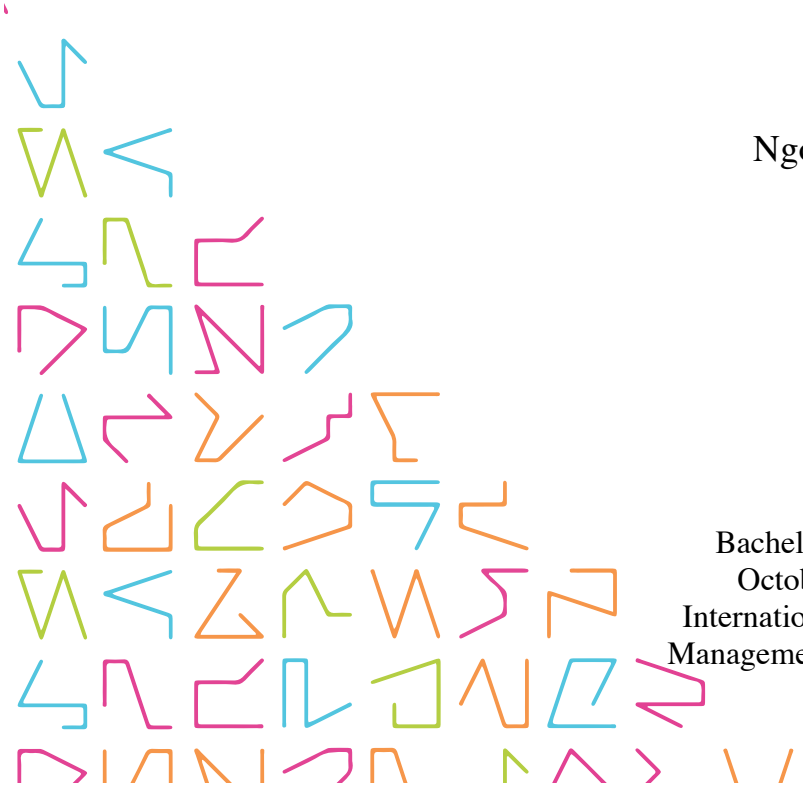
TAMPERE UNIVERSITY
OF APPLIED SCIENCES

# THE IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM TO TESTING LABORATORY

In Compliance with ISO/IEC 17025:2005

Standard

Ngoc Bui



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**ABSTRACT**

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The Implementation of Quality Management System to Laboratory Testing Business In Compliance with ISO/IEC 17025 Standard

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The thesis was written to serve the purpose of its commissioned company, to have a quality management system ready for accreditation. As the commissioned company is laboratorial based with different services of digital television testing services, it was required to follow ISO/IEC 17025:2005 standard. Therefore, the thesis main objective was to study how to successfully implement quality management system in conformance with the standard.

Implementation of quality management system and improvement of quality process is an objective of many companies. In many companies, having a quality management system is part of strategic business development. A company with good quality practices easily gains trust and interest from existing customers as well as from potential customers. Quality is a broad topic and it indeed cannot be covered thoroughly within this project, so the author focused in three important angles that could help the process of implementing quality system become easier to the company. Those are the requirements of ISO/IEC 17025:2005 standard, the construction of a quality handbook, and the company's readiness to accreditation.

The thesis consists of nine chapters, expanding from the theory of quality, management system, ISO/IEC 17025:2005 until the results of internal studies and final discussion of the author. During the project, researches and study were made through qualitative methods to gain necessary information for analysis. The primary data was collected through questionnaire, interviews, observations and study of internal documents. The secondary date was collected from reliable sources of information, including guidebooks and standards related to the study.

According to the findings, the company was mostly conforming with the standard, and there was need for little changes or updates in the system to be fully conformance. Other objectives set in the beginning of the project were achieved: the ISO/IEC 17025:2005 was fully examined and the quality handbook was completed. The author would suggest external sample audit as the next step before the company applies for certification of standard conformance.

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Key words: quality management system, quality handbook, ISO/IEC 17025:2005

**CONTENTS**

## ABBREVIATIONS AND TERMS

| | |
|---|---|
| ID | Identification |
| ISO | International Organization for Standardization |
| IEC | International Electro-Technical Commission |
| QMS | Quality Management System |
| SOPs | Standard Operational Procedures |
| SVN | (Apache) Subversion |
| TV | Television |

# 1 INTRODUCTION

## 1.1. Background

The thesis was written for the commissioned case company, known as a test laboratory for professional digital television test services. In an effort to realize its globalization and internationalization process, the company was seeking for a solution to improve business performance and to expand operation activities. One of the solutions suggested is implementation of quality management system based on ISO/IEC 17025:2005 standard and accreditation. The implementation of quality management system promises to improve the business performance, operating procedures as well as its customer services, which will be explained further in the thesis.

## 1.2. Thesis purpose and goals

As the ground for project is mentioned above, this thesis is thus created to serve as a tool to assist the implementation of quality management system to the company's daily operation. The thesis results from study the current situation of the company regarding quality management, and from study of external materials, it gives guidelines to the company on what shall be implemented or modified to match with the standard requirements.

By the end of the thesis project, the quality management system should be implemented, while a quality handbook is presented to customers as a marketing tool and to assist the company's staff in following the regulations in the quality management system.

## 1.3. Thesis structure

The thesis is constructed to nine chapters. The first chapter explains the background of the topic, purpose, scope and structure of the thesis. In this chapter, the readers understand the purpose and construction of the thesis project. The second chapter introduces the case company, in which the author has been assigned the project. This chapter will briefly explain the current industry situation and company's services. The third chapter lays the framework and research questions, as well as discusses further on research methodology and data collection methods. The fourth chapter reviews general principles

and ideas of quality from current literature sources. The fifth chapter discusses the quality management system, and the benefits and barriers when constructing it. This chapter focuses on the quality management system in electro technical laboratories and how it should comply with ISO 17025:2005 standard. A deeper detail of ISO 17025:2005 standard is made in the sixth chapter, where the author will go through each clause and highlights important points that shall be implemented in a quality management system. The seventh chapter describes the project process and result from readiness analysis. The eighth chapter discusses the findings. The ninth chapter finally gives conclusion on the thesis project. At the end of the thesis, there are reference list and appendixes.

# 2 COMPANY INTRODUCTION

The case company is a privately owned, independent and impartial test laboratory for professional digital television test services. Established in 2004 in Tampere, the technology city of Finland, the company has been working in telecommunication field for more than ten years. The company's main business activities are full-scale digital TV device testing services to TV broadcasters, network operators and device manufacturers. The case company has completed over hundreds of tests to all clients around the world. Most of the clients are TV manufacturers, set-top-box manufacturers, and telecommunication service providers, as well as governmental bodies.

## 2.1. Digital TV laboratories

Digital TV testing is a combination of commercial business and traditional laboratorial testing activities. Digital TV testing laboratories work closely with government bodies and regulators. In normal cases, the customers are identified as manufacturers and service providers.

The market for this business type is very competitive, varies and changes quickly from time to time, due to the fast-pace changing technological nature of the industry. Modification in regulations, development of new technology or even adjustment in business strategies from any market players can easily affect the business. In the other hand, it happens often that the domestic market becomes saturated extremely fast and the company has to start finding new opportunities abroad. Those opportunities come from developing countries, where technology and infrastructure are one-step behind the world leading operators.

When company operates to global market level, the management has to implement innovative processes into the organization continuously to establish a solid ground for the business amongst other competitors. During those changes, it is crucial to maintain the validity of tests and control of quality assurance. Implementation and accreditation of quality management system to relevant standards is suggested as an international recognition for small and medium business in global market.

### 2.2. Services

Main services that the laboratory offers include:

- Verification and acceptance tests
- Customized test-projects
- Consulting
- Customized test environments

The laboratory has established general procedures for each of the services. Below is a sample procedure for verification and acceptance tests:

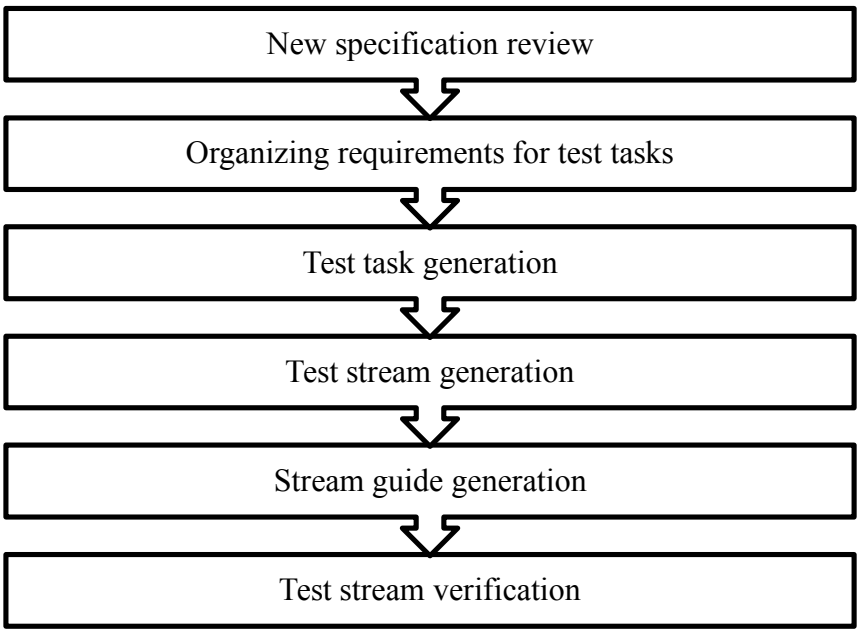


**Figure 1. An example of the laboratory's testing procedures.**

Focusing on ISO/IEC 17025:2005 standard, the scope of this project relates more to testing activities and test-projects rather than consulting services. Those are the fields that require strict control of quality management and an elaboration on quality of testing can assist the company in going global.

# 3 RESEARCH METHODOLOGY AND FRAMEWORK

## 3.1. Research framework

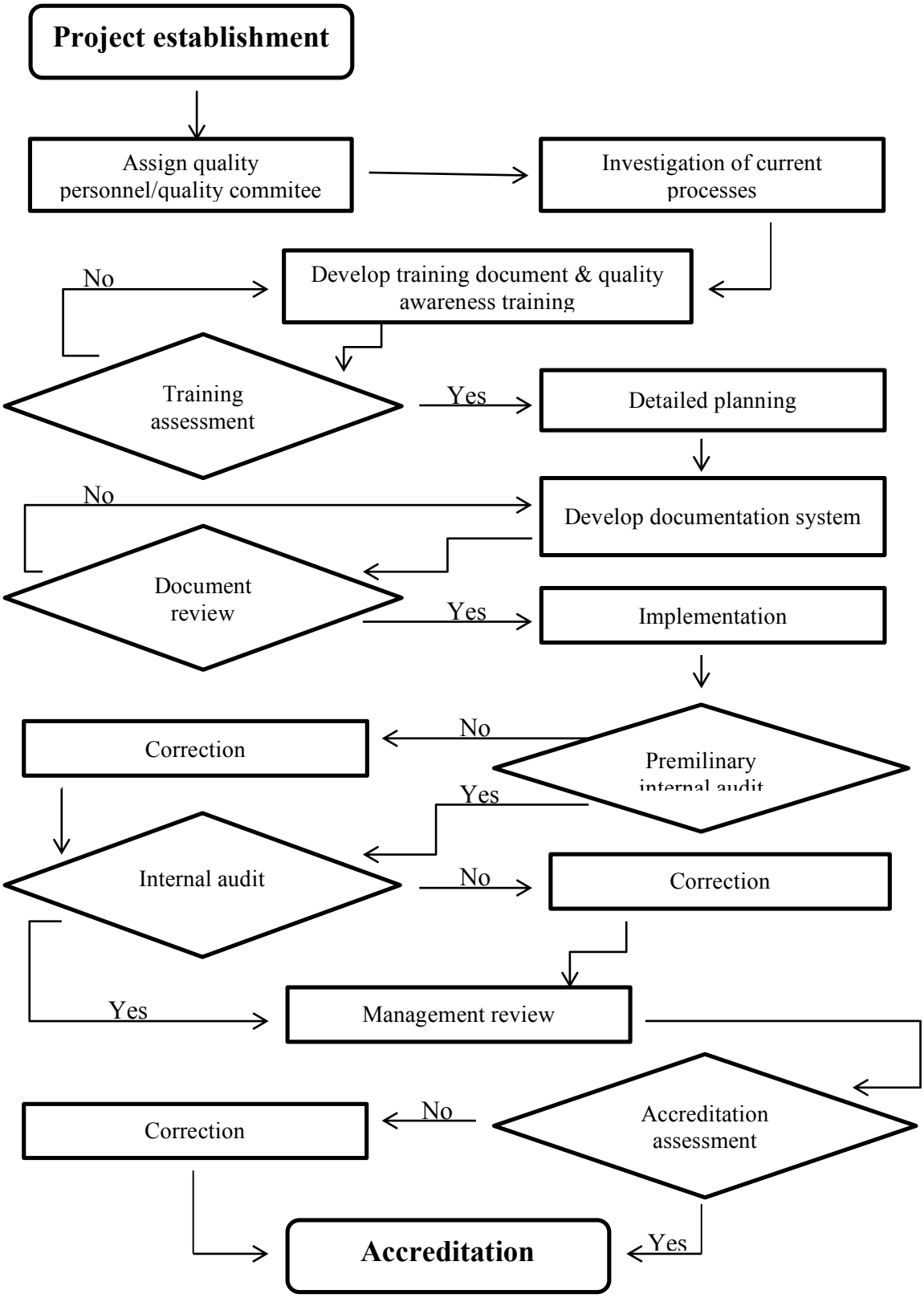


**Figure 2. Implementation process flowchart**

### 3.2. Research questions

As mentioned in the first chapter, the company initial request was to create a quality handbook for the laboratory. However, during the working process, other questions came up and there was need for further study on quality management system. Because the company also wished to acquire accreditation, it was important to study the whole system rather than a single piece. Therefore, the author came up with the project and research questions was defined to help keeping the line.

The project starts with the question "How to successfully implement a quality management system in accordance with ISO/IEC 17025:2005 standard?". Being able to answer this question is extremely important because it helps the commissioned company to get closer to acquire the accreditation. Since the staff also needs to get familiar with the standard, the author decides to study closely requirements of quality management system. This leads to the first sub-research question, "What is included in the theory of quality management?". The second task given was to construct the quality handbook, as a part of the quality system, so therefore the question is to learn how the quality handbook should be and what elements as well as structure it should have. Finally, it is also necessary to learn how the company is ready in case of assessment, so forth the third question was raised to examine the business readiness.


**Figure 3. Research questions**

### 3.3. Research methodology and data collection

There have been different suggestions on how the processes of implementing the system should be done from various sources, but the author found the flowchart illustrated above suits best to the case company and provides reliable and valid result. The whole project was study based on ISO 17025 standard and its requirements, in combination of research of related topics such as quality management, quality accreditation and quality documentation. The research framework was concluded after such study on different materials and guidelines in the field.

The process for implementing quality management system includes steps from identifying goals and objectives to building missing elements and getting prepared for accreditation. However, due to the length and width of the research, the thesis contains only a part from the whole implementation process. Within the scope of this thesis, the author aims to explore in details the investigation of current processes before implementation and the development of documentation system.

During the project, different qualitative research methods were used to collect necessary data and information to build up the quality management system. The primary and secondary data were collected through interviews with staff and managers, literature reviews and study of the concept through books and reliable internet sources, and analysis of all existing internal documents provided by the company. The interviews were conduct to understand the awareness of staff and managers concerning quality issues, while other materials gave the writer different perspectives about the company's readiness to a total quality management system.

As the concept was rarely recognized by staff in the beginning, observation was the mostly used method while conducting the project to understand the impact of different steps on the system and to modify the processes if needed. The writer's access to the company's internal system also helps to study the current situation effectively. The internal documentation system already has plenty of required documents for the quality management system. Those were later organized and modified to become a documentation system that suits the requirements from ISO 17025 standard.

# 4 DISCUSSION OF QUALITY

In order to successfully implement a quality management system, quality shall be reviewed and thoroughly understood. Through study of current literatures, different angles of quality and quality management shall be examined and creates a mutual understanding between the writer and staff about the project. This later on will help the project to be executed correctly.

## 4.1. Quality concept and perspectives

Quality has been a common concept in history, and also, has been one of the most controversial concepts. It is because of the variation of human perception in the world, as well as the difference in culture, that make the concept of quality and quality assurance vary from place to place. As there are different ways to understand and interpret the concept of quality, there are also neither way to define quality simply with a single perspective.

In previous study, quality regards mostly to the satisfaction of customers, and it is heavily related to the product (Juran, 1998.). ISO, in their DIS 9000:2000, however, has given a brief definition about quality. It is defined that "Quality is the collection of product/service/system/process to satisfy the needs of customers and all relevant parties." (ISO, 9000:2000.). Therefore, quality is not just characteristic of a product used daily, but also applied to a process or system.

In modern business context, the concept of quality expands to processes, organization, responsibilities, work instructions and resources to meet normal ISO standards (Hoyle, 2007.). It is an essential approach and a tool for all business looking for sustainable development. This could be simply explained in a way that, when a business implements quality into all the process, improvement of business performance can always be created and renewed. After all, quality has become a necessary factor for a successful business (Schneider-White 2004, 10.)

### 4.1.1 Quality in laboratories

From several definitions that quality could be understood, there is one that more noticeable and suitable in laboratorial work, known as “freedom from defects, imperfections or contamination” (Hoyle, 2007.) In this particular context, Juran’s opinion of quality as the “conformance to customer needs” is not completely correct anymore (Juran, 1998.)

Laboratories generally have a slightly different approach towards quality and customers. It has become crucial to determine the validity and to improve the results delivered. Even if a laboratory is operated as a private business, the accuracy, quality and validity of results are still more important than customers’ opinions. Thus, it turns into a questionable matter if assessing quality shall be done on the single point of view of the users or customers.

Quality in laboratories can be considered as work to be done in order to conform to requirements and guidelines from standardized and accredited organizations. Under business angle, it is an act to be accepted by the customers.

### 4.2. Quality management

Quality is not born itself without planning or action. It is a result of change management and other factors that strongly links together. For a business to achieve the aimed quality, the secrets lie in knowledge and control of those factors. Management work in the field of quality is known as quality management.

Quality management could be applied in all fields and industries, not only in manufacturing but also in other businesses, varies in all forms of organizations, from small to big and scaling from domestic to international. Quality management assures that the business does exactly what shall be done and what shall not.

When thinking about quality management in an organization, the manager must have equivalent knowledge and experience in the field of quality control for solving quality problems. Guiding and controlling quality work usually includes planning, creating solid objectives, assuring and improving the total process continuously.

#### 4.2.1 Quality management principles

According to ISO standard, there are eight quality management principles for businesses to achieve better quality performance (SFS-EN ISO 9000, 2005.) They are customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making and mutual beneficial supplier relationship. The next part will study further values of those principles and explain why they are important when considering implementation of quality management system into an organization.


**Figure 4. Principles of Quality Management (SFS-EN ISO 9000, 2005.)**

- **Customer focus**

  Customers' demand shapes the market and businesses are dependent on them. It is essential for business to focus in their customers first, as they play a decisive role in the success of a business. In order to win customers, business needs to spend more time and resources to understand their current and future needs.

The goal of the business shall not only meet, but also to exceed customers' expectation (Hoyle, 2007.) When focusing on the customers, business minimizes unnecessary processes in production and services, maximizing profits and sustaining.

- **Leadership**

Leadership is the second principle in quality management. Employees always need a clear goal and vision from the management to produce stable quality services and products. A good leadership creates cohesiveness between the mission and the vision of business, as well as strong communications within the organization (Hoyle, 2007.) They facilitate employees to work towards the same goal of the business by establishing and maintaining an ideal internal working environment.

Through leadership, the company could enhance employees' loyalty and commitment for their work, thus reducing operational costs such as inefficiency, layoff, trainings….

- **Involvement of people**

In the third principle, human factor is considered as the most important resource of a business. Businesses are dependent on the customers, but they are comprised by employees. This tackles an important aspect of the game, that staff directly decides and affects the quality of product. Employees shall be competence for their tasks and motivated by the top management. This creates a total involvement of employees with knowledge and experience, which is considerably valuable for the business (Hoyle, 2007.)

- **Process approach**

In this fourth principle, process approach is taken into account as the core of quality management system. The idea of process approach is that goals and objectives in an organization are achieved more effectively when sources and re-

lated activities are managed as a process (Hoyle, 2007.) This means that every single activity in the whole organization shall have a clear objective and all of them shall share a common goal.

Goal prioritization helps in reducing redundant activities and costs that are not related to the system. From another point of view, the benefit of process approach is also that when the business put concentration in the processes to make it a homogenous system, risks and threats are also inspected and therefore eliminated.

- **System approach to management**

The fifth principle refers to system approach, known as the process of defining, understanding and managing a system in which processes are linked with goals to bring effectiveness to the business (Hoyle, 2007.)

Knowing well about one process is not enough, the management and personnel responsible for it shall ensure the harmonization between processes in the whole system. The principle emphasizes in managing processes with defined roles and responsibilities to guarantee effectiveness and efficiency.

- **Continual improvement**

The sixth principle of quality management, continual improvement, should be a permanent objective, as well as a method in operating a business (Hoyle, 2007.) As development in industries occur continuously with time, there are always spaces for improvement in business. Those improvements can be recognized from customer feedbacks, internal communications, threats and risks, or products and services and so on.

Continual improvement shall be made on a regular basis to minimize defects and improve performance so that it benefits the business (ISO, 2013.)

- **Factual approach to decision making**

The seventh principle of quality management mentions the effect of rational decisions based on facts and figures. When all decisions and actions of a business operation management system is made based on the analysis of factual data and information, they become more effective (Hoyle, 2007.)

However, Hoyle reminds that the management needs to work on the backward process, in which decisions are chosen before collection of data. This is an interesting point when referring to costs reduction in quality management: backward process helps addressing the right problem and reduces waste of resources from unnecessary data collection.

- **Mutual beneficial supplier relationship**

Business always operates with different relationships. They could be relationship with customers, with agents, with suppliers and so on. Supplier relationships relates to any connection a business has with another party, in which the business receives products or services from that party. When customer relationship is a crucial factor deciding the strategy of a business, supplier relationship works as a supporting factor to help pushing forward the business along the road. Unlike end users-customer relationship, business and supplier are depending on each other, and a mutually beneficial relationship will improve each other's competence to create values (Hoyle, 2007.)

Communication and planning with supplier is important to create strong relationships and strategic alliances. By maintaining and sharing a common business strategy, both parties benefit from their relationship when prediction on the market needs is made better and opportunities can be quickly seized, while reduction of costs and optimization of resources are managed effectively.

### 4.2.2 Quality management key aspects

There are four different quality management key aspects: quality planning, quality control, quality improvement, and quality assurance (Hoyle, 2007.) These activities help quality management to be prepared, executed, reviewed and improved effectively and to fulfil quality requirements.

- **Quality planning**

  Quality planning sets strategic or operational quality objectives and specify processes and resources to fulfil those objectives. This includes a sequence of activities (Juran, 1998.)

  - Define goals and objectives
  - Identify the customers and stakeholders related to the objectives
  - Determine the needs of those stakeholders and prioritize them
  - Develop products or services that match those needs
  - Develop processes for production, promotion and distribution
  - Establish process controls and put the plans to actions.

- **Quality control**

  Quality control are the activities after quality planning to ensure that the quality requirements are fulfilled. Juran (1992) defined steps for quality control to be accomplished as follow:

  - Determine the subject of control
  - Establish measurement for control subject
  - Establish a standard level of performance
  - Select an instrument to detect variation in comparison with the standard
  - Implement measurement tool appropriately during, before or after the process depending on set targets
  - Collect and transfer data for analysis
  - Verify and compare the results with standards
  - Diagnose the cause of any nonconformities
  - Propose and implement corrective/preventive actions to resolve nonconformities.

- **Quality improvement**

  The purpose of quality improvement is to create better performance in quality management by continuous assessment the validity and sustainability of current processes. Quality improvement initiates change and increase the ability to ful-

fil quality requirements (Bergman & Klefsjo, 2010.) Hoyle (2007) pointed out that quality improvement could be done by better control or raising standards through accomplishment of the steps below:

- Define the (new) objectives
- Define the policies needