



**ESTABLISHING QUALITY SYSTEM IN ACCREDITED
BIOMEDICAL CALIBRATION LABORATORY**

ROZIAH BINTI ABDUL LATIFF

MASTER OF SCIENCE IN TECHNOLOGY MANAGEMENT

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Faculty of Technology Management and Technopreneurship

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ROZIAH BINTI ABDUL LATIFF

**A thesis submitted
in fulfillment of the requirements for the degree of
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2016

DECLARATION

I declare that this thesis entitled “Establishing Quality System in Accredited Biomedical Calibration Laboratory” is the result of my own research except as cited in the references. The thesis has not been accepted for any degree and is not concurrently submitted in candidature of any other degree.

Signature :

Name : ROZIAH BINTI ABDUL LATIFF.

Date : MAY 2016 .

APPROVAL

I hereby declare that I have read this thesis and in my opinion this thesis is sufficient in terms of scope and quality for the award of Master of Science in Technology Management.

Signature :

Supervisor Name : PM DR IZ Aidin Bin Abdul Majid

Date : MAY 2016 .

DEDICATION

This thesis is dedicated to:

The sake of Allah, my Creator and my Master,

My great teacher and messenger, Muhammad (May Allah bless and grant him),

who taught us the purpose of life,

A special feeling of gratitude to my loving parents, my dearest husband,

my beloved kids for being there for me through the entire programme.

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who read my numerous revisions and helped make some sense of the confusion.

Special thanks goes to the members of staff Centre for Medical Electronic Technology

(CMET) for their encourage and continued supported me throughout the process.

ABSTRACT

Medical equipment requires confirmation whether they comply with the specifications and safety regulations before they can be used in healthcare facilities. Politeknik Sultan Salahuddin Abdul Aziz Shah (PSA) has set up the biomedical equipment analyzer calibration laboratory starting from October, 2010. These stations are capable to test and calibrate medical device analyzers such as patient simulator, safety analyzer, infusion pump etc. PSA plans to apply ISO/IEC 17025 certification, specifically for laboratory accreditation for the calibration laboratory to ensure and establish its reliability and commitments towards providing quality services. The purposes of this study are to discover the perceived service quality of Biomedical Calibration Laboratory, to analyze the SERVQUAL dimensions in the context of setting-up accredited Biomedical Calibration Laboratory and to evaluate the relationship between the SERVQUAL factors towards the perceived service quality of Biomedical Calibration Laboratory. The methodology used in this research are both quantitative and qualitative method. The five SERVQUAL dimensions: tangible, reliability, responsiveness, assurance and empathy are being used in contributing perceived service quality of Biomedical Calibration Laboratory. The dimensions in this study are used as a guidelines in the quality manual to establish quality service of accredited Biomedical Calibration Laboratory in Malaysia, based on the experience gained after going through the whole systems, the proposed process also can be used by other health care industries.

ABSTRAK

Peralatan perubatan memerlukan pengesahan bahawa peralatan tersebut mematuhi spesifikasi dan peraturan keselamatan sebelum digunakan dalam fasiliti penjagaan kesihatan. Politeknik Sultan Salahuddin Abdul Aziz Shah (PSA) telah menubuhkan makmal kalibrasi peralatan bioperubatan sejak Oktober 2010. PSA bercadang untuk memohon ISO/IEC 17025 iaitu pensijilan makmal akreditasi bagi makmal kalibrasi untuk mewujudkan kebolehpercayaan dan komitmen kearah perkhidmatan yang berkualiti. Tujuan kajian ini adalah untuk mencari kualiti perkhidmatan Makmal Penentukuran Bio Perubatan, untuk menganalisis dimensi SERVQUAL dalam konteks menubuhkan Makmal Akreditasi Bio Perubatan yang diiktiraf, untuk menilai hubungan di antara dimensi SERVQUAL terhadap kualiti perkhidmatan Makmal Kalibrasi Bio Perubatan. Metodologi yang digunakan dalam kajian ini adalah kaedah kuantitatif dan kualitatif. Lima dimensi SERVQUAL: ketara, kebolehpercayaan, responsif, jaminan dan empati telah digunakan dalam dimensi kualiti perkhidmatan Makmal Kalibrasi Bio Perubatan. Dimensi dalam kajian ini digunakan dalam garis panduan manual kualiti untuk mewujudkan kualiti perkhidmatan Makmal Akreditasi Bio Perubatan di Malaysia, berdasarkan pengalaman daripada sistem, proses ini juga boleh digunakan oleh industri penjagaan kesihatan lain.

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CHAPTER 1

INTRODUCTION

1.1 Introduction

The first chapter in this thesis discusses the background of study, introduces the accreditation MS ISO/IEC 17025 and service quality. This follows by the problem statement, research objective, research question and hypothesis, significance of the study and disposition of the thesis which will help readers to understand the insight of the research area. The purpose of this study is to develop guidelines in the quality manual to establish service quality of accredited Biomedical Calibration Laboratory in Malaysia.

