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

LEW HON CHUNG

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
UNIVERSITY MALAYSIA PAHANG

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EXAMINERS APPROVAL

We certify that the project entitled “Development of MS ISO/IEC 17025 Quality System (General Requirements for the Competence of Testing and Calibration Laboratories) for FKM Laboratory” is written by Lew Hon Chung. 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 DECELARATION

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.

Signature

Name of Supervisor : MAHENDRAN SAMYKANO

Position : LECTURER

Date :

STUDENT'S DECLARATION

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

Signature

Name : LEW HON CHUNG

ID Number : ME 06020

Date :

Dedicate to my parents,
brothers, sister and
all my best friends

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ABSTRACT

This report describe about the development of MS ISO/IEC 17025:2005 quality manual and system procedure for FKM laboratory, University Malaysia Pahang (UMP). This report consists of five chapters which are Introduction, Literature Review, Methodology, Results and Conclusion. The objectives of this project are study and identify the clauses of MS ISO/IEC 17025:2005 and develop the quality manual and system procedure according to the standard requirement for FKM laboratory. Studies and understanding the clauses is important before developing the quality manual and system procedure. This standard is divided to two main requirements which are management requirement and technical requirement. The management requirement of this standard is similar with the requirement of ISO 9001. The requirement of ISO 9001 was being studies. A workshop of MS ISO/IEC 17025:2005 was being attended to understand more clear on the clauses and some important information to develop the quality manual and system procedure. After that, one of the accredited MS ISO/IEC 17025 laboratories has been chosen to visit. It was also to understand more deep in developing the quality manual and system procedure; and ensures that the quality manual and system procedure is developing in the right path. The quality manual is developing as the policy and objective of the laboratory. The system procedure will been develop as a procedure to achieve the objective of the quality manual. The forms are creating as an evidence to support the requirements of the standard. The quality manual had been developed from clause 4.9 to clause 4.15 which is clauses of management requirement of the standard. The system procedure also had been developed for each of the clauses except the clause 4.10 improvement. This clause not required any system procedure because this clause had related with the entire clause to ensure that the quality management system is continual improve. Some of the form had been created such as Non-Conforming Investigation Form, Corrective and Preventive Action Form. The schedule for the internal audit and management review had been developed. The audit checklist had been created for the auditor use during the audit process. All the documents will be proposed to FKM laboratory for the accreditation of MS ISO/IEC 17025:2005. In conclusion, the objective of the project had been achieved where the entire related document had been developed.

ABSTRAK

Laporan ini membentangkan tentang menyediakan sistem manual kualiti dan prosedur untuk MS ISO/IEC 17025:2005 pada makmal FKM Universiti Malaysia Pahang (UMP). Laporan ini terdiri daripada lima bab iaitu Pengenalan, Tinjauan Pustaka, Metodologi, Keputusan dan Kesimpulan. Objektif projek ini ialah mengkaji dan mengenalpasti klausa daripada MS ISO/IEC 17025:2005 dan menyediakan sistem manual kualiti dan prosedur yang sesuai dengan keperluan piawai untuk FKM makmal. Belajar dan memahami klausa adalah penting sebelum menyediakan sistem manual kualiti dan prosedur. Piawaian ini dibahagi kepada dua bahagian iaitu bahagian keperluan pengurusan dan bahagian keperluan teknikal. Keperluan pengurusan piawai ini adalah lebih kurang same dengan keperluan piawai ISO 9001. Piawai ISO 9001 juga perlu memahami dengan jelas. Satu Bengkel tentang MS ISO/IEC 17025:2005 telah disertai bertujuan memahami lebih lanjut tentang piawai tersebut dan mengumpul maklumat-maklumat penting untuk menyediakan manual kualiti dan prosedur. Selepas itu, salah satu makmal yang telah mendapat terakreditasi MS ISO/IEC 17025:2005 telah dipilih untuk dikunjungi. Ini juga dapat memahami lebih dalam untuk menyediakan manual kualiti dan prosedur dan memastikan manual kualiti dan prosedur yang dihasilkan mengikut arah yang betul. Manual kualiti disediakna sebagai dasar dan tujuan makmal. Sistem prosedur disediakan sebagia prosedur untuk mencapai tujuan manual kualiti. Borang-borang yang tertentu disediakan sebagai bukti untuk menyokong keperluan piawai tersebut. Manual kualiti yang telah disediakan adalah daripada klausa 4.9 ke klausa 4.15. klausa tersebut adalah klause keperluan pengurusan bagi piawai tersebut. Prosedur bagi setiap clause telah juga disediakan kecuali klause 4.10. klause 4.10 tidak memerlukan prosedur kerana klause ini berkaitan rapat dengan klause yang lain dan klause ini bertujuan untuk memastikan sistem pergurusan kualiti sentiasa diperbaiki. Beberapa borang telah disediakan seperti borang penyelidikan ketidaksesuaian, borang tindakan koretif dan borang tindakan pencegahan. Jadual untuk audit dalaman and tinjauan pergurusan telah disediakan. Senarai semak audit telah disediakan untuk kegunaan semase audit prosess. Semua dokumen yang disediakan adalah untuk FKM makmal mendapat akreditasi MS ISO/IEC 17025:2005. Kesimpulannya, tujuan projek ini telah dicapai di mana semua dokumen telah dihasilkan.

