Total quality management (TQM) of clinical engineering in New Zealand public hospitals

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Southern Cross University

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Total Quality Management (TQM) of clinical engineering in New Zealand public hospitals

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Student Number 21156502

Thesis

Submitted to the School of Business and Tourism, Southern Cross University, Australia, in partial fulfilment of the requirement for the degree of Doctor of Business Administration

June 2015 Signature:
STATEMENT OF ORIGINAL AUTHORSHIP

I certify that this is my own work and the substance of this thesis has not been previously submitted for any degree and is not currently submitted to any degree.

I also certify that to the best of my knowledge, any help received in preparing this thesis and all sources used have been acknowledged in this thesis.

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I also wish to express my deep gratitude to my wife Sunita Varma, my sons Varun Varma and Vikas Varma and daughter-in-law Neelum Varma for their encouragement and for spurring me on through the several difficult phases of the study.

Finally, I dedicate this study to my mother Shiu Kauri and late father Ram Prasad, who have been there for me through the good and the bad times.
ABSTRACT

In the modern world, medical technology plays a very significant role in the healthcare delivery system. Biomedical engineers design and develop technologies for healthcare, usually in an academic or manufacturing setting. Biomedical engineers work mostly in large hospitals solving medical-device problems. Biomedical equipment engineers, technicians and technologists work primarily on the frontline in healthcare facilities. They inspect, repair, calibrate and performance verify medical devices and other complicated medical systems. Service quality and internal customer satisfaction are therefore important within the hospital environment. Furthermore, healthcare technology (clinical equipment) has been used as a proactive tactical and strategic resource, as a tool and as a change agent in the medical industry.

However, technology can malfunction, and the manner in which it is used can create technology-induced hostility amongst patients. Unsafe equipment can be dangerous for operators as well as to the patients, and can cause incorrect diagnoses, injuries and even death in patients.

If sophisticated biomedical equipment is to be used effectively, it requires a comprehensive management programme, as well as the expertise to ensure equipment is performing as per the manufacturer’s specifications. The emergence of this phenomenon prompted the current study of Total Quality Management (TQM) as it pertains to biomedical engineering in New Zealand public hospitals.

This research explores the ways in which TQM can benefit biomedical engineering departments in New Zealand public hospitals by providing a framework to manage medical technology and to improve service quality to internal customers and the clinicians who are using the equipment.

Following a review of the literature relating to TQM, service quality and customer satisfaction, research questions were developed. In this thesis, the analysis undertaken is qualitative and is based on case study methodology. Data were collected from biomedical engineering departments
of four New Zealand public hospitals. Data gathered from the case studies were subjected to a thematic analysis.

The findings indicate that biomedical engineering departments in New Zealand public hospitals have responsibility for managing biomedical technology. These departments are involved in all phases of biomedical equipment life cycles including planning, trialling, purchasing, acceptance testing, commissioning for patient use and decommissioning when obsolete. The outcomes of this study suggest that biomedical engineering is a vital link in patient treatment within the healthcare industry. This study also reveals that biomedical engineering tasks are carried out by frontline engineers, technicians and technologists inspecting and repairing medical devices.

This study provides valuable information on the management of biomedical equipment, service quality and internal customer satisfaction, and recommends the two most effective models for managing biomedical equipment in public hospitals.
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<td>51</td>
</tr>
<tr>
<td>ICT</td>
<td>Information and communication technologies</td>
<td>64</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electro-technical Commission</td>
<td>65</td>
</tr>
<tr>
<td>TIS</td>
<td>Thai industrial Standards</td>
<td>65</td>
</tr>
<tr>
<td>BSI</td>
<td>British Standards Institution</td>
<td>65</td>
</tr>
<tr>
<td>SABS</td>
<td>South African Bureau of Standards</td>
<td>65</td>
</tr>
<tr>
<td>CSA</td>
<td>Canadian General Standards Board</td>
<td>65</td>
</tr>
<tr>
<td>ICU</td>
<td>Intensive care unit</td>
<td>65</td>
</tr>
<tr>
<td>SNZ</td>
<td>Standards New Zealand</td>
<td>65</td>
</tr>
<tr>
<td>SCM</td>
<td>Supply chain management</td>
<td>68</td>
</tr>
<tr>
<td>EAM</td>
<td>Enterprise Asset Management</td>
<td>156</td>
</tr>
<tr>
<td>BIMS</td>
<td>Business Information Management System</td>
<td>140</td>
</tr>
<tr>
<td>ISOQA</td>
<td>ISO quality assurance</td>
<td>162</td>
</tr>
<tr>
<td>BPM</td>
<td>Business process management</td>
<td>165</td>
</tr>
</tbody>
</table>
CHAPTER 1: INTRODUCTION

Structure of the chapter

The aim of this chapter is to orientate the reader by setting the scene and providing an overview of the thesis. The structure of the chapter is illustrated in Figure 1.1 below.

Figure 1.1: Structure of the chapter

Source: Developed by the researcher for this research.
1.1 Background of the research

Technology has revolutionised the management of healthcare organisations by changing the way in which people work and interact. Healthcare today is characterised by more to know, more to manage, more to watch, and more to do, and more people are involved in doing it than in the past. With ever evolving technology, even the simplest operative and invasive procedure involves the use of specialised medical equipment. In the last few decades, investments in biomedical research have increased steadily, resulting in an extraordinary expansion of medical knowledge and technology (Blumenthal, 1994; Morales & Blumenthal, 2004).

Given that the organisation and delivery of patient care is more complex than ever before and that healthcare organisations have become increasingly technology-driven, sustainable reliability in the biomedical engineering sector of healthcare is essential. There is no doubt in anyone’s mind that technological developments impact significantly on medical care, surgical techniques, equipment and health services (Kunst & Lemmink, 2000).

However, technology can malfunction, and the manner in which it is used can create technology-induced hostility in patients. Unsafe equipment can be dangerous to operators as well as to patients, with the potential to cause incorrect diagnoses, injuries and even death (Varma & El-Kafafi, 2011). In the present climate, with emphasis on patient safety and quality outcomes, the issue for biomedical engineering departments is ensuring that any equipment used in the hospital is safe and is in proper working order. Therefore, biomedical engineering departments play a significant role in the healthcare industry.

1.1.1 The role of the biomedical engineering services in healthcare

The role of biomedical engineering is to meet challenges by providing safe and effective management of technology used for patient diagnosis, therapy and monitoring within healthcare institutions (Bronzino, 1992). This implies involvement in all phases of the biomedical equipment lifecycle including equipment selection, acceptance testing, training in safe and effective use, equipment safety, maintenance and final disposal or replacement.

Biomedical engineers are responsible for explaining new technologies and their impact on operating costs, as well as for translating technological ideas, problems and concepts into a non-
technical language so that a wide range of people (i.e., outside the biomedical field) can understand those concepts with ease.

Moreover, biomedical engineers and technicians are uniquely qualified to understand the many subtleties of medical devices and the various levels of equipment alarm operations related to clinical parameters. Engineers and technicians tend to have a very good understanding of the inner workings of medical devices, and are good at picking out situations where clinical staff may run into difficulties when using a certain type of device or feature (Keller, 2006).

Trip and Drea (2002) suggested that if clinicians are satisfied with the quality of service provided by the biomedical engineering department and have a good working relationship with members of the biomedical team; this will increase the biomedical engineering department’s profile within the hospital. It is essential that service providers (biomedical engineering departments in New Zealand public hospitals) are aware of their internal customers’ (clinical staff) perceptions of the service quality provided, as those perceptions are linked to achieving customer satisfaction. Measuring and assessing service quality should be an essential consideration for any service provider (Cunningham, Young & Lee, 2000). According to the very nature of the healthcare business, services are not ‘products’ that can be easily accessed through the sense of touch (Cunningham et al., 2000). It is important to understand how medical technology is currently managed in New Zealand public hospitals to maintain quality and customer satisfaction. This phenomenon prompted the current study of Total Quality Management (TQM) as it pertains to biomedical engineering in New Zealand public hospitals.

1.2 Objective of the research

The aim of this research is to study biomedical engineering departments in New Zealand public hospitals and to explore how TQM can enable these departments to manage biomedical technology and improve service quality and customer satisfaction. This study also investigates which service and customer satisfaction models are the most suitable and effective for managing biomedical technology in New Zealand public hospitals.

1.3 Research questions

This thesis was designed primarily to explore how TQM can benefit biomedical engineering departments in New Zealand public hospitals by managing medical technology and
by improving service quality and customer satisfaction. To address research objectives, the following research questions were developed. The central question is underpinned by three specific sub-research questions, as outlined below.

_How can TQM benefit biomedical engineering departments in New Zealand public hospitals in managing medical technology and in improving service quality and customer satisfaction?_

**Sub-research questions**

(1) _What are the current systems used in New Zealand public hospitals for managing medical technology?_

(2) _How are service quality and customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?_

(3) _Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals?_

1.4 **Importance of the research**

This research is important for the following reasons:

(i) Limited academic research exists in the field of biomedical technology management, and this is emphasised by the fact that most previous research has been based on clinical data. The researcher was unable to find any previous academic research related to quality management systems (QMSs) of biomedical engineering departments in New Zealand public hospitals. This will be the first empirical study to explore the current biomedical technology management systems used in New Zealand public hospitals.

(ii) Locally and internationally, TQM has been studied in various sectors. However, there is not much research on government-owned New Zealand public hospitals, especially in the technology management area. The researcher found no research on internal customer satisfaction and the quality of service provided by biomedical engineering departments in New Zealand public hospitals.
(iii) This research documents the way biomedical engineering equipment is currently managed and the role of biomedical engineering departments in New Zealand public hospitals. It explores how TQM can benefit biomedical engineering departments in managing medical technology and in improving service quality and customer satisfaction.

1.5 Methodology

Because this research is exploratory rather than confirmatory, a qualitative research approach using New Zealand public hospitals as case studies has been employed. This qualitative approach has been selected for two reasons. First, given the case study focus, the nature of the data is verbal, and the research problem is focused on the questions “how”, and “what”. Therefore, a qualitative method is appropriate (Yin, 1994). In particular, there is fairly wide consensus that qualitative research is a naturalistic, interpretative approach concerned with understanding the meanings that people attach to phenomena such as actions, decisions, beliefs and values (Snape & Spencer, 2003). The primary advantage of case study research is that an entire organisation or entity can be investigated in depth with meticulous attention to details (Zikmund, 2003).

Second, a qualitative approach allows the researcher to get close to the object of enquiry, and in this particular study, to gain an in-depth understanding of the numerous underlying factors associated with the business strategies used by biomedical engineering departments in New Zealand public hospitals. A qualitative approach can obtain real, rich and deep information that is considered important, relevant and significant (Yin, 1994).

A case study approach is preferred for the following reasons:

(i) Gummesson (2000) suggests that case study research methodology has particular value in the applied sciences in which the aim is to study the problem in depth, place it in context and understand the stages in the process. The aim of this study is to explore the benefits of TQM for biomedical engineering departments in New Zealand public hospitals in managing medical technology and in improving service quality and customer satisfaction; because this is an in-depth study describing the real world, case study methodology is appropriate.
(ii) The researcher is able to examine “what”, “how” and “why” questions related to contemporary issue, without totally controlling the research setting.

(iii) This study is conducted in public hospitals across New Zealand. It examines the constraints of daily practices, as well as biomedical engineers’ and technicians’ perceptions of TQM, service quality and customer satisfaction. The information collected is descriptive in nature. Therefore, case study methodology is appropriate for this research.

(iv) This research also focuses on observations, meaningful characterisations, interpretations and other expressive descriptions, for which the use of case studies is appropriate.

(v) Case studies do not require significant control over behaviour and access to actual behavioural events (Yin, 1994).

Using a case study approach within a broad qualitative framework, data in this research were collected in a series of face-to-face interviews, through observation and document reviews. Data collected from face-to-face interviews were analysed thematically, and the findings were drawn from the sub-research questions. To maintain credibility and validity, data collected from face-to-face interviews were triangulated against findings from document reviews and observations (Neuman, 2003).

1.6 Outline of the thesis

This thesis follows the standard five-chapter format developed by Perry (1998). The format is illustrated in Figure 1.2.
Figure 1.2: Outline of the thesis

- Introduction
- Literature review
- Methodology
- Analysis and discussion
- Findings and implications

Source: Developed by the researcher for this research.

A brief summary of the contents of each chapter is presented below.

Chapter 1
As previously discussed, the initial chapter sets the scene for this study. It introduces research objectives, including research questions and justification. It then discusses the methodology utilised to explore the research objective and introduces supporting sub-research questions. It finishes with definitions for key terms used in this study and limitations with regard to the study’s scope.

Chapter 2
Chapter 2 presents the literature review and develops the framework of the research underpinning data collection and data analysis. This chapter also reviews the existing academic literature in three sections. The first section considers the theoretical aspects of TQM. It highlights TQM philosophy, the views of quality experts, styles of leadership, QMSs and some
elements of TQM and the International Organisation for Standardisation (ISO) 9000 series of standards, which are based on the TQM system.

The second section of Chapter 2 reviews literature on quality in healthcare, with the main focus on biomedical engineering and dimensions of quality, tools for measuring quality, quality assurance (QA) in a healthcare context and the role of biomedical engineering departments in the healthcare industry.

The third section refers to the key elements of service quality, customer satisfaction and various models of service quality and customer satisfaction in reference to biomedical technology management in New Zealand public hospitals.

The chapter concludes with a discussion of the research gaps relating to service quality and customer satisfaction, specifically in the biomedical engineering departments of New Zealand public hospitals.

**Chapter 3**

This chapter establishes research methodology. It explains and justifies the use of case study methodology for collecting and analysing data. The chapter also identifies criteria used for selecting cases (hospitals). It discusses data collection strategies, strengths, limitations, validity, reliability and ethical considerations of the case study method.

**Chapter 4**

Chapter 4 discusses the background of participants and profiles of the hospitals used as case studies in this research. It describes the actual data collection techniques used and the approach to data analysis to address the research objectives and sub-research questions. Individual case study interviews are contextually analysed to answer each sub-research question. Cross-case analysis is undertaken to compare and explore similarities and differences in themes, patterns, involvement of biomedical staff and their roles in New Zealand public hospitals. The findings are reported using the participants’ own words where possible. This chapter concludes with a summary of the overall findings from multiple sources.
Chapter 5

Chapter 5 discusses the results of the data analysis and compares these findings with theories discussed in the literature review (Chapter 2). It presents the conclusions for each sub-research question. Particular reference is made to the contribution of this research to the understanding of the research objective. Chapter 5 also discusses the implications of theory and practices, and study limitations. It concludes by recommending the two most effective models for biomedical engineering departments in New Zealand public hospitals for managing biomedical technology.

1.7 Relationship between thesis chapters

Figure 1.2 in the previous section (Section 1.6) illustrates the relationship between the chapters and their component parts. Figure 1.3 (below) demonstrates the conceptual linkage between chapters.

Figure 1.3: Relationship between the thesis chapters

Source: Developed by the researcher for this research.
1.8 Limitations of the research

This research has some limitations for the following reasons.

(i) The geographic scope is limited to New Zealand.
(ii) This research is focused primarily on biomedical engineering departments and their service to internal customers in public hospitals in New Zealand, and does not include private hospitals.
(iii) This research examines service quality and customer satisfaction from the management perspective only.
(iv) Only responses from biomedical engineering staff are considered in the analysis. Clinicians (internal customers) did not take part in this research.

1.9 Definitions of major terms

The definitions of the major terms used in this thesis are presented below:

Service quality: Service quality is defined as the ability of a company to meet or exceed the customer’s expectations (Parasuraman, Zeithaml & Berry, 1988).

Quality assurance (QA): Quality assurance is an effort to change or improve the level of service based upon measures of quality (Goetsch & Davis, 2006).

Customer satisfaction (in the context of biomedical engineering services): The degree to which customer expectations of a product or service are met or exceeded (Farris, Bendle, Pfeifer & Reibstein, 2010). Note: a detailed discussion of the concept is provided in Chapter 2.

Methodology: The approach used to organise the entire process of a research study (Hussey & Hussey, 1997).

Thematic analysis: An approach to dealing with data that involves the creation and application of ‘codes’ to data (Flick & Kardorff, 2004).

Content analysis: A research technique for the objective, systematic, and quantitative description of the manifest content of communication that systematically converts text to
numeric variables for subsequent quantitative analysis (Hussey & Hussey, 1997; Zikmund, 2000).

**Data**: Raw, unanalysed facts that are measures or attributes of phenomena, which are out of context and have no relation to other facts (Loshin, 2001; Zikmund, 2000).

**Reliability**: A demonstration that the operations of a study can be repeated with the same results (Yin, 2003a, p. 34).

**Validity**: The ability of a scale or measuring instrument to measure what is intended to be measured (Zikmund, 2000, p. 281).

**Electrical safety**: Recognising hazards associated with the use of electrical energy and taking precautions so that hazards do not cause injury or death (Cadick, Capelli-Schellpfeffer & Neitzel, 2006).

**Electrocardiogram (ECG)**: An electrical recording of the heart that is used in the investigation of heart disease (Klabunde, 2005).

**Medical device**: Products used for medical purposes in diagnosis, therapy or surgery (McGraw-Hill, 2002).

**Theory**: A set of interrelated variables, definitions and propositions that presents a systematic view of phenomena by specifying relationships between variables with the purpose of explaining natural phenomena (Hussey & Hussey, 1997).
Epilogue

This chapter has provided an overview of the thesis. The chapter began with an introduction and explained the background to this research, followed by a brief overview of research objectives and questions. It then justified the choice of methodology. This was followed by a thesis outline, synopsis of chapter contents, and a discussion of structure and description of the relationship between the five chapters. Finally, the limitations of this research were discussed and definitions of major terms used were provided. The next chapter will review the literature on TQM.
CHAPTER 2: LITERATURE REVIEW

Prologue

The purpose of this chapter is to undertake a literature review focusing on TQM as a model for biomedical technology management and to explore the key issues involved in achieving service quality and internal customer satisfaction in New Zealand public hospitals. Based on the proposed research questions, a concept map for the literature review is illustrated in Figure 2.1 on the following page.

This literature review is presented in three sections. The first section is a review of theoretical concepts underpinning TQM. The second section is a review exploring literature on service quality in healthcare, with the main focus on biomedical engineering, followed by a third section in which the interaction between different aspects of service quality and customer satisfaction are delineated.

Each major theme is reviewed in the biomedical technology management and healthcare context of New Zealand public hospitals, so that the focus remains on the research questions mentioned earlier. The literature review is summarised, and knowledge gaps identified are listed in Section 2.4. The identified gaps in the literature provide the foundation for reconfirming the research questions.
Figure 2.1: Concept map

Source: Developed by the researcher for this research.
The basic thrust of this research is to determine how TQM can benefit biomedical engineering departments in New Zealand public hospitals by providing tools to better manage medical technology, and to improve service quality and internal customer satisfaction.

Thus, understanding the parameters of TQM, service quality and customer satisfaction is essential for this research. The following section introduces the theory and literature defining TQM parameters.

2.1 Total Quality Management (TQM)

This section reviews aspects of the theoretical literature on TQM. In this section, the researcher explores the philosophy behind TQM, the views of quality specialists, styles of leadership in the context of TQM and the elements of customer satisfaction.

2.1.1 Overview and quality specialists

In the modern world, TQM has become a part of corporate management on a global scale (Lakle & Mohanty, 1994; Melan, 1998). Quality is studied under the overall umbrella of TQM. The core philosophy of TQM as it is understood today is that each step in a production or service encompasses the entire organisation from the supplier to the customer, both internal and external to the organisation. Suppliers have to meet customer requirements, both stated and implied, at the lowest cost. Moreover, waste elimination and continuous improvement are ongoing activities (Heizer & Render, 2004).

By adopting a TQM philosophy, managers commit to a continuous company-wide drive towards excellence in all aspects of products and services that are important to the customer (Heizer & Render, 2004). According to James (1996), TQM is essentially about the development of an ideology or philosophy focused on actions designed to satisfy customers completely through continuous improvement. James (1996) identifies the principal objectives for an organisation as customer support, customer service and customer satisfaction. Heizer and Render (2004) suggest that when TQM is working well, it allows organisations to empower members to make appropriate and reasonable decisions at their level to improve processes or products. It also builds commitment and a sense of belonging. This allows opportunities for upward and downward communication and a free exchange of ideas.
The early development of TQM was influenced by a number of quality ‘gurus’, or specialists, such as W. Edwards Deming, Joseph M. Juran, Philip B. Crosby, Armand Feigenbaum and Kaoru Ishikawa. These ‘gurus’ are the major contributors in the quality discipline. They have similar views on customer satisfaction, leadership, cost reduction, management processes, training and education, teamwork and work culture. This research discusses all of these elements from the perspective of a range of quality management specialists.

The following section presents the major literary contributions towards quality management theory.

(1) **W. Edwards Deming**

Deming (1982) is the internationally renowned consultant who worked on Walter Shewhart’s original version of the Shewhart Cycle, known as PDCA (Plan-Do-Check-Act). Shewhart’s PDCA cycle draws its structure from the notion that constant evolution of management practices as well as the willingness of management to adopt supported ideas but disregard unsupported ideas, is the key to the evolution of a successful enterprise (Shewhart, 1939).

Deming also warned his audience that the PDCA version is not accurate, because during translation, he found that the Japanese language did not have a word for “trial”. Therefore, they used the word “do”. He suggested that the PDCA version should be replaced with a Plan-Trial-Check-Act (PTCA) version in which “T” refers to “trial” (Gitlow & Haward, 1989).

Deming’s (1986) work influenced Japanese industrialists to adopt new principles of management, and revolutionised their service quality and production. Deming stressed that by improving quality, it is possible to increase productivity, which results in the improved competitiveness of a business enterprise. Deming suggested that improvement of quality transfers waste of man hours and of machine time into the manufacture of good products and better service. Higher quality can mean better satisfied customers, increased market share, improved customer retention, more loyal customers and even premium prices (Gaither & Frazier, 1999). Deming’s approach can be summarised in his 14-point programme (Deming, 1986). The programme is summarised in the list below.

(i) Create constancy of purpose for improvement of products and services.
(ii) Refuse to allow commonly accepted levels of delay or mistakes, defective material or defective workmanship.

(iii) Cease dependence on mass inspections to achieve quality.

(iv) Reduce the number of suppliers. Buy on statistical evidence, not price.

(v) Constantly and forever improve the systems of cost, quality, productivity and service.

(vi) Institute modern methods of training on the job.

(vii) Focus supervision on helping people to do a better job.

(viii) Drive out fear.

(ix) Break down barriers between departments. Encourage problem solving through teamwork.

(x) Eliminate numerical goals, slogans and posters for the workforce.

(xi) Use statistical methods for continuing improvement of quality and productivity and eliminate work standards prescribing numerical quotas.

(xii) Remove barriers to pride of workshop.

(xiii) Institute a vigorous programme of education and training.

(xiv) Clearly define management’s permanent commitment to quality and productivity.

Deming (1986) offered these 14 key principles to managers for transforming business effectiveness. He suggested that these points must be implemented in their entirety in order to be effective. To skip one point would inhibit the effectiveness of the other 13 points.

From these initial concepts, Deming later developed what he referred to as the “system of profound knowledge” (Bauer, Reiner & Schamschale, 2000, p. 412). This means appreciation of a system, knowledge about variation, theory of knowledge and psychology. Deming stated that top managers could improve company systems and structures only if they understood the company as a complex system (Bauer et al., 2000, p. 412).

In 1986, Deming made a major contribution towards the handling of management crises in his well-known book *Out of Crisis*. This book is regarded as a classic of literature on quality management. It reflects Deming’s experience in introducing quality management to Japan, and the goal was to transform the style of American leadership in the same way. His book sets out the methods that taught industry the power of quality.
In 1988, Deming broadened the use of the PDCA cycle to apply to all situations at all levels, with an emphasis on learning and improvement, and called it Plan-Do-Study-Act (PDSA) (Beckford, 1998). This model has been in use for 60 years now, and is still commonly known as PDCA/PDSA; it is clearly relevant in today’s healthcare industry, providing a defined and well tested process to achieve lasting improvement to the problems and challenges the healthcare industry is now facing (Berwick, 2003). One of the unique features of this model is the cyclical nature of impacting and assessing change, most effectively accomplished through small and frequent PDSAs rather than big and slow ones (Berwick, 2003; Bialek, Duffy & Moran, 2009).

The PDCA/PDSA cycle is illustrated in Figure 2.2. This cycle is iterative; when one action is systematically completed, it recommences without ceasing. Today, the Deming wheel is used at all levels in some TQM organisations (Tague, 2004).

Figure 2.2: Deming’s PDCA wheel

Source: Adapted from Tague (2004, p. 390).
Figure 2.2 above shows Deming's PDCA cycle. The PDCA cycle is commonly used to coordinate continuous improvement efforts. It emphasises and demonstrates that improvement programmes must start with careful planning and must result in effective action before moving on again to more careful planning, in a continuous cycle.

For successful implementation of PDCA, the following steps are suggested:

**Step 1: Plan an improvement**

The goal at this stage is to decide what needs to be done and how best it can be done. Achievement of this goal occurs through reviewing and studying current work processes and available data. This stage involves examining currently failing methods or problem areas.

**Step 2: Do the planned activity**

Stage 2 involves implementing the improvement or problem-solving plan by actually doing it. This implementation stage occurs when the plan is actually tried in the operational context. The people responsible need to be trained and equipped with the resources necessary to complete the task. This stage itself may involve a mini PDCA cycle as the problems of implementation are discovered and resolved. At this point, problems begin to arise if implementation of the plan is not providing the desired results.

**Step 3: Check the results**

The newly implemented solution is evaluated to see whether it has resulted in the expected performance improvement in Stage 3. Analysing the new data and measuring the results reveals whether the implementation of the plan is yielding the results that it should.

**Step 4: Act on the results**

If implementation is successful, Stage 4 involves putting controls in place so that the issue never returns. If the change is not successful, this stage allows adjustment where necessary to overcome problems, and formalises the new body of knowledge before starting the PDCA cycle over again. In starting over again, operators may take any corrective action that is required, lock
in the positive outcomes and return to the planning stage, and repeat as necessary (Tague, 2004, pp. 390-392).

(2) Joseph M. Juran

Juran’s major contribution to the quality world has been in the field of management, particularly quality management. His approach involves more process-oriented ideas with a managerial flavour (Kruger, 2001). Juran presented the view that quality consists of those product features that meet the needs of customers and thereby provide product satisfaction, and that quality consists of freedom from deficiencies (Juran, 1988).

According to Juran (1988), to demonstrate commitment to quality, management should establish a quality council to coordinate the company’s various activities. Further, management should establish quantitative quality goals and should have a time frame for achievement of those goals. Once the time frame and specific goals are established, it is management’s responsibility to provide the resources. As part of his contribution towards quality theory, Juran also developed the improvement spiral showing that quality improvement is a continuous process and not just a start and end point (Bauer et al., 2000). In addition, Juran pioneered the concept of internal customer/supplier relationships. He envisaged that the people who work in an organisation are providing products or services to one another. This can be applied to the information flow in an office setting or to production on the shop floor, where different workers are involved at different phases of a manufacturing process. They are dependent on one another to do a good job (Beckford, 1998). Juran described this interdependence as an internal customer relationship (Juran, 1993).

(3) Philip B. Crosby

Crosby’s view of product or service quality stresses that all measured characteristics of the product or service must satisfy the characteristic’s specification criteria (Crosby, 1979). He identified “customer requirements” as the goal to which one aspires in pursuit of quality (Crosby, 1981). He proposed a quality management grid that describes the stages of TQM implementation relative to managements’ understanding of problem-solving techniques, the organisational approach and results achieved. Crosby’s opinion was that his TQM matrix represents a mature
implementation of the TQM philosophy (Crosby, 1981). Crosby’s philosophy is seen by many, for example Gilbert (1992), to be encapsulated in his five absolutes of quality management.

(i) Quality is defined as conformity to requirements, not as “goodness” or “elegance”.
(ii) There is no such thing as a quality problem.
(iii) It is always cheaper to do it right first time.
(iv) The only performance measurement is the cost of quality.
(v) The only performance standard is zero defects.

(4) **Kaoru Ishikawa**

Ishikawa took the view that for TQM to be successful, the tools and techniques of using data to make decisions must be understood by the workers, frontline supervisors and managers. Ishikawa’s view on TQM can be summarised as follows:

(i) Quality is equivalent to consumer satisfaction.
(ii) Quality must be defined comprehensively. It is not enough to say a product is of high quality. We must focus attention on the quality of every facet of the organisation.
(iii) The price of the product or service is an important part of its quality. Ishikawa argues that no matter how high the quality is, if the product is overpriced it cannot gain customer satisfaction (Ishikawa, 1985).

(5) **Armand Feigenbaum**

Armand Feigenbaum can be considered the originator of the concept of “total quality control” in which quality improvement is taken from its traditional place on the shop floor to spread its influence throughout the organisation (Garvin, 1993). He contributed two main ideas, namely:

(i) Quality is the responsibility of everyone in the organisation. Quality is not only produced by the production department but also marketing, finance, maintenance, purchasing and other support services of the organisation (Kruger, 2001).
(ii) The cost of non-quality, which is the cost of control and cost of failure to control, can be minimised. Cost of control should be measured by prevention of cost. This can be achieved by providing quality staff training, and by developing quality and procedure manuals. This should keep mistakes to a minimum (Kruger, 2001). Feigenbaum’s (1991) emphasis is on organisations designing their own quality systems that involve every employee, rather than creating only managerial awareness about quality in the organisation.

### 2.1.2 TQM elements for customer satisfaction and cost reduction

The basic principle of the TQM philosophy for doing any business is to satisfy the customer and the supplier, and to continuously improve business processes (Reed, Lemak & Mero, 2000). Researchers Kruger (2001), Virmani (2002), Scott (2005) and Frederick (2010) reported five key elements of TQM that can be transferred to any business setting. These elements are customer satisfaction, cost reduction, leadership and management, training and education and organisational culture.

Furthermore, although the philosophy of each of the quality experts (gurus) discussed previously is different, the work of these experts within the field of TQM has been influential in many ways, and there are similarities between them as well as differences. A comparison of the commonalities between the quality gurus’ philosophies is illustrated in Table 2.1 below.
Table 2.1: Commonalities amongst seminal TQM views

<table>
<thead>
<tr>
<th>Subject</th>
<th>Views of the quality gurus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer satisfaction</td>
<td>The customer defines quality; consumers are the most important part of the production.</td>
</tr>
<tr>
<td>Cost reduction</td>
<td>Doing it right first time means less waste, less rework and lower cost.</td>
</tr>
<tr>
<td>Leadership and top management commitment</td>
<td>Management’s job is leadership (to demonstrate constancy of purpose in their focus on quality).</td>
</tr>
<tr>
<td>Training and education</td>
<td>Vigorous, continuous programmes for training employees in new knowledge and techniques are</td>
</tr>
</tbody>
</table>
Teamwork | Cross-functional teams can create improvement in products, service and quality, and can reduce costs. | Major quality improvement projects are multi-functional in nature, thus requiring multifunctional teams. | Use management teams for internal communication, and quality councils for internal/external communication. | Quality control committees should have representatives from all functional areas. | Major quality improvement projects are multifunctional in nature, thus requiring multifunctional teams. |

Organisational culture | A new philosophy is required: drive out fear of quotas, fear of questioning accepted methods, etc., and still pride in quality. | Changing to a companywide quality system means changing existing cultural patterns; there may well be cultural resistance. | Quality commitment is a genuine belief by employees in the importance of good quality, workmanship, good design and service. | Quality control is a spirit of quality from CEO to the shop; it is a communication channel and means of participation. | Changing to a company-wide quality system means changing existing cultural patterns.

*Source:* Adapted from Reed, Lemak and Mero (2000, p. 8).
An evaluation of the concepts held in common by experts of TQM reveals that customer satisfaction and reducing costs are two achievable elements. Further, it can be said that these elements are achievable via the following six processes:

1. leadership,
2. training and education,
3. teamwork,
4. changing organisational culture,
5. employee empowerment, and
6. implementing QMSs.

In the context of biomedical engineering, the six TQM elements are important in order to achieve service quality, customer satisfaction and cost reductions. The elements listed above are discussed in the context of biomedical engineering in the following sections.

(1) **Leadership**

Research on TQM has consistently found a strong link between successful TQM implementation and leadership (Deming, 1982; Ehrenberg & Stupak, 1994; Zairi, 2002); in general, these authors have argued that top management’s ability to create a vision and to promote change to improve service quality are at the heart of successful TQM implementation. The researcher’s view is that in the specific context of New Zealand healthcare, leaders must understand the elements that can and cannot be changed because of the nature of service. They must create an environment in which they can empower employees to act independently and interdependently. Previous research suggests that worker empowerment is an important element of TQM for keeping employees satisfied and proactive (Gaines, 1994). Gaines (1994) also suggested that a key component in achieving organisational transformation involves enabling employees to become comfortable with change. This comfort level may be the most important outcome of having employees take charge of their own personal growth and satisfaction.
In the context of biomedical engineering departments, leadership is an important element in delivering quality service. Two styles of leadership, transformational and transactional, are discussed below.

(i) **Transformational leadership**

A transformational style of leadership has traditionally been defined as the display of charisma, intellectual stimulation and individualised consideration (Avolio, Bass & Jung, 1999; Northouse, 2001). Further, a transformational leader provides a sense of mission and is able to articulate an inspirational vision (El-Kafafi, 2012) through which such a leader develops pride and self-esteem to attain a favourable organisational image. The charisma dimension is associated with a leader who instils faith and respect in subordinates and who provides a sense of mission to a team through excellent communication skills. The intellectual stimulation dimension characterises a leader who promotes intelligence, rationality and careful problem solving, and who encourages subordinates to pursue innovative solutions to problems. A transformational leader also gives personal attention to subordinates, has empathy, and trusts, respects and treats each employee as an individual, and takes an interest in the long-term development of each employee. According to Nemanich and Keller (2007) and Kirkbridge (2006), transformational leaders place followers’ needs before their own, inspiring followers to achieve a higher level of awareness, and enabling the organisation to achieve greater vision. The higher level of awareness encourages followers to address old problems in new ways, promoting increased learning and higher quality. Avolio et al. (1999) argued that transformational leaders convince followers to strive for higher expectations, which allows for greater quality achievements. A summary of transformational leadership characteristics is provided in Table 2.2 below.
Table 2.2: Summary of transformational leadership style

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Characteristics explained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idealised influence</td>
<td>• The leader displays behaviour associated with organisational goals. The leader’s influence is measured by employee engagement in the organisation and a willingness to emulate the general behaviour expressed by the leadership as a whole.</td>
</tr>
<tr>
<td>Inspirational motivation</td>
<td>• The leader provides an environment that represents energy and perseverance, and recognises exceptional followers who are willing to go beyond average followers in order to accomplish organisational goals.</td>
</tr>
<tr>
<td>Intellectual stimulation</td>
<td>• The leader provides an environment that encourages followers to challenge the status quo in the quest to continually improve the overall organisation. Leaders and followers openly exchange high expectations, creating a vision that demands higher standards.</td>
</tr>
<tr>
<td>Individualised consideration</td>
<td>• The leader recognises that each follower is an individual with individual needs to be developed within the organisation. Followers are provided with the opportunity for personal attention and learning opportunities to develop higher levels of potential.</td>
</tr>
<tr>
<td>Communication</td>
<td>• The leader provides a sense of mission to a team through excellent communication skills.</td>
</tr>
</tbody>
</table>

*Source*: Adapted from Avolio et al. (1999, p. 7).

(ii) **Transactional leadership**

The transactional style of leadership is based on an exchange process whereby followers are rewarded for accomplishing specified goals, rendering certain services or achieving a certain level of performance (Jung & Sosik, 2002). According to Bass, Avolio and Goodheim (1987), transactional leadership can be conceptualised using a two-factor model, either passive or active. Passive transactional leadership, or management by exception (MBE), allows the status quo to exist as long as the old ways are working. If things go wrong, however, a leader practising passive MBE will take actions that often have negative connotations. For example, “if this mistake happens again, I will have to write you up” is a common theme in passive MBE.

In contrast, active transactional leadership involves an interaction between leader and follower that emphasises a more proactive, positive exchange; for example, providing appropriate rewards when followers meet agreed-upon objectives. The emphasis with active transactional leadership is on rewarding followers for achieving expected performance (Boerner,
Eisenbeiss & Griesser, 2007). Such leadership includes the acquisition of information to determine what the current needs of subordinates are, as well as helping them to address the task and role requirements that result in desired outcomes. This form of leadership also motivates followers to work for transcendental goals and arouses higher-level needs for self-actualisation rather than immediate self-interest. The active transactional leadership style provides high satisfaction and organisational identification (Wu, 2009; Epitropaki & Martin, 2005). A summary of transactional leadership characteristics is provided in Table 2.3.

Table 2.3: Summary of transactional leadership style

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Characteristics explained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contingent reward</td>
<td>• The interaction of the leader and follower focuses on the exchange of what is expected and what is desired. Exchanges include acknowledgement of completed tasks and additional responsibilities within the organisation. Exchanges are generally positive, but may be negative in the form of punishment.</td>
</tr>
<tr>
<td>Management by exception (MBE): passive transactions.</td>
<td>• The leader monitors activities for irregularities and failures that have occurred or may occur. Attention is placed on discovery of mistakes.</td>
</tr>
<tr>
<td>Staff satisfaction</td>
<td>• The leader allows the status quo to continue without addressing weakness within the organisation. Reinforcement, when used, is in the form of criticism and negative feedback.</td>
</tr>
<tr>
<td>Motivation</td>
<td>• The leaders tend to have higher agreement on the strategic goals of the organisation. Leaders voluntarily help their employees and prevent the occurrence of work-related problems which ultimately enhances job satisfaction amongst employees.</td>
</tr>
<tr>
<td>Source: Adapted from Avolio et al. (1999).</td>
<td></td>
</tr>
</tbody>
</table>

In summary, transformational leaders encourage followers to perform at maximum levels. They achieve maximum performance because of their ability to inspire followers, to raise their followers’ criteria for success, and to have followers think ‘outside the box’ and explore alternative methods for solving problems (Bass, 1985). By linking individual needs to what the leader expects to accomplish, as well as to rewards desired by followers, the motivational levels of followers can be enhanced. In the context of quality, transformational leadership is considered
to be most effective in achieving the high performance demanded by high levels of quality (Bass, 1985). Transformational leaders attempt to and succeed in raising colleagues, subordinates, followers, clients or constituencies to a greater awareness of the issues of consequence (Madzor, 2005). This heightening of awareness requires a leader with a vision, self-confidence, and inner strength to argue successfully for what he/she sees is right or good, not for what is popular or is acceptable according to the established wisdom of the time. The transformational leadership paradigm focuses more on what the leader accomplishes, rather than his or her personal characteristics. In turbulent environments, transformational leaders are likely to be more effective because they seek new ways of working, seek opportunities in the face of risk, prefer effective answers to efficient answers and are less likely to support the status quo (Lowe, Kroeck & Siva-Subramaniam, 1995). They may therefore react effectively to changes in the external environment or may anticipate such changes and provide a vision for customer satisfaction.

A number of studies suggest that transformational leadership has a profound, positive influence on subordinates’ efforts and satisfaction (Howell & Frost, 1989; Parry, 2000). Alimo-Metcalfe and Alban-Metcalfe (2005) argued that management of healthcare services has become a major priority of public policy, to maximise value from the huge commitment of resources and to improve the quality of healthcare itself. Furthermore, in healthcare, leadership needs to be fostered in many domains such as the clinical, technical, management, policy, education, research and regulatory domains. The very language of quality has caused confusion amongst biomedical engineers, physicians and clinicians, as few have encountered terms such as TQM, Continuous Quality Improvement (CQI), or indeed, quality management or quality improvement, within their traditional professional medical and technical training.

In the context of healthcare, biomedical engineering departments by their nature are hierarchical establishments with strong interdepartmental barriers, staffed by professionals who are accustomed to working autonomously rather than working with administrators in making administrative decisions. These professionals form what can be called occupational subcultures, in the sense that they share in common a distinctive ideology and identifiable cultural forms or practices that are inherent in their occupation (Jung & Sosik, 2002; Zabada, Asubonteng & Munchus, 1998).

A comparison of the views of different authors suggests that a transformational style of leadership is more appropriate for biomedical engineering departments in hospitals, because when a
leader recognises each follower as an individual with individual needs to be developed within the organisation, quality can be realised in the often stressful public hospital environment. Followers must be provided with the opportunity for personal attention and learning opportunities to develop higher levels of potential that will have a positive effect on the organisation. Further, leaders and followers should openly exchange high expectations, creating a vision that demands higher standards and leads to better patient care.

(2) **Training and education**

Training and education form a vital part of any TQM system. Training is considered a vehicle for implementing and reinforcing quality practices (Reed et al., 2000). Scholars suggest that training is the cornerstone of any TQM implementation (Deming, 1986; Juran, 1993; Sherkenbach, 1986). Employees must receive adequate training to use quantitative tools and techniques, work in a team environment, improve communication skills and coordinate activities. Therefore, one of the basic concepts of TQM is continuous training. Oakland (1993) believed that training is the single most significant component in trying to improve service quality, while Dale (1999) suggested that continuous training contributes to the establishment of a common language throughout the business. Overall, the literature suggests that training is widely recognised by organisational development experts as an important component in successfully planned change efforts.

Training and education are important in preparing an organisation for change, in accomplishing the change itself and in institutionalising change as a permanent part of the organisation. The importance of training in the successful implementation of TQM programmes is also widely acknowledged by authors like Palo and Padhi (2003), Reed et al. (2000) and Juran (1993), because training provides an opportunity to inform employees about the goals of TQM, and it provides workers with the skills and knowledge needed to achieve those goals. Lack of understanding and proper training can contribute to worker resistance. Proper training can also provide an opportunity to empower and motivate employees, reducing employee resistance and increasing the chances of TQM success. Furthermore, Mueller and Carter (2005) argued that training in general is either practical or attitudinal, i.e., training someone to do a job or task, or training someone to approach the job or task in a positive way. According to Beckford (1998), training should include the following seven elements.
(i) *New employee induction course.* The induction course presents the employer with an ideal opportunity to emphasise the company’s commitment to quality service and their expectations of new employees.

(ii) *People-handling skills for supervisors who manage service givers.* Supervisors need to be able to train staff themselves, coach and counsel their staff, communicate, delegate, motivate and set goals for staff. It is also useful to train them in interviewing techniques.

(iii) *Quality service skills for supervisors.* Supervisors managing service providers need to know how to provide a quality service themselves and how to handle dissatisfied customers positively.

(iv) *Quality service concepts for managers and executives.* If TQM is a fairly new concept to an organisation, it is likely that managers and executives will not be familiar with it. Managers and executives need to know what the concept of a quality service culture is all about.

(v) *Management development programmes.* Even if managers and executives are familiar with the concept, they may find it difficult to adapt or change long-established working practices to fit in with the new corporate culture. They therefore need to learn and practise how to manage successfully within a quality service culture.

(vi) *Organisation awareness training.* Everyone within the organisation should know and understand the company’s business, its purposes and plans, and where it stands within the market. Also important is passing on the traditions, values and norms of the organisation, and communicating the aims and direction of the company in the future.

(vii) *Technical training.* Alongside attitudinal training goes skill training at all levels of the organisation. If employees are learning new skills valuable to the organisation, they should be rewarded in some way.

(viii) *Interpersonal and communications skills for service providers.* Service providers should receive ongoing training, but should also be able to approach their supervisors for coaching. It is reported in the literature that in addition to the training courses that are made available throughout an organisation, the training staff or department should follow developments in the field and make information available to interested parties.
(3) **Teamwork**

Teamwork is given a central role in TQM. Based on McGregor’s X and Y assumption theory (McGregor, 1960), the ability to make decisions is widely distributed amongst the population, regardless of organisational rank. According to Bishop and Scott (1997), the team offers a perfect mechanism for satisfying the needs of all the members and for providing synergy and loyalty.

Likert (1961) and Frederick (2010) presented the view that everyone is part of one or more teams, whether production- or service-oriented, or part of the management structure of the organisation. The performance of the teams within an organisation is, therefore, an important variable in the performance of the organisation as a whole. Crucial to the performance of the teams are the abilities and behaviours of their members. Relevant to this are the roles that team members play. Belbin (1993) defines a team role as a tendency to behave, contribute and interrelate in a particular way.

Emmons, Weiner, Fernandez, and Tu (2012) suggested that a team role enables an individual to benefit from self-knowledge and to adjust according to the external situation. People are often chosen to be members of a team on the basis of their functional roles, these being considered most appropriate to the tasks that the team has to perform. Writers such as Belbin (1993) and Parker (1990) have discussed the notions of team roles or team players. They claim that individuals will not only bring the characteristics of their functional roles to their activities as members of a team, but will also, naturally, take up one or more additional roles. For instance, a person might be naturally imaginative and have good ideas. Another might be good at gathering information, whilst another might take the role of coordinator of other people’s contributions. It can be said that teams are appropriate when there is a need for coordination of activity and when a major breakthrough in performance is required. Furthermore, teams are very useful for the integration of activities, generating production efficiencies and service (Quazi, Hong & Meng, 2002), and for providing innovative approaches to production or service issues (Eisenhardt & Tabrizi, 1995).

Therefore, it can be said that in the specific case of healthcare, a shared commitment to teamwork, participative safety, high standards of performance and systemic support for cooperation, communication and trust are critical to teamwork. In the data collection stage of this
research, the researcher will investigate and observe the role of biomedical engineers as team members in selected hospitals (cases).

(4) Organisational culture

The term “organisational culture” has proved extremely popular with management theorists (Williams & Torrens, 1993; Guangming, Clarke & Lehaney, 2000) and managers alike since the publication of *In Search of Excellence* (Peters & Waterman, 1982). This researcher accepts Martins & Terblanche’s view that the word “culture” has its theoretical roots within social anthropology and was first used in a holistic way to describe the qualities of a human group that are passed from one generation to the next (Martins & Terblanche, 2003). Today, culture can be seen in different levels of business organisations.

The aspect of culture has been emphasised by the founding fathers of TQM. Total Quality Management de-emphasises status distinctions and empowers employees to make decisions and to use their own intelligence (Crosby, 1981). Organisational culture is defined as the general pattern of mindsets, beliefs and values that team members of an organisation share in common, and which shape the easily observable behaviours, practices and other artefacts of the organisation (Sathe, 1985). Schein (1985) defined culture as a system of norms, shared values, concerns and common beliefs that are understood and accepted by the members of the organisation. The members of the organisation accept these as valid, follow them and teach them to incoming members as a pattern to be followed for problem solving and as a required thinking style and behaviour. Newcomers to an organisation may bring with them prior expectations about the culture when they join, but culture is also transmitted to new arrivals by established staff, sometimes explicitly but more often implicitly. The organisational culture is shaped and articulated not just by individuals but also by new and old organisational features.

Based on Garvin’s (1993) transcendent view of quality, TQM is itself a philosophy with its own existence which does not incline towards any particular country or national culture. Similarly, Martins & Terblanche (2003) pointed out that TQM is embedded within its own set of cultural beliefs, norms, values and assumptions. However, when implementing TQM in a particular cultural setting, the fusion effect of the respective organisational culture itself is of great importance. Total Quality Management can also be described as the development of an organisational culture, which is defined by, and supports, the constant attainment of customer
satisfaction through an integrated system of techniques and tools. The culture requires quality in all aspects of the organisation’s operations, with things being done right the first time and defects and waste eradicated from operations (Guangming et al., 2000). Total Quality Management is the culture of an organisation committed to total customer satisfaction through continuous improvement. In such a culture, resources, materials, equipment and QMSs are cost-effectively implemented and fully utilised (Gunasekaran, 1999). In a similar vein, Mani, Murugan and Rajendran (2003) reported that the implementation of TQM is one of the most complex activities that any company can attempt, owing to the fact that it involves a change in the working culture and also impacts on people. Vanisina (1990) argued that successful implementation of TQM requires an assessment of the organisational culture and the implementation of an integrated process for change in organisational behaviour. Bright and Cooper (1993), however, decried the lack of empirical and theoretical work in examining the connection between organisational culture and TQM, particularly with regard to the use of quality tools, techniques and systems in the implementation of TQM. Therefore, it can be said that the successful implementation of TQM requires that the values of the organisation are changed so as to harmonise with the values of TQM. Changing the values of an organisation is, however, not an easy task, because values are deeply grounded in the organisational culture. Black and Porter (1996) reported that culture has been found to be an important factor in empirically validated studies, which sought to define “critical success factors (CSF)” for successful implementation of TQM.

From the definitions, the researcher has identified three main themes or perspectives related to organisational culture. First, culture is a learned entity (Williams & Torrens, 1993). At a basic level, culture may be defined as the way we do things or the way we think about things (Williams & Torrens, 1993). A widely accepted definition of culture provided by Schein (1984) is the pattern of basic assumptions that a given group has invented, discovered or developed in learning to cope with problems of external adaptation and internal integration. These assumptions have worked well enough to be considered valid, and therefore to be taught to new members as the correct way to perceive, think and feel in relation to problems. The key feature is that culture is taught to new members as the correct way to behave, thus perpetuating organisational survival and growth.

Second, corporate culture offers a contrast to the past rigidity of management models (Davis, 1984). Davis (1984) defines culture as the pattern of shared beliefs and values that give
members of an institution meaning and provide them with the rules for behaviour in their organisation. An examination of organisational culture begins by distinguishing between fundamental guiding beliefs and daily beliefs. Guiding beliefs provide the context for the practical ‘nitty-gritty’ beliefs of everyday life; in other words, guiding beliefs give direction to daily beliefs. As fundamental precepts, guiding beliefs rarely change because they are in the realm of universal truth. Daily beliefs are also part of the company culture and can be described as the rules and feelings about everyday behaviour. However, these are dynamic and situational, and change to match the context.

A third perspective is seeing culture as strategy. Bate (1995), in a wide-ranging analysis, fundamentally disagreed with the distinction between strategy and culture. To Bate (1995), the separation of the two concepts has no validity, since they are synonymous. He suggested that culture and strategy depend upon one another. That is, culture is a strategic phenomenon and strategy is a cultural phenomenon. The implications of such beliefs are two-fold.

(i) Strategy formulation of any kind is a cultural activity.
(ii) Cultural change is strategic change.

The rational outcome of these statements is that any attempt to set up a separate cultural change programme is fundamentally flawed, because cultural change is already taking place within formal and informal strategic planning processes (Bate, 1995).

(5) Employee empowerment

In recent years, the term “empowerment” has become part of everyday management language (Cunningham, Hyman & Baldry, 1996; Virmani, 2002). It has also been associated with popular management movements such as human resource management (HRM) and TQM. Empowerment is regarded as providing a solution to the age-old problem of bureaucratic workplaces in which creativity is stifled and workers become alienated, showing discontent through individual or collective means. Furthermore, Wilkinson (1998) argued that the term “empowerment” is generally used to refer to a form of employee involvement initiative, which was widespread from the 1980s and focused on task-based involvement and attitudinal change. Wilkinson (1998) suggested that, unlike industrial democracy, there is no notion of workers
having a right to decide what empowerment means to them. It is employers who decide whether and how to empower employees. While there is a wide range of programmes and initiatives which are titled “empowerment” and which vary as to the extent of power which employees actually exercise, most are purposefully designed not to give workers a very significant role in decision making, but rather to secure an enhanced employee contribution to the organisation. Empowerment takes place within the context of a strict management agenda. Empowerment schemes tend to be direct and based on individuals or small groups (usually the work group or teams), a clear contrast with industrial democracy and participative schemes, such as consultative committees that are collectivist and representative in nature.

However, Hales (2000) and Wilkinson (1998) both suggested that when we view empowerment through an economic lens, it can be assumed that workers have the opportunity to contribute to organisational success, and as they are closer to the work situation, they may be able to suggest improvements that management would be unable to suggest by virtue of their position in the hierarchy. In the context of biomedical engineering, it is this researcher’s view that empowerment would also increase job satisfaction and improve turnover, as biomedical engineers would feel more committed to organisational goals.

In addition, as the engineers are empowered, the need for complex and dysfunctional systems of control is reduced, thus increasing efficiency (Oloko & Ogutu, 2012; Ongore, 2009; Ozaralli, 2003). According to the cited researchers’ observations, the processes of organisations such as public hospitals can become dysfunctional due to lack of communication, lack of training, lack of resources and budget constraints. To maintain efficiency, it is in the interest of the organisation to achieve greater flexibility through the use of its team members. Rather than trying to control team members, and telling them what to do and how to do their work, the researchers cited above state that solutions to these common organisational problems lie with team members; after all, the engineers and technicians who work in the front-line are true experts on how to resolve day-to-day equipment problems.

Therefore, management should promote knowledge sharing amongst team members and teach the engineers and technicians how to assess risks inherent in their work and in the decisions they must make. Management should also allow engineers and technicians to supply their ideas to improve processes, and should empower them to make decisions at their level, thus creating a culture in which all team members can feel appreciated through making contributions
towards improving efficiency and enhancing internal customer satisfaction. This argument emphasises the need for faster decisions in a changing marketplace, with employees closest to the customer/product best placed to make decisions concerning related issues.

Furthermore, the role of empowerment in TQM can be seen in a Delphi study which identifies internal and external cooperation and employee fulfilment as two of the concepts underlying the Deming management method (Itzhaky, Gerber & Dekel, 2004). Internal and external cooperation subsumes teamwork and collaborative organisation, whereas employee fulfilment can be considered to subsume employee empowerment. Similarly, “involvement and empowerment of all organisational members in cooperative efforts to achieve quality improvement” is an element of TQM (Waldman, 1994, p. 510). Therefore, there seems to be no question that teams and employee empowerment occupy a central role in TQM.

(6) Quality management systems (QMSs)

A QMS constitutes a formal record of the organisation’s method of managing the quality of its products or services. It enables the organisation to demonstrate to itself, its customers, and most importantly to its independent accreditation body that it has established an effective system for managing the quality of its products or services (Beckford, 1998). A QMS offers a framework which can act as a catalyst for quality to become embedded throughout the organisation (Williams & Buswell, 2003). Therefore, a QMS should also be capable of improving the organisation’s ability to continuously improve, because an organisation’s QMS provides products and services that meet customer requirements. Customer requirements may include availability, delivery, reliability, maintainability and cost effectiveness, amongst many other features of a product. To achieve this, many organisations adopt the ISO 9000 series of standards for QA and continuous improvement to their products and services (Scott, 2005). Therefore, it is important to understand the ISO 9000 series of standards and its relationship with TQM.

The International Organisation for Standardisation developed the ISO 9000 series in the mid-1980s. However, the standard on which ISO 9001 was ultimately based preceded ISO 9001 by many years, and was known as BS5750. BS5750 arose out of production line-style manufacturing, this being the predominant industry in the United Kingdom (UK) at the time. This manufacturing emphasis, however, caused many problems with BS5750’s use and
interpretation when endeavouring to apply it to service sector-type businesses that have proliferated since the 1980s. In 1987, the BS5750 name was dropped in favour of the international standard, known since by its generic convention ISO 9000, and the use of the standard then spread beyond the borders of the UK throughout many other industrialised countries (British Standards Institute, 2004).

The ISO 9000 is a series of standards dealing with QMSs that can be used for external QA purposes. It sets standards for systems and paperwork (not products) by providing organisations with guidelines on how to establish systems for managing quality products and systems (Barnes, 1998; Brymen, 2004). Registration to the standards demonstrates to customers that the supplying organisation has achieved a basic level of QA through the formalisation and documentation of its QMS (Beattie & Sohal, 1999). While the initial thrust for the development of the standards came from the energy, defence and telecommunications equipment industries, its subsequent predominant users have been small- to medium-sized manufacturing organisations. As a result, much of the accumulated knowledge on ISO 9000 is formed by the experiences of the manufacturing industry (Conti, 1999). The ISO 9000 version 2000, published in December 2000, is based on eight principles listed below:

- Principle 1: customer focus;
- Principle 2: leadership;
- Principle 3: involvement of people;
- Principle 4: process approach;
- Principle 5: systems approach to management;
- Principle 6: continuous improvement;
- Principle 7: factual approach to decision making; and

Principles 1, 3, 6 and 7 of ISO 9000:2000 lean towards service quality and customer satisfaction. The eight principles also closely resemble the enablers for TQM implementation. Kartha (2002) argued that ISO 9000:2000 closely reflects the basic principles of TQM. The 9001:2000 model is a process-based QMS, as shown in Figure 2.3.
Figure 2.3: Model of a process-based quality management system (QMS)


The ISO 9000 series consists of five basic subsets:

- ISO 9000: a guideline for determining which contractual series an organisation should apply;
• ISO 9001: the contractual standard for companies that research, design, ship, install and service what they manufacture;
• ISO 9002: the contractual standard for companies that manufacture and install products, but are not involved in design;
• ISO 9003: the contractual standard for companies that assemble and test products that have been designed and produced elsewhere (typically includes warehousing and distribution companies); and
• ISO 9004: a guidance document for a quality system more comprehensive than those laid out in the contractual standards. Designed to be used as a first-party document by an organisation as it designs and implements an internal QMS (Hoyle, 2002).

Thus, companies pursuing ISO 9000 certification must select the standard (ISO 9001, 9002 or 9003) that best suits their needs. These standards are now accepted internationally as an approach to quality systems. In general, the standards describe a number of issues on which the quality system of an organisation can be assessed by an external party (a certification institute, which itself has been accredited by a national accreditation body). If the quality system conforms to these (minimum) standards, then a certificate can be issued and formal registration takes place, which indicates that the quality system meets the requirements of the ISO 9000 series. An ISO certificate does not guarantee that the processes or the products are of the highest quality. It only states that there is a system in place that provides confidence that the organisation will be consistent in its management processes. Since there is a need to describe procedures and to keep track of noncompliance, ISO is often seen as a bureaucratic process involving manuals and record keeping.

There is a close relationship between ISO and TQM. The philosophy of TQM is dynamic, based on continuous improvement and change, and usually aims at the highest quality in processes, products and services (Khanna, Vrat, Shankar & Sahay, 2002). It has much to do with culture and the attitudes and the behaviour of everyone in the organisation, and it is based on the transformational style of leadership that seeks to make use of employee knowledge as much as possible.

The relationship between ISO 9000 and TQM can be illustrated by placing ISO 9000 in the perspective of the award models (e.g., the Australian quality awards model, the Malcolm
Baldrige national quality award model and the European quality award model). The overlap between the ISO 9000 criteria and the criteria of these award models mainly covers the processes category of the award models (Hui & Chuan, 2002). From the viewpoint of ISO 9000, processes have to be described in procedures, and defects have to be handled in a way also described in a procedure. The TQM view of processes is much more focused on understanding them and the reasons for variations, rather than developing profound knowledge, as Deming (1986) has stated. Thus, ISO 9000 and TQM have different goals and different perspectives. Generally speaking, ISO 9000 is part of the total quality concept and may or may not be seen as a prerequisite for broader issues of quality.

The philosophy of ISO 9000 has made customers the focal point of the quality-based management system. The role of management is “to ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction” (Magd & Curry, 2003, p. 244). The purpose of customer satisfaction measurement is to clarify the extent to which the organisation is achieving that goal. Therefore, to get a reliable measure of customer satisfaction, one must have an accurate understanding of the customer requirements that the organisation is striving to meet. As previously shown in Figure 2.3, ISO 9001:2000 makes customers’ requirements the starting point of the QMS. Another similarity between TQM and ISO 9000:2000 has been identified by Magd and Curry (2003). They have mapped Deming’s system of profound knowledge with the components of ISO 9000:2000 (Table 2.4).
Table 2.4: *ISO 9000 processes*

<table>
<thead>
<tr>
<th>ISO 9000 assessment</th>
<th>• The initial assessment is a detailed review of the company’s quality systems and procedures compared with ISO 9000 requirements. This process defines the scope of the ISO project.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality assurance (QA) manual</td>
<td>• While ISO 9000 standards do not require a QA and policy manual, they do require the company to document everything it does and every system that affects the quality of the finished product. The quality manual is often used because it is a good way to get all the necessary documentation together in one place.</td>
</tr>
<tr>
<td>Training</td>
<td>• Every employee needs training in two areas. First, they need an overall understanding of ISO 9000 vocabulary, requirements, role of the quality manual, and benefits that will be derived from the system. Second, they need to be aware of the actual day-to-day process of upgrading and improving procedures.</td>
</tr>
<tr>
<td>Documentation of work instructions</td>
<td>• Processes that have been improved will need new documentation. Once completed, this documentation should outline every process a company undertakes that affects the quality of a finished product.</td>
</tr>
<tr>
<td>Registration audit</td>
<td>• The final step in the ISO 9000 programme is an audit by a company-chosen registrar to see that the system is working as described in the quality manual and that the system meets ISO 9000 requirements.</td>
</tr>
</tbody>
</table>

*Source: Adapted from Magd and Curry (2003, p. 246).*
The elements of Deming’s profound knowledge are illustrated in the Table 2.5.

Table 2.5: ISO 9000 and Deming’s system of profound knowledge

| Systems knowledge | • The system contains interrelated components working together in harmony. Managers should ensure communication and cooperation amongst the different parts of the system, and each component has a duty to contribute to the whole system. Therefore, it is not important if any of the components is losing money as long as each component contributes to the success of the other components. |
| Knowledge of variation | • Deming emphasises the need to understand variations between people, processes, products and outcomes; nothing remains constant. Managers should consider variations in process capability and control charts, and most importantly, variations in people. |
| Knowledge of theory | • Practice based on past experience is a very important element for managers. Deming claimed that there is no true value to any conditions; any experience might yield different results when different procedures are used. |
| Knowledge of psychology | • Management should understand the human side of the organisation and the human interaction of employees. People differ, and management should use these differences to optimise success by providing individualised incentives and motivation to succeed. |

*Source*: Adapted from Magd and Curry (2003, p. 247).

As shown in Table 2.5, the first three elements of Deming’s profound knowledge and the ISO 9000:2000 process/system approach complement each other (Magd & Curry, 2003). However, Deming’s knowledge of psychology is not evident in ISO 9000, because ISO 9000 does not focus on human interactions (Magd & Curry, 2003). The authors concluded that “ISO 9000 can be implemented first to create stability and consistency in the organisation’s work, then the implementation of TQM can enhance employee motivation and operational efficiency, and achieve overall organisational success and performance” (Magd & Curry, 2003, p. 252).

The first set of constructs revolved around a discussion of TQM elements for customer satisfaction and cost reduction. The second set of constructs referred to eight principles of the ISO 9000:2000 management system. At data collection and analysis stages of this study, these
two sets of constructs were studied to observe how they were applied in biomedical engineering departmental processes to achieve internal customer satisfaction and good budget management.

Literature reveals that although TQM overlaps with other models, several researchers believe that TQM is still the most appropriate and popular management system throughout all types of business organisations. For example, Mauch (2010) believes that the complex organisations in modern times trigger the need to improve customer services, which TQM can fulfil by providing tools to better manage and to obtain the ability to measure service quality. Micklewright (2010) reported that organisations that follow the principles of TQM can achieve cost reductions and customer satisfaction. In addition, Slack, Brandon, Johnston and Betts (2012) suggest that TQM initiatives can increase customer satisfaction. Finally, Rust & Huang (2012) contends that when processes are improved, efficiency is thereby improved, and that this TQM approach leads to customer satisfaction.

The main focus of this research is on healthcare. Therefore, the second section of this chapter will review literature specific to the field of healthcare.

2.2 Quality in healthcare

Section 2 is organised into eight subsections as illustrated by the concept map in Figure 2.1. The section starts with an introduction. Then, in the current section 2.2, quality is defined and discussed in the healthcare context. A discussion of the domains and dimensions of quality follows. Next, quality in healthcare, QA and its relevance in healthcare, and a review of the tools for measuring quality in healthcare are discussed. The section finishes with an analysis of the role of biomedical engineering in hospitals.

Prologue

In the mid-1990s, New Zealand’s Ministry of Health directed public hospitals to operate like business organisations (Easton, 1994). This was part of the government-led reforms of the health sector. Changes to the health system during the 1990s attempted to introduce market principles as a way of improving efficiency and of ensuring the public accountability of health services (Coster & Buetow, 2003). Now, the government provides a yearly operating budget to hospitals, depending upon the types of therapy and services they provide to the community (Ministry of Health New Zealand, 2011). This has increased competition amongst public
healthcare providers. Hospital managers are trying to decrease operating costs, expand access, and improve service quality to assure the Ministry of Health that a high-quality service is provided to the community in a cost-effective manner. A cost-effective and high-quality service allows hospitals to expand their business and to secure a higher level of funding from the Ministry of Health.

Healthcare is a complex environment due to its multiple stakeholders and many internal and external customers. Public hospitals have to cope with environmental pressures such as demographic changes and the aging of populations, as well as the emergence of new treatments and technologies, and public hospitals must provide consistently high-quality, failure-free service in order to remain competitive with private hospitals (Roberts, Madsen, Desai & Van, 2005). Not surprisingly, service quality and the closely related internal customer-satisfaction constructs are of vital concern for New Zealand public hospitals. In the current climate, there are many issues facing healthcare that originate within the hospital itself, such as advances in technology and science, uncertainty about treatment effectiveness, the explosion of information and its accessibility, and growing demands for services, patient safety and complexity in the inter-departmental processes that support patient care (Waring, McDonald & Harrison, 2006).

The main focus of this research is on the biomedical engineering departments in public hospitals, with particular emphasis on the improvement of service quality and customer satisfaction within the hospital. Therefore, it is important to define quality in the context of healthcare and to understand the biomedical engineering department’s role in the hospital and its relationship with internal customers.

2.2.1 Definition of quality in healthcare

The core philosophy of quality management is to lead and operate an organisation successfully in a systematic and transparent manner that gives employees direction and control (El-Kafafi, 2006). However, the meaning of quality has remained elusive, leading to misunderstandings and hindering efforts to improve healthcare (Campbell, Roland & Buetow, 2000). From the literature, two types of definitions of “quality” can be identified. They are generic definitions and disaggregated definitions. Generic definitions of quality may be short phrases, such as zero defects” (Crosby, 1979), “fitness for use” (Juran, 1988) and “satisfying the customer” (Peters, 1987). The disaggregated definition is more specific. Literature reveals that
quality in healthcare has not been consistently defined. For example, Donabedian (1980) defines quality in healthcare as the kind of care which is expected to maximise an inclusive measure of patient welfare, after one has taken into account the balance of expected gains and losses that altered the process of care in all its parts.

2.2.2 Dimensions of quality

Dickens (1994) reported that the definitions of quality recognise explicitly that quality is a complex multi-component entity in which each component is separable and definable. Disaggregated definitions have the advantage of being specific and are therefore able to bridge the gap between the needs of individuals and the population (Campbell et al., 2000; Maxwell, 1992). Quality can also be viewed from different stakeholder perspectives; for example, client quality, professional quality and management quality (Ovretveit, 1991). Each perspective values the individual dimensions of quality differently. For example, efficiency is more important to funders than to hospital professionals.

2.2.3 Domains of quality

In search of a common language or framework for understanding quality, Campbell et al. (2000) and their colleagues proposed resolving the differences in stakeholder valuations by reducing the multiple dimensions of quality to two domains: access and effectiveness. Access describes whether people (can) get care when they need it. Effectiveness relates to the outcomes of this delivery of care and whether or not it has actually worked. Table 2.6 presents the views of different authors on domains versus dimensions of quality.
## Table 2.6: Domains versus dimensions of quality

<table>
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<tbody>
<tr>
<td>Effectiveness</td>
<td>• Efficiency • Relevance</td>
<td>• Efficacy • Efficiency</td>
<td>• Efficacy</td>
<td>• Efficiency • Technical competence • Accessibility</td>
<td>• Efficiency • Appropriate ness</td>
<td>• Efficiency • Competence • Appropriateness</td>
<td>• Efficiency • Service • Quality outcomes</td>
</tr>
<tr>
<td>Access</td>
<td>• Accessibility • Equity • Acceptability</td>
<td>• Equity • Legitimacy • Safety</td>
<td>• Equity • Continuity • Patient safety • Safety</td>
<td>• Equity • Acceptability • Respect • Choice • Availability of information</td>
<td>• Equity • Consumer participation • Safety</td>
<td>• Relevance • Equity • Acceptability • Competence • Improving service delivery • Affordability • Safety • Feedback</td>
<td>• Equity • Social security • Financial protection • Safety • Cultural barriers</td>
</tr>
</tbody>
</table>

Sources: Adapted from Maxwell (1992); Donabedian (1990); O’Leary and O’Leary (1992); Klein (1998); National Advisory Committee on Health and Disability (2001); Ware (2013); Gutierrez, Saiso, Dolci & Avila (2014).
By evaluating the commonalities between different authors, it can be noted that in the “effectiveness” category in the domain column, authors have listed efficacy, efficiency and appropriateness, technical competence, outcomes, relevance and service quality as the key dimensions of quality; and in the “access” category, the authors have listed acceptability, legitimacy, competence, improving service delivery, affordability, safety, continuity, respect, choice, cultural barriers and consumer feedback as the key dimensions of quality. Further evaluation indicates that equity, efficiency and safety are the common dimensions noted by authors.

Equity is the domain of access and describes the extent to which all individuals can access the care they need, rather than the same (or equal) care, which may not be what they need. Efficiency is the dimension of effectiveness and relates to benefits to individuals in terms of delivery of care and whether or not that care actually worked.

### 2.2.4 Quality in hospitals

Technology has revolutionised the management of healthcare organisations by changing the way in which people work and interact. In last few decades, investments in biomedical research have increased steadily, resulting in an extraordinary expansion of medical knowledge and technology (Blumenthal, 1994; Grimes, 2004). The modern method of organising and delivering care is more complex. To cope with fast-changing medical technologies, the healthcare industry is relying heavily on information and communication technologies (ICT), and so called electronic health, or e-health (Healy, 2007). It can be said that e-health is the main feature defining modern healthcare. E-health is described as the application of ICT across the entire range of functions that affect the healthcare sector. E-health represents the interaction between patients and health/service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals. E-health tools play an important role in improving the health of citizens. If the e-health tools and services are used appropriately, they may provide better and more efficient healthcare services for all people. Examples include health information networks, electronic health records, telemedicine services, wearable and portable systems that communicate, health portals and many other ICT-based tools.
E-health encourages alternative ways to better health. For example, clinicians have a choice of different technologies for diagnostics (e.g., magnetic resonance imaging and computerised tomography scans), and surgeons have the option to use different equipment and techniques for surgical procedures. Such options are made possible by the use of modern technology and ICT systems (Cerrato, 2012). For this reason, research in biomedical and healthcare informatics is the prerequisite for the development of e-health applications.

Information and communication technologies also play an important role in biomedical technology management, especially in patients’ data networking (for example, in-patient monitoring systems in intensive care units (ICUs), and the downloading of patients’ data from diagnostic equipment for clinicians and medical specialists (McMullan, 2006). Information and communication technology is also widely used for clinical equipment testing and calibration. Around the world, medical testing and technology-driven therapy and technology performance are guided by medical standards prescribed by the medical authorities of each country, for example, the British Standards Institution (BSI), Thai Industrial Standards (TIS), the South African Bureau of Standards (SABS) and the Canadian General Standards Board (CSA). Similarly, in New Zealand modern methods of delivering care, surgical techniques, medical testing and technology management follow the rest of the world and are guided by the medical standards of New Zealand, known as Standards New Zealand (SNZ). Standards New Zealand is a government organisation responsible for developing and marketing national, regional and international standards and offering an independent service to a wide range of organisations in New Zealand. The majority of the standards are developed in partnership with Australia. These standards represent Australia and New Zealand in ISO, the International Electro-technical Commission (IEC) and other related governing bodies. Standards New Zealand ensures that New Zealand’s voice is heard worldwide (Quality Health New Zealand, 2006).

Standards New Zealand works closely with Australia and has joint Australian/New Zealand standards. There are several standards that hospitals, medical laboratories and biomedical engineering currently use to foster continuous improvement and to promote best practice in the healthcare industry. Some of the standards that relate closely to this research are listed below:
There are other related standards such as AS/NZS 3000:2007: electrical installations, respiratory protective devices (NZS/AS 1716: 2012) and risk management (AS/NZS 4360:1999).

Looking at the standards mentioned above, it can be said that technological development and quality standards clearly have an important effect on service quality in hospital care, specifically in medical practices, surgical techniques, administration of drugs, equipment use and organisation of services (Kunst & Lemmink, 2000). To comply with the standards, healthcare organisations need to have some QA system in place. The next section discusses QA and its importance in healthcare.

2.2.5 Quality assurance and its importance in healthcare

Quality assurance is one of the key elements underpinning service quality and customer satisfaction, and can be defined as an effort to change or improve the level of service based upon measures of quality (Krishu, 2011; Camacho & Rubin, 1998; Hall, Epstein, Deciantis, & McNeil, 1993). Furthermore, QA is a systematisation, documentation and assessment of certain evaluation activities, and should be seen as a stimulus that makes business activities as rigorous and pertinent as possible (Varma & El-Kafafi, 2011; Kletz, 2001).

In the 1970s, researchers worked to help establish QA programmes in hospitals and other healthcare facilities (Egdahl & Gertman, 1976). Egdahl and Gertman (1976) reported that at times, many QA deficiencies were attributable to physicians’ habits and behaviours, and more importantly, to the characteristics of the healthcare system. Some examples included the adequacy of equipment and facilities, qualifications, organisation of the medical staff and the administrative structure of programmes providing care (Egdahl & Gertman, 1976). Researchers recommended the development of criteria for condition-specific, explicit processes, the
development of disease-specific outcome measures, and development of measures quantifying service delivery structures (Hall et al., 1993) to address these problems.

Hall et al. (1993) suggest that good quality care makes, for example, medical instruments safer and more effective. Unsafe instruments can be dangerous to operators and patients. Poorly delivered services can cause incorrect diagnoses, injuries and even death. Therefore, to maintain a sustainable reliability of clinical equipment, a good QA programme can be utilised in identifying clinical equipment as being defective (El-Kafafi & Varma, 2012). A well maintained and calibrated instrument eliminates doubts regarding equipment safety and misdiagnoses, increases clinicians’ confidence in patient treatment and increases the patient’s confidence in the healthcare system. In contrast, poorly maintained or un-calibrated instruments can discourage clinicians from carrying out high-tech therapies. Unsafe practices, poorly maintained equipment or even discourteous treatment dissatisfies patients, discourages them from seeking care and returning for services, and prompts them to switch physicians (Hall et al., 1993). Hall et al. (1993) further argue that healthcare staff derive greater personal and professional satisfaction from their jobs when they can offer good quality care and can feel that their work is valuable.

All hospitals have some form of QA systems to comply with regulatory and accreditation requirements (Camacho & Rubin, 1998). Systems incorporate physician reviews and retrospective analyses of clinical records using a two-step method. Non-physicians screen medical records for signs of potential substandard care; then, physicians review these records to determine if there is a quality problem (Camacho & Rubin, 1998). Similarly, biomedical engineering departments currently follow the medical equipment management standard (AS/NZS 3551:2012) as part of their QA programme. From the biomedical engineering department’s perspective, technology is a key element in patient treatment. It can facilitate service delivery to the benefit of patients and providers (Walker & Craig-lees, 2002). It can be used as a productive, tactical and strategic resource, as a change agent and as a tool. In the search for continuous improvement, service quality and customer satisfaction, tools for measuring quality are important and should be utilised as needed. The tools for measuring quality in healthcare are discussed in the following section.
2.2.6 Tools for measuring quality in healthcare

There are several tools for measuring quality and customer satisfaction, and many of these can be interchangeable. However, there is an accepted set of eight basic tools for measuring quality. These are: check sheets, Pareto charts, histograms, scatter diagrams (correlation diagrams), cause-and-effect diagrams (fishbone diagrams), graph-and-control (run) charts, Six Sigma and stratification. Many service organisations are making use of control charts as part of their quality systems and activities (Grigg & Walls, 2007). Just as quality management tools and techniques have been applied successfully in the manufacturing and industrial services sector, they also have been adapted to healthcare (Barry & Smith, 2005). Grigg and Walls (2006) suggested that quality tools can offer some operational benefits, such as quality improvement, and cost reduction or efficiency improvement, which are all linked to a proactive desire to improve biomedical engineering services to internal customers.

Healthcare services increasingly use modern management tools and techniques such as CQI, TQM, process re-engineering, benchmarking, supply chain management (SCM) and Six Sigma to satisfy both internal and external customers (Dey & Hariharan, 2006). The tools are applied to measure service quality in order to identify causes of poor performance and to drive solutions for superior achievement. Fernandes and Christenson (1995) reported that in healthcare, CQI has been applied successfully in the emergency departments of many hospitals. Continuous quality improvement includes statistical quality and process control as well as other quantitative tools such as check sheets, histograms, Pareto analysis, cause-and-effect diagrams and flow charts (Bell & Krivich, 2000).

Furthermore, Deming's PDCA cycle, utilisation review and management have been suggested for quality improvement in healthcare services by researchers like Berwick (1998) and Van Matre (1992). Lurie, Merrens, Lee and Splaine (2002) suggested that although various performance improvement programmes contribute towards improved performance and service quality, their effectiveness depends on how efficiently they can be integrated with organisational strategies and project management practices.

Six Sigma was introduced in hospital-based healthcare to improve management of mortality and morbidity (Barry & Smith, 2005). For example, Six Sigma was implemented at the Red Cross Hospital in Beverwijk, the Netherlands. Six Sigma offered a number of quality management techniques that could solve the hospital's problems, but some of its concepts had to
be tailored to better apply to the local healthcare industry. Six Sigma was well received by employees, and its data-driven approach was helpful in establishing support during implementation of the recommendations (Van den Heuvel & Bisgaard, 2005). Many contemporary practices involve general guidelines that do not address the unique problems of specific services in the hospital-based healthcare system (Lurie et al., 2002). There is a need to determine an integrated model for biomedical engineering that can provide all the aspects of quality improvement, from concept to implementation, for superior performance.

Five S (5S) was also introduced in public hospitals as a tool to measure quality in healthcare. Five S is a value-oriented business model developed in the work environment to maintain order, to increase productivity and to reduce wastage. Five S represents the initial letters of the words “seiri” (tidiness), “seiton” (order), “seiso” (cleanliness), “seiketsu” (standardisation) and “shitsuke” (discipline) in the Japanese language (Osada, 1995; Hirano, 1995). The components of 5S refer to the issues that have come to the fore in hospitals’ continuing quality improvement efforts since the 1950s. The use of 5S as a business model occurred for the first time in the 1980s by Osada and then by Hirano (Suarez-Barraza & Ramis-Pujol, 2012).

The authors Suarez-Barraza & Ramis-Pujol (2012) reported that Osada’s approach to 5S was based on organisational development, learning and change, while Hirano’s approach was mainly to use 5S as a tool to differentiate the firm from its competitors. Based on the five quality pillars, 5S is also a useful guide in quality service process design. In today’s healthcare organisations, growing attention is paid to service design in response to issues such as increasing customer expectations, customer feedback, fast aging of customers, services’ loss of attractiveness and new regulations. Depending upon the circumstances, the rapid design of services is crucial for healthcare organisations. Designing all processes according to the 5S guidelines helps to maintain a robust system that delivers quality and value (Casadesus-Masanell & Ricart, 2010).

Kamdampully (2006) suggests that in order to define what work will be performed, it is not sufficient to reply only to the question of “what” will be delivered to the customer, but that “how” it will be delivered is also important. In addition, Gapp, Fisher and Kobayashi (2008) argue that as the first step of continuous improvement, 5S is a value-oriented business model.
Although physical factors and order have an important place in 5S, it is considered very limiting to use this quality measurement tool as a housekeeping technique only.

In recent years, hospitals also have introduced Quality Control Circles (QCC) to sustain improvement in their processes. According to Tong (2009), QCC has been gradually applied in the medical and healthcare fields. The main goal is to increase the morale of medical workers by improving their awareness of spotting and solving medical problems, improving medical working environments, and eventually increasing the quality of medical care, reducing the costs of medical management, and increasing the efficiency of medical services.

On one hand, the practitioners in the administrative arm of healthcare have begun to give their full attention to medical continuous quality improvement and medical safety management, and have formed a good medical quality management philosophy. On the other hand, with the development of the market economy system, hospital staff delivering medical care also have formed a quality consciousness to some extent, and have now gradually begun to pay attention to the construction of medical quality as a concept (Wang, 2009). QCC activity reflects the people-oriented core idea of management. It has been successfully used in overseas business circles for several decades and has been gradually extended to hospital management in recent years (Wang, 2009). This suggests that biomedical engineering departments can also utilise QCC to increase the morale of biomedical engineering teams by utilising scientific quality management knowledge and tools, and by raising team awareness about spotting and solving medical problems. Spiegel, Mlczoch-Czerny, Jens and Dowrick (2012) suggest that training workers at the grassroots level can increase the awareness of amending problems and can increase work efficiency. In this way, a harmonious work team can be built, the quality of medical services can be improved, and hospital costs can be decreased. Therefore, it is important to understand the role biomedical engineering plays in hospitals.

2.2.7 The role of biomedical engineering departments

Biomedical engineering involves meeting technology management challenges that can be broadly defined as providing a safe and effective management of technology used for patient diagnosis, therapy and monitoring within healthcare institutions (Bronzino, 1992; Keller, 2006). This implies involvement in all phases of the equipment lifecycle including selection, acceptance testing, training in safe and effective use, equipment safety, maintenance and final disposal or
replacement (Bronzino, 1992). Biomedical engineers are responsible for explaining new technologies and their impact on operating costs, and are also responsible for translating technological ideas, problems and concepts into a language that nontechnical people can readily understand. Bronzino (1992) suggested that biomedical engineering departments usually perform the following tasks:

(i) corrective maintenance and calibration of medical equipment;
(ii) inspections (acceptance testing) for new equipment acquisitions and for equipment returned after an outside repair is performed, before the equipment is designated for patient use (Grigg & Walls, 2007);
(iii) preventive maintenance and periodic inspections of equipment as per medical equipment management standard (for example AS/NZS 3551:2012 for New Zealand and Australia);
(iv) equipment safety checks such as screening hazard notices, performing equipment and electrical safety checks and generally contributing to a safer environment;
(v) training users on the safe, effective use of technologies and prevention of equipment misuse or abuse and accidents related to the use of equipment;
(vi) pre-purchase consultation, especially where the clinical engineering department is expected to repair the equipment after expiry of the warranty, and sometimes even during the warranty period;
(vii) physiological measurements requiring personnel with a technical background, such as the catheterisation procedure and cardiac investigation studies;
(viii) clinical research and development, including equipment modification and design (this activity contributes important skills to medical researchers and brings the clinical engineer in closer contact with direct patient care, and it provides a multidisciplinary approach to problem solving and to the quality of patient care); and
(ix) administrative duties relating to the department’s budgets, staffing, planning, training and development.
This role description seems to have acquired general acceptance in many parts of the world, including the United States (Betts, 1987; Bronzino, 1985), Canada (Frize, 1988), Japan (Kanai, 1986), and the United Kingdom (Dey & Hariharan, 2006; Keller, 2006; Whelpton, 1988). In Australia and New Zealand, the biomedical engineer’s role is prescribed under Australian/New Zealand standards for management of medical equipment (AS/NZS 3551:2012). Furthermore, clinical engineers are uniquely qualified to understand the many subtleties of medical devices and their alarm functions, such as high blood pressure alarm and low patient temperature alarm. They tend to have a very good understanding of the inner workings of the devices and are good at identifying situations where clinical staff may run into trouble when using a certain type of device or feature (Keller, 2006).

Kortum (2010) suggests that the modern era has seen the application of biomedical engineering in almost every branch of medicine, so much so that the practice of medicine is now completely dependent on the work and support of biomedical engineers. The introduction of electronic patient records, complex and extremely powerful electro-medical equipment and devices, and minimally invasive technologies is just the beginning. The future holds new possibilities of providing telemedicine and e-health services, new ways of home self-care and sophisticated medical equipment. Therefore, biomedical engineers are required to continuously up-skill to understand and apply technological advances in electronics and mechanical engineering, computer science and ICT. The blending of all these fields requires biomedical engineers to seek solutions to problems related to clinical equipment. As a consequence, a biomedical engineer is positioned to work at the intersection of engineering, mathematics, physics, biology and medicine to solve equipment-related problems (Kortum, 2010).

Therefore, maintenance of medical equipment has become more important than ever before. It is necessary to study the setup of the department and function of the biomedical engineer in any medical equipment maintenance system. Zasimova and Shishkin (2013) reported that when it comes to medical equipment maintenance, hospitals’ biomedical engineers should play the role of gatekeeper to monitor equipment movements to and from the hospital. They should also be responsible for managing the entire life cycle of all clinical equipment in the hospital.

Yi, Qi and Zhi (2014) report that appropriate deployment of technological innovations contributes to improvements in the quality of healthcare delivery, containment of costs, and
increased access to the healthcare system. Hospitals have been allocating a significant portion of their resources to procuring and managing capital assets. In addition, they are continually faced with demands for new medical equipment and are also asked to manage existing inventory. From the literature, it can be concluded that although medical technology has changed over the years, and that biomedical engineers are now dealing with more complex technology, their actual role and responsibilities within the hospital have remained the same. Thus, biomedical engineering is a necessary component of the healthcare system. This profession provides knowledge and leadership in maintaining, applying, acquiring, and managing safe and effective use of medical technology.

In this section, the main focus was on quality in healthcare. The next section of this literature review will focus on the interaction between different aspects of service quality and customer satisfaction relevant to the healthcare sector.

2.3 Service quality and customer satisfaction

This section reviews literature, including theoretical models, on service quality and customer satisfaction. The theoretical models will assist the researcher in determining a suitable and effective service quality and customer satisfaction model for biomedical engineering departments in New Zealand public hospitals.

The section is organised in three subsections: service quality, customer satisfaction and the models of service quality and customer satisfaction. It starts with a discussion on service quality in general, followed by a definition of service quality relevant to the healthcare sector. It then reviews the theory and models of service quality and discusses customer satisfaction in relation to healthcare. Finally, this section concludes with a discussion on service quality and customer satisfaction models for biomedical engineering.

2.3.1 Service quality

Service quality is considered a major weapon that companies can use to differentiate themselves from other organisations to gain competitive advantage (Gwynne, Devlin & Ennew, 2002). According to Ghobadian, Speller and Jones (1994), service quality is a major key to increasing profits. In addition, the nature of service differs from the nature of a product, because products are easy to measure, examine and judge, while the value of services is not so easy to
ascertain (Ghobadian et al., 1994). Quality in a service business has become a measure of the extent to which the service provided meets the customer’s expectations. Service quality is commonly noted as an important prerequisite for establishing and sustaining a satisfying relationship with valued customers. It contributes significantly to consumers’ overall impression of the relative inferiority/superiority of the organisation and its services. Therefore, service quality is a key to survival for all servicing organisations (Cronin & Taylor, 1992). Maintaining service quality at a certain level and improving service quality must be a lifetime endeavour for those companies who seek customer loyalty (Cronin & Taylor, 1992; Poon, 2004). Therefore, in the following section, the researcher examines quality in particular, explores service quality and reviews various meanings of the word “quality” to clarify the distinctions researchers make when applying the concepts of “quality to service”, “quality tools”, “service quality” and “service models”.

### 2.3.2 Definition of service quality

Service quality has been defined in many ways, because service quality cannot be seen and is therefore more difficult to measure (Chen & Lee, 2006). Service quality is defined as the ability of a company to meet or exceed the customer’s expectations (Parasuraman et al., 1988). Customer satisfaction results from service quality being greater than customer expectations (Parasuraman et al., 1988). The definition proposed by Parasuraman, Zeithaml and Berry (1985) presents the same idea as Gronroos (1984). They define service quality as the difference between a customer’s expectation and their actual experience. Service quality can be seen as the difference between the service provided by the service provider and the quality of performance the customer hopes to receive from the service provider, before the encounter takes place (Gronroos, 1988; Parasuraman et al., 1985).

In the context of healthcare, many definitions of quality are accepted. Quality is a word that evokes different concepts for different people. Therefore, how to define quality within healthcare remains a major concern and is further complicated by the wide range of stakeholders, each having differing perceptions of quality (Joss & Kogan, 1995). Quality management, as opposed to QA within healthcare, has grown in importance in recent years, because hospitals believe that quality improvement programmes will lead to higher quality patient care, improved patient satisfaction, enhanced employee morale and lower cost of service delivery (Roshee &
Fawdar, 2005). McGlynn (1995) argued that a simple definition of service quality is the art of doing the right thing, at the right time, in the right way, for the right person and having the best possible results. According to McGlynn (1995), healthcare is valued not only as the means to good health and long life, but as a symbol of democratic rights and citizenship to which everyone is entitled.

However, to this researcher’s knowledge, healthcare is not just another service industry, because its fundamental nature is characterised by people taking care of other people in times of need and stress. Patients are ill, families are worried and the outcome may be uncertain. Stable, trusting relationships between a patient and the people providing care can be critical to healing or managing an illness. Therefore, a suitable definition for quality medical care is a perennial problem amongst medical care administrators and researchers.

2.3.3 Service quality models

The foundation of service quality theory lies in the product quality and customer satisfaction literature. Early conceptualisation was based on the disconfirmation paradigm employed in the physical goods literature, and suggests that quality results from a comparison of perceived with expected performance (Gronroos, 2001; Parasuraman et al., 1985; Churchill & Surprenant, 1982).

The literature is populated with several service quality models. The researcher found at least four models that relate closely to service industry and this research. These models are discussed below.

(1) The SERVQUAL model

In the SERVQUAL model, quality is defined by the gap between what a customer expects and what the customer perceives (Parasuraman et al., 1988). Gronroos (1988) suggested that quality consists of seven attributes: (1) security, (2) consistency, (3) attitude, (4) competence, (5) condition, (6) availability and (7) timing. Furthermore, Sasser and Jones (1995) proposed that customers tend to evaluate service quality by using ten common factors: (1) reliability, (2) responsiveness, (3) competence, (4) access, (5) tangibility, (6) courtesy, (7) security, (8) understanding/knowing, (9) credibility and (10) communication. Parasuraman et al. (1988) further simplified these ten service quality attributes into five dimensions: (1) tangibility, (2)
reliability, (3) responsiveness, (4) assurance and (5) empathy, which later become well known as the SERVQUAL approach to measurement of the quality concept. Parasuraman et al. (1988) hypothesised that these five dimensions are related to the discrepancy between the consumer’s expectations and perceptions (gaps). Kassim and Bojei (2002) argued that service quality, as perceived by consumers, stems from a comparison between what consumers feel the service firm should offer (their expectations) and their perceptions of the service provider’s performance.

In the SERVQUAL model, Parasuraman et al. (1988) identified five gaps listed below and illustrated in Figure 2.4.

**Gap 1: Consumer expectation and management perception gap**

Service organisations may not always understand what features a service must have in order to meet consumer needs, and what performance levels are needed to deliver high-quality service for each feature. This could affect the way customers evaluate service quality.

**Gap 2: Management perception of consumer expectations service quality specification gap**

This gap arises when the organisation identifies what the customer wants, but the means to meet this expectation do not exist. Some factors that might affect the service quality perception of the customer are resource constraints, market conditions and management indifference.

**Gap 3: Service quality specifications and actual service delivery gap**

Companies could have guidelines for performing a service well and treating customers correctly, but such guidelines do not mean high service quality service is assured. Employees play an important role in ensuring good service quality perception, and their performance cannot be standardised. This affects the delivery of service, which has an impact on the way customers perceive service quality.

**Gap 4: Service delivery and communications to consumer gap**

External communications can affect not only the customer’s expectations of service but also the customer’s perceptions of the delivered service.
Gap 5: Expected service and perceived service gap

This is the difference between the consumer’s expectation and perceived service. This gap depends on size and direction of the four gaps associated with the delivery of service quality on the supplier’s side.

Throughout the 1990s, SERVQUAL, the instrument developed by Parasuraman, Zeithaml, and Berry (1994), remained the most widely used to measure service quality. Despite its popularity, a number of criticisms have been levelled at the SERVQUAL instrument, aimed at both the conceptual and the operational level. Some of the criticisms are summarised below.

(i) One area of criticism has been the dimensionality, applicability and lack of validity of the SERVQUAL model, especially with respect to the dependence or independence of the five main variables (Cronin & Taylor, 1992).
(ii) Some researchers claim that SERVQUAL domains may not be consistent. For example, with process quality, customer evaluation occurs while the service is being performed. For outcome quality, evaluation happens after service performance and focuses on “what” service is delivered. However, the SERVQUAL model does not explicitly reflect both of these dimensions; rather, it offers a functional dimension only (Baker & Lamb, 1993; Gronroos, 2001).
(iii) The most notable critics have been Cronin and Taylor (1992) and Teas (1993), who developed their own measurement instruments. Based on a review of the service quality and customer satisfaction literature, Cronin and Taylor (1992) concluded that current performance best reflects a customer’s perception of service quality, and that expectations are not part of the SERVQUAL concept.
Figure 2.4: SERVQUAL (Gap) model

Source: Adapted from Parasuraman et al. (1985, p. 41).
(2) The SERVPERF model

The SERVPERF model is a performance-only-based approach to measuring service quality. This model was originally developed by Cronin and Taylor (1992), has been applied in several studies and has yielded useful practical applications to date. For example, Robinson (1999), who evaluated the perception of service quality in the healthcare service industry by using the performance-only approach (SERVPERF method), concluded that asking patients and clients about their level of customer satisfaction with regards to service gave better results (i.e., service was more easily administrated and interpreted) than did the SERVQUAL approach (Brogowicz, Delene & Lyth, 1990; Cronin & Taylor, 1992).

Despite its popularity, the SERVPERF model (Figure 2.5) also has had its critics. The most notable critics have been Jayasundra, Ngulube and Minish-Majanja (2009), who claimed that the SERVPERF model’s measures are static, in that they do not consider the history of the service, and therefore fail to capture the dynamics of changing expectations. The SERVPERF model is illustrated in Figure 2.5.
Figure 2.5: SERVPERF model

Source: Adapted from Brogowicz et al. (1990, p. 27).
(3) The Nordic Service Quality Model (NSQM)

Gronroos (1984), in addition to adapting the disconfirmation paradigm (that is, the difference between perception and expectation) to the measurement of service quality, proposed the Nordic Service Quality Model (NSQM) as an alternative, and identified two service quality dimensions, as shown in Figure 2.6. Dimension 1, or functional quality, represents how the service is delivered (that is, it defines the customer’s perceptions of the interactions that take place during service delivery), while Dimension 2 (that is, the service product) or technical quality reflects the outcome of the service act, or what the customer receives in the service encounter. Lassar, Manolis and Winsor (2000) observed that in high-contact services, such as private banking and wealth management, the technical and functional quality dimensions are better suited to predict levels of service quality and customer satisfaction when customers expect a high level of face-to-face contact and expert advice.

In addition, NSQM recognises impacts of image on service quality. Image is very important to service organisations. It can be built up by technical and functional quality of service including other factors such as pricing, public relations and relationships between service firms and their clients (Gronroos, 2006). Technical quality is defined as what the customer receives in interactions with the organisation. Functional quality is defined as how the customer receives the service. While technical and functional qualities are interrelated, Gronroos (2007) concluded that functional quality was more important to perceived service quality than other variables. Corporate image is more dependent on customer service, supplier interactions and word-of-mouth communication than traditional marketing activities. Furthermore, the performance of contact personnel compensates for both temporary problems with technical quality and overall lower technical quality (Gronroos, 1983). Gronroos (1988) emphasised that the following six criteria of good perceived service quality are the determinants that need to be considered when evaluating any organisation:

(i) professionalism and skill,
(ii) attitude and behaviour,
(iii) accessibility and flexibility,
(iv) reliability and trustworthiness,
(v) service recovery, and
(vi) reputation and credibility.

The service quality model is presented in Figure 2.6.

Figure 2.6: Nordic Service Quality Model

Source: Adapted from Gronroos (1984, p. 37).

(4) The Three-component model

Rust and Oliver (1994a) improved upon the earlier model that evolved from the technical and functional quality dimensions, and introduced the three-component model with three dimensions (Figure 2.7). This model consists of the service product (that is, technical quality), the service delivery (that is, functional quality) and the service environment. Although Rust and Oliver (1994b) did not test their conceptualisation, support has been found for similar models in retail businesses such as banking (McDougall & Levesque, 2000).
The three components of the model are discussed below.

(i) **Service product**

The service product involves service features or specifications of the service on offer (Rust & Oliver, 1994b). The service product has been termed the technical quality of what the customer is actually receiving from the service (Gronroos, 1990) and the outcome of quality (Parasuraman et al., 1985), because the service is evaluated after performance (Swartz & Brown, 1989). Sekaran (2000) defined service product as a service or a package of services that is typically provided for a targeted consumer. In the healthcare context, services are particularly complex in their characteristics, are heterogeneous in their range of medical specialisations and associated services, and ambiguous in the sense that the average customer has no technical knowledge with which to understand her or his particular needs or the services available to satisfy them. Thus, accepting this complexity, heterogeneity and ambiguity, the quality of the product should not only be assessed from the customer’s point of view, but also from the provider’s perspective (Sekaran, 2000).

(ii) **Service delivery**

The second element of service quality in this model is its delivery process. In any service organisation, including healthcare, perceptions of service quality are critical for both employees
and customers (Rust & Oliver, 1994b). In the context of healthcare, services are an intangible performance. Personal experiences can vary from one hospital to another and from one hospital department to another because of the nature of treatment and service. Evaluation of healthcare service quality is difficult compared to physical goods, because most goods are relatively high in search qualities, that is, qualities like colour, shape, size and appearance that a customer can see and assess prior to purchase. However, in this researcher’s view, healthcare can only be assessed on the basis of actual experience with the quality of delivery (for example, patient care, pain management, courtesy and personal treatment). Thus, enhancement of technological delivery capability, such as user-friendly tests and diagnostic equipment that is efficient and reliable, plays a crucial role in establishing the seamlessness of the service delivery to external customers. Finally, biomedical service tends to require more experience and to have more credence qualities when compared with retail service (Young & Wilkinson, 2002). For example, in this research, it is anticipated that most of the services of biomedical engineering departments in public hospitals would require biomedical science knowledge, technical expertise and local knowledge that all contribute to the multidimensional nature of quality-related performance (for example, data networking, patient monitoring systems and self-operating diagnostic equipment) and that involve considerable interaction between clinical staff and biomedical engineers and technicians.

(iii) Service environment

The third element of service quality, the service environment, can be classified into the internal and external environment. The internal environment includes corporate culture, organisational structure, customer generation and retention, employee support and reward systems. The external environment is another aspect of the customer’s experience of a service or tangible cues such as location (Bitner, 1990). Service environment relates to the effects of the surroundings on customer and employee beliefs, attitudes and performance, including ambience and service capability (Bitner & Hubbert, 1994). These tangible cues could be the appearance, confidence and courtesy of the front-line staff as well as written communication and customer billing (Douglas & Connor, 2003; Johnson & Fornell, 1991).
2.3.4 Customer satisfaction

In addition to service quality, customer satisfaction continues to be of significant managerial importance. There is mounting evidence to show that service quality is a crucial variable that leads to customer satisfaction (Oliver, 1981; Olsen, 2002). Healthcare is one of the many service industries where customer satisfaction has been an increasing focus of research. This is mainly because of the fact that the public healthcare sector is experiencing growing levels of competition from private healthcare providers (Cronin, Brady & Huit, 2000).

The next two subsections (2.3.5 and 2.3.6) will discuss theoretical definitions of customer satisfaction, followed by a review of customer satisfaction models.

2.3.5 Customer satisfaction definition

Despite extensive research in the years since Cardozo’s classic article “An experimental study of customer effort, expectation and satisfaction” (Cardozo, 1965), researchers have yet to develop a consensual definition of consumer satisfaction. For example, Rust and Oliver (1994a, p. 16) defined satisfaction as the “customer’s fulfilment response”, which is an evaluation as well as an emotion-based response to a service. It is an indication of the customer’s belief in the probability of a service leading to a positive feeling. Cronin, Brady and Huit (2000) defined service satisfaction using items that include interest, enjoyment, surprise, anger, wise choice and doing the right thing. For Johnson and Fornell (1991), “satisfaction is a customer’s overall evaluation based on the entire purchase and consumption experience with a product over time” (p. 274).

From the various definitions, it is clear that customer satisfaction has different levels of specificity. Although satisfaction with a product’s attributes, or a consumption experience, may be desirable, satisfaction with a service product or its delivery (the “core” service) is more fundamental, and therefore the focus of this research. As this research is specific to the healthcare industry, the customer satisfaction definition provided by Johnson and Fornell (1991) can be regarded as particularly appropriate: “satisfaction is a customer’s post-purchase evaluation of the overall service experience, including process and outcome. It is an affective state in which the customers’ needs during the course of the service experience have been met or surprisingly exceeded” (p. 274).
2.3.6 Customer satisfaction models

In the context of biomedical engineering, customer satisfaction is measured to determine how well biomedical engineering services meet or exceed internal customer expectations. These expectations often reflect many aspects of the biomedical engineering service and activities, and include how the department operates in the hospital environment. The measure of customer satisfaction is an overall psychological evaluation that is based on the internal customer experience. In the course of the literature review, the researcher analysed several customer satisfaction models relevant to the research topic, which are explored in more detail below.

(1) The Disconfirmation model

The Customer Satisfaction model in Figure 2.8 is based on the disconfirmation of expectation theory (Churchill & Suprenant, 1982; Oliver, 1981) from which the SERVQUAL model is derived:

\[
\text{Customer Satisfaction (CS) = Performance (P) – Expectations (E).}
\]

The model predicts a decrease in customer satisfaction as expectations increase, and vice versa. Expectations serve as a standard, or point of contrast, against which customers are presumed to evaluate performance information when judging satisfaction. However, this model may be problematic in the context of cumulative customer satisfaction as it holds that customers do not learn from experience, which is unlikely in the real world (Caruana, 2002; Johnson & Fornell, 1991).
Source: Developed by the researcher for this research.

(2) The Performance/perceived Satisfaction model

Some researchers have not been able to find a direct effect of expectations on consumer satisfaction. Instead, they found only an indirect effect through perceived quality and disconfirmation. This type of model predicts that customers’ perception of performance (P) of a product/service, and their expectations (E) regarding that performance, have positive effects on customer satisfaction (CS), as shown in Figure 2.9. Performance is defined as the perceived level of product or service quality relative to the price customers pay, that is, performance or value has a positive effect on customer satisfaction. Normally, expectation has a direct positive effect on customer satisfaction (Johnson & Fornell, 1991). However, when customers lack experience with a product/service, or because the product/service is complex, expectations have no effect on performance of the product or service. In general, service performance information is weaker than product performance information (Zeithaml, 1988). Given the heterogeneity or inherent variability of services relative to products (Gronroos, 1984), Anderson and Sullivan (1993) concluded that perceived service quality has a greater impact on customer service than is normally assumed in the traditional confirmation of expectation theory.
Figure 2.9: *Performance/perceived Satisfaction Quality model*

Source: Developed by the researcher for this research.

(3) **The Perceived Service and Satisfaction model**

This model, developed by Spreng and Mackoy (1996), attempts to enhance understanding of the constructs underpinning perceived service quality and consumer satisfaction (Figure 2.10). The model highlights the effects of expectations, perceived performance desires, desired congruency and expectation disconfirmation on overall service quality and customer satisfaction. In the context of biomedical engineering, these are measured through a set of ten attributes, namely:

(i) convenience in making an appointment;
(ii) friendliness of the staff;
(iii) the engineer’s listening skills;
(iv) the provision of accurate information by the attending engineer;
(v) knowledge of the engineer;
(vi) consistency of advice given;
(vii) the engineer’s willingness to assist with long-range planning;
(viii) the engineer’s helpfulness in choosing the right equipment for patient treatment;
(ix) the engineer’s demonstrated level of interest in safety; and
(x) the professional conduct of the engineer.

The perceived Service and Satisfaction model is presented in Figure 2.10.
(4) **The service quality, customer value and customer satisfaction integrative model**

This model’s focus is on the post-purchase decision process (Oh, 1999), or how clinicians review biomedical engineering services in the case of New Zealand public hospitals (Figure 2.11). Arrows in Figure 2.11 indicate causal directions. The model incorporates key variables such as perceptions, service quality, consumer satisfaction, customer value and intentions to repurchase (re-use biomedical services). Finally, word-of-mouth communication is conceptualised as a direct, combined function of perceptions, value, satisfaction and intention to continue using the biomedical engineering service.

The model provides evidence that customer value has a significant role in customers’ post-purchase decision-making process. It is an immediate antecedent to customer satisfaction and re-use of service intentions (Looy, Gemmel & Dierdonck, 2003). The model indicates that the
perceived price of the service has a negative influence on perceived customer value and no relationship with perceived service quality.
Figure 2.11: *Service quality, customer value and customer satisfaction model*

*Source:* Adapted from Oh (1999, p. 67).
The Six Sigma quality improvement model

Six Sigma was first mooted in the 1980s as the in-house quality improvement plan for Motorola, and subsequently grew into a multi-billion-dollar effort adopted by many world-class companies (Revere & Black, 2003). Theoretically, Six Sigma is a statistical concept representing the variability of a data set about its mean. If a data set is normally distributed (the Bell curve), then about 68% of the data will fall within one sigma of the mean, 95% within two sigma, 99.7% within three and 99.99% within four sigma (Revere & Black, 2003). Process capability measures the process mean with respect to the nearest customer specification limit. The statement that a process has a capability of four sigma therefore indicates that the non-conforming (or defect) rate is about six per hundred thousand. According to Revere and Black (2003), “Six Sigma evaluates the capability of a process to perform defect free, where a defect is defined as anything that results in customer dissatisfaction” (p. 379).

Conceptually, Six Sigma is the process of designing, improving and monitoring all of a firm’s activities to minimise and eliminate waste, while increasing customer satisfaction and profitability. A fundamental philosophy of this practice is to reduce variation in all product or service delivery processes. Six Sigma is a vigorous statistical process control used to enhance traditional quality tools such as CQI and TQM. Practitioners use statistical analysis and systematic problem-solving techniques that target the root cause of variations. Once these variations are identified, the process is modified and monitored to ensure that process improvement is sustained on a long-term basis. The methodology is now used in a variety of settings outside of manufacturing, including extensive use by financial services firms and aircraft designers. The primary goal of Six Sigma is to curb and eventually eliminate the number of defects that occur in a given process (Revere & Black, 2003). Furthermore, according to industry experts (Lazarus & Bulter, 2001), integrating Six Sigma with existing CQI efforts could lead healthcare organisations to achieve exponential improvements in the area of patient safety.

The Continuous Quality Improvement (CQI) model

Quality improvements (QI), often used interchangeably with TQM, or CQI, are two frequently heard buzz-words throughout the service industries including healthcare (Donabedian, 1980). Furthermore, CQI, also commonly known as the Donabedian model in the healthcare industry, focuses on processes, recognises both internal and external customers and promotes the
need for objective data to analyse and improve processes. It can be said that much of the CQI concept has been developed from the work of Donabedian, a well-known physician who first created a model for assessing quality that has now become the standard in the healthcare services field. This model proposes that healthcare quality should be examined in three domains: structure, process and outcome (Donabedian, 1980) (Figure 2.12).

Figure 2.12: Continuous Quality Improvement model (Donabedian model)

Source: Adapted from Donabedian (1980, p. 81).

The intensity of global competition has led to an even greater interest in continuously improving products, services and processes (Garvin, 1993; Parasuraman et al., 1985). While the importance of values for the success of CQI is widely recognised, little research has been conducted specifically in this area. Related values are usually addressed within the context of TQM. These values include humility (Gibson, 1995), openness (Steyn, 1999; Roberts, 1992), respect for people (Mehta, 1999), responsibility and integrity (Goetsch & Davis, 2000), empathy, responsiveness (Parasuraman et al., 1985), trust (Wilson, 1995; Drucker, 1974) and cooperation (Oakland, 1997). These values provide the answers to the fundamental questions of “why should we continuously improve?” or “what values should we want to improve?” Since the objective of CQI is customer satisfaction, it is arguable that the values driving CQI are basically the same values that ensure commitment to customer satisfaction. These values enable employees to achieve the objective of continuous improvement, which is customer satisfaction. Since the objective of continuous improvement is customer satisfaction, the basic values that establish and
reinforce commitment to customer satisfaction should be the driving values of continuous improvement.

In recent years, other models have emerged that overlap with the CQI model. Some of these models are Six Sigma, Lean, TQM and the SERVQUAL model. All these models overlap with each other in one or more ways. All models share a common goal of removing waste and reducing costs in one way or another. Factors such as customer feedback, communication, traceability and usage of quality tools are common between the models.

However, each model has slightly different emphases on how it can be applied in different types of businesses. Researchers have attempted to find a perfect model for measuring service quality to cover all factors and to provide answers that can meet any organisation’s requirements. Researchers Seth, Deslmuck and Vrat (2005), Ovretveit (2009) and Chassin and Loeb (2011) found that all models have advantages and disadvantages. Therefore, researchers could not unanimously agree to any one particular quality model that would work for all organisations. For instance, Six Sigma has found its place in healthcare by providing a focus on reducing variability within standard processes, but it has its disadvantages. Its focus on one process may alter another process, because Six Sigma does not normally recognise several issues at once. The Six Sigma model is designed to be applied to all aspects of the production and planning process; however, it may create rigidity and bureaucracy that can result in delays and can stifle creativity.

In the case of the Lean model, the single biggest criticism is that this model maintains a constant focus on improvement and elimination of waste. Hanna and Sethuraman (2005) report that constant focus on improvement and elimination of waste can become an obsession and can cause stress in the workforce. This constant focus can make the workplace too clinical and impersonal, with workers under relentless pressure to do better than before. While such pressures may lead to workers stepping out of their comfort zones and assuming a sense of urgency, it also increases stress levels considerably, and high stress levels can have detrimental effects on productivity and efficiency.

Similarly, one can say that the SERVQUAL model focuses on the processes of service delivery, not on the outcomes of the encounter. Although SERVQUAL shares the same goals as other models mentioned above, it fails to draw on established economic, statistical and psychological theory. Ladhari (2009) reported that the SERVQUAL model is based on a disconfirmation paradigm rather than on an attitudinal paradigm.
The CQI model is, overall, an effective way for a company to operate; however, as a business strategy, this model does have its own disadvantages as well. Training employees to work in a continuous improvement environment takes time and money. Aatons, Hurlburt and Horwitz (2011) reported that a number of factors contribute to the sustained interest and enthusiasm for CQI in the healthcare industry, despite the limited empirical evidence delineating its impact and cost. The first argument for CQI is direct impact on internal quality, such as improvement to processes, procedures and systems. The second argument for CQI is that CQI systems can be designed or redesigned to reduce costs at the same time as they are also used to make improvements. The third argument relates to the set of benefits associated with the CQI plan that empowers employees in healthcare through participation in decision making. For instance, organisations such as biomedical engineering departments using a top-down approach can involve all quality elements to work hand-in-hand with each other. Such organisations can also use the CQI approach to work concurrently and continuously to build organisational commitment to quality.

In conclusion, it can be said that a considerable amount of research has been done in the field of service quality and customer satisfaction (Bolton & Drew, 1991; Gronroos, 2001), and in the field of product quality (Garvin, 1988). After reviewing the literature, it can also be said that CQI and SERVQUAL service quality and customer satisfaction models are popular in comparison to other models. Continuous quality improvement and SERVQUAL models have generally been considered to be the most useful methods for researchers and businesses to evaluate service quality and customer satisfaction.

How these models apply to biomedical engineering’s service to internal customers in New Zealand’s public hospitals remains unknown, because only limited research in this area has been undertaken to date.

2.4 Identification of research gaps requiring investigation

In summary, the literature review identified the following research gaps.

(i) The literature review failed to reveal any systematic study of biomedical technology management in New Zealand public hospitals. Although the enablers of TQM are identified, they have not yet been integrated into a model, nor has any
suitable model been suggested that can be used by biomedical engineering departments in New Zealand public hospitals for managing medical technology.

(ii) No studies were found that investigate the effectiveness of current biomedical equipment management systems employed by New Zealand public hospitals.

(iii) No service quality and customer satisfaction study has been conducted specifically on the biomedical engineering department of any New Zealand public hospital.

(iv) No recommended model for service quality and customer satisfaction has been developed specifically for biomedical engineering departments and their internal customers in public hospitals exists.

From the gaps identified in the literature review, the following research questions were developed.

**Main research question**

*How can TQM benefit biomedical engineering departments in New Zealand public hospitals in managing medical technology and in improving service quality and customer satisfaction?*

**Sub-research questions**

(i) *What are the current systems used in New Zealand public hospitals for managing medical technology?*

(ii) *How are service quality and customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?*

(iii) *Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals?*
**Epilogue**

This chapter has reviewed academic literature in relation to the research focusing on TQM as a model of biomedical technology management and the key issues involved in service quality and customer satisfaction in New Zealand public hospitals. The literature review was discussed in three sections. The first section reviewed the theoretical aspects of the literature on TQM. The second section reviewed literature on quality in healthcare, with the main focus on biomedical engineering. The third section focused on the interaction between different aspects of service quality and customer satisfaction. Various service quality and customer satisfaction models that relate closely to this research were also reviewed.

The review also identified gaps in the literature defining biomedical technology management, as discussed in Section 2.4 above. The gaps identified in the literature provide the foundation for reconfirming the research questions. These research questions will be examined by employing case study methodology, which is described in Chapter 3.
CHAPTER 3: METHODOLOGY

Prologue

This chapter describes the research paradigm, and examines and evaluates methodologies to be used for this research. There are eight sections in this chapter. The chapter begins with an introduction followed by selection and justification of the research paradigm. The next section discusses the research design and methodology. The data collection strategy, limitations of the case study methodology and ethical considerations are addressed in sequence. The chapter finishes with a summary and epilogue.

The structure of Chapter 3 is shown in Figure 3.1.
Figure 3.1: Structure of the chapter

Prologue

Selection and justification of the research paradigm

Methodology

Criteria for judging case study design

Criteria for case selection

Data collection

Data analysis

Limitations of methodology

Ethical considerations

Epilogue

Source: Adapted from Perry (2001).
3.1 Selection and justification of the research paradigm

This section elaborates on the research paradigm, describes the approach to theory construction and justifies the choice of research design. Generally speaking, paradigms ask what the research problem is and which methodological approach is most suitable to handle the problem. Crotty (1998) suggested that a researcher should consider four questions when designing the research framework.

(i) What epistemology (theory of knowledge) informs the researcher (examples: objectivism or subjectivism)?

(ii) What theoretical perspective lies behind the methodology in question (examples: positivism, post-positivism, interpretive or critical theory)?

(iii) What methodology (plan of action) governs the choice and use of methods (examples: critical theory, experimental research, survey research or ethnography)?

(iv) Which methods (techniques) does the researcher propose to use (examples: questionnaire, interview or focus group)?

To develop a research map with the above ideas in mind, it is desirable to understand different philosophies and methodologies used in business research. In business research, there is a spectrum of research methods available. For each research method, there is an underpinning philosophical view regarding how the world is viewed (ontology), the relationship between the researcher and the researched (epistemology) and the technique (methodology) used by the researcher (Easterby-smith, Thorpe & Lowe, 1991). Table 3.1 presents a comparison of alternative paradigms.
Table 3.1: *Comparison of alternative research paradigms*

<table>
<thead>
<tr>
<th>Item</th>
<th>Objective</th>
<th>Subjective</th>
<th>Interpretative</th>
<th>Phenomenology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ontology</strong> (form and nature of reality)</td>
<td>Naïve realism:</td>
<td>Critical realism:</td>
<td>Historical realism:</td>
<td>Relativism:</td>
</tr>
<tr>
<td></td>
<td>‘Real’ reality is only imperfectly and probabilistically apprehensible because of human mental limitations and the complexity of the world.</td>
<td>‘Reality’ is shaped by social and other forces, and research should emancipate the perceptions of co-researchers/participants.</td>
<td>‘Reality’ is constructed by people (and a researcher).</td>
<td>Therefore, there is no truth.</td>
</tr>
<tr>
<td><strong>Epistemology</strong> (nature of the relationship between the researcher and reality)</td>
<td>Objectivist:</td>
<td>Modified objectivist:</td>
<td>Subjectivist:</td>
<td>Subjectivist:</td>
</tr>
<tr>
<td></td>
<td>‘Disinterested scientist or one way mirror’ observer</td>
<td>Observer with some level of participation as dualism is not possible to maintain.</td>
<td>‘Transformative individual’ within a group</td>
<td>‘Passionate participant’</td>
</tr>
<tr>
<td><strong>Common methodologies</strong> (techniques of collecting data)</td>
<td>Experiments/surveys:</td>
<td>Case studies/convergent interviews/structured interviews:</td>
<td>Action research</td>
<td>In-depth, unstructured interviews; participant observation</td>
</tr>
<tr>
<td></td>
<td>Verification of hypotheses; chiefly quantitative methods</td>
<td>Triangulation, interpretation of research issues, mainly qualitative methods</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Sources:* Adapted from Guba and Lincoln (1994); Easterby-Smith et al. (1991); Perry, Alizadeh and Riege (1997).
To determine the most appropriate method for this research, a brief integrative review of different research methods is presented below.

(i) A positivist holds the opinion that the processes of the external world and their property can be objectively observed, defined and measured, rather than “subjectively inferred through sensation, reflection and intuition” (Easterby et al., 1991, p. 22). The happenings of the world are socially constructed. That is, one should try to understand why different people have different experiences of the same situation, rather than trying to look for external causes and fundamental laws to explain their behaviour. A positivist view is appropriate in natural science where there is arguably a single, apprehensible reality whose nature can be known and categorised in order to be defined and measured (Perry, Riege & Brown, 1999). Under the positivist paradigm, the researcher is viewed as independent of the research he or she is conducting. The researcher’s focus is only on description, explanation and the uncovering of facts (Ticehurst & Veal, 2000). This is because the researcher sees the world as an external and objective phenomenon. In essence, positivist paradigm researchers will use facts and observations to explain behaviours, using theories and models they have developed (Ticehurst & Veal, 2000).

A positivist approach may not be suitable in social science research where each situation is unique, and a person within a situation can give different responses depending on the nature of reality as he/she perceives it (Ticehurst & Veal, 2000). Also, where the emphasis is on exploring the structure and the process of a phenomenon, there are many variables which interact with one another. Therefore, it may not be possible to establish a cause-and-effect relationship amongst all the variables. However, wherever it is possible to identify and define constructs that are invariant across situations, a positivist approach has the advantage of being generalisable and reliable.

(ii) Realism strives towards an understanding of the common reality of an economic system in which people operate independently (Perry, Alizadeh & Riege, 1997). Much like positivism, realism holds that there is a reality, but it is not possible to comprehend that reality fully and perfectly (Guba & Lincoln, 1994). Like critical theory and constructivism, realism is concerned with more aspects of reality than those which can be sensed (Perry et al., 1997). However, realism differs from constructivism and critical theory in that it does not hold perception as reality, suggesting instead that perception is a window into reality, from which a picture of
reality can be triangulated with other perceptions (Perry et al., 1997). Realists do not accept the possibility of a ‘factual’ account of events and situations, seeking instead a relativistic, albeit shared, understanding of the phenomena (Orlikowski & Baroudi, 1991). For realists, there is one reality with a ‘real’ world to discover, even if it may only be imperfectly and probabilistically apprehensible (Guba & Lincoln, 1994). Thus, the aim of the researcher should be to apprehend that reality as closely as possible through the widest possible critical examination. In order to arrive at an objective account of events, the realist paradigm depends on triangulating several perceptions of that reality to capture a better picture of the phenomenon (Perry et al., 1997). Triangulation should be used as a way of falsifying (rather than verifying) hypotheses. The epistemology of realism means that the researcher is neither isolated from the research (as with positivism), nor involved in the findings in a passionate or an emancipating way. Rather, the researcher is part of the research process, but triangulation allows the researcher to remain objective. He or she cannot remain completely value-free but can aim to be value-aware (Perry et al., 1997).

(iii) Critical theory is related to the critique and transformation of social, political, cultural, economic, and ethnic and gender values over an extended period of time. Critical theorists contend that knowledge consists of a series of structural/historical insights that will be changed over time (Guba & Lincoln, 1994). The research inquiry within this paradigm is concerned with long-term ethnographic and historical studies of organisational processes, structures and changes. Therefore, assumptions made by critical theorists are subjective, and their knowledge is grounded in social and historical routines that are value-dependent and not value-free (Anderson, 1986; Peter, 1992).

(iv) Constructivism adopts a critically relativist ontology. Truth is perceived as the construction of a particular belief held in a particular context. As Peter (1992) noted, “to state that a proposition is true is to state a subjective belief that one holds about the proposition” (pp. 76-77). Constructivists believe that ‘reality’ consists of multiple realities that are socially and experimentally based rather than objectively determined, and are based on the intangible mental constructions of the individuals conducting the research. Constructivism explores the ideologies and values that lie behind the findings, and in this respect, constructivism is similar to critical
theory. Knowledge is created in the interaction between and amongst interviewers and respondents (Guba & Lincoln, 1994). Constructivists see that “perception is reality” (Perry et al., 1997, p. 8). Therefore, the constructivist paradigm emphasises that research is a product of the values of researchers and cannot be independent of them (Mertens, 2005).

3.1.1 Justification of research paradigm

The realist paradigm was considered appropriate for this research because it allows a clear understanding of the complexity of ‘real world’ service quality and customer satisfaction. The realist paradigm repudiates the notion of many realities and insists that there is one reality (Healy & Perry, 2000), even though it is imperfectly and probabilistically apprehended (Guba & Lincoln, 1994). This paradigm asserts the difference between reality and perceptions of reality.

Perception is not considered to be reality (Perry et al., 1999). Many perceptions need to be triangulated to obtain a better picture of reality (Perry et al., 1999). Given the complexity of the TQM phenomenon, the realist paradigm allows the researcher to triangulate many perceptions as a ‘window’ through which to gain a better picture of reality (Perry et al., 1997; Perry et al., 1999) in TQM, especially with regards to service quality and customer satisfaction. Through triangulation, utilisation of qualitative techniques, taking an interpretative approach and collecting situational information in the natural setting, the researcher was able to obtain a clearer understanding of reality in New Zealand public hospitals.

3.2 Methodology

Typically, research designs can be divided into two kinds of methodologies: qualitative and quantitative (Ticehurst & Veal, 2000). Both have unique characteristics and are appropriate in different situations.

(1) Quantitative research

Generally, the quantitative approach provides facts about phenomena and involves statistical analysis. The quantitative approach usually involves large numbers of people or organisations, and uses techniques such as computer software to analyse data collected from surveys, observation or secondary sources (Zikmund, 2000). Quantitative research methodology
primarily comprises numbers used to define variables, statistics, hypotheses, replications and scales (Neuman, 2006). The quantitative approach is used to support or reject hypotheses or explanations of phenomena rather than to explain why and how phenomena occur (Yin, 1994). One of the disadvantages of a quantitative approach is that, while it gives an objective view/perspective, not everything can be quantified. Even when the scale is carefully constructed, there is no continuum (Zikmund, 2000).

(2) Qualitative research

In contrast, qualitative research can be defined as a technique that seeks to describe, decode and translate phenomena in terms of meaning rather than frequency (Hyde, 2000). A qualitative approach is one in which the inquirer often makes knowledge claims based primarily on constructivist perspectives, or advocacy/participatory perspectives, or both (Creswell, 2003). Mertens (2005) suggested that keywords associated with qualitative methods include complexity, context exploration, discovery and inductive logic. Qualitative research uses strategies of inquiry such as narratives, phenomenologies, ethnographies, grounded theory studies or case studies (Creswell, 2003). This allows the researcher to gather information and explore issues in depth to obtain a clearer understanding of reality in New Zealand public hospitals, especially when the researcher is interested in a less structured format with fewer respondents than in a quantitative approach (Bellenger, Bernhardt & Goldtucker, 1989). Furthermore, qualitative research uses words, sentences and paragraphs rather than numbers (Neuman, 2006). Unlike quantitative methods, which are used to test a theory and make generalisations about populations, qualitative methods are used to build theory and to allow the gathering of deep and rich information (Eisenhardt, 1989), which is considered important, relevant and significant (Yin, 1994), and the qualitative approach therefore offers greater insight (Easterby-Smith et al., 1991). Qualitative research usually uses a small sample and has the power to provide insights rather than measurements (De Ruyter & Scoll, 1998).