1.2 Background of Study

In this study, guidelines in the quality manual will be developed and it will be used for ISO/IEC 17025 application. Once the laboratory is accredited the global recognised standard MS ISO 17025, it is ready to start operations and the quality system can be established.

1.2.1 Accreditation and MS ISO/IEC 17025

This International Standard is applicable to all laboratories regardless the extent of the scope of testing and/or calibration activities. In Malaysia, Guide 25 was first introduced on 1st July 1987. This was followed by a national unified

laboratory accreditation scheme known as National Laboratory Accreditation Scheme of Malaysia or Skim Akreditasi Makmal Malaysia (SAMM) which was introduced on 15th August 1990.

MS ISO/IEC 17025 is an international standard for laboratories that wish to be accredited under the SAMM scheme of accreditation that operates management system requirements, technical requirements, is able to consistently generate technically valid results and is constantly being reviewed and improved.

The accreditation is based upon an agreed standard with specified measurement parameters identified and uncertainties. Accreditation most often involves on-site assessments, proficiency testing and periodic follow-ups. The purpose of accreditation is to provide customers of the laboratory with a high degree of confidence that the laboratory has the technical competency and adequate quality system to perform calibrations to an agreed standard. The fundamental reason for accrediting any laboratory is to provide assurance to its customers that its measurements are correct. In short, customers are demanding high quality in all aspects of business. Many users of calibration and/or measurement services will require that their suppliers be accredited to realize the benefits of accreditation. Important decisions that affect product quality, health and safety, the environment and competitiveness are based on those services.

A documented quality management system has to be produced before the laboratory becomes accredited. The usual contents of the quality manual following the outline of the MS ISO/IEC 17025 standard, addressing all the requirements of the standard have been developed in this study. It can be used as a guide to implement a quality management system in biomedical calibration laboratory.

1.2.2 Service Quality (SERVQUAL)

In their early writing, Lewis and Booms (1983) state that “service quality is a measure of how well the service level delivered matches customer expectations”. Service quality is an ambiguous term. Pirsig (1987) states that “although we cannot define quality, we know what quality is”. Parasuraman, Zeithaml and Berry (1985) at first state that “quality is zero defects – doing it right the first time” then in year 1990, they found “quality is exceeding what customers expect from the service”. Delivering quality service means conforming to customer’s expectations on a consistent basis.

SERVQUAL tool established by Parasuraman et al. (1991) has been used in the study in order to measure the quality of educational services being provided by the university on all the five dimensions of quality i.e. reliability, responsiveness, assurance, empathy and tangibles. The SERVQUAL instrument has been the predominant method used to measure consumer’s perceptions of service quality. Van Iwaarden et al. (2003) state the five generic dimensions are as follows:

- i. **Reliability:** The ability to perform the promised service accurately and dependably.
- ii. **Responsiveness:** Provide prompt service and the willingness to help customers.
- iii. **Assurance:** The knowledge and ability to inspire trust and confidence as well as the courtesy of employees.
- iv. **Empathy:** The provision of individualised attention to customers and being caring.
- v. **Tangibles:** The appearance of physical facilities, equipment, experienced

personnel and communication materials.

Van Iwaarden et al. (2003) also stated that the philosophy that drives modern company management demands a quality- centred operation. This means that calibration laboratories will be more and more involved in the total quality effort of the company. Laboratories will become more aware of overall company requirements with respect to quality management programs. Quality is examined as it relates to what metrology laboratories must do to comply with its specifications. The concept of service quality in the laboratory would focus both on the functional quality as well as technical quality. No matter what kind of quality system a company has, preparing for accreditation can be a time-consuming task requiring detailed planning, adequate resources and commitment to get the job done in time.

1.2.3 Perceived Service Quality

Perceived quality can be defined as the customer's perception of the overall quality or superiority of a product or service with respect to its intended purpose, relative to alternatives. Perceived quality is, first, a perception by customers. It thus differs from several related concepts.

This chapter comes out with a brief explanation regarding the perceived service quality towards service quality in Biomedical Calibration Laboratory based on five dimensions of SERVQUAL model. Establishing service quality in Biomedical Calibration Laboratory may be one of the major ways of differentiation. The quality system must focus on customers' satisfaction and strive to exceed customers' expectations. The only way to accomplish this is by a thorough understanding of all five related dimensions.

