

![Flowchart of Pharma Company Manufacturing Equipment Development Process]

**Figure 7.3: Pharma Company Manufacturing Equipment Development Flowchart**

Pharma Company begins the process with the creation of a User Requirements Specification (URS) document. The URS contains instruction on requirements for the equipment manufacturer to design and build into the equipment. Pharma Company pay particular attention to ensuring that equipment is compatible with the existing GMP process and is appropriate for use in cleanroom facilities. The level of instruction given in the URS is dependent on the risk associated with the equipment and the extent of custom build in the equipment. A formal Design Qualification stage utilises peer review to ensure that the designed equipment, if built, will satisfy all the detailed specified requirements.

Factory Acceptance Tests (FATS) are conducted during the build of the equipment at the equipment supplier facility to ensure that requirements are being fulfilled. Pharma Company conduct FATs with their own equipment
operators as a means of ensuring the human factors considerations are representative of the operators who will be using the equipment in production, typically this will involve sending a tall and a small operator and taking into consideration their experiences with the usability of the equipment. Site Acceptance Tests (SATs) are performed when the equipment is delivered to Pharma Company’s facility. The SAT is a commissioning phase which verifies the system is installed properly and interfaces with other systems and peripherals in its working environment. The working environment is of particular importance as product is manufactured in a cleanroom environment and filled aseptically.

Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) protocols are used to produce a validation program specific to the product in question. The results and experiences of the URS, DQ, FAT and SAT stages can be leveraged for IQ, OQ and PQ activities.

A ‘case by case’ approach is used each time EQ/PV is required, as the specific requirements will be driven by the process requirements. Pharma Company has a robust internal documented system for defining the procedure for conducting EQ/PV and has templates of the required forms and protocols which can be developed for each specific case.

The Key Informants of Pharma Company view the manufacturing equipment as ‘ready for its intended use’ when each component of the EQ/PV process has been completed. Of particular importance are activities which verify that the functionality described in the URS perform as expected in the use environment and that the results of sampling of output of the manufacturing process demonstrates capability of the process to produce product to the required quality. The Key Informants stress that while the equipment is ready, critical to quality parameters must be monitored on an ongoing basis to ensure performance remains as per the validated state.
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**EQ/PV Prerequisites**

Pharma Company place more emphasis than MedDev Company and Combo Company on the importance of pre-qualification activities. While the URS is common to each company, the formal DQ stage and the FAT and SAT tests detailed earlier are required due to the custom nature of the equipment. FMEA is the risk management tool of choice in Pharma Company, this live document identifies the rationale for activities undertaken in a risk based approach to EQ/PV. Supplier evaluation is a key input to the manufacturing process which is managed externally to the EQ/PV process, suppliers’ quality management systems are routinely audited by Pharma Company.

**IQ/OQ/PQ Protocols**

Similar to MedDev Company, Pharma Company has template protocols for IQ, OQ and PQ. These protocols contain the generic checks, tests and verifications required for each process/equipment. Specific risk driven requirements will be additional to these requirements.

In developing the **Installation Qualification** protocol, Pharma Company will refer to the FMEA, URS, DQ, FAT and SAT of the equipment in question and to the company MVP as a macro level guidance document. The IQ acceptance tests detail criteria for utilities, safety checks, details of spare parts that must be kept on site and verification of preventative maintenance and calibration schedules. Environmental impacts and aspects, ergonomics and human factors are considered in the design and build stages of the equipment but not formally captured in the qualification protocols.

In developing the **Operational Qualification** protocol, Pharma Company will refer to the FMEA, URS, DQ, FAT and SAT of the equipment in question and to the company MVP as a macro level guidance document. The functional specification of the URS is of particular importance to the OQ. The OQ considers:

- Training
- Functional Testing
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- Alarms and limits
- Data Connections
- Utility Failure
- Verification that cleaning validation has been completed
- ‘Worst Case’ testing
- Environmental monitoring instruments

The requirement for training of equipment operators is captured in the OQ. Functional testing describes a series of operational checks to be performed and the acceptance criteria for each, for example to verify that where the equipment must perform a fill that the actual fill volume achieves required fill volume within a stated tolerance. Alarms and limits and utility failure are utilised to verify a fail to safety condition and to ensure that fail states are recorded. Data connections verify compatibility with ancillary equipment. Environmental monitoring instruments are integrated into critical equipment to verify that air particulate count and potential contamination are controlled at critical locations. The Director of Quality noted that ‘worst case’ testing is becoming less relevant as modern manufacturing equipment becomes more capable in terms of feedback loops controlling critical parameters. In recent years, worst case testing is performed only to discover the margin of safety available in critical parameters before failure occurs, rather than to establish operating windows. In Pharma Company all process characterisation/optimisation studies are performed earlier during process development.

In developing the **Performance Qualification** protocol, Pharma Company will again refer to the FMEA, URS, DQ, FAT and SAT of the equipment in question and to the company MVP as a macro level guidance document. As also in the OQ, the functional specification of the URS is of particular importance to the PQ. The focus of the PQ is environmental conditions and verifying the consistency of output of the equipment. Environmental conditions are tested using environmental monitors to verify that the equipment/process can achieve and
maintain a state of being free of contamination. Output of the equipment is verified by sampling of product from three independent production batches. Each batch must reflect anticipated production conditions and must follow the established SOP for the process/equipment. While the sampling plan changes depending on risk and batch size, the sample size must be statistically based. As product sampling requires destructive testing the PQ stage can have significant cost implications, it is therefore imperative for Pharma Company that all preceding stages of process development and validation have been developed and executed to identify and mitigate risk to product quality and verify the capability of the manufacturing system.

Peer review approval of the validation documentation in Pharma Company mirrors that of MedDev Company and Combo Company, as does the strict maintenance of the validated state where any changes to the process or equipment, which may be due to process optimisation development work or to address problems encountered in production or to address new risks that have been identified, must go through a formal change control process which will again be peer reviewed. Pharma Company require periodic revalidation, the schedule for which is risk based, in addition to revalidation which will be performed if ongoing monitoring suggest the equipment is losing its capability to maintain the validated state.

**Macro Level Questions**

The Key Informants of Pharma Company were asked to appraise the equipment qualification process in terms of providing an effective framework for addressing quality, maintenance/calibration, reliability and safety considerations. Regarding quality, the Key Informants viewed the testing and subsequent confidence obtained in the ability of the equipment/process output to meet required product requirements as the central benefit of the overall EQ/PV process, arguing that through the EQ/PV process and ongoing process monitoring the potential for quality issues at a later stage are dramatically reduced.
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Maintenance and calibration considerations are addressed initially during URS creation and the FAT to ensure that the equipment is designed to facilitate ease of maintenance and calibration. The IQ subsequently verifies that a Preventative Maintenance (PM) program and calibration schedule had been put in place. Initially the PM and calibration schedules will be based on manufacturers recommendations, over time the schedules may be altered, often to reduce costs, based on historical information and risk analysis. The EQ/PV process will also verify that appropriate training has been completed and that requirements for spare parts had been addressed. The Key Informants are satisfied that this puts in place suitable structures to manage maintenance and calibration requirements over the lifecycle of the equipment.