The limitations of qualitative research are that it tends not to be generalisable to a large population and to result in fairly subjective conclusions. As a consequence, the two kinds of methodology are different in both a practical and philosophical sense (De Ruyter & Scoll, 1998).
3.2.1 Justification for the preferred methodology

For this study, a qualitative research methodology was selected for two reasons. First, the nature of the data are verbal, and the research problems are focused on the questions “how”, “why” and “what”. Therefore, a qualitative approach is suitable for this research. In particular, there is fairly wide consensus that qualitative research is a naturalistic, interpretative approach concerned with understanding the meanings that people attach to phenomena such as actions, decisions, beliefs and values (Snape & Spencer, 2003). Second, a qualitative approach enables the researcher to get close to the object of enquiry and to gain an in-depth understanding of the numerous factors underlying the business strategies used by biomedical engineering departments in New Zealand public hospitals. Using a qualitative approach, the researcher can obtain ‘real’, ‘rich’ and ‘deep’ information that is considered important, relevant and significant (Yin, 1994).

Furthermore, in this research the prime method of data collection is the face-to-face interview. Face-to-face interview encourages interviewees to share their experiences and to provide as much information as is possible in a free-flowing environment (Cooper & Emory, 1995; Neuman, 2006). In this research, the data are verbal and descriptive in nature, where interviewees explain the processes, systems and activities of biomedical engineering within the hospitals. Therefore, the qualitative method was more appropriate for this research.

3.2.2 Justification for using case study methodology

Robson (2002, p. 178) defines case study as “a strategy for doing research which involves an empirical investigation of a particular contemporary phenomenon within its real life context using multiple sources of evidence”. Given that this research is exploratory, the researcher decided that the use of a case study approach would enable the collection of open-ended, emerging data from which themes could then be developed (Creswell, 2003).

Kidder (1982) suggests that case studies can be used to provide descriptions. The more the object of the study is a specific, unique, bounded system, the greater the usefulness of the epistemological rationale (Stake, 2005). The primary advantage of the case study is that an entire organisation or entity can be investigated in depth and with meticulous attention to detail (Zikmund, 2003). A case study may be simple or complex, but the case is specific (Stake, 2005).

There are three major reasons for using the qualitative research methodology of case study for this research:
(i) Gummesson (2000) suggested that a case study research methodology has particular value in the applied sciences where the research aim is to study a problem in detail, place it in context and understand stages in a process. This research aims to discover and describe the answer to the question, *How can TQM benefit biomedical engineering departments in New Zealand public hospitals in managing medical technology and in improving service quality and customer satisfaction?* This is not a question for statistical analysis; this research topic aims to undertake an in-depth study to explore the ‘real world’, and therefore case study is appropriate.

(ii) Case study enables the researcher to examine “how” and “what” questions in a research situation in which it is not critical that the researcher totally controls the research setting, and also in which the research problem is concerned with a contemporary issue (Yin, 1994).

(iii) This study is conducted in healthcare institutions. It examines the constraints of everyday life, namely biomedical engineers’ and technicians’ perceptions of service quality and customer satisfaction at the present time. The data are descriptive in nature. Therefore, case study is appropriate for this research (Mertens, 2005).

### 3.3 The criteria for judging case study design quality

This section examines how case study research methodology meets four formal research criteria: construct validity, internal validity, external validity and reliability (Yin, 1994). Each of these criteria is discussed and applied within the context of this research design. The most significant criteria for evaluation of business research are reliability and validity (Neuman, 2006). Unlike quantitative-oriented writers, qualitative-oriented writers tend to place less importance on such issues, and it is largely up to the researcher to decide whether it is appropriate to apply such criteria in evaluating the research (Bryman & Bell, 2007). Yin (2003a) argued that because case study research is one form of empirical social research, the widely recognised tests to establish the quality of social research should also apply to case studies. Yin’s (2003a) four criteria are summarised in Table 3.2 below.
Table 3.2: *Four tests for judging the quality of case studies*

<table>
<thead>
<tr>
<th>Validity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Construct validity</td>
<td>Establishing correct operational measures for the concepts being studied.</td>
</tr>
<tr>
<td>Internal validity</td>
<td>Establishing a causal relationship, whereby certain conditions are shown to lead to other conditions, as distinguished from spurious relationships (this applies to explanatory or causal studies, not descriptive or exploratory studies).</td>
</tr>
<tr>
<td>External validity</td>
<td>Establishing the domain to which a study’s findings can be generalised.</td>
</tr>
<tr>
<td>Reliability</td>
<td>Demonstrating that the operations of a study – such as the data collection procedures – can be repeated, with the same results.</td>
</tr>
</tbody>
</table>

*Source:* Adapted from Yin (2003a, p. 34).

### 3.3.1 Construct validity

Construct validity involves establishing correct operational measures for the concepts being studied. There are three strategies used to increase the construct validity of case research (Yin, 2003a). First, Yin (2003a) suggests that multiple sources of evidence are used so that the inquiry can be conducted in a converging manner. Second, Yin (1994) proposed that a chain of evidence be established so that the evidence is able to be followed from the beginning of the research to its conclusion. For this, the researcher used research codes for referencing all sources of information. This provided evidence of the original sources from where the information was obtained. The researcher also used quotations from original sources in the data analysis in order to present data that ‘tell it like it is’ (Yin, 1994). Third, the draft report of the case study research was reviewed by a research supervisor so that ambiguous descriptions could be clarified.
3.3.2 Internal validity

Often used for explanatory or causal research, internal validity requires that there be no internal errors in the design of the research project (Neuman, 2006). Yin (2003a, p. 34) identified four strategies to enhance internal validity in research design:

(i) identify and match patterns;
(ii) build explanations from congruent data;
(iii) address rival explanations; and
(iv) use logic models to reach conclusions.

In this research, the researcher used pattern-matching and cross-case analysis strategies to deepen understanding of the collected data and to build a picture of reality through examination of similarities and differences across cases. With this process, the researcher discerned a pattern more easily and quickly than by merely describing each case (Miles & Huberman, 1994).

Alizadeh (1996) suggested that if patterns correspond, such results can confer internal validity to case studies. The analytical tactic of pattern-matching also illustrated the concept of internal validity by displaying the patterns of data in figures and tables, and explained the similarities and differences of emerging patterns. This pattern-matching logic compared an empirically based pattern with a predicted one.

3.3.3 External validity

External validity or transferability is defined as the extent to which research findings can be transferred or generalised (Lincoln & Guba, 1985; Yin, 1994). Within the context of this research design, external validity is achieved by using multiple-case design. First, through triangulating multiple sources of data from multiple case studies, data from different cases were used to corroborate and elaborate on the research questions. Second, care was taken to select the appropriate cases, as well as qualified participants (experienced biomedical engineers, technicians and administrators) to ensure external validity in determining a suitable and effective service and customer satisfaction model for biomedical engineering.
3.3.4 Reliability

Reliability suggests that the findings of a study will be repeated or will re-occur if the study is conducted again in an identical or analogous context (Neuman, 2006). The reliability concern in a case study is to be sure that the same findings or conclusions will be reached when two researchers conduct the same case study, following the same procedures, but in a tandem manner (Yin, 2003a). Yin (2003a) also suggested the use of a case study protocol and the development of a case study database in order to achieve reliability in case study analysis. A case study database needs to be established to collate the evidence used in analysis of case research, for instance the interviewer’s guide, interview transcripts and interview recordings. For this research, the researcher developed an interview schedule and guide that included the research questions and a set of probe questions designed to answer the research questions, as shown in Appendix 2. The interview transcripts and tape recorded data from the interviews were loaded into the database for analysis.

3.4 The criteria for case selection

This section examines the type of case designs available for case selection. It also explains the conditions that the researcher believes are most suitable for this choice. Yin (1994) suggests that there are four types of case research design (Table 3.3).

Table 3.3: Four types of case research design

<table>
<thead>
<tr>
<th>Type</th>
<th>Single case design</th>
<th>Multiple case design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holistic (single unit of analysis)</td>
<td>Type 1</td>
<td>Type 3</td>
</tr>
<tr>
<td>Embedded (multiple units of analysis)</td>
<td>Type 2</td>
<td>Type 4</td>
</tr>
</tbody>
</table>

Source: Adapted from Yin (1994, p. 39).

According to Yin (1994), Type 1 involves a single case design with a holistic or single unit of analysis (column 1, row 1). Type 2 is a single case design with embedded or multiple units of analysis (column 1, row 2). Type 3 involves multiple case designs with a single unit of analysis (column 2, row 1), and Type 4 involves multiple case designs with multiple units of analysis (column 2, row 2).
A case is considered to be holistic if it contains only one unit of analysis, or embedded if it contains multiple units of analysis (Perry, 2001; Yin, 1994). If the research is about what a person can do, the unit of analysis is an individual. Sometimes researchers use small cases that are a part of a big case that is the unit of analysis for a study. These parts, or sub-cases, are called “embedded cases”, because they are embedded in the bigger unit of analysis (Carson, Gilmore, Perry & Gronhaug, 2001). A holistic design is used when the research requires information at a broad or ‘abstract’ level, or when logical subunits are not identifiable (Yin, 1994). For the current study, it was necessary to ask which case type would be suitable and whether the researcher should use single or multiple case studies.

3.4.1 Single versus multiple case studies

There are no precise guides to the number of cases that should be used in a qualitative case study design. Lincoln and Guba (1985) suggested sampling cases until saturation is reached. Patton (1990) claimed that there are no rules for sample sizes for qualitative research. However, there are two common approaches for case study research, single case study and multiple case studies. Both approaches have their own distinct characteristics, and are used in different situations.

This research does not meet the criteria for adopting a single case-study approach because there is no unique case. Therefore, multiple case design Type 3 (Table 3.3) is the most suitable for this research, because it consists of multiple cases within a single unit of analysis (cases: four public hospitals; single unit of analysis: each biomedical engineering department). Researchers and authors present different views in support of the use of multiple case studies.

(i) Multiple case studies are a methodologically rigorous approach built upon replication logic (Parkhe, 1993; Yin, 1989).
(ii) Multiple case studies offer a full suite of evidence (Yin, 1994).
(iii) Multiple case studies can be used for theory generation (Gersick, 1998).
(iv) Multiple case studies can be used for descriptive studies and investigations of complex behavioural phenomena (Yin, 1989).
(v) Multiple case studies offer a compelling triangulation of evidence (Bonoma, 1985; Eisenhardt, 1989).
3.4.2 Number of case studies used for this research

According to Patton (1990), the size of the sample depends on what the researcher wants to find out, how the findings will be used and what resources researchers have for the study, including time and budget. For this study, the researcher considered the views of several authors in regard to number of cases. For example, Miles and Huberman (1994) recommended that more than 15 cases make a study ‘unwieldy’, while Lincoln and Guba (1985) asserted that in selection, ‘redundancy’ should be avoided, and also recommended that three cases are sufficient, depending on the existence of extensive background cases and collected industry research. Yin (1994) also suggested that in any research, a selection of the optimal number of cases is a critical decision (Yin, 1994). Eisenhardt’s (1989) view is that while there is no ideal number of cases, a number between four and ten cases is ideal. With fewer than four cases, it is difficult to generate theory with much complexity, and the study’s empirical grounding is likely to be unconvincing. Further, Carson et al. (2001) suggested an upper limit of twelve cases, because of the high costs involved in qualitative interviews, and the quantity of qualitative data which can be effectively assimilated.

Based on experts’ views, the researcher decided to use four case studies. The chosen cases are four public hospitals in the North Island of New Zealand. These hospitals provide a wide range of medical services and have the ability to carry out complex medical procedures using complex technology. They have large quantities of medical equipment and employ biomedical engineers and technicians. The fact that the researcher resides in the North Island meant that access was relatively easy and that the research was therefore more cost effective.

Four participants from each biomedical engineering department were chosen for interview. The participants were chosen from the following hierarchical levels: (1) manager, (2) supervisor, (3) senior biomedical engineer, (4) biomedical engineer and (5) technician. In some hospitals, participants from all five hierarchical levels could not be interviewed because all hierarchical levels were not present.

A total of sixteen interviews were conducted (with four participants from each hospital). The researcher also collected data by reviewing departmental documents and by observing biomedical engineering departments’ day-to-day activities in all four case studies (public hospitals).
3.5 Data collection

This section describes the procedures followed for the collection of data, and consists of five subsections: case study protocol, data collection techniques, data triangulation, case study transcripts and data documentation and storage.

3.5.1 Case study protocol

A case study protocol is essential for multiple case design Type 3 (described in Section 3.3.4) in order to improve the reliability of the study. This provides a framework that enables replication of the research process (Yin, 2003b). The case study protocol for this research involved an overview of the case study, which included the research objectives, case study questions and relevant readings (the research objectives and research questions are presented in the introductory chapter).

Field procedures involved presenting the credentials of the researcher, including ethical approval from the university (Southern Cross University, Australia) and approvals from the hospitals and the biomedical engineering departments to conduct the research. An assurance of confidentiality was also important for gaining the cooperation and trust of interviewees. To establish confidentiality, the researcher sent a cover letter to each biomedical engineering department outlining the researcher’s background and the research objectives, and asking permission to interview staff members (Appendix 1). The researcher also provided a consent form to each interviewee to signify their agreement to participate in this research (Appendix 2). The researcher also developed specific questions to enable the collection of data to answer the research questions (Appendix 3).

3.5.2 Data collection techniques

To answer the main research question, it was necessary to obtain responses to three sub-questions. For this research the researcher used three techniques to collect data that answered the sub-research questions (Table 3.4).
Table 3.4: *Data collection techniques*

<table>
<thead>
<tr>
<th>Research questions</th>
<th>Techniques used and data sources</th>
</tr>
</thead>
</table>
| 1 What are the current systems used in New Zealand public hospitals for managing medical technology? | **Techniques:**  
  * Face-to-face interviews.  
  * Documentation review: analysis of organisational charts, departmental quality manuals, job descriptions, reporting methods, protocols and system procedures, job instructions, records and traceability, and operational documents. |
| 2 How are service quality and customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals? | **Techniques:**  
  * Face-to-face interviews  
  * Participants’ responses to set interview questions (Appendix 3).  
  * Documentation:-review of processes, protocols and procedures.  
  * Observation (partial participation):-actions, behaviours and communication that took place in biomedical engineering departments.  
  * Day-to-day activities of biomedical engineering staff and their relationships with clinicians and other support staff in the hospital. |
| 3 Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals? | **Techniques:**  
  * Face-to-face interviews  
  * Observation (collected data was compared with theoretical models from the literature review) |

*Source: Adapted from Collis and Hussey (2003, p. 151).*
The methods illustrated in Table 3.4 are discussed below:

(1) **Face-to-face interviews**

In this research, face-to-face interviews were the prime method of data collection. The interviews were conducted at either the participant’s workplace, a hospital meeting room or in the cafeteria during the lunch hour and after working hours. Face-to-face interviews provided the opportunity to encourage completeness of response, to observe the non-verbal behaviour of participants, to correct misunderstandings arising from written questions and to inquire about more complex questions (Creswell, 2003; Neuman, 2003). As recommended in Bryman (2004), the researcher developed an interview guide containing semi-structured questions (Appendix 3).

Interviewees selected for this study were from four case studies (four hospitals). Interviewees were engaged in biomedical engineering activities and included managers, supervisors, biomedical engineers and technicians. All interviewees were asked the same set of questions to ensure that no significant data were lost and to enable cross-data checks. The interview duration ranged from 35 to 45 minutes for each interviewee. The data gathered in the interviews contributed towards answering all three sub-research questions.

(2) **Documentation review**

This study also collected data from internal documents, such as organisational charts, departmental quality manuals, departmental procedures and protocols, job descriptions, reporting templates for medical equipment servicing, quality reports, recommended communication methods and biomedical equipment management records. Data from these documents were used to support or confirm data collected during interviews.

The information from the organisational charts, quality manuals and job descriptions demonstrated the organisational structure of biomedical engineering departments, and departmental documents assisted in answering sub-research question 1: *What are the current systems used in New Zealand public hospitals for managing medical technology?* Information gathered from procedures and protocols, monthly service reports, quality and management reports and methods of complaint reporting and investigation demonstrated how well service quality and customer satisfaction were currently being achieved by biomedical engineering
departments in public hospitals. Information from these documents was also used to confirm data collected from face-to-face interviews.

(3) Observation

Direct observation is used in business research and is a systematic process of recording the behavioural patterns of people, objects and occurrences without questioning or communicating with the individuals under investigation (Zikmund, 1997). Sometimes, it is impossible to fully understand the programme under study without personally experiencing it (Patton, 2002). There are three main types of observation:

(i) non-participant,
(ii) participant, and
(iii) partial-participant observation (Collis & Hussey, 2003).

In non-participant observation, the observer is separated from what is observed, and the subjects of the research may or may not be aware of being observed. In a participant observation, the investigator remains as non-committal as possible, and in partial participation, the investigator engages partially with the subject to gain an understanding of the activities (Bryman & Bell, 2007; Collis & Hussey, 2003).

In this research, the technique of partial-participant observation was used. As observer, the researcher played a passive role and there was no attempt to control or manipulate any situation. The intention was to observe departmental staff in action, confirm data collected from interviews and gather any additional information that may have been missed during the interviews. Partial participation enabled the researcher to ask questions about what task was carried out and why, so that answers could be related to departmental documents and interviewees’ comments. This observational technique was valid, because it provided insights into the nature of the phenomena observed (Cavana, Delahaye & Sekaran, 2001). Further supporting this approach, Cavana et al. (2001) cited the following advantages in undertaking observational studies.

(i) Information gained through observation events is generally more reliable and free from respondent bias.
(ii) Environmental influences on specific outcomes are easier to note in observational studies.

(iii) Groups of individuals from whom it may be difficult to otherwise obtain information may be easier to observe.

In this study, the researcher observed day-to-day activities of biomedical engineering departments for six weeks. Observations included such things as the staff attitudes, motivation, the planning of daily activities and handling of service requests, acceptance checks, day-to-day handling and management of equipment, internal and external customer relationships and customer communication. Notes were taken, and the information gathered from observations was triangulated against data collected from other sources in this research to confirm that the information provided was consistent. The information gathered through observation assisted in answering sub-research question 2: ‘How are service quality and customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?’

(4) Literature review

Information obtained during the literature review was weighed against information obtained from face-to-face interviews, documents and direct observation in order to answer sub-research question 3: Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals?

3.5.3 Data triangulation

Triangulation is a process of observing something from multiple positions (Neuman, 2003). Neuman (2003) pointed out that when this is applied to social research, it is better to look at something from several angles than to look at it in only one way. The purpose of triangulation in qualitative research is to increase the credibility and validity of the results. Several scholars have aimed to define triangulation through the years:
(i) Cohen and Manion (2000) defined triangulation as an attempt to map out, or explain more fully the richness and complexity of human behaviour by studying it from more than one standpoint.

(ii) Altrichter, Posch and Somekh (2006) contended that triangulation gives a more detailed and balanced picture of the situation.

(iii) According to O’Donoghue and Punch (2003), triangulation is a method of cross-checking data from multiple sources to search for regularities, or patterns.

As reported previously, data were collected from four participating hospitals (cases) using interviews, document reviews and observation. Data from each source were cross-checked for accuracy. That is, the information given by the interviewee was triangulated against information gathered from document reviews and observations. This allowed the researcher to ensure that information was not lost. Each source of evidence confirmed or provided additional information that was missing (or was insufficient) from other sources. This meant comparing and cross-checking the consistency of information derived by different data collection techniques. The triangulation for this research was achieved by:

(i) checking for consistency in terms of what biomedical engineers reported about the same thing (same interview question);
(ii) comparing observational data with interview data; and
(iii) comparing information collected from interviews, documents and observation for consistency and for the purpose of increasing data richness.

This triangulation process was applied to each case study (hospital).

3.5.4 Case study transcripts

Case interviews were recorded on tape, transcribed by using Altas ti7 software (qualitative data analysis software) and then reconfirmed by transcribing manually so that valuable information was not lost. The transcribed data were reviewed, categorised under key words
contained in the transcripts and coded. The data were then re-organised by using thematic analysis.

### 3.5.5 Documents and storage

A database of primary data from the interviews, documents and observation was created by using a combination of hard and soft copy in an individual file for each case. The documents included: interview notes, tape recordings of interview, transcripts and data obtained from hospital documents and any observations made during data collection.

### 3.6 Data analysis

This study used a theoretical proposition strategy to focus attention on the relevant data (Yin, 2003b). This strategy linked the original propositions to the empirical settings, as it assisted in organising the entire case study and defining alternative explanations for examination (Yin, 2003b). Theoretical proposition strategy was also useful where the study obtained extensive information from “how” and “what” questions, because it provided a structure for the information that was collected in preparation for thematic analysis (Yin, 2003b).

#### 3.6.1 Thematic analysis

Thematic analysis involves the creation and application of ‘codes’ to data (Flick & Kardorff, 2004). Thematic analysis is characteristic of most qualitative research and is part of the preliminary procedures for data analysis in qualitative research (Braun & Clarke, 2006). It is used by scholars and researchers in literature, psychology, sociology, cultural anthropology and many other fields (Denzin & Lincoln, 1994; Miller & Lee, 2001). Thematic analysis can be a beneficial bridge between researchers of varying orientations and fields (Denzin & Lincoln, 1994), because it allows a qualitative researcher to communicate more easily his or her observations. One aspect of case research is that it requires a very methodical approach, given its large quantity of free-flowing text. Coding is regularly used to reduce the large quantities of text produced by in-depth interviews to a manageable form (Jackson & Trochim, 2002).

The collected data from hospital interviews were analysed as follows. First, the collected data were transcribed. Then, the transcript was read carefully. Meaningful phrases were
highlighted, and emerging themes were noted and coded. Finally, codes were grouped as themes that recur through being similar or connected to each other in a patterned way.

3.6.2 Data coding

Information was coded using a content analysis approach to break down, conceptualise and reassemble data in new ways (Douglas, 2003). Content analysis involves the identification of patterns, not the counting of occurrences (Corbin, 1986). For this research, the encoded data were analysed using the techniques of categorising. A core or central category was defined as information that appeared most often in the data and could be increasingly related to other categories.

With this approach, recurring themes, categories or metaphors were created (Douglas, 2003). Themes came from words, sentences or phrases containing a single concept, or from whole paragraphs (Carson et al., 2001). This reduction to single concepts facilitated categorisation, sorting and analysis so that each concept could be considered separately (Jackson & Trochim, 2002; Miles & Huberman, 1994). New nodes (categories) were developed from the data, with the relationship between the new nodes enlightening the research. This process of data analysis included three procedures, namely open coding, axial coding and selective coding (Miles & Huberman, 1994; Miller & Lee, 2001). The coded data was then analysed in four stages using thematic analysis and a four-stage analytical procedure:

(i) The first stage consisted of an evaluation of all information collected from tape-recorded interviews, hand-written notes from the interviews and documents and information collected via observation. A primary review was undertaken from the first draft of each hospital case to ensure accuracy and completeness. Then, the content of the first draft was re-read and evaluated to understand the information collected from the cases.

(ii) In the second stage, keywords or themes relating to the research question were categorised into tables for each case study. The relevant keywords or themes from case study documents were also categorised in order to compare those keywords or themes, as well as supporting information collected from interviews. At this stage, the researcher also reviewed the process of reducing data from the first draft, using open coding.
(iii) In the third stage, data from the second draft was analysed by relying on the theoretical propositions (research questions) to identify categories that emerged from the data and described the individual event, or role patterns of individual staff of the biomedical engineering departments under study. The researcher also reviewed explanations of patterns from biomedical engineering staff members’ job descriptions in each case, using axial coding.

(iv) In the fourth stage, events or pattern of activities were selectively coded and compared to identify similarities and differences in overall patterns, using a cross-case analysis technique. Coding results depicted the overall pattern of biomedical engineering’s current activities relating to sub-research questions 1 and 2. Finally, coding results were also examined in relation to proposed service quality and internal customer satisfaction models in order to assess the suitability of proposed models answering sub-research question 3.

3.7 Limitations of methodology

Although case study methodology has the potential to generate new theory in disciplines that have limited theoretical research underpinning practical application (Yin, 2003b), case study research still evokes some criticism. This section discusses the limitations of a case study approach and how these limitations were addressed in this research.

(i) First, the use of case studies often results in complex theories if the boundaries of the research are not well defined, and the scope of the research is too broad (Eisenhardt, 1989; Parkhe, 1993). The researcher addressed this limitation by reviewing the literature carefully in order to determine a clear focus for the study, as reflected in the specific nature of the thesis objectives.

(ii) Second, case research methodology can be insufficient for theory development, because it employs a single methodology to investigate a phenomenon (Parkhe, 1993). In response to this criticism, this study investigated multiple cases and multiple sources of evidence.

(iii) The third criticism of case studies is that they can be difficult to conduct for operational and logistical reasons (Yin, 1994b). This problem was overcome by giving advance notice to participants and by making appointments for interviews.
The researcher pre-arranged access to biomedical engineering departments for interviews and observational sessions with the participating hospitals.

(iv) Finally, it may be a concern that the findings of this research are specific to New Zealand public hospitals only. To overcome this, further studies should be undertaken in other hospitals both in New Zealand and overseas. Understanding the limitations of the current study will enable researchers to address these limitations in future studies.

3.8 Ethical considerations

Adhering to ethical standards of conduct in this research was vital. The researcher had an obligation to respect the rights, needs, values and desires of the participants (Creswell, 1998). Several key ethical issues were addressed.

(i) All interviews were conducted at the discretion of the participants.

(ii) The interviewees were treated with respect and were fully informed about the research verbally, and a copy of the research cover letter was made available for them to read (Appendix 1).

(iii) The identity of those interviewed is, and will continue to be, kept confidential.

(iv) The researcher ensured that research results would be used only for the purpose of the academic research, as outlined in the research protocols.

(v) A consent form was provided to each participant before the commencement of the interview.

(vi) This form was explained in detail and was signed by both the researcher and the participant.

(vii) The form detailed the procedures to be followed, the responsibilities of both parties, freedom of consent issues, the ability to withdraw at any-time, and the possibility of further questions if required (Appendix 2).

(viii) Interviews were tape-recorded after obtaining interviewees’ consent. The interviewees were informed that the tape would remain in the possession of the
researcher for a period of seven years and would not be used for other research programmes.

Epilogue

This chapter described various paradigms governing the quantitative and qualitative approaches prevalent in business research. It has also underlined alternative research methodologies and has provided justifications for use of the case study methodology for this research. In this chapter, the researcher also discussed the concept of research design and other issues such as validity and reliability. Further, data collection techniques and triangulation of data from different sources were explained. Finally, the researcher reviewed the limitations of case study methodology and relevant ethical issues. Chapter 4 will present field data and discuss the results of the data analysis.
CHAPTER 4: ANALYSIS AND DISCUSSION

Prologue

This chapter presents case study data, discusses the approach to data analysis and introduces categories that emerge from the data analysis. The chapter consists of five sections, and begins with a visual overview of the chapter structure (Figure 4.1). Then, the chapter discusses the participants’ backgrounds and the profiles of the hospitals used as case studies in this research. The chapter then describes the actual data collection techniques used and describes data analysis in detail. Section 4.4 analyses the collected data and discusses results from multiple sources, including face-to-face interviews, document reviews and observations. The results are then reported using the participants’ own words where possible. Chapter 4 concludes with cross-case analyses and a summary of the overall results from multiple sources. The structure map of the chapter is illustrated in Figure 4.1.
Figure 4.1: Structure of the chapter

Prologue

Case profiles

Research approach and data collection techniques

Approach to data analysis

In-depth, face-to-face interview analysis

Document review analysis

Observation analysis

Data analysis

Cross-case analysis

Epilogue

Source: Developed by the researcher for this research.
4.1 Case profiles

This section presents a summary profile of the four public hospitals used as case studies. Profile details include the size of the hospital, the number of patients and the types of services each hospital provides. For privacy reasons, the names and locations of the case study hospitals are omitted. The hospitals are referred to as Case A, Case B, Case C and Case D. The four chosen cases provide a wide range of medical services and have teaching and training facilities. They can execute complex medical procedures using advanced technology, and they employ numerous biomedical engineers and technicians. A summary of the selected case profiles is presented in Table 4.1.
<table>
<thead>
<tr>
<th>Case study</th>
<th>Type of hospital</th>
<th>Number of patient beds</th>
<th>Number of staff (full and part-time)</th>
<th>Approximate number of patients admitted per year</th>
<th>Types of service provided</th>
</tr>
</thead>
</table>
| **A**      | Public hospital  | 700                    | 10,000                               | 44,500 including day patients                   | • Provides services for acute medical, ambulatory, community and mental health patients including cardiothoracic and intensive care unit (ICU), trauma services, emergency department, neurosurgery with neuro high dependency unit, children’s intensive care unit, neonatal intensive care, heart, lung, liver and renal transplant service, high-risk obstetrics, oncology, and women’s health (specialist services). Surgical services for ear, nose and throat (ENT), urology, vascular, neurosurgery, paediatrics, radiology and psychiatry are provided.  
• Utilises leading-edge medical technology to treat patients.  
• Has a teaching and training centre for undergraduates and postgraduate medical and allied health science students. |
| **B**      | Public hospital  | 216                    | 2,500                                | 100,000 including inpatients, outpatients and day patients | • Specialises in children’s health  
• Is a major teaching centre for paediatrics.  
• Utilises a wide range of medical equipment.  
• Has a support service to assist clinicians and to train new graduates.  
• Has cardiothoracic and intensive care units (ICUs), children’s ICUs, neonatal intensive care, renal dialysis service, high-risk obstetrics and surgical services for ear, nose and throat (ENT). |
### Table 4.1

<table>
<thead>
<tr>
<th></th>
<th>Public hospital</th>
<th>Patient beds</th>
<th>Staff (full and part-time)</th>
<th>Inpatients and Outpatients</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>700</td>
<td>4,700</td>
<td>91,000</td>
<td>354,000</td>
</tr>
<tr>
<td>D</td>
<td>600</td>
<td>6,000</td>
<td>39,350</td>
<td>161,500</td>
</tr>
</tbody>
</table>

- Provides niche specialist tertiary services for the region.
- Specialises in orthopaedics, spinal injury and burn treatments. Other services include cardiothoracic and intensive care unit (ICU), children’s ICU, neonatal intensive care, renal dialysis service, high-risk obstetrics, surgical services for ear, nose and throat (ENT), reconstructive and maxillofacial surgery together with general surgery, paediatrics, emergency care and mental health.
- Has a teaching and training centre.
- Provides specialist treatment for burn patients.
- Provides acute medical, ambulatory, community, specialist and emergency services in the region.
- Other services include cardiothoracic and intensive care unit (ICU), emergency care, children’s ICU, neonatal intensive care, renal dialysis service, high-risk obstetrics, surgical services for ear, nose and throat (ENT), respiratory service together with general surgery, paediatrics, emergency care and mental health.
- Caters to the teaching and training of new graduates and postgraduates in medical science.
- Utilises leading-edge medical technology to treat patients.

**Source:** Developed by the researcher for this research.

Table 4.1 illustrates the sizes of the hospital (cases) and the types of services the hospitals provide to the community. In addition to the general community services typical of New Zealand public hospitals, these case hospitals also specialise in certain treatments. For example, Case A provides high-tech specialised therapies such as heart and kidney transplants. Case B specialises in children’s health and provides specialist paediatric services, while Case C provides specialist treatment to burn patients and has a spinal unit. Case D is a major regional hospital.
4.2 Research approach and data collection techniques

As previously discussed, this research uses a case study approach focusing on the biomedical engineering departments of public hospitals. Data was collected through:

(i) face-to-face interviews,
(ii) departmental document reviews, and
(iii) observations.

4.2.1 Data collection from face-to-face interviews

The primary method for collecting data was the face-to-face interview. As previously mentioned, 16 interviews were conducted in four case study hospitals. Participants included biomedical engineering managers, biomedical engineering supervisors, senior biomedical engineers, biomedical engineers, and technicians. For privacy reasons, the names of the interviewees cannot be mentioned. Instead, the interviewees are referred to as participants one to sixteen in abbreviated format, e.g., “PT 1” or “PT 16” (Appendix 4). Each interview was conducted at the participant’s workplace, in a hospital meeting room, in the office after working hours, or in the cafeteria during the lunch hour. The interviews were recorded, and hand-written notes were also taken. The background of the interviewees is discussed in the next subsection.

4.2.1.1 Participants’ backgrounds

The participants selected for face-to-face interviews work in New Zealand public hospitals (cases) and have several years of biomedical engineering experience. A brief profile of each participant (interviewee) is presented in Tables 4.2, 4.3, 4.4 and 4.5, highlighting experience in relation to the position held.
Case A

Table 4.2: Participant profiles, Case A

<table>
<thead>
<tr>
<th>Position of participant</th>
<th>Years of experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical engineering manager</td>
<td>20</td>
</tr>
<tr>
<td>Biomedical engineering supervisor</td>
<td>15.5</td>
</tr>
<tr>
<td>Senior biomedical engineer</td>
<td>12</td>
</tr>
<tr>
<td>Biomedical engineer</td>
<td>4.5</td>
</tr>
</tbody>
</table>

*Source:* Developed by the researcher for this research.

Case B

Table 4.3: Participant profiles, Case B

<table>
<thead>
<tr>
<th>Position of participant</th>
<th>Years of experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical engineering manager</td>
<td>12</td>
</tr>
<tr>
<td>Biomedical engineering supervisor</td>
<td>14</td>
</tr>
<tr>
<td>Senior biomedical engineer</td>
<td>15</td>
</tr>
<tr>
<td>Biomedical engineer</td>
<td>5</td>
</tr>
</tbody>
</table>

*Source:* Developed by the researcher for this research.

Case C

Table 4.4: Participant profiles, Case C

<table>
<thead>
<tr>
<th>Position of participant</th>
<th>Years of experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical engineering supervisor</td>
<td>10</td>
</tr>
<tr>
<td>Senior biomedical engineer</td>
<td>6</td>
</tr>
<tr>
<td>Biomedical engineer</td>
<td>11</td>
</tr>
<tr>
<td>Biomedical engineering technician</td>
<td>5</td>
</tr>
</tbody>
</table>

*Source:* Developed by the researcher for this research.
Note: Case C’s biomedical engineering department is a branch of facilities management and does not have a manager of its own.

Case D

Table 4.5: Participant profiles, Case D

<table>
<thead>
<tr>
<th>Position of participant</th>
<th>Years of experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical engineering supervisor</td>
<td>8</td>
</tr>
<tr>
<td>Senior biomedical engineer</td>
<td>4</td>
</tr>
<tr>
<td>Biomedical engineer</td>
<td>5</td>
</tr>
<tr>
<td>Biomedical engineering technician</td>
<td>3</td>
</tr>
</tbody>
</table>

Source: Developed by the researcher for this research

Note: Case study D is also part of the facilities management department and does not have a manager of its own.

4.2.2 Data collection from document reviews

Data collected from the sixteen interviews was compared with data obtained from a review of departmental documents. A review of departmental documents helped balance arguments and verify data obtained from other sources (Yin, 2003b). Key internal documents reviewed included those addressing departmental structure, quality manuals, documents on policies, procedures and protocols, job descriptions, reporting templates for medical equipment servicing, quality reports, recommended communication methods, biomedical equipment management records, equipment handling protocols, QA manuals and training protocols. This data collection technique enabled a better understanding of the themes raised in face-to-face interviews, and further supported those findings through triangulation (Bryman & Bell, 2007). Comprehensive reviews of data collected during this research are kept in the researcher’s database and are available upon approval from the interviewees and the researcher.
4.2.3 Data collection from observations

Observation by partial participation was also used to understand how biomedical engineering departments operate and provide services to internal customers. Data collected through partial participation observation enabled a fuller understanding of relevant information arising from subsequent interviews and document reviews (Yin, 2003b). This approach provided an opportunity to observe activities that are executed by biomedical engineering teams, and their behaviours in the process.

Observation was both structured and unstructured, because the purpose was to capture behaviour, the general atmosphere and the moods of the members of the biomedical engineering departments, while also verifying data collected during face-to-face interviews and through document reviews.

During structured observation, the researcher directly observed the behaviour of the biomedical engineers and technicians engaged in day-to-day activities. Unstructured observation involved unplanned and informal watching and recording of activities as they occurred. The researcher was not directly involved in any activities being observed. Observations were recorded by taking notes on everything that happened in the presence of the observer. Sophisticated recording devices such as video cameras could not be used, because such devices were prohibited in the hospitals.

On the first day of observation, the researcher was greeted by the biomedical engineering manager or supervisor of each case (hospital), who then introduced the researcher to the members of the biomedical engineering team. The manager or supervisor outlined the department’s basic functions and its role in the public hospital system. This person also explained the department’s rules, health and safety protocols and hospital policies.

The observations continued for 12 weeks amongst all four cases, between the months of January 2011 and March 2011 (Table 4.6). Observations were executed in blocks of four to five hours at different times so that a wide range of biomedical activities could be captured. The observation was planned for six weeks in each case over the period of twelve weeks (first week of January 2011 to last week of March 2011). For Cases B and C, observation for a full six weeks was not possible, because Case B had special projects in progress and the hospital was very busy. In Case C, the biomedical engineers were involved in relocating clinics and medical wards to a newly constructed building. Therefore, only three weeks of observation was possible.
Table 4.6: Observation schedule for four cases (hospitals)

<table>
<thead>
<tr>
<th>Week</th>
<th>Days</th>
<th>Case A</th>
<th>Case B</th>
<th>Case C</th>
<th>Case D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Monday-Wednesday</td>
<td>8.00am-1.00pm</td>
<td>2.00pm-6.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Tuesday-Friday</td>
<td></td>
<td>8.00am-5.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Monday-Tuesday</td>
<td>8.00am-11.00am</td>
<td>1.00pm-5.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Monday-Friday</td>
<td>1.00pm-4.00pm</td>
<td>8.00am-1.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Monday-Friday</td>
<td>2.00pm-6.00pm</td>
<td>8.00am-1.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Tuesday-Friday</td>
<td>8.00am-1.00pm</td>
<td>2.00pm-6.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Wednesday-Friday</td>
<td>10.00am-3.00pm</td>
<td>11.00am-4.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Tuesday-Thursday</td>
<td>7.00am-10.30am</td>
<td>1.00pm-5.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Wednesday-Friday</td>
<td>7.00am-11.00am</td>
<td>2.00pm-6.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Monday-Friday</td>
<td>2.00pm-6.00pm</td>
<td>8.00am-1.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Wednesday-Friday</td>
<td>8.00am-1.00pm</td>
<td>2.00pm-6.00pm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Monday-Wednesday</td>
<td>11.00am-3.00pm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Developed by the researcher for this research.

The observation protocol covered week, time, location, observation and interpretations of the events (Appendix 5). This protocol was based on a guide for observation developed by Creswell (2003). Particular attention was given to the themes that emerged from interviews. An observation diary was kept, and on-site discussions were conducted with employees whose duties or position allowed them to describe the phenomenon under observation. What the employees did and the meaning the employees gave to their behaviour was recorded in writing.

Observations occurred mainly in the biomedical engineering workshops, medical wards, and acute clinical areas of the case study hospitals. On several occasions, observations were conducted in medical wards, clinics and acute clinical areas. On account of time constraints, the researcher focused observations on issues that related to the research questions, for example, key elements of the biomedical engineering service and the flow of day-to-day activities.
4.3 Approach to data analysis

This section discusses how data collected from multiple sources were analysed. In this study, the researcher used pattern-matching and comparative analysis strategies in tandem. These methods involved looking for recurring patterns in case data to identify and compare similarities between different empirical patterns from each data source (Creswell, 1998). The data were descriptive in nature, and required a methodical approach to address the large quantity of free-flowing text. Multiple techniques of data collection allowed the researcher to triangulate the collected data. Triangulation of data from multiple sources by using cross-case analysis maintained the credibility and validity of the results (Figure 4.2).

Figure 4.2: Triangulation of data analysis

Source: Developed by the researcher for this research.

4.3.1 Data analysis from face-to-face interviews

As previously mentioned, the researcher used thematic analysis to evaluate the collected data (Figure 4.3).
In thematic analysis, coding is used to reduce large quantities of text produced by face-to-face interviews into a manageable form without losing meaning (Jackson & Trochim, 2002). In this research, data analysis was executed using the following steps. First, the collected data was transcribed using Atlas.ti version 7 software. This qualitative data analysis software was developed by Atlas.ti Scientific Software Development GmbH, Berlin. This software was chosen for the following reasons.

(i) The researcher was familiar with the software.
(ii) The software has advanced functions such as cloud views, query tools, and table cells, all of which allow easy manipulation of data.
(iii) Coded information is easy to display alphabetically or by frequency; therefore, data is easy to manage.

To ensure that valuable information was not lost, the researcher also transcribed data manually, and compared it with data transcribed using Atlas.ti version 7 software. The transcript was then read carefully. Meaningful phrases were highlighted and coded using an accepted content analysis approach to breakdown the data, conceptualise, and reassemble content in novel, meaningful ways (Douglas, 2003; Varma & El-Kafafi, 2011).

This approach involved three procedures: open coding, axial coding and selective coding. The coded results were tabulated to determine what, if any patterns were emerging from the data. Potential themes were noted by analysing the data from different angles. Finally, codes were
grouped into recurring themes that were similar or connected to each other in a patterned way. The coding process of data analysis is discussed in the next subsection.