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LIST OF ABBREVIATIONS

FKM	Fakulti Kerjuruteraan Mekanikal
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MS	Malaysia Standard
NC	Non-Conformance
QMS	Quality Management System
SAMM	Skim Akreditasi Makmal Malaysia
TQM	Total Quality Management
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 on development of MS ISO/IEC 17025 quality system for FKM laboratory.

1.2 Project Background

ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standard. In this project, we are going to implement the MS ISO/IEC 17025:2005 to our FKM laboratory. MS ISO/IEC 17025:2005 specifies general requirements for the competence to carry out tests and/or calibrations, including sampling. It is applicable for all organization that performing tests and/or calibrations. MS ISO/IEC 17025 consists of 15 management clauses and 10 technical clauses. This ISO standard is use to develop the laboratory high quality management system and technical operations.

In order to get the accredited the MS ISO/IEC 17025, we have to satisfy the requirements of the ISO/IEC 17025. We have to study and apply the technical and management requirement of the ISO/IEC 17025. The requirement documentation is quality manual, master plans, standard operation procedures and records. Firstly, they include the high level policy which is the quality manual to document the laboratory strategy and

planning. The quality manual is the quality plan that should document the laboratory overall concept on how to comply with MS ISO/IEC 17025. Next are the procedures, templates and checklist for the implementation. Finally are recorded the calibration records, maintenance, training records and test results.

By implement the MS ISO/IEC 17025, it enhancing the laboratory competence to be recognized nationally and internationally. It is also building up the confidence and reliability in the test results or calibration results generated by the accredited laboratory and the facilitating trade in national and international market. The accredited laboratory will be used as testing unit of the regulator.

1.3 Project Objective

The project objective is to:

i. Study and identify the clauses of MS ISO/IEC 17025:2005.
ii. Develop the quality manual and system procedures for FKM laboratory according to MS ISO/IEC 17025:2005.

1.4 Project Scope

i. The general knowledge of the clauses MS ISO/IEC 17025:2005.
ii. The application of the management requirements of MS ISO/IEC 17025:2005 from clause 4.9 to clause 4.15.
iii. Develop the quality manual and system procedures of MS ISO/IEC 17025:2005 at FKM laboratory.

1.5 Problem statement

According to the University Malaysia Pahang, Faculty Mechanical Engineering (FKM) vision is to become a world class competency-based mechanical engineering faculty. The mission is to produce global mechanical engineering with high level of knowledge, learning

capability, competency and integrity. Moreover, FKM committed to enhance research and development towards introducing commercial viable products and services in manufacturing and automotive sectors. On the way to achieve the vision and mission, one of the ways is accredited to the ISO standard. ISO standards that can implementation in FKM laboratory is MS ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* for the automotive laboratory. This is a way for FKM to achieve the vision and provide a high quality of management and technical service in FKM laboratory.

At this present, the testing and/or calibration activities quality level are question mark. The research and development done by the lecturer and student are not recognized by other organization. Even how good the research and development have been done but other people are not recognized it otherwise if there have been certificated with ISO series quality. By implement the MS ISO/IEC 17025, the testing and/or calibration activities can perform in standard quality level. It also enhances the procedure of testing and/or calibration activities. This will improve the P&P (pengajaran dan pembelajaan), which is lesson and learning through the testing and/or calibration experiment that related to the subject course. Moreover, the research activities and development will be acceptable internationally.

1.6 The Importance of the Study

Nowadays, quality is important in business and industries world. Many of the customer required high quality product and service. In order to fulfill the requirement of the customer, the company must have a quality system to ensure that their product or service that provided has high quality to fulfill the customer requirement.

For a laboratory that only provided testing and calibration to the customer, the laboratory should have a quality system that to ensure the testing and calibration result has high quality that fulfill the requirement of the customers. MS ISO/IEC 17025 is one of the standard for testing and calibration activities. If the laboratory has been accredited with this standard, the testing and calibration results are being recognize by internationally. The

engineering who involve with the testing and calibration activities must have the quality system knowledge to ensure that the testing and calibration result are reliable and confidential.

In this project, some of the clauses in MS ISO/IEC 17025:2005 contain mechanical elements that required engineering knowledge to fulfill the requirements of the standard. The ISO standard is one of the Industrial Engineering tools.

