DEVELOPMENT OF MS ISO/IEC 17025 QUALITY SYSTEM (GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES) FOR FKM LABORATORY

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Thesis submitted in fulfillment of the requirements
for the award of the degree of
Bachelor of Mechanical Engineering with Manufacturing Engineering

Faculty of Mechanical Engineering
UNIVERSITI MALAYSIA PAHANG

NOVEMBER 2009

EXAMINERS APPROVAL

We certify that the project entitled "Development of MS ISO/IEC 17025:2005 Quality System (General requirements for the competence of testing and calibration laboratories) for FKM Laboratory" is written by Hue Wei Jy. We have examined the final copy of this project and in our opinion; it is fully adequate in terms of scope and quality for the award of the degree of Bachelor of Engineering. We herewith recommend that it be accepted in partial fulfilment of the requirements for the degree of Bachelor of Mechanical Engineering with Manufacturing Engineering.

Examiner Signature

SUPERVISOR'S DECLARATION

I hereby declare that I have checked this project and in my opinion, this project is adequate in terms of scope and quality for the award of the degree of Bachelor of Mechanical Engineering with Manufacturing Engineering.

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Name of Supervisor: MAHENDRAN SAMYKANO
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STUDENT'S DECLARATION

I hereby declare that the work in this project is my own except for quotations and summaries which have been duly acknowledged. The project has not been accepted for any degree and is not concurrently submitted for award of other degree.

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ACKNOWLEDGEMENTS

This thesis is one of the requirements in obtaining the Bachelor of Mechanical Engineering with Manufacturing Engineering. I have been accompanied and supported by many people in this journey. It is a pleasant aspect that I have now the opportunity to express my gratitude to all of them.

First, a very special thank to my supervisor, Mr. Mahendran of his great patient and efforts in explaining things clearly. He guided me in identifying the clauses and giving me a chance to attend the training program for the implementation of MS ISO/IEC 17025:2005. He also guided me in developing the quality manual, system procedure, as well as the forms and records.

By the way, I would like to thank Mr. Pua Hiang and Miss Siti Tasliah for giving a good explanation in developing the quality documents such as quality manual, procedure as well as forms.

I would also like to thank my parents and elder sisters for giving me supports and lots of care. They did a fine job in raising me. I would like to thank them for all they are, and all they have done for me.

Lastly, I would like to thank to all my fellow friends for giving me supports and advice to me to keep looking forward when I am facing a lot of problems and boundaries in completing my Final Year Project.

ABSTRACT

This report illustrates the development of quality documents of MS ISO/IEC 17025:2005 at FKM Laboratory of Universiti Malaysia Pahang (UMP). This report consists of five chapters which are Introduction, Literature Review, and Methodology, Results and Discussions, and Conclusion. The objectives of this project are to identify the clauses of MS ISO/IEC 17025:2005 and develop the quality documents according to the standard for FKM Laboratory. MS ISO/IEC 17025:2005 mainly divides into two main clauses which are management requirements and technical requirements. The management requirements are similar to the requirements of ISO 9001. To understand more on the project, the requirements of ISO 9001 were being studied. After referred to several books, the requirements of ISO 9001 are actually borrow from the principles of total quality management (TQM). Therefore, the principles of TQM and the studies that relate to quality were also being studied. In order to achieve the objectives of the project, it is important to understand the clauses of MS ISO/IEC 17025:2005. Therefore, the clauses of the standard were being studied. After that, the quality documents such as quality manual and system procedure were developed for FKM Laboratory according to MS ISO/IEC 17025:2005. To have a clearer mind in developing the quality documents, a course on MS ISO/IEC 17025:2005 was attended to understand more on the clauses as well as the development of quality manual. By the way, one of the accredited laboratories had been chosen to visit. It was also to make sure the quality manual and procedure that had been develop is in the right path. Thus, the laboratory visit is necessary. The documents that had been developed in this project are quality manual, system procedure, and forms and records. Quality manual had been developed for clause 4.1 to clause 4.8. System procedure also had been developed for clause 4.3 to clause 4.8. The system procedure for clause 4.1 and clause 4.2 were not developed since all the requirements had already stated in quality manual. For clause 4.5 which is subcontracting tests and calibrations, is not applicable since FKM Laboratory is more focus on the activities of research and development. All the documents will be proposed to FKM Laboratory management to the accreditation of MS ISO/IEC 17025:2005. In conclusion, the objectives had been achieved where all the related documents had been developed after identify the clauses.

ABSTRAK

Laporan ini menggambarkan penghasilan dokumen kualiti MS ISO/IEC 17025:2005 pada Makmal FKM Universiti Malaysia Pahang. Laporan ini terdiri daripada lima bab iaitu Pengenalan, Tinjauan Pustaka, Metodologi, Keputusan dan Perbincangan, dan Kesimpulan. Objektif bagi projek ini adalah untuk mengenalpasti klausa daripada MS ISO/IEC 17025:2005 dan menhasilkan dokumen-dokumen kualiti berdasarkan piawai untuk Makmal FKM. Oleh sebab itu, keperluan piawai telah dipelajari. MS ISO/IEC 17025:2005 terutamanya terbahagi kepada dua klausa utama iaitu keperluan pengurusan dan keperluan teknikal. Keperluan pengurusan adalah serupa dengan keperluan ISO 9001. Untuk memahami lebih lanjut tentang projek ini, keperluan ISO 9001 juga telah dipelajari. Setelah merujuk kepada beberapa buku, keperluan ISO 9001 sebenarnya meminjam daripada prinsip-prinsip total quality management (TQM). Maka, prinsip-prinsip TQM dan penyelidikan yang berkaitan dengan kualiti juga telah dipelajari. Untuk mencapai objektif projek ini, memahami keperluan MS ISO/IEC 17025:2005 adalah penting. Selepas itu, dokumen-dokumen kualiti seperti manual kualiti dan prosedur sistem telah dihasilkan untuk Makmal FKM berdasarkan MS ISO/IEC 17025:2005. Bagi mempunyai pemikiran yang lebih jelas dalam menhaislkan dokumen kualiti, satu kursus tentang MS ISO/IEC 17025:2005 telah dihadiri dan klausa telah dapat difahami secara lebih mendalam serta garis panduan untuk menghasilkan manual kualiti. Di samping itu, salah satu makmal yang terakreditasi telah dipilih untuk dilawat. Lawatan itu juga adalah untuk memastikan manual kualiti dan prosedur yang telah dihasilkan adalah benar. Maka, lawatan ke makmal yang terakreditasi adalah diperlukan. Dokumen-dokumen yang telah dihasilkan ialah manual kualiti, prosedur system, boring dan rekod. Manual kualiti telah dihasilkan bagi klausa 4.1 hingga klausa 4.8. Prosedur sistem juga telah dihasilkan bagi klausa 4.3 hingga klausa 4.8. Prosedur sistem bagi klausa 4.1 dan klausa 4.2 tidak dihasilkan disebabkan semua keperluan telah dinyatakan di manual kualiti. Bagi klausa 4.5 iaitu subkontrak ujian dan kalibrasi tidak dihasilkan kerana Makmal FKM lebih fokus dalam aktiviti penyelidikan dan pembangunan. Semua dokumen akan dicadangkan untuk akreditasi Makmal FKM ke MS ISO/IEC 17025:2005. Sebagai kesimpulan, objektif bagi projek ini telah dicapai di mana dokumen-dokumen yang berkaitan telah dihaislkan selepas klausa dikenalpasti.

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LIST OF ABBREVIATIONS

A2LA	American Associated for Laboratories Accreditation
FKM	Fakulti Kejuruteraan Mekanikal
EN	European standard
IEC	International Electro-technical Commission
ISO	International Organization for Standardization
MS	Malaysian Standard
PT	Proficiency testing
QA	Quality assurance
QC	Quality control
QMS	Quality management system
TC	Technical Committee
TQM	Total quality management
TS	Technical Specifications
UMP	University Malaysia Pahang

CHAPTER 1

INTRODUCTION

1.1 Introduction

This chapter gives a description about the project background including several approaches. It also introduces the objective, scopes, problem statement of this project which is the development of quality manual and system procedure of MS ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories.*

1.2 Project Backgrounds

ISO, International Organization for Standardization, is the world's largest developer and publisher of International Standards. ISO is a non-governmental organization that forms a bridge between public and private sectors.

Those standards ensure the quality, environmental friendliness, safety, reliability, efficiency, and interchangeability of the products and services of an organization at an economical cost. It facilitates the trade between countries by make it fairer. The most important, ISO standards protect consumers and users in terms of products and services.

This project will focus on MS ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories.* MS ISO/IEC 17025:2005 is the standard which specifies the general requirements for the competence of laboratories to

carry out testing and calibration. This standard contains management requirements and technical requirements which applicable to all organizations that performing testing and calibration activities. This standard is usually applied in an organization or company that has testing and calibration laboratories. The testing and calibration laboratories that comply with this standard will operate in accordance with ISO 9001.

By implementing this, the organizations or companies accredited from this standard, which is MS ISO/IEC 17025:2005; it can get the benefits of world class performance even though it is only a small business or a small-scale companies. The flexible procedures that implemented will reduce the paperwork and improve the quality of the products or services. Hence, it increases the business and enhances the competence of the organizations or companies. The organizations or companies can prove to their clients that the analysis is done within a well quality system. As a result, customers are satisfied with the products or services. The laboratory also built up the confidence and reliability in the test results or calibration results by providing additional information about the quality of the measurement made during the calibration process.

To implement MS ISO/IEC 17025:2005, there is a variety of documents should be developed. First, they include a high level policy, which is a quality plan or quality manual to document the strategy, approaches and planning of a company. Second are the system procedures, templates and checklists for consistent and efficient implementation. Finally are the records, which developed on a regular basis such as calibration records, maintenance, training activities and tests results.

After finished prepare all the documentations, an internal audit should be conducted as the same way as external audit. It is very useful as it required all the regulations. It can improve the quality and efficiency of an organization to prepare for external audit. After that, an external audit from accreditation bodies should be carried out. A corrective and preventive action plan should be developed if necessary. After the approval, the organization can start to develop and implement the procedures of MS ISO/IEC 17025:2005.

This project only consider in the development of quality manual and system procedure. Quality manual is the quality plan that should document by the laboratory about the overall concept on how to comply with MS ISO/IEC 17025:2005. It should be developed at the highest level and well communicated to all employees. Quality manual is important because it maintains the quality system up-to-date as it needs to review periodically. It provides a good working environment for staff by providing procedures of method of working. By implementing the efficient management systems, it improves the efficiency and profitability. Quality manual will refer to system procedure on how to perform the management system. It also provides the procedures to handle the complaints from customers so that the organization can meet and exceed the expectations of the customers. Hence, it increases the business of an organization.

1.3 Project Objectives

- To study and identify the clauses of MS ISO/IEC 17025:2005
- To develop quality manual and system procedure for FKM Laboratory according to MS ISO/IEC 17025:2005

1.4 Project Scopes

The scope of the project will be carried out the studies of:

- The general knowledge of the clauses MS ISO/IEC 17025:2005
- The application of the management requirements, from Clause 4.1 to Clause 4.8, of MS ISO/IEC 17025:2005
- The development of quality manual and system procedure for FKM Laboratory

1.5 Problem Statement

Faculty of Mechanical Engineering (FKM: Fakulti Kejuruteraan Mekanikal) of University Malaysia Pahang (UMP), is dedicated to produce global mechanical engineers with high level of knowledge, learning capability, competency and integrity. In order to become a world class competency-based mechanical engineering faculty, FKM is also committed to enhance the research and development towards introducing commercially viable products and services in manufacturing and automotive sectors.

To become a world class competency-based mechanical engineering faculty, it must be ensure that the laboratories of FKM obtain high level of quality in terms of management and technical. In order to achieve the quality, the laboratories can be accredited with ISO standard. One of the standards that can be implementing in the laboratories is MS ISO/IEC 17025:2005, which can be applied in FKM Laboratory. By applying this, it not only can enhance the testing and calibration activities, it also can improve the P&P (pengajaran dan pembelajaran), which also known as lesson and learning. Moreover, it also enhances the research activities by obtaining the results which are acceptable internationally.

1.6 The Importance of the Study

Nowadays, quality is an important element in business and industries. In order to fulfill the requirements of customer, the product and or services that provided by a company must be in good quality to exceed the expectation of the customers.

To ensure the quality of a product, it comes to the testing, calibration, and production. In this case, a company or organization which has the testing and calibration laboratory needs to ensure the competence of the laboratory so that the results for testing and calibration activities are reliable. To ensure the competence, a quality system is required. The engineers who involve in the testing and calibration activities have to have the quality system knowledge. Hence, the results of testing and calibration laboratories are reliable and customers also confidence with the results.

In this project, there are some mechanical elements that contain in the clauses of MS ISO/IEC 17025:2005 where engineers need to perform their duties to fulfill the requirements of the standard. On the other hand, ISO is also one of the Industrial Engineering tools.

For example, in clause 4.4 which is review for requests, tenders and contracts, Technical Manager needs to make sure the competent of the engineer in determining the test and calibration method for the testing and calibration activities that provided by FKM Laboratory if the customer does not specify the test and calibration method. The method selected shall be appropriate and published either in international, regional or national standards, or in relevant scientific texts or journals. In testing and calibration activities, Standard Method is encouraged to use. If a Standard Method is used, the method should be verified to make sure it meets the needs of the customer and is appropriate to the test and calibration. By the way, if the method that instructed by customers is not a Standard Method, the method and procedure shall be validate before use. In a testing and calibration activity, engineer should determine the testing parameters and select the apparatus and equipment. All the details of testing and calibration work including the method should be included in the quotation.

Besides, procedures to estimate the uncertainty of measurement for all calibrations shall be developed and implement. All the uncertainty components are important since in certain cases of test method, it may preclude the calculation of uncertainty of measurement. Engineer shall identify all the components of uncertainty to make a reasonable estimation as well as to make sure the results reported does not give a wrong impression of uncertainty. The reasonable estimation is based on the knowledge of the performance of the method.

Another mechanical element can be seen in clause 4.6 which is purchasing services and supplies, where engineer needs to choose the specifications of the equipment or apparatus that purchased for the purpose of testing and calibration activities fulfill the requirements. When the equipment or apparatus purchased arrive and before it store at the appropriate places, the equipment or apparatus must be checked to make sure it comply to

the specifications. It is also needed to make sure the equipment is calibrated. Engineer shall perform the maintenance job to make sure the equipment function properly and comply with the accuracy requirements and specifications relevant to the test and calibration. It is also to make sure it meets the requirements of the laboratory and specifications.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUTION

This chapter will focus on the studies that related to this topic. Firstly, the clauses of MS ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories* had been studied to understand all the requirements that needed to implement this standard. This standard mainly includes two parts, which are management requirements (clause 4) and technical requirements (clause 5). The management requirements of MS ISO/IEC 17025:2005 is similar to the requirements of ISO 9001:2000, *Quality Management System - Requirements*. To understand more on the project, the requirements of ISO 9001:2000 was also being studied. After referring to several books, the principles of quality management of ISO 9001:2000 are actually borrow from the management principles of total quality management (TQM). Eight of the management principles of TQM have been used in ISO 9001:2000. Therefore, this chapter not only includes the studies of MS ISO/IEC 17025:2005, it also includes ISO 9001:2000 and quality management system (QMS) as well as TQM.

2.2 QUALITY

There are many different definitions and dimensions of quality due to different point of views.

According to David Gravin of the Harvard School (1984), the dimensions of quality given are not mutually exclusive, although they relate primarily to the quality of the product. The definition of quality is given by the eight quality dimensions which are performance, features, reliability, conformance, durability, serviceability, aesthetics, and perceived quality.

Service quality is perhaps more difficult to define than product quality. A set of service quality dimensions that is widely cited has been compiled by Parasuraman, Zeithamel and Berry in 1985. The dimensions are tangibles, service reliability, responsiveness, assurance, empathy, availability, timeliness, professionalism, completeness, and pleasantness

Another authoritative definition of quality is from Ray Wild (2002). He stated that the quality of a product or service is the degree to which it satisfies customer requirements. It influenced by the design quality and process quality. Design quality is the degree to which the specification of the product or service satisfies customers' requirements. Process quality is the degree to which the product or service, which is made available to the customer, conforms to specification. (Basu, 2004)

In technical usage, quality is widely accepted to have two meanings:

- A characteristic of a product or service that bears on its availability to satisfy stated or implied needs
- A product or service free of deficiencies

The quality experts of the 20th century, P.B. Crosby, W.E. Deming, and J.M. Juran, defined quality and it falls into two categories:

- Quality is about satisfying applicable specifications. Quality is a simple matter of producing products or delivering services whose measurable

characteristics satisfy a fixed set of specifications that usually numerically defined.

- Quality is about satisfying the customer. Independent of any of their measurable characteristics, quality products simply is those that satisfy customer expectations for their use or consumption.

2.2.1 P.B. Crosby: Four Absolutes of Quality Management and 14-Step Quality Improvement Plan

2.2.1.1 Four Absolutes of Quality Management

1. Quality has to be defined as conformance to requirements, not as goodness or elegance. Management must establish requirements, supply the wherewithal, and encourage and help employees to get the job done. The basis of this policy is "Do it right the first time."
2. The system for assuring quality is prevention, not appraisal. The first step to defect and error prevention is to understand the process by which a product is produced. When a defect occurs, discovery and elimination are top priorities. Prevention is a knowledge issue for quality-focused workers.
3. The performance standard must be zero defects. The only performance standard that makes sense for "Do it right the first time" is zero defects. Zero defects needs to be a performance standard for everyone in the company.
4. The measurement of quality is the price of nonconformance, not indices. A dollar figure can be established for the cost of quality by determining the difference between the price of nonconformance and the price of conformance.

2.2.1.2 14-Step Quality Improvement Plan

1. Management commitment
2. Quality improvement team
3. Quality measurement

4. Cost of quality
5. Quality awareness
6. Corrective action
7. Zero defects planning
8. Supervisor training
9. Zero defects day
10. Goal setting
11. Error cause removal
12. Employee recognition
13. Quality councils
14. Repeat the cycle of improvement

2.2.2 W.E. Deming 14 Points

1. Create constancy of purpose towards improvement of product and service, with the aim to become competitive, stay in business, and provide jobs.
2. Adopt the new philosophy. We are in a new economic age. Western management must awaken to the challenge, learn its responsibilities, and take leadership for change.
3. Cease dependence on inspection to achieve quality. Eliminate the need for inspection on a mass basis by creating quality into the product in the first place.
4. End the practice of awarding business in the basis of price tag. Instead, minimize total cost. Move toward a single supplier for any one item, on a long term relationship of loyalty and trust.
5. Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs.
6. Institute training the job.
7. Institute leadership. The aim of leadership should be help people and technology work better.
8. Drive out fear so that everyone can work effectively for the company.
9. Break down barriers between departments so that people work as a team.

10. Eliminate slogan, exhortations, and targets for the work force. They create adversarial relationships.
11. Eliminate quotas and management by objectives (MBO). Substitute leadership.
12. Remove barriers that rob the hourly worker of his right to pride of workmanship.
13. Institute a vigorous program of education and self-improvement.
14. Put everyone in the company to work to accomplish the transformation. The transformation is everyone's job.

2.2.3 J.M. Juran: Quality Trilogy and 10-Step Quality Improvement Process

Juran trilogy summarizes three primary managerial functions: quality planning, quality control, and quality improvement.

Quality planning involves developing the products, systems, and processes needed to meet or exceed customer expectations. The following steps are required:

1. Determine who the customers are.
2. Identify customers' needs.
3. Develop products with features that respond to customer needs.
4. Develop systems and processes that allow the organization to produce these features.
5. Deploy the plans to operational levels.

Quality control involves the following steps:

1. Assess actual quality performance.
2. Compare performance with goals.
3. Act on differences between performance and goals.

Quality improvement is an ongoing activity that never ends and involves the following steps:

1. Develop the infrastructure necessary to make annual quality improvements.
2. Identify specific areas in need of improvements, and implement improvement project.
3. Establish a project team with responsibilities for completing each improvement project.
4. Provide teams with what they need to be able to diagnose problems, to determine root causes, develop solutions, and establish controls that will maintain gains made.

Quality improvement process to achieve continuous quality improvements involves the following steps:

1. Build awareness for the need and opportunity for improvement.
2. Set goals for improvement.
3. Organize to meet the goals that have been set.
4. Provide training throughout the organization.
5. Carry out projects to solve problems.
6. Report progress.
7. Give recognition.
8. Communicate results.
9. Keep score.
10. Maintain momentum by building improvement into the company's regular system.

Although there are different views from the quality experts, but there are certain common threads:

1. Management responsibility
    - Critical role to play in instituting quality in a company.
2. Quality awareness

- Raise the awareness of quality issues throughout the company.

3. Training
    - To develop a quality orientation in personnel.
    - Changing traditional mindsets.
4. Goals and measurements
    - Established for improvements,
    - Progress should be measured and reported against the identified goals.
5. Corrective and preventive action
    - To perform root cause analysis and effectively correct problems and to prevent new ones.
6. Continuous improvement
    - Continual and never-endings

(Nanda, 2005)

2.2.4 Hierarchy of Quality

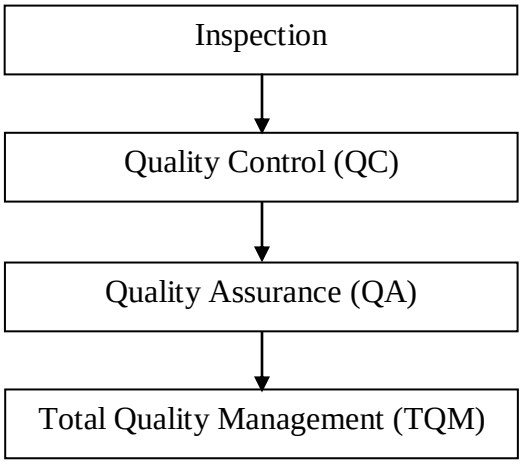


Figure 2.1: Hierarchy of Quality

Source: Basu 2004

2.2.4.1 Inspection

Quality by inspection is an expansive method of achieving a basic level of quality. It requires the employment of people to check on the operation. Inspection and supervision do not add value to a product, they merely add to the cost. However, the inspection of results with specified requirements is often necessary to ensure regulatory or approved standards.

2.2.4.2 Quality Control

Quality control (QC) is the next stage above quality inspection. The control process is based on the statistical method which includes the phases of analysis, relation and generalization. Activities relating to quality control include:

- Monitoring process performance
- Acceptance sampling
- Designing and maintaining control charts

2.2.4.3 Quality Assurance

Quality assurance (QA) relates to activities needed to provide adequate confidence that an entity will fulfill requirements for quality. The first two stages, inspection and QC, are based on a detection approach and relate to ‘after the event’, while QA is aimed at preventing mistakes. QA activities include:

- Approved supplier scheme
- Operator training
- Process improvement

2.2.4.4 Total Quality Management (TQM)

Total quality management (TQM) has been defined in ISO 8402 in the year 1995, as the management approach of an organization, centered on quality, based on the participation of all its members and aiming at long term success through customer satisfaction, and benefits to all the members of the organization and society. The holistic view of TQM supports the idea that the quality is the responsibility of all employees and not just quality managers. TQM encompasses all three dimensions of quality which are product quality, process quality, and organization quality.

2.2.5 Tools and Techniques

Tools and techniques can be broadly defined as the practical methods and skills applied to specific activities to enable improvement. A specific tool has a defined role and a technique role and a technique may comprise the application of several such tools. Tools and techniques are essential ingredients of a process. These are the instrumental to the success of a quality programme.

Examples of tools:

- Cause and effect diagram
- Pareto analysis
- Relationship diagram
- Control chart
- Histogram
- Flow chart
- Five S

Example of techniques:

i. Quantitative

- Failure mode and effects analysis (FMEA)
- Statistical process control (SPC)
- Quality function deployment (QFD)
- Design of experiments (DOE)
- Design for Six Sigma (DFSS)

ii. Qualitative

- Benchmarking
- Kanban
- Quality management systems (ISO 9000)

(Basu, 2004)

2.3 TOTAL QUALITY MANAGEMENT (TQM)

Total quality management (TQM) has been defined in ISO 8402 in the year 1995, as the management approach of an organization, centered on quality, based on the participation of all its members and aiming at long term success through customer satisfaction, and benefits to all the members of the organization and society. The holistic view of TQM supports the idea that the quality is the responsibility of all employees and not just quality managers. TQM encompasses all three dimensions of quality which are product quality, process quality, and organization quality. (Basu, 2004)

Following an international conference in May 1990, the Conference Board summarized the key issues and terminology related to TQM:

- The ***cost of quality*** as the measure of non-quality and a measure of how the quality process is progressing.
- A ***cultural change*** that appreciates the primary need to meet customer requirements, implements a management philosophy that acknowledges this emphasis, encourages employee involvement, and embraces the ethic of continuous improvement.
- ***Enabling mechanism of change,*** including training, and education, communication, recognition, management behavior, teamwork, and customer satisfaction programs.
- ***Implementing TQM*** by defining the mission, identifying the output, identifying the customers, negotiating customer requirements, developing a "supplier specification" that details customer objectives, and determining the activities required to fulfill those objectives.
- ***Management behavior*** that includes acting as a role models, using quality processes and tools, encouraging communication, sponsoring feedback activities, and fostering and providing a supporting environment.

(Omachonu and Ross, 2000)

2.3.1 Eight quality management principles from TQM

Eight quality management principles are defined in ISO 9000:2000 as:

1. *Customer focus.* Organization depend on their customers and therefore should understand current and future customer needs, meet customer requirements and strive to exceed customer expectation.
2. *Leadership.* Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
3. *Involvement of people.* People at all levels are essence of an organization and their full involvement enables their abilities to be used for the organization's benefits.

4. *Process approach.* A desired result is achieved more efficiently when activities and related resources are managed as a process.
5. *System approach to management.* Indentifying, understanding, and managing interrelated process as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.
6. *Continual improvement.* Continual improvement of the organization's overall performance should be a permanent objective of the organization.
7. *Factual approach to decision-making.* Effective decisions are based on the analysis of data and information.
8. *Mutually beneficial supplier relationships.* An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both crate value.

(Dale, Wiele, and Iwaarden, 2007)

2.4 QUALITY MANAGEMENT SYSTEM (QMS)

Quality management system (QMS) is quality management practices such as quality planning, quality control, quality assurance, and quality improvement. A QMS is not a temporary fad, but a permanent part of an organization with a direct bearing on how the organization conducts its business.

A QMS has structure, a defined scope, responsibilities, necessary content in terms of defined processes and supporting QMS documentation, and required resources to accomplish quality planning, quality control, quality assurance, and continuous quality improvement activities. A QMS is not static. It must be improved continually in order to enhance organizational effectiveness and efficiency.

According to ISO 8402, a quality management system consists of the organizational structure, procedures, process, and resources needed to implement quality management. (Nanda, 2005)

2.4.1 Reasons for Implementing QMS

Implementation of QMS documentation offers short-term and long-term rewards.

By defining the processes and supporting QMS documentation as the basis for repetition can help to reduce and eliminate variation within process execution. It make the improvement in operational more efficient. By implementing the corrective and preventive solutions that can identify root causes of quality problems, effectiveness of the organizations can be improved. QMS also enables an organization to focus on how it executes business processes which able to monitor and analyze process performance for continual improvement. Hence, it improve productivity, on-time delivery performance, and within budget project execution.

Since quality management practices are continually improved, QMS results in higher-quality products and services which also can improve the customer satisfaction levels. This enables the organizations to retain customers, attract new ones, increase market sure, and enhance top-line revenue growth. As a result, it enhances an organization's competitive position.

By the way, QMS reduces or eliminates an organization's dependence on a few individuals for information regarding critical processes, because such processes are now formally documented. This reduces organizational vulnerability to employee turnover. QMS also reduces waste of resources and loss of reputation resulting from ejecting and rework of interior-quality products. This enables the organization to perform a proactive mode, which means performing preventive action.

Lastly, QMS promotes employee understanding that quality is everyone's responsibility. The realization that each employee contributes to the achievement of quality requirements helps in quality improvements across the organization at all levels. (Nanda, 2005)

2.5 ISO 9001

ISO formed Technical Committee 176 (TC 176) to harmonize the national and international quality standards that exists throughout the world in 1970s and 1980s. TC 176's objective was to develop a universally accepted set of quality standards.

TC 176 has aligned ISO 9000 very much closer with the total quality management (TQM) approach, which is the management system that started develop by the Japanese in 1950. By the early 1970s, TQM had been widely accepted in Japan. By 1980, the western world began to take note and ISO 9001:1987 was developed where it borrowed some of the elements of TQM.

However, ISO 9001:2000 *Quality Management Systems – Requirements* has made a giant leap in comparison, especially in the area of continual improvement, which has gone from just cursory treatment to being a firm requirement. The standard are incorporates with the eight principles that come directly from TQM. The principles are customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision-making, and mutually beneficial supplier relationships.

As a result of ISO 9001, any organization supplying products or services is able to develop and employ a quality management system (QMS) that is recognized by customers worldwide. Customers who deal with ISO 9001 registered organizations can expect that purchased goods and services will conform to a set of standards they recognize.