4.3.2 Data coding

Interview transcripts were first coded using open coding. This process involved close scrutiny of interview transcripts “word-for-word, line-by-line and phrase-by-phase”, and detailed comparison with notes taken during the interviews (Douglas, 2003, pp. 47-50). The aim of open coding was twofold: to begin the unrestricted labelling of all data and to assign representational and conceptual codes to each and every incident highlighted within the data (Douglas, 2003). The open coding process revealed that comments made by participants contained information that could be coded under more than one category. For example, a participant’s response to an interview question regarding customer satisfaction was broken down and was coded under three different categories as presented in Table 4.7. Participant 15’s (PT 15’s) comment was: “If the level of service is good and there is no complaint, then one would expect that the customer is satisfied.” This comment contains information on service, customer complaints and customer satisfaction. Therefore, the comment was coded under three categories (customer service, customer complaints and customer satisfaction) as shown below.

Table 4.7: Open coding example

<table>
<thead>
<tr>
<th>PT 15’s comment</th>
<th>Code</th>
<th>Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the level of service is good and there is no complaint, then one would expect the customer is satisfied.</td>
<td>SF6</td>
<td>Service</td>
</tr>
<tr>
<td></td>
<td>SF3</td>
<td>Customer complaints</td>
</tr>
<tr>
<td></td>
<td>SF1</td>
<td>Customer satisfaction</td>
</tr>
</tbody>
</table>

Source: Developed by the researcher for this research.

Furthermore, some data were coded under numerous categories to emphasise various facets of an event (Douglas, 2003). For example, for question 11, “Do you believe that customer service can be improved?” and question 12, “If yes, can you please explain how it can be improved?” (Appendix 3, Part B, questions 11 and 12), PT 11 responded, “Yes, the
improvements can be made by refining processes, communication with the customers and by improving on our quality of service.”

Since the participants’ responses addressed processes, customer communication and quality of service, the responses were coded under process, customer communication, and quality of service (Table 4.8).

Table 4.8: Example of data coded to numerous categories

<table>
<thead>
<tr>
<th>Participant 11 (interview response)</th>
<th>Process</th>
<th>Customer communication</th>
<th>Quality of service</th>
</tr>
</thead>
<tbody>
<tr>
<td>The improvements can be made by refining processes, communication with the customers, and improving on our quality of service.</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Source: Developed by the researcher for this research.

In this case, one statement contained information that could be categorised under three categories: process, customer communication and quality of service. Therefore, the statement was coded under three separate headings.

4.3.3 Axial coding

Once open coding was completed, data were regrouped for the purpose of developing the core code. Major (core) codes emerged as aggregates of the most closely interrelated (or overlapping) open codes for which supporting evidence was strong (Douglas, 2003). For ethical reasons, full documentation of interviews is not included in this thesis. Instead, a description of core codes specific to this research is presented in Appendix 6.

4.3.4 Selective coding

Selective coding was the final step in the encoding process. Data were interpreted and subsequently linked, which allowed categories to emerge. The focal point was a central phenomenon that emerged from the previous coding stage and best described the research question under investigation. The encoding process was highly iterative, with new codes being developed from initial ‘conceptual’ codes. Codes were subsequently analysed using established methods of content analysis (Corbin, 1986).
4.3.5 Content analysis

Content analysis involved identification of patterns and categorising. This process involved the development of codes as described in the previous section, which were then grouped using content, conditions and consequences derived from the data. A core or central category was determined as information that appeared most often in the data could be increasingly related to other categories.

In this content analysis, 56 categories emerged from the face-to-face interview data. Therefore, data analysis was refined to reveal emerging themes. When emerging themes were reconsidered, 46 categories were interrelated (Table 4.9). These 46 categories were further condensed into ten key categories (Table 4.9).
<table>
<thead>
<tr>
<th>Category number</th>
<th>Emerging categories</th>
<th>Components of biomedical engineering services linked to the emerging category</th>
</tr>
</thead>
</table>
| 1               | Management systems                       | • Departmental procedures  
• Protocols and policies  
• Records and traceability  
• Internal communications  
• Management models  
• Processes of management  
• Management objectives  
• Compliance with medical technical standards |
| 2               | Role of biomedical engineering           | • Routine maintenance of clinical equipment  
• Clinical equipment repairs and management processes  
• Equipment receipts and acceptance checking  
• Decommissioning  
• Trialling new equipment  
• General technical support  
• Equipment down time |
| 3               | Quality assurance (QA)                   | • Performance verification of clinical equipment  
• Electrical safety testing |
| 4               | Training and development                 | • Training methods  
• Quality of service  
• Target achievements |
| 5               | Customer satisfaction and service quality| • Quality of service  
• Response time  
• Communication and feedback  
• Cost effectiveness  
• Departmental meetings  
• Quality review  
• Management review |
| 6               | Technical service and support to         | • Internal customers  
• Equipment evaluation  
• Assistance to clinicians on equipment issues |
|                 | internal customers                       |                                                                          |
|   | Records and traceability | Equipment databases  
|   |                          | Equipment registration and acceptance  
|   |                          | Service records  
|   |                          | Equipment history records  
|   |                          | Communication/reports  
|   |                          | Test equipment records  
|   |                          | Status reports  
|   |                          | Audits  
|   | Complaint handling | Complaint handling processes  
|   |                          | Complaint investigations  
|   |                          | Complaint reporting methods  
|   | Internal communication and feedback | Customer communication  
|   |                          | Internal communication and management reporting  
|   |                          | Meetings  
|   | Suitable and effective model for biomedical engineering departments in New Zealand public hospitals | Service quality and customer satisfaction models currently in use  
|   |                          | Possible service quality and customer satisfaction models that can be used for biomedical engineering departments  

Source: Developed by the researcher for this research.

Note: Components of biomedical engineering services are interrelated; several components comprise a category.

Categorisation was also used to analyse data collected from document reviews and observations. The ten categories (themes) were carefully evaluated and regrouped by affiliation to sub-research question (Table 4.10).
Table 4.10: Themes relating to sub-research questions

<table>
<thead>
<tr>
<th>Categories</th>
<th>Sub-research questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>What are the current systems used in New Zealand public hospitals to manage medical technology?</td>
</tr>
<tr>
<td>3-9</td>
<td>How are service quality and internal customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?</td>
</tr>
<tr>
<td>10</td>
<td>Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals?</td>
</tr>
</tbody>
</table>

*Source: Developed by the researcher for this research.*

Table 4.10 shows that categories 1 and 2 relate closely to sub-research question 1, categories 3-9 relate to question 2 and category 10 relates to question 3.

### 4.4 Data analysis

This section presents data collected from multiple sources, analysis collected data and presents the results of analysis from all four case studies (cases) under investigation.

#### 4.4.1 Face-to-face interviews

*Category 1*

*Management systems of biomedical engineering departments*

Qualitative analysis illustrates the current hierarchical structure of each case and describes current management systems.

**Case A**

Case A’s biomedical engineering department has a hierarchical structure (Figure 4.4). The responsibilities of the staff depend on their place in the hierarchy. Case A has a manager, two supervisors, four senior engineers, eight engineers, twelve technicians and two administrators. The manager has overall responsibility for the department. The supervisors plans and manages day-to-day biomedical activities and assists the manager in decision making. Senior biomedical
engineers are more involved in special projects. Engineers and technicians are frontline staff who carry out day-to-day biomedical engineering-related tasks.

Figure 4.4: Hierarchical structure of the biomedical engineering department of Case A

![Hierarchical structure of the biomedical engineering department of Case A](image)

*Source:* Developed by the researcher for this research.

All participants in Case A believed that TQM is important to their organisation, because it is a management system in which the entire department is committed to provide quality service. However, the participants’ opinions differed regarding the type of management system currently being used. Participants PT 1 and PT 2 identified their current system as the “ISO 9001 risk management system”, while PT 3 thought it was “health and safety in the workplace management system”, and PT 4 identified it as the “ISO 9001 process management system”. Interview data suggest that although the current management system is working well, it can be further refined by improving internal communication and in better managing processes such as reporting methods, management of internal documents and incident reporting arising from equipment malfunction. The analysis also suggests the management needs to conduct awareness training to better inform the staff on their current management system, because the majority of their staff are not aware of their current management system.
Case B

Analysis of Case B interview transcripts shows that the biomedical engineering department has a hierarchical structure similar to Case A, consisting of a manager, a supervisor, three senior engineers, eight engineers, ten technicians, three trainee technicians and two administrative staff (Figure 4.5). Administrative staff report directly to the biomedical engineering supervisor and the biomedical engineering manager. The supervisor assists in planning of day-to-day biomedical activities and assists the manager in decision making. Senior biomedical engineers plan the day-to-day activities in consultation with the supervisor and also are more involved in special projects. Engineers, technicians and trainee technicians are frontline staff who carry out day-to-day biomedical engineering-related tasks.

Figure 4.5: Hierarchical structure of the biomedical engineering department of Case B

Source: Developed by the researcher for this research.

The majority of Case B participants suggested that they were currently using ISO 9000:2000 process management systems (PT 5, PT 6 and PT 8) except PT 7, who thought they were using a “service management system”. There was an indication that the staff are focused on their level of responsibilities in the department’s hierarchical structure and are not aware of the overall management system of the department. Data analysis also suggests that Case B participants believed their current management system was working well. However, in
interviews, the majority of them felt that there was room for improvement in management processes including internal communication, processes of equipment fault management and response times, management of trial equipment and new clinical equipment, and training of biomedical engineers and technicians.

Case C

The hierarchical structure of the biomedical engineering department in Case C consists of a biomedical engineering supervisor, four senior engineers, six engineers, seven technicians, four trainees technicians and two administrative staff (Figure 4.6). The biomedical engineering department is a branch of facilities management, and therefore it does not have a manager of its own. The supervisor plans and manages day-to-day biomedical activities. Senior biomedical engineers are more involved in special projects. Engineers and technicians are frontline staff who carry out day-to-day biomedical engineering-related tasks, while administrative staff assist in day-to-day administration task including data entry in equipment database.

Figure 4.6: Hierarchical structure of the biomedical engineering department of Case C

![Hierarchical structure of the biomedical engineering department of Case C](image)

Source: Developed by the researcher for this research.

Case C participants believed that TQM is important to biomedical engineering departments because it enables hospital-wide drives towards excellence. Participant PT 9 mentioned and participant PT 10 agreed that they were currently using an “ISO 9000 process management system”, while PT 11 thought it was called an “ISO risk management system”. Participant PT 12
was not sure of the current management system used by the biomedical engineering department in Case C. This indicates that there is a limited knowledge of current management systems amongst the staff, and suggests that there is a lack of awareness training on their management system. Participants believed their current hierarchical structure was working well despite the department being a subsidiary branch of the facilities management department. However, the researcher believes that the services of hospital C (Case C) could be refined by improving management processes and therefore, service quality.

**Case D**

The departmental structure of Case D is the same as Case C except for the number of staff at each hierarchical level. Case D has a biomedical engineering supervisor, five senior engineers, seven engineers, nine technicians, four trainee technicians and two administrative staff. The biomedical engineering department is a branch of facilities management, much like Case C (Figure 4.7).

**Figure 4.7: Hierarchical structure of the biomedical engineering department of Case D**

![Hierarchical structure diagram](source)

*Source: Developed by the researcher for this research.*

Participants from Case D believed that TQM is important to their organisation, because it is an accepted approach to improving quality and performance to meet and exceed customer expectations.
Participant 13 mentioned that the department’s current management system complies with the “ISO 9000 risk management system”. Participant PT 14 mentioned and participant PT 15 also agreed that their current management system was the “ISO 9000 process management system”. Participant 16 was not sure of the management system currently used by the biomedical engineering department. This reveals that Case D may need to improve its internal communication and raise awareness of management systems and processes amongst their staff. Analysis suggests that management should review its policy on training and internal communication. Data analysis also reveals that all participants agreed that their current departmental structure is working well.

Analysis in all four cases shows that they have a hierarchical structure consisting of a manager, supervisor, senior engineers, engineers, technicians, trainees and administrative staff. The responsibilities of the staff depend on their place in the hierarchy. The manager has the overall responsibility for the department. The supervisor plans and manages day-to-day biomedical activities and assists the manager in decision making. Senior biomedical engineers are more involved in special projects. Engineers and technicians are frontline staff who carry out day-to-day biomedical engineering-related tasks. Analysis also indicates that although Cases C and D are branches of the facilities management department, the responsibility of the biomedical engineering staff do not change.

From the analysis, it is clear that TQM is important to all four cases because it is an accepted approach to improving quality and performance to meet and exceed customer expectations. It is a management system by which the entire department is committed to provide quality service. All staff from all four cases believe that their current hierarchical structure is working well. However, analysis suggests that the participants of all cases also believe that their current management system could be further refined to improve service quality.

**Category 2**

*The role of biomedical engineering departments*

Data analysis from all interviewees shows that biomedical engineering departments play a vital role in public hospitals in New Zealand. Analysis reveals that biomedical engineering departments provide technical support on all aspects of clinical equipment to the entire hospital in all four cases. They also assist clinicians on equipment-related matters and promote safety to
both patients and equipment operators. The key roles of biomedical engineering departments in all cases are listed below.

**Cases A to D**

The biomedical engineering department in all cases provides technical support to the hospital in the following ways:

(i) pre-purchase consultation, especially where the clinical engineering department is expected to repair equipment after expiry of the warranty, and sometimes even during the warranty period;

(ii) incoming inspections (acceptance testing) for new equipment acquisitions and for equipment returned after outside repairs;

(iii) corrective maintenance and calibration of all types of medical equipment;

(iv) preventive maintenance and periodic inspections of equipment as per management programmes for medical devices standard AS/NZS 3551:2012 (Australian/New Zealand management programme for medical devices);

(v) maintaining equipment safety such as screening hazard notices and performing electrical safety checks for the safety of patients and end users;

(vi) provision of a multidisciplinary approach to problem solving and to the quality of patient care;

(vii) assisting biomedical managers in administrative duties relating to the department’s resource planning, training and development;

(viii) investigating incidents concerning equipment malfunction;

(ix) offering technical support to all clinicians on clinical equipment-related matters when required;

(x) assisting in the introduction and trial of new technology; and

(xi) maintaining general reliability in equipment control and asset management.
Category 3

Quality assurance (QA)

All hospitals (cases) that participated in this research have QA programmes for managing clinical equipment. The interviewees of cases believe that the QA programme helps in enhancing efficiency and customer satisfaction. Under these programmes, all clinical equipment is performance-verified to ensure that it is being operated within the manufacturers’ specifications and is electrically safe.

Cases A to D

The analysis shows that all cases have a QA programme for existing clinical equipment in the hospital. Under this programme, most existing clinical equipment is performance verified at least once per year. Each clinical area is systematically scheduled for QA inspections throughout the year, and performance of the equipment is verified as per the AS/NZS3551:2012 standard. While conducting QA (performance verification) checks, if any equipment is found to be faulty or out of manufacturer’s specification, minor repairs are executed during QA checks. Otherwise, equipment is removed from service, and repairs are executed in the biomedical engineering workshop. All results obtained from QA checks are recorded in the equipment database.

Analysis also reveals that in Cases C and D a comprehensive QA programme for all existing clinical equipment is not conducted due to lack of resources. Therefore, the department have done a risk analysis and have decided to QA check on high-risk equipment only (such as ECG machines, electro-surgical instruments, infusion pumps and defibrillators).

Category 4

Training and development

The interview data analysis indicates that all four hospitals (cases) have staff development plans for every biomedical engineering employee.

Case A

The participant PT 2 (supervisor) in Case A reported:

“Hospitals have a wide range of clinical equipment; therefore, it is impossible for any engineer or technician to be familiar with all types of clinical equipment. Therefore,
management feels that training is vital for the biomedical engineering department’s success because biomedical engineers and technicians are the frontline staff and are always in contact with the internal customers. They are expected to work on the equipment and have responsibility to repair and calibrate medical instruments that get used on patients. Therefore, training is essential.”

Staff progressing through the training plan are exposed to different types of equipment. Once staff gain product knowledge, experience and competency with one aspect of the equipment, they progress to the next level of training. The training occurs both on the job and off the job. On-the-job training is conducted within the hospital on actual equipment, and off-the-job training is conducted either in a training institution or at the manufacturer’s factory.

Case B

The participant PT 5 (manager) in Case B reported that a “different type of training is required at different levels of responsibility. For example, a supervisor needs training on people handling skills whereas engineers and technicians at the frontline require hands-on training in clinical equipment”. In Case B, the participant PT 5 reported and PT 6 agreed that “training is important for the department because it improves quality as well as customer satisfaction”.

Participant PT 7 reported that training is delivered in two forms. “On-the-job training takes place in a normal working environment, using the actual tools, equipment, documents or material that staff will use when fully trained. Training is conducted by a senior staff member through lectures and hands-on training and off-the-job training takes place away from the normal work place. This type of training is conducted in a classroom situation on specific equipment. In some cases this is conducted by the manufacturer at the manufacturing site.”

Participant PT 8 also reported that training is delivered in two forms. “On-the-job training takes place in a normal working environment, using the actual tools, equipment, documents and Off-the-job training takes place away from the normal work place.”

Data analysis shows that once a training need is established, staff who are likely to be working on the equipment are taught by the manufacturers, or by experienced members of the department who share their skills and knowledge in the form of in-service training. Once the training is complete and the trainer feels that the engineer is competent, the engineer is allowed to work without supervision and is empowered to make decisions regarding that equipment.
Case C

Participant PT 9 (supervisor) in Case C reported that frontline staff are trained with internal customers as their focus.

“The management feels that training is vital for the biomedical engineering department’s success, because biomedical engineers and technicians are the frontline staff and are always in contact with the internal customers. Therefore, the biomedical engineering department has a training programme for all engineers and technicians who work in the frontline of the business.”

Participants PT 9 and participant PT 12 reported that training is delivered in two forms. “On-the-job training takes place in a normal working environment and training is conducted by a senior staff member through lectures and hands-on training.” (PT 9).

Furthermore, “off-the-job training takes place away from the normal work place. This type of training is conducted usually at the hospital’s training centre on specific equipment or by the manufacturer at the manufacturing site”. (PT 12).

Data analysis shows that training needs are determined during an acceptance check of new equipment by senior staff with the help of manufacturer’s recommendations.

Case D

Biomedical engineering staff are exposed to different types of clinical equipment as part of their training programme. Once they gain specific technical knowledge, experience and competency, they then progress to the next type of equipment. Like other cases, Case D also conducts two forms of training. On-the-job training occurs in a normal working environment, using the actual tools, equipment, documents and materials that staff use when fully competent. Training is conducted by a senior staff member through lectures and hands-on practical experience. Off-the-job training occurs away from the normal work place. This type of training is usually conducted in a classroom or training centre on specific equipment. In some cases, this training is conducted by the manufacturer at the manufacturing site.

Analysis reveals that all cases hold training for their staff using two common methods: on-the-job training is conducted within the hospital in a normal working environment, and off-the-job training takes place away from the normal work place.
Category 5

Customer satisfaction and service quality

Data analysis shows that the majority of participants strongly believed that if internal customers receive the level of service they expect, or they receive technical support when needed, they are satisfied with biomedical engineering services being provided.

Case A

Data analysis reveals that customer satisfaction and service quality are important to this biomedical engineering department. Participants considered that a high level of service quality:

- “promotes the department’s profile in the hospital” (PT 1);
- “improves relationship with the internal customers” (PT 3);
- “offers opportunities to continuously improve service” (PT 2);
- “gives the department a feeling that it is achieving its objectives” (PT 4);
- “reflects on the department’s ability to provide technical support to the hospital in a fast-changing industry” (PT 4);
- “assists in conducting annual customer surveys to determine the customers’ needs” (PT 1 reported and agreed by PT 4); and
- “allows the engineers to work at their own pace to maintain quality of the workmanship and minimise return jobs” (PT 1).

Case B

All participants from Case B strongly believed that service quality and customer satisfaction are important for their department. Data analysis shows that they have a quality manual that prescribes biomedical engineering-related processes. Participants reported that service quality and customer satisfaction:

- “are achieved by maintaining a good working relationship with clinicians and other support staff” (PT 5);
- “are measured by carrying out annual surveys” (PT 6 and also agreed by PT 7 and PT 8);
• “are determined by number of complaints received from internal customers” (PT 6 and also agreed by participant PT 7);
• “are determined by analysing feedback and comments made during the annual survey” (PT 6); and
• “are determined by keeping equipment downtime to a minimum” (PT 1, and also agreed by PT 3 and PT 4).

Case C

All participants from Case C indicated that service quality and customer satisfaction are important for their biomedical engineering department. The department achieves service quality and customer satisfaction by:

• “analysing customer feedback from the annual survey to determine customer needs” (PT 10);
• “efficient QA programme on clinical equipment. The QA programme assists in keeping equipment downtime to minimum” (PT 11);
• “offering customers good technical support when it is needed” (PT 12); and
• “good communication and feedback, and by keeping comprehensive records on clinical equipment, so that information can be extracted from the database quickly when required” (PT 9).

Case D

All participants from Case D shared the views of Cases A, B and C that service quality and customer satisfaction are important drivers for biomedical engineering departments. Participants PT 15 reported that “if the customers get the level of service they expect or they get the technical support when it is needed, then they are satisfied with the biomedical service”. Case D participants reported that the biomedical engineering department achieves service quality and customer satisfaction by:

• “maintaining a good working relationship with clinical staff and other hospital staff” (PT 13);
• “analysing customer feedback from the annual survey to determine the customer’s perception of the biomedical service” (PT 16);
• “offering customers’ good technical support and advice as and when it is needed” (PT 13, and this statement was also supported by participants PT 15 and PT 16); and
• “allowing biomedical engineering staff to work at their own pace so that the quality of the workmanship is not comprised” (PT 14, and participants PT 13 and PT 16 also agreed).

It is clear from the analysis that all participants have a firm belief that service quality and customer satisfaction are important for their departments. They believe that customer satisfaction and service quality promote the biomedical engineering departments’ profiles in the hospital setting. The cases currently achieve service quality and customer satisfaction by maintaining a good working relationship with clinicians and other support staff, by maintaining good communication and feedback, by keeping comprehensive records on clinical equipment and by running an efficient QA programme for all types of clinical equipment.

**Category 6**

*Technical service and support to internal customers*

**Cases A to D**

In all cases, the biomedical engineering department is responsible for all existing hospital equipment. The engineers and technicians are involved in all phases of the clinical equipment lifecycle. All cases systematically execute biomedical engineering-related tasks. Their processes and procedures relating to the management of clinical equipment are similar. There are several processes and procedures relating to the management of clinical equipment. These processes and procedures are used to provide the following services:

(i) corrective maintenance and recalibration of medical equipment;
(ii) incoming inspections (acceptance testing) for new equipment acquisitions;
(iii) preventive maintenance and periodic inspections of equipment as per the medical equipment management standard (AS/NZS 3551:2012- Management programme for medical devices for New Zealand and Australia);
(iv) equipment safety, such as screening hazard notices, performance verification checks and ensuring that the equipment is hazard free;
(v) training operators to safely and effectively use of clinical equipment;
(vi) explaining new technologies and their impacts on operating costs, and translating technological ideas, problems and concepts into a language that non-technical people can readily understand;
(vii) assisting clinicians with equipment-related problems; and
(viii) checking electrical safety when equipment is returned from outside repair, before putting the equipment back into clinical use.

**Category 7**

**Records and traceability**

Detailed records of clinical equipment and departmental documents are kept by staff in the biomedical engineering departments of all four hospitals that participated in this case study for traceability of information.

**Case A**

Case A stores all departmental documents and clinical equipment records electronically in a database called Enterprise Asset Management (EAM). The manager (PT 1) reported and agreed by supervisor (PT 2) of Case A that “the database content is controlled by the biomedical engineering department and day to day management of the hardware is managed by the IT department of the hospital”. All Case A participants reported similar understandings of how records are kept.

When new equipment is purchased by the hospital, it gets allocated with an asset registration number (a bar-coded number). All information regarding the equipment is loaded against this asset number including make, model, software revision, method of testing, reference
service documents, calibration details, electrical class of the equipment and its location in the hospital.

The data reveal that when equipment reaches the end of its life, or when equipment is uneconomical to maintain, it is decommissioned and removed from the database. The manager (PT 1) mentions that “information stored in the database is handy for asset planning”.

Case B

Case B staff keep all departmental documents and clinical equipment records in an electronic equipment database called Tec-Track. The manager (PT 5) reported that “the database content is controlled by the biomedical engineering department, and the systems software and management of hardware such as repair maintenance and upgrades are managed by the IT department of the hospital”. This was confirmed by the supervisor (PT 6).

Participant 7 (PT 7) in Case B reported, “when new equipment is purchased by the hospital it gets allocated with an asset registration number (a bar-coded number)”. All participants reported that information regarding the equipment is loaded against this asset number (PT 5, PT 6, PT 7 and PT 8). Participants PT 5 stated, “information from the database can be retrieved by various ways; for example, it can be searched by the serial number, asset number, order number and job number”.

Case C

Case C keeps all departmental documents and clinical equipment records in EAM, like Case A. The supervisor (PT 9) explained that “the biomedical engineering department decides what information needs to be recorded in the database and the IT department of the hospital manages the hardware and the software part of the system”. All participants in Case C (PT 9, PT 10, PT 11 and PT 12) reported that, when new equipment is purchased by the hospital, it gets allocated with an asset registration number. All information available in relation to the equipment is loaded against this asset number. Records can be retrieved from the database by searching under various search fields. For example, equipment records can be searched by serial number, asset number and purchase order number. Supervisor (PT 9) stated, “reports are often
generated from stored information in the database for the purpose of service history, equipment status, cost of maintenance and asset planning”.

Case D

Case D’s equipment database is called Business Information Management System (BIMS). All departmental documents as well as equipment records are kept electronically in a biomedical equipment database. “The database records are controlled by the biomedical engineering department and the systems software and management of hardware such as software upgrades, repair and maintenance is managed by the IT department of the hospital.” (PT 13). Reports on service history, equipment status reports, cost of maintenance and asset planning are generated from the stored records in the equipment database for management and planning purposes.

This research shows that all four biomedical engineering departments keep records of various types in their equipment databases to assist in traceability of information. Records kept included departmental documents as well as equipment records. These records can be retrieved from databases using various search fields. It was found that although the cases were using different software, the type of equipment records were similar if not same. This did not have any effect of the traceability of information. In all cases, the database content is controlled by the biomedical engineering departments; the software and management of the hardware such as software upgrades, repair and maintenance is managed by the IT department of the hospital.

Category 8

Complaint handling

In all cases complaints are reported via phone, email and in person. Data analysis suggests that all four cases classify customer complaints into three main categories:

(i) biomedical engineering service complaints,
(ii) equipment complaints, and
(iii) incident reports.
All cases regard a biomedical engineering service complaint as an operational issue; therefore, it is managed by the supervisor or manager. An equipment complaint (such as equipment malfunction) is regarded as a service request; therefore, the service request procedure is followed. If the complaint was incident-related and patient injury has occurred, then a reference number is immediately allocated for identification and forwarded to a senior member or supervisor. The complaint gets evaluated, and an investigation is initiated.

Case A

Once the investigation is complete, the incident report is discussed in the biomedical quality review meeting. If required, the department initiates corrective action to prevent future incidents. Copies of the investigation report and the outcome of the investigation are forwarded to the health and safety officer for records.

Case B

Upon completion of the investigation, a report is presented to the supervisor, who evaluates the report and forwards a copy to both the biomedical manager and to hospital risk management managers. The report gets tabled in the biomedical engineering department’s quality review meeting for discussion. If required, corrective action is implemented to prevent any further incidents. Upon completion, investigation of the incident is formally closed, and the risk management team is advised.

Case C

Upon completion of the investigation, a supervisor evaluates the incident report, and a copy is submitted to the hospital’s risk and disability committee, which consists of members from the health and safety team, clinical staff members and a member from the biomedical engineering department. The committee evaluates and recommends appropriate corrective action. If corrective action is required, an action plan is drawn up and implemented. The report is also discussed in the biomedical engineering department’s management and quality meeting.
Case D

When the investigation is complete, the report is submitted to the supervisor. The supervisor evaluates the report and discusses it with the manager. A copy of the report is sent to the hospital’s risk and disability committee, which consists of a team of representatives from the clinical area, the biomedical engineering department and the health and safety team of the hospital. The committee evaluates the report and recommends appropriate corrective action to prevent such incidents in the future. The complaint is formally closed once the corrective action is implemented.

From the analysis it can be said that all four cases have a well-documented procedure for complaint handling. All cases classify customer complaints into three main categories. Analysis suggests that complaints in all cases are handled in a similar way.

Category 9
Internal communication and feedback

This research reveals that clear communication is a vital tool for biomedical engineering departments’ success. Therefore, these departments use several communication tools to conduct their day-to-day business.

Cases A to D

All cases use common methods of communication (such as telephone, email, face-to-face discussions, written reports and meetings) to keep internal customers well informed on clinical equipment matters and biomedical engineering issues. Feedback on day-to-day activities, such as discussions of technical issues at the patient’s bedside and reporting on equipment malfunctions, patient parameter programming in clinical equipment and advice on setting the alarm limits in equipment, is usually in the form of face-to-face and telephone communication. Formal communication is used for service reports, departmental circulars, technical bulletins, repair quotes, recommendations and incident reports.

Category 10
A suitable and effective model for biomedical engineering departments in New Zealand public hospitals
Based on participants’ (interviewees’) experience and biomedical engineering knowledge, the researcher sought ideas for the most suitable and effective management model for medical technology within public hospitals. The participants were asked if they were familiar with any service quality and customer satisfaction model that could be adopted by biomedical engineering departments of New Zealand public hospitals. Almost all participants gave a positive response to this question (Appendix 3, Part C, Questions 1-4).

(i) Service quality

The participants recommended various models for service quality based on their experience and knowledge. The recommended models are illustrated in Table 4.11.

Case A

Case A participants’ opinions on service quality models are illustrates in Table 4.11

<table>
<thead>
<tr>
<th>Models recommended by participants</th>
<th>Number of recommendations</th>
<th>Participants’ opinions on adoptable models</th>
</tr>
</thead>
</table>
| Continuous Quality Improvement (CQI) model | 2 | • “Focuses on process and continually monitors for improvement, and improvements can be made in small increments” (PT 1).  
• “Focuses on process and improvements can be made in small increments. This will suit the department well” (PT 3). |
| SERVQUAL model | 1 | • “It allows us to measure customers’ perceptions of service quality” (PT 2). |
| ISO Quality Assurance (ISOQA) model | 1 | • “Prevents quality problems because it recommends to follow processes and procedures on every task performed” (PT 4). |

Source: Developed by the researcher for this research.

Table 4.11 shows that two participants in Case A suggested the CQI model for service quality. In their opinions, this model would help biomedical engineering to focus on process, continually monitor for improvements and allow improvements to be made in small increments.
One participant recommended the SERVQUAL model. In his view, this model could be used to measure customer’s perceptions of service quality. Another participant recommended the ISO Quality Assurance (ISOQA) model. In this participant’s opinion, the ISOQA model prevents the quality problem by enforcing the staff to follow correct processes and procedures to enhance service quality.

**Case B**

Case B participants’ opinions on service quality models are illustrated in Table 4.12.

Table 4.12: *Service quality models recommended by Case B participants*

<table>
<thead>
<tr>
<th>Models recommended by participants</th>
<th>Number of recommendations</th>
<th>Participants’ opinions on adoptable models</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous Quality Improvement (CQI) model</td>
<td>1</td>
<td>• “Focuses on process and continually monitors for improvement and improvements can be made in small increments” (PT 5).</td>
</tr>
<tr>
<td>SERVQUAL model</td>
<td>2</td>
<td>• “It allows us to measure customers’ perceptions of service quality” (PT 7).</td>
</tr>
<tr>
<td>Nordic Service Quality Model (NSQM)</td>
<td>1</td>
<td>• “Allows us to measure and determine the gaps in the service that can be improved” (PT 8).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• “This model provides both technical and functional quality of service including other factors such as pricing and customer relationships” (PT 6).</td>
</tr>
</tbody>
</table>

*Source: Developed by the researcher for this research.*

Table 4.12 shows that one participant recommended the CQI model for service quality. In this participant’s opinion, CQI is superior, because it focuses on processes and continually monitors for improvement. Two participants suggested the SERVQUAL model. In their view, this model would assist managers to measure customers’ perception of service quality. One participant, in contrast, recommended NSQM. In this participant’s opinion, the NSQM would allow biomedical engineering departments to provide technical quality, reliability and trustworthiness, and to build a good relationship with internal customers.
**Case C**

Case C participants’ opinions on service quality models are illustrated in Table 4.13.

<table>
<thead>
<tr>
<th>Models recommended by participants</th>
<th>Number of recommendations</th>
<th>Participants’ opinions on adoptable models</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous Quality Improvement (CQI) model</td>
<td>2</td>
<td>• “Continually monitors for improvement, and improvements can be made in small increments” (PT 9).</td>
</tr>
<tr>
<td>SERVQUAL model</td>
<td>1</td>
<td>• “It allows us to measure customers’ perceptions of service quality” (PT 11).</td>
</tr>
<tr>
<td>Nordic Service Quality Model (NSQM)</td>
<td>1</td>
<td>• This model has ability to provide technical quality as well as functional quality of service such as reliability in service, accessibility and flexibility and customer relationships” (PT 10).</td>
</tr>
</tbody>
</table>

Source: Developed by the researcher for this research.

Table 4.13 shows that two participants recommended the CQI model. In their opinion, this model could be adopted by biomedical engineering departments, because it focuses on processes and continually monitors for improvement, and improvements can be made in small increments. One participant recommended the SERVQUAL model. In this participant’s view, the SERVQUAL model assists in the measurement of customers’ perception of service quality and is therefore superior. Another participant recommended NSQM. In this participants view, NSQM would provide both technical and functional quality of service including other factors such as technical quality, reliability, accessibility and flexibility.

**Case D**

Case D participants’ opinions on service quality models are illustrated in Table 4.14.
Table 4.14: Service quality models recommended by Case D participants

<table>
<thead>
<tr>
<th>Models recommended by participants</th>
<th>Number of recommendations</th>
<th>Participants’ opinions on adoptable models</th>
</tr>
</thead>
</table>
| Continuous Quality Improvement (CQI) model | 2 | • “This models focuses on processes and continually monitors for improvements” (PT 13).  
• “Continuous improvements can be made in small increments. This will not have great effect on resources” (PT 16). |
| Business Process Management (BPM) model | 1 | • “Allows continuous evaluation of biomedical engineering processes for improvement” (PT 14). |
| ISO Quality Assurance (ISOQA) model | 1 | • “Prevents quality problems because its emphasis is on processes and do it right first time” (PT 15). |

*Source: Developed by the researcher for this research.*

Table 4.14 shows that two participants from Case D suggested CQI. In their opinion, this model could be adopted by biomedical engineering departments, because it focuses on process and continually monitors for improvement. In this model, improvements can be made in small increments. One participant recommended the Business Process Management (BPM) model, suggesting that it would allow staff to continuously evaluate biomedical engineering processes for improvement. In another participant’s opinion, the ISO QA model would be the most appropriate for biomedical engineering, because it prevents quality problems.

Analysis of all four cases shows that the participants favoured different models for achieving service quality. The models most recommended by participants for biomedical engineering were CQI, SERVQUAL model, the ISO QA model, NSQM and the BPM model. The participants who recommended CQI believe that it encompasses all aspects of biomedical engineering services. It allows continuous assessment of procedures, processes and protocols. In using this model, participants believed that departments could continually assess services offered to internal customers, and thereby make improvements.

Similarly, some participants believed that the SERVQUAL model could provide an opportunity to measure customers’ perceptions of service quality, and that the ISOQA model could effectively prevent quality problems from occurring. The participants who suggested NSQM believed that it had ability to provide technical quality as well as functional quality.
Interestingly, participants who suggested the BPM model thought that it would be an excellent tool for continually evaluating biomedical engineering processes for improvement.

(ii) Customer satisfaction models

Participants were asked for their recommendations on the most suitable and effective customer satisfaction model for biomedical engineering departments in New Zealand public hospitals (Appendix 3, Part C, Questions 5-9). Based on their experience and knowledge of the biomedical engineering business, the participants offered various suggestions.

Case A

The customer satisfaction models suggested by Case A participants are illustrated in Table 4.15.

Table 4.15: Customer satisfaction models recommended by Case A participants

<table>
<thead>
<tr>
<th>Customer satisfaction models recommended by participants</th>
<th>Number of recommendations</th>
<th>Participants’ opinions on adoptable models</th>
</tr>
</thead>
</table>
| Continuous Quality Improvement (CQI) model              | 2                         | • “In this model, improvements are made in small increments. It is a never-ending task. The department can assess the customers’ needs and make improvements to satisfy customers” (PT 1).  
• “It allows continuous improvement by making small changes. It is easier to make small changes than to make a big change in one go” (PT 3). |
| Performance/perceived Satisfaction model                | 1                         | • “Expected service has direct effects on customer satisfaction. Therefore, this model can be adopted however due to limited resource and budget constraints, not sure if this can be implemented fully” (PT 2). |
| Customer Support model                                 | 1                         | • “With an attitude to fix whatever problem the customer is facing, this model will improve relationships with internal customers. Hence, it will improve customer satisfaction. This is only achievable with more resources and higher budget” (PT 4). |

Source: Developed by the researcher for this research.
Table 4.15 shows that two participants suggested the CQI model. In this model, improvements are made in small increments, which is a never-ending task. In the participants’ opinions, biomedical engineering can make small changes more easily than making one big change. In their opinions, this model would work well for biomedical engineering departments. One participant suggested the Performance/perceived Satisfaction model. In this participant’s opinion, expected service has direct effects on customer satisfaction. This model, as described by interviewees, could be adapted by biomedical engineering but would require more resources. Another participant mentioned the Customer Support model. In this participant’s view, biomedical engineering’s positive attitude towards its internal customers would improve relationships under the banner of customer support; hence, this model would improve customer satisfaction.

**Case B**

Case B participants’ opinions of customer satisfaction models are illustrated in Table 4.16.

<table>
<thead>
<tr>
<th>Customer satisfaction models recommended by participants</th>
<th>Number of recommendations</th>
<th>Participants’ opinions on adoptable models</th>
</tr>
</thead>
</table>
| Continuous Quality Improvement (CQI) model               | 2                         | • “In this model, improvements are made in small increments. The department can assess the customers’ needs and make improvements to satisfy customers” (PT5).  
• “Allow continuous improvement by making small changes than to make a big change in one go. This model will work for biomedical engineering department because it will not require lot of resources in one go” (PT 6). |
| Customer Support model                                   | 1                         | • “With an attitude to support the customer in all technical problems, this model will improve relationships with internal customers. Hence, it will improve customer satisfaction” (PT 8). |
Business Excellence model

- “Focus is on management level of the department who make policies, procedures and protocols. Can be used to refine processes of management that reflect on service quality and will enhance customer satisfaction. It can be implemented for biomedical engineering departments if there are ample resources” (PT 7).

Source: Developed by the researcher for this research.

Two participants suggested CQI (Table 4.16). In their opinions, this model would allow improvements in small increments, which means that making improvements is a never-ending, but achievable task. In these participants’ opinions, CQI would work well. One participant tabled the Customer Support model. In this participant’s view, if members of the biomedical engineering team have a positive attitude towards internal customers and try to fulfil their needs, this model could be used to improve customer relationships and customer satisfaction. One participant suggested the Business Excellence model, because under this regime management could refine service quality processes and thereby enhance customer satisfaction.

Case C

Customer satisfaction models suggested by Case C participants are illustrated in Table 4.17.

Table 4.17: Customer satisfaction models recommended by Case C participants

<table>
<thead>
<tr>
<th>Customer satisfaction models recommended by participants</th>
<th>Number of recommendations</th>
<th>Participants’ opinions on adoptable models</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous Quality Improvement (CQI) model</td>
<td>1</td>
<td>“In this model, improvements are made in small increments. The department can assess the customers’ needs and make improvements to satisfy customers” (PT 9).</td>
</tr>
<tr>
<td>Performance/perceived Satisfaction model</td>
<td>1</td>
<td>“Expected service has direct effects on customer satisfaction. This model will work if there is enough resources and right level of budget allocated to the department” (PT12).</td>
</tr>
</tbody>
</table>
Six Sigma model | 2 | • “Although it is more suitable for manufacturing and commercial types of business, it can be used by biomedical engineering departments to improve quality of service by being efficient and reducing defects” (PT 11).
• “Can be adopted, but departments need to have more resource” (PT 10).

Source: Developed by the researcher for this research.

In Case C, two participants believed that Six Sigma would improve customer satisfaction, because this model can be used by businesses to increase efficiency by reducing defects. In participants’ opinions, this model could be implemented in biomedical engineering departments with more resources. One participant suggested the Performance/perceived Satisfaction model, and believed that it would have direct effects on internal customer satisfaction. This participant had limited practical experience with this model; therefore, the participant was not sure if the model would work well in a biomedical engineering type of business. One participant mooted CQI, because it can be adopted to make small changes for improvement in an arena where resources are scarce.

Case D

Customer satisfaction models suggested by Case D participants are illustrated in Table 4.18.

Table 4.18: Customer satisfaction models recommended by Case D participants

<table>
<thead>
<tr>
<th>Customer satisfaction models recommended by participants</th>
<th>Number of recommendations</th>
<th>Participants’ opinions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous Quality Improvement (CQI) model</td>
<td>1</td>
<td>• “In this model, improvements are made in small increments. It is a never-ending task. The department can assess the customers’ needs and make improvements to satisfy customers. It is easier to make small changes than to make a big change in one go” (PT 13).</td>
</tr>
<tr>
<td>Six Sigma model</td>
<td>2</td>
<td>• “Although it is more suitable for manufacturing and...</td>
</tr>
</tbody>
</table>
commercial types of business, it can be used by biomedical engineering departments to improve quality of service and customer satisfaction” (PT 15).