During developing the quality manual, the policy of the quality manual must follow the requirement of the MS ISO/IEC 17025:2005 requirements. The system procedure is developed according to the imagination when facing the problem and it is developed to solve the problem. For examples the non-conforming work occurred in the tensile test, the procedure will be developed with detail process to be follow to solve the non-conforming work using the mechanical engineering knowledge about the tensile test. With the mechanical engineering knowledge, it will be easier for the responsible personnel to investigate and solve the problem because they are knowledgeable in the tensile test machine. The form will be created for the responsible personnel to fill the investigation information and the result of the corrective action or preventive action. The criteria in the form in create is necessary information for the responsible personnel to fill in.

According to the requirement of the standard, uncertainty of the test method and equipment of the testing machine should have the procedure to estimate the uncertainty. As a mechanical engineer should have the knowledge on how to estimate the uncertainty of the test method and equipment of the testing. The knowledge are being use to develop the procedure for other responsible personnel to follow the instruction to estimate the uncertainty. It is important to ensure the result reported does not give any wrong impression of uncertainty.

The testing method should be undergoing validation process according to the standard requirement. Method validation is to ensure that the analytical methodology is accurate, specified, reproducible and rugged over the specified range that an analytic will

be analyzed. All the analytical methods must be validated and used, appropriately in order to ensure that reliable test results are produced. If the laboratory has adopted the standardized testing method, the testing method has to verify and ensure that the method is suitable for the analytical before putting it into use. .

1.7 Benefit

i. Enhance the laboratory competence to be recognized nationally and internationally.
ii. The accredited laboratory can generated the confidence and reliability in test results and calibration results.
iii. Provide standard testing and/or calibration service for customer.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

A review of the literature was performed to identify studies relevant to the topic. The main sources for the literature search was MS ISO/IEC 17025:2005 quality manual. Other sources including book, online book and online website such as Simply Quality. Combinations of the keywords were used to identify relevant material; ISO, ISO 17025, ISO 9001, ISO 900, quality, quality management, total quality management. A limited number of studies were found that the detail on procedures to implement the ISO 17025 and the overview for the detain content of the ISO 17025. All the details for the ISO standard are requiring payment. The documentation details are private and cannot publish for all the public. Most of the studies are about the general definition and information. Besides, studies about the comparison between the ISO 17025 with ISO 9001. After that, studies the general step of implementation MS ISO 17025:2005. The emergent themes may be divided into quality, quality management, total quality management, ISO 9000, ISO 9001, ISO 17025, comparison of ISO, documenting the ISO standard.

2.2 Quality

In technical usage, the word *quality* is widely accepted to have two meaning which are (Quality Glossary, 2002):

i. A characteristic of a product or service that bears on its ability to satisfy stated or implied needs.
ii. A product or service free of deficiencies.

Other definition:

Broadly categorized, there quality experts' definition of quality fall into two categories (Hoyer, 2001):

i. Quality is about satisfying applicable specification. Quality is a simple matter of producing products or delivering services whose measurable characteristic satisfies a fixed set of specifications that usually are numerically defined.

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

2.2.1 Philip B. Crosby

Philip B. Crosby is one of the quality gurus. According to Crosby, the definition of quality is conformance to requirement. Crosby had stated five absolutes of quality management (Beckford, 2002):

2.2.1.1 Quality as Conformance.

The quality product or service is referring to one which meets the requirements of the customer. Management must establish requirements help the employees to get the job done.

2.2.1.2 No Such Thing as a Quality Problem.

The product and service quality do not exist as a matters, they are a result of the management process. If the process has inherent quality, then the product will emerge. The management must lead the worker toward the quality outcomes.

2.2.1.3 Always Cheaper First Time.

A company relies that mass inspection of the final output to improve quality id doomed to stagnation. It is possible for the company to go further. So, Crosby suggested that a company focused on inspection will be achieving more than it deserves if it stagnates.

2.2.1.4 The Measurement of Performance is the Cost of Quality.

The cost of quality is always a measurable item.

2.2.1.5 Zero Defects.

By developed a quality process and product from the outset with no expectation of failure.

2.2.2 Quality Management

Quality management comprises all activities that are required to plan for quality in an organization and all activities that are required to satisfy quality objectives (Nanda, 2005).

2.2.2.1 Content of Quality Management

Quality management comprises the following four elements:

Table 2.1: Elements of Quality Management

Element	Description
Quality planning	Establish a quality objective as the target to achieve it. The achievement can plan incrementally, so that it can continue improvement towards to achieve the objective. The planning is depend on the product release cycle time which is the period time that the organization begin with initial identification of product until final product to the customer.
Quality control	The quality activities use to detect and eliminate defect in a product. The organization needs to monitor a process to ensure its output reach the required quality and correct discrepancies when it's occur.
Quality assurance	Quality assurance include the planned and systematic activities implement the quality system to provide confidents that a product or service will fulfill the requirement quality (Quality Glossary, 2002). It is not guarantee that the requirement for quality will be meet.
Quality improvement	Quality improvements defined as enhance in the effectiveness and efficiency of process, and enhance in the extent to which a product satisfies applicable requirement. The quality improvement for a product or service is never ending and keeps on continual quality improvement.