The Key Informants view reliability as a function of ongoing trending analysis, reasoning that as reliability is a function of time the EQ/PV process shows potential capability of the equipment only, additional controls are needed to maintain the validated state and ensure reliability. Safety requirements are stated in the URS and tested in the OQ; these requirements include specification for emergency stops, interlocks and the human interface of the equipment. The Key Informants view this method as adequate in assessing functional safety of equipment.

Both Key Informants of Pharma Company regard the URS as the key element of the EQ/PV process, stating that the URS ensures quality by design of the equipment and provides the requirements from which EQ/PV protocols can be developed. Both Key Informants agree also that a poorly specified URS will be the most likely root cause of equipment quality issues in regular production. In terms of specific techniques used in the EQ process, FMEA has been shown to be the foundation of the risk based approach to EQ activities.

Closing Questions

The Key Informants of Pharma Company are confident that the Equipment Qualification process as currently in place is comprehensive in supporting
regulatory and company goals. They do, however, stress again that EQ/PV testing results are a ‘snapshot in time’ and the robust controls must be put in place to maintain this state.

The final question of the case study related to seeking the Key Informant’s opinion on how healthcare could best utilise and benefit from the Equipment Qualification framework. The Key Informants’ unanimous opinion on this reflected that of the Key Informants of MedDev Company and Combo Company; that accountability and responsibilities established in EQ, particularly those relating to maintenance and calibration functions, are of central importance.

Key Findings of Pharma Company Case Study

The purpose of this case study was to explore the approach adopted by a pharmaceutical manufacturer to the equipment qualification/process validation function and to extract best practice from this sector. The key findings of this case study were as follows:

- An emphasis on design and build stage activities
- A risk based approach
- An emphasis on product Quality Assurance
- Functional safety and human interface requirements are considered at design and build stages
- Consideration of the use environment is of critical importance in ensuring product is contamination free
- EQ/PV regarded as a snapshot in time – (need for ongoing control systems)
- Template IQ/OQ/PQ protocols facilitate systematic approach
- Documentation and peer review creates responsibility and ownership

Throughout the case study of Pharma Company it was apparent that the EQ/PV system had a heavier emphasis on front end EQ/PV activities, this is primarily
because manufacturing equipment is custom built. The IQ/OQ/PQ protocols broadly replicated that of Combo Company and MedDev Company.

In common with MedDev Company, Pharma Company adopt a risk based approach to generating EQ/PV requirements, primarily utilising the FMEA tool. In common with MedDev Company and Combo Company the EQ/PV system is heavily biased towards Quality Assurance and establishing confidence in the ability of the equipment to produce a desired output within the production process. Pharma Company does incorporate environmental, safety and ergonomic requirements into the URS and subsequent IQ and OQ protocols, though such considerations are more critical to Pharma Company than the other companies as the equipment is custom built and therefore will not have been CE marked by the manufacturer.

Pharma Company also place considerable importance on designing for and verifying the capability of equipment in the use environment. This requirement is risk driven as the product is filled aseptically.

A further aspect of the EQ/PV process that was identified and highlighted by the Key Informants in Pharma Company is that EQ/PV represents a snapshot in time, representing potential capability of the equipment only. Additional ongoing control systems are needed to maintain the validated state.

Finally, the importance of robust documentation; availability of guidance documents and template protocols, peer review of protocols and the recording of all activities completed which was highlighted in MedDev Company and Combo Company was also evident in Pharma Company.
7.3 Phase II: Requirements Analysis Case Studies

The objective of the healthcare requirements analysis case studies was to develop an understanding of current activities undertaken in hospitals from when medical equipment is delivered to the hospital to when the first patient interacts with the equipment. Building on this understanding the case study aims to identify requirements and recommendations for tools, methods and considerations for inclusion in the proposed Equipment Qualification framework.

Both the clinical engineering and medical physics case studies were conducted in a large public hospital in Ireland which operates under the governance of the Health Service Executive.

7.3.1 Clinical Engineering Case Study

The Key Informant for the clinical engineering case study was the Head of Clinical Engineering of the hospital. Data was collected through a semi-structured interview as per the Healthcare Case Study Protocol in Appendix VI.

Understanding the acceptance testing process

The initial question of the case study was to explore current practices of acceptance testing activities undertaken in hospitals from when medical equipment is delivered to when the first patient interacts with the equipment. The Key Informant stated that the acceptance testing activities can be broadly categorised as technical activities and user related activities.

Technical activities begin prior to receipt of the medical equipment and involve preparing the use environment to facilitate the new equipment. Utilities such as medical gases, IT systems and electricity must be in place before the equipment arrives. On delivery of the equipment functional and configuration tests are completed, using patient simulation where required. Alarm verification is a particularly important aspect of the functional testing. The clinical engineer will
confirm that all required accessories and consumables are appropriate and available. Electrical safety testing is completed as per the international standard IEC 60601 on medical electrical equipment.

User related activities also begin prior to purchase of new medical equipment. The clinical engineers often visit other hospitals to conduct equipment appraisals and gain recommendations and feedback from users of the equipment. Upon purchase of the equipment user related activities concern training requirements. The clinical engineer determines which staff groups need to be trained and manages how and when the training will be delivered and what training materials are required. Acceptance testing activities are undertaken on a ‘case by case’ approach and are planned and completed in conjunction with the medical equipment supplier. The manufacturer’s installation and operating manuals are the primary reference point for guiding activities. Typically the purchase agreement with the equipment supplier will include requirements for the supplier to perform installation, training and ongoing maintenance and calibration of the equipment.

Requirements for documentation of acceptance testing activities are minimal; typically the clinical engineer will sign off an installation sheet with a basic statement to confirm that the equipment has been installed correctly and is ready for use. There is no requirement for peer review. The Key Informant acknowledges that improvements in documentation practices would be beneficial.

**Components of the acceptance testing process**

Risk based activities are not formally adopted by the clinical engineers. The Key Informant argues, however, that clinical engineers are at all times conscious of risk through training and experience in working with medical equipment. The Key Informant recognises the value of a risk based approach but is hesitant to recommend tools such as FMEA, which he argues are excessively time consuming and do not add sufficient value to the acceptance testing process. The Key
Informant recommends the inclusion of a risk management component in the proposed Equipment Qualification framework, though advises that the method adopted must add value rather than burden for clinical engineers.

Quality and safety are seen as inter-related by the Key Informant. The Key Informant stresses that quality and safety are of central importance in the medical equipment lifecycle, stating that the business case for new medical equipment is primarily driven by quality and safety capabilities. Quality and safety considerations in the acceptance testing stage of the equipment lifecycle are primarily addressed through functional tests and patient simulations to verify that the equipment performs as expected. The manufacturer of the equipment provides direction on which tests must be conducted.

External environmental considerations are not formally addressed. The Key Informant argues that typically medical equipment have no significant environmental aspects and consequently have a low risk of environmental impact in either normal operating or fault conditions.

Ergonomics/Human Factors are not formally considered. The Key Informant acknowledges that an ergonomics/human factors checklist would be a useful tool for acceptance testing. The Key Informant notes that the procurement stage of the equipment lifecycle presents a valuable opportunity to address ergonomics/human factors, whereby supplier agreements would have stated requirements for the equipment to achieve regarding ergonomics/human factors.