• “It promotes efficiency by reducing defects. Can be adopted, but department needs to increase its current level of resources” (PT 16).

<table>
<thead>
<tr>
<th>Business Excellence model</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>• “Focus is on management level of the department who make policies, procedures and protocols. It allows us to refine processes of management that reflect on service quality and will enhance customer satisfaction. It is adaptable if there is right level of resource” (PT 14).</td>
<td></td>
</tr>
</tbody>
</table>

Source: Developed by the researcher for this research.

Unlike Case C, two participants in Case D touted Six Sigma model as a method to achieve improved customer satisfaction. In their opinions, this model could increase the department’s efficiency by reducing defects. They believed that Six Sigma could be implemented with additional resources. One participant mentioned the CQI model. In his opinion, improvements could be made in small increments, which would work well for the biomedical engineering type of business. Another participant suggested that the Business Excellence model would work well to enhance customer satisfaction. Management could use this model to refine its service quality processes.

The final analysis shows that participants from all four cases (hospitals) recommended five models for customer satisfaction. Most participants supported CQI as the most appropriate model for achieving customer satisfaction. In their opinions, this model would allow biomedical engineering departments to continually assess the services they provide to internal customers, plus provide room to make procedural adjustments and alter customer feedback methods to better meet customer needs. Data analysis suggests that in the participants’ opinions, CQI is ideal for achieving service quality and customer satisfaction.

The second most recommended model amongst the participants was the Six Sigma model. In participants’ opinions, this model could be readily adopted by biomedical engineering departments for achieving customer satisfaction. However, biomedical engineering departments would require more resources to implement it properly. In the current financial climate, hospitals
are continuously under pressure to keep costs down. Therefore, although the Six Sigma model could work for biomedical engineering, it may not be effective due to budget constraints.

Other models suggested by participants were the Business Excellence model, Performance/perceived Satisfaction model and the Customer Support model. The participants who suggested the Customer Support model believed that this model would promote positive attitudes in biomedical engineering teams, leading to fulfilment of internal customers’ needs; therefore, adopting this model would improve customer relationships and customer satisfaction. The participants who recommended the Business Excellence model believed that this model would allow management to refine processes that enhance service quality and therefore customer satisfaction.

4.4.2 Document reviews

Document review was the second method of data collection offering the researcher an opportunity to gather and analyse large volumes of information from departmental documents relevant to this study. Data collected from document reviews were analysed and condensed, yielding eleven distinct categories (Table 4.19).

<table>
<thead>
<tr>
<th>No.</th>
<th>Departmental document categories</th>
<th>Documents available for review</th>
<th>Documents cited and reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Case A</td>
<td>Case B</td>
</tr>
<tr>
<td>1</td>
<td>Management systems</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Role of biomedical engineering</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Quality assurance (QA)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>Training and development</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>Customer satisfaction and service quality</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Service and support to internal customers</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>7</td>
<td>Records and traceability</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>8</td>
<td>Quality review</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Documents of Case D not reviewed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Management review</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>10</td>
<td>Internal audit</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Documents of Case D not reviewed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Internal communication and feedback</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Source:* Developed by the researcher for this research.

Table 4.19 shows that eleven categories emerged from the document review. Case documents were reviewed by category, except categories 8 and 10 in Cases C and D, because documents were not available from those hospitals.

**Category 1**

*Management systems*

Document review reveals that all four cases have a quality manual that defines policies and processes, including regulatory requirements. These manuals provide guidelines for departments to meet both customers’ needs and departmental objectives. The documentation system is organised hierarchically in all four cases. Higher-tiered management documents have a wider scope with reduced detail, and more generally described management systems; in lower-tiered documents, scope is reduced and the level of detail is increased (Figure 4.8). For example, Tier 1 includes high-level policy documents, Tier 2 includes procedural documents, Tier 3 refers to work instructions, Tier 4 refers to forms and templates and Tier 5 relates to equipment records.
Figure 4.8: *The hierarchical structure of the departmental documents*

Source: Developed for this research by the researcher.
Case A

Quality manuals are departmental documents describing management responsibilities, resource management, equipment management, protocols and procedures for equipment handling, internal and external communications and codes of conduct. The scope of the documents suggests that they should be reviewed frequently, but examination suggests that this does not occur. In fact, documents are only reviewed when the staff feel review is necessary, despite the fact that the quality manual prescribes a two-to-three yearly review cycle. Records show that when department decide to make changes to any existing documents, they follow document control process.

Document review further shows that Case A has a triangular hierarchical structure in which staff responsibility is commensurate with their position within the department. For example, the manager has overall responsibility for the biomedical engineering department. The supervisor plans and manages day-to-day activities, assists the manager in strategic business plans, and also assists and advises engineers and technicians in making technical decisions. Case A also uses an ISO 9000-based management system and has a continuous improvement approach towards their entire business.

Case B

Case B also has a quality manual that describes policies, procedures, management responsibilities, resource management, equipment management, protocols and procedures for equipment handling, internal and external communication and codes of conduct. Case B’s quality manual states that all documents should be frequently reviewed. Analysis shows that documents are only reviewed as necessary, like Case A. Case B has a triangular hierarchical structure much the same as Case A. Also like Case A, the department uses an ISO 9000-based management system and has a continuous improvement approach towards their entire business.

Case C

Case C’s quality manual covers the same categories, including codes of conduct. Case C is a branch of the facilities management department; therefore, biomedical engineering does not have a dedicated manager. Rather, the department has a supervisor who reports to the manager of the facilities management department. The supervisor plans and manages day-to-day activities,
assists the facilities manager in developing strategic business plans and also advises engineers and technicians in making technical decisions. Case C’s management system is based on the ISO 9000 risk management system, and takes a customer-focused approach to meet its objectives. Departmental documents show that processes and procedures are not regularly reviewed. Reviews only occur when senior staff members decide that a review is necessary.

**Case D**

Like Case C, Case D has a quality manual that refers to the same aspects of quality management and conduct. Case D is a branch of the facilities management department; the department has a supervisor who reports to the facilities management head. The supervisor plans and manages biomedical engineering’s day-to-day activities. Case D’s management system is also based on the ISO 9000 risk management system, and takes a customer focused approach to meet its objectives. The quality manual states that departmental documents should be reviewed regularly. However, documents reveal that processes and procedures are only reviewed when staff determine that a review would be beneficial.

The documents of all four cases illustrate that, in fact, reviews occur infrequently. Analysis clearly shows that all cases have a quality manual that defines policies and processes, including regulatory requirements, and that the documentation system is organised hierarchically.

**Category 2**

**The role of biomedical engineering departments**

Departmental documents show that the biomedical engineering departments play a key role in hospitals. Most functions of the biomedical engineering team are similar across the four cases.

**Cases A to D**

Departmental documents in all cases stipulate that biomedical engineering’s role is to manage biomedical technology and provide technical support to clinicians. The document review illustrates that biomedical engineering departments manage all clinical equipment for the hospital. Key elements of their service include:
(i) pre-purchase consultations, in which the department investigates the competence of suppliers, checks equipment specifications, and analyses future maintenance costs;

(ii) incoming inspections (acceptance testing) of new equipment either purchased by the hospital or brought in for clinical trials;

(iii) preventive maintenance and periodic inspections (QA) of equipment as per the medical equipment management standard (AS/NZS 3551:2012- Management programme for medical devices for New Zealand and Australia);

(iv) equipment safety checks such as screening hazard notices and performing electrical safety tests;

(v) training equipment users on the safe and effective use of new technologies;

(vi) providing technical advice and assisting clinicians with physiological measurements in clinical procedures such as catheterisation procedures, cardiac investigation studies, patient data networking, alarm setting, and patient parameter programming;

(vii) general technical support with operational and technical issues at the patient’s bedside;

(viii) equipment registration and decommissioning;

(ix) advising the hospital on regulatory issues relating to clinical equipment; and

(x) management of the equipment database.

Analysis reveals that biomedical engineering departments provide technical support on all aspects of clinical equipment, as reported by participants in face-to-face interviews. They also assist clinicians on equipment-related matters and promote safety to both the patients as well as equipment operators.

Category 3

Quality assurance (QA)

This category discusses the QA programmes of each case.
Case A

Case A’s quality manual clearly states that QA on all biomedical equipment is to be executed once per year to verify that it is operating within the manufacturer’s specifications. The QA programme is supported by a series of departmental procedures that describe testing methods. Document review illustrates that the QA programme is executed throughout the year. Each clinical area is scheduled for QA checks at different times so that the equipment is not out of service for longer periods or all at once. Quality assurance records are kept in an electronic database. Departmental quality review documents for the QA programme show that Case A has an 80% success rate in achieving QA programme.

Case B

The quality manual in Case B also stipulates that biomedical equipment should be QA tested once per year. Document review reveals that QA checks on clinical equipment are executed throughout the year, in accordance with the manual. Under Case B’s QA programme, equipment is performance verified and records are kept in the equipment database for future reference. Departmental quality and QA documents state that the department has a 75% success rate in achieving its QA programme goals, lower than Case A by 5%.

Case C

Case C’s documents also clearly state that QA checks are to be carried out once a year to verify that equipment is operating within manufacturers’ specifications. Case C also has a QA programme scheduled to run throughout the year. Analysis reveals that only high-risk equipment is performance verified under the QA program. All QA checks are carried out in accordance with the AS/NZS3551:2012 standard. QA records are kept in an electronic database. Departmental quality and management review documents state that the QA programme success rate averages 76%.

Case D

The Case D, the QA scenario mirrors that of the other hospitals. Document review indicates that due to a lack of resources, Case D carries out QA checks once a year on high-risk equipment only. Other biomedical equipment is performance verified if time permits. All checks
are carried out in accordance with the AS/NZS3551:2012 standard. Quality assurance records are kept in a database. Management review documents state that the department has up to an 80% success rate with its QA programme.

In summary, all cases have a QA programme for clinical equipment. Under their QA programmes, hospital equipment is performance verified to confirm that it is operating within manufacturers’ specifications. Quality assurance programmes are executed throughout the year. All clinical wards including clinics are scheduled for QA checks on existing clinical equipment at different times of the year so that the equipment is not out of service for long periods. Analysis of QA and management review documents shows that success rate of QA programmes in all cases is between 75%–80%.

**Category 4**

*Training and development*

The documents of all cases reveal that there is a training and development plan for all engineers and technicians. Training is provided in two forms.

(i) On-the-job training occurs in a normal working environment, using the actual tools, equipment, documents and material that staff would normally use when fully competent.

(ii) Off-the-job training occurs away from the normal workplace. This type of training is usually conducted in a classroom situation on specific equipment. In some cases, this training is conducted by the manufacturer at the manufacturing site.

**Case A**

A review of departmental documents suggests that engineers and technicians who attain a tertiary level qualification in engineering, medical science or the equivalent are recruited to work in Case A’s biomedical engineering department. Senior staff assess new personnel when they join the department, and training and development plans are established. Training is provided in accordance with the training plan.

Once training is complete, the trainer assesses the trainee engineer to be competent; the newly trained engineer is allowed to work without supervision and is empowered to make
decisions regarding clinical equipment. Training records show that most training is conducted within the hospital. Records of training are kept by the human resources department.

**Case B**

Case B’s departmental documents specify that all biomedical engineers and technicians should be appropriately trained before they can carry out biomedical tasks unsupervised. According to departmental documents, training usually begins with hospital policies and health and safety, followed by training on various types of clinical equipment. Once their training is complete, junior engineers and technicians are allowed to work alone. Their training records are kept by the human resources department.

**Case C**

Case C has a policy of recruiting staff who have attained tertiary level qualifications in engineering or medical science. The biomedical engineering department develops training programme for all engineers and technicians. On account of budget constraints, most training is held on the job. Experienced members of the department conduct training. Some off-the-job training is also provided to engineers, mostly by equipment manufacturers. The department frequently conducts awareness training to keep engineers and technicians informed on changes in regulations, software upgrades and new equipment purchases.

**Case D**

Case D’s documents suggest that engineers and technicians who have attained a tertiary-level qualification in engineering and have previous experience are recruited, like other cases (hospitals). Staff are trained in accordance to the training plan. Most training is held on the job and is conducted by senior members of the department or the equipment suppliers. Once staff gain good product knowledge and experience on one equipment type, they progress to the next equipment type. Some off-the-job training is also provided to engineers, mostly by manufacturers.
It is clear from the document analysis that all four cases only recruit engineers and technicians who have attained a tertiary-level qualification in engineering or medical science. According to hospital documents, post-recruitment trainings are conducted in two forms:

(i) on-the-job training, and  
(ii) off-the-job training.

Category 5

Customer satisfaction and service quality

This category discusses how cases measure service quality.

Case A

Case A conducts customer satisfaction surveys once a year to determine their customers’ perception of service quality. The results of the survey are used to evaluate:

(i) the current level of internal customer satisfaction with biomedical engineering services;  
(ii) how to improve customer satisfaction;  
(iii) whether a need exists to improve current biomedical engineering practices to achieve higher levels of customer satisfaction; and  
(iv) what level of resources will be required to meet the customers’ needs in the near future.

Case B

Case B also conducts annual customer surveys to measure customer perceptions of service quality.

Case B uses survey results to determine:

(i) the current level of internal customer satisfaction with biomedical engineering services;
(ii) whether additional services are required by their internal customers and how these needs can be met with the current level of resources;

(iii) how improvements can be made in current practices to enhance customer requirements; and

(iv) how customer satisfaction can be improved.

**Case C**

Case C likewise carries out annual surveys to measure customer satisfaction. This biomedical engineering department uses survey results to understand:

(i) the current level of internal customer satisfaction with biomedical engineering services;

(ii) future resources that will be required to maintain a high level of customer satisfaction;

(iii) whether the department is achieving its objectives; and

(iv) improvements that can be made in current practices to enhance service quality and customer satisfaction.

**Case D**

Document review suggests that unlike other cases, Case D conducts annual surveys to measure service quality and customer satisfaction. The survey results are used to determine:

(i) customers’ perceptions of the current level of service;

(ii) whether the department is providing cost-effective services with current resources;

(iii) future resources that will be required to maintain a high level of customer satisfaction; and

(iv) how improvements can be made to enhance service quality and customer satisfaction.

The document review indicates that all cases conduct customer surveys once a year to determine their customer’s perceptions of service quality. From the results of this annual survey,
cases determine if they are achieving objectives, what improvements are needed in current services, future resources that may be needed and how improvements can be made to enhance service quality and customer satisfaction.

**Category 6**

*Service and support to internal customers*

Documents in this category describe how cases handle service requests for medical devices.

**Case A**

Case A has a well-defined process for servicing medical devices. AS/NZS3551:2012 standard (a management programme for medical devices for New Zealand and Australia) guidelines are closely followed for managing medical equipment. The equipment servicing process is clearly written and easy to follow. Equipment servicing processes state that service requests can be received from internal customers in various ways, including email, telephone calls or in-person visits. Upon completion of the service, equipment is performance verified, and its electrical safety is tested.

**Case B**

Case B also closely follows AS/NZS3551:2012 guidelines for equipment servicing. The equipment servicing process is used for servicing and calibrating clinical equipment. Documents state that service requests can be received via email, telephone calls or in-person visits. After servicing, equipment is performance verified and tested for electrical safety.

**Case C**

Case C also adheres to AS/NZS3551:2012 guidelines for equipment servicing. Case C has a well-defined process for equipment servicing. Official documents state that service requests can be received from internal customers in various ways such as email, telephone calls or in-person visits.
Case D

Like other cases, Case D has a well-defined equipment servicing process based on the AS/NZS3551:2012 standard.

Indeed, document analysis shows that all cases follow AS/NZS3551:2012 guidelines for servicing and managing biomedical equipment, as reported by the participants during face-to-face interviews. The researcher found that equipment servicing processes are clearly written and easy to follow in all cases.

Category 7
Records and traceability

This category describes how cases manage records of biomedical equipment and departmental documents.

Case A

In Case A, the biomedical engineering department keeps various types of departmental documents electronically in their EAM database. The database includes documents such as the quality manual, equipment service histories, job instructions, processes and procedures and other biomedical-related documents. The equipment records in the database suggest that most biomedical engineering equipment has a lifespan of seven years. All biomedical engineering staff have access to the database.

Case B

Case B keeps various departmental documents electronically in their Tec-Track database. Documents available include quality manuals, equipment service histories, job instructions, processes, procedures and other supporting documents. Equipment records in the database indicate that most clinical equipment reaches the end of its useful life within seven years. Every staff member has access to the database. The information in the database is used for various purposes such as equipment reports, tracing maintenance costs of equipment and asset planning.
Case C

Case C also uses the EAM database. It holds electronic records of equipment service histories, job instructions, processes, procedures and other supporting documents. The equipment records indicate that the majority of the equipment gets replaced within five to seven years. Information can be retrieved via several search fields, such as serial number, asset registration number and purchase order number.

Case D

Departmental documents are kept electronically in the BIMS database. Equipment details can be retrieved by searching in the database; documents available for retrieval include the quality manual, equipment service histories, job instructions, processes, procedures, records of decommissioned items and other supporting documents. All biomedical engineering staff have access to the database.

The researcher has found that all case studies (hospitals) keep various types of departmental and equipment records electronically in their equipment databases for future reference. Equipment information can be retrieved from databases easily, because several search fields such as serial number, asset registration number and purchase order number are active. Cases studies use different software packages to support their equipment databases.

Category 8

Quality reviews

This category explains how cases review their service quality.

Cases A and B

Case A holds a monthly quality review meeting in which biomedical engineering staff discuss the following:

(i) changes in departmental quality practices, procedures and equipment handling protocols;
(ii) reviews and updates of QA and electrical safety testing programmes;
(iii) customer feedback;
(iv) complaints and compliments from customers;
(v) follow-up on the results of internal and external audits; and
(vi) general discussion of quality issues such as training, operational issues that could affect service quality and customer satisfaction.

Case C
Case C has no scheduled meetings for quality review. Rather, quality-related issues are discussed in management review meetings. Under Case C’s quality agenda, the following are discussed:

(i) departmental quality practices, procedures and equipment handling protocols;
(ii) follow-up on the results of internal and external audits;
(iii) health and safety issues; and
(iv) general quality issues such as reworks, customer complaints and training.

Case D
Case D does not hold separate quality review meetings; quality issues are discussed in management review meetings instead. The following quality-related issues are discussed in their management review meetings:

(i) amendments and new releases of biomedical and electrical regulations;
(ii) training requirements to maintain service quality;
(iii) costs relating to quality issues;
(iv) complaints and compliments from customers;
(v) health and safety issues; and
(vi) improvements in current services.

Documents suggest that Case A holds quality review meetings every month, Case B every second month, and Cases C and D discuss quality-related issues in their management review meetings. Analysis shows that although cases are holding their meetings at different time intervals, there is no evidence of any adverse effects on internal customer service.
**Category 9**

*Management review*

This category discusses management review in all cases.

**Case A**

It was established that Case A holds management review meeting monthly. In management review meetings, management issues, business and financial matters are discussed. Discussions address business plans, projects, budgets, resources levels and how service quality and customer satisfaction can be improved.

**Case B**

Case B holds its management review meeting every second month. In the management review meeting, management issues, business and financial matters are discussed. These discussions address projects, budgets, resourcing, staff training, equipment-related incident investigations and how service quality and customer satisfaction can be improved.

**Case C**

Case C holds management review meetings every three months (quarterly). These meetings also address issues such as projects, budgets, resourcing, staff training, equipment-related incident investigations and how service quality and customer satisfaction can be improved.

**Case D**

Case D’s management review meetings are held every six months (half-yearly). Like other cases, the meetings address business plans, projects, budgets, resourcing and how service quality and customer satisfaction can be improved.

Documents review show that cases hold management reviews at different time intervals. Case A holds management review meetings monthly, Case B every second month, Case C every three months and Case D every six months. Mainly, management issues are discussed in these meetings. Cases C and D also discusses quality issues in their management meetings.
**Category 10**

*Internal audits*

In this category, the internal audits of the cases are discussed.

**Case A**

Departmental documents clearly state that Case A conducts regular internal audits. The results of the internal audits were available for review.

**Case B**

Case B’s documents suggest that regular internal audits are conducted, but documentation regarding internal audits is not complete. During the document review, a complete audit result could not be found, because paperwork was not complete and documents therefore could not be accessed.

**Case C**

Case C conducts regular internal audits, but like Case B, documentation remains incomplete. Some documents relating to internal audit results and corrective actions could not be found. Some corrective actions and audit recommendations were incomplete.

**Case D**

The quality manual clearly states that regular audits should be executed. However, internal audits are not conducted at all; therefore, documents relating to internal audits were not available.

In summary, only Case A holds internal audits regularly and keeps detailed, complete records. Cases B and C also conduct internal audits, but the issues arising from internal audits are not documented properly. The documents suggest that the matters arising from internal audits are not actioned and that internal audit documents are incomplete. Regular internal audits are not conducted in Case D.
It can be said that lack of regular audits can have effects on quality of service. It is the researcher’s view that regular audits can assist biomedical engineering departments in achieving their objectives by examining, evaluating and improving their activities through internal audits.

**Category 11**

*Internal communication and feedback*

The analysis shows that all cases are using the same methods of communicating and feedback.

**Cases A to D**

All cases’ documents show that these hospitals use two common methods of communication and feedback.

(i) *Informal communication and feedback*: includes phone discussions and verbal discussions at the patient’s bedside in medical wards regarding equipment malfunction, technical operations of clinical equipment and other biomedical-related issues.

(ii) *Formal communication and feedback*: includes service reports, meetings, training reports, emails and departmental circulars.

**4.4.3 Case study observations**

Observation was the third method of data collection. This approach enabled the researcher to observe frontline biomedical engineering staff actively engaged in the business of providing service to clinicians. Data collected from observations were analysed and condensed into eleven categories, similar to or the same as categories obtained from face-to-face interviews. These eleven categories gave the researcher an opportunity to triangulate with data collected from face-to-face interviews and with data obtained from document reviews (Table 4.20).
### Table 4.20: Case study observations

<table>
<thead>
<tr>
<th>No.</th>
<th>Category</th>
<th>Observed</th>
<th>Summary of the analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Accessibility</td>
<td>Yes</td>
<td>• The department is centrally positioned in the hospital and can be located easily.</td>
</tr>
<tr>
<td>2</td>
<td>Current management system</td>
<td>Yes</td>
<td>• The management system is based on the ISO 9000 management system. Quality manuals are available and are consulted regularly.                                                      • The structure of the department consists of a manager, supervisor, senior engineers, engineers, technicians and administrative staff. The staff were generally happy in their jobs.</td>
</tr>
<tr>
<td>3</td>
<td>Role of biomedical engineering</td>
<td>Yes</td>
<td>• The biomedical engineering department provides technical service and support, and manages clinical technology for the entire hospital.</td>
</tr>
<tr>
<td>4</td>
<td>Quality assurance (QA)</td>
<td>Yes</td>
<td>• QA programme is in place for all clinical equipment.</td>
</tr>
<tr>
<td>5</td>
<td>Training and development</td>
<td>Yes</td>
<td>• Staff are given limited on-the-job and off-the-job training on specialist equipment.</td>
</tr>
<tr>
<td>6</td>
<td>Customer satisfaction and service quality</td>
<td>Yes</td>
<td>• Various processes and procedures are in place for biomedical engineering tasks. Advice and assistance are often given to clinicians on technical issues.</td>
</tr>
<tr>
<td>7</td>
<td>Equipment control (asset registration and decommissioning)</td>
<td>Yes</td>
<td>• Processes are in place for equipment control including acceptance, registration and decommissioning, testing, repair and calibration.                                                      • Equipment details are loaded into the equipment database for traceability.</td>
</tr>
<tr>
<td>8</td>
<td>Records and traceability</td>
<td>Yes</td>
<td>• All cases keep records in electronic form in equipment databases.</td>
</tr>
<tr>
<td>9</td>
<td>Departmental meetings</td>
<td>Yes</td>
<td>• Operational issues are discussed in departmental meetings.</td>
</tr>
</tbody>
</table>
Common methods of communication include verbal, phone, and face-to-face discussions for day-to-day activities, email, reports and meetings for formal communication.

All cases have procedures in place for complaints investigations.

Source: Developed by the researcher for this research.

The eleven categories illustrated in Table 4.20 are discussed below:

**Category 1**

**Accessibility**

This category is a discussion about how biomedical engineering departments maintain contact with internal customers, keep response times for clinical support to a minimum and maintain good working relationships.

**Case A**

Case A’s biomedical engineering workshop is within the hospital complex, close to the clinical wards. Internal customers walk in and out of the workshop freely to seek assistance and advice from biomedical engineers and technicians. Case A also has satellite workshops close to acute areas to maintain minimum response times for technical support. During observation, it was noticed that the staff were prepared to listen to the clinician’s concerns and discussed their problems in a professional manner. There were instances when engineers and technicians went out of their way to assist the internal customers. The senior members displayed transformational style of leadership by giving personal attention to junior members, had empathy, trust and respect, and treated them as individuals. Senior staff also encouraged junior staff to learn new technology.

**Case B**

The workshop is clearly labelled for incoming and outgoing equipment. A good working relationship exists between all staff, including senior members and supervisors. The supervisor,
as a leader, promotes intelligence and rationality, and encourages members to pursue innovative solutions to operational as well as equipment-related problems. The biomedical engineering workshop is located within the hospital complex, close to clinical wards. It also has a satellite workshop close to acute services to keep response times to a minimum. Service calls are frequently received via phone and in person. Technicians and engineers frequently visit wards to assist clinicians. Like Case A, Case B also has satellite workshops close to acute areas to maintain minimum response times for technical support. Direct observation shows that Case B’s staff operate as a team and enjoy their work environment. It was noticed that the staff had good working relationships and showed respect when communicating with internal customers. They put extra effort into their jobs to assist clinicians on equipment-related problems.

**Case C**

The biomedical engineering department in Case C has one central workshop located within the hospital complex. The workshop has ample facilities to carry out biomedical tasks. Observation reveals that the workshop is clearly labelled for incoming and outgoing equipment. A good working relationship exists between all staff, including senior members and supervisors of the department and internal customers. Biomedical engineering team members are supportive and helpful to each other and share tasks to maintain minimum equipment downtime. During busy times, staff members were prepared to work extra time at short notice to relieve work pressure.

**Case D**

Like Case C, Case D also has one central workshop located within the hospital complex and has ample facilities to carry out biomedical tasks. Internal customers walk in and out of the workshop freely to seek assistance and advice from engineers and technicians. The workshop is clearly labelled for incoming and outgoing equipment. A good working relationship exists between biomedical engineering staff and clinicians.

Category 1 observations reveal that the cases are practicing transformational styles of leadership and that senior staff had empathy, trust and respect for all staff members. Biomedical engineering workshops are easily accessible by clinicians and hospital support staff. Cases A and B have satellite workshops near acute services so that they can keep response times to a
minimum, while cases C and D have one central workshop located in the main hospital complex. Biomedical engineers and technicians can be contacted by phone and email. Internal customers walk freely in and out of the workshops to seek assistance and advice in all cases. Internal customers are generally satisfied with the service they get from biomedical engineering teams. The members of all cases show respect and empathy, and are always willing to listen to their customers’ concerns and to put extra efforts in to solve equipment-related problems.

Category 2

Current management systems

This category discusses how current management practices are executed.

Case A

Observation suggests that Case A’s management system is based on the principles of the ISO 9000 management system. Their quality manual is available to all departmental staff and is frequently consulted by engineers and technicians. This biomedical engineering department has a hierarchical structure in which the level of responsibility is in accordance with one’s position in the department. Case A’s biomedical engineering department follows the AS/NZS3551:2012 standard (a management programme for medical devices for New Zealand and Australia) for equipment management. On several occasions, the researcher noticed staff members discussing ways and means of improving their current processes.

Case B

Direct observation shows that an electronic copy of the quality manual is stored in the equipment database. Engineers, technicians and other staff engaged in biomedical engineering tasks frequently refer to the quality manual for processes, procedures and service guidelines. The database is frequently updated with equipment details. Case B also follows AS/NZS3551:2012 standards for managing equipment. Their management system is based on ISO 9000 management system principles, and staff take a process approach to deliver service to internal customers; the hierarchical structure is the same as in Case A.
Case C

Observation suggests that Case C also has an ISO 9000-based management system and a quality manual that outlines processes and procedures. Case C also follows the AS/NZS3551:2012 standard for managing biomedical engineering equipment. The department’s structure is a hierarchical structure, as in other cases (hospitals). Case C uses a customer-focused approach comprised of interdepartmental meetings, day-to-day communications and customer feedback to identify internal customer needs.

Case D

Case D takes a customer-focused approach, similar to Case C. Case D staff use meetings, day-to-day communications and customer feedback to identify internal customers’ needs. They also have an ISO 9000-based management system. Like the other three cases, Case D has a quality manual that describes processes and procedures. Case D follows the AS/NZS3551:2012 standard for managing biomedical equipment, and has a hierarchical structure mimicking Case C’s.

From direct observation, the researcher has established that all cases are using an ISO 9000 based management system and that all cases follow the AS/NZS3551:2012 standard to manage clinical equipment. Furthermore, Cases A and B take an open approach towards process improvement, and welcome new ideas from staff, while Cases C and D are more customer focused.

Category 3

The role of biomedical engineering

This category explores the role of biomedical engineering departments in public hospitals. Observations revealed that in all cases, biomedical engineering’s role is to manage all existing clinical equipment in the hospital. Biomedical engineering departments provide technical support on all aspects of clinical equipment, as reported by participants in face-to-face interviews. They also assist clinicians on equipment-related matters and promote safety to both the patients and equipment operators.
Case A

Frontline staff actively engage in various biomedical engineering-related tasks such as equipment registration, acceptance testing of new equipment and repairing and calibrating medical equipment. During observation, the researcher noticed on several occasions senior engineers who were evaluating new equipment that the hospital intended to purchase. On several occasions, the researcher also observed engineers and technicians giving advice by phone to the clinicians.

Case B

Observations at Case B suggested that biomedical engineers and technicians engage in day-to-day activities of the biomedical engineering department. On several occasions it was noticed that the supervisor and the biomedical engineering manager were discussing equipment maintenance cost, health and safety issues and resources required for special projects, such as the installation of clinical equipment in the operating theatre. The researcher also observed biomedical engineers assisting clinicians in setting up equipment at patients’ bedsides and giving technical advice to clinicians by phone.

Case C

During observation, the researcher noticed biomedical engineers and technicians actively engaging in various biomedical engineering duties. The researcher observed the biomedical engineering team discussing costs of installing new equipment in the ICU with the supplier. The engineers and technicians were evaluating test results obtained from an electro-surgical unit. A couple of technicians were engaged in repairing a faulty patient monitor. Clearly, these observations show that Case C’s biomedical engineering department plays a vital role in the hospital, especially in regards to cost negotiations, equipment safety and equipment management.

Case D

In Case D, the researcher observed biomedical engineering staff carrying out tasks much the same as in other cases. Observation revealed that the supervisor and engineers assist the purchasing department in capital equipment purchases by giving technical advice. On several
occasions, the researcher noticed engineers and technicians discussing equipment faults and repair options, and assisting clinicians with equipment-related problems.

Cumulative observations showed that frontline biomedical engineering staff actively engage in various types of biomedical engineering duties, including registration and acceptance testing of new equipment, repairing and calibrating medical equipment, performing preventive maintenance and electrical safety tests, installing and commissioning of new equipment and providing in-service training to clinicians. From observations, it can be said that biomedical engineering departments manage all clinical equipment; therefore, they play a vital role in public hospitals.

**Category 4**

*Quality assurance (QA)*

In all four cases, biomedical engineering departments use the term “QA programme” or “QA check” to describe performance verification of clinical equipment. Category 4 describes how QA is carried out on all clinical equipment within the hospital setting.

**Cases A to D**

For QA programmes, all clinical areas are scheduled for QA checks at different times throughout the year. Equipment is performance verified as per the manufacturers’ instructions, using a pre-prepared QA check sheet or as per the technical manual. After QA checks, the equipment is electrical safety tested and returned for clinical use. If the equipment is found to be faulty or fails to meet the manufacturer’s specifications, it is removed from service, repaired and returned for clinical use at a later time. Results from QA checks are loaded into the equipment database for future reference.

**Category 5**

*Training and development*

Category 5 describes how training is conducted in biomedical engineering departments.
Case A
The researcher witnessed technicians being trained by the senior engineer on a patient monitoring system. Various types of training resources are also available to engineers and technicians in their biomedical engineering department library.

Case B
During the observation period, some unplanned on-the-job training was conducted in-house by the senior engineers, but no formal training was conducted for biomedical engineering staff. However, an email on safe usage of medical devices was circulated to the biomedical engineering team and to the nurse managers of acute services.

Case C
During the observation period, formal on-the-job training was conducted for the biomedical engineering staff. The researcher observed two on-the-job trainings being given to technicians and senior engineers on high-risk equipment (training on the use of a ventilator and an infusion device).

Case D
The researcher witnessed at least one training session for engineers and technicians that was conducted on servo ventilators on site by the nurse educator from the ICU. This training provided an overview of the different modes of ventilation. The educator went through the clinical aspects of ventilation, followed by patient setup. At the end of the training session, each trainee practised by setting up a dummy patient on a ventilator.

During the observation period, the researcher witnessed some on-the-job trainings for high-risk clinical equipment. Engineers and technicians were provided with both written notes and hands-on experience; however, the researcher did not observe any external training.

Category 6
Service quality and customer satisfaction

This category discusses how cases achieve service quality and customer satisfaction.
Cases A to D

During observation, the researcher noticed that technicians and engineers carried out service request tasks in a professional and timely manner. Their swift responses minimised equipment downtime. Biomedical engineering staff had a good relationship with their internal customers (clinicians). They maintained service quality by meeting deadlines and by keeping the end user well informed about the status of their equipment. Further observations revealed that engineers and technicians are often contacted by clinicians to solve equipment-related problems in the medical wards and at the patient’s bedside. Comprehensive records of clinical equipment were available in all four cases’ clinical equipment databases. Equipment reports were extracted efficiently from the equipment databases when required.

Category 7
Clinical equipment control

This category explains how clinical equipment is controlled by biomedical engineering departments in all four cases.

Case A

All incoming equipment is acceptance checked and tested. In this process, equipment is checked against the delivery paperwork for correctness. The new equipment is asset registered and performance verified as per the manufacturer’s specifications. Details are loaded into the database. Old and obsolete equipment is decommissioned through an equipment decommissioning process, formally removed from clinical use and written off.

Case B

All incoming new equipment purchased by the hospital is delivered to the inwards goods department of the hospital. The equipment is then forwarded to the biomedical engineering department, where the process of commissioning commences. Equipment is asset registered, acceptance checked and a QA check sheet is prepared. Equipment details are loaded into the equipment database. Any equipment leaving the hospital for outside repair is also controlled by the biomedical engineering department. Obsolete equipment is decommissioned and removed from the database.
Case C

All incoming equipment to hospital C must first go through an acceptance check. The supplier must provide a copy of test results to confirm that the equipment has been tested. The equipment is then registered, and the details are recorded in an electronic database. Once the acceptance check process is complete, the equipment is released for clinical use. When equipment becomes obsolete or is found to be uneconomical to repair, it is decommissioned and removed from service.

Case D

Case D’s equipment control process is similar to Case C’s process, where the supplier provides a copy of test results as evidence that the equipment has been tested. Incoming equipment is asset registered, electrical safety tested and details of the equipment are loaded into the equipment database. Once the acceptance check process is completed, it is released for clinical use. Any equipment leaving the hospital for outside repair is recorded in the equipment database. When the equipment becomes obsolete, it is decommissioned and removed from the equipment database.

It was established from observation that all cases carry out asset registration and acceptance checks on all incoming clinical equipment. Cases A and B carry out full acceptance check and tests on new equipment, and Cases C and D will accept suppliers’ test results and will only carry out electrical safety tests. Equipment leaving hospitals for outside repairs is recorded. Equipment details are frequently updated in the databases.

Category 8

Records and traceability

This category discusses how cases manage departmental documents and equipment information. Observations show that all four cases (A, B, C and D) store departmental documents including equipment records in their electronic databases. Engineers, technicians, supervisors and administrative staff frequently consult equipment databases for records and equipment-related information such as service history, purchase order details, spare part details
Category 9

Monthly departmental meetings (operational issues)

This category discusses the contents of departmental meetings.

Case A

Departmental meetings are conducted monthly by the supervisor. In these meetings, operational issues are discussed, such as:

(i) changes in electrical regulations;
(ii) service request issues concerning clinical equipment such as spare part availability, service response times and equipment downtime;
(iii) issues relating to progress on QA programmes;
(iv) training requirements and progress on training and development programmes;
(v) administration issues such as records and traceability, incomplete paperwork and service reports;
(vi) service complaints regarding poor communication and customer feedback; and
(vii) internal audits, projects and general business such as annual leave.

Case B

The monthly departmental meeting is led by the supervisor. The points of discussion at this meeting include:

(i) progress of the electrical safety testing programme;
(ii) progress of QA checks;
(iii) administration issues such as records and traceability, incomplete paperwork and service reports;
(iv) internal and external training;
(v) management and control of new and trial equipment coming to the hospital; and
(vi) general discussion on service quality and customer feedback.

Case C

The researcher learned that the supervisor leads monthly departmental meetings at Case C, in which the team discusses departmental operational matters. Key discussions address:

(i) service request issues such as equipment faults, preventive maintenance, service response times and pending repairs;
(ii) changes in biomedical engineering and electrical regulations;
(iii) issues relating to QA checks and progress achieved in QA programmes;
(iv) administration issues such as records and traceability, incomplete paperwork and service reports;
(v) management and control of clinical equipment such as new and obsolete equipment; and
(vi) general discussions on training, internal audits and annual leave.

Case D

Case D also held departmental meetings once per month. The supervisor conducts the meeting, and the team discusses the following points:

(i) service request issues concerning clinical equipment such as equipment faults, preventive maintenance, service response times and pending repairs;
(ii) management of departmental records for traceability;
(iii) administration issues such as incomplete paperwork, special projects and service reports;
(iv) progress of the electrical safety testing programme;
(v) training requirements and progress on training and development programmes; and
(vi) general discussion such as projects and customer feedback.

Observation reveals that monthly departmental meetings in all four cases focus on operational issues. These meetings are conducted by the supervisor, and all members are given
opportunity to give feedback on biomedical-related issues such as projects, service tasks and plans for the following month.

**Category 10**

*Internal communication and feedback*

This category discusses the four cases’ internal communication and feedback methods.

**Cases A to D**

Observation shows that all cases use two common methods of communication and feedback:

(i) informal communication and feedback includes phone discussions, verbal discussions concerning equipment malfunctions at the patient’s bedside, technical operations of clinical equipment and other issues; and

(ii) formal communication and feedback includes service reports, meetings, training reports, emails and departmental circulars.

**Category 11**

*Internal customer complaint handling*

This category discusses how biomedical engineering services and internal customer complaints are handled by the cases.

**Cases A to D**

Observation reveals that all cases classify customer complaints into three main categories:

(i) service complaints: biomedical engineering service-related complaints;

(ii) equipment malfunction: equipment malfunction-related complaints; and

(iii) equipment-related incidents: patient injury due to equipment malfunction.

During observation, several equipment malfunctions were reported. Some complaints regarding biomedical services were recorded as well; these complaints arose because the status
of the equipment was not reported to the end user. No incident-related complaints were recorded. From the analysis, it can be said that in all four cases, complaint handling procedures were virtually identical.

4.5 Cross-case analysis

Cross-case analysis is a research method that facilitates the comparison of commonalities and difference in events, activities and processes that are the units of analysis in case studies (Khan & Van Wynsberghe, 2008). In the previous section, the researcher discussed data collected from three methods and analysed emerging themes from the four hospital cases.

In this section the researcher is using cross-case analysis to examine the commonalities and differences amongst the four cases. First, cross-case analysis is conducted separately for face-to-face interviews, followed by cross analysis of document reviews and the observational analysis. The cross-case analysis summary is presented at the end of this section.

4.5.1 Face-to-face interviews

Cross-case analysis of the interview results is presented in Table 4.21.

<table>
<thead>
<tr>
<th>Commonalities</th>
<th>Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All cases have a hierarchical structure consisting of a manager, supervisor, senior engineers, engineers, technicians, trainees and administrative staff. The responsibilities of the staff depend on their place in the hierarchy.</td>
<td>• Cases A and B use a Continuous Quality Improvement (CQI) system and Cases C and D use a risk management system.</td>
</tr>
<tr>
<td>• All cases have a quality manual that provides detailed information on processes, protocols and procedures for biomedical engineering services.</td>
<td>• Cases A, B and C carry out internal audits once a year and Case D does not hold internal audits.</td>
</tr>
<tr>
<td>• In all cases, biomedical engineering departments are responsible for managing all aspects of medical technology.</td>
<td>• Complaint management is the same amongst the cases, but incident investigation reporting methods are different.</td>
</tr>
</tbody>
</table>
- Biomedical engineering departments are responsible for explaining new technologies and their impacts on operating costs.
- Biomedical engineering departments manage all phases of clinical equipment lifecycles.
- All equipment arriving at the hospital is asset registered and electrical safety tested; equipment details are recorded in the equipment database.
- All cases run QA programmes for clinical equipment. Under these programmes, all existing clinical equipment in the hospital is performance verified to ensure that it is operating within the manufacturer’s specifications.
- Cases have training and development programmes available for biomedical engineers and technicians.
- Cases measure service quality and customer satisfaction by customer feedback, number of return jobs and annual customer surveys.
- All cases keep various types of biomedical engineering departmental documents in electronic form in a database.
- All cases use the same methods of communication and feedback (i.e., formal and informal).
- All cases have regular departmental meetings. Mostly operational issues are discussed in these meetings.
- Cases A and B carry out performance verification checks on all existing clinical equipment, and Cases C and D carry out performance verification checks on high-risk clinical equipment only.
- Equipment databases use different software packages.
- Cases A and B carry out full acceptance tests on new equipment, and Cases C and D accept the suppliers’ test results but carry out electrical safety tests only.
- Cases A and D emphasise time management and promote minimum equipment downtime.
- Cases B and C allow staff to work at their own pace and promote innovative methods to solve equipment faults.
- Case A holds quality review meetings monthly, and Case B holds a meeting every second month, while Cases C and D do not have separate quality review meetings, they discuss quality issues in their management review meetings.
- Cases hold management review meetings at different time intervals: Case A monthly, Case B every second month, Case C every three months and Case D every six months.