Source: Nanda (2005)

2.3 Total Quality Management

Total quality management (TQM) is a continuous process of improvement for individual, groups of people and whole organizations (Kanji & Asher, 1996).

TQM is "a system of continuous improvement employing participative management and centered on the needs of customers" (Jurow & Barnard, 1993). Key components of TQM are employee involvement and training, problem-solving teams, statistical methods, long-term goals and thinking, and recognition that the system, not people, produces inefficiencies. Libraries can benefit from TQM in three ways: breaking down interdepartmental barriers; redefining the beneficiaries of library services as internal customers (staff) and external customers (patrons); and reaching a state of continuous improvement (Jurow & Barnard, 1993).

The methods for implementing this approach come from the teachings of such quality leaders as Philip B. Crosby, W. Edwards Deming. The principle of TQM is based on the Deming's fourteen points (Beckford, 2002):

i. Create constancy of purpose to improve product and service.
ii. Adopt a new philosophy for new economic age, with management learning what their responsibilities are and assuming leadership for change.
iii. Cease dependence on mass inspection to achieve quality, by building quality into the product.
iv. End the awarding of business on price; award business on total cost and move towards single suppliers.
v. Aim for contribution improvement of the system of production and service to improve productivity and quality and to decrease.
vi. Institute training on the job.
vii. Institute leadership with the aim of supervising people to help them to do a better job.
viii. Drive out fear so that everyone can work effectively together for the organization.

ix. Break down barriers between departments. Encourage research, design, sales and production to work together to foresee difficulties in production and use.

x. Eliminate slogans, exhortations and numerical targets for the workforce since they are divisor and anyway difficulties belong to the whole system.

xi. Eliminate quotes or work standards and management by objectives or numerical goals; leadership should be substituted instead.

xii. Remove barriers that rob people of their right to pride in their work.

xiii. Institute a vigorous education and self-improvement.

xiv. Put everyone in the company to work to accomplish the transformation.

2.4 ISO 9001:2000 Quality Management

ISO 9001:2000 Quality Management defines as what the organization does to ensure that its products or services satisfy the customer's quality requirements and comply with any regulations applicable to those products or services.

2.4.1 Overview and Content of ISO 9001:2000 Quality Management

Content of ISO 9001:2000 consists of quality management system, management responsibility, resources management, product realization requirement, and measurement, analysis and improvement requirements. The contents refer to Appendix A. The standard consists of eight sections. The important section is section four to section eight (Simply Quality, 2001).

2.4.1.1 Section 4: Quality Management System

The quality management system is the collection of processes, documents, resources and monitoring system in an organization regarding to the product and service quality. The documentation requirements are quality manual, quality policy and quality objective. Quality manual is the document that describes the processes of implement the standard.

2.4.1.2 Section 5: Management Responsibility

The top management in an organization has the responsibilities on establish the quality policy and quality objective, product and service quality, provide the operation of QMS, and review the operation of the QMS. The quality policy is the main goal of QMS that set by the organization. The top management must appoint a person to ensure the process flow of QMS, reporting the performance and analysis the product and customer service.

2.4.1.3 Section 6: Resource Management

It is provide the people, equipment, tools, and material need to maintain the QMS. Organization should ensure that the personnel have the certain level of education, training, skills and experience to carry out the work. The work environment must meet the quality requirements.

2.4.1.4 Section 7: Product Realization

The product is undergoes verification, monitoring, inspection and test activities, so that the product reach the requirement. The requirement needs to review and explain the product to the customer. Customer will be informing about the product information and give the feedback about the product and service that the organization provide. Organization need to defined the design and development process and establish the responsible and authority of the personnel.

The output product must reach the requirements of the product. Review the design and development work product and identify the solution if the product fail to meet the requirements. Verify according to the design and development planning. Organization must establish criteria of choosing the suppliers based on the suppliers ability to provide the product or service.

Plan production, installation, and service process and provide an environment in a work condition which can proceed in an orderly fashion. Process validation demonstrates that operation of the process achieves the planned result. Organization must take care on the customer property. The measuring equipment must take care in good condition and ensure that it reach the high accuracy on measurement.

2.1.4.5 Section 8: Measurement, Analysis and Improvement Requirements

The QMS are planned with improvement procedures and ensure that the product reach the requirement. Compare the actual result and planned result, so can plan corrective action to make sure the product and service reach the requirement. Monitor and measure the product to reach the requirement. Organization need to collect the data and analysis the effectiveness of the system. Establish the solution when problem occurs. Preventive action involves identification the problem, root cause, and planning to prevent the problem being occurred.

2.5 ISO/IEC 17025:2005 General Requirements for Competence of Test and Calibration Laboratories.

ISO 17025 contain all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results (ISO/IEC 17025, 2005). ISO 17025 is applies to all organization that performing tests and/or calibration.