Maintenance and calibration requirements are typically incorporated into the purchase agreement with the equipment supplier. The clinical engineer’s primary input to this function is at the procurement stage when the total cost of ownership is calculated. The total cost of ownership considers the frequency of maintenance and calibration activities and the associated supplier labour and consumable costs. The Key Informant notes that calibration requirements are
becoming less common in more modern medical equipment. While lean methods are not formally considered during the acceptance testing, the Key Informant believes in the potential of lean to increase equipment use efficiencies and aid in facilitating a systems view of how the medical equipment being installed fits into the overall value stream.

Difficulties with the existing acceptance testing process

The Key Informant cites user misuse issues as the primary recurring cause of adverse incidents in the equipment lifecycle. While the acceptance testing activities include a training component for users, a learning curve is evident as frontline staff become familiar with the new equipment. The Key Informant has not seen any recurring technical problems.

The primary causes of setbacks, delays and non-conformances during the acceptance testing activities are difficulties in scheduling clinical staff for training and equipment familiarisation. The clinical engineering team has had success with preparing offline training modules which users can utilise at off-peak times, for many users this is the early hours of the morning when the majority of patients are sleeping. The scheduling of technical install activities can also create logistical difficulties as patients will often need to be moved to alternative locations for the duration of the install.

Perceived value of Equipment Qualification framework for healthcare

For the final question of the case study the Equipment Qualification process and components of the framework was explained to the Key Informant. Reflecting on the proposed framework the Key Informant is confident that clinical engineering could benefit in terms of being provided with a systematic approach and one which facilitates good documentation practices. The Key Informant advocates the use of a risk based approach to identify key characteristics of the equipment which can induce error, particularly those related to how users interact with alarms. This risk based approach however, must be appropriate in considering the time restraints imposed on clinical engineering staff.
Key Findings of Clinical Engineering Case Study

The objective of the healthcare case study was to develop an understanding of current the acceptance testing activities undertaken in hospitals from when medical equipment is delivered to the hospital to when the first patient interacts with the equipment. Building on this understanding the case study identified requirements and recommendations for tools, methods and considerations for inclusion in the proposed Equipment Qualification framework. The key findings of this case study were as follows:

- Acceptance testing activities are categorised as technical and user related activities
  - Technical activities are primarily provision of utilities, electrical safety testing, functional and configuration tests and alarm verification
  - User related activities primarily concerns training
- The scope of acceptance testing activities for medical equipment in healthcare is less developed than those for manufacturing equipment in industry
- Typically the purchase agreement with the equipment supplier will include requirements for the supplier to perform installation, training and ongoing maintenance and calibration of the equipment.
- Requirements for documentation of the acceptance testing activities are minimal
- Risk based activities are not formally adopted
- Quality and safety for the acceptance testing are viewed as inter-related and is the critical consideration for clinical engineers
- The external environment and ergonomics/human factors are not formally considered
- Potential value of lean methods highlighted
- The proposed Equipment Qualification framework must be cognisant of time restraints on healthcare staff
7.3.2 Medical Physics Case Study

The Key Informant for the medical physics case study was the Head of Radiotherapy Physics of the hospital. Data was collected through a semi-structured interview as per the Healthcare Case Study Protocol in Appendix VI.

*Understanding the acceptance testing process*

The linear accelerator\(^30\) (linac), used for external beam radiation treatments for patients with cancer, is the most complex medical equipment in radiotherapy and therefore was the focus of this case study. The selection and specification of a linac is based on clinical needs. The process of purchase, acceptance testing, and commissioning of a linac is a major undertaking that can take up a considerable amount of time, effort, and expense. Input is sought from a multidisciplinary team including radiation oncologists, physicists and facility engineers. Preparation for delivery of a linac requires the design and construction of the facility to house the new machine. The equipment supplier is responsible for installation of the machine, initial safety checks and initial radiation survey.

The installation is followed by acceptance testing to ensure that the machine meets the product specifications and the purchase agreement. The supplier conducts acceptance testing in partnership with the medical physics team. The process of commissioning a linac for clinical use includes comprehensive measurements of dosimetric parameters that are necessary to test the treatment planning systems used to select optimal radiation modality and treatment technique for individual patients. The commissioning phase establishes the baseline quality assurance parameters.

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\(^{30}\) A linear particle accelerator is a type of particle accelerator that greatly increases the velocity of charged subatomic particles or ions by subjecting the charged particles to a series of oscillating electric potentials along a linear beamline.
A ‘case by case’ approach is used for each individual linac as the rate of technological change in radiotherapy requires different tests for different equipment capabilities. The manufacturer supplies the testing requirements which are based on international best practice.

While a significant amount of testing is completed and data collected during acceptance testing of the linac, the records of this data tend to exist in different formats (both soft and hard-copies) and in different locations. There is a reliance on the medical physicists to recall where the relevant data is stored. The Key Informant acknowledges that improvements in documentation practices would be beneficial.

**Components of the acceptance testing process**

Risk assessment in radiotherapy is conducted at a macro level and concerns implementing pre-emptive and ongoing risk control measures. Risk assessments are informed by best practice guidelines from organisations such as the Institute of Physics and Engineering in Medicine and The American Association of Physicists in Medicine. As there will always be risk in the use of radiation the As Low as Reasonably Achievable (ALARA) approach is used in determining the risk to patients, where the medical physicists determine whether benefits outweigh potential dangers in treatment. Risk is also assessed in terms of hazards for third parties such as radiotherapy staff, visitors, cleaning staff. While specific risk assessment techniques are not formally required, the use of techniques such as Failure Modes and Effects Analysis (Ciocca et al., 2012), Fault Tree Analysis (Ekaette et al., 2007) and the Structured What If Technique (Card et al., 2012b) have been reported in the literature.

As in the Clinical Engineering case study, quality and safety are seen as inter-related by the Key Informant. The Key Informant stresses that quality feeds directly into safety. Quality and safety considerations are primarily addressed through functional tests and simulations to verify that the equipment performs as expected. The manufacturer of the equipment provides direction on which
tests must be conducted. The medical physics team consider any quality issue as a potential safety concern. Additional safety considerations such as manual handling, slips, trips and falls are not examined during equipment acceptance testing.

Environmental considerations are of significant concern due to the use of radiation. The design of the facility is of particular importance in containing the radiation. The facility is tested for potential radiation leaks initially and on an ongoing basis.

Ergonomics/Human Factors are considered, though appraisal relies on informal feedback from healthcare staff rather than explicit checks to be performed. The Key Informant stresses the importance of multidisciplinary teams in human factors appraisals to gain feedback from a range of stakeholders on potential for use error and the physical layout of the workspace.

As also found in the clinical engineering case study, maintenance and calibration requirements are typically incorporated into the purchase agreement with the equipment supplier. A limited range of maintenance can be completed by appropriately trained in-house staff. The medical physicist’s primary input is in the scheduling of the maintenance with the supplier.

Calibration on key process characteristics is conducted daily, weekly and monthly after maintenance, applying varying degrees of tolerance depending on the criticality of the parameter being calibrated. All measuring equipment used in calibration must be traceable back to an international standard. Maintenance and calibration are of much greater concern to medical physicists than clinical engineers due to the nature of the medical equipment with which they work.

While lean methods are not formally considered during the acceptance testing, the Key Informant believes in the potential of lean to increase patient throughput. The Key Informant described activities which reflect lean practices;
aspects of Single Minute Exchange of Dies (SMED) are evident in the structuring of calibration activities and aspects of value stream mapping are evident in workflow enhancement efforts, such as concurrent activities, to reduce patient throughput times. Process control is evident in assigning action levels to machine parameters, where parameter drift is addressed before an out of tolerance condition occurs.