For most organizations, the rationale for implementing ISO 9001 should include one or more of the following:

- To improve product or service quality and consistency

- To improve organizational performance through better management of processes and resources
- To have a quality management system that will be recognized by customers worldwide

ISO 9001:2000 *Quality Management Systems – Requirements*, is the requirements standard to which ISO 9000 users must conform. ISO 9001:2000 specifies requirements for a quality management system that can be used for international application by organizations, or for certifications, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirement. It is applicable to any kind of organization, regardless to its activities. (Goetsch and Davis, 2002)

2.5.1 Principle Elements of ISO 9001

There are five principles of elements of ISO 9001. The five main elements are:

1. Quality management system
    - The organization shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements.
    - Documentation requirements.
2. Management responsibility
    - Management commitment
    - Customer focus
    - Quality policy
    - Planning
    - Responsibility, authority, and communication
3. Resource management
    - Provision of resources
    - Human resources

- Infrastructure
- Work environment

4. Product realization
    - Planning of product realization
    - Customer-related processes
    - Design and development
    - Purchasing
    - Production and service provision
    - Control of monitoring and measuring devices
5. Measurement, analysis and improvement
    - The organization shall plan and implement the monitoring, measurement, analysis, and improvement process needed to:
        a) Demonstrate conformity of the product
        b) Ensure conformity of the quality management system
        c) Continually improve the effectiveness of the quality management system
    - Monitoring and measurement
    - Control of non-conforming product
    - Analysis of data
    - Improvement

(Dale, Wiele and Iwaarden, 2007)

2.6 ISO/IEC 17025

Industry often depends on reliable assessment of testing and calibration laboratories.

Accredited testing and calibration laboratories should satisfy the international standard ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, which is the general requirements that should satisfy by the accredited testing and/or calibration laboratories. Accreditation bodies that recognize the

competence of testing and/or calibration laboratories should use this International Standard as the basis for their accreditation.

ISO/IEC 17025 was prepared by the ISO Committee on conformity assessment (CASCO). This ISO is recognized globally by the International Laboratory Accreditation Cooperation and the Asia Pacific Laboratory Accreditation Cooperation, and nationally by the National Cooperation for Laboratory Accreditation.

ISO 17025:1999 was the first edition of this ISO. It referred to ISO 9001:1994 and ISO 9002:1994. It was produces as the result of extensive in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it replaced. It contained all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system. The requirements are technically competent, and are able to generate technically valid results.

These standards have been superseded by ISO 9001:2000, which made an alignment of ISO/IEC 17025 necessary. In second edition, ISO 17025:2005, clauses have been amended or added only when considered necessary in the light of ISO 9001:2000. There are no essential changes to the technical requirements (Clause 5 in ISO/IEC 17025:2005). The modifications relate mainly to the management requirements (Clause 4 in ISO/IEC 17025:2005) in the document to reflect the content of ISO 9001:2000.

The new edition of the ISO/IEC 17025, which published in July 2005, had published of an ISO/IEC standard acknowledged as the international benchmark. It is to approve the competence of the testing and calibration laboratories that play a vital role in trade, in product development and manufacturing, and to protect consumer.

The new, 2005 edition ensure its compatibility with the requirements of ISO 9001:2000 which is the requirements of quality management system. This became necessary because of the generalized adoption of quality management systems confirming to ISO 9001:2000, including many of the organizations that testing and calibration

laboratories serve. Growth of the use of management systems has increased the need to ensure that laboratories can operate to a quality management system that is seen as compliant with ISO 9001 as well as ISO/IEC 17025. The laboratories usually are a part of larger organizations or offer other services. (ISO/IEC 17025, 2005)

Testing and calibration laboratories that complied with ISO/IEC 17025 will also operate in accordance with ISO 9001. The acceptance of testing and calibration results between countries should be facilitated with ISO/IEC 17025 and if they obtained the accreditation bodies which have entered into mutual recognition agreements with equivalent bodies in other countries using this standard. The use of this International Standard will facilitate cooperation between laboratories and other bodies. It assists in the exchange of information and experience, and in the harmonization of standards and procedures.

Laboratories may choose to be accredited to ISO/IEC 17025, or to be certified to ISO 9001, or both, but the process of accreditation and certification would still be two separate actions. However, only ISO/IEC 17025 can be used to demonstrate the technical competence specific to laboratories. (ISO/IEC 17025 (2005); *Standard Accreditation News*, 17 October)

2.6.1 Testing

Testing is divided into two parts:

- Description of input data
- Precise description of correct output for that input

The results of each test should be thoroughly inspected. It must be written for invalid and unexpected as well as valid and expected input conditions. (Leveson, 1999)

Testing helps to minimize technical barriers to trade and reduce the financial burden on manufacturers. Almost any evaluation of a product, material or piece of equipment is based on the reports from accredited testing laboratories. Accredited testing laboratories are supported by accredited calibration laboratories. (iasonline)

2.6.2 Calibration

Calibration is a process of comparing a measurement device, which is an unknown, with the measurement standard, which is a better standard. A measurement standard is considered as the reference. Calibration helps to evaluate and document the accuracy of a measuring device.

A typical commercial calibration references a manufactures calibration procedure. It is performed with a reference standard at least four times more accurate than the instrument under test. (DavisCalibration)

Calibration relies on people, who must be qualified to perform the calibration. An instrument that has been calibrated provides the engineer a basis for interpreting the device's output indication. It provides assurance in the measurement.

2.6.3 The Content of ISO/IEC 17025:2005

The standard itself is divided into five major sections:

1. Scope
2. Normative references
3. Terms and definitions
4. Management requirements
5. Technical requirements

Section 1, section 2, and section 3 which are the scope of this standard, normative references, and terms and definitions are for guidance but not for auditable. The important part of this standard is section 4 and section 5, management requirements and technical requirements.

The content of ISO/IEC 17025:2005 are included in Appendix A1.

In section 4, management requirements, the requirements are very similar to the requirements in ISO 9001. ISO/IEC 17025 adds the emphasis to documentation and records specific to laboratory environments. For example, Clause 4.1, Organization, it lays out the specific requirements for the company's ethnics. The standard emphasizes the requirements that the laboratory shall have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial, and other pressures and influences that may adversely affect the quality of their work. Similar requirements are mandated for other protections, such as those related to customer confidentiality, impartiality and operational integrity. The purpose is to ensure that any testing or calibration results can be relied on confidence.

In section 5, technical requirements, provide the specific details for the company to accomplish with regards to its operations and activities. Most of the clauses in section 5 are not difficult to present during implementation. For example, Clause 5.2, Personnel, it emphasizes more requirements to ensure employees are technically proficient and free from any conflicts of interest. Another example is Clause 5.5, Equipment, which defines requirements to ensure the equipment in the laboratory is properly calibrated itself, and suitably handled and use.

However, there are some important sub-clauses under section 5. One of them is under Clause 5.4.6, Estimation of uncertainty of measurement, which introduces the concept of uncertainty measurement. Uncertainty measurement forces laboratories to determine the factors that negatively affect the accuracy of measurement.

There is one difficult element found, which is Clause 5.9. It assures the quality of test and calibration results. The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring shall be planned and reviewed and may include participation in inter-laboratory comparison or proficiency-testing programs. Proficiency testing is a way to compare the results of activities with a pool of other companies in the same field and same activities. Then, a proficient score is assigned based on the ranking. In order to engage proficient testing, the organization or companies must apply to PT providers. (Quantum Associates)

2.6.4 Management Requirements (Clause 4)

4.1 Organization

Laboratory is responsible to carry out testing and calibration activities legally to ensure that the lab is able to produce a result that reflects the actual characteristics of the item tested. The laboratory is also responsible to prevent and minimize the conflicts of interest that may adversely affect the quality of work. The laboratory shall define the policies and procedures to avoid the possibility of impropriety personnel, and it is place within the parent organization.

4.2 Management system

The laboratory shall establish quality manual and implement it to ensure the test and/or calibration results. This document included the policies, systems, programmes, procedures and instructions that related to quality.

4.3 Document control

The laboratory shall establish procedures to control all the documents that approved for use by authorized personnel. It requires the procedures that ensure the documents are reviewed periodically, obsolete documents are removed from use, and the retention of the obsolete documents are suitably marked. The procedures also allow the changes of the documents. This clause is to ensure each person of the organization has the current version of document to perform his work.

4.4 Review of request, tenders and contracts

The policies and procedures for these reviews is to ensure the requirements of the documents are understood and the laboratory has the capability and capacity to perform the work. It is also to make sure the test has met the customers' requirements.

4.5 Subcontracting of tests and calibrations

It involves the subcontracted work of a laboratory. The company that subcontracts the work must be able to demonstrate that subcontractor is competent to perform the work.

4.6 Purchasing services and supplies

The laboratory shall have the policies and procedures for the purchasing of services and supplies such as calibration services, reagents, test suppliers, and equipments. It is to ensure that they do not buy the equipments and materials that can affect the quality of the tests and/or calibrations.

4.7 Service to the customer

The laboratory shall be willing to deal with communication, advice and guidance for customers in technical opinions and interpretations based on results. The laboratory provides the customer with the opportunity to clarify to their work request.

4.8 Complaints

The laboratory shall have a policy or procedure for handling of complaints from clients.

4.9 Control of nonconforming testing and/or calibration work

The laboratory shall have a policy and procedures which shall be implementing when any aspect of work do not meet with the requirements such as errors occur in testing activities, test items are not stored properly and environmental conditions fail. The policy and procedures should include the responsibilities of the

management, evaluation of the significance of testing and/or calibration work, corrective action and many others.

4.10 Improvement

The laboratory shall implement the policies for continual improvement.

4.11 Corrective action

The laboratory shall establish a policy and procedure to identify the root causes and take corrective actions when needed to eliminate and prevent the problems.

4.12 Preventive action

Action plans will be develop and implement when needed to reduce the nonconformities. It shall include the initiative to ensure the actions taken are effective.

4.13 Control of records

The laboratory shall establish procedures to protect the quality and technical records that included reports, management reviews, and the records of corrective and preventive actions.

4.14 Internal audits

The laboratory shall conduct internal audits to comply the requirements of the management systems. If there is doubt during the internal audit programmes, corrective action shall be taken by the laboratory.

4.15 Management reviews

The laboratory's top management shall conduct a review of management system and test works to ensure the laboratory is involved in continuous process improvement. The review shall include the suitability of policies and procedures, the outcome of internal audits, corrective and preventive actions, customer feedback, complaints, recommendations for improvement and etcetera.

2.6.5 Technical Requirements (Clause 5)

5.1 General

This section included the factors that affect the correctness and reliability of the test and calibrations. These factors shall be taken into consideration in developing procedures.

5.2 Personnel

The laboratory shall ensure that the person who performs the tests and/or calibrations is qualified. The laboratory shall develop and document the training programmes for the personnel in planning tests and calibrations, evaluating results, interpreting reports and training programmes.

5.3 Accommodation and environmental conditions

The laboratory shall ensure that the environmental conditions do not affect the quality of measurement and to ensure there is a good housekeeping in the laboratory,

5.4 Test and calibration methods and method validation

The laboratory shall have methods and procedures for tests and calibrations that meet the needs of customers. The laboratory also shall have instruction on the use of equipment and handling of items for testing and calibrations. Furthermore, the laboratory shall have procedures to estimate the uncertainty of measurement.

5.5 Equipment

The laboratory shall provide all items of tests and calibrations. All the equipments used must be properly maintained, calibrated, and operates by authorized personnel.

5.6 Measurement traceability

The laboratory shall establish programme and procedure for the calibration of equipments which used for tests and calibration. The equipment used must have a significant effect on accuracy or validity of the results.

5.7 Sampling

The laboratory shall sampling plan and procedures which should be reasonable based on statistical method. The laboratory also shall procedures to record the relevant data and operations.

5.8 Handling of test and calibration items

The laboratory shall procedures to transport, handle, protect, store, and retain the test and/or calibration items. The laboratory shall have a system to indentify the test and/or calibration items. To avoid the items from loss and damage, there shall have procedures and appropriate facilities.

5.9 Assuring the quality test and calibration results

To monitor the validity of tests and calibrations undertaken, the laboratory shall have quality control procedures. The data of the quality control shall be analyzed. To prevent problem and incorrect results, action plan shall be carried out.

5.10 Reporting the results

The results of each tests or calibrations shall be reported clearly in a test report or a calibration certificate. A test report shall obtain the interpretation of test results and the results of sampling. While for calibration certificate, it shall only relate to the quantities and results of functional tests. The opinions and interpretations made shall also document and so the results of tests that perform by subcontractor.

(ISO/IEC 17025, 2005)

2.6.6 The Use of ISO/IEC 17025

ISO/IEC 17025 is the criteria for laboratory accreditation by accreditation bodies. ISO/IEC 17025 is used as the requirements for testing and calibration laboratories that wish to demonstrate the quality system, technical competence, and generate technically valid results. The standard also used to confirm and recognize the competence of laboratories by their clients or regulators.

If testing and laboratories comply with this standard, they will operate the quality system for their testing and/or calibration activities that also meet the requirements of ISO 9001, an international standard for quality management system.

If the testing and calibration laboratory of an organization or company is accredited with ISO/IEC 17025, the organization or company will gain many benefits from there especially in terms of quality. (TIS 17025 (ISO.IEC 17025) What is Standard?)

2.6.7 Who Should Implement ISO/IEC 17025

As we know, ISO/IEC 17025 is the standard that especially produced for the testing and/or calibration laboratories of organizations or companies. It contained all the requirements that testing and calibration laboratories have to meet with. In fact, who or what kind of organizations or companies should implement this standard?

An analytical testing laboratory of a company or an organization, who has registered to ISO 9001 should implement ISO/IEC 17025 if the laboratories activities are subjected to an audit as ISO/IEC 17025 contained the requirements which the laboratory should meet. Testing laboratories that want to prove to their clients that the analyses are done within a well recognized quality system should also implement ISO/IEC 17025 due to the standard is recognized globally. It can facilitate the trade in national and international market.

However, direct suppliers that supply equipment to the organizations those obtain or require the ISO/IEC 17025 certification, such as ISO/TS 16949, *Quality management system – Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations*, should implement this standard so that they are recognized by their client. Those laboratories that getting the official accreditation status by an accreditation body, such as A2LA, should also obtain the qualification of ISO/IEC 17025 to enhance the competence and also to be recognized. A2LA is nonprofit, non-governmental, public services, and membership society. The mission of A2LA is to provide comprehensive services in laboratory accreditation and laboratory related training.

Laboratory accreditation is based on internationally accepted criteria for competence, ISO/IEC 17025.