Growth in the use of management systems generally has increased the need to ensure that laboratories which form part of larger organization or offer other services can operate to a quality management system that is seen as compliant with ISO 9001 as well as with this International Standard (ISO/IEC 17025, 2005). Therefore, ISO 17025 was written to all incorporate all the ISO 9001 requirements that are relevant to the scope of testing and calibration services as well as specifying the technical requirement for technical competence.

2.5.1 Testing and Calibration

Testing in human being tells what level of knowledge or skill has been acquired. In computer hardware and software development, testing is used at key checkpoints in the overall process to determine whether objectives are being met (SeachWinDevelopment).

Calibration is the process of determining the performance parameters of an artifact, instrument, or system by comparing it with measurement standards (Answers). Calibration assures that a device or system will produce results which meet or exceed some defined criteria with a specified degree of confidence.

2.5.2 History

ISO 17025 was first published in 1999 as a replacement to ISO Guide 25. The first edition referred to ISO 9001:1994 and ISO 9002:1994 (ISO/IEC 17025, 2005). In year 2000, there standard have been superseded by ISO 9001:2000.

ISO Guide 25 was a well used document published by ISO, but did not have the entire management requirement that were outlined in ISO 9001:2000. ISO Guide 25 was revised and reissued in May 2005. An alignment has been made and the ISO Guide 25 was replaced by the ISO/IEC 17025:2005. ISO/IEC 17025:2005 now includes all the management requirement s that was incorporated into new ISO 9001:2000 standard. ISO 17025:2005 is the most up to date version.

Accreditation bodies recognize that the competence of testing and calibration laboratories should use this International Standard as the basis for their accreditation (ISO/IEC 17025, 2005).

2.5.3 Content of MS ISO/IEC 17025

Content MS ISO/IEC 17025 has 15 management requirements and 10 technical requirements. The 15 management clauses are the requirements for the management in an organization. The management requirement is more on planning for improvement, service for the customer, formation of the organization and internal auditing system. The 10 technical clauses are the requirement more on the testing and/or calibration activities, equipment, reference standard and result of report. The content of MS ISO/IEC 17025 can refer to the Appendix B.

2.5.4 Overview of the Content of MS ISO/IEC 17025:2005

The ISO 17025 standard is comprised of 5 elements:

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

Element 4 and 5 contains the actual accreditation requirements. There are 15 management requirements and 10 technical requirements. These requirements outline what a laboratory must do to become accredited. The overview details of management requirement technical requirement are show in below (ISO/IEC 17025, 2005).

2.5.5 Element 4: Management Requirement

4.1 Organization

The laboratory needs to define the organization management structure. Specify the responsibility of the organization and personnel in testing and calibration activities.

4.2 Management system

Establish, implement and maintain the management system. The quality policy statement should be defined in quality manual. The quality manual includes quality service; standard service; the roles and implement the policy and procedure; responsibilities of testing and calibration.

4.3 Document control

All the documents issued to personnel should be review and approved for use by authorized personnel prior to issue. Revised to ensure that continuing suitability and compliance with applicable requirements.

4.4 Review of request, tenders and contracts

Establish and maintain procedures for the review of requests, tenders and contracts including the method use for requirement. Record of review shall be maintained. It covers any work that is subcontracted by the laboratory. Contract review process shall be repeated and any amendments shall be communicated to all affected person.

4.5 Subcontracting of test and calibration

When the overload works occur, the work will sub to the subcontractor. Laboratory is responsible with the subcontractor work and maintains a register of all subcontractors that it uses for test and/or calibrations add as record of the evidence of compliance.

4.6 Purchasing service and supplies

The reception, storage of reagents and laboratory consumable material relevant for tests and/or calibration as complying with standard requirements. Record of action taken to check compliance shall be maintain and evaluate supplies of critical consumables and supplier service.

4.7 Service to the client

Laboratory should be cooperate and provide the high quality service for the customer to ensure they confident in laboratory performance. The feedback from customer should be use to analyze for improvement purpose in management system.

4.8 Complaints

Record all the complaints from the customer, then investigate and corrective action to overcome it by laboratory.

4.9 Control of non-conforming testing and/or calibration work

Laboratory shall responsibilities and authorities for the management of nonconforming work. They should evaluation of the nonconforming work and correction action is taken. The correction action procedures should be promptly followed.

4.10 Improvement

Improve the effectiveness of its management system through the quality manual, quality objective, audit result, analysis of data, correction and preventive actions.

4.11 Corrective action

Corrective action is an action to eliminate the root cause of non-conforming work. The process of corrective action is start with investigation to determine the root cause, select the appropriate corrective action, implement and monitor the action taken.

4.12 Preventive action

Preventive action is an action to prevent the potential root cause of non-conforming work.

4.13 Control of records

Quality record should include report from internal audit and management review and also records of corrective and prevention. All record is legible. The record of testing and/or calibration shall be original with the specification information. All the data shall be keeping as record although a mistake occur in the data records.