Difficulties with the existing acceptance testing process

The Key Informant cites facility issues as being the most frequent causes of problems in current medical equipment installation activities. Typically, these problems may relate to provision of services such as electricity, water and air conditioning. In installations where such issues arise, difficulties in negotiations with machine supplier often follow, where the machine supplier may not progress with the installation until facility problems are resolved.

The primary causes of setbacks, delays and non-conformances during the acceptance testing activities are difficulties in scheduling clinical staff and support staff such as electricians, plumbers for training and equipment familiarisation. Also due to the complexity of the equipment, when an issue occurs it can often take a significant amount of time to identify the root cause of the problem.

Perceived value of Equipment Qualification framework for healthcare

For the final question of the case study the Equipment Qualification process and components of the framework was explained to the Key Informant. The views of the Medical Physics Key Informant reflect those of the Clinical Engineering Key Informant; i.e. a view of confidence in the framework providing value through a systematic approach in standardising the common steps of radiation therapy equipment acceptance testing and facilitating good documentation practices. The Key Informant highlights further value in having documented evidence of utility appraisal when resolving difficulties with suppliers and in having an
equipment history log for training and informing support staff who are not directly familiar with the specific equipment.

In terms of adapting a manufacturing practice for healthcare the Key Informant stresses the importance of being cognisant of culture and the multidisciplinary nature of healthcare; it is important that all stakeholders have an opportunity to have input into acceptance testing activities. Furthermore, the Key Informant stresses the importance of flexibility in the utilisation of the equipment as, unlike in manufacturing, each patient (input) is unique and presents unique challenges for the healthcare team.

**Key Findings of Medical Physics Case Study**

The objective of the medical physics case study was to develop an understanding of current the equipment acceptance testing activities undertaken in hospitals from when radiation therapy medical equipment is delivered to the hospital to when the first patient interacts with the equipment. This case study, as with the clinical engineering case study, aims to identify requirements and recommendations for tools, methods and considerations for inclusion in the proposed Equipment Qualification framework. The key findings of this case study, which were in common with the clinical engineering case study, are as follows:

- The scope of acceptance testing activities for medical equipment in healthcare is less developed than those for manufacturing equipment in industry
- Typically the purchase agreement with the equipment supplier will include requirements for the supplier to perform installation, training and ongoing maintenance of the equipment.
- Risk based activities are not formally adopted for each item of equipment
- Quality and safety for the acceptance testing are viewed as inter-related and is the critical consideration for medical physicists
- Ergonomics/human factors are not formally considered
Potential value of lean methods highlighted
The proposed Equipment Qualification framework must be cognisant of time restraints on healthcare staff

The following findings which were not apparent in clinical engineering are considerations for medical physicists:
- Calibration is a key consideration which is performed in-house
- The external environment can be substantially impacted by radiation if the appropriate controls have not been demonstrated to be effective
- Documentation of equipment acceptance testing activities exists, though files are often in different formats and in different locations. Often, only one individual will know where files are stored

Throughout both the clinical engineering and medical physics case studies it was apparent that the acceptance testing activities for equipment in hospitals vary significantly from those of medical device, pharmaceutical and combination product manufacturing industries. Systematic acceptance testing activities or methods are not formalised in the hospital and there is a reliance on the tacit knowledge of the healthcare teams to manage risk. Furthermore, there is a substantial reliance on the equipment supplier for guidance on functional and safety tests and ongoing maintenance.

Overall, existing practices suggest that the adoption of an Equipment Qualification process could improve the acceptance testing of medical equipment in healthcare in terms of providing guidance on considerations for acceptance testing activities, the introduction of lean methods and the formalised documentation of completed activities. However, it is also apparent that the proposed Equipment Qualification process must add value rather than burden, in particular in the time required to conduct pre-emptive risk assessment.
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7.4 Phase III: Requirements Analysis Self-Completion Questionnaire

The purpose of the requirements analysis self-completion questionnaire was to obtain views on the strengths and weaknesses of current acceptance testing activities and to extract identified requirements and recommendations for tools, methods and considerations for inclusion in the proposed Equipment Qualification framework from healthcare stakeholders. This section describes the findings of the self-completion questionnaire. The stakeholder requirements identified in this phase will be integrated, and developed where appropriate, into a best practice Equipment Qualification framework for healthcare.

Profile of Respondents

As described in Chapter Six, purposive sampling and snowball sampling were the non-probability sampling methods employed to reach respondents to the questionnaire. The method of distributing the questionnaire was to request the professional organisations for clinical engineers and medical physicists in Ireland to distribute the questionnaire to its members. Respondents were also approached directly through the online business network, LinkedIn. Respondents contacted through LinkedIn were also asked to distribute the questionnaire to colleagues in clinical engineering and medical physics.

As shown in Figure 7.4, there were a total of 76 respondents to the questionnaire, 44 of whom described their role as clinical engineering with the remaining 32 describing their role as medical physicists. Unfortunately, due to the hidden nature of the target population and the limitations of the sampling method the response rate to the questionnaire is unknown as it is impossible to quantify how many individuals were invited to complete the questionnaire.
Chapter Seven: Fieldwork Results and Analysis

The employment setting for respondents was as per Figure 7.5 below. Two respondents who selected ‘Other’ as current employment setting stated in the comment section that he/she worked in a university and a voluntary hospital.

Figure 7.6 shows that respondents cover the scope of responsibilities in medical equipment acceptance testing activities, from being ‘Hands On’ in conducting acceptance testing activities (28%) to being a ‘Policy Maker’ in giving guidance and requirements for acceptance testing activities (9%). The remaining 63% stated that they have responsibilities in both giving guidance and requirements for acceptance testing activities and also conducting acceptance testing activities.
In order to obtain views on the overall effectiveness of current practices in medical equipment acceptance testing respondents were asked to rate the effectiveness of current practices in the following:

- Verifying medical equipment is functioning correctly
- Minimising potential for equipment failure
- Minimising potential for use error
- Maximising potential for productive work practices

Respondents rated each statement on a five point Likert scale, ranging from Not Effective to Very Effective. Results are presented and discussed in Figure 7.7 to Figure 7.10.

**Respondents’ Assessment of Current Practices:**

*Verifying Medical Equipment is Functioning Correctly*

As shown in Figure 7.7, respondents are unanimous in their belief that current medical equipment acceptance testing activities are effective in verifying that the equipment is functioning correctly. This trend was particularly evident in the medical physics cohort who all gave rating of Effective or Very Effective.
In the comments section for this question one clinical engineering respondent stated that the effectiveness of functionality testing is based on testing being ‘conducted in accordance with manufacturer performance test procedures together with electrical safety testing (EST) and other hospital acceptance criteria such as documentation etc.’.

This strong confidence in existing methods for verifying equipment is functioning correctly indicates that the proposed Equipment Qualification framework can leverage existing practices.

Respondents’ Assessment of Current Practices:

Minimising Potential for Equipment Failure

Respondents, when asked on their rating of the effectiveness of current acceptance testing methods in minimising the potential for equipment failure, had differing views as presented in Figure 7.8:
Minimising the potential for equipment failure is tightly coupled with the domains of risk assessment, quality assurance, maintenance and calibration. Respondents in a subsequent question, again on a five point Likert scale, were asked to rate the effectiveness of current practices in addressing each of these domains. Applying the Likert weighted mean analysis\(^{31}\) to the responses to each domain shows that the weighted mean for each is as per Figure 7.9.

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\(^{31}\) In Likert scale questionnaires the ordinal scale responses may be coded with weights (Adanza, 1995). In this question the codes were as follows; Not Effective = 1, Somewhat Effective = 2, Moderately Effective = 3, Effective = 4 and Very Effective = 5. The weighted mean (the average of the sum of the coded ratings) is useful in summarising the central tendency of a Likert question.
Chapter Seven: Fieldwork Results and Analysis

It is evident from Figure 7.9 that respondents collectively rate the practices in addressing quality assurance and calibration as effective in current acceptance testing activities. This finding reflects the findings of the fieldwork case studies, where radiation based medical equipment in particular, is subject to extensive quality assurance and calibration testing and implementation of controls. Respondents are less confident, however, in the effectiveness of existing practices which address risk assessment and maintenance.

The implications of findings of this question for the Equipment Qualification framework are that while existing quality assurance and calibration practices can be leveraged, an improved risk assessment method and maintenance program implementation is desirable.

Respondents’ Assessment of Current Practices:

Minimising Potential for Use Error

Respondents, when asked on their rating of the effectiveness of current acceptance testing methods in minimising the potential for use error, demonstrate clear concerns as presented in Figure 7.10.

![Figure 7.10: Respondent Rating of Effectiveness of Minimising Potential for Use Error](image)
Minimising the potential for use error is tightly coupled with the domains of risk assessment, safety and Ergonomics / Human Factors. Respondents in a subsequent question, again on a five point Likert scale, were asked to rate the effectiveness of current practices in addressing each of these domains. Figure 7.11 presents the Likert weighted mean of the responses to each domain which supports the minimising of potential for use error.

![Domains Supporting the Minimising of Potential for Equipment Failure](image)

**Figure 7.11: Respondent Rating of Effectiveness of Domains Supporting the Minimising of Potential for Use Error**

It is evident from Figure 7.11 that respondents collectively rate the practices in addressing safety as effective in current acceptance testing activities. However, respondents do not rate highly the effectiveness of existing practices which address risk assessment and in particular, Human Factors / Ergonomics. This lack of confidence in human factors / ergonomics reflects the overall concern in the effectiveness of practices in minimising potential for use error as demonstrated in Figure 7.10.

While the Equipment Qualification framework can confidently leverage existing safety testing practices, an improved risk assessment method is desirable and a robust approach to Human Factors / Ergonomics methods is necessary.
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Respondents’ Assessment of Current Practices:

Maximising Potential for Productive Work Practices

Respondents, when asked on their rating of the effectiveness of current acceptance testing methods in maximising potential of productive work practices, demonstrate differing views as presented in Figure 7.12 below:

![Maximising Potential for Productive Work Practices](image)

**Figure 7.12: Respondent Rating of Effectiveness of Maximising Potential for Productive Work Practices**

Maximising the potential for productive work practices is tightly coupled with the domain of lean methods. Respondents in a subsequent question, again on a five point Likert scale, were asked to rate the effectiveness of current practices in lean methods. The responses to this question gave a Likert weighted mean of 2.33, demonstrating that in general respondents do not see lean methods as being applied effectively. Indeed, three respondents specifically indicated in the comment field for this question that they are not familiar enough with lean to apply its techniques effectively.
Respondents’ Assessment of Current Practices:

Concerns Regarding Existing Practices

In order to discover any potential obstacles that may be encountered in developing and using an Equipment Qualification framework, respondents were asked the following questions:

- Are you aware of any major or recurring problems/issues resulting from current acceptance testing activities?
- Are you aware of any recurring causes for setbacks/delays/non-conformances or other problems during acceptance testing activities?

Each question was presented with a Yes or No option and a comment box for respondents to describe the rationale and further information to clarify their answer. There were 65 responses (11 respondents skipped the question) to the ‘Are you aware of any major or recurring problems/issues resulting from current acceptance testing activities? Of the 65 responses 80% (n=52) of respondents answered ‘No’ with 20% (n=13) answering ‘Yes’.

Unfortunately, only three respondents stated the rationale behind their answer, with one respondent stating ‘More commissioning and validation documentation should be used to gather information on the equipment which could highlight and trace failures and weaknesses with the equipment’ and another listing the following difficulties; ‘Difficulty to fully test equipment requiring dedicated test equipment. Difficulty in getting consultant staff and medical staff to participate in training and acceptance training prior to use. Expense of single use items that may limit testing’. Finally one respondent recorded the following; ‘Supplier not completing Electrical Safety Testing on site of delivery. Delivery Transportation of the equipment may have affected the integrity of the equipment’.

The stated difficulties reflect issues which the Equipment Qualification framework will address;

- EQ protocols will facilitate documented practices
Chapter Seven: Fieldwork Results and Analysis

- EQ framework will identify failures and weaknesses in the equipment through identification of tests required
- EQ framework will require verification that Electrical safety testing has been completed
- EQ framework is conducted in the use environment immediately prior to clinical use to identify any potential issues with the integrity of the equipment after delivery

For the ‘Are you aware of any recurring causes for setbacks/delays/non-conformances or other problems during acceptance testing activities?’ question, there were, again, 65 responses (11 respondents skipped the question) and again of the 65 responses 80% (n=52) of respondents answered ‘No’ with 20% (n=13) answering ‘Yes’.

In the comment section, just one respondent stated his/her rationale for answering Yes, stating that a lack of financial support to complete action points / recommendations arising from acceptance testing is a recurring problem in his/her work. Tackling the financial support to potential practitioners of the Equipment Qualification framework is beyond the scope of this thesis.

Respondents’ Recommendations for Future Practices
In order to ensure that the developed Equipment Qualification framework can meet potential users identified needs, respondents were presented with the following:

Please recommend tools, methods and considerations that you would like to see addressed in the proposed acceptance testing guidance, for each of the following:

- Risk Assessment
- Quality Assurance
- Safety
- Ergonomics / Human Factors
- Maintenance
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- Calibration
- Environment (prevention of pollution)
- Lean Methods
- Other (please explain)

The most notable aspect of respondents reaction to this request was the lack of answers given, ranging from zero to four responses per listed item. While this lack of response may be due respondents lacking sufficient knowledge in suitable tools/methods/considerations to recommend, or simply that respondents did not have time and/or inclination to complete this question, it is difficult to speculate in the absence of a rationale. Nevertheless, those answers that were given will be discussed in the following paragraphs.

For risk assessment respondents (n=3) recommended that each individual piece of equipment should be risk assessed, with an emphasis of risk relating to user training. It was also recommended that risk assessment should be reviewed and audited as required.

Regarding quality assurance, responses (n=4) recommended that the quality systems and quality test procedures used should be documented. A medical physics respondent also stated that performance verification tools, legislation and guidelines, appropriate test equipment and continuous professional development of staff should be considered in quality assurance.

Also under quality assurance a particularly interesting response was given by a clinical engineer, who stated that IQ, OQ and PQ should be completed for medical equipment. As this respondent left his LinkedIn contact details, it was found that this respondent has extensive experience in pharmaceutical manufacturing as a field service engineer and a validation/commissioning engineer. However, despite protracted efforts, the respondent could not be contacted directly to further explore his views on Equipment Qualification.
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Responses under safety (n=4) highlighted that electrical safety testing is of paramount importance, with attention also given to legislation and guidelines relevant to the equipment, education and training of staff and consulting Material safety Data Sheets (MSDS) where appropriate. A clinical engineering respondent also recommended that risks should be expressly displayed on each piece of equipment.