Lastly, this standard can be used for all regulated laboratories as a basis for their operations since many organizations are implementing it in their laboratories, and recognize it when they conduct their audits. (EuroQuest)

2.6.8 Benefits of ISO/IEC 17025

By obtaining the accreditation of ISO/IEC 17025, the laboratory can enhance the competence and can be recognized either nationally or internationally or both. The laboratories also can get the acceptance of test and calibration certificates from the laboratories which accredited by Thai Industrial Standards Institute between countries. The countries are the members of Asia Pacific Laboratory Accreditation Cooperation, and International Laboratory Accreditation Cooperation Mutual Recognition Arrangements of the technical equivalence. Hence, it can facilitate the trade not only in national market but also in international market.

Moreover, it also helps to reduce the technical barriers to trade since there will be no repeated test in the country who imported the products or equipments. (TIS 17025 (ISO.IEC 17025) What is Standard?)

Being accredited to ISO/IEC 17025, the laboratory can build up the confidence and reliability in the test results or calibration results. It not only provides additional information about the quality of the measurement made during the calibration process, it also provides a means of assessing the relative quality and capability of different calibration laboratories and suppliers. (EuroQuest)

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

To achieve the objectives and the goal of the project, the methodology is important to make sure the fluent of the project. Basically, this chapter will discuss on how to develop the quality documents for FKM Laboratory according to MS ISO/IEC 17025:2005. Before the development of quality documents, it is important to understand the clauses. Therefore, the requirements were being studied. A course on MS ISO/IEC 17025:2005 had been attended to have a better understanding on the clauses. To have a clearer mind in developing the quality documents, one of the laboratories of SIRIM QAS International Sdn. Bhd. had been chosen to visit. The laboratory visit was also to make sure the quality documents that had been developed is in the right path.

3.2 MS ISO/IEC 17025:2005 COURSE

A course on MS ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories* had been attended during the semester break at University Malaysia Pahang Gambang Campus. The course was divided into two sessions which were 21 May 2009 to 23 May 2009 and 4 June 2009 to 5 June 2009.

The speaker, Mr. Pua Hiang, gave a good explanation on the clauses as well as the development of quality manual. Policy, purpose, scope, and references are the criteria that needed to be included in the quality manual. By the way, every page of the quality

documents should include the title, reference number, revision number, issue date, issue number, and page number.

3.3 LABORATORY VISIT

3.3.1 Company Choosing

Some of the companies that have the testing and calibration laboratories and accredited with MS ISO/IEC 17025:2005 had been chosen to consider for the laboratories visit. Those companies were chosen from the website of the Department of Standards Malaysia which is http://www.standardsmalaysia.gov.my/.

Since the standard will be implemented in FKM Laboratory, those laboratories chosen are related to the field of mechanical engineering. The type of test of the laboratories included vibration testing, material testing such as hardness testing, bending test, drop test and etcetera, which are also available in the FKM Laboratory.

3.3.2 Discuss with Supervisor

After discussed with supervisor on the laboratories that going to visit, Mechanical & Automotive Section (MAST-Testing Group) SIRIM QAS International Sdn. Bhd. which located in Shah Alam, Selangor had been chosen. It is accredited with the standard and obtained the testing that available in FKM Laboratory.

3.3.3 Letter Preparation

After contacted the person in charge of the laboratory, a letter was prepared. To make sure the laboratory clear with the purpose of the laboratory visit, the objective and the scope of the laboratory visit was stated in the letter.

Since the visit was more concerned in the development of quality manual and system procedure, the person in charge of Mechanical & Automotive Section (MAST-Testing Group) had recommended another section which was Technical and Calibration Section (TCST-Testing Group). Another letter had been prepared and sent to the Technical and Calibration Section (TCST-Testing Group).

The purpose of the laboratory visit was to ensure that the quality documents that developed are in the right path.

3.3.4 Visit to the Laboratory

The visit was done on 15 August 2009 at the Technical and Calibration Section (TCST-Testing Group). The person in charge of the section was not available on the day of the visit and the visit was in charge by Miss Siti Tasliah. Due to the unavailable of the person in charge, the quality documents could not be shown since it is confidential. However, Miss Siti Tasliah had given a good explanation in developing the system procedure. The purpose, scope, definitions, procedure, records and references are needed to be included in the system procedure.

3.4 DOCUMENTATION OF QUALITY DOCUMENTS

3.4.1 Study and Understand the Clauses

To develop the quality documents for MS ISO/IEC 17025:2005, from Clause 4.1 to Clause 4.8, it is needed to understand and identify the requirements of the clauses. It is also important to identify the type of documents that needed to develop to implement MS ISO/IEC 17025:2005. One of the most important documents that needed to develop is quality manual. The quality manual should contain all the requirements that have been stated in the standard. Quality manual shall make reference to supporting procedures such as system procedure and work instruction.

3.4.2 Structure of Documentation

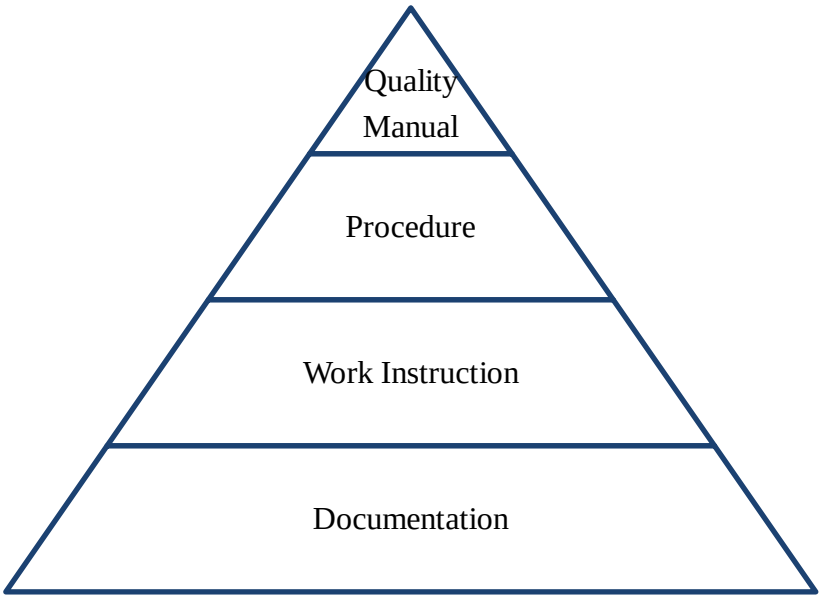


Figure 3.1: Documentation Pyramid

Source: Hashim 2007

3.4.2.1 Quality Manual

Quality manual states the quality system policies and statements of the organization. The quality policies statement shall be issued under the authority of the top management of the company. It shall include all the requirements that have been stated in the standard. It shall develop at the highest level. Quality manual provides a good working environment for staff by providing procedures of method of working. So, quality manual should be well communicated to all employees.

3.4.2.2 Procedure

Procedure shows the details on how the commitment is applied to the company operations. It describes who, what, when, where, how quality management systems are to be performed. Procedure should be referred to the policy or statement that stated in the quality manual.

3.4.2.3 Work Instruction

Work instruction describes who, what, when, where, how testing and calibration processes or other activities are to be performed. It is the additional detail on how specific jobs are carried out.

3.4.2.4 Documentation

Documentation referred to the records of all the tests and calibrations results, maintenance and training records. It also included the complaints and the corrective actions taken by the laboratories.

3.4.3 Developing Quality Documents

Quality manual is based on the quality standard of MS ISO/IEC 17025:2005. It should include the aspects of all the regulations and quality standards applied within the laboratory. Quality manual has references to the system procedure.

4.1 Organization

The laboratory must be authorized. It can be proved by Tax ID, Article of Incorporation, or other types of documents. Management system must be implemented and maintained to satisfy customer's needs. The management system must cover activities that carried out by the laboratories. Potential conflicts of interest must be identified in organization chart. Key personnel, such as program

manager, quality manager, technical manager and etcetera are appointed and their responsibilities are described in the quality manual. The appoint letter is used to appoint the key personnel. To make sure they free from any pressures that may affect their quality of work, training or orientation program is established and is recorded. There shall be a policy that addresses this issue. The policy and procedures to protect customers' confidential information, to protect the electronic storage and transmission of results also shall be established. Procedure shall establish to ensure that communication processes is practiced in an effective way.

4.2 Management system

This section shall elaborate the management system of the organization. Quality policies, systems, programmes, procedures, and instructions shall be established. Quality manual defined the quality system and policies. The overall objectives also shall be included in this section. The quality policies statement shall describe the purpose of management system. Quality manual shall make reference to supporting documents which are procedures and work instructions. By the way, top management shall provide evidence showing the improvement of the management system and shall communicate to the organization about the importance of meeting customer requirements. Procedure shall establish if there is change in the management system and make sure it does not interfere with the goals and objectives that have been established.

4.3 Document control

4.3.1 General

Procedures shall be established to control and protect all the documents.

4.3.2 Document approval and issue

To show evidence of approval is with a signature on the documents. The master list should indicate the current revision of all documents. All controlled documents should have a list of who gets the document to prevent unintentional use of obsolete documents. The procedure to control

documents shall establish. The identification of the documents should include the date of issue, revision identification, page numbering, the total number of pages, and the issuing authorities.

4.3.3 Document changes

The procedure for Document Changes is same with the procedure of clause 4.3.2. There shall be evidence to prove the documents have been looked at within a reasonable period (usually one year). If the changes of documents are allowed by hand-pending, the procedures for such amendments shall be defined. The amendments shall be clearly marked, initialed and dated.

4.4 Review of request, tenders and contracts

The policies and procedures of the review of request, tenders and contracts shall be established. Records of review shall be maintained. The review will cover any work that provided by the laboratiry. If the contract needs to be amended, the same contract review process shall be repeated and recorded.

4.5 Subcontracting of tests and calibrations

A laboratory only will subcontracts work due to certain reasons, such as manpower shortage, over work load, or need further expertise. When the laboratory intends to subcontract, approval from client is needed (preferable in writing). A file for all subcontractors shall be maintained.

4.6 Purchasing services and supplies

Policy and procedure shall establish to purchase the services and supplies. The policies and procedures shall cover the purchase, receiving and storage of reagents and laboratory consumable materials relevant to the tests and calibrations. The item purchase must comply with the specific requirements and approval of the item is recorded. The approved supplier list is maintained. If the purchasing documents for items affect the quality of tests and calibrations, it shall be reviewed and approved. Records shall be maintained for the evaluation of suppliers of critical consumables,

supplies, and services. The procedures for handling consumable materials and purchasing documents that contains descriptions also shall be established. For the purchase of documents that contains descriptions, those documents shall be approved and reviewed for technical content prior. The evaluation of suppliers of critical consumables and services that affect the results of tests and/or calibrations also shall be documented.

4.7 Service to the customer

Laboratory shall communicate with their clients and seek for feedback. The feedback shall be used to analyze the improvement of the management system and testing and calibration activities as well as customer service. Feedback can be from client surveys, feedback forms, collected by sales people or through the customer service department.

4.8 Complaints

This section shall have a policy and procedure to handle the complaints from their clients. All the complaints shall be documented to investigate the corrective actions. The laboratory shall have a procedure to handle complaints, include the investigation of the complaints. The corrective actions taken to correct the problems also shall be documented.

CHAPTER 4

RESULTS AND DISCUSSIONS

4.1 INTRODUCTION

In this chapter, it describes about the results and discussions of the documents that had been proposed. It can be observed that documents that had been developed for FKM Laboratory according to the requirements of MS ISO/IEC 17025:2005. The types of documents that had been developed are quality manual, system procedure, and forms. All the documents are important to make sure that it fulfills all the requirements that have been stated in the standard of MS ISO/IEC 17025:2005. Hence, FKM Laboratory can be prepared to the accreditation to MS ISO/IEC 17025:2005.

4.2 QUALITY MANUAL

The proposed quality manual had been developed for clause 4.1 to clause 4.8.

4.1 Organization
4.2 Management system
4.3 Document control
4.4 Review of requests, tenders and contracts
4.5 Subcontracting of tests and calibrations
4.6 Purchasing services and supplies
4.7 Service to the customer
4.8 Complaints

4.1 ORGANIZATION

4.1.1 FKM Laboratory is registered and held legally responsible.

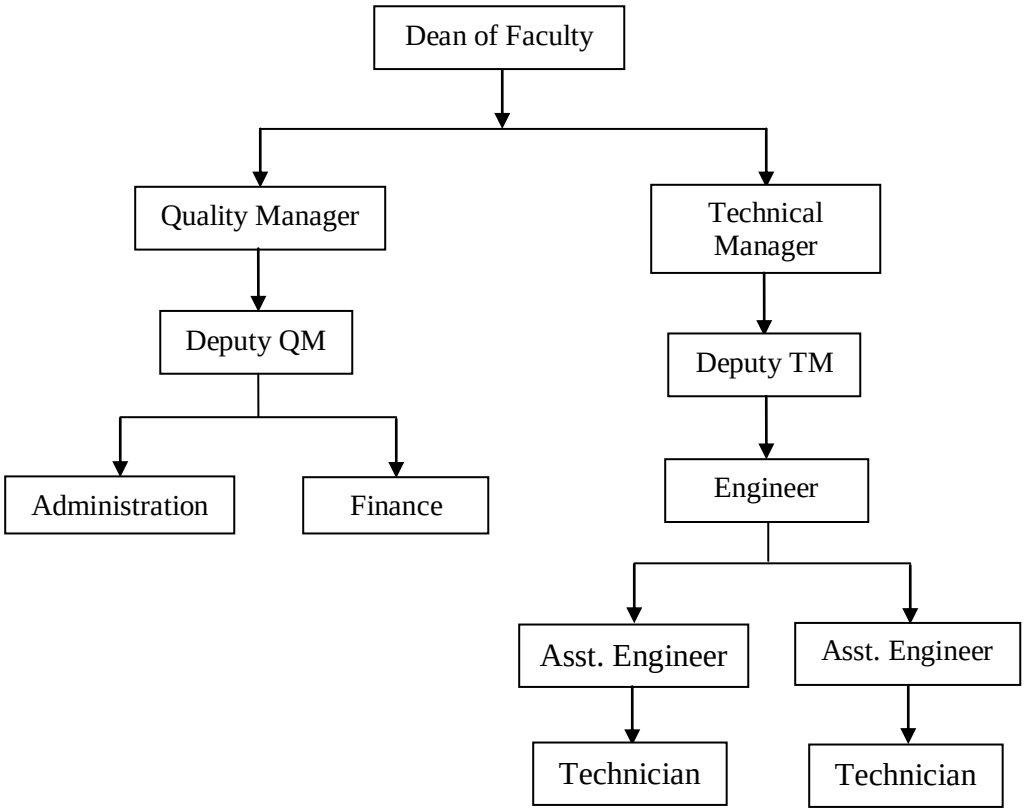
Address: Faculty of Mechanical Engineering
Universiti Malaysia Pahang,
26600 Pekan,
Pahang Darul Makmur,
MALAYSIA.