**Source:** Developed by the researcher for this research.

Table 4.21 shows that all cases operate under a hierarchical structure. Staff responsibilities depend on their place in the hierarchy. The manager has overall responsibility for the department. The supervisor plans and manages day-to-day biomedical activities and assists the
manager in decision making. Senior biomedical engineers, engineers and technicians are frontline operators who carry out special projects and day-to-day tasks.

It is clear that TQM is important to biomedical engineering departments, because all have quality manuals that provide detailed information on processes, protocols and procedures for providing biomedical engineering services. Face-to-face interview data and cross-case analysis confirm that Cases A and B use continuous improvement systems, and that Cases C and D prefer risk management systems to deliver biomedical engineering services to internal customers.

From cross-case analysis, it is also clear that biomedical engineering departments in all cases provide technical support for clinical equipment operations to the entire hospital, and have the responsibility of explaining new technologies and their impacts on operating costs. Biomedical engineering staff also assist clinicians on equipment-related matters and promote safety to both the patients and equipment operators. All cases keep records, including management system documents and equipment details in databases. Software used for equipment databases is different across cases. Equipment arriving in hospitals is controlled by asset registration, acceptance checks and electrical safety testing. The information from databases can be retrieved by using various search fields, such as asset registration numbers, equipment model and document numbers.

Quality assurance programmes (performance verification) for all existing clinical equipment is run by all cases. Under these programmes, clinical equipment is performance verified to confirm that it is operating within manufacturers’ specifications. Analysis shows that due to a lack of resources, Cases C and D carry out performance verification checks on high-risk equipment only. All cases hold on-the-job or off-the-job-training to up-skill their staff. Good working relationships exist between biomedical staff and clinicians (internal customers). Furthermore, both formal and informal methods of communication are used by all cases to facilitate good customer relations. Cross-case analysis reveals that Cases A and D emphasise time management to keep equipment downtime to a minimum, whereas Cases B and C allow engineers to work at their own pace and motivate them to use innovative methods for solving equipment faults, as long as they observe regulatory requirements. All cases have a well-documented complaints handling procedure. The complaint handling and investigation processes are the same across cases, but the outcomes of the investigations are reported differently. In Case A, incident reports are discussed in the biomedical quality review meeting, Case B forwards a
copy of the report to the biomedical manager and hospital risk management and Case C submits its reports to the biomedical engineering supervisor and a copy to the disability committee; in Case D, the supervisor evaluates the report and discusses it with the manager, after which a copy is forwarded to the disabilities committee.

Cross-case analysis also shows that all hospitals measure service quality and customer satisfaction by customer feedback, return jobs and by annual customer surveys. All cases hold various types of meetings including monthly departmental meetings, quality review meetings and management review meetings. In the monthly meeting, staff discuss operational issues. In quality review meetings, quality issues are discussed. Case A conducts these meetings monthly, Case B every second month and Cases C and D discuss quality issues in their management review meetings. Cross-case analysis also shows that cases hold management review meetings at different time intervals: Case A monthly, Case B every second month, Case C every three months and Case D every six months. From the data analysis, it seems that although the meetings are conducted at different time intervals, the biomedical engineering service is not comprised.

Cross-case analysis reveals that all cases except Case D carry out internal audits once a year. In this researcher’s view, regular internal audits are beneficial to all cases, because audits can assist biomedical engineering departments in achieving their objectives by examining, evaluating and improving their activities through internal audits.

### 4.5.2 Document review

Cross-case analysis for document reviews is conducted in the context of all cases’ current management systems. This review confirms the interview results. The researcher examined the commonalities and differences amongst the four cases. The commonalities and differences are presented in Table 4.22.
Table 4.22: *Commonalities and differences in document reviews*

<table>
<thead>
<tr>
<th>Commonalities</th>
<th>Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cases have hierarchical structures consisting of a manager, supervisor,</td>
<td>Amongst cases, different software packages are used for maintaining</td>
</tr>
<tr>
<td>senior engineers, engineers, technicians, trainees and administrative staff.</td>
<td>equipment databases.</td>
</tr>
<tr>
<td>The responsibilities of the members depend on their place in the hierarchy.</td>
<td>Incident investigation and reporting methods are different amongst the</td>
</tr>
<tr>
<td></td>
<td>cases.</td>
</tr>
<tr>
<td>All cases have a quality manual that defines policies and processes including</td>
<td></td>
</tr>
<tr>
<td>the regulatory requirements of the department.</td>
<td></td>
</tr>
<tr>
<td>In all cases, the documentation system is organised hierarchically.</td>
<td></td>
</tr>
<tr>
<td>Cases keep various types of departmental and equipment records electronically</td>
<td></td>
</tr>
<tr>
<td>in their equipment databases.</td>
<td></td>
</tr>
<tr>
<td>All cases provide technical support for all existing clinical equipment in</td>
<td>Cases hold management review meetings at different time intervals: Case A</td>
</tr>
<tr>
<td>the entire hospital.</td>
<td>monthly, Case B every second month, Case C every three months and Case D</td>
</tr>
<tr>
<td></td>
<td>every six months.</td>
</tr>
<tr>
<td>All cases run QA (performance verification) programmes for all existing</td>
<td></td>
</tr>
<tr>
<td>clinical equipment in the hospital.</td>
<td></td>
</tr>
<tr>
<td>All cases recruit biomedical engineers and technicians who have attained a</td>
<td>Case A holds quality review meetings monthly, and Case B every second month;</td>
</tr>
<tr>
<td>tertiary level qualification in engineering and have previous experience.</td>
<td>quality review meetings are not conducted in cases C and D, but quality</td>
</tr>
<tr>
<td></td>
<td>issues are discussed in their management review meetings.</td>
</tr>
<tr>
<td>All cases conduct training in two forms: on-the-job and off-the-job training.</td>
<td></td>
</tr>
<tr>
<td>All cases conduct customer surveys once a year.</td>
<td>Cases A, B and C carry out internal audits once a year and Case D does not</td>
</tr>
<tr>
<td>Cases use both formal and informal communication styles. Departmental</td>
<td>hold internal audits.</td>
</tr>
<tr>
<td>meetings are held monthly and staff discuss operational issues.</td>
<td></td>
</tr>
</tbody>
</table>
In all cases, departmental documents are not reviewed regularly. Documents are only reviewed when staff feel it is necessary.

Source: Developed by the researcher for this research.

In Table 4.22, cross-case analysis of departmental documents reveals that all cases have hierarchical structures consisting of a manager, supervisor, senior engineers, engineers, technicians, trainees and administrative staff. As reported by interviewees, staff responsibilities depend on their place in the hierarchy. All cases have a quality manual that defines policies and processes, including the regulatory requirements of the department. This manual provides guidelines for the department to meet both customers’ needs and the department’s objectives. In all cases, the documentation system is organised hierarchically. Higher-tiered documents have a wider scope with reduced detail and more generally described management systems. In lower-tiered documents, scope is reduced and level of detail increased. Analysis reveals that all cases are using ISO 9000-based management systems. Analysis indicates that in all cases, all types of departmental documents should be reviewed more frequently. All cases keep departmental and equipment records electronically in their equipment databases. Different software is used for equipment databases in each case. Information from the databases can be retrieved via several search fields, such as serial numbers, and equipment model, asset registration number and purchase order numbers.

All four cases’ documents also state that QA programmes (performance verification) should be conducted on clinical equipment in the hospital once a year. Cross-case analysis shows that QA programmes are executed throughout the year. Each clinical area is scheduled for QA checks at different times of the year so that equipment is not out of service for long periods or all at once. Departmental documents of all cases (hospitals) state that cases are achieving 75%–80% success on their QA programmes. All cases follow AS/NZS3551:2012 guidelines for servicing and managing biomedical equipment.

Staff recruitment policies consistently state that biomedical engineering departments should hire biomedical engineers and technicians who have attained a tertiary-level qualification in engineering and who have had previous experience. Documents also reveal that biomedical engineering personnel have individualised training and development plans. Trainings are conducted either on the job or off the job. Documents also suggest that all four cases conduct
customer surveys once a year to determine their customers’ perceptions on service quality and customer satisfaction. Cases determine if they are achieving their objectives from the results of their annual surveys, what improvements are needed in current services, future resources that may be needed and how improvements can enhance service quality, thereby realising improved customer satisfaction.

Cross-case analysis shows that all cases hold various forms of meetings. Departmental meetings, in which operational issues are discussed, are held monthly. Case A holds quality review meetings every month, Case B every second month and Cases C and D discuss quality-related issues in their management review meetings. Management review meetings are held at different time intervals. Case A holds management review meetings monthly, Case B every second month, Case C every three months and Case D has its management meeting every six months. Analysis reveals that only Case A holds internal audits regularly and keeps detailed, complete records. Cases B and C also conduct internal audits, but the issues arising from internal audits are not documented well. Documents suggest that the matters arising from internal audits are not actioned fully, and that some documents relating to internal audits are incomplete. Regular internal audits are not conducted at all in Case D. All cases conduct their daily business using both formal and informal communication. Formal communication includes reports, meetings, emails and departmental circulars. Informal communication includes phone and verbal face-to-face discussions.

4.5.3 Observations

Cross-case analysis of observations is conducted in the context of biomedical engineering services in all four cases (hospitals). The commonalities and the differences gathered from cross-case analysis are presented in Table 4.23.
Table 4.23: Commonalities and differences in observational studies

<table>
<thead>
<tr>
<th>Commonalities</th>
<th>Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Biomedical engineering departments are all centrally located in hospitals. Internal customers can contact the biomedical team at any time for assistance and advice.</td>
<td>• Cases A and B have biomedical engineering departments, whereas biomedical engineering in Cases C and D is a branch of the facilities management department.</td>
</tr>
<tr>
<td>• Management systems are based on the ISO 9000 system. All cases have a quality manual that defines policies and processes, including regulatory requirements. Equipment-related processes are clearly written and easy to follow. Quality manuals are available to all staff.</td>
<td>• Cases A and B conduct full acceptance tests on new equipment, and Cases C and D accept the suppliers’ test results and carry out electrical safety tests only.</td>
</tr>
<tr>
<td>• All cases use both formal and informal methods of communication and feedback for their internal customers.</td>
<td>• Cases A and B have one main workshop plus satellite workshops near acute wards to keep response times to a minimum, whereas Cases C and D only have one main workshop centrally located in the hospital complex.</td>
</tr>
<tr>
<td>• All cases provide biomedical engineering services, and manage clinical technology for the entire hospital.</td>
<td>• All cases have equipment databases in which departmental documents and equipment records are kept electronically. Cases use different software packages for their equipment databases.</td>
</tr>
<tr>
<td>• All cases have a QA programme and performance verify all existing clinical equipment in the hospital.</td>
<td>• Training is conducted either on-the-job or off-the-job to up-skill engineers and technicians who work on specialised medical equipment.</td>
</tr>
<tr>
<td>• All cases have a good working relationship with their internal customers.</td>
<td>• All cases have a good working relationship with their internal customers.</td>
</tr>
<tr>
<td>• All medical equipment is controlled by asset registration and details are kept electronically in equipment databases. All incoming equipment is acceptance and electrical safety tested.</td>
<td>• Cases A and B carry out performance verification checks on all existing clinical equipment, and Cases C and D carry out performance verification checks on high-risk clinical equipment only.</td>
</tr>
</tbody>
</table>
Monthly departmental meetings are held in which staff discuss operational issues.

*Source:* Developed by the researcher for this research.

Observational cross-case analysis suggests that all cases’ biomedical engineering workshops are centrally located within hospital complexes, and are easily accessible by their internal customers. Cases A and B also have satellite workshops near acute services to keep response times to a minimum. Biomedical staff are easily contactable, and internal customers often visit workshops seeking assistance and advice from biomedical engineers and technicians. The biomedical teams of cases C and D are part of the hospitals’ facilities management departments. From cross-case analysis, the researcher established that all cases are using ISO 9000-based management systems and that all cases follow AS/NZS3551:2012 standards. Cases A and B take an open approach towards process improvement and welcome new ideas from staff, while Cases B and C are more customer focused. Frontline biomedical staff actively engage in various types of biomedical engineering duties, including equipment registration, acceptance testing of new equipment, repairing and calibrating equipment, performing preventive maintenance and electrical safety tests, installing and commissioning new equipment and providing in-service training to clinicians. Biomedical equipment in all cases is controlled by asset registration and by keeping records in electronic equipment databases.

All cases use both formal and informal methods of communication for technical advice and assistance. Members of all cases have a good working relationship with their internal customers (clinicians).

**4.5.4 Summary of cross-case analysis**

Analysis of multiple sources of data and cross-case analysis clearly suggest that all cases have a triangular structure, in which the responsibilities of the staff depend on their place in the hierarchy. There is no doubt that biomedical engineering departments provide technical support on all aspects of clinical equipment to the entire hospital. Cross-case analysis reveals that all cases have a quality manual that defines policies and processes, including regulatory
requirements of the department. Quality manuals provide guidelines for departments to meet customer needs and to fulfil the departmental objectives.

In all cases, documentation systems are organised hierarchically. Higher-tiered documents have a wider scope with fewer details, and describe management systems in a general manner. In lower-tiered documents, scope reduces and level of detail increases. Staff working in the frontline engage in maintaining lower-level documents. This is one of the reasons why some staff did not know the type of the management system they were operating under.

Analysis of departmental quality manuals of all four cases reveals that all departmental documents should be reviewed frequently. In practice, documents are only reviewed when the members of the department feel review is necessary. Analysis reveals that all cases are using ISO 9000-based management systems and that they follow the AS/NZS3551:2012 standards. All cases control clinical equipment by keeping records of equipment details in their databases. These records can be retrieved from the databases by searching under various search fields. Cases use different software packages for their equipment databases. All equipment coming into the hospital is asset registered and acceptance tested, and obsolete equipment is decommissioned and removed from databases. Databases are updated frequently by the biomedical engineering staff.

Departmental documents clearly state that under QA programmes, all existing clinical equipment should be performance verified once a year. Analysis shows that due to lack of resources, Cases C and D performance verify high-risk clinical equipment only. Departmental documents further reveal that biomedical engineering departments recruit biomedical engineers and technicians who have attained a tertiary-level qualification in engineering and have previous biomedical engineering experience. All engineers and technicians are given training on various types of clinical equipment.

All cases use customer surveys results to determine if they are achieving customer service objectives, what improvements are needed in current services and future resources that may be needed to enhance service quality and customer satisfaction. Both formal and informal methods of communication are used to conduct everyday business. Furthermore, biomedical staff believe service quality and customer satisfaction are important to their departments, because quality and satisfaction raise the department’s profile in the hospital.
Amongst all cases, the complaint handling procedures are well documented. All cases classify customer complaints into three main categories. These are biomedical engineering service complaints, equipment complaints and complaints related to incidents resulting from equipment malfunction. Analysis suggests that investigations of incidents relating to clinical equipment malfunction are handled and investigated in a similar way in all hospitals. However, the reporting of the investigation outcomes is different.

In Case A, an investigation report is discussed in a quality review meeting, and if necessary, corrective action is implemented and details are sent to the health and safety officer. In cases B and C, an investigation report is presented to the supervisor and discussed in the next quality review meeting. Appropriate corrective action is implemented, and details sent to the risk committee. In Case D, the report is evaluated by the supervisor, and the supervisor discusses it with the manager. A copy of the report is sent to the disability committee. The committee evaluates the report and recommends possible corrective action. In all cases, the incident reports are formally closed once the investigation is complete and appropriate actions have been taken.

The researcher established that all four cases (hospitals) conduct monthly departmental meetings to discuss operational issues. Quality and management review meetings are held at different time intervals. Case A holds internal audits regularly and keeps detailed records. Cases B and C also conduct internal audits, but the issues arising from these audits are not actioned properly, nor are they documented in full. Regular internal audits are not conducted by Case D.

**Epilogue**

This chapter contained analyses of the data collected from multiple sources. The first section of the chapter introduced the case studies used in this research. The second section discussed the participants’ backgrounds, the profiles of the hospitals used as case studies and the data collection techniques. The third section discussed the research approach and data analysis. The fourth section of this chapter analysed the data collected from multiple sources, including face-to-face interviews, document reviews and direct observation. The analysis was supported by interview transcripts where possible. Chapter 4 concluded with a cross-case analysis. The next chapter will discuss the findings and implications of this research.
CHAPTER 5: FINDINGS AND IMPLICATIONS

Prologue

In the previous chapter, data collected from multiple sources were described and analysed. Using cross-case analysis, the commonalities and differences amongst the cases under investigation were presented. The objective of this chapter is to draw the elements of the study together, including current management systems, the role of biomedical engineering departments, QA and internal communication methods; to examine the implications of the findings on core themes; and to explore how the findings relate to the literature. In summary, this chapter will discuss the findings of this research. Particular reference is made to the contribution of this research to the understanding of the research objectives and the research questions. The research questions are reiterated below.

Main research question

How can TQM benefit biomedical engineering departments in New Zealand public hospitals in managing medical technology and in improving service quality and customer satisfaction?

Sub-research questions

(1) What are the current systems used in New Zealand public hospitals for managing medical technology?
(2) How are service quality and customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?
(3) Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals?

This chapter also addresses the implications of these findings for further development of theory and practice. The limitations of the study are discussed. Finally, the two most effective models for managing biomedical technology to improve service quality and internal customer
satisfaction in biomedical engineering departments in New Zealand public hospitals are recommended.

The structural map of the chapter is illustrated in Figure 5.1.
Figure 5.1: *Structure of the chapter*

*Prologue*

Findings from data analysis

Conclusions from findings

Recommendations

Implications for theory and practice

Limitations of this research

Suggestions for future research

Conclusion

*Source*: Developed by the researcher for this research.
5.1 Findings from data analysis

This section discusses the findings for each question that have been extracted from data analysis.

5.1.1 Sub-research question 1 findings

*What are the current systems used in New Zealand public hospitals for managing medical technology?*

(1) *Current management systems*

Analysis reveals that biomedical engineering departments of all cases (Cases A to D) have a triangular hierarchical structure, in which the responsibility of staff is commensurate with their position in the department (Figure 5.2).
Figure 5.2: Hierarchical structures of the biomedical engineering departments in the four case study hospitals

Source: Developed by the researcher for this research.

Figure 5.2 illustrates that the manager has overall responsibility for the department. The supervisor plans and manages day-to-day biomedical engineering activities, assists the manager in strategic business plans, and assists and advises engineers and technicians in making technical decisions. Senior biomedical engineers are more involved in special projects, and assist management in making technical decisions. They also get actively involved in repair, maintenance, calibration and the evaluation of complex biomedical equipment and systems, whereas technicians carry out general biomedical engineering duties. All cases demonstrate a transformational style of leadership. Managers, supervisors and senior members instil faith, respect and empathy in their subordinates and provide a sense of mission to the team through good communication skills.
The members of the biomedical engineering departments have a good understanding of the TQM concept. Staff from all four cases (hospitals) have a firm belief that TQM is important to their organisation. It was found that although the majority of participants have a sound knowledge of the protocols (rules) of the department in terms of conduct, they are not sure what type of management system they are currently using. Service tasks are carried out as per the prescribed electrical standard for medical devices (AS/NZS 3551:2012). Based on document reviews, all four cases are using an ISO 9000-based management system. Cases A and B are using continuous improvement systems and Cases C and D are currently using the risk management system.

(2) Roles of biomedical engineering departments

Generally, the biomedical engineering department’s role in a public hospital is to meet technology management challenges and to provide service and technical support to the hospital. The department’s functions can be broadly defined as providing the safe and effective management of technology used for patient diagnosis, therapy and patient monitoring within healthcare institutions (Bronzino, 1992).

The multiple data sources and cross-case analysis (Cases A, B, C and D) clearly show that biomedical engineering departments in New Zealand public hospitals provide technical support on all aspects of clinical equipment to the entire hospital. They manage all phases of the medical equipment lifecycle, including selection and purchasing, acceptance testing, installation, commissioning, repair, maintenance and decommissioning of obsolete and unsafe equipment.

5.1.2 Sub-research question 2 findings

How are service quality and customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?

(1) Quality assurance (QA)

This research found that all cases have a QA programme for clinical equipment. Under these programmes, clinical equipment is performance verified to ensure it is operating within the manufacturer’s specifications and is electrically safe. Each clinical area is systematically scheduled for the QA programme throughout the year, and performance of the equipment is
verified as per the AS/NZS3551:2012 standard. Due to a lack of resources, Cases C and D carry out QA checks on high-risk equipment only. All participants (interviewees) believed that the QA programme helps in enhancing efficiency and customer satisfaction.

The departmental documents of all four cases show that they are achieving 75%–80% success rate in implementing their QA programme. Staff from all four cases (hospitals) believe that the current QA success rate can be improved with more resources.

(2) Training and development

All four hospitals run a training and development plan for biomedical engineering staff. Engineers and technicians progress through the training plan and become competent on various types of clinical equipment. Once staff members gain product knowledge, experience and competency with one aspect of the equipment, they progress to the next level of training. Training needs are determined during an acceptance of new equipment by senior staff, with the help of the manufacturer’s recommendations. Once a training need is established, the staff who are likely to be working on the equipment are trained by the manufacturers or by the experienced members of the biomedical team.

Sometimes, training is conducted by the hospital’s clinical educators to provide a clinical overview of the procedure in which the equipment will be used. Once the training is completed and the trainer/assessor feels that the engineer or technician is competent, then the trainee is allowed to work without supervision and is empowered to make decisions regarding clinical equipment. Furthermore, experienced members share their skills and knowledge with other members of the department in the form of in-service training. Training is delivered by two methods:

(i) on-the-job training: occurs in a normal working environment, using the actual tools, equipment, documents and materials that staff use when fully certified. Training is conducted by a senior staff member through lectures and hands-on practice sessions.
(ii) off-the-job training: occurs away from the normal workplace. This type of training is usually conducted in a classroom situation on specific equipment. Occasionally, training is conducted by the manufacturer at the manufacturing site.
(3) **Customer satisfaction and service quality**

Analysis suggests that participants generally focus on how fast equipment can be returned to the end user after service, and how quickly the department can solve equipment-related problems for clinicians, both in the workshop and at the patient’s bedside. Most biomedical engineering staff believe that if internal customers receive the level of service they expect, or if they receive technical support in times of need, they will be satisfied with the service provided. The general view of the participants in all four cases is that customer satisfaction and service quality are important. They are confident that a high level of customer satisfaction and service quality:

(i) promote the department’s profile in the hospital;
(ii) offer opportunities to continuously improve service;
(iii) give the department a feeling that it is achieving its objectives;
(iv) reflect on the department’s ability to provide technical support to the hospital in a fast-changing industry; and
(v) are achieved by maintaining good working relationships with clinicians and other support staff.

(4) **Technical service and support to internal customers**

All clinical areas of the hospital contain clinical equipment. Therefore, all clinical departments of public hospitals (cases) are internal customers of the biomedical engineering division. All four cases have processes and procedures relating to the management of clinical equipment, handling, repair, calibration and preventive maintenance. Cases take a systematic approach to carrying out biomedical engineering-related tasks. Engineers and technicians provide technical support to the hospital and to the clinicians in the following ways:

(i) corrective maintenance and recalibration of medical equipment;
(ii) incoming inspections (acceptance testing) of new equipment acquisitions;
(iii) preventive maintenance and periodic inspections of equipment as per the medical equipment management standard AS/NZS 3551:2012;
(iv) equipment safety checks such as screening hazard notices, performing verification checks and ensuring equipment is hazard free;

(v) training equipment users (clinicians and operators) in the safe and effective use of clinical equipment;

(vi) taking responsibility for explaining new technologies and their impact on operating costs, translating technological ideas, problems, and concepts into a language that non-technical people can readily understand;

(vii) assisting clinicians with equipment-related problems; and

(viii) checking for electrical safety on equipment returned from outside repair before returning it for clinical use.

(5) Records and traceability

Biomedical engineering departments keep various types of records for future information and traceability. Such documents include quality manuals, process descriptions, job instructions, test protocols, equipment service history, management and other biomedical engineering-related documents. Findings reveal that although the content of equipment databases is similar across all four cases, the software packages are different. In all four cases, the database content is controlled by the biomedical engineering department, and the management of software and hardware is controlled by the IT department.

Comprehensive details of clinical equipment are recorded in the equipment database. These documents include equipment registration details, service history, software upgrades, QA results, electrical safety test results and equipment decommissioning records. Information can be retrieved from the equipment database in various ways, such as searching under different search fields (for example, serial number, registration number and purchase order number). Stored information is used for generating reports on service history, equipment status reports, cost of maintenance and asset planning.

(6) Complaint handling

All four hospitals classify customer complaints into three main categories:
(i) *Service complaint* – service complaints are regarded as an operational issue; therefore, they are managed by the supervisor or manager.

(ii) *Equipment complaint* – equipment complaints are regarded as service requests; therefore, service request procedures are followed.

(iii) *Incident reports* – if a complaint is incident-related and patient injury has occurred, a reference number is immediately allocated for identification and forwarded to a senior member or supervisor. The complaint gets evaluated and an investigation is initiated.

The complaints are reported by various methods such as phone calls, email and in person. Participants of all four cases have a good working knowledge of their institution’s complaint handling process. It was found that although complaint handling categories are the same amongst the cases, the investigation reporting methods are different:

**Case A:** Incident reports are discussed in monthly biomedical quality review meetings. If required, the department initiates corrective action to prevent future incidents. A copy of the investigation report and the outcome of the investigation are forwarded to the health and safety officer. Upon completion of the corrective action, the investigation report is formally closed.

**Case B:** Upon completion of the investigation, a report is presented to the supervisor who evaluates the report, one copy is forwarded to the biomedical manager and a copy is forwarded to the hospital risk management team. The report also gets tabled in the department’s quality review meeting for discussion. If required, corrective action is implemented to prevent any further incidents. The investigation is then formally closed, and the risk management team is advised.

**Case C:** The supervisor of the biomedical engineering department evaluates the incident investigation report, and a copy is submitted to the risk and disability committee. If corrective action is required, an action plan is developed and implemented. Upon completion, the complaint is formally closed, and the risk and disability committee is advised. This report is also discussed
in the biomedical engineering’s management and quality meeting to determine if additional action is required to prevent future incidents.

**Case D:** The supervisor evaluates the report and discusses it with his or her manager. A copy of the report is sent to the risk and disability committee, which consists of a team of representatives from the clinical area, the biomedical engineering department and the health and safety team of the hospital. The committee evaluates the incident investigation report and recommends appropriate corrective action. The complaint is formally closed once the corrective action is implemented.

(7) *Internal communication and feedback*

This research reveals that internal communication is a vital tool underpinning biomedical engineering departments’ success as service providers. All four departments use a wide range of communication tools to conduct day-to-day business. Case staff believe that communication is not only important, but also keeps everyone well informed and ‘on the same page’.

All four cases use the same methods of communication (telephone, email, informal face-to-face contact, written reports and formal meetings) to keep internal customers well informed about clinical equipment matters and biomedical engineering issues. Feedback on day-to-day activities such as discussion of technical issues at the patient’s bedside and reporting on equipment malfunction, patient parameter programming and advice on setting the alarm limits in equipment is usually in the form of face-to-face conversations and telephone communications. Formal communication is used for service reports, department circulars, technical bulletins, repair quotations, recommendations and incident investigations.

### 5.1.3 Sub-research question 3 findings

*Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals?*

(1) *Suitable and effective models for biomedical engineering departments recommended by participants*
(i) **Service quality models**

Analysis of interview responses shows that participants in all four cases have limited knowledge of theoretical service quality models. However, based on their practical knowledge and experience with different models and their knowledge of the biomedical engineering business, research participants suggested five possibilities. The models are ranked numerically in order of popularity, with rank 1 being the most popular with interviewees, and rank 5 being the least favoured:

1. Continuous Quality Improvement model;
2. the SERVEQUAL model;
3. the ISO- Quality Assurance model;
4. the Nordic model; and
5. the Processes Management model.

Seven participants recommended the CQI model. They believed that this model would effect a continuous change, that is, small incremental and affordable changes. According to the participants, small changes can be adopted easily in a department like biomedical engineering; resource limitations preclude large changes. Four participants recommended the SERVQUAL model. In their view, SERVQUAL would provide an opportunity to measure customers’ perceptions of service quality before a service encounter, as well as their perceptions of the actual service delivered by the biomedical engineering department after the encounter. Two participants recommended the ISOQA model, because in their opinion, this model might prevent quality problems from occurring. Fewer quality problems lead to fewer defects, and this in turn engenders high service quality and customer satisfaction. Two participants recommended NSQM. In these participants’ views, NSQM would provide both technical and functional quality of service including other factors such as technical quality, reliability, accessibility and flexibility. The was also recommended by one participant. He believed that if processes are managed well, quality of service will always remain high.
(ii) Customer satisfaction models

Participants in all four cases recommended five customer satisfaction models based on their experience and knowledge of the biomedical engineering business in public hospitals. The models are ranked numerically in order of popularity, with rank 1 being the most popular with interviewees, and rank 5 being the least favoured:

(1) Continuous Quality Improvement model
(2) the Six Sigma model;
(3) the Customer Support model;
(4) the Business Excellence model; and
(5) the Performance/perceived Satisfaction model.

Analysis shows that six participants believed that the CQI model is the most appropriate for gaining and measuring customer satisfaction. In these participants’ opinions, this model would allow biomedical engineering departments to continually assess the services they provide to their internal customers and to make improvements to their procedures, processes, protocols, customer feedback methods and current practices to better meet customer needs. Interview analysis suggests that participants feel that the CQI model could be readily adopted by biomedical engineering departments, because it can cater to improving both service quality and meeting customer satisfaction requirements.

The second most popular model amongst the participants was the Six Sigma model. Four participants recommended this model. Participants felt that this model could also be adopted, because it could increase productivity by reducing defects. However, participants also signalled that biomedical engineering departments would require more resources initially to implement the model properly. Participants who recommended the Six Sigma model believed that in the current climate, hospitals are continuously under pressure to keep costs down. Therefore, although Six Sigma could work for biomedical engineering, this model may not in fact be an effective option due to budget constraints.

Two participants recommended the Performance/perceived Satisfaction model. In their opinion, the Performance/perceived Satisfaction model highlights the effects of expectations, perceived performance desires, desired congruency and expectation disconfirmation on overall
service quality and customer satisfaction. By adopting the Performance/perceived Satisfaction model, biomedical engineering could achieve customer satisfaction by:

(i) having a good working relationship with the internal customers;
(ii) providing accurate information to internal customers regarding their equipment;
(iii) assisting clinicians in choosing reliable equipment; and
(iv) providing professional advice.

Two participants recommended the Customer Support model. In their view, the Customer Support model could greatly enhance service delivery, as well as provide valuable insights on where to focus resources and improvement efforts for the greatest impact. This model could give biomedical engineering staff the freedom to decide on which part of their business to concentrate more resources to best improve service quality.

The Business Excellence model was also recommended by two participants. In their opinion, the Business Excellence model would allow biomedical engineering departments to systematically use quality management principles and tools to improve performance and processes by focusing on policy, people management and resource allocation. In their view, this model could be introduced at management level. Management could then set policies, develop a unified customer service vision and allocate resources to planning, training and development, engaging with frontline staff and assisting in process improvements. Participants were not sure if this model would work for biomedical engineering departments in public hospitals because of the nature of the business. In their view, it was worth investigating further on the possibility of adopting this model.

5.2 Conclusions from findings

In the above section, findings were discussed in respect to each sub-research question. In this section, conclusions are drawn from these findings.

5.2.1 Sub-research question 1

What are the current systems used in New Zealand public hospitals for managing medical technology?
This research found that the biomedical engineering departments involved in this study follow the ISO 9000 total quality concept and are using ISO 9000-based management systems. The cases are using ISO 9000 series of standards for quality management to reduce non-conformance and to maintain performance commensurate with internal customer expectations by providing a cost-effective biomedical service within the department’s capacity.

All cases have a quality manual that outlines departmental policy and procedures, a QA programme, complaint handling and traceability procedures, equipment commissioning and decommissioning and other biomedical engineering-related processes to fulfil regulatory requirements. Cases use quality manuals and QA checks to enhance and maintain customer satisfaction through quality monitoring and service upgrades.

The responsibilities of the staff depend upon their place in the hierarchy. The manager has overall responsibility for the department. The supervisor plans and manages day-to-day activities, assists the manager in strategic business plans and also advises engineers and technicians in making technical decisions. Senior biomedical engineers are more involved in special projects and assist management in making technical decisions. They are actively involved in repairs, maintenance, calibration, and evaluation of complex clinical equipment and systems, whereas technicians carry out general biomedical engineering duties.

This research concludes that the hospitals’ biomedical engineering departments work towards ensuring that all their functions interrelate and work efficiently and effectively. Although most of the participants have limited knowledge of the different types of management systems and models, they are well aware of the contents of their own quality manuals and interrelated functions, and are carrying out tasks as outlined in their institution’s quality manuals.

Although all cases are using the ISO 9000 total quality concept, they use different management systems to meet ISO 9000 requirements. As discussed previously, Cases A and B use a continuous improvement system to achieve their objectives, while Cases C and D use a risk management system. Case documents for this research reveal that currently, all cases are providing a satisfactory level of service to their internal customers but that there is room for improvement. Furthermore, although hospital quality manuals state that regular audits should be conducted, only Case A can produce evidence of regular audits, both internal and external. Therefore, this research concludes that most of the cases (biomedical engineering departments)
are not properly audited for the services they provide. This can have adverse impact on quality of service.

5.2.2 Sub-research question 2

*How are service quality and internal customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?*

This research found that all cases (hospitals) are using Deming’s wheel, commonly known as PDCA (Tague, 2004) for quality improvements and control (Figure 5.3). During this study, the PDCA approach was clearly noticeable in clinical equipment management-related processes in all four hospitals. One example of PDCA application was demonstrated in the QA process used for clinical equipment, a key element of biomedical engineering services that contributes towards service quality and customer satisfaction. The application of PDCA in biomedical engineering is illustrated in Figure 5.3.

![Figure 5.3: Application of PDCA in biomedical service](image)

*Source: Adapted from Tague (2004, p. 390).*

As shown in Figure 5.3, QA is carried out on clinical equipment to determine whether the equipment conforms to the manufacturer’s specifications. If the equipment conforms, it remains
in clinical use; otherwise, remedial action is taken by removing the non-conforming equipment from clinical use. Upon removal, the unit is re-checked, repaired, recalibrated and performance verified before it is returned for clinical use.

Clearly, biomedical engineering departments are customer focused and are using structured methods to define biomedical-related activities by identifying the interfacing processes for key activities, and by establishing clear responsibilities for all staff (management, senior engineers, engineers, technicians and administrative staff). Quality control activities are focused on improving processes and procedures including maintenance of clinical equipment, QA, electrical safety testing, records for traceability and other technical issues related to clinical equipment such as recalls, equipment trials and hazard monitoring.

This study concludes that all four biomedical engineering departments studied have a clear vision for managing clinical equipment. Their prime objective is to minimise repairs, allowing for maximum uptime use of the equipment at minimum maintenance costs. This is in line with the views of Geotsch and Davis (2006), who suggested that to achieve service quality and customer satisfaction, an organisation must be customer focused and should appropriately manage measurements of quality, people and processes within the organisation. To this end, all four biomedical departments keep a detailed history of clinical equipment in use, and track records for traceability. Such records are valuable when planning yearly budgets and determining preferred suppliers.

Furthermore, this research finds that all four biomedical engineering departments have limited resources, although the hospitals experience high demand for technological support in terms of equipment management, maintenance and technical advice. At times, service response times are delayed due to a lack of resources, resulting in delayed patient treatment.

Even through differences in organisational practices of the case hospitals exist, little difference is evident in the ways they provide biomedical engineering services to their internal customers. All four cases have similar processes, procedures and systems in place to provide quality service and customer satisfaction. Furthermore, case documents for this research reveal that all cases are providing a satisfactory level of service to their internal customers. The factors contributing to this outcome include good corporate culture and leadership, organisational structure, processes, staff attitude and capability, good utilisation of customer feedback, high
standards of training, traceability of records and clinical equipment management and maintaining good working relationships with internal customers, as presented in Figure 5.4.

Figure 5.4: *Factors contributing to service quality and customer satisfaction*

Although internal customers are happy with the current level of biomedical engineering service, there is still room for improvement, especially in the existing processes and procedures, staff training plans, reporting methods, customer feedback and determining and improving the gaps in biomedical engineering services.

Several studies have concluded that service quality and customer satisfaction are effective rather than cognitive constructs (Oliver, 1981; Olsen, 2002). This research concludes that service quality is a crucial variable that leads to customer satisfaction, and is important for biomedical engineering departments in hospitals. Service quality depends on product knowledge, equipment accuracy and the skills of service providers. This study confirms that biomedical engineering technicians and engineers in the four case hospitals have biomedical science knowledge and technical expertise that contribute to the multidimensional nature of quality-related performance.
(for example data networking, patient monitoring and self-operating diagnostic equipment). For efficient and quality biomedical service, it is important that biomedical engineers and technicians interact with clinical staff, IT teams, system administrators and other support staff including anaesthetics technicians and radiographers.

This research also highlights that in the hospital environment, leadership is an important factor that contributes to service quality and customer satisfaction. As reported in the literature, leadership creates a vision, promotes change and provides an environment in which employees can be empowered to act independently to improve service quality (Kirkbridge, 2006). Based on these findings, it can be concluded that biomedical engineering departments practise a transformational style of leadership. Research clearly shows that managers, supervisors and senior engineers are displaying charisma and intellectually stimulating characteristics. The charisma dimension indicates that leaders have persuasive personalities, and that they inspire and motivate engineers and technicians through good communication. Leaders’ intellectually stimulating characteristics promote intelligent, rational and careful problem-solving techniques. To maintain service quality and customer satisfaction, supervisors encourage staff to pursue innovative solutions to equipment-related problems, provided they follow service protocols and policies and act within regulatory requirements.

According to this research, most clinical equipment has an average working lifespan of seven years. When equipment is no longer useful or cannot be maintained, it is decommissioned and removed from equipment databases. The processes for replacing decommissioned equipment are activated by forwarding a request to the appropriate unit manager. Once approval for a replacement is obtained from the unit manager, biomedical engineers assist clinicians in sourcing, purchasing, evaluating, trialling and training staff to use new equipment. This research found that when new equipment is delivered to the biomedical engineering department, it is acceptance tested and that appropriate information is loaded into the database. In-service training is given to clinicians, and the equipment is put into service. Thereafter, equipment is managed and supported by the biomedical engineering departments. This strategy is common to all four cases (public hospitals) for purchasing, managing and maintaining control of clinical equipment. The clinical equipment management lifecycle is illustrated in Figure 5.5.
Figure 5.5: Management of clinical equipment throughout its life cycle

Source: Developed by the researcher for this research.

Note: Equipment is managed by biomedical engineers who provide technical support and service, and who review and monitor equipment performance via a QA programme.

Biomedical engineering departments in public hospitals are continuously working towards improving their service quality by establishing, evaluating and prioritising their internal customers’ needs and expectations. This research shows that biomedical engineering staff actively promote good working relationships with members of the clinical teams, specialists and clinicians. Biomedical engineering teams keep their internal customers well informed about equipment status.

This study also illustrates unequivocally that biomedical engineering departments measure customer satisfaction and service quality through a combination of annual customer surveys, reviews of service history to determine the number of reworks, customer complaints, equipment downtime and customer feedback. This documentation helps them to determine when service shortfalls occur and allows them to take appropriate actions to minimise equipment-related risks.

Findings further illustrate that although several processes and procedures are in place, gaps still exit in biomedical engineering services due to under resourcing, incomplete staff training, lack of thorough internal audits, budget constraints and advances in medical technology that require specialised training. Biomedical engineering departments are operating on a tightly
controlled budget and often not in a position to increase manpower. This researcher concludes that additional resources are needed to deliver effective and efficient biomedical services, keep up-to-date with new technology and to support clinicians during busy periods. The lack of resources is a contributing factor in the failure to evaluate departmental procedures and processes on regular basis.

The literature review supports the case hospital managers’ attitude that training is considered a vehicle for implementing and reinforcing quality practices when dealing with patient-applied clinical equipment (Reed et al., 2000). However, this research also found that under case hospitals’ current budget allocations, biomedical engineering departments can afford to send only limited numbers of staff on specialised training. Instead, they depend heavily on factory-level trainings offered by equipment manufacturers. The lack of fully trained staff results in longer equipment downtime and longer response times for service calls. When specialised equipment cannot be maintained by in-house technicians and engineers due to lack of training, they must depend on outside suppliers, which causes delays in patient treatment. This situation confirms the fact that biomedical engineering departments play a significant role in maintaining service quality and internal customer satisfaction in New Zealand public hospitals.

