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

NOVEMBER 2009

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

ACKNOWLEDGEMENTS

I am grateful and would like to express my sincere gratitude to my supervisor, Mr. Mahendran of his patient; continuous encouragement and constant support in develop the quality manual and system procedure. He guided me in identifying the clauses of the standard and giving me a chance to attend the workshop of understanding of MS ISO/IEC 17025:2005. He also explains and guides me on the right path to developing the quality manual and system procedure. I am truly grateful for his progressive vision about my training in science as well as engineering, his tolerance of my naïve mistakes, and his commitment to my future career.

By the way, I would like to thank Mr. Pua Hiang and Miss Siti Tasliah for giving a good explanation for the clauses of the standard and guide me in the direction to develop the quality manual and system procedure.

My sincere thanks go to my group members that together develop the quality manual and system procedure for MS ISO/IEC 17025:2005 for FKM laboratory. They were helped me when I am facing a lot of problem. We also shared our knowledge with each other. I also would like to thank to the member of the staff of Mechanical Engineering Department, UMP, who helped me in many ways and made my stay in UMP pleasant and unforgettable.

Lastly, I acknowledge my sincere indebtedness and gratitude to my parent for their love, dream and sacrifice throughout my life. Special thanks should be given to my fellow friends. I would like to acknowledge their comments and suggestions, which was crucial for the successful completion of this study.

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.

TABLE OF CONTENTS

CHAPTER 3 METHODOLOGY

LIST OF TABLES

LIST OF FIGURES

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.

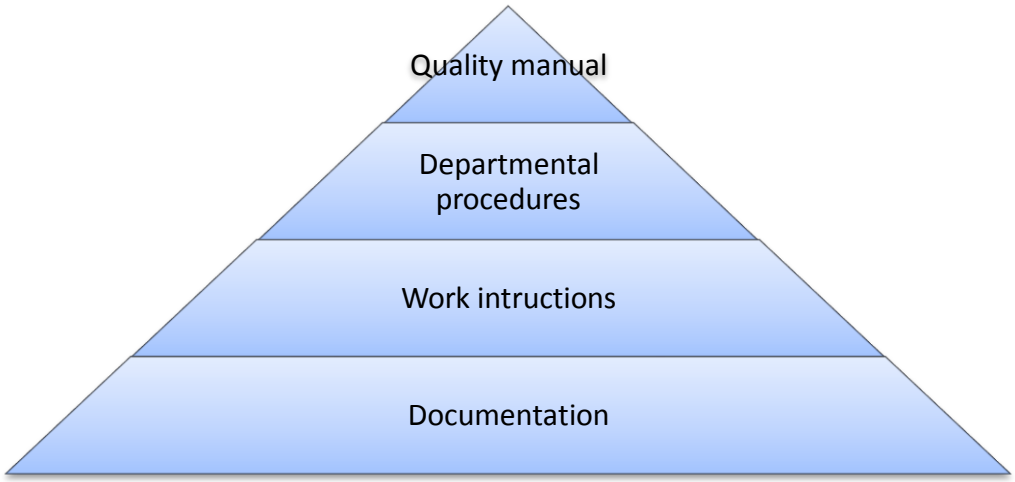


Figure 3.1 Documentation Pyramid

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.

CHAPTER 4

RESULT AND DISCUSSION

4.1 Introduction

This chapter discuss about develop of the Quality Manual for FKM laboratory according to the standard requirement MS ISO/IEC 17025:2005. The Quality Manual will support by develop the procedure and work instruction to achieve the standard requirement. Some related forms are being created as evidence to proof that the procedure and work instruction can meet the standard requirement.

4.2 Quality Manual

Clauses that be covered in the Quality Manual is from clauses 4.9 to clauses 4.15 which that have been state in the scope of this project. In the management requirement of MS ISO/IEC 17025:2005 consist 15 clauses, only 7 clauses will be covered. Below is the list of the clauses that have been developed.

Table 4.1: List of Clauses have been Created

No.	Clauses of Quality Manual	
1.	4.9	Control of Non-conforming Testing and/or Calibration Work
2.	4.10	Improvement
3.	4.11	Corrective Action
4.	4.12	Preventive Action
5.	4.13	Control of Records
6.	4.14	Internal Audits
7.	4.15	Management Review

4.9 CONTROL OF NON-CONFORMING TESTING AND/OR CALIBRATION WORK

4.9.1 Purpose

To establish and maintain the procedure to carry out testing activities to prevent any future recurrence.

4.9.2 Policy Statement

The laboratory shall establish and maintain the procedures to ensure the control of non-conforming activities carry out effectiveness, systematical and satisfied the requirement of MS ISO/IEC 17025.

4.9.3 Scope

Cover all the non-conforming testing activities carries out in the laboratory.

4.9.4 Procedure

Any non-conforming activities can occur in customer complaint, quality manual, testing method, checking of consumable material, staff observation or supervision, test report and calibration certificate checking, management review and internal or external audit.

4.9.4.1 Laboratory shall ensure that:

a) The Quality manager is responsibilities and authorities for identified non-conforming work (1). The non-conforming work is halted and corrective action is taken and withholding of test report (2);
b) Quality Manager responsible to evaluate the significant of the non-conforming work (1);
c) Corrective action is taken immediately, together with decision about the acceptability of the non-conforming work (2);
d) The customer is notified and work is recalled, if necessary;
e) Defined the responsibility for authorizing the resumption work.

4.9.4.2 Recurrence

If the non-conforming work could recur, or that there is doubt about the compliance of the laboratory operation with its own policies and procedure, the Corrective Action Procedure are promptly followed to identify the root cause and to eliminate the cause (2).

4.9.5 Reference

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

---

(1) Procedure for Control of Non-conforming Work
(2) Procedure for Corrective Action

4.10 Improvement

4.10.1 Purpose

To establish a policy for continually improvement the effectiveness of its management system.

4.10.2 Policy Statement

The Laboratory shall continually improve the Quality Management System through the use of quality policy, quality objective, internal and external audit result, corrective action, preventive action, customer feedback and management review.

4.10.3 Scope

Covers the improvement through quality policy, quality objective, audit results, corrective action, preventive action, customer feedback and management review.

4.10.4 Procedure

a) Quality objective are defined by the following method, "SMART".

S – Specific
M – Measureable
A – Achievable
R – Realistic
T – Time bound

b) The laboratory shall continual improve the Quality Management System based on the available resources of the organization.

c) The Technical Manager and/or Quality Manager shall ensure that the integrity of the Quality Management System is maintained when changes are made to the work and review for effectiveness (1).

d) The records of all improvement activities shall be maintain.

4.10.5 Reference

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

---

(1) Procedure for Management Review

4.11 Corrective Action

4.11.1 Purpose

To establish a policy and procedure and shall designate appropriate authorities to eliminate the cause in a time frame by implement appropriate corrective action.

4.11.2 Policy Statement

When a non-conforming work needed corrective action, the cause of non-conformance shall be investigate, a corrective action will be selected based on the root cause, implement the corrective action and monitor the effectiveness of the action taken.

4.11.3 Procedure

4.11.3.1 General

The potential cause identified through customer complaint, quality manual, quality objective, audit results, staff observation, test report and management review.

4.11.3.2 Cause analysis

Quality Manager shall establish a Corrective Action Team to start on investigation to determine the root cause of the non-conforming work (1).

---

(1) Procedure for Corrective Action

4.11.3.3 Selection and implementation of corrective action

The Corrective Action Team shall select and implement the appropriate corrective action to eliminate the root cause that had been identified (1).

4.11.3.4 Monitoring of corrective actions

Quality Manager shall monitor the corrective action to ensure the action taken can eliminate the root cause totally and effectively (1).

4.11.3.5 Addition audit

Where the identification of non-conformities or departures casts doubts on the laboratory compliance with MS ISO/IEC 17025, the area of activity are audited as soon as possible accordance with 4.14 Internal Audit (2).

4.11.4 Reference

MS ISO/IEC 17025:2005 “General requirement for the competence of testing and calibration laboratories”.