4.1.2 FKM Laboratory is responsible to carry out testing and calibration activities to meet the requirements of MS ISO/IEC 17025 and to satisfy the needs of customer and STANDARD MALAYSIA authorities.

4.1.3 The management system covers work carried out in the laboratory's permanent facilities.

4.1.4 The responsibilities and authorities of key personnel of FKM Laboratory are defined to identify potential conflicts of interest.

Organization Structure:



a) Dean of Faculty shall responsible for the whole laboratory, quality control, results of testing and calibration activities and the performance of the staff. He shall accountable for any problems related to the nature of laboratory work.

b) Dean of Faculty shall ensure the quality management system is established, implemented, controlled, maintained and continually improves.

c) Quality Manager shall ensure the quality management system is established, implemented, controlled, maintained and continually improves.

d) Quality Manager is responsible to control all the quality system documents and review or update the documents when necessary.

e) Quality Manager should ensure that the quality management system is improved continually.

f) Technical Manager shall have the overall responsibilities for all the technical operations.

g) Technical Manager shall ensure the procedures of the testing and calibration activities are carried out accurately and all the test and calibration equipments are in good condition.

h) In the absence of Quality Manager, Deputy Quality Manager will perform the responsibilities of Quality Manager. In the absence of Technical Manager, Deputy Technical Manager will perform the responsibilities of Technical Manager.

i) Engineer shall perform maintenance job to make sure the equipment of the laboratory is always in good condition so it will not adversely affect the results of testing and calibration.

j) Engineer shall have the responsibilities in the validation and verification of the testing and calibration methods.

k) In the absence of Engineer, Assistant Engineer shall responsible to take over the responsibilities of Engineer.

l) Technician shall be responsible to carry out the testing activities that provided by FKM Laboratory.

m) Administration Manager shall responsible for the administrative work of the faculty.

n) Finance Manager shall responsible for the accounting work of the faculty.

o) Each personnel shall be responsible to ensure the requirements of the quality management system are fully implemented and all the documents are kept properly.

p) The training program attended by staff is described in Personnel Training Program.

4.1.5

a) FKM Laboratory is managed by trained personnel for implementation, maintenance and improvement of the management system. The authorities and responsibilities of the managerial and technical personnel are defined.

b) The management and personnel of FKM Laboratory are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of work.

c) The customers' confidential information and proprietary rights is protected by suitable system procedures. The laboratories store the results in a confidential place without the existence of third party (1).

d) FKM Laboratory has policies and procedures to avoid the involvement in any activities that would diminish the confidence in its competence, impartiality, judgement or operational integrity.

e) The organization structure of FKM Laboratory has established with defined responsibilities and authorities of key personnel.

f) Management representative is appointed to maintain the improvement of the operation. Technical manager manages technical operation. The responsibilities and authorities of all managerial and technical personnel are described in this manual.

g) FKM Laboratory maintains adequate supervision by providing training to all technical personnel (2).

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(1) Refer UMP-FKM/SP/M04 Procedure for Service to the Customers
(2) Refer UMP-FKM/SP/T01 Procedure for Personnel Training Program

h) FKM Laboratory has technical management that has overall responsibilities for technical operations and the provision of the resources.

i) Quality manager is appointed to develop, document and implement the systems, procedures, work instructions and control the documents. He is responsible for documentation; implement the corrective and preventive actions on customer complaints and from internal audit findings (1).

j) Deputies are appointed for key managerial personnel.

k) Daily review meeting is conducted to ensure all personnel are aware of the importance of their activities and contribution to the achievement of the objectives of the management system (2).

4.1.6 Effective communication occurs within the laboratory regarding the effectiveness of the management system.

REFERENCES:	UMP-FKM/SP/M04	Procedure for Service to the Customers
	UMP-FKM/SP/M11	Procedure for Internal Audit
	UMP-FKM/SP/M12	Procedure for Management Review
	UMP-FKM/SP/T01	Procedure for Personnel Training Program

(1) Refer UMP-FKM/SP/M11 Procedure for Internal Audit
(2) Refer UMP-FKM/SP/M12 Procedure for Management Review

4.2 MANAGEMENT SYSTEM

POLICY: To establish a quality system in testing and calibration services based on the requirements of MS ISO/IEC 17025 and FKM Laboratory's commitment to policy and maintain good professional practices.

SCOPE: Establish, implementation, and maintain management system.

PURPOSE: To ensure the results and services provided by FKM Laboratory meet the requirements of MS ISO/IEC 17025 and customer's requirements.

ACTIONS AND METHODS:

4.2.1 The Quality Management System of FKM Laboratory is based on the requirements of MS ISO/IEC 17025, and covers the activities of the laboratory. The element of the system are documented in the following documents (1):

- Laboratory Quality Manual
- Laboratory System Procedure
- Work Instructions
- Forms and Records

The system is implemented through training programs, review meetings, posters display boards so that all personnel are communicated and made to understand and follow the same. The required manual is made to appropriate personnel for reference (2).

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(1) Refer UMP-FKM/SP/M01 Procedure for Document Control
(2) Refer UMP-FKM/SP/T01 Procedure for Personnel Training Program

4.2.2 Quality Management Policy

Quality Policy

FKM Laboratory is committed follow good professional practice and the quality of testing and calibration activities by implementing MS ISO/IEC 17025.

FKM laboratory renders the following standards of services to its customers in material testing.

- Quality
- Service provision
- Reliability
- Confidentiality

Objectives of the policy are achieved by:

- A committed team effort.
- Continuous training of all the technical staff to upgrade their skills and in sophistication of equipment to achieve the constant improvement in quality of testing and calibration activities.
- Using Standard Method to meet the customer requirement.
- A management system that meet the requirements of MS ISO/IEC 17025.
- Continuous system improvement.
- Periodically review of quality management system documentation.

Management is appropriately empowered to ensure these requirements are met.

FKM Laboratory is committed that any point of time, the customer will not put an embarrassment based on the results reported by the laboratory.

4.2.3 The Quality Manager shall provide evidence of commitment to the development and implementation the management system and continually improving its effectiveness.

4.2.4 The Quality Manager shall communication to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

4.2.5 The Quality Manual addresses all elements of quality and has references to System Procedure including Technical Procedure. Work Instructions are referred to System Procedure. These documents are available at appropriate places for ready reference to the working personnel. They are under control of Quality Manager and Technical Manager.

4.2.6 The roles and responsibilities of technical management and the quality manager are defined in this manual.

4.2.7 The Quality Manager shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

REFERENCES: UMP-FKM/SP/M01 Procedure for Document Control
UMP-FKM/SP/T01 Procedure for Personnel Training Program

4.3 DOCUMENT CONTROL

POLICY: FKM Laboratory shall establish a system procedure for documentation and control the documents.

SCOPE: Covers all quality documents of FKM Laboratory.

PURPOSE: To ensure all the documents are updated, reviewed and maintained in a systematic way.

ACTIONS AND METHODS:

4.3.1 General

FKM Laboratory has documented procedures to control all documents including Quality Manual, System Procedure, Work Instructions, regulations, specifications, calibration records, etc. They are hard copies.

4.3.2 Document approval and issued

4.3.2.1 Documents issued to personnel in the laboratory are reviewed and approved for use by Quality Manager. Master list shall be generated to identify the current revision status.

4.3.2.2 The procedures are established to ensure:

a. Authorized editions of appropriate documents are available at appropriate places to the effective functioning of the quality system are performed. They are under control of Quality Manager.

DISTRIBUTION OF QUALITY MANUAL

Copy No.	Copy Holder
1.	Dean of Faculty
2.	Quality Manager
3.	Technical Manager
4.	STANDARDS MALAYSIA

b. Documents are reviewed once a year and revised to ensure continuing suitability and compliance with the requirements of MS ISO/IEC 17025. Review is also carried out due to any complaint, internal and external audit.

c. Invalid or obsolete documents are promptly removed from all points of issue or use.

d. Obsolete documents retained for legal are suitably marked.

4.3.2.3 All documents are uniquely identified along with data of issue, revision, pages, including total number of pages etc. The approval and issuing authority are identified. Only master copy is authorized in all pages.

4.3.3 Document changes

4.3.3.1 The management periodically reviews the documents based on the change of standards, audit, complaints, and quality to ensure the suitability and compliance with MS ISO/IEC 17025. Changes to document are reviewed and approved by the same function that performed the original review (1).

4.3.3.2 The altered or new text is identified either in the document or attachments.

4.3.3.3 FKM Laboratory does not allow amendment of documents by hand.

4.3.3.4 FKM Laboratory uses computer and hardcopy as storage medium for documents.

REFERENCE: FKM-UMP/SP/M01 Procedure for Document Control

RECORDS: UMP-FKM/REC/M001 Amendment Record Sheet
UMP-FKM/REC/M002 Issue Control Sheet

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(1) Refer UMP-FKM/REC/M001 Amendment Record Sheet

4.4 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

POLICY: FKM Laboratory shall develop and maintain a system procedure to understand the customer requirements clearly and executing the contract review.

SCOPE: Covers all the test enquiries and requests as receive by FKM Laboratory.

PURPOSE: To ensure FKM Laboratory has the capability and resources to meet the obligations to the customer and to fulfill their requirements.

ACTIONS AND METHODS:

4.4.1 The procedures for the review of requests, tenders and contracts which leading to a contract for testing and calibration are established to ensure that:

a. The testing and calibration procedure used by the lab is Standard Method unless instructed by the customer.
b. The laboratory has the capability and resources to meet MS ISO/IEC 17025;
c. The appropriate test and calibration method is selected and is capable of meeting the customers' requirements.

4.4.2 The records of the review of the test request and the discussion or communication to the client are maintained.

4.4.3 FKM Laboratory does not give any sub-contracting work.

4.4.4 Any deviation from the contract is informed to the customer and all relevant personnel either orally or in writing.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel. FKM Laboratory informs the customer of any delay due to breakdown of equipment or unforeseen circumstances.

REFERENCE: UMP-FKM/SP/M02		Procedure for Review of Requests, Tenders and Contracts
RECORDS:	UMP-FKM/REC/M003	Laboratory Request From
	UMP-FKM/REC/M004	Purchase Order

4.5 SUBCONTRACTING OF TESTS AND CALIBRATIONS

Not applicable.

4.6 PURCHASING SERVICES AND SUPPLIES

POLICY: FKM Laboratory's policy is to ensure the selection of services or supplies is systematic and controlled so that it will not adversely affect the quality of testing and calibration.

SCOPE: Covers all the services and supplies to FKM Laboratory as it has a direct impact on the quality of testing and calibration.

PURPOSE: To ensure the services and supplies meet the requirements of the laboratory and specifications.

ACTIONS AND METHODS:

4.6.1 The selection of services and supplies of the standard test and calibration methods are being established. Purchased items are inspected and approved prior to use and records are maintained (1). The calibration of equipment required is being carried out by STANDARDS MALAYSIA accredited agencies only.

4.6.2 Purchased supplies and materials that affect the quality of tests and calibrations are not used until verified as complying with standard specifications.

4.6.3 Purchasing documents shall be reviewed and approved for technical content prior to release.

4.6.4 All vendors of services and supplies are evaluated and the records of these evaluations shall be maintained (2).

REFERENCE: UMP-FKM/SP/M03 Procedure for Purchasing Services and Supplies

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(1) Refer UMP-FKM/REC/M006 Supplier Evaluation Form
(2) Refer UMP-FKM/REC/M005 Approved Vendor List

RECORDS:	UMP-FKM/REC/M005	Approved Vendor List
	UMP-FKM/REC/M006	Supplier Evaluation Form
	UMP-FKM/REC/M007	Purchase Order
	UMP-FKM/REC/M008	List of Laboratory Equipment

4.7 SERVICE TO THE CUSTOMER

POLICY: FKM Laboratory shall establish and maintain the procedure to initiate guidelines to cooperate with customers by providing testing services and to render customer satisfaction.

SCOPE: Covers the activities of customer service of FKM Laboratory.

PURPOSE: To ensure customer's requirements are met by providing appropriate services and customer's confidential information is protected.

ACTIONS AND METHODS:

4.7.1 FKM Laboratory is willing to cooperate with customers and to monitor their testing and calibration and allow the customers to witness the test in relevant areas protecting other customer confidential information.

4.7.2 Feedback from customer is encouraged and is maintain by Quality Manager to improve the management system, testing and calibration activities, and customer service (1).

REFERENCE: UMP-FKM/SP/M04 Procedure for Service to the Customer

RECORD: UMP-FKM/REC/009 Customer Feedback Form

(1) Refer UMP-FKM/REC/009 Customer Feedback Form

4.8 COMPLAINTS

POLICY: FKM Laboratory's policy is to give priority to customers' feedback and complaints and resolve them in a stipulated period to attain continuous improvement.

SCOPE: Covers all complaints regarding to service, standards, accuracy of reports and quality system.

PURPOSE: To ensure the service that carried out by FKM Laboratory meet the customer's requirements.

RESPONSIBILITIES: Quality Manager

ACTIONS AND METHODS:

4.8.1 Complaints received from customer are treated identically and are recorded (1). All complaints are reviewed and corrective actions are taken immediately (2).

REFERENCES:	UMP-FKM/SP/M05	Procedure for Complaints
	UMP-FKM/SP/M08	Procedure for Corrective Action
	UMP-FKM/SP/M12	Procedure for Management Review
RECORD:	UMP-FKM/REC/010	Complaints Form

(1) Refer UMP-FKM/REC/010 Complaints Form
(2) Refer UMP-FKM/SP/M08 Procedure for Corrective Action

4.3 SYSTEM PROCEDURE

The system procedure had been proposed. The system procedure that had been developed was:

4.3 Procedure for Document Control

4.4 Procedure for Review of Requests, Tenders and Contracts

4.6 Procedure for Purchasing Services and Supplies

4.7 Procedure for Service to the Customers

4.8 Procedure for Complaints

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M01 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Document Control**	Issue No : 1 Page : 1 of 14

SYSTEM PROCEDURE

DOCUMENT CONTROL

This System Procedure is duty authorized by the Dean of Faculty and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by:

_____
Dean of Faculty
(date)

Released by:

_____
Quality Manager
(date)

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M01 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Document Control**	Issue No : 1 Page : 2 of 14

1.0 Purpose

To assure the quality system documents are properly developed, reviewed, updated, and maintained through a systematic way of distribution.

2.0 Scope

This procedure applies to control all the quality system documents including test and calibration methods, system procedures, work instructions, and all other related documents.

3.0 Definition

3.1 Quality Management System – The organization structure, procedures, and processes needed to implement the Quality Management.
3.2 Document Distribution List – Illustrate the distribution of quality system documents.
3.3 Registered Holder List – Illustrate who are the registered holders.
3.4 Master List of Quality System Documents – Illustrate the status and revision of the management system documents.
3.5 Document Control Sheet – Illustrate retention period, storage location and responsibilities maintenance of all the documents.

4.0 Responsibilities

4.1 Quality manager shall be responsible to control and maintain all the quality system documents.
4.2 It is the responsibility of Quality Manager to review and update the quality system documents when necessary.
4.3 All the staff shall be responsible for the safekeeping of the quality documents in the appropriate place.

5.0 Associated Document

5.1 UMP-FKM/QM/M01 Laboratory Quality Manual

6.0 Instructions of Forms

6.1 UMP-FKM/REC/M001 Amendment Record
6.2 UMP-FKM/REC/M002 Issue Control Sheet

7.0 Policy and Procedure Instructions

7.1 Policy

FKM Laboratory shall establish a system procedure for documentation and control the documents.

7.2 Quality Documents Structure

7.2.1 Each page of the Quality Documents shall contain the following:

1. Title
2. Reference number
3. Revision number
4. Issue date
5. Issue number
6. Page number

7.2.1.1 Title

Title is the name of the document as shown in the content page that reflects the area of application.

7.2.1.2 Reference Number

Reference Number is the document number of Quality Document. Each document will be allocated a unique alphanumeric code by Quality Manager.
Eg. UMP-FKM/SP/M02.

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i ii iii

i. Six letter code denoting University Malaysia Pahang, Fakulti Kejuruteraan Mekanikal.
Eg. UMP-FKM.
ii. Two letter code denoting Quality Manual, System Procedures, Work Instructions, etc.
Eg. QM, WI, REC, etc.

iii. For System Procedures, one letter denoting the type of procedure, M (Management Requirements) or T (Technical Requirements), followed by two-digit code denoting the number from 01-99.
Eg. M01, T02, etc.

For Work Instructions, three-digit code denoting instructions number from 001-999.

For Technical Manual, three letters denoting manual type, followed by two-digit code denoting the number from 01-99.

7.2.1.3 Revision Number

Revision Number shall be increased by one digit (eg. 0 to 1, and so on) when an amendment is made to a particular section.

7.2.1.4 Issue Date

Issue Date is the effective date of the document when the latest revision of the document is done.

7.2.1.5 Issue Number

Issue Number shall be increased by one digit (eg. 1 to 2, and so on) when major changes are made to meet the new requirement or procedure. The decision for a new issue shall be made by Dean of Faculty and authorized by Quality Manager.

7.2.1.6 Page Number

Page Number refers to the page of the Quality Document, in ascending order, within the whole document.

7.2.2 The Quality Manual format and contain the following:

1. Policy
2. Scope
3. Purpose
4. Actions and Methods

7.2.2.1 Policy

It stated the organization decisions and management mechanisms arranged to reach the goals.

7.2.2.2 Scope

It details the range of the procedure.

7.2.2.3 Purpose

It stated the objectives of the system procedure.

7.2.2.4 Actions and Methods

The activities that need to carry out in order to fulfill the requirements of the standard.

7.2.3 The System Procedures format and contain the following:

1. Title Page
2. Purpose
3. Scope
4. Definitions
5. Responsibilities
6. Associated Document
7. Instructions for Forms
8. Policy and Procedure Instructions
9. References

7.2.3.1 Title Page

It includes the title and the authorization of the system procedure.

7.2.3.2 Purpose

It stated the objective of the system procedure.

7.2.3.3 Scope

It details the range of the procedure.

7.2.3.4 Definitions

It defines the standard terms.

7.2.3.5 Responsibilities

The person in-charge in the particular section.

7.2.3.6 Associated Document

The documents that related to the procedures and generated as a result of the procedures.

7.2.3.7 Instructions for Forms

The related forms need to be used.

7.2.3.8 Policy and Procedure Instructions

It describes the procedure to implement the standard by stating who, what, when, where, and how.

7.2.3.9 References

The documents that have a bearing on the activities discussed.

7.3 Quality Manual

7.3.1 Document Approval and Issued

a) Management Representative shall review all the management system documents.
b) Quality Manager shall approve all the management system documents and authorize by Dean of Faculty.
c) Quality Manager is the person who ensures that each copy of the Quality Manual is serially numbered.
d) The Quality Manual are reviewed every once a year by the Quality Manager.
e) Quality Manager holds the master copy of the Quality Manual. Those Quality Manual holders are listed in the Quality Manual.

f) The copy that issued to other party will be indicated by an "UNCONTROLLED COPY" chop. This copy may only be issued after authorization of Quality Manager.

7.3.2 Document Changes

a) If a quality management system is considered necessary to revise, the request of document changes should be addressed by Quality Manager.
b) The changes of document undergo the process of review, approval, and authorization.
c) Each amendment shall be introduced by issuing of new page for each issue existence.
d) Amended section shall be indicated by an "AMENDED" chop while added section shall be indicated by an "ADDED" chop. Deleted section shall be indicated by a "DELETED" chop.
e) All the changes or amendment shall be updated in the Amendment Record and approved by Quality Manager.
f) The Amendment Record shall be attached at the front page of the Quality Manual. A complete sections or pages shall be reissued. The old issued shall be indicated with "OBSOLETE" while the new issued will be indicated with "CONTROLLED COPY".
g) Quality Manual's holders shall ensure that the obsolete copies are removed and destroyed.
h) The master list of the quality system documents shall be maintained and kept by Quality Manager.

7.4 System Procedure and Work Instructions

7.4.1 Document Approval and Issued

a) All the System Procedure shall be prepared by Quality Manager.
b) The originator shall forward the documents for review and approval from Quality Manager.
c) Master copy of the document is kept by Quality Manager.

d) The distribution copy shall be indicated by a "CONTROLLED COPY" chop.
e) The controlled copy shall be made available at appropriate places.
f) All authorized personnel according to the Document Distribution List and Registered Holder List, which authorized by Quality Manager, shall acknowledge on the Issue Control Sheet.
g) Registered Holder shall return all Controlled Documents to Quality Manager upon the termination of employment with FKM. The registered holder shall sign on the Registered Holder List to acknowledge the return of the documents.
h) The copy that issued to other party will be indicated by an "UNCONTROLLED COPY" chop. This copy may only be issued after authorization of Quality Manager.

7.4.2 Document Changes

a) Quality Manager shall review the quality system documents every once a year or when there is a need arises at a feasible and effective solution. With the approval of Quality Manager, the document shall be updated and issued.
b) Minor changes on the documents are also allowed with the approval from Quality Manager.
c) The Amendment Record shall be attached at the front page of the System Procedure. A complete sections or pages shall be reissued. The old issued shall be indicated with "OBSOLETE" while the new issued will be indicated with "CONTROLLED COPY" (1).
d) The holders of the documents shall sign the Document Control Sheet and Registered Holder List. The holders shall responsible for its proper insertion and disposal of the obsolete document.

7.5 Supporting Documents

7.5.1 Document Approval and Issued

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(1) Refer UMP-FKM/REC/M001 Amendment Record

a) All the supporting documents such as forms and records shall be prepared by Deputy Quality Manager.
b) The documents shall forward to Quality Manager for review and approval.

7.5.2 Document Changes

a) The changes of the forms and documents shall be updated by Deputy Quality Manager and approve by Quality Manager.

8.0 Reference

MS ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories.*

DOCUMENT DISTRIBUTION LIST

DOCUMENT TYPE	Dean	QM	TM	DM	Engr.	Asst. Engr.	Tech.	Adm.	Fin.
1. Quality Manual	Y	Y	Y	Y					
2. System Procedure	Y	Y	Y	Y					
3. Forms/Records	Y	Y	Y						

1. Dean — Dean of Faculty
2. QM — Quality Manager
3. TM — Technical Manager
4. DM — Deputy Manger
5. Engr. — Engineer
6. Asst. Engr. — Assistant Engineer
7. Tech. — Technician
8. Adm. — Administration
9. Fin. — Finance

Quality Manager: _____ Date: _____

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M01 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Document Control**	Issue No : 1 Page : 11 of 14

REGISTERED HOLDER LIST

NAME	POST	COPY NO.	RECEIVE		RETURN	
			DATE	SIGN	DATE	SIGN

MASTER LIST OF QUALITY SYSTEM DOCUMENTS
Quality Manual / System Procedure / Work Instructions

REF NO.	TITLE	ISSUE	LAST AMENDMENTS DATE
Quality Manual	**Management Requirements**		
UMP-FKM/QM/M01	Laboratory Quality Manual	1	
Quality Manual	**Technical Requirements**		
System Procedure	**Management Requirements**		
UMP-FKM/SP/M01	Procedure for Document Control	1	
UMP-FKM/SP/M02	Procedure for Review of Requests, Tenders and Contracts	1	
UMP-FKM/SP/M03	Procedure for Purchasing Services and Supplies	1	
UMP-FKM/SP/M04	Procedure for Service to the Customer	1	
UMP-FKM/SP/M05	Procedure for Complaints	1	

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M01 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Document Control**	Issue No : 1 Page : 13 of 14

System Procedure	**Technical Requirements**		
Forms / Documents			
UMP-FKM/REC/M001	Amendment Record	1	
UMP-FKM/REC/M002	Issue Control Sheet	1	
UMP-FKM/REC/M003	Laboratory Request Form	1	
UMP-FKM/REC/M004	Purchase Order	1	
UMP-FKM/REC/M005	Approved Vendor List	1	
UMP-FKM/REC/M006	Supplier Evaluation Form	1	
UMP-FKM/REC/M007	Purchase Order	1	
UMP-FKM/REC/M008	List of Laboratory Equipment	1	
UMP-FKM/REC/M009	Customer Feedback Form	1	
UMP-FKM/REC/M010	Complaints Form	1	

DOCUMENT CONTROL SHEET

DOCUME-NT TYPE	RELEVANT TO FKM QUALITY MANAGEMENT SYSTEM OPERATIONS	INITIAL ISSUE IDENTIFICATION PARTICULARS	STORAGE LOCATION	ARCHIVING PERIOD (YEAR)	RESPONSIBIL-ITY

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M02 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Review of Requests, Tenders and Contracts**	Issue No : 1 Page : 1 of 5

SYSTEM PROCEDURE

REVIEW OF REQUESTS, TENDERS AND CONTRACTS

This System Procedure is duty authorized by the Dean of Faculty and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by:

_____
Dean of Faculty
(date)

Released by:

_____
Quality Manager
(date)

1.0 Purpose

This document is established to describe the procedure to enable the review of requests, tenders, and contracts can be conducted in an effective and efficient way in order to meet the customer requirements.

2.0 Scope

This procedure covers all the requests, tenders, and contracts for the testing and calibration services provided by FKM laboratory.

3.0 Definitions

Contract – an agreement between customer and laboratory for testing activities.

4.0 Responsibility

4.1 Quality Manager shall be responsible to review the requests, tenders, and contracts according to the procedure.

4.2 Technical Manager shall be responsible to ensure the appropriate personnel and the resources for testing and calibration activities are available to carry out the testing and calibration activities.

4.3 Quality Manager shall review or update the document when necessary.

4.4 Each individual shall ensure that works are performed in accordance with the agreed procedure.

5.0 Associated Document

5.1 UMP-FKM/QM/M01 Laboratory Quality Manual

6.0 Instruction for Forms

6.1 UMP-FKM/REC/M003 Laboratory Request Form

7.0 Policy and Procedure Instructions

7.1 Policy

FKM Laboratory shall develop and maintain a system procedure to understand the customer requirements clearly and executing the contract review.

7.2 Initial Enquiry

7.2.1 The enquiry for testing and calibration activities can be from any companies, project owners or engineers in local or overseas.

7.2.2 The enquiry can be done orally or in written which consist with an enquiry letter together with details such as the number of the samples to be tested, their nature, testing parameters and etc. Quality Manager and Technical Manager shall be responsible to review the enquiry.

7.2.3 Further information from the customer shall be request by Quality Manager if the information is insufficient.

7.2.4 If the enquiry is unsuitable, Quality Manager shall be informed. Quality Manager shall inform the customer and return the enquiry documents if necessary.

7.2.5 The suitable enquiry shall be recorded in date and numerical order.

7.2.6 After the suitable enquiry is accepted, Technical Manager shall check the availability of the equipment and the competent of the engineers. The testing and calibration activities shall be carried out only if the resources are available and sufficient.

7.2.7 Technical Manager shall define and run assessment of the customer requirement and review the contract.

7.2.8 Quality Manager shall process the request and accept the request.

7.2.9 If the resources are not available or insufficient, FKM Laboratory shall not accept the enquiry.

7.3 Quotation

7.3.1 The quotation shall be initiated once it is confirmed that FKM Laboratory has the capability to carry out the testing and calibration activities and to meet the customer's requirement.

7.3.2 The quotation shall be orally or in written.

7.3.3 The quotation shall state the type of testing work, test and calibration method, quantity as well as the cost.

7.3.4 Quality Manager shall agree with the rates and terms of payment of the customer and a quotation will be prepared based on the information.

7.3.5 A quotation raised shall have the minimum following details:

a. Company's name
b. Name of the requestor
c. Date
d. Name of recipient
e. Details of the quotation include type of testing work, test and calibration method, quantity, and cost.
f. Name and signature of the authorize personnel
g. Payment term
h. FKM Laboratory Terms and Conditions

7.3.6 A typed written quotation will have a quotation reference number and the quotation will be maintained.

7.4 Confirmation of Contract

7.4.1 When the quotation is accept, the customer shall confirm and acknowledge receipt by signing and return to FKM Laboratory through fax or email.

7.4.2 Alternatively, customer can issue a written Purchase Order based on the latest quotation and agreed terms. The Purchase Order normally accepts the written quotation.

7.4.3 If the customer only able to provide the confirmation of the request orally, this shall be recorded by Quality Manager in the Laboratory Request Form.

7.4.4 The Purchase Order shall be filled together with the quotation in Order Receive File.

7.4.5 Should the agreed rates be exceeded, a further Purchase Order should be issued by the customer to cover the additional testing and calibration activities.

7.5 Amendment of Review of Contract

7.5.1 A new quotation or a new Purchase Order shall be prepared if there are changes in the requirements that made before the work is commenced. The testing and calibration is updated continuously depending in the customer Purchase Order.

7.5.2 If it is request orally, a fresh Laboratory Request Form shall be issued with clear indication in the "Remarks" section of the form describing that it is supersedes the original (1).

7.5.3 If there is a deviation from the contract or need to amend the contract, the work shall be halted and the same contract review process shall be repeated. The amendments shall be made and communicated to all affected personnel in written.

7.5.4 After all the differences and queries are resolve, work shall be continued.

7.5.5 Review of each testing and calibration, pertinent discussions with a customer relating to the customer's requirements, and any documents that related to any deviation shall be maintained.

8.0 Reference

MS ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories.*

(1) Refer UMP-FKM/REC/M003 Laboratory Request Form

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M03 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Purchasing Services and Supplies**	Issue No : 1 Page : 1 of 4

SYSTEM PROCEDURE

PURCHASING SERVICES AND SUPPLIES

This System Procedure is duty authorized by the Dean of Faculty and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by:

_____
Dean of Faculty
(date)

Released by:

_____
Quality Manager
(date)

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M03 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Purchasing Services and Supplies**	Issue No : 1 Page : 2 of 4

1.0 Purpose

This document is established to ensure that the selection of services and supplies, which will have a direct impact on the quality of testing and calibration, is systematic and controlled.

2.0 Scope

This procedure is applicable to all the purchasing of services and supplies used in FKM Laboratory.

3.0 Definitions

3.1 Vendor – Company that provide goods or services to FKM Laboratory.

4.0 Responsibility

4.1 Quality Manager shall collect and maintain the Approved Panel of Suppliers as a quality record.

4.2 It is the responsible for Technical Manager for review, sourcing, selection and purchasing of the test equipment and materials.

5.0 Associated Document

5.1 UMP-FKM/QM/M01 Laboratory Quality Manual

6.0 Instruction for Forms

6.1 UMP-FKM/REC/M004 Approved Vendor List
6.2 UMP-FKM/REC/M005 Supplier Evaluation Form
6.3 UMP-FKM/REC/M006 Purchase Order
6.4 UMP-FKM/REC/M007 List of Laboratory Equipment

7.0 Policy and Procedure Instructions

7.1 Policy

FKM Laboratory's policy is to ensure the selection of services or supplies is systematic and controlled so that it will not adversely affect the quality of testing and calibration.

7.2 Selection of Suppliers

7.2.1 Suppliers shall be assessed by Quality Manager and selected for the Approved Panel of Suppliers based on the usage experience, operating reliability and compatibility.

7.2.2 The suppliers in the Approved Panel of Suppliers shall have ensured that the product meet the requirements of specifications.

7.2.3 Approved Panel of Suppliers shall be updated when a new supplier is approved or an existing supplier is dropped by Quality Manager.

7.3 Purchasing Procedure

7.3.1 All the requests order of purchasing services and supplies from the requesting personnel must be supported by a Purchase Order verified and approved for technical content by Deputy Quality Manager and acceptance by the Quality Manager prior to release.

7.3.2 Details regarding to quality shall be referred to the Deputy Quality Manager. For verification and approval before overall approved by the Quality Manager.

7.3.3 All the purchases of services and supplies shall be made from the Approved Panel of Suppliers.

7.3.4 FKM Laboratory shall stay with the present list of suppliers unless better compatible suppliers can be sourced.

7.3.5 The suppliers who do not hold the approved shall not be used until they have been inspected or otherwise verified with the standard specifications or requirements.

7.3.6 Purchase orders are raised for all purchased supplies and shall clearly describe and specify the supplies. The description may include type, precise identification, specification, inspection instructions, quality required and quality management system under which they are made.

7.3.7 All the purchasing shall be documented.

7.4 Review and Evaluation of Vendors

7.4.1 Quality Manager shall review and evaluate the Approved Vendors List once a year (1).

---

(1) Refer UMP-FKM/REC/M004 Approved Vendors List

7.4.2 The review and evaluation of vendors shall be include the following criteria:

- Ability to meet the specified quality specification
- Price competitiveness
- Service provided includes technical assistance, follow-up and feedback.
- Provide timely delivery
- Terms of payment

7.4.3 The review and evaluation shall be recorded in the Supplier Evaluation Form and approved by Quality Manager (1).

7.5 Procedure for Receiving Purchases

7.5.1 General Items

7.5.1.1 When the purchase items are arrived, the technical person who in-charge shall verify the items received and record it in the Purchase Order, with the receiving date and receiver's name (1).

7.5.1.2 The purchase item shall be stored in an appropriate place.

7.5.2 Equipment or apparatus

7.5.2.1 When the equipment or apparatus is arrived, the checking shall be done by the technical person who purchases the equipment or apparatus. The acceptance authorities are Quality Manager.

7.5.2.2 The equipments shall be check compliance to the specifications and recorded.

7.5.2.3 The delivery order shall be acknowledged after the equipments specifications are checked and the requirements are fulfilled.

7.5.2.4 The Deputy Technical Manager shall update the List of Laboratory Equipment (2).

8.0 Reference

MS ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories.*

---

(1) Refer UMP-FKM/REC/M006 Purchase Order
(2) Refer UMP-FKM/REC/M007 List of Laboratory Equipment

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M04 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Service to the Customer**	Issue No : 1 Page : 1 of 4

SYSTEM PROCEDURE

SERVICE TO THE CUSTOMER

This System Procedure is duty authorized by the Dean of Faculty and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by:

_____
Dean of Faculty
(date)

Released by:

_____
Quality Manager
(date)

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M04 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Service to the Customer**	Issue No : 1 Page : 2 of 4

1.0 Purpose

This document is established to ensure customer's requirements are met by providing appropriate services and customer's confidential information is protected.

2.0 Scope

This procedure applies to the customer service and to improve the Quality Management System of the laboratory.

3.0 Definitions

3.1 Service - The results generated from any activities that provided to the customers to meet the customer requirements.

3.2 Customer - The customers of the testing and calibration can be come from any companies.

4.0 Responsibility

4.1 Quality Manager is responsible in the implementation of this policy and procedure.

4.2 It is the responsibility of Quality Manager to review and update the documents when necessary.

5.0 Associated Document

5.1 UMP-FKM/QM/M01 Laboratory Quality Manual

6.0 Instruction for Forms

6.1 UMP-FKM/REC/022 Laboratory Manual Registration Log Book

6.2 UMP-FKM/REC/009 Customer Feedback Form

7.0 Policy and Procedure Instructions

7.1 Policy

FKM Laboratory shall establish and maintain the procedure to initiate guidelines to cooperate with customers by providing testing and calibration services and to render customer satisfaction.

7.2 Confidentiality

7.2.1 All the staff of FKM Laboratory is responsible to protect the confidential information of customer.
7.2.2 All the results of testing and calibration activities are kept in a confidential place without the existing of third party.
7.2.3 The confidential place only can be access by the Dean of the Faculty and Technical Manager.
7.2.4 Technical Manager is responsible for the storage of the confidential information and results of the testing and calibration activities.
7.2.5 All testing personnel have signed the letter of appointment of which shall prohibit them from disclosing information.

7.3 Communication with Customer

7.3.1 FKM Laboratory shall maintain good communication with customers throughout the work.
7.3.2 All written communication will be filled in the project folder, as well as the verbal communication which should be noted down in practice notes.
7.3.3 FKM Laboratory shall inform the customer any delay or deviation in the performance of the testing and calibration activities.

7.4 Witnessing

7.4.1 Customers can request to witness the testing and calibration activities in relevant areas while on the other hand protecting other customers' confidential information.
7.4.2 All the requests of witnessing shall be written and shall be reviewed by Technical Manager.
7.4.3 The details of communication, request, and job performed shall be recorded in the Laboratory Manual Registration Log Book.
7.4.4 All customer request correspondences, Laboratory Manual Registration Log Book, and other relevant documents shall be maintained.

7.5 Customer's Feedback

7.5.1 The feedback from the customers may be received in writing or through e-mail by using the Customer Feedback Form (1).
7.5.2 The feedback received is recorded and maintain by the Quality Manager.
7.5.3 It will be review and evaluated in the management review meeting (2).
7.5.4 Actions will be taken to improve the Quality Management System of the laboratory, testing and calibration activities, and customer service.

8.0 Reference

MS ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories.*

---

(1) Refer UMP-FKM/REC/008 Customer Feedback Form
(2) Refer UMP-FKM/SP/M12 Procedure for Management Review

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M05 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Complaints**	Issue No : 1 Page : 1 of 4

SYSTEM PROCEDURE

COMPLAINTS

This System Procedure is duty authorized by the Dean of Faculty and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by:

_____
Dean of Faculty
(date)

Released by:

_____
Quality Manager
(date)

	LABORATORY SYSTEM PROCEDURE	Reference: UMP-FKM/SP/M05 Revision : 0 Issue Date:
UMP FKM Laboratory	**Procedure for Complaints**	Issue No : 1 Page : 2 of 4

1.0 Purpose

This document is established to describe the procedure to resolve customer's complaints effectively.

2.0 Scope

This procedure covers all the complaints that received from internal or external customers.

3.0 Definitions

3.1 Complaint – a report of dissatisfaction with the services provided by the laboratory from customers

3.2 Internally – staff within the organization

3.3 Externally – customers outside the organization or from other companies

4.0 Responsibility

4.1 Quality Manager shall ensure all the complaints are resolved accordingly and corrective actions are carried out.

4.2 It is the responsibilities of all the staff the report all the complaints received from the customers.

4.3 Quality Manager shall review and update all the related documents when necessary.

5.0 Associated Document

5.1 UMP-FKM/QM/M01 Laboratory Quality Manual

5.2 UMP-FKM/SP/M08 Procedure for Corrective Action

5.3 UMP-FKM/SP/M12 Procedure for Management Review

6.0 Instruction for Forms

6.1 UMP-FKM/REC/009 Complaints Form

7.0 Policy and Procedure Instructions

7.1 Policy

FKM Laboratory's policy is to give priority to customers' feedback and complaints and resolve them in a stipulated period to attain continuous improvement.

7.2 Procedure

7.2.1 The staffs who receive the complaint shall be recorded in the Complaints Form (1) and referred to the attention of Quality Manager immediately.

7.2.2 The Complaints Form includes:

a) Name of company
b) Name of complaint
c) Date of complaint
d) Nature of complaint
e) Project name (if applicable)
f) Corrective action to be taken

7.2.3 Investigation

7.2.3.1 Quality Manager shall immediately look into the nature of the complaints and relate to the affected department as well as the affected persons.

7.2.3.2 All the facts and related documents on the case concerned shall be collected by the Quality Manager.

7.2.3.3 Quality Manager and the related department shall investigate the root cause of the complaints.

7.2.3.4 However, if the complaints found to be no basis, no further action will be taken. Rejection of the customer complaint shall be carried out in writing.

7.2.4 Findings

7.2.4.1 The investigation findings shall be recorded according to the Complaint Form (1) by Quality Manager.

7.2.4.2 All the related documents shall be forwarded or returned to Quality Manager after the investigation is completed and corrective action shall be carried out according to the Procedure for Corrective Action (2).

---

(1) Refer UMP-FKM/REC/001 Compliant Forms
(2) Refer UMP-FKM/SP/M08 Procedure for Corrective Action

7.2.4.3 Quality Manager will maintain all the related documents and review in the Management Review (1).

8.0 Reference

MS ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories.*

(1) Refer UMP-FKM/SP/M12 Procedure for Management Review

4.4 FORMS AND RECORDS

Forms and records that had been proposed are as below:

i. Amendment Record
ii. Issue Control Sheet
iii. Laboratory Request Form
iv. Approved Vendor List
v. Supplier Evaluation Form
vi. Purchase Order
vii. List of Laboratory Equipment
viii. Customer Feedback Form
ix. Complaints Form

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M001

AMENDMENT RECORD SHEET

Date	Document Types/Reference	Context

Prepared by:

_____
Quality Manager
Date:

Approved by:

_____
Quality Manager
Date:

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M002

ISSUE CONTROL SHEET

DOCUME-NT TYPE	RELEVANT TO FKM QUALITY MANAGEMENT SYSTEM OPERATIONS	INITIAL ISSUE IDENTIFICATION PARTICULARS	STORAGE LOCATION	ARCHIVING PERIOD (YEAR)	RESPONSIBIL-ITY

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M003

LABORATORY REQUEST FORM

Requestor:	
Name of Company and Address:	
Tel:	E-mail:
Part Name:	
Tests Requested: Metals: Aluminium ( ) Cast Iron ( ) Steel ( ) Brass ( ) Titanium ( ) Plastic: PP ( ) ABS ( )	
Remarks:	

Signature:

_____
(name)
Date:

Review by

_____
Quality Manager
Date:

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M004

APPROVED VENDOR LIST

No.	Vendor	Equipments	Approved Date

Prepared by:

_____
Technical Manager
Date:

Review by:

_____
Technical Manager
Date:

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M005

SUPPLIER EVALUATION FORM

Supplier Name and Address:	
Tel:	E-mail:

	Rating	Comments
Quality: A. Quality System	_____	_____
B. Concern for Quality	_____	_____
Price: A. Price – Quality	_____	_____
B. Price – Negotiation/quote	_____	_____
= Actual Price	_____	_____
Performance: A. Technical Ability	_____	_____
B. Capability	_____	_____
C. On-time delivery	_____	_____
D. Technical Assistance	_____	_____

Rating: Excellent 5
Good 4
Average 3
Poor 2
Very poor 1
Negative 0

Take the total points from each rated block and divide by the total blocks rated for the supplier.

$$\frac{\text{Total Points from blocks}}{\text{Total Blocks Rated}} = \text{____}$$

Must be > 2. If ≤ 2, supplier development must be considered.

Prepared by:

_____
Technical Manager
Date:

Review by:

_____
Quality Manager
Date:

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M006

PURCHASE ORDER FORM

Purchase Order: Date:

Project Number:

Vendor:

Part Name	Quantity	Description	Required Date	Price
			TOTAL	

Ordered by:

_____
(name)
Date:

Authorized by:

_____
(Quality Manager)
Date:

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M007

LIST OF LABORATORY EQUIPMENT

No.	Equipment / Apparatus	Date

Prepared by:

_____
Technical Manager
Date:

Review by:

_____
Technical Manager
Date:

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M008

CUSTOMERS FEEDBACK FORM

Name:	
Name of Company and Address:	
Tel:	E-mail:
Suggestion(s):	
Department dealing with :	
Person(s) dealing with:	
Corrective Action:	

Signature:

_____
(name)
Date:

Review by

_____
Quality Manager
Date:

FKM LABORATORY
FACULTY OF MECHANICAL ENGINEERING
UNIVERSITI MALAYSIA PAHANG (UMP)

UMP-FKM/REC/M009

COMPLAINTS FORM

Name:	
Name of Company and Address:	
Tel:	E-mail:
Project Name: (if applicable)	
Exact Nature of the Complaint:	
Department dealing with :	
Person(s) dealing with:	
Corrective Action:	

Signature:

_____
(name)
Date:

Review by

_____
Quality Manager
Date:

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

In this project, the development of quality documents of MS ISO/IEC 17025:2005 is being carried out by understanding the clause, laboratory visit, and developing the quality manual. On the other hand, system procedure, forms and records were also being developed.

The objectives had achieved, which are to study and identify the clauses of MS ISO/IEC 17025:2005 as well as to develop the quality manual and system procedure for FKM Laboratory according to MS ISO/IEC 17025:2005. The requirements of the standard also had been studied as well as the requirements of ISO 9001:2000. The studies that relate to quality such as total quality management (TQM) and quality management system (QMS) were also being studied.

In order to achieve the objectives, it is very important to understand the clauses and make sure all the documentation developed is in the correct path. Therefore, a MS ISO/IEC 17025:2005 course was attended and the laboratory visit in Shah Alam. The quality documents such as quality manual and system procedure were developed for clause 4.1 to clause 4.8.

In this way, FKM Laboratory can be accredited to MS ISO/IEC 17025:2005 and mechanical engineers with high level of knowledge, learning capability, competency and integrity can be produced. By the way, the research and development activities can be

enhance as well as the P&P (pengajaran dan pembelajaran), which also known as lesson and learning.

5.2 RECOMMENDATIONS

To have a clearer mind in the development of the quality system as well as the development of quality documents such as quality manual and system procedure of MS ISO/IEC 17025:2005 for FKM Laboratory, it is recommended that:

i. A team that develops the quality system of MS ISO/IEC 17025:2005 shall be established.
ii. Two or three more laboratories that accredited to MS ISO/IEC 17025:2005 shall be chosen to visit by the team that develops the quality documents.
iii. Benchmarking on the accredited laboratory shall be done.
iv. Using ISO software to create the ISO files and to manipulate the content of existing ISO files.
v. A training program on developing the quality documents as well as checking the documents that developed shall be given to the team that develops the quality documents.

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APPENDIX A1

THE CONTENT OF ISO 17025:2005

1. Scope
2. Normative references
3. Terms and definitions
4. Management requirements
   - 4.1 Organization
   - 4.2 Management system
   - 4.3 Document control
     - 4.3.1 General
     - 4.3.2 Document approval and issue
     - 4.3.3 Document changes
   - 4.4 Review of request, tenders and contracts
   - 4.5 Subcontracting of tests and calibrations
   - 4.6 Purchasing services and supplies
   - 4.7 Service to the customer
   - 4.8 Complaints
   - 4.9 Control of nonconforming testing and/or calibration work
   - 4.10 Improvement
   - 4.11 Corrective action
     - 4.11.1 General
     - 4.11.2 Cause analysis
     - 4.11.3 Selection and implementation of corrective actions
     - 4.11.4 Monitoring of correction actions
     - 4.11.5 Additional audits
   - 4.12 Preventive action
   - 4.13 Control of records
     - 4.13.1 General
     - 4.13.2 Technical records
   - 4.14 Internal audits

- 4.15 Management reviews

5. Technical requirements
   - 5.1 General
   - 5.2 Personnel
   - 5.3 Accommodation and environmental conditions
   - 5.4 Test and calibration methods and method validation
     - 5.4.1 General
     - 5.4.2 Selection of methods
     - 5.4.3 Laboratory-developed methods
     - 5.4.4 Non-standard methods
     - 5.4.5 Validation of methods
     - 5.4.6 Estimation of uncertainty measurement
     - 5.4.7 Control of data
   - 5.5 Equipment
   - 5.6 Measurement traceability
     - 5.6.1 General
     - 5.6.2 Specific requirements
     - 5.6.3 Reference standards and reference materials
   - 5.7 Sampling
   - 5.8 Handling of test and calibration items
   - 5.9 Assuring the quality test and calibration results
   - 5.10 Reporting the results
     - 5.10.1 General
     - 5.10.2 Test reports and calibration certificates
     - 5.10.3 Test reports
     - 5.10.4 Calibration certificates
     - 5.10.5 Opinions and interpretations
     - 5.10.6 Testing and calibration results obtained from subcontractors
     - 5.10.7 Electronic transmission of results
     - 5.10.8 Format of reports and certificates
     - 5.10.9 Amendments to test reports and calibration certificates

APPENDIX A2

THE CONTENT OF ISO 9001:2000

1. Scope
    1.1 General
    1.2 Application
2. Normative reference
3. Terms and definition
4. Quality management system (QMS)
    4.1 General requirements
    4.2 Documentation requirements
        4.2.1 General
        4.2.2 Quality manual
        4.2.3 Control of documents
        4.2.4 Control of records
5. Management responsibilities
    5.1 Management commitment
    5.2 Customer focus
    5.3 Quality policy
    5.4 Planning
        5.4.1 Quality objectives
        5.4.2 Quality management system planning
    5.5 Responsibilities, authority, and communication
        5.5.1 Responsibility and authority
        5.5.2 Management representative
        5.5.3 Internal communication
    5.6 Management review
        5.6.1 General
        5.6.2 Review input
        5.6.3 Review output
6. Resource management

- 6.1 Provision of resources
- 6.2 Human resources
  - 6.2.1 General
  - 6.2.2 Competence, awareness, and training
- 6.3 Infrastructure
- 6.4 Work environment

7. Product Realization
   - 7.1 Planning for product realization
   - 7.2 Customer related processes
     - 7.2.1 Determination of requirements related to the product
     - 7.2.2 Review of requirements related to the product
     - 7.2.3 Customer communication
   - 7.3 Design and development
     - 7.3.1 Design and development planning
     - 7.3.2 Design and development input
     - 7.3.3 Design and development outputs
     - 7.3.4 Design and development review
     - 7.3.5 Design and development verification
     - 7.3.6 Design and development validation
     - 7.3.7 Control of design and development changes
   - 7.4 Purchasing
     - 7.4.1 Purchasing process
     - 7.4.2 Purchasing information
     - 7.4.3 Verification of purchased product
   - 7.5 Production and service provision
     - 7.5.1 Control of production and service provision
     - 7.5.2 Validation of processes for production and service provision
     - 7.5.3 Identification and traceability
     - 7.5.4 Customer property
     - 7.5.5 Preservation of product
   - 7.6 Control of monitoring and measuring device

8. Measurement, analysis, and improvement
    - 8.1 General
    - 8.2 Monitoring and measurement
        - 8.2.1 Customer satisfaction
        - 8.2.2 Internal audit
        - 8.2.3 Monitoring and measurement of processes
        - 8.2.4 Monitoring and measurement of product
    - 8.3 Control of nonconforming product
    - 8.4 Analysis of data
    - 8.5 Improvement
        - 8.5.1 Continual improvement
        - 8.5.2 Corrective action
        - 8.5.3 Preventive action

APPENDIX B

Nominal Cross-References to ISO 9001:2000

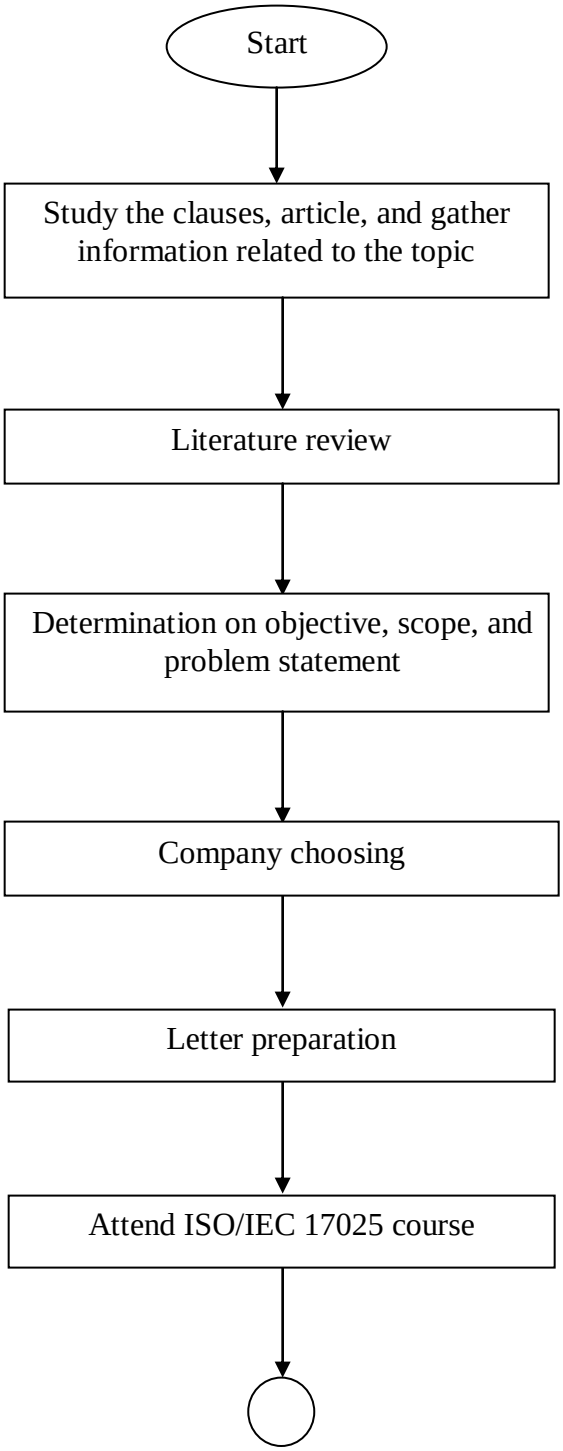
ISO 9001:2000	**ISO/IEC 17025**
Clause 1	Clause 1
Clause 2	Clause 2
Clause 3	Clause 3
4.1	4.1, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.2, 4.2.1, 4.2.2, 4.2.3, 4.2.4
4.2 1	4.2.2, 4.2.3, 4.3.1
4.2.2	4.2.2, 4.2.3, 4.2.4
4.2.3	4.3
4.2.4	4.3.1, 4.12
5.1	4.2.2, 4.2.3
5.1 a)	4.1.2, 4.1.6
5.1 b)	4.2.2
5.1 c)	4.2.2
5.1 d)	4.15
5.1 e)	4.1.5
5.2	4.4.1
5.3	4.2.2
5.3 a)	4.2.2
5.3 b)	4.2.3
5.3 c)	4.2.2
5.3 d)	4.2.2
5.3 e)	4.2.2
5.4.1	4.2.2 c)
5.4.2	4.2.1

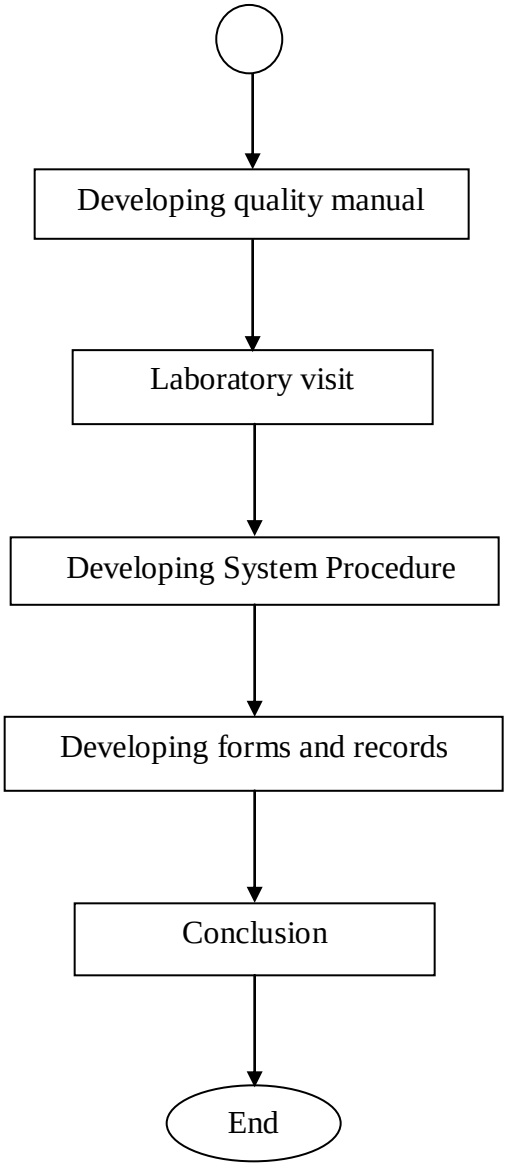
5.4.2 a)	4.2.1
5.4.2 b)	4.2.1
5.5.1	4.1.5 a), f), h)
5.5.2	4.1.5 i)
5.5.2 a)	4.1.5 i)
5.5.2 b)	4.11.1
5.5.2 c)	4.2.4
5.5.3	4.1.6
5.6.1	4.15
5.6.2	4.15
5.6.3	4.15
6.1 a)	4.10
6.1 b)	4.4.1, 4.7, 5.4.2, 5.4.3, 5.4.4, 5.10.1
6.2.1	5.2.1
6.2.2 a)	5.2.2, 5.5.3
6.2.2 b)	5.2.1, 5.2.2
6.2.2 c)	5.2.2
6.2.2 d)	4.1.5 k)
6.2.2 e)	5.2.5
6.3.1 a)	4.1.3, 4.12.1.2, 4.12.1.3, 5.3
6.3.1 b)	4.12.1.4, 5.4.7.2, 5.5, 5.6
6.3.1 c)	4.6, 5.5.6, 5.6.3.4, 5.8, 5.10
6.4	5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5
7.1	5.1
7.1 a)	4.2.2
7.1 b)	4.1.5 a), 4.2.1, 4.2.3
7.1 c)	5.4, 5.9

7.1 d)	4.1, 5.4, 5.9
7.2.1	4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 5.4, 5.9, 5.10
7.2.2	4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 5.4, 5.9, 5.10
7.2.3	4.4.2, 4.4.4, 4.5, 4.7, 4.8
7.3	5, 5.4, 5.9
7.4.1	4.6.1, 4.6.2, 4.6.4
7.4.2	4.6.3
7.4.3	4.6.2
7.5.1	5.1, 5.2, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9
7.5.2	5.2.5, 5.4.2, 5.4.5
7.5.3	5.8.2
7.5.4	4.1.5 c), 5.8
7.5.5	4.6.1, 4.12, 5.8, 5.10
7.6	5.4, 5.5
8.1	4.10, 5.4, 5.9
8.2.1	4.10
8.2.2	4.11.5, 4.14
8.2.3	4.11.5, 4.14, 5.9
8.2.4	4.5, 4.6, 4.9, 5.5.2, 5.5.9, 5.8, 5.8.3, 5.8.4, 5.9
8.3	4.9
8.4	4.10, 5.9
8.5.1	4.10, 4.12
8.5.2	4.11, 4.12
8.5.3	4.9, 4.11, 4.12

APPENDIX C

FLOW CHART/PROJECT FLOW FOR FYP




Developing quality manual
Laboratory visit
Developing System Procedure
Developing forms and records
Conclusion
End