4.14 Internal audits

The internal audit shall be perform in periodically and consist of the management system and testing and/or calibration activities. The finding of audit shall be recorded as implementation and effectiveness of the correction action that have been taken.

4.15 Management review

The top management needs to have a review on the management system and testing and/or calibration activities to ensure their suitability, effectiveness and necessary changes or improvement on their laboratory. The review covers all the documentation and the action that arises from them should be recorded.

2.5.6 Element 5: Technical Requirement

5.1 General

When carry out a testing and/or calibration activity, many factor are been determine for the correctness and reliability. The laboratory shall take account the factor that influent the result of testing and/or calibration.

5.2 Personnel

The laboratory management shall ensure the operator for specific equipment testing and/or calibration must have education requirement or have been undergo the training. The personnel should responsible with the job description in managerial, technical involve in testing and/or calibration.

5.3 Accommodation and environment condition

Laboratory shall to ensure that all the testing and/or calibration are carry out under a good environment condition such as lightning and safety.

5.4 Test and calibration method validation

Laboratory shall prepare the method, procedures and instruction for each testing and/or calibration including sampling, handling, transport and storage. The laboratory shall have instruction on the method use the equipment for testing and/or calibration. Laboratory should establish procedures for measure the uncertainty.

5.5 Equipment

The equipment must achieve the international standard and the software shall be recorded for each testing and calibration including the specification. The equipment shall be operated by authorized personnel. Laboratory have highlight the safety and maintained to ensure the equipment can functional well.

5.6 Measurement traceability

The laboratory should establish a programme and procedure for the equipment that use for testing and/or calibration purpose. Laboratory have to ensure that the testing result using that equipment must accurate and validate.

5.7 Sampling

The sampling plan and procedures shall base on appropriate statistical methods and to ensure the validity of the test and calibration results. The laboratory shall have the procedures for recording relevant data which include the sampling procedures, identification of the sample and environment condition.

5.8 Handling of test and calibration items

Laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and disposal of test and calibration items. Laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the testing and calibration during storage and handling process.

5.9 Assuring the quality of test and calibration results

Laboratory shall have quality control procedures for monitoring the validity of tests and calibration activities. The monitoring plan and review may include regular use of certification and correlation of result for different characteristic of an item.

5.10 Reporting of results

The result of the testing and/or calibration should be clearly and accurate defined in the report or a calibration certificate.

2.6 Comparison of ISO/IEC 17025:2005 with ISO 9001:2000

The management requirement and technical requirement of the ISO/IEC 17025 mainly is based on the clause of ISO 9001. ISO/IEC 17025 has specified detail on reporting of results for testing and calibration compare with ISO 9001. The control of document and record in ISO 9001 is separate to two in ISO/IEC 17025 become control of records and document control. The corrective and preventive action is more detail in ISO/IEC 17025. The nominal cross-reference ISO/IEC 17025 to ISO 9001 can refer to Appendix C.

CHAPTER 3

METHODOLOGY

3.1 Introduction

This chapter described about the methods had taken in order to develop the quality manual for FKM automotive laboratory according to MS ISO/IEC 17025:2005. Methodology is one of the most important elements to be considered to make sure that fluent of the project and get the results. In other words, methodology can be described as framework where it contains the element of the work based on the objective and scope of the project. These methods will be the guideline for this project and important procedure to ensure the flow of research move smoothly as planned. This included laboratory visit, documentation process, preparing quality manual and system procedures.

3.2 Attended MS ISO/IEC 17025:2005 Workshop

A workshop of MS ISO/IEC 17025:2005 *General requirement for the competence of testing and calibration laboratories* had been attended during the semester break at University Malaysia Pahang Gambang Campus. The workshop 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, an assessor of the Department of Standard Malaysia for the laboratory Accreditation Scheme of Malaysia (SAMM) MS ISO/IEC 17025. He had experience worked as a forensic chemist at Department of Chemistry Malaysia for 30 years

and specialize in criminalistics and narcotics. His current works as a lecturer Forensic Science Programme at University Kebangsaan Malaysia.

The main purpose of the workshop is to given a training and understanding on the clauses of the MS ISO/IEC 17025:2005 to develop the quality manual and system procedures. He gave a detail explanation for each clause and highlights the information that include in the quality manual and system procedures. He also gave the direction to get the accreditation of the MS ISO/IEC 17025 and information to maintain after gets the accreditation. He also shared his experience with the attendees.

3.3 Laboratory Visit

In Malaysia, there a lot of laboratories have the testing and/or calibration laboratories are accredited with ISO/IEC 17025.

Since FKM are going to implement for automotive laboratory, those laboratories chosen must have related to mechanical automotive testing and/or calibration. The available testing in FKM laboratory such as vibration test, hardness test, bending test and drop test.

3.3.1 Laboratory Choosing

Those laboratories can find from website of the Department of Standard Malaysia. Many types of testing and/or calibration can get from that website and also involve different field of engineering. Those laboratories chosen are related to the field of mechanical engineering.