---

(1) Procedure for Corrective Action
(2) Procedure for Internal Audits

4.12 Preventive Action

4.12.1 Purpose

To ensure the laboratory able to maintain the standard of the Quality Management System.

4.12.2 Policy Statement

To establish a procedure to prevent the potential non-conformance occur in laboratory Quality Management System.

4.12.3 Scope

Covers all the quality related laboratory activities.

4.12.4 Procedure

4.12.4.1 The laboratory shall indentify the potential root cause of non-conformance and needed improvement to prevent unwanted non-conformance occur (1).

4.12.4.2 The action plans for preventive actions are developed, implemented and monitored to ensure the action taken can be reduce any reoccurrence non-conformance (2).

4.12.4.3 Quality Manager should review and maintain the preventive action and ensure the action taken is effective.

---

(1) Procedure for Control of Non-conforming Work
(2) Procedure for Preventive Action

4.12.4.4 The action is taken as an opportunity for further improvement.

4.12.5 Reference

MS ISO/IEC 17025:2005 “General requirement for the competence of testing and calibration laboratories”.

4.13 Control of Records

4.13.1 Purpose

To ensure all quality records related to testing activities are proper identified, maintain, filing, update, kept, and disposal according to the requirement of the laboratory.

4.13.2 Policy Statement

To establish procedure for the maintenance, retention and disposal all quality records related to testing activities.

4.13.3 Scope

Covers all records related to testing and quality system.

4.13.4 Procedure

4.13.4.1 General

The laboratory has established a documentation system for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records include report from internal audits, management review, corrective action and preventive action.

4.13.4.2 Legibility, storage and retention

Records are to be legible. The records may be in hard copy or electronic media. The laboratory reports are stored and retained in a suitable environment to prevent damage or deterioration and to prevent loss. The laboratory reports can be retrieved by requesting the reports. The laboratory shall establish a retention times for all the records (1).

4.13.4.3 Security and confidential

All records shall be held secure and in confidence.

4.13.4.4 Electronic records

Laboratory shall establish a procedure to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these record (1).

---

(1) Procedure for Control of Records

4.13.4.5 Technical records

4.13.4.5.1 Technical records and audit trial

The laboratory's reports retain include the original observation, derived data, sufficient information to establish an internal and external test report, form, orders, log book, raw data registers and testing reports for a defined period.
If identified the factor affecting the uncertainty, the test shall repeated the test under same condition according to Standard Malaysia requirement.

4.13.4.5.2 Recording

Ensure observation, data and calculations are recorded at the time they are made and identifiable to the task.

4.13.4.5.3 Corrections to records

When errors occur in records, not erased, not made illegible or not deleted. The correct value is entered alongside, initialed and dated by the responsible personnel. In the case of records stored electronically, equivalent shall be taken to avoid loss or change of original data.

4.13.5 Reference

MS ISO/IEC 17025:2005 “General requirement for the competence of testing and calibration laboratories”.

4.14 Internal Audits

4.14.1 Purpose

To ensure laboratory quality system is implemented and verifies the operation to comply with MS ISO/IEC 17025.

4.14.2 Policy Statement

The laboratory shall carry out an internal audit to verify the Quality Management System activities comply with the laboratory plan and requirement of the standard and to determine the effectiveness of the Quality Management System.

4.14.3 Scope

Covers all quality related with laboratory activities.

4.14.4 Procedure

4.14.4.1 General

a) Quality Manager should conduct an internal audit once a year according to the schedule and procedure (1).
b) The internal audits program shall address all elements of the management system, including testing activities.

---

(1) Procedure for Internal Audits

c) The auditor is trained and qualified personnel, whenever resources permit, and independent of the activity to be audited (1).

4.14.4.2 Corrective action

When a non-conformance found through the audit process, a corrective action shall be implement to solve the non-conformance (2).

4.14.4.3 Records

The area of activities audits, the audit findings and corrective actions that arise from them should be recorded.

4.14.4.4 Follow-up audits

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken and discussed in management review (1).

4.14.5 Reference

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

---

(1) Procedure for Internal Audits
(2) Procedure for Corrective Action

4.15 Management Review

4.15.1 Purpose

To ensure the laboratory Quality Management System are continuing suitability and effectiveness and introduce changes for improvement.

4.15.2 Policy Statement

To establish a procedure to review the laboratory quality system to ensure management system and the testing activities continuing suitability and effectiveness, and introduce necessary changes for improvement.

4.15.3 Scope

Covers all quality matters as per the agenda

4.15.4 Procedure

4.15.4.1 General

Quality Manager shall organize the management review one time a year according to the schedule and procedure (1).

---

(1) Procedure for Management Review

4.15.4.2 The review shall include agenda:

a) Previous management review minute;
b) Suitability of policy and procedure;
c) Internal and external audit results;
d) Corrective and preventive action report;
e) Customer feedback report;
f) Personnel report;
g) Other relevant issue.

4.15.4.3 Actions and records

The findings and the action that arise in the management review shall be record in the review minute (1).

4.15.5 Reference

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

---

(1) Procedure for Management Review

4.3 System Procedure

There six procedures are been developed to support the Quality Manual. The procedure will explain the detail instruction and the process flow to carry out according to the standard requirements. The procedure will lead the user to the right direction and complete the task within the time frame. Below is the list of procedures that have been developed.

Table 4.2: List of Procedures have been Created

No.	Procedure for Quality Manual
1.	Procedure for Control of Non-conforming Testing and/or Calibration Work
2.	Procedure for Corrective Action
3.	Procedure for Preventive Action
4.	Procedure for Control of Records
5.	Procedure for Internal Audits
6.	Procedure for Management Review

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Control of Non-Conforming Work**	

SYSTEM PROCEDURE

CONTROL OF NON-CONFORMING WORK

This System Procedure is duty authorized by the Technical Manager and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by:

Released by:

_____

Technical Manager
(date)

_____

Quality Manager
(date)

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Control of Non-Conforming Work**	

1.0 Purpose

The purpose of this procedure is to establish a process of identifying and investigation the non-conforming work in Quality Management System for taking action to mitigate any impact cause and applying corrective and preventive action to maintain the effectiveness of Quality Management System.

2.0 Scope

This procedure covers non-conformance testing conducted by FKM laboratory and non-conforming work related with the laboratory process.

3.0 Definition

3.1	Non-conforming work	Any deviation from work standards, practices, procedures, and management system performance that could not follow the standard requirement.
3.2	Corrective action	Corrective action taken to address the cause(s) of an actual non-conformance must be appropriate to solve the problem and encountered the impact of the non-conformance.
3.3	Preventive action	Preventive action as an implementing modifying procedure to avoid repetition of the non-conformance or prevent a potential non-conformities form occurring.

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Control of Non-Conforming Work**	

4.0 Responsibilities

4.1 Quality Manager shall monitor the flow of this policy and procedures.

4.2 Each personnel should propose to Quality Manager when a non-conforming work had been identified.

4.3 Each personnel shall provide support to the responsible personnel in implement this policy and procedure.

4.4 Quality Manager responsible for the review and update this document when needed.

5.0 Associated Document

5.1 Laboratory Quality Manual

5.2 Procedure for Customer Complaint

5.3 Procedure for Corrective Action

5.4 Procedure for Preventive Action

5.5 Procedure for Management Review

5.6 Procedure for Internal Audits

6.0 Instruction of Forms

6.1 Non-Conformity Investigation Form

7.0 Policy and Procedure Instruction

7.1 Policy Statement

The laboratory shall establish and maintain the procedure to ensure the testing activities that carry out are satisfy the standard requirement and agreed customer requirement to achieve zero non-conforming work.

7.2 Identification of non-conformance testing

7.2.1 When a non-conformance work is identified, the underlying cause(s) of the non-conformance work must be investigated.

7.2.2 Non-conformance works may identified from:

- workplace inspections and testing
- internal and external audit
- work procedure
- customer complaint and feedback
- corrective and preventive action
- management review
- pass experience
- customer requirement
- supervisor observation

7.2.3 When the Supervisor identified the non-conformance work, they must inform to Quality Manager through tag, note, e-mail or memo

7.2.4 Quality Manager will assign the personnel who identified the non-conformance will start to gather the information. The personnel will complete the Non-Conformity Investigation Form with data necessary to clearly define the nature of the non-conformance and notify to the Quality Manager as soon as possible.

7.2.5 The Non-Conformity Investigation Form shall submit to Quality Manager with detail the nature and scale of the non-conforming work for review and approval (1).

---

(1) Non-Conformity Investigation Form

7.2.6 Based on the information in the Non-Conformity Investigation Form, Technical Supervisor or Quality Manager will examine and analyze the non-conforming work to decide necessary to stop the work or not. Technical Supervisor or Quality Manager have the authority and responsible to stop the work due to safety concern (1).

7.3 Problem Solving

7.3.1 If there is potential for the non-conforming work to reoccur somewhere else in the Quality Management System or if there is an adverse impact on the Quality Management System of work generated, it will be addressed through formal corrective action(2).

7.3.2 If the non-conforming work is not addressed through the process, it will be evaluate by the Quality Manager to determine if it is an opportunity for a preventive action or improvement action (3).

7.3.3 Action will be taken according to the Procedure for Corrective Action / Procedure for Preventive Action.

7.3.4 The Quality Manager shall announce to all relevant personnel that no test report should be release during the trouble-shooting period without the concern from the Quality Manager.

7.3.5 Customer should be noticed of the non-conforming work and the data should be recall.

---

(1) Refer to Non-Conformity Investigation Form
(2) Procedure for Corrective Action
(3) Procedure for Preventive Action

7.4 Evaluation

7.4.1 Quality Manager shall consultation with Technical Supervisor to determine the result generated from the corrective and preventive action is acceptable or the work should be repeated.

7.4.2 Quality Manager shall resumption the work when the non-conforming work has been resolved.

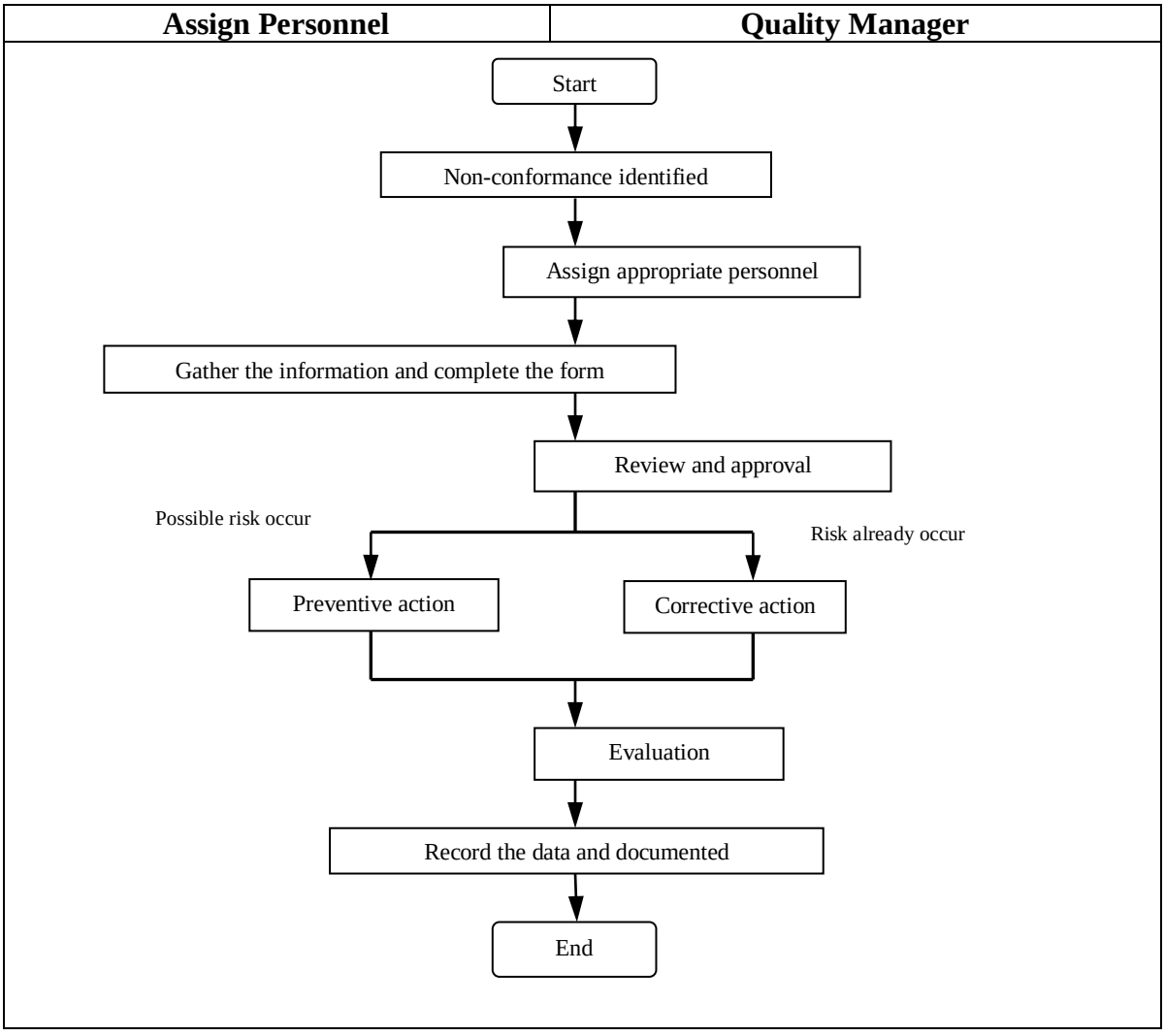
7.5 All the form and data should be proper recorded and documented.

8.0 Reference

MS ISO/IEC 17025:2005 “General requirement for the competence of testing and calibration laboratories”.

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Control of Non-Conforming Work**	

Flow Chart of Procedure for Control of Non-Conforming Work



Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Corrective Action**	

SYSTEM PROCEDURE

PROCEDURE FOR CORRECTIVE ACTION

This System Procedure is duty authorized by the Technical Manager and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by: Released by:

_____ _____

Technical Manager
(date)

Quality Manager
(date)

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Corrective Action**	

1.0 Propose:

The purpose of this procedure is to define the process for handling of non-conformance work and taking action to mitigate the impact cause, monitor and improve the action taken.

2.0 Scope

2.1 This procedure covers the collection of data on the actual non-conformance and analyzes the root cause with implement the action to eliminate the root cause.

2.2 The procedure set out the range of corrective action and how to implement the action

3.0 Definition

3.1	Non-Conforming work	A failure work or process that not satisfies the requirement of the standard of the quality system.
3.2	Corrective action	A plan that create by the management to eliminate the root cause and improve the quality system.
3.3	Cause Analysis	Analysis the root cause of the problem.

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Corrective Action**	

4.0 Responsibilities

4.1 Quality Manager has the authority to set the period time for the Corrective Action Team to solve the non-conformance work

4.2 The Corrective Action Team had to pass the Corrective Action Report after the corrective actions are fully implemented for Quality Manager to review.

5.0 Associated Document

5.1 Laboratory Quality Manual
5.2 Procedure for Customer Complaint
5.3 Procedure for Control of Non-Conformance work
5.4 Procedure for Preventive Action
5.5 Procedure for Internal Audit
5.6 Procedure for Management Review

6.0 Instruction for forms

6.1 Non-Conformity Investigation Form
6.2 Corrective Action Form

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Corrective Action**	

7.0 Procedure

7.1 Policy Statement

When a non-conforming work needed corrective action, the cause of non-conformance shall be investigate, a corrective action will be selected based on the root cause, implement the corrective action and monitor the effectiveness of the action taken.