1.3 Problem Statement

Referring to the regulation, Medical Devices Act 2012 (ACT 737) Malaysia requires all devices regarded as experimental in their home country to be internationally certified by a conformity assessment body that shall be a body registered under this act, before being used in Malaysia. There are at least 500,000 medical device products in Malaysia covered under this act and 90 % of these devices are imported. Currently, there is no established system in Malaysia to address the issue regarding traceability of biomedical devices to ensure the quality of healthcare in Malaysia.. This research will discover the perceived service quality and analyze the SERVQUAL element in setting up the Biomedical Calibration Laboratory (BMCL), Polytechnic Sultan Salahuddin Abdul Aziz Shah (PSA). Finally, it can be used to establish the service quality system to other healthcare industries in Malaysia in line with the regulation of Medical Device Act 2012.

M.J Turner et al. stated that in the past the practitioner could easily detect the malfunction or inadequate performance of medical equipment since it is simple. Modern medical equipment is very complex, employs a wide variety of physiological measurements made by instruments whose performance is difficult to verify by inspection. There is a need to establish a system to ensure medical measurement systems are traceably calibrated to improve the quality of healthcare and reduce the overall costs to society in the long term. All the medical equipment used in either hospitals or laboratories, need to be calibrated from time to time. This is to ensure the accuracy of measurements taken using this equipment and eventually to monitor a patient's condition. Calibration is an operation establishing the relation between quantity values provided by measurement standards and the corresponding indications of a measuring system, carried out under specified conditions and including evaluation of measurement uncertainty. Calibration can be done

to confirm the accuracy of the equipment. This only can be done in a laboratory. Therefore, a medical equipment calibration laboratory is required to perform specific types of measurement, testing and calibration to ensure this equipment are compatible to use. There is a need to have proper documented traceability of biomedical equipment so that safety and the quality of all medical equipment can be guaranteed. Performance of measuring and testing equipment may change with time causing wear and tear, overloaded or because of improper use. The accuracy of the equipment needs to be checked from time to time. To overcome these problem all measuring and testing equipment need to be measured and calibrated for a specific time interval.

Currently, there is no such laboratory in Malaysia. Traditionally, all the medical equipment are being accessed by the suppliers who bring the equipment in. If they are found faulty, the equipment is sent back to the manufacturer for maintenance or repairing. This can be time-consuming and costly. Most of the equipment or products are imported from USA, United Kingdom, Japan, Germany, Korea etc. The representative suppliers from Malaysia have to send back the equipment to the manufacturer which will take some time to deliver the equipment. The cost to calibrate the equipment will also increase due to the transportation fees and tax. Therefore, the setting up of a calibration laboratory locally is so timely. Setting up an accredited laboratory will meet legal requirements by Medical Device Authority, Ministry of Health. It also fulfils biomedical industry requirement, improves measurements quality, formal recognition of competency and increases the confidence of customers.

1.4 Research Objective

The research is embarked through Biomedical Calibration Laboratory (BMCL) which is in the process of becoming an accredited laboratory under MS ISO/IEC 17025 from Department of Standards Malaysia. In order to be accredited, all the test equipment used in the laboratory need to have clear traceability to the recognized standards. The purposes of this study are as follows:-

- i. To discover the perceived service quality of Biomedical Calibration Laboratory.
- ii. To analyze the SERVQUAL dimensions in the context of setting-up accredited Biomedical Calibration Laboratory.
- iii. To evaluate the relationship between the SERVQUAL factors towards the perceived service quality of Biomedical Calibration Laboratory.

1.5 Research Question

This research aims to develop guideline, service quality related documentation in applying MS ISO/IEC 17025 Accreditation BMCL. Therefore the central research questions for this study are listed as follows:-

- i. What is the perceived service quality of Biomedical Calibration Laboratory?
- ii. What are the pertinent SERVQUAL elements in setting up the Biomedical Calibration Laboratory?
- iii. How does the SERVQUAL factor lead to perceived service quality of Biomedical Calibration Laboratory?

1.6 Significance of the Study

This study identifies the perceived service quality of Biomedical Calibration Laboratory, evaluates the pertinent SERVQUAL elements in setting up the Biomedical Calibration Laboratory and analyzes how far the SERVQUAL factors lead to perceived service quality in the laboratory.

As a result, this study can be used as a guideline, service quality related documentation in applying for MS ISO/IEC 17025. BMCL Accreditation and can give benefits to the organization to generate income in the future as there is no such laboratory in Malaysia. BMCL, Polytechnic Sultan Salahuddin Abdul Aziz Shah (PSA) will be the pioneer laboratory to serve the country.

This research will studies and establish the traceability of BMCL, Polytechnic Sultan Salahuddin Abdul Aziz Shah (PSA) to be proposed to the other healthcare industries in Malaysia in line with the regulation of Medical Device Act 2012.

1.7 Definition of Terms

1.7.1 Service Quality

Service quality is often conceptualized as the comparison of service expectations with actual performance perceptions by Zeithaml, Berry, and Parasuraman (1990). Definition by <http://www.businessdictionary.com>, service quality is an assessment of how well a delivered service conforms to the client's expectation.