The solitary response under the topic of Human Factors / Ergonomics (n=1) recommended a review of common user related calls, environment and use considerations and work task analysis to be incorporated into acceptance testing.

The topic of maintenance received the most responses (n=5). Responses highlighted the requirement for a maintenance plan developed in accordance with manufacturer’s recommendations. A public hospital respondent also raised the issue of standardisation of maintenance practices throughout the health service by developing Standard Operating Procedures (SOPs) for equipment that is standard to many facilities. This respondent suggests that such SOPs should be developed within the clinical engineering structure already in the health service.

Regarding calibration, responses (n=4) again highlighted the importance of following the manufacturers recommendations in developing and implementing a calibration plan and procedures. A medical physics respondent also recommended that acceptance testing documentation should list special tools, software etc. required for calibration and a clear statement of the accuracy and uncertainty specifications for the calibrated parameters.

Responses concerning Environment (prevention of pollution) (n=3) recommend that acceptance testing should verify that relevant legislation and guidelines are being followed, that MSDS and disposal information are readily available and that all environmental hazards have been assessed.
The solitary response under the topic of lean (n=1), while not providing tools or methods, cautioned that lean methods can sometimes be hard to apply in a working hospital.

Under the heading of ‘Other (please explain)’ there were no responses, indicating that the preceding list of headings captured all the required domains for consideration in acceptance testing.

**Key Findings of the Self-Completion Questionnaire**

The purpose of self-completion questionnaire was to obtain views on the strengths and weaknesses of current acceptance testing activities and to extract identified requirements and recommendations for tools, methods and considerations for inclusion in the proposed Equipment Qualification framework from healthcare stakeholders. The key findings of self-completion questionnaire were as follows:

- Existing practices for verifying that medical equipment is functioning correctly can be leveraged by the proposed Equipment Qualification framework
- Respondents do not display consensus in rating the effectiveness of current practices in minimising potential for equipment failure
- An improved risk assessment method is desirable
- An improved maintenance program implementation method is desirable
- Respondents demonstrate clear concerns in the effectiveness of current practices in minimising potential for use error
- Deficiencies in current Human Factors / Ergonomics practices is evident
- Respondents did not display consensus in rating the effectiveness of current practices in maximising potential for productive work practices
- An evident lack of familiarity with lean methods
- A strong emphasis on developing functionality tests, safety tests and calibration and maintenance schedules based on manufacturers recommendations
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- A stated request for more thorough testing, standardisation and greater documentation of acceptance testing activities

The findings of the self-completion questionnaire complement those of the clinical engineering and medical physics case studies in supporting the rationale for the implementation of an Equipment Qualification framework which will provide guidance on and standardise the scope of acceptance testing activities while also ensuring activities undertaken are documented, auditable and available for reference in the ongoing management of the equipment.
Chapter Eight: Equipment Qualification Framework Development

8.1 Introduction

As introduced in Chapter One, this research aims to assess how the well-developed practices, protocols and tools of equipment qualification in manufacturing can be transferred, developed and modified for application in healthcare. In Chapter One the research question of this thesis was stated as follows:

‘How can the protocols, practices and tools of Equipment Qualification be developed and modified for application in healthcare?’

In order to answer the research question the following objectives were identified:

1. To explore, through a review of the literature, best practice in supporting disciplines to Equipment Qualification
2. To benchmark, through case studies, best practice methods used in manufacturing industries for Equipment Qualification.
3. To determine the identified and unidentified requirements of key stakeholders of activities within the scope of Equipment Qualification activities in healthcare.
4. Informed by the results of 1 to 3 above, to develop a framework to assist healthcare providers in applying best practice methods in the qualification of medical equipment.

Objective 1 was addressed in Chapter Four & Chapter Five of the literature, through a review of Equipment Qualification methods in manufacturing industries and a critical review of the supporting disciplines to Equipment Qualification which extracted methods and tools which represent best practice, within the scope of Equipment Qualification activities, in the respective domains of risk management, quality, safety and reliability, maintenance and calibration, human factors engineering and lean methods.
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Chapter Seven addresses Objective 2, through presenting the results and findings of benchmarking studies in industries where the Equipment Qualification method is utilised. Chapter Seven also addresses Objective 3, through presenting the requirements of stakeholders of the Equipment Qualification framework.

In this chapter, Objective 4 will be addressed through a synthesis of the best practice methods identified in the preceding literature review and fieldwork phases of the research. This chapter presents the development the Equipment Qualification framework\(^{32}\). The IDEFØ model depicts the Equipment Qualification process at a macro level while the IQ, OQ and PQ template protocols provide direction on recommended structure and content of protocols.

8.2 Equipment Qualification IDEFØ Model

IDEFØ models are based on the Inputs-Controls-Outputs-Mechanisms (ICOMs) structure. To recall, the elements of ICOMs are as defined as follows:

- Inputs are data or objects that are consumed or transformed by an activity.
- Outputs are data or objects that are the direct result of an activity.
- Controls are data or objects that specify conditions that must exist for an activity to produce correct outputs.
- Mechanisms support the successful completion of an activity.

The IDEFØ model of Equipment Qualification for healthcare is presented in Figure 8.1. In the following sections the rationale for inclusion of each element of model is described at a macro level. In the protocol templates, presented in Appendices VII, VIII and IX, requirements are specified to include the purpose of each component, the method for executing specific tests and acceptance criteria for each element.

\(^{32}\) As described in Chapter Three, a framework is an explicit set of ideas which exist to help practitioners in thinking about a business process; providing guidance for choosing best practice by identifying and showing the relationship between topics.
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Figure 8.1: Equipment Qualification for Healthcare IDEFØ Model

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8.2.1 ICOMs Common to IQ, OQ and PQ

As Installation Qualification, Operational Qualification and Performance Qualification have common ICOMs, the components common to each will be discussed below rather than replicated in the discussion of each individual qualification stage.

Inputs
Risk Assessment, Commissioning Report and Supplier Characterisation are common inputs to Installation Qualification, Operational Qualification and Performance Qualification.

Risk Assessment
A risk based approach to healthcare practices in general is advocated in the literature and required by regulators. Throughout the manufacturing industry case studies the most evident input to the Equipment Qualification process is a risk assessment. Failure Modes and Effects Analysis (FMEA) is the predominant risk assessment tool employed. While FMEA has been shown to be a powerful tool in managing single point failure modes it has also been described by IEC 60812 Analysis Techniques for System Reliability – Procedure for Failure Mode and Effects Analysis (FMEA) as unsuitable for consideration of dependent failures or failures resulting from a sequence of events. Cognisant of Reasons Swiss Cheese Model, FMEA cannot, therefore, be expected to singularly encapsulate the risk assessment needs of an EQ process for healthcare.