7.2 Procedure

7.2.1 General

7.2.1.1 Corrective action is a reactive process to address concerns or issue after they have occurred.

7.2.1.2 Appropriate and timely corrective action must take according to the nature of the non-conformance work.

7.2.2 Identification and investigation

7.2.2.1 Quality Manager shall review the non-conformance that describe in the Non-Conformity Investigation Form (1).

7.2.2.2 Quality Manager shall establish a Corrective Action Team to solve the non-conformance and minimizing any impact from the non-conformance.

7.2.2.3 Each team member must ensure that the problem is closed to their satisfaction.

---

(1) Non-conforming Investigation Form

7.2.2.4 Use 5W1H method to gather the information.

i. Who was present?
ii. What is in place?
iii. When the non-conformance occurred?
iv. Where the non-conformance occurred?
v. How the non-conformance occurred?

7.2.2.5 All the information shall record in Corrective Action Form (1).

7.2.3 Cause and impact

7.2.3.1 Clearly define the cause and impact of the non-conformance occurred.

7.2.3.2 Use the fishbone diagram to brainstorm the problem, list the 3 most probable causes and analysis to determine the root cause, clearly define the root causes.

7.2.4 Selection of corrective action

7.2.4.1 Corrective Action Team should list the result of the probable causes using tree diagram.

7.2.4.2 Set the action plans and realistic target date for the action to be complete.

---

(1) Corrective Action Form

7.2.4.3 The Corrective Action Form had to complete with the action will been implemented.

7.2.4.4 The Corrective Action Form shall pass to Quality Manager for review and approval.

7.2.4.5 Corrective Action Team shall implement the corrective action when the Quality Manager approval the corrective action to be taken.

7.2.5 Monitoring

7.2.5.1 Technical Supervisor shall monitor the action taken are focused to eliminate the root cause and action taken are fully implemented.

7.2.5.2 If the corrective action is not fully implemented, team member had to develop a new corrective action to replace it and ensure the new corrective action is implemented.

7.2.6 Follow-up

7.2.6.1 A review done by Quality Manager to ensure all corrective action is effectiveness implemented as stated.

7.2.6.2 If the corrective action is not effectiveness, the team had responsible to rework to find another corrective action that can fully eliminate the root causes.

7.2.6.3 Corrective Action Team shall develop Corrective Action Report and submitted to Quality Manager.

7.2.6.4 If the corrective action cannot be resolved by the specified due date, Quality Manager will review the information and assign an alternated due date.

8.0 Reference

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

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Corrective Action**	

Flow Chart of Procedure for Corrective Action

Responsible	Flow chart
	Start
	Non-conformance need corrective action
Quality Manager	Form the corrective action team
Corrective Action Member	Investigation and gather the data
	Determine the cause and impact
	Decided the action to be taken
Technical Supervisor	Monitor
	Yes / No
Quality Manager	Review the effectiveness
	Yes / No
Corrective Action Member	Complete the Corrective Action Report
	End

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Preventive Action**	

SYSTEM PROCEDURE

PREVENTIVE ACTION

This System Procedure is duty authorized by the Technical Manager and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by: Released by:

_____ _____

Technical Manager
(date)

Quality Manager
(date)

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Preventive Action**	

1.0 Purpose

This procedure is to define the process and responsible that ensure all concerns are appropriate manage and eliminate the cause of potential non-conformance work in order to prevent their occurrence.

2.0 Scope

This procedure covers the collection of data on potential non-conformance, analysis of the potential root cause of the non-conformance and actual planning to prevent occurrence of non-conformities.

3.0 Definition

3.1	Non-conformity	Does not fulfill the specific requirement
3.2	Preventive action	An action taken to eliminate the potential root causes and prevent reoccurrence

4.0 Responsibilities

4.1 The responsible personnel have to finish the job based on the time given by the Quality Manager.

4.2 The responsible personnel have to complete the Preventive Action Report within 1 week after the preventive action had been complete implemented and the report are checking by Quality Manager.

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Preventive Action**	

5.0 Associated document

5.1 Laboratory Quality Manual
5.2 Procedure for Control of Non-conforming Work
5.3 Procedure for Corrective Action
5.4 Procedure for Internal Audit
5.5 Procedure for Management Review

6.0 Instruction for forms

6.1 Non-conforming Investigation Form
6.2 Preventive Action Form

7.0 Procedure

7.1 Policy Statement

To establish a procedure to prevent the potential non-conformance occur in laboratory Quality Management System.

7.2 Procedure

7.2.1 General

7.2.1.1 Preventive action is a proactive process intended to prevent potential concern before they occurs or become severe.

7.2.1.2 Preventive action address the underlying causes of the non-conforming work is long-term solution and typically take more time to implement.

7.2.2 Identification and investigation

7.2.2.1 When receive potential non-conforming work from the Non-conforming Investigation Form, Quality Manager shall assign Preventive Action Team to investigate the potential non-conformance (1).

7.2.2.2 The Preventive Action Team will gather data and interview appropriate personnel in order to collect all the information that will lead to complete understanding of the potential non-conformance.

7.2.2.3 The Preventive Action Team shall record the information gather in the Preventive Action Form and determine the potential root cause of the non-conformance (2).

7.2.2.4 Quality Manager shall evaluate needed of the preventive action when potential root cause is identified.

7.2.3 Implement the preventive action

7.2.3.1 Preventive action is developing using fish-bone method to test the potential root cause and eliminate the existence of the root cause.

---

(1) Non-conforming Investigation Form
(2) Preventive Action Form

7.2.3.2 The Preventive Action Team are responsible to balance the investment required against the like hood of the problem developing into non-conformance and potential impact it would have.

7.2.4 Monitor and verification

7.2.4.1 Quality Manager should review the impact of the preventive action and verify that the root cause has been addresses and the record correctly maintained.

7.2.4.2 If the preventive action is not valid, they have to establish a new preventive action to prevent the non-conformance. If the preventive action valid, they have to complete the Preventive Action Form (1).

7.2.5 Follow-up

7.2.5.1 Quality Manager shall perform a follow-up audit within 1 week to examine that the preventive action are fully implemented.

7.2.5.2 If the preventive action is no fully implemented, they have to develop a new preventive action to replace this preventive action.

7.2.5.3 Quality Manager should perform second follow-up audit after 3 months of the preventive action had been implemented.

---

(1) Preventive Action Form

7.2.5.4 Quality Manager shall evaluate the effectiveness of the preventive action in order to prevent or eliminate the potential root cause.

7.2.5.5 If the preventive action is effective, the responsible team has to complete the Preventive Action Report.

7.2.5.6 If preventive action is not effectiveness, they have to start over again to develop a new preventive action with starting to determine the potential root cause of the non-conformance.

7.2.6 The effectiveness and implementation will be regularly review and recorded as part of management review and continue improvement.

8.0 Reference

MS ISO/IEC 17025:2005 “General requirement for the competence of testing and calibration laboratories”.

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Control of Record**	

SYSTEM PROCEDURE

CONTROL OF RECORD

This System Procedure is duty authorized by the Technical Manager and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by:

Released by:

_____

Technical Manager
(date)

_____

Quality Manager
(date)

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Control of Record**	

1.0 Purpose

This procedure is to provide a system and instruction to assign responsibilities for establishing, storage, and retention of record.

2.0 Scope

This procedure applies to the control of all the records that demonstrate conformance to our Quality Management System as is identified on the record control list.

3.0 Definition

3.1	Quality record	A document recording specific information that release to a procedure or work instruction. Quality records are proof that an organization is complying with its procedures and policies.
3.2	Technical record	A document of evidence for testing that has been carried out and specified quality is achieved.
3.3	Evidence	Information that pertains to the quality of an item, process, or element of a quality system.

4.0 Responsibilities

4.1 Quality Manager should maintain and update the master list of records which specifies the name, type of record, the form number, the personnel responsible to keep the record and the retention time.

4.2 Each individual shall responsible for the maintenance of his or her respective documentation and record of work.

5.0 Associated document

5.1 Laboratory Quality Manual
5.2 Document Control Procedure
5.3 Procedure for Review of Requests, Tenders and Contracts
5.4 Procedure for Purchasing Service and Supplies
5.5 Procedure for Service to the Customers
5.6 Procedure for Complaints
5.7 Procedure for Control of Non-conforming work
5.8 Procedure for Corrective Action
5.9 Procedure for Preventive Action
5.10 Procedure for Control of Record
5.11 Procedure for Internal Audit
5.12 Procedure for Management Review
5.13 Procedure for Personnel Training Group
5.14 Procedure for Laboratory Accommodation and Environmental Condition
5.15 Procedure for Selection of Test and Calibration Methods
5.16 Procedure for Validation of Test and Calibration Methods
5.17 Procedure for Estimation of Uncertainty of Measurement
5.18 Procedure for Handling of Reference Standards and Materials
5.19 Procedure for Handling of Test Items
5.20 Procedure for Assuring the Quality of Test Results
5.21 Procedure for Reporting the Results
5.22 Master List of Quality Management System Documents

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Control of Record**	

6.0 Instruction of forms

6.1 Master List of Quality Records

7.0 Procedure

7.1 Policy Statement

To establish procedure for the maintenance, retention and disposal all quality records related to testing activities.

7.2 Procedure

7.2.1 Quality records

Quality records include the following but not limit to:

7.2.1.1 Equipment service maintenance and external calibration report
7.2.1.2 Customer complaint records
7.2.1.3 Laboratory testing record
7.2.1.4 Equipment calibration record
7.2.1.5 Internal and external audit record
7.2.1.6 Non-conforming investigation record
7.2.1.7 Management review
7.2.1.8 Corrective action report
7.2.1.9 Preventive action report
7.2.1.10 Personnel training and qualification record
7.2.1.11 Test and calibration procedure

7.2.2 Filling

All record generate or receive shall be indexed and filling according to the activities and type of record.

7.2.2.1 Customer file

Customer file include, not limit to:

i. Customer feedback
ii. Customer complaint record
iii. Test record and raw data record

7.2.2.2 Testing records and worksheet

The complete record filled according to the specific job/ report number. For the same type of file, it shall be filled according in ascending numerical order and keep in a folder.

7.2.2.3 Equipment service and maintenance

The record of service maintenance is filed in Equipment Service Maintenance file according to respective equipment.

7.2.2.4 Equipment calibration record

The external or internal calibration record will filed in Equipment Calibration Record file according to respective equipment.

7.2.2.5 Personnel qualification record

Personnel qualification record with orderly indexing of respective personnel shall filed in Personnel Qualification Record file.

7.2.2.6 Personnel training record

The technical training and evaluation record for respective personnel shall file in Personnel Training Record file.

7.2.2.7 Other quality record

The other quality records are filled according to their respective area.

7.2.3 Store and access

7.2.3.1 Quality Manager shall responsible for storage and protection of all the quality record in a respective location.

7.2.3.2 All the quality record are accessible by authorized personnel for security and protection from unauthorized access, amendment and customer confidential.

7.2.3.3 All electronic data shall be back-up and kept in a safe location.

7.2.4 Retention of records

Quality Manager has the authority to distribute and control the original document or copies of the record to ensure that only appropriate personnel will receive the record and the retention time of the personnel kept the record.

7.2.5 Destruction of records

Destruction of the original records is not permitted. Quality Manager should be responsible for authorizing exception, as stipulated by this procedure. Exception will not be granted unless following condition exists:

i. Specific approval has been given;
ii. The document have been completed;
iii. Original copies have been successfully copied into another medium;
iv. One year has passed since the end of the retention of the record.

8.0 Reference

MS ISO/IEC 17025:2005 “General requirement for the competence of testing and calibration laboratories”.

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Internal Audit**	

SYSTEM PROCEDURE

PROCEDURE FOR INTERNAL AUDIT

This System Procedure is duty authorized by the Technical Manager and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by: Released by:

_____ _____

Technical Manager
(date)

Quality Manager
(date)

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Internal Audit**	

1.0 Purpose

The objective of internal audit is to assist in the effective discharge of their responsible and promote effectiveness management system through the provision of information with analysis; recommendation and suggestion for continue improvement.

2.0 Scope

Internal audit is authorized to have full, free and unrestricted access to review and evaluate all policies, procedure, records, and practices of any laboratory activity program of the laboratory.

3.0 Definition

3.1	Audit	An examination of a company activities or product to determine if a company is doing what is say it doing.
3.2	Audit interview	A method of collecting information through question and observation.
3.3	Auditee	A personnel to be audited.
3.4	Audit team	A group of individual selected to perform an internal audit.
3.5	Process audit	An audit that focuses on process and not a specific person or product.
3.6	Audit checklist	Define the scope and depth of the audit
3.7	Internal audit	A quality audit carried out by a laboratory for the purpose to ensure the quality management system are effectiveness.

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Internal Audit**	

4.0 Responsibilities

4.1 Quality Manager should plan and schedule the internal audit activities.

4.2 Quality Manager shall ensure that audit procedure are documented the result of finding and corrective action needed for the non-conformity found during internal audit.

5.0 Associated document

5.1 Laboratory Quality Manual
5.2 Document Control Procedure
5.3 Procedure for Non-conforming work
5.4 Procedure for Corrective Action
5.5 Procedure for Preventive Action
5.6 Procedure for Management Review

6.0 Instruction of forms

6.1 Audit schedule
6.2 Audit checklist
6.3 Non-conforming report

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Internal Audit**	

7.0 Procedure

7.1 Policy statement

The laboratory shall carry out an internal audit to verify the Quality Management System activities comply with the laboratory plan and requirement of the standard and to determine the effectiveness of the Quality Management System.

7.2 Audit plan

7.2.1 Quality Manager shall establish and maintain an audit plan which includes the element and requirement of MS ISO/IEC 17025.

7.2.2 Quality Manager shall determine the objective of the quality audit; identify time and resources needed for the audit plan.

7.2.3 The audit plan should conduct according to the schedule. If the audit plan could not conduct according to the schedule, Quality Manager responsible to reschedule the audit plans to a suitable date.

7.3 Auditor

7.3.1 The auditor shall selected from personnel who independent of the area to being audited.

7.3.2 The auditor shall undergoes some training and understand the requirement of MS ISO/IEC 17025.

7.3.3 Guide for the auditor during conduct an audit:

7.3.3.1 Refresh familiarly with MS ISO/IEC 17025 and relevant SAMM technical note.

7.3.3.2 Plan with Quality Manager and brief the overall process audit plan to the auditee or related personnel.

7.3.3.3 Note down the observation and audit finding during the audit process.

7.3.3.4 Examine the laboratory procedure and work instruction of the audit laboratory with referring to the requirement of MS ISO/IEC 17025.

7.3.3.5 Item to be carries during the audit process:

i. Procedure and work instruction
ii. Quality Manual
iii. Internal Audit Report
iv. Non-Conforming Investigation Form
v. Audit Checklist

7.4 Auditor procedure

7.4.1 Quality Manager shall held a meeting 1 week before the audit date and brief the audit plan to the auditor, auditee and respective personnel.

7.4.2 All the personnel who involve in the audit process will be informed the time, date, location, purpose and scope of the audit.

7.4.3 The auditor should observe the following guideline during auditing:

7.4.3.1 Be punctual and appropriate dressed;

7.4.3.2 Bring along copies of relevant quality standard and checklist;

7.4.3.3 Must be courteous, polite and humble.

7.4.4 The audit process shall include:

7.4.4.1 Checking of document;

7.4.4.2 Personnel observation;

7.4.4.3 Inspection of procedure and work instruction;

7.4.4.4 Interviewing of staffs.

7.5 Reporting the finding

7.5.1 The auditor shall record the entire relevant audit finding.

7.5.2 The statement use in writing must be clear, affirmative and concise.

7.5.3 Any of the founding of non-conformance will be detailed in the Non-Conformity Report with sign by the auditor and auditee.

7.6 Reporting the audit

7.6.1 The auditor shall write the audit report and issued to Quality Manager before the closing date of the internal audit.

7.6.2 The audit report should include the opening and closing meeting attendance records, founding of non-conformance and observation of the auditor.