5.2.3 Sub-research question 3

Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals?

Biomedical engineering staff have incomplete theoretical knowledge of service quality and customer satisfaction models. Based on practical experience and knowledge of the biomedical engineering business, participants suggested several models. The CQI model was the most well-known. The SERVQUAL and Six Sigma models were the second most recommended, followed by ISOQA models, Nordic and the Performance/perceived Satisfaction models, respectively. In participants’ opinions, these models could be adapted by biomedical engineering departments to manage specialised medical technology and services more effectively.
5.3 Recommendations

Four recommendations arise from this research.

(1) Recommendation regarding suitable and effective models for management of biomedical engineering in New Zealand hospitals

After careful analysis of interview transcripts, document reviews, observational data, findings and theories, the researcher can recommend two models to biomedical engineering departments for managing biomedical technology effectively and efficiently in New Zealand public hospitals. These are the CQI and the SERVQUAL models. Other models discussed in this study are not recommended for the following reasons:

(i) they are not suitable because biomedical engineering is a service type of industry;
(ii) they are not cost effective for the public healthcare sector;
(iii) hospitals operate on a very tight and controlled budget, and therefore they have limited resources for implementing more complicated models; and
(iv) reducing cost is important, but at the same time, patient safety cannot be compromised.

(i) The Continuous Quality Improvement (CQI) model

The researcher recommends the CQI model for biomedical technology management in New Zealand public hospitals, because CQI is an approach to quality management that focuses on processes, recognises both internal and external customers and promotes the need for objective data to analyse and improve processes. In other words, this model is a PDCA cycle that can be followed even when resources are limited.

The CQI model supports practices, programmes and policies by ensuring regular assessment of where and how improvements need to be made in biomedical services. The key to continuous improvement lies in acknowledging and treating those closest to the work as professionals and respected experts. This approach creates an environment in which those who are closest to clinical areas are also actively engaged in assessing the outcomes of practices and programmes, and are actively making improvements based on those assessments. The CQI model also enables biomedical engineering staff to interact effectively, have constructive and
honest communication and participate in decision-making processes. Under the CQI model, biomedical engineering departments can take a long-term approach by improving services incrementally without putting too much pressure on limited resources.

Furthermore, a review of the extant theory combined with the findings from this research suggests that the CQI model is ideal for biomedical engineering departments in New Zealand public hospitals, because it allows a tight integration of all biomedical engineering-related functions that could lead to high-quality service through the continuous improvement efforts of all biomedical engineering staff. Biomedical engineering departments can enhance service quality and customer satisfaction by using a realistic version of the CQI model, and can embed systems within their organisation that will ensure continual quality and productivity improvements.

Continuous improvement also has advantages because it is one of the tools underlying the philosophies of TQM. CQI is a long-term approach that systematically seeks to achieve small incremental changes in processes in order to improve the efficiency and quality of the service. Given that the New Zealand case study hospitals operate on tight budgets, lack of resources is always an issue for biomedical engineering departments. Lack of adequate and secure funding affects both short- and long-term improvements in work processes and staff morale. Consequently, biomedical engineering departments in the chosen cases are less able to examine and improve current processes until they have a realistic model to follow that fits their straightened circumstances.

Under the CQI model, biomedical engineering departments can measure quality indicators such as service response time, return jobs and customer complaints in order to initiate and drive changes to biomedical engineering processes in a never-ending cycle of continuous improvement. Once one improvement is complete, another can be initiated (Figure 5.6).
Figure 5.6: Continuous quality improvement model framework for biomedical engineering

\[\text{Figure 5.6: Continuous quality improvement model framework for biomedical engineering}\]

Source: Adapted from Tague (2004, p. 390).

Figure 5.6 shows how CQI can work for biomedical engineering departments. They can drive their own continuous improvement process by observing and analysing current processes one by one. Once issues that need improvement are identified, ideas can be developed and action can be taken by implementing changes and by following up. If the results are beneficial, the department can continue the change process and look for the next area to improve.

The CQI model can also shape the values that establish and reinforce commitment to customer satisfaction in the clinical environment. These values can be categorised as respect, responsibility, empathy, trust, openness and cooperation between biomedical staff and clinicians. When these values are closely examined in the context of biomedical engineering services and in the light of the research findings, they can be characterised as follows.

**Respect**

Respect for internal customers is a foundation for Total Quality Improvement (TQI). This research shows that biomedical engineering staff hold much respect for clinicians. Respecting customers (clinicians) means listening to their concerns, communicating with them kindly, and most importantly, making sure that technical services provided match their expectations.

**Responsibility**

It is the role of the biomedical engineering departments to provide technical support and service to all clinical wards, clinics and the diagnostic laboratory of the hospital, and to ensure
that biomedical engineering-related services are performed within the expected timeframe and budget, and are of highest quality.

**Empathy**

This research clearly shows that continuous efforts to achieve customer satisfaction are part of the biomedical engineering culture. Engineers, technicians and support staff go above and beyond their stated responsibilities to offer help where they can in order to relieve work pressure on clinicians.

**Humbleness**

Humbleness is an essential ingredient for motivating biomedical staff to achieve organisational effectiveness. Staff appreciate feedback from their internal customers. They listen to their concerns and appreciate suggestions. Most importantly, they accept that customers are always right and try to improve their services in order to satisfy them. They are not concerned about status differentiation; they respect their colleagues regardless of their positions in the department or in the hospital.

**Trust**

Trust is an important value for sustaining continuous improvement. This research clearly shows that trust is the foundation of hospital teamwork, staff involvement and empowerment. These elements are essential factors for CQI.

**Openness**

Openness is also critical to bringing about a quality change. For example, open communication is the most central prerequisite for successful quality initiatives. Openness is necessary for effective involvement when making technical decisions concerning clinical equipment. This study shows that biomedical engineering departments keep their customers well informed about the status of their equipment, and fully involve key staff when making decisions on purchasing of clinical equipment.
Cooperation

The study confirms that cooperation improves communication, enhances innovation and opens opportunities for knowledge sharing between the biomedical engineering department and the clinicians.

In short, this study finds that frontline biomedical engineering professionals are in touch with the realities of the business. These professionals are key members of biomedical engineering teams. Therefore, under the CQI model, these key contributors can evaluate current processes, assist in process improvement and assist to introduce continuous change without requiring resources beyond what are available. Furthermore, under the CQI model, biomedical engineering departments will not need a special team or additional resources to monitor and evaluate current practices to facilitate improvements. A CQI model can simultaneously improve both the quality and the cost of running the biomedical engineering service. If a joint effort on quality and process improvement is adopted by biomedical engineering departments, the multiple benefits of CQI can contribute towards service quality and customer satisfaction, and decrease the costs of running biomedical services in New Zealand public hospitals. The quality and process improvement cycle is illustrated in Figure 5.7.
Figure 5.7: *The quality and process improvement cycle*

Source: Developed by the researcher for this research.

Figure 5.7 illustrates how quality and process improvements are mutually reinforcing and can add capacity to biomedical engineering departments. Figure 5.7 also shows that process involvement contributes towards the support of quality, and ultimately, improves both cost/benefit ratios and customer service in parallel.
Finally, first-hand observation of biomedical engineering departmental activities, combined with other data, reveals that the CQI model will assist team members to uncover problems by concentrating their attention on perfecting processes. The CQI model can help to establish long-term goals for biomedical engineering departments to keep abreast of change. If this model is correctly implemented, it can become part of a departmental culture in which all employees can feel they are making a contribution towards improving services and enhancing customer satisfaction.

(ii) The SERVQUAL model

This research recommends the SERVQUAL model as the second most effective tool for managing biomedical technology in New Zealand public hospitals. This recommendation is supported by peer-reviewed literature discussed in Chapter 2. As previously mentioned, simplified domains of service quality attributes are tangibility, reliability, responsiveness, assurance and empathy. These attributes provide an approach to the measurement of quality concepts. The SERVQUAL model can be used to analyse gaps between internal customers’ perceptions and expectations concerning biomedical services. In other words, using the SERVQUAL model, departments can measure the quality of service they provide to internal customers. This measurement can be achieved in various ways, including keeping track of service response times and the number of re-works, regular contact with internal customers, seeking customer feedback and conducting surveys to measure expected and perceived service.

From these measurements, the department can identify gaps in their service. Once the department has identified the gaps in its service, management can make improvements to achieve better customer satisfaction by focusing on improving tangibility, reliability, responsiveness, assurance and empathy. Biomedical engineering departments can also use identified service gaps to diagnose where performance improvement can best be targeted with available resources. This result can be achieved by identifying the largest negative gaps, then making an assessment to determine where expectations are highest. Once this assessment has been done, biomedical engineering departments can prioritise performance improvements. Under the SERVQUAL model, the results of annual customer satisfaction surveys will allow comparison of the affected customers’ perceptions and the expectations of the service over time. Such comparisons will help
biomedical engineering departments determine the effectiveness of performance improvement initiatives in targeted dimensions.

Clinicians, or internal customers, clearly have high expectations regarding the promptness of service and the accuracy of clinical equipment. By adopting the SERVQUAL model, biomedical engineering departments can assess multiple dimensions of service quality to ascertain current service levels and to determine which part of the service needs improvement. The department can then design service delivery processes and allocate the appropriate resources to provide quality service. The SERVQUAL model will assist biomedical engineering departments to deliver the most cost effective and highest standard of technology support by maintaining a high level of service quality, including patient safety.

This research also establishes that all service quality attributes (tangibility, reliability, responsiveness, assurance and empathy) of the SERVQUAL model, as discussed in the literature review, are equally important for biomedical engineering departments. These five attributes are examined in the context of biomedical engineering services below.

*Tangibility*

Equipment must have up-to-date records, be clean, clearly labelled and traceable. These aspects are important for biomedical engineering, because most of the time there is no face-to-face contact with biomedical engineers when equipment is in use on the patient. Therefore, the need to have clean, correctly labelled, safe and well-functioning equipment is paramount.

*Reliability*

The quality of patient treatment relies on the reliability and accuracy of clinical equipment and the competency of operators and clinicians alike. Diagnostic equipment must be available when required by clinicians. If it is not functioning correctly or if the clinician cannot trust it, they lose confidence in the results produced by the equipment, which in turn results in dissatisfaction. This situation also affects the clinician’s confidence in treating patients. Therefore, biomedical engineering departments and their staff are responsible for more than ensuring that the equipment is up-to-date and meets the manufacturer’s specifications and regulatory requirements at all times; they are indirectly responsible for the quality of healthcare offered to patients.
Responsiveness

One aspect of responsiveness is prompt service. This research reveals that the amount of time it takes to respond to a service call or to assist a clinician at the patient’s bedside is very important. A delay in response can result in delays in patient treatment, cancellation of surgical procedures or can even prove critical to a patient’s survival. Therefore, technical support is crucial to clinicians who are required to make decisions based on results obtained from medical equipment.

Assurance

Assurance is also an important factor for both biomedical engineering departments and equipment operators, because when clinicians query the operation of or the diagnostic result produced by a particular piece of equipment, they must be assured that the operator has handled the equipment correctly, that the equipment is functioning correctly and that the results are accurate. Therefore, an engineer’s competence is vital in answering clinicians’ questions and in providing reassurance.

The other aspect of assurance is trust. Clinicians must have confidence and trust in engineers when taking their advice on clinical equipment. Clinicians should also have trust and confidence in the equipment itself, meaning that it should work correctly at all times. One good example is a defibrillator unit. When needed, the unit should work without failure to revive a patient who is having a cardiac arrest.

Empathy

In the context of biomedical engineering, there are several factors including access to biomedical services when needed, communication and understanding of internal customers’ needs; these factors can be described as empathy. Biomedical engineering staff must sometimes go beyond their role descriptions to assist internal customers. For example, when a piece of equipment is broken and clinicians need it for a very sick patient, biomedical engineers may take initiative to contact the supplier and arrange a temporary replacement while the hospital’s unit is being restored. This was confirmed during observation, when the researcher observed an
engineer in Case B arranging infusion equipment (an infusion pump) on loan from a supplier for a very sick patient.

Furthermore, biomedical engineers and technicians must sometimes put in extra effort to support clinicians. During critical moments such as natural disasters, when high demand on resources arises in the clinical area, engineers try to relieve work pressures by offering help where they can. These five attributes of the SERVQUAL model (as discussed above) and its relationship to customer satisfaction are illustrated in Figure 5.8.
Figure 5.8: Relationship between service quality and customer satisfaction based on the SERVQUAL model

Source: Developed by the researcher for this research.

Figure 5.8 shows how different functions of biomedical engineering services are interrelated and how the elements of each attribute are crucial to equipment management. Clearly, all attributes of the SERVQUAL model are equally important to biomedical engineering departments.
(2) **Recommendations on improvements in service quality and customer satisfaction via staff training**

This research found that one of the biggest challenges facing biomedical engineering professionals is keeping up with myriad improvements in biomedical equipment technology, as well as keeping pace with increasingly high expectations from internal customers for technology support. The researcher recommends that biomedical engineering departments implement a more robust equipment management and training programme to improve technical skills that in turn will improve service quality and internal customer satisfaction. Lack of trained staff results in longer response times for service calls and longer equipment downtimes, when specialised equipment cannot be maintained by in-house technicians and engineers due to lack of training. Hospitals then must depend on outside suppliers, which causes delays in patient treatment.

This research shows that management and senior staff should invest more time and resources in awareness training to ensure that everyone within the organisation understands the biomedical engineering business, its purpose, plans, management system and where it stands within the organisation. Biomedical engineering departments should also be encouraged to send more engineers and technicians to factory-level training on specialised biomedical equipment. Many medical device manufacturers have excellent training materials and other resources that can be used to help frontline engineers gain maximum knowledge in minimum time.

(3) **Recommendations on service quality and customer satisfaction tools**

The biomedical engineering departments of all four cases represented in this study are currently not utilising service quality and customer satisfaction measurement tools fully, because they believe that these tools are time consuming and require more resources than what is available to them. This research recommends that biomedical engineering departments utilise service quality and customer satisfaction tools more comprehensively to realise further improvements. Quality tools such as Pareto analysis and histograms can assist to identify weaknesses in biomedical service provisions and can prompt management to take appropriate actions for remedy (Grigg and Walls, 2007). Pareto analysis can yield a graphical overview of the problems associated with biomedical engineering service processes by ranking them from
most to least frequent. The department can use such a ranking to prioritise problem areas for improvement.

Histograms can also assist in obtaining statistical information that can be used to refine the processes and ultimately improve customer service. This tool can be used to graphically analyse the types of return jobs biomedical engineering departments get from their internal customers. The results from histograms can assist managers and frontline staff to take actions to reduce the number of return jobs. The four biomedical engineering departments studied can also use the PDCA cycle for continuous improvement in processes. Such targeted usage of service quality and customer service tools may engage more resources initially, but service quality and customer satisfaction will improve in the long run.

(4) Recommendations on appropriate resourcing of biomedical engineering departments

Biomedical engineering departments involved in this study have limited resources, because hospitals experience high demand for technological support in terms of equipment management, technical assistance in equipment operations, maintenance and technical advice. Since biomedical equipment plays an important role in patient treatment, hospitals must have enough resources to maintain efficient technical support and the highest level of service quality to guarantee the safety of patients and operators alike. Therefore, hospital management should evaluate and increase their support for biomedical engineering departments.

5.4 Implications for theory and practice

This section discusses theoretical and practical implications of this research.

(i) Theoretical implications

Limited research has been conducted in the area of biomedical engineering services. The researcher could not find any previous research focused on the management of biomedical technology or biomedical equipment management in New Zealand public hospitals, especially in the area of service quality and internal customer satisfaction. Therefore, the main objective of this research was to determine how TQM can benefit biomedical engineering departments in managing medical technology and in improving service quality and customer satisfaction. To
meet the objectives of this research, the following research questions were developed, and current theories and practices were reviewed.

Main research question

*How can TQM benefit biomedical engineering departments in New Zealand public hospitals in managing medical technology and in improving service quality and customer satisfaction?*

Sub-research questions

1. *What are the current systems used in New Zealand public hospitals for managing medical technology?*
2. *How are service quality and customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?*
3. *Which service and customer satisfaction models would be the most suitable and effective for biomedical engineering departments in New Zealand public hospitals?*

The literature review reveals that there is limited information on biomedical technology management in New Zealand public hospitals. What does exist seldom acknowledges the importance of biomedical equipment management. This study documents the way biomedical engineering equipment is managed in New Zealand public hospitals. This research also highlights the importance of service quality, internal customer satisfaction and the role of biomedical engineering in public hospitals. This study contributes to the body of knowledge on how TQM can assist biomedical engineering departments in managing medical technology and in improving service quality and internal customer satisfaction. Furthermore, service quality is a crucial variable that leads to customer satisfaction and is therefore important for biomedical engineering departments in hospitals. Service quality depends on the level of product knowledge, the accuracy of biomedical equipment and the skills of the service providers.

(ii) Practical implications

This research also highlights several practical implications, and recommends the two most suitable and effective models for managing medical technology in New Zealand public hospitals.
These models can improve efficiency, service quality and internal customer satisfaction in New Zealand public hospitals.

The first model is the CQI model (Figure 5.6), which allows biomedical engineering departments to take a long-term approach to improving services without putting pressure on resources. Departments can measure quality indicators to initiate and drive changes to biomedical engineering processes in a never-ending cycle of continuous improvement. Once one improvement is complete, another improvement can be initiated. This model also provides the opportunity to improve service quality and internal customer satisfaction in a cost-effective manner.

The second model this research recommends is SERVQUAL. All attributes of the SERVQUAL model (tangibility, reliability, responsiveness, assurance and empathy), as illustrated in Figure 5.8, are equally important to biomedical engineering. Using this model, biomedical engineering departments can measure and analyse gaps between perceptions and expectations experienced by their internal customers, and take actions to close identified gaps between delivery and expectations, thereby increasing service quality and customer satisfaction.

This study is not intended to generalise research findings; rather, these findings are offered as an alternative to reconstruct the existing literature on biomedical engineering services in public hospitals, and could serve as a benchmark for future research.

The researcher will promote the idea of implementing the two recommended models in biomedical engineering departments via biomedical engineering conferences and through discussion with the managers of biomedical engineering departments in New Zealand public hospitals.

5.5 Limitations of this research

This is a qualitative case study focused on the biomedical engineering departments of four public hospitals in New Zealand. Although the findings are considered relevant in improving the quality of service and customer satisfaction through TQM in biomedical engineering equipment management in the hospitals in which the research was conducted, the findings may not necessarily be directly applicable to other hospitals in New Zealand or other similar size hospitals in the other countries. However, this limitation does not mean that the findings cannot be applied to other hospitals within New Zealand or overseas. The outcomes of this research can
assist and guide managers to find ways to manage biomedical equipment and achieve internal customer satisfaction in other hospitals.

5.6 Suggestions for future research

Since limited information exists on biomedical engineering services and biomedical equipment management in public hospitals in the New Zealand context, similar research utilising broader case studies and the same or a different methodology would be very helpful.

While a qualitative case study method was used in this research, a quantitative method could confirm these findings and build on this research through further investigations of TQM as it applies to biomedical equipment management in New Zealand’s public hospitals.

5.7 Conclusion

This chapter has discussed the analysis of the original research results gleaned from multiple sources, as described in Chapter 4. The findings from Chapter 4 were analysed, and conclusions were drawn in respect to each of the three sub-research questions.

From this research, we can infer that biomedical engineering departments play a significant role in New Zealand public hospitals by managing medical technology and by providing technical support to clinicians at all levels. Biomedical engineering departments follow the ISO 9000 total quality concept and are using the ISO 9000 series of standards for quality management to reduce non-conformance, and to maintain customer expectations by providing cost effective biomedical services within the department’s capacity. This research shows that the biomedical engineering departments of all hospital cases observed currently achieve service quality and internal customer satisfaction through a combination of several methods and intangible factors. The intangible factors include corporate culture and leadership, attitude, dedication and staff commitment, and the methodologies used include organisational structure, processes, ensuring staff capability, relying on customer feedback, training and record keeping for traceability. This research reveals that even though a difference in organisational practices exists between hospitals, little difference exists in the way biomedical engineering services are provided to internal customers. The research also reveals that all of the cases are using Deming’s wheel (PDCA) to manage biomedical engineering-related processes. The transformational style of leadership also allows supervisors to encourage staff to pursue innovative solutions to
equipment-related problems. Despite budget constraints and a lack of resources, technicians and engineers are continually trying to improve service quality to fulfil their customers’ needs and expectations.

This study shows that TQM is still appropriate for biomedical engineering departments in New Zealand public hospitals for several reasons. Some key reasons are listed below.

(i) TQM aims at improving quality through continual process improvement. Continual improvement can drive biomedical engineering departments to be both analytical and creative in finding ways to become more competitive and more effective at meeting internal customer expectations.

(ii) A TQM programme will assist in eliminating mistakes and waste, which will reduce equipment downtime and return jobs. This can significantly reduce costs to the department and the hospital as a whole.

(iii) A continuous process of improvement approach will enable small, incremental gains towards the goal of total quality. Large gains will be accomplished by small, sustainable improvements over the long term. This concept necessitates a long-term approach by managers and the willingness to invest in the present for benefits that manifest themselves in the future. A corollary of continuous improvement is that workers and management develop an appreciation for, and confidence in, TQM over time.

(iv) TQM promotes knowledge sharing. This will result in a deepening and broadening of biomedical engineers’ and technicians’ knowledge and skills. Knowledge sharing based on TQM thus results in less time taken to complete tasks, hence reducing cost and equipment downtime.

(v) TQM heralds a change in work culture by educating all employees on quality and by making quality the concern of everybody, rather than a select few. The focus on quality leads to a proactive work culture aimed at preventing mistakes rather than correcting mistakes.

This research concludes that although several processes and procedures are in place, gaps still exist in biomedical engineering services due to under resourcing, inadequate staff training, budget constraints and the unrelenting pace of improvements in medical technology. Finally, this
study recommends two models that are deemed suitable for the management of biomedical equipment in New Zealand public hospitals.
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Appendices

Appendix 1

Participant consent form

CONSENT FORM

(This consent form is based on the National Statement on Ethical Conduct in Human Research (National Statement/NS))

Title of research project: Total Quality Management (TQM) of Clinical Engineering in New Zealand Public Hospitals

Research approval number: ECN-10-036

Name of the researcher: Sushil Pramod Varma

NOTE: This consent form will remain with the Southern Cross University researcher for their records.
Tick the box that applies, sign and date and give to the researcher

I agree to take part in the Southern Cross University
research project specified above. Yes ☐ No ☐

I have been provided with information about the purpose, methods,
demands, risks, inconveniences and possible outcomes of this research.
I understand this information. Yes ☐ No ☐

I agree to be interviewed by the researcher. Yes ☐ No ☐

I agree to allow the interview to be audio-taped. Yes ☐ No ☐

I understand that my participation is voluntary. Yes ☐ No ☐

I can choose not to participate in part or all of this research at any time,
Without consequence. Yes ☐ No ☐

I understand that any information that may identify me, will be
de-identified at the time of analysis of any data. Therefore, I, or
any information I have provided cannot be linked to my person/
company. (Privacy Act 1988 Cth) Yes ☐ No ☐

I understand that all information gathered in this research is confidential.
It is kept securely and confidentially for 7 years at the University (unless
there are special circumstances, that have been explained to me). Yes ☐ No ☐

I am aware that I can contact the researcher at any
time with any queries. Yes ☐ No ☐
I understand that the ethical aspects of this research have been approved by the SCU Human Research Ethics Committee.  

Yes [ ]  No [ ]

If I have concerns about the ethical conduct of this research I understand that I can contact the SCU Ethics Complaints Officer.  

Yes [ ]  No [ ]

Participant’s name: ________________________________

Participant’s signature: ____________________________

Date: ____________________________

Contact Tel: ____________________________

Email: ____________________________
Research cover letter

Date: 1st October, 2009

Attn: Biomedical Engineering Manager

  XX Public Hospital
  New Zealand

Dear Sir

  My name is Sushil Pramod Varma and I am studying for a Doctor of Business Administration at Southern Cross University, Australia (SCU). I am researching in the subject of Total Quality Management (TQM) of clinical engineering in New Zealand public hospitals. I am investigating how TQM can benefit biomedical engineering departments of NZ public hospitals by improving service quality and internal customer satisfaction. The outcome of this research will contribute to the knowledge in healthcare technology management, in particular biomedical engineering management in public healthcare. The results can therefore assist managers and
engineers of biomedical engineering departments of New Zealand public hospitals to improve service quality and internal customer satisfaction.

Your organisation is invited to take part in this research by agreeing to allow your team to participate in the research interview, and by agreeing to allow the researcher access to review departmental documents and to observe the day-to-day activities of the organisation. The detail of the research is provided below.

**Name of project:** Total Quality Management (TQM) of biomedical/clinical engineering in New Zealand public hospitals.

**Procedures to be followed:**

I will be asking several open-ended questions that will allow full and honest answers from the participating members of the biomedical team. The interview will be approximately 50 minutes in length and will be tape recorded if agreed by the participant. The interviews will be conducted in the workshops of the organisation where the biomedical team works. If participants prefer to move away from their work environment to be interviewed, then a meeting room or other appropriate room within the organisation will be used. I will be taking notes and tape recording the interview, and a transcript will be provided to participants if they wish to receive a copy of the interview.

All tapes and transcriptions will be securely held for a period of seven years, and all identifying aspects will be removed from the transcriptions. No remuneration will be provided to participants.

**Possible discomforts and risks**

There will be no possible discomforts or risks to the participants, as participation in this study is voluntary. Neither participants’ names nor any identifying information will be disclosed or published, other than the participant’s role or position within the organisation. Neither patients’ details nor participants’ personal data will be required for this research. This research will be focused solely on biomedical engineering services in the hospital. The only inconvenience to the participants will be to make time for this interview, in their free time. This
could be during the lunch hour or after work. The participants are not expected to leave their place of employment for the interviews.

**Responsibilities of the researcher**

Any information that is obtained in connection with this study and that can be used to identify participants will remain totally confidential and will not be disclosed to any other member of your organisation.

Interviews will be tape recorded only after obtaining the participant’s approval. I will be advising participants in the study that the tape will remain in my possession and will be transcribed by me personally. Tapes and their transcriptions will be locked in a secure and safe location. The tapes will be erased and the transcriptions shredded after seven years, or at a time determined by the ethics committee of the university.

**Responsibilities of the participant**

I would appreciate it if participants would fully disclose any information they feel is relevant to the research without fear of being identified from within the organisation. As a participant in the study, identity will be kept confidential and superiors will not be notified of who is participating in the study.

**Freedom of consent**

As a participant or as an organisation, you are free to withdraw your consent and to discontinue participation at any time. As this study is of a voluntary nature and as a participant in the research, you have decided to volunteer your time and assist in the research. I want participants to clearly understand that their participation in my research programme is purely voluntary, and I would also like the participants to assure me that they have not been coerced to participate in any way. Each participant will be required to complete a consent form before the interview is conducted.

**Inquiries**

If you have any questions, please feel free to contact my supervisor.
Supervisor’s contact details
Dr. Siham El Kafafi
Senior Lecturer
Manukau Business School
Manukau Institute of Technology
Ph. +64 9 9688701

Researcher’s contact details
Sushil Pramod Varma
Phone: 064 09 2638179
Or email: varma.sushil@fphcare.co.nz

Or if you have any problems associated with this research project, please contact:
Ethics Complaints Officer
Graduate Research College
Ph. +61 2 6620 3705

I would like to thank you for considering my request.

Kind Regards

Varma Sushil

MBA, NZOQ, NZCE, Dip. Tel. Eng

NZ Customer Service/Service Manager
Fisher & Paykel Healthcare Ltd.
Freephone: 0800 503 553
Freefax: 0800 658 923
Mobile: 021 956 511
Email: varma.sushil@fphcare.co.nz
Appendix 2

Consent form

Consent to participate in the research

Part A: For the participant to complete

Please sign below to signify your agreement to participate in this research, and return it to me. You will be given a copy of this form to keep.

I have read the information above, and agree to participate in the study entitled “Total Quality Management (TQM) of Clinical Engineering in New Zealand public hospitals”. I am over the age of 18 years and I agree to the researcher taking hand-written notes and tape recording the interview.

Name of subject: ____________________________________________________________

Signature of subject: _________________________________________________________

Date: ______________________________________________________________________

All participants are entitled to receive the results of research in which they have participated.

Do you wish to receive the results of the research?  Yes: ___  No: ___

If yes, please provide your email address: ________________________________________
**Part B: For the researcher to complete**

I certify that the terms of the form have been verbally explained to the subject, that the subject appears to understand the terms prior to signing the form and that I asked the subject if she/he needed to discuss the project with an independent person before signing, and she/he declined (or has done so).

Signature of the researcher: __________________________________________________

Date: _____________________________________________________________________
Appendix 3

Questionnaire

Research questions (face-to-face interviews)

Part A Research question 1
What is the current management system in New Zealand public hospitals for managing medical technology?

Interview questions

<table>
<thead>
<tr>
<th>Question number</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>In your opinion, what is the definition of Total Quality Management (TQM)?</td>
</tr>
<tr>
<td>2</td>
<td>Do you think TQM is important to your organisation?</td>
</tr>
<tr>
<td>3</td>
<td>In your view, what management system is your biomedical engineering department currently using to fulfil its objectives?</td>
</tr>
<tr>
<td>4</td>
<td>In your opinion, how well is the current management system achieving its objectives?</td>
</tr>
<tr>
<td>5</td>
<td>Can you please give some examples?</td>
</tr>
<tr>
<td>6</td>
<td>What are the department’s procedures and protocols for servicing medical equipment in your hospital?</td>
</tr>
<tr>
<td>7</td>
<td>How often are these protocols and procedures evaluated?</td>
</tr>
<tr>
<td>8</td>
<td>Who is responsible for departmental policies and decision making?</td>
</tr>
<tr>
<td>9</td>
<td>What are the key elements of your service?</td>
</tr>
<tr>
<td>10</td>
<td>In your view, how are these key elements achieved?</td>
</tr>
<tr>
<td>11</td>
<td>What is the current method for record keeping and traceability?</td>
</tr>
<tr>
<td>12</td>
<td>What are the common methods of internal communication?</td>
</tr>
</tbody>
</table>
**Part B  Research question 2**

*How is service quality and internal customer satisfaction currently achieved by biomedical engineering departments in New Zealand public hospitals?*

**Interview questions**

<table>
<thead>
<tr>
<th>Question number</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>In your opinion, what is the definition of service quality?</td>
</tr>
<tr>
<td>2</td>
<td>Do you think service quality is important to biomedical engineering departments?</td>
</tr>
<tr>
<td>3</td>
<td>In your own words, what do you think customer satisfaction refers to?</td>
</tr>
<tr>
<td>4</td>
<td>Can you please explain what the biomedical engineering department’s role is in your hospital?</td>
</tr>
<tr>
<td>5</td>
<td>In the context of the biomedical engineering department, who do you provide service to? Why?</td>
</tr>
<tr>
<td>6</td>
<td>Can you please name some of those services?</td>
</tr>
<tr>
<td>7</td>
<td>What are the methods of communication with your internal customers?</td>
</tr>
<tr>
<td>8</td>
<td>Is there a complaint handling procedure that your department follows? If yes, how does it work? If no, why do you think it is not important to have one?</td>
</tr>
<tr>
<td>9</td>
<td>What is your response time for reported complaints about equipment?</td>
</tr>
<tr>
<td>10</td>
<td>Do you give feedback to your customers on the services you provide? If yes, how do you do this? If no, why not?</td>
</tr>
<tr>
<td>11</td>
<td>Do you believe that customer service can be improved?</td>
</tr>
<tr>
<td>12</td>
<td>If yes, can you please explain how it can be improved? If no, why not?</td>
</tr>
<tr>
<td>13</td>
<td>In your view, how much focus does your department have on its internal customers?</td>
</tr>
<tr>
<td>14</td>
<td>Would you like to see your biomedical engineering department have more customer focus? If yes, how might this be done? If no, why not?</td>
</tr>
<tr>
<td>15</td>
<td>In your view, how well does your department measure service quality and customer satisfaction?</td>
</tr>
<tr>
<td>16</td>
<td>Do you think your biomedical engineering department needs to improve on its...</td>
</tr>
</tbody>
</table>
service quality and customer satisfaction? Can you please explain why?

17 How does your biomedical engineering department decide on training and how does it measure competency of its staff?

18 In your view, how well does your department ensure quality service for its customers?

Part C  Research question 3

Which service and customer satisfaction models are currently available and what would be the most suitable and effective model for biomedical engineering departments in New Zealand public hospitals?

Interview questions

<table>
<thead>
<tr>
<th>Question number</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Do you know what management system is used by other organisations like yours?</td>
</tr>
<tr>
<td>2</td>
<td>If yes, what is their management system?</td>
</tr>
<tr>
<td>3</td>
<td>Are you familiar with any service quality models that can be adopted by the biomedical engineering department?</td>
</tr>
<tr>
<td>4</td>
<td>If yes, please explain.</td>
</tr>
<tr>
<td>5</td>
<td>Are you familiar with any customer satisfaction model?</td>
</tr>
<tr>
<td>6</td>
<td>If yes, what is it called?</td>
</tr>
<tr>
<td>7</td>
<td>Do you think it can be adopted by your biomedical engineering department?</td>
</tr>
<tr>
<td>8</td>
<td>If yes, please explain.</td>
</tr>
<tr>
<td>9</td>
<td>If no, why not?</td>
</tr>
</tbody>
</table>
## Appendix 4

### Interview schedule

<table>
<thead>
<tr>
<th>Participant</th>
<th>Date</th>
<th>Location</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital A (Case study A)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT 1</td>
<td>06/01/2011</td>
<td>Manager’s office</td>
<td>Biomedical engineer manager</td>
</tr>
<tr>
<td>PT 2</td>
<td>07/01/2011</td>
<td>Supervisor’s office</td>
<td>Biomedical supervisor</td>
</tr>
<tr>
<td>PT 3</td>
<td>23/12/2010</td>
<td>Tea room</td>
<td>Senior biomedical engineer</td>
</tr>
<tr>
<td>PT 4</td>
<td>04/01/2011</td>
<td>Meeting room</td>
<td>Biomedical engineer</td>
</tr>
<tr>
<td><strong>Hospital B (Case study B)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT 5</td>
<td>21/12/2010</td>
<td>Manager’s office</td>
<td>Biomedical engineer manager</td>
</tr>
<tr>
<td>PT 6</td>
<td>22/12/2010</td>
<td>Supervisor’s office</td>
<td>Biomedical supervisor</td>
</tr>
<tr>
<td>PT 7</td>
<td>04/01/2011</td>
<td>Meeting room</td>
<td>Senior biomedical engineer</td>
</tr>
<tr>
<td>PT 8</td>
<td>05/01/2011</td>
<td>Meeting room</td>
<td>Biomedical engineer</td>
</tr>
<tr>
<td><strong>Hospital C (Case study C)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT 9</td>
<td>27/12/2010</td>
<td>Supervisor’s office</td>
<td>Supervisor/biomedical engineer in-charge</td>
</tr>
<tr>
<td>PT 10</td>
<td>05/01/2011</td>
<td>Meeting room</td>
<td>Senior biomedical engineer</td>
</tr>
<tr>
<td>PT 11</td>
<td>05/01/2011</td>
<td>Meeting room</td>
<td>Biomedical engineer</td>
</tr>
<tr>
<td>PT 12</td>
<td>07/01/2011</td>
<td>Lunch room</td>
<td>Biomedical engineer</td>
</tr>
<tr>
<td><strong>Hospital D (Case study D)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT 13</td>
<td>06/01/2011</td>
<td>Supervisor’s office</td>
<td>Supervisor/biomedical engineer-in-charge</td>
</tr>
<tr>
<td>PT 14</td>
<td>04/01/2011</td>
<td>Meeting room</td>
<td>Senior biomedical engineer</td>
</tr>
<tr>
<td>PT 15</td>
<td>03/01/2011</td>
<td>Tea room</td>
<td>Biomedical engineer</td>
</tr>
<tr>
<td>PT 16</td>
<td>28/12/2010</td>
<td>Hospital canteen</td>
<td>Biomedical engineer</td>
</tr>
</tbody>
</table>

*Source:* Developed for this research by the researcher.
### Appendix 5

**Observation protocol template**

<table>
<thead>
<tr>
<th>Observation protocol</th>
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<tbody>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Location:</td>
</tr>
<tr>
<td>Observation of the event:</td>
</tr>
<tr>
<td>Interpretation of the event:</td>
</tr>
</tbody>
</table>

*Source:* Developed by the researcher for this research.
## Appendix 6

**Glossary of codes**

**Research question 1**

<table>
<thead>
<tr>
<th>Code/abbreviation</th>
<th>Definition of code</th>
</tr>
</thead>
<tbody>
<tr>
<td>TQM</td>
<td>Definition of Total Quality Management</td>
</tr>
<tr>
<td>TQMimpt</td>
<td>Confirmation that TQM is important</td>
</tr>
<tr>
<td>ISO-1</td>
<td>ISO 90001</td>
</tr>
<tr>
<td>SMS</td>
<td>Service management system</td>
</tr>
<tr>
<td>Achobj</td>
<td>Achieving objectives</td>
</tr>
<tr>
<td>Achobj eg</td>
<td>Achieving objectives, examples of objectives</td>
</tr>
<tr>
<td>SERV</td>
<td>Protocols for servicing medical equipment</td>
</tr>
<tr>
<td>EVaPP</td>
<td>Evaluation of procedures and protocols</td>
</tr>
<tr>
<td>Pol&amp;dec</td>
<td>Departmental policies and decision-making responsibility</td>
</tr>
<tr>
<td>KE Ser</td>
<td>Key elements of services</td>
</tr>
<tr>
<td>KE Ach</td>
<td>Key elements achieved</td>
</tr>
<tr>
<td>Trace Rec</td>
<td>Traceability and records</td>
</tr>
<tr>
<td>Coms</td>
<td>Internal communication methods</td>
</tr>
</tbody>
</table>

*Source*: Developed by the researcher for this research.
Glossary of codes, continued

Research question 2

<table>
<thead>
<tr>
<th>Code/abbreviation</th>
<th>Definition of code</th>
</tr>
</thead>
<tbody>
<tr>
<td>SQ</td>
<td>Service quality definition</td>
</tr>
<tr>
<td>SQimp</td>
<td>Confirmation that service quality is important</td>
</tr>
<tr>
<td>SF</td>
<td>Customer satisfaction definition</td>
</tr>
<tr>
<td>SCut</td>
<td>Service customers</td>
</tr>
<tr>
<td>Sertyp</td>
<td>Type of service</td>
</tr>
<tr>
<td>Cust com</td>
<td>Methods of communication to customer</td>
</tr>
<tr>
<td>Cplt pro</td>
<td>Complaint handling procedure</td>
</tr>
<tr>
<td>Cpro-des</td>
<td>Complaint handling procedure definition</td>
</tr>
<tr>
<td>Resptm</td>
<td>Response time</td>
</tr>
<tr>
<td>Cust FB</td>
<td>Feedback to customers</td>
</tr>
<tr>
<td>Cust FBm</td>
<td>Method of customer feedback</td>
</tr>
<tr>
<td>CS imp</td>
<td>Customer service improvement</td>
</tr>
<tr>
<td>CSImd</td>
<td>Improvement method for customer feedback</td>
</tr>
<tr>
<td>Cust FBmi</td>
<td>Confirmation that customer feedback is important</td>
</tr>
<tr>
<td>ICust F</td>
<td>Focus on internal customers</td>
</tr>
<tr>
<td>Custfoc</td>
<td>Level of customer focus</td>
</tr>
<tr>
<td>CustfIp</td>
<td>Improvements in customer focus</td>
</tr>
<tr>
<td>MorcF</td>
<td>More customer focus required</td>
</tr>
<tr>
<td>CSQSM</td>
<td>Measure of customer service quality and customer satisfaction</td>
</tr>
<tr>
<td>SQCSIlp</td>
<td>Improvement on service quality and customer satisfaction</td>
</tr>
<tr>
<td>SlpRn</td>
<td>Service quality improvement rationale</td>
</tr>
<tr>
<td>Cmptcy</td>
<td>Method of measuring staff competency</td>
</tr>
<tr>
<td>QA1</td>
<td>Quality assurance and safety test program</td>
</tr>
</tbody>
</table>

Source: Developed by the researcher for this research.
Research question 3

<table>
<thead>
<tr>
<th>Code/abbreviation</th>
<th>Definition of code</th>
</tr>
</thead>
<tbody>
<tr>
<td>OrgMs</td>
<td>Organisational management system</td>
</tr>
<tr>
<td>Magsystyp</td>
<td>Type of management system</td>
</tr>
<tr>
<td>SQmodl</td>
<td>Service quality model</td>
</tr>
<tr>
<td>SQmodlE</td>
<td>Adoptable service quality model explanation</td>
</tr>
<tr>
<td>CSmodlfy</td>
<td>Familiarity with customer satisfaction model</td>
</tr>
<tr>
<td>CSMdTp</td>
<td>Type of customer satisfaction model</td>
</tr>
<tr>
<td>CSmdadp</td>
<td>Adoptability of customer satisfaction model</td>
</tr>
<tr>
<td>CSmdadpE</td>
<td>Explanation of adoptable customer satisfaction model</td>
</tr>
<tr>
<td>CS adopt</td>
<td>Reason why customer satisfaction model is adoptable</td>
</tr>
</tbody>
</table>

Source: Developed by the researcher for this research.

The end