The Structured What-If Technique (SWIFT) has been shown in Section 5.2.1 to provide a systematic, team orientated approach to risk assessment which is less time consuming than other systematic techniques such as FMEA. Time constraints for risk assessment were a major concern raised in both the clinical engineering and medical physics case study. The SWIFT method is, therefore, advised as the risk assessment method to be adopted in the EQ framework.
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**Supplier Characterisation**

Supplier Characterisation is an umbrella term to describe activities related to evaluating suppliers prior to protocol development and execution. Design Qualification, Factory Acceptance Tests (FATs) and supplier auditing are the primary method of supplier characterisation. Also within the scope of this term are objective elements such as supplier quality system certification, delivery performance and cost while subjective elements will include reputation and trust in the supplier. Supplier Characterisation can also be seen as a supporting function to a risk based approach. The importance and value of Supplier Characterisation as an input to the EQ is dependent on the level of customisation of the equipment in question.

In healthcare, where the medical equipment will have been independently verified and CE marked, Supplier Characterisation can be expected to be a consideration to be cognisant of when developing EQ protocols, rather than direct specifications which will become testing or verification activities.

**Commissioning Report**

Currently in healthcare, commissioning is undertaken before release of equipment for clinical use. It is the intention of this Equipment Qualification framework to leverage these current practices. In doing so, the framework is cognisant of a lean approach in avoiding duplication of workload while also aiding in the integration of an EQ process with existing methods. Therefore the commissioning report will be a key input to the Installation Qualification initially, and subsequent OQ and PQ requirements may be based on the requirements of the report of each respective stage.

**Controls**

Legislative Requirements, Regulatory Requirements and Training are common controls to Installation Qualification, Operational Qualification and Performance Qualification.
Chapter Eight: Equipment Qualification Framework Development

Legislative Requirements

The primary legislation for consideration in Equipment Qualification for healthcare is the Safety, Health and Welfare at Work Act 2005 and General Application Regulations 2007. The requirements of this legislation can be incorporated into the IQ template protocol.

To develop each equipment specific protocol, the author of the protocol must have knowledge of the Safety, Health and Welfare at Work Act 2005 and General Application Regulations 2007 and any additional legislative requirements, if applicable to the specific medical equipment.

Regulatory Requirements

The use of Equipment Qualification fulfils regulatory requirements that new equipment should be subject to an acceptance procedure before being put in to use. The primary regulatory requirements for consideration in developing the Equipment Qualification protocols are the publications of the Health Products Regulatory Authority (HPRA), the Health Information and Quality Authority (HIQA) and the Health and Safety Authority (HSA). Public healthcare facilities in Ireland will also be regulated by corporate policies of the Health Service Executive. The documentation and guidance of each regulatory body, along with major international regulatory bodies, are discussed in Section 2.4.

To develop each equipment specific protocol, the author of the protocol must have knowledge of the regulatory requirements specific to his/her healthcare facility and have knowledge and understanding of the medical equipment and its clinical application.

Training

The author of the protocol and those responsible for execution and peer review of the protocols must have training and competency in Equipment Qualification and the components of the protocol. Training requirements for each protocol component is discussed further in the following sections.
Chapter Eight: Equipment Qualification Framework Development

**Mechanisms**

*Template Protocol*

The qualification protocol is a written plan stating how the stage of qualification will be conducted and defining acceptance criteria for each protocol element. The template protocol provides guidance for the author on the structure of the protocol and considerations for inclusion in the finalised protocol for the specific medical equipment being qualified. Therefore, the template protocol is a mechanism rather than a control.

**Outputs**

*Deviation / Incident Report*

A deviation occurs if the actual result of a protocol check or activity does not fulfil the expected result. Deviation reports should include a description of how the actual results differ from the expected results, a root cause analysis of the deviation and details of the corrective action made to the testing protocol or the system to correct the deviation. In cases where the deviation presents a user safety hazard appropriate consideration needs to be given to the Principles of Prevention discussed in Section 5.4.2.

A deviation that causes, or has the potential to cause, unexpected or unwanted effects involving the health and safety of patient’s, users or other persons should be reported to the Health Products Regulatory Agency (HPRA) via the HPRA Incident Reporting system (HPRA, 2012).

To successfully manage protocol deviations, the person responsible for executing the protocol must have knowledge and understanding of the HPRA medical device incident reporting system, root cause analysis and have knowledge and understanding of the medical equipment and its clinical application.

*Qualification Phase Closure*

Qualification Phase Closure entails formal confirmation of the closure of the respective IQ, OQ or PQ. The qualification phase can only be deemed complete
when all protocol acceptance criteria have been successfully achieved and deviations, if encountered, have been resolved. Accountable stakeholders, who can be defined locally for each organisation, should review the test results and deviations in order to complete the peer review of the results of the qualification phase. The qualification protocol should have a section to capture this approval.

8.2.2 Installation Qualification

The function of Installation Qualification (IQ) is to verify that the medical equipment is installed according to the manufacturer’s recommendations. The IQ stage of Equipment Qualification presents an opportune time to perform static checks and to address legislative and regulatory requirements.

**Inputs**

The Inputs to Installation Qualification are Risk Assessment, Commissioning Reports and Supplier Characterisation as detailed in Section 8.2.1.

**Controls**

The Controls of Installation Qualification are Legislative Requirements, Regulatory Requirements and Training as detailed in Section 8.2.1.

**Mechanisms**

In addition to the protocol template as described in Section 8.2.1, Documentation Verification, Equipment Characterisation and Facility Characterisation support successful Installation Qualification.

**Documentation Review**

In documentation review the IQ seeks to verify that supporting documentation such as purchase orders, commissioning report, user requirement specifications, CE certificate, electrical diagrams, details of spare parts and instruction manuals have been received and are stored appropriately.
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*Equipment Characterisation*

Equipment Characterisation is an umbrella term to describe activities related to static checks including equipment visual inspection, safety, human factors and factors related to the external environment. Also within the scope of this term is verification that asset management practices have been completed and that maintenance and calibration schedules are in place where applicable.

Training of users, which was shown through the clinical engineering case study to be a key consideration when introducing new medical equipment for use, can be verified under Equipment Characterisation. As each individual type of medical equipment will have unique requirements and challenges, the training of users should be managed externally to the EQ process. Within the IQ protocol, verification of completion of training can be provided along with commentary on the nature of the training, recommendations for re-training and the storage location of training material and records.

To develop and execute equipment characterisation for each equipment specific IQ protocol, the author of the IQ must have knowledge and understanding of the medical equipment, best practice in the management of the equipment and its clinical application.

*Facility Characterisation*

Facility Characterisation is an umbrella term to describe activities related to inspecting the workplace to verify that safety requirements have been achieved and that required utilities for the equipment meet specification.

*Lean Verification*

In the literature review, the primary Lean (Table 5.7) tools were listed and described and a rating of the applicability of the tool for the Equipment Qualification of medical equipment in healthcare was given. This review categorised Standard Work, Total Productive Maintenance and 5S as the most
applicable tools for inclusion in the EQ framework. Standard Work, Total Productive Maintenance and 5S are a function of IQ activities.

To develop and execute facility characterisation tests for each equipment specific IQ protocol, the author of the IQ must have knowledge and understanding of the medical equipment and its clinical application, the utility requirements of the equipment and competency in the lean tools of 5S, standard work and Total Productive Maintenance.

Outputs
In addition to a Deviation / Incident Report and Qualification Phase Closure as described in Section 8.2.1, a Maintenance / Calibration schedule is an output of Installation Qualification.

Maintenance / Calibration Schedule
The healthcare case studies showed that the purchase agreement with the equipment supplier typically includes requirements for the supplier to perform maintenance and calibration of the equipment. This Equipment Qualification framework can leverage these current practices and verify that the schedules have been agreed with the equipment supplier. If any additional in-house maintenance or calibration is to be performed the IQ should verify that schedules are in place and that staff are trained and competent in maintenance and calibration activities.
8.2.3 Operational Qualification

Operational Qualification is the documentation of objective evidence showing that the equipment operates according to specifications. Operational qualification consists of primarily dynamic checks which challenge the equipment to demonstrate the robustness of the equipment, i.e. that the equipment can operate satisfactorily under ‘worst-case’ conditions.

Inputs
The Inputs to Operational Qualification are Risk Assessment, Commissioning reports and Supplier Characterisation as detailed in Section 8.2.1.

Controls
In addition to Legislative Requirements, Regulatory Requirements and Training as described in Section 8.2.1, Installation Qualification Closure is a critical control for Operational Qualification as the OQ should not commence until the IQ is completed.

Mechanisms
In addition to the protocol template as described in Section 8.2.1, Functional Challenge Test and Summative Usability Test support successful Operational Qualification.

Functional Challenge Test
A functional test is undertaken to confirm that the equipment fulfils its functional specification. A functional challenge test is a test in which the equipment functionality is challenged to demonstrate the robustness of the equipment, i.e. that the equipment can operate satisfactorily under ‘worst-case’ conditions. The functional challenge test should verify that each critical feature and function is working correctly in start-up, routine operating conditions, fault operating conditions and shutdown.
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To develop and execute the functional challenge test for each equipment specific IQ protocol, the author of the IQ must have knowledge and understanding of the medical equipment and its clinical application.

**Summative Usability Test**

It was found in the literature review that the techniques of summative usability tests most appropriately reflect the usability evaluation needs of healthcare. The ANSI/AAMI HE75 standard, which gives detail and guidance in conducting summative usability tests can be seen as the ‘go to’ reference guide for healthcare stakeholders. Guidance on developing the ANSI/AAMI HE75 usability test plan is presented in Section 5.6.1 of this thesis. The usability inspection method of cognitive walk-throughs most appropriately reflects the needs of healthcare in appraising new medical equipment, as the focus of cognitive walk-throughs is evaluating the user interface, with special attention to how well the interface supports “exploratory learning,” i.e. first-time use without formal training (Rieman et al., 1995).

To develop and execute the summative usability test for each equipment specific IQ protocol, the author of the IQ must have knowledge and understanding of summative usability testing, with particular competency in the cognitive walk-through technique.

**Outputs**

The outputs of Operational Qualification are Deviation / Incident Report and Qualification Phase Closure as detailed in Section 8.2.1.
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8.2.4 Performance Qualification

Performance Qualification is establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements.

**Inputs**

The Inputs to Operational Qualification are Risk Assessment, Commissioning reports and Supplier Characterisation as detailed in Section 8.2.1.

**Controls**

In addition to Legislative Requirements, Regulatory Requirements and Training as described in Section 8.2.1, Operational Qualification Closure is a critical control for Performance Qualification as the PQ should not commence until the OQ is completed.

**Mechanisms**

In addition to the protocol template as described in Section 8.2.1, Patient Simulation and Capability Analysis support successful Operational Qualification.

*Patient Simulation*

As found in the healthcare benchmarking case studies, patient simulation is an important aspect of the evaluation of medical equipment before use. It is the intention of the Equipment Qualification framework to leverage existing practices in patient simulation.

*Capability Analysis*

Capability Analysis was shown in Table 5.6 of the literature review as being a Six sigma tool which is of high applicability to Equipment Qualification in healthcare. Capability Analysis can be used together with patient simulation to assess the stability of critical equipment outputs.
To develop and execute patient simulation and capability analysis tests for each equipment specific PQ protocol, the author of the PQ must have knowledge and understanding of the medical equipment and its clinical application and competency in the Capability Analysis methods.

**Outputs**

The outputs of Operational Qualification are Deviation / Incident Report and Qualification Phase Closure as detailed in Section 8.2.1.

### 8.3 Equipment Qualification Template Protocols

An Equipment Qualification protocol is a document that describes the objective(s), methodology, actions, verifications, responsibilities, and acceptance criteria to be used to demonstrate fulfilment of specified requirements. A template protocol provides an outline of the structure and content of an IQ, OQ or PQ protocol which can then be modified for the purposes of each individual piece of equipment based on risk assessment and the unique challenges of the equipment. Table 8.1 lists each section of the protocol and the inclusion rationale for each. The templates for IQ, OQ and PQ are presented in Appendices VII, VIII and IX respectively.
### Table 8.1: Template Protocol Content

<table>
<thead>
<tr>
<th>Section</th>
<th>Applicable Protocol(s)</th>
<th>Inclusion Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>IQ, OQ &amp; PQ</td>
<td>State the purpose of the protocol</td>
</tr>
<tr>
<td>Scope</td>
<td>IQ, OQ &amp; PQ</td>
<td>State the scope of the protocol</td>
</tr>
<tr>
<td>System Description</td>
<td>IQ, OQ &amp; PQ</td>
<td>Describe the machine and other equipment, software or systems with which the equipment interacts</td>
</tr>
<tr>
<td>References</td>
<td>IQ, OQ &amp; PQ</td>
<td>List all documents which were referred to in developing the protocol</td>
</tr>
<tr>
<td>Responsibilities</td>
<td>IQ, OQ &amp; PQ</td>
<td>Identify the division of responsibilities for protocol requirements</td>
</tr>
<tr>
<td>Pre-requisites</td>
<td>IQ, OQ &amp; PQ</td>
<td>Verify that all activities that must be completed prior to protocol execution have been completed</td>
</tr>
<tr>
<td>Documentation Verification</td>
<td>IQ only</td>
<td>Verify that equipment documentation is available and record the storage location</td>
</tr>
<tr>
<td>System Acceptance Test – Equipment Characterisation</td>
<td>IQ only</td>
<td>As described in Section 8.2.2</td>
</tr>
<tr>
<td>System Acceptance Test – Facility Characterisation</td>
<td>IQ only</td>
<td>As described in Section 8.2.2</td>
</tr>
<tr>
<td>System Acceptance Test – Lean Verification</td>
<td>IQ only</td>
<td>As described in Section 8.2.2</td>
</tr>
<tr>
<td>System Acceptance Test – Functional Challenge Test</td>
<td>OQ only</td>
<td>As described in Section 8.2.3</td>
</tr>
<tr>
<td>System Acceptance Test – Summative Usability Test</td>
<td>OQ only</td>
<td>As described in Section 8.2.3</td>
</tr>
<tr>
<td>System Acceptance Test – Patient Simulation</td>
<td>PQ only</td>
<td>As described in Section 8.2.4</td>
</tr>
<tr>
<td>System Acceptance Test – Capability Analysis</td>
<td>PQ only</td>
<td>As described in Section 8.2.4</td>
</tr>
<tr>
<td>Deviation Report</td>
<td>IQ, OQ &amp; PQ</td>
<td>Discuss and justifies deviations to the protocol</td>
</tr>
<tr>
<td>Summary &amp; Closure</td>
<td>IQ, OQ &amp; PQ</td>
<td>Summarise protocol results and provide evidence of peer review</td>
</tr>
</tbody>
</table>