7.6.3 The audit report shall contain only those finding declared at the closing meeting.

7.7 Measuring the effectiveness of Quality Management System

7.7.1 Quality Manager responsible to take the action according to the Procedure for Non-Conforming work, Procedure for Corrective Action and Procedure for Preventive Action when the non-conformance is identified during the audit.

7.8 Follow-up audit

7.8.1 A follow-up audit be performed upon corrective action have been taken effective.

7.9 Management review

7.9.1 The result of the internal audit will be one of the input for management review.

8.0 Reference

MS ISO/IEC 17025:2005 “General requirement for the competence of testing and calibration laboratories”.

---

(1) Procedure for Non-Conforming work
(2) Procedure for Corrective Action
(3) Procedure for Preventive Action

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Management Review**	

SYSTEM PROCEDURE

PROCEDURE FOR MANAGEMENT REVIEW

This System Procedure is duty authorized by the Technical Manager and released by the Quality Manager as:-

CONTROLLED COPY NO: 1

to the register holder and location as :-

HOLDER :

LOCATION :

Authorized by: Released by:

_____ _____

Technical Manager
(date)

Quality Manager
(date)

Universiti Malaysia PAHANG	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Management Review**	

1.0 Purpose

This procedure is to establish a systematically process review on the Quality Management System by the top management to ensure it continuing suitability, adequacy and effectiveness.

2.0 Scope

This procedure applied to the number who involved in the management review meeting and describes the review procedure to conduct the meeting.

3.0 Definition

3.1	Management review	A systematic evaluation on the status and adequacy of the Quality Management System in relation to quality policy and objective of the laboratory.
3.2	Quality Management System	The organizational structure, procedure and resources needed to implement Quality Management.

4.0 Responsibilities

4.1 Director shall chair the management review meeting

4.2 Quality Manager has the responsible to establish the management review schedule and the agenda of the meeting.

4.3 Secretary has the responsible to record the minute of meeting and informs the agenda to each of the members of Management Review Team.

4.4 Each of the members is responsible to recommend any idea that relevant during the management review meeting.

5.0 Associated document

5.1 Laboratory Quality Manual

5.2 Document Control Procedure

6.0 Instruction of forms

Not applicable

7.0 Procedure

7.1 Policy statement

To establish a procedure to review the laboratory quality system to ensure management system and the testing activities continuing suitability and effectiveness, and introduce necessary changes for improvement

7.2 Procedure

7.2.1 Management review is held two times per year according to the schedule and divided to two sessions. The first session is from January to Jun while second sessions are from July to December. The management review meeting must held before the ending of each session.

7.2.2 The management review team must include: Director, Deputy Director, Quality Manager, Technical Manager, Senior Engineers, Technical Supervisors and Secretary.

7.2.3 During conducting a formal management review, the majority of the member of the management review team must be present. If any member cannot attend, they have to send to the representative in their place to act on their behalf.

7.2.4 Agenda must give to the members 3 days before the meeting date. If there have any changing of the agenda, inform the members as soon as possible.

7.2.5 The input of the management review shall include information on:

i. Previous management review minute;
ii. Quality policy and procedure;
iii. Internal and external audit results;
iv. Personnel report;
v. Corrective and preventive action report;
vi. Customer feedback report;
vii. Other relevant issue;

7.2.6 Flow of performance the meeting:

i. Apologies for absence;
ii. Review the minutes of previous management review;
iii. Review the quality policy and procedure;
iv. Review the internal and external audit result;
v. Review the corrective and preventive action report;
vi. Review the customer feedback report;
vii. Matter arising;
viii. Discussion and recommendation for improvement;
ix. Planning the next year activities;
x. End for the meeting.

7.2.7 Director must start the meeting with apologies for absence and briefly the agenda of the meeting. Director will present the minute of previous management review and the quality policy and procedure.

7.2.8 Technical Manager will present the report internal and external audit report and report if change in the volume and type of work of the personnel.

7.2.9 Quality Manager will present the corrective and preventive action report, customer feedback and customer complaint report.

7.2.10 Each of the members is responsibilities to propose any recommendation and idea for planning the coming session activities.

7.2.11 During the review, members is recommend to ask any classification necessary to determine the suitability, adequacy and effectiveness of the Quality Management System and make suggest any that feel are necessary to ensure the system achieve the requirement of the standard.

7.2.12 All the report and recommendation during the meeting must be documented into the minutes of the meeting.

8.0 Reference

MS ISO/IEC 17025:2005 “General requirement for the competence of testing and calibration laboratories”.

Universiti Malaysia PAHANG Engineering • Technology • Creativity	**LABORATORY SYSTEM PROCEDURE**	Reference : Revision : Issue Date : Issue No : Page :
University Malaysia Pahang Faculty of Mechanical	**Procedure for Management Review**	

Responsible	Flow of the management review meeting
Quality Manager	Start → Organize the management review meeting
Director	Briefly the agenda of the meeting → Review the previous management review minutes → Review the quality policy and procedure
Technical Manager	Review the report from internal and external audit report and report of change in the volume and type of work of the personnel
Quality Manager	Review the corrective and preventive action report, customer feedback report and customer complaint report
Director	Matter arising → Discussion and recommendation for improvement → Planning the next session activities → End

4.4 Evidence Document

Evidence form is use to record the result of the procedure and stand as a proof that the result is done according to the procedure. Evidence is also important as a sources to be use to improve the quality management system. The evidence will storage and keep as reference for future uses. Below is the list of evidence that have created.

Table 4.3: List of Evidences have been Created

No.	Forms for Quality Manual	Refer
1.	Non-Conforming Investigation Form	Appendix D
2.	Corrective Action Form	Appendix E
3.	Preventive Action Form	Appendix F
4.	Master List of Quality Records	Appendix G
5.	Schedule of Internal Audits	Appendix H
6.	Internal Audits Check List Form	Appendix I
7.	Schedule of Management Review	Appendix J

CHAPTER 5

CONCLUSION AND RECOMMENDATION

5.1 Introduction

This chapter concludes the summary about the overall thesis. This chapter will discuss about the outcome of the thesis. The outcome of this thesis is to develop the quality manual which has been developed the chapter 4.

5.2 Conclusion

If a laboratories wish to implement the ISO standard, the laboratory have to develop the quality manual as a first step in the process of implement the ISO standard. The quality manual is the quality policy for the laboratory. Not all the laboratory have to implement any ISO standard, it is depend on the laboratory vision, mission and objective. FKM laboratory wish to provide the testing service for the customer and internal research purpose, so the FKM laboratory is on the process implement the MS ISO/IEC 17025:2005.

Before starting to develop the quality manual, understand about the clauses of the MS ISO/IEC 17025:2005 is important. The quality manual must use the standard as a basic requirement. All the clauses may not be cover in the quality manual; it is depend on the laboratory objective. The clause that being develop in this thesis is from clause 4.9 to clause 4.15 which is control of non-conforming testing and/or calibration, improvement,

corrective action, preventive action, control of records, internal audits and management review. This 7 clause only cover half part of the management requirement of the standard.

The requirement in the standard is a general requirement, some of the relevant procedure needs to be developed to support and lead the clause to achieve the clause objective and complete the task on the clause. The procedure that have been develop such as procedure for non-conforming work, procedure for corrective action, procedure for preventive action, procedure for control of records, procedure for internal audits and procedure for management review. This procedure will lead the user to the right direction according to the quality manual and follow the standard to complete the task.

Supporting document are be created to use to record the result that carry out through the procedure and also as a proof for the procedure and the quality manual are followed the requirement of the standard. Supporting document that have been create in this thesis such as non-conforming investigation form, corrective action form, preventive action form and internal audits checklist.

The quality manual, procedure related to the quality manual and the supporting document is very important for the laboratory to get the accreditation of MS ISO/IEC 17025:2005. The external auditor will use the standard requirement as basic to evaluate the quality manual, procedure and supporting document of the laboratory and make a conclusion that the laboratory satisfies with the requirement of the standard.