3.3.2 Discuss with Supervisor

After discussion with supervisor about the laboratory visit, Mechanical & Automotive Section (MEST – Testing Group) SIRIM QAS International Sdn. Bhd. has been chosen. This laboratory located in Shan Alam, Selangor.

3.3.3 Letter Preparation

An official letter was prepared after contacted with the person in charge. The letter is written to inform to the person in charge about the purpose and scope of visit the laboratory. The letter need include the visit date, time and number of person involve with the visit. The purpose of the laboratory visit is to learn the methodology on preparing the quality manual and system procedures for ISO 17025.

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

3.3.4 Visit to the Laboratory

The laboratory 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 they were sent a representative Miss Siti Tasliah to in charge for the visit. Due to the person in charge was not presented, the quality documents could not be shown since it is confidential. However, Miss Siti Tasliah had given explanation in developing the system procedures.

3.4 Documentation

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. (Clause 4.1, ISO 9001:2000).

Documentation is a set of documents such as specification document, record and standard procedure operation. Document is information for all the meaningful data. Quality management system is a management system to drive and control an organization to achieve the quality standard. Quality manual is the document specifying the quality management system of an organization.

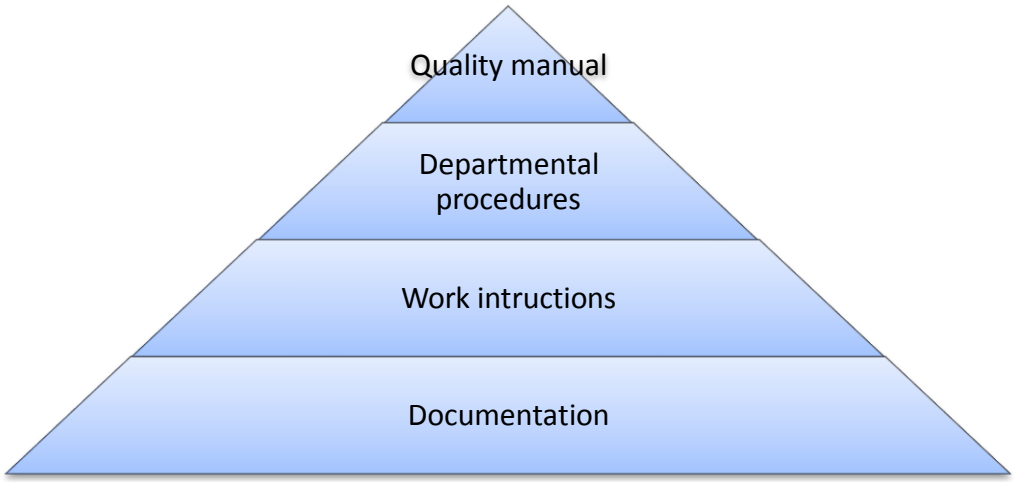

Figure 3.1 Documentation Pyramid

Sources: Hashim (2007)

3.4.1 Level 1: Quality Manual

The quality manual is at highest level document at the peak of a pyramid. The quality system and acting as a directory for the documentation and procedures for the following processes. The quality manual is need for:

Communicating the organization's quality policy procedures and requirements.

Describe and implement an effective quality system.

Provide improved control of practices and facilitating assurance activities.

Provide the documented bases for auditing the quality system.

Provide continuity of the quality system and its requirements during changing circumstances.

3.4.2 Level 2: Departmental Procedure

Departmental procedures detail on how that commitment is applied to the company operations and lay down procedures for the management to control the system.

3.4.3 Level 3: Work Instructions

Work instruction is detail the day-today operations to provide control of quality and being applied in the manner laid down in operation procedures.

3.4.4 Level 4: Documentation

Relates to all the forms, documents, records, labels, tickets, job cards, purchase orders, goods inwards notes etc. that are used to support the requirement level above.

3.5 Preparing the Quality Manual

Quality manual is the important state for the road to achieve the certification of MS ISO/IEC 17025:2005. Quality manual is the level 1 in documentation process. The quality manual is prepared based on the clauses of the requirement. The clause content in this project is management requirement from 4.9 to 4.15.

3.5.1 Clause 4.9 Control of Nonconforming Testing and Calibration Work

3.5.1.1 Quality Manual

To identify nonconforming work with regard to any aspect of testing of the results of the work do not conform to agree upon requirements of the customer.

3.5.1.2 Procedure

In an organization meeting, the top management has to recognize the important of controlling nonconforming work to every one of the staff. During the meeting, they have to assign an individual or a team to make the investigation to detect the nonconforming work. They can use the process-monitoring technique to detect the nonconforming work. A monitoring form need to create for record the information of the process of the work, final product and the service receive by the customer.