5.3 Recommendation

In order to have an ideal to develop the quality system with the quality document such as quality manual, system procedure and evidence**,** the clauses and the meaning of the standard must be understand clearly. It is recommended that:

i. Establish a team specifically and responsible to develop the quality system.

ii. Training on developing the quality system should be held for the team that responsible to develop the quality system.

iii. Two or three laboratory visit should be done for further more understand about the clauses and the development of the quality system. The laboratory chosen must have accredited with the standard of MS ISO/IEC 17025.

iv. Benchmarking on the laboratory that has been accredited of MS ISO/IEC 17025 should be done.

v. Include the model for Quality Management Software in developing the quality system.

REFERENCES

Answers. (online) http://www.answers.com/topic/calibration (20 January 2009).

Beckford, J. (2002). *Quality 2nd edition.* Routledge. (online) http://books.google.com.my/books?id=_4XTZZ01i8MC&printsec=frontcover&dq=quality#PPA51,M1 (23 January 2009)

Hashim,M. (2007). *Quality Management System ISO 9001:2000.* (slide). UKM.

Hoyer, R.W. & Hoyer, B.B.Y. (2001). "*What is Quality?*" *Quality Progress*.

Jurow, S. & Barnard, S. B. (1993). Introduction: TQM fundamentals and overview of contents. "Journal of Library Administration," 18(1/2), 1-13. (EJ 469 099)

Kanji, K. & Asher, M. (1996). *100 Methods for Total Quality Management*. SAGE. http://books.google.com.my/books?id=uov0Xi2zJOUC&printsec=frontcover&dq=total+quality+managemnt#PPA1,M1 (3 February 2009)

MS ISO/IEC 17025:2005. *General Requirement for the Competence of Testing and Calibration Laboratories.* Malaysia: ISO/IEC

Nanda,V. (2005). *Quality Management System Handbook for Product Development Companies.* USA: Taylor & Francis.

Quality Glossary (2002). *Quality Progress.*

Simply Quality. (2001). What are the requirements of the ISO 9001:2000 Standard? (online) http://www.simplyquality.org/whatr2000.htm (4 February 2009)

SeachWinDevelopment. (online) http://searchwindevelopment.techtarget.com/sDefinition/0,,sid8_gci534970,00.html (20 January 2009)

APPENDIX A

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

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 C

Nominal Cross-References to ISO/IEC 17025 to ISO 9001

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

ISO 9001:2000	ISO/IEC 17025
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 D

Non-Conforming Investigation Form

Universiti Malaysia PAHANG
Engineering • Technology • Creativity

Faculty of Mechanical Laboratory

NCIF No.: _____

Non-Conformity Investigation Form

Name : _____
Position : _____
Phone : _____

Type of non-conformance work
- ☐ Product
- ☐ Process
- ☐ Quality System

Description of problem:

_____

What is specified requirement are not fulfilled?

_____

Root cause of non-conformance work:

_____

Non-conformance detected by: _____ Date: _____

Signature

Review by
Name : _____
Position : _____
Phone : _____

Disposition
- ☐ Scrap
- ☐ Return
- ☐ Rework
- ☐ Repair
- ☐ Customer notification required

Comment:

_____

_____

Corrective action requested ☐ Yes ☐ No

Preventive action requested ☐ Yes ☐ No

Disposition approval by: _____ Date:_____

Signature

Appendix E

Corrective Action Form

Universiti Malaysia PAHANG
Engineering • Technology • Creativity

Faculty of Mechanical Laboratory

Corrective Action Form

Name: Date: No.:

Section A: Problem description

Personnel involve :
Location :
Description of problem :

Non-conformance Rating:
- ☐ Major
- ☐ Moderate
- ☐ Minor
- ☐ Improvement

How was the event discovered?
- ☐ Accident
- ☐ Audit
- ☐ Workplace inspection
- ☐ Hazardous condition observation
- ☐ Other: _____

Section B: Indentify of root causes

1.
2.
3.

Section C: Corrective Action Taken

No	Corrective action	Responsible	Due date

Section D: Approval

Prepare by: _____ Date :

Approve by: _____ Date :

Appendix F

Preventive Action Form

Universiti Malaysia PAHANG
Engineering • Technology • Creativity

Faculty of Mechanical Laboratory

Preventive Action Form

Name: Date: No.:

Section A: Problem description

Personnel involve :
Location :
Description of problem :

Non-conformance Rating:
- ☐ Major
- ☐ Moderate
- ☐ Minor
- ☐ Improvement

How was the event discovered?
- ☐ Accident
- ☐ Audit
- ☐ Workplace inspection
- ☐ Hazardous condition observation
- ☐ Other: _____

Section B: Indentify of root causes

1.
2.
3.

Section C: Preventive Action Taken

No	Corrective action	Responsible	Due date

Section D: Approval

Prepare by: _____ Date :

Approve by: _____ Date :

Appendix G

Master Lists of Quality Records

Faculty of Mechanical Laboratory

Master List of Quality Records

Prepare by : _____ Update no. _____

Review by : _____

Name of Record	Form No.	Keeping by	Retention Time

Appendix H

Schedule of Internal Audits

Universiti Malaysia PAHANG
Engineering • Technology • Creativity

Faculty of Mechanical Laboratory

Internal Audit Schedule

January

Su	Mo	Tu	We	Th	Fr	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

February

Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28						

March

Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

April

Su	Mo	Tu	We	Th	Fr	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

May

Su	Mo	Tu	We	Th	Fr	Sa
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

Jun

Su	Mo	Tu	We	Th	Fr	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

July

Su	Mo	Tu	We	Th	Fr	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

August

Su	Mo	Tu	We	Th	Fr	Sa
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

September

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

October

Su	Mo	Tu	We	Th	Fr	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

November

Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

December

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

Appendix I

Internal Audits Checklist Form

Universiti Malaysia PAHANG
Engineering • Technology • Creativity

Faculty of Mechanical Laboratory

Internal Audit Checklist Form

No.	Question on the Quality Manual	N/A	D*	I*	Comments
4.0	Management Requirement				
4.1	Organization				
4.1.5	a. Do they have managerial and technical personnel • to carry out their duties, including the implementation maintenance and improvement of the QMS • to identify the occurrence of departures from the MS procedure for performing test/calibrations • to initial action to prevent or minimize such departures				
	b. Are all laboratory employees free from any undue commercial, financial and other pressure that may affect the quality of their work?				
	c. Any policies and procedures to ensure the protection of client's confidentiality and proprietary rights established and maintained?				
	d. Are policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?				
	e. Are key position in this chart defined?				
	f. For those who manage, perform and verify work, are their responsibilities and authorities defined?				
	g. Are the supervision of laboratory staff and assessment of the results adequate and suitable?				
	h & i. Are there appointer Quality & Technical manager and their responsibilities & authorities defined?				
	j. Are there appointed deputies for all key managerial personnel?				
4.2	Quality System				
4.2.1	i. Any policies, system, programmed, procedures, and instruction to extent to ensure the quality of test/calibration results achieved and maintained?				
	ii. Where are the quality documents located/kept?				
	iii. How do you make the system's documentation				

	communicated to, understood by, available to, and implemented by the appropriate personnel?				
4.3	Document Control				
4.3.1	General				
	i. What is the policy & procedure on document control in the lab?				
4.3.2	Document approval & Issue				
4.3.2.1	Any master list or equivalent document control.				
4.3.2.2	a. Is it ensured the revision of document is available at the relevant places?				
	b. Are obsolete documents i. Removed from all point of used ii. Clearly marked as obsolete or destroyed iii. Retained for legal or knowledge preservation and identified as such?				
4.3.2.3	Any unique identification on MS documents has been implemented by lab?				
4.3.3	Document Changes				
4.3.3.3	Are procedure and responsibilities for handling changes defined and documented?				
4.4	Review of Requests, Tenders and Contracts				
4.4.1	a. Are there documented policies and procedures for contract review?				
	b. Requests, tenders and contracts – are they review for: i. Correct definition including the methods ii. Documentation iii. Capabilities and resources such as facilities, manpower, materials, skills, etc. fill the customer requirement?				
	*Are request/tender matched and resolved for any differences before confirmation?				
	*Is contract accepted by both the lab & customer				
4.4.2	Are review to contracts and discussions with the client documented and records maintained?				
4.4.3	Does the review cover subcontract work by the laboratory?				
4.4.4	Does the lab inform the client of any deviation from the contract?				
4.4.5	Does the lab inform to all affected personnel when there are change in the contract?				
4.5	Subcontracting of tests				
4.6	Purchasing service & suppliers				
4.6.1	Are there a policy & procedure for selection & purchasing of service & supplies?				
4.6.3	Are there the evaluation record for items affecting the quality of laboratory. output? i. How do they carry out the evaluation? ii. Based on what criteria they do the selection? iii. Who is authorized and responsible for the approval?				
4.6.4	Is there a list of approved suppliers? i. Please show the list ii. How do monitor the performance? iii. If the supplier is below acceptable performance. What action will been do?				

	iv. Any record of termination?				
4.7	Service to the customer				
4.7.1	Are there have the procedure of customer servicing including: i. Confidentiality? ii. Security? iii. Visitors? iv. Packaging & delivery?				
4.7.2	Are there any records show? i. The feedback from customer? ii. The action taken by laboratory related to the feedback from customer? iii. Evidence of communication? iv. Packaging & delivery record?				
4.8	Complaints				
	*What are the policy & procedure to solve complaints?				
	*How to record the complaints?				
	*Who responsible to do the investigation?				
	*Who approve the corrective action?				
4.9	Control of Non-conforming (NC) Testing and/or Calibration Work				
4.9.1	What are the policy & procedure on the control of non-conforming test?				
	How does the lab handle the NC occurred?				
4.9.2	Is there any record on corrective action?				
	Who is responsible to verify the corrective action?				
	Does the lab notify their client and where is the record?				
4.10	Improvement				
	Is there have any record of improvement of the lab quality management system?				
4.11	Corrective Action				
4.11.1	What are the policy & procedure to implement the corrective action?				
4.11.2	Does the lab have procedure to investigate the root cause?				
4.11.3	Does the lab have the procedure to implement the corrective action?				
4.11.4	Who is responsible to monitor the corrective action?				
4.11.5	Is there have an addition audit after the corrective action have been taken?				
4.12	Preventive Action				
4.12.1	What are the policy & procedure to implement the preventive action?				
4.12.2	Who is responsible to verify the preventive action?				
4.13	Control of Records				
4.13.1	What are the policy & procedure for control of records?				
	Are the records being legible and stored?				
	Are the record being held secure and in confidential?				
	Are the record have being back-up?				

4.13.2	Technical records				
	Record for each test whether sufficient to establish for audit trial?				
	Check either observation or data have been recorded at the time they are made & identifiable?				
	How does the lab handle with the mistakes occur in records?				
4.14	Internal Audits				
4.14.1	What are the policy & procedure for internal audits?				
4.14.2	Is the lab has the procedure to solve the NC found result from internal audits?				
4.14.3	Is that the audit result and corrective action taken have been recorded?				
4.14.4	Is the lab has follow-up audit after the corrective action taken?				
4.15	Management Reviews				
4.15.1	What are the policy & procedure for management review				
4.15.2	Is the lab recorded the management review minute?				
5.0	TECHNICAL REQUIREMENT				
5.2	Personnel				
5.2.1	Check either the lab staff are competence to do the job				
5.2.3	Who supervised the contracted and additional technical				
5.3	Accommodation & Environmental Conditions				
5.3.1	Any procedure related to accommodation & environmental conditions?				
5.3.2	Any record on environment monitoring?				
5.3.3& 5.3.4	Any safety/security procedure and record?				
5.3.5	Any housekeeping program/record?				
5.4	Test & Calibration Methods and Method Validation				
5.4.1	Any procedure related to test method and method validation?				
5.4.2	*Where is the list of the test method used by the lab?				
	*Does the lab have records related to measurement of uncertainty, validation, verification, conformation of the test method?				
	*How does the lab make the selection of test method?				
5.4.3	Is the lab has any laboratory-developed methods?				
5.4.4	Is the lab has any non-standard methods? Any validation on their test?				
5.4.5	Validation of test method				
	Check either non-standard method, laboratory-developed method, standard methods used outside their intended scope and notification standard method are fit for the intended use.				
5.4.6	Estimation of uncertainty of measurement				
	Any procedure to estimate the uncertainty of measurement?				

5.4.7	Control of data				
	Check either all calculation & data transfers are subjected to appropriate checks?				
	Any computer software developed by the user?				
	Any procedure for protecting the data?				
	Check either computer and automated equipment are maintain?				
5.5	Equipment				
5.5.1	Is all equipment required for the correct performances of the test?				
5.5.2	Check either equipment or its software used for testing/calibration and sampling can comply with specification relevant to the test/calibration concerned?				
	Are the equipment and its software checked and/or calibrated before used?				
	Where are the record & certificates of calibration and the statement of fit for use?				
5.5.3	Does the equipment operated by authorized staff?				
	Any up-to-date instruction on the use and maintenance are available?				
5.5.5	Check either the record consist of the following information; i. Identity of the items & software ii. Manufacturer name, model iii. Complies with spec relevant to the test iv. Current location v. Manufacturer instructions vi. Dates, result & copy of reports and certificates of calibration, adjustment, acceptance criteria & due date of nest calibration vii. Maintenance and calibration plans viii. Any damage, malfunction, modification or repair to the equipment.				
5.5.6	What are the policy & procedure related to equipment?				
5.5.7& 5.5.8	How does the lab control the non-conforming instrument? How does the lab label their instrument?				
5.5.10	Are intermediate checks needed to maintain confidence in the calibration status?				
5.5.11	Where are the record, logbook and information related to the instrument?				
5.6	Measurement Traceability				
5.6.1	What are the policy & procedure related to measurement traceability?				
	Where is the list of the apparatus, instrument and/or reference material that need to be calibrated?				
5.6.2	Any programme for calibration of equipment?				
5.6.3	Any programme and procedure for the calibration of reference standard?				
	Any checking on the internal reference material?				
	Any procedure and schedule for intermediate checks?				
	Any procedure for safe handling, transport, storage and use of reference standard to prevent contamination or deterioration?				

5.7	Sampling				
5.7.1	What are the policy & procedure related to sampling?				
	Do the lab have method of sampling and the sampling plan?				
5.8	Handling of Test & Calibration Items				
5.8.1	What are the policy & procedure related to handling of test/calibration items?				
5.8.3	Does the lab have the procedure on non-conforming items and where is the record?				
5.9	Assuring the Quality of Test and Calibration Results				
5.9.1	What are the policy & procedure related to assuring the quality of test and calibration results?				
5.9.2	What is the control action taken by the lab?				
	How the lab ensure that they have sufficient supervision on quality control action?				
5.10	Reporting the Results				
5.10.2	Any standard format of the test report/calibration certificate?				
5.10.3	Any interpretation of test results?				
	Check the test report containing the results of sampling?				
5.10.4	Calibration certificates				
5.10.5	Are the opinion and interpretation clearly stated in the test report?				
5.10.6	Testing and calibration results obtained from subcontractor				
5.10.7	How the lab control the results through electronic transmission?				
5.10.8	Format of reports and calibration				
	Any design for report produced by the lab?				
5.10.9	Any amendment on the test reports produced by the lab?				

Remark

NA: Not Applicable D: Documented I: Implemented

Appendix J

Schedule of Management Review

Universiti Malaysia PAHANG
Engineering • Technology • Creativity

Faculty of Mechanical Laboratory

Management Review Schedule

January

Su	Mo	Tu	We	Th	Fr	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

February

Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28						

March

Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

April

Su	Mo	Tu	We	Th	Fr	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

May

Su	Mo	Tu	We	Th	Fr	Sa
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

Jun

Su	Mo	Tu	We	Th	Fr	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

July

Su	Mo	Tu	We	Th	Fr	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

August

Su	Mo	Tu	We	Th	Fr	Sa
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

September

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

October

Su	Mo	Tu	We	Th	Fr	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

November

Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

December

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	