When the nonconforming work has been detected, all the process need to stop to reduce the nonconforming product. Modification for the process is needed so that the process can been continued to carry out. After the modification, the process has been undergoes re-qualified to ensure that nonconforming work does not occur. The nonconforming problem and action need to record. Customer shall be notified of nonconforming work using customer call back form. Top management or the authorized personnel will be noticed of nonconforming work using note, memo or e-mail.

The responsible personnel need to define the root cause and determine the action to solve the nonconforming work. Corrective and preventive action may include as initial required. Result of the investigation will used to improve the process and the quality management system until meet the requirement. All the applicable information need to record in nonconforming report. This report is clearly defined the natural nonconforming work and addition supporting information and implementation. This record will place in a folder.

3.5.2 Clause 4.10 Improvement

3.5.2.1 Quality Manual

Continue improve the effectiveness of management system.

3.5.2.2 Procedure

Top management has to review all the latest version of the document such as quality policy, audit result, analysis of data, corrective action, preventive action, and management review. A meeting will be held to discuss the improvement action to ensure that the management system is continuing improve. The minutes of meeting is recorded and keep it in a folder for review and reference.

3.5.3 Clause 4.11 Corrective Action

3.5.3.1 Quality Manual

To identify and disposing of nonconforming work in management system or technical operation.

3.5.3.2 Procedure

Corrective action is an action to eliminate the cause of a detected nonconformity. Top management has to assign an individual or a team responsible for the corrective action. An investigation has been done to identify the problem. These problems may involve in work process or customer complaint.

Once the problem identified, indicate the root cause and develop an action to solve the problem and ensure that the nonconforming work does not recur. Create a corrective action form to record the information of the process and action taken to solve the problem.

Top management will review the record of corrective work. After get approval from the top management, the authorities will monitor the corrective action follow the record that has been approved. A corrective action record document needs to create to record the process

after the corrective action has been taken. This record will review and evaluate by top management.

3.5.4 Clause 4.12 Preventive Action

3.5.4.1 Quality Manual

Identify the process and quality system improvement opportunities. Develop an action plans to reduce the likelihood of the occurrence of such nonconformities and improve the quality system.

3.5.4.2 Procedure

Top management need to hold a meeting to identify the improvement for nonconformities. After identify the improvement action, make the decision whether the preventive action is applicable or not. If applicable, top management has to develop a new plan to prevent the nonconformities occur. Top management has to assign an individual responsible for the new plan. After the new plan get the approval from the top management, the authorities will carry out the new plan and monitor it. The information during carry out and result need to record in the preventive action form.

3.5.5 Clause 4.13 Control of Records

3.5.5.1 Quality Manual

Maintain the quality records and effective operation of the quality management system can be demonstrated.

3.5.5.3 Procedure

Top management has to identify the latest version of the document which should be marked with the version number. Use the old version as reference and comparison with the new version. Create a record control list document. This document consist of identify quality records, person in charge, retention period, review and approval. The record can be in electronic and hard copy which may keep in office or warehouse environment. The record also needs to have a backup to prevent loss of data.

The technical record should retain records of original observation, derived data and sufficient information. The authorities should record the data during the testing or calibration is carrying out. Observation, data calculation and specific task should be including in the records.

3.5.6 Clause 4.14 Internal Audit

3.5.6.1 Quality Manual

Perform periodically according to the schedule to verify the effectiveness of the operation continue to comply with the requirement.

3.5.6.3 Procedure

Top management has to form a audit team to do the planning for the audit plan. The plan must include the objective, scope and schedule. Review the previous audit report will help them to carry out a more effective audit plan. After the new plan has done, it must propose to the top management to get the approval.

After the audit plan had been approved, a meeting will be held to brief the audit plan to each staff. Make a revision about the record of policy, system procedure, status complaint and results of management review with voluntary requirement and other relevant

document. An interview has to carry out for the staff. Observe the activities and condition of each staff. Response and evidence should be audit progress.

The audit team should hold a meeting to report the audit progress. The finding and observation will be document include the corrective action taken during the audit process. The audit documents need to summarize to form a audit result document. The final document must include the scope, describe the source of evidence used, the finding and result. Top management will responsibility to follow up the audit results.

3.5.7 Clause 4.15 Management Review

3.5.7.1 Quality Manual

Assess the effectiveness and continue suitability of the quality system to satisfy the requirements.

3.5.7.2 Procedure

Top management has to conduct a planning schedule for periodic management review. Assign an individual or team to carry out the plan. The authorities have to follow-up action from the previous management review such as customer feedback, corrective and preventive action, and results of internal audit. Conduct a review form to record the information during carry out the review process. A meeting will held to reporting the result of the review that have been done. Based on the management review, top management will determine and record whether the quality management is still effective.

3.6 Compile the Quality Manual and System Procedure

Quality manual and system procedure are the document use to apply the certification of ISO/IEC 17025. The quality manual needs to compile all the 15 clauses

management requirement and 10 clauses technical requirement. Before taking to apply the certification, quality manual must fulfill the requirement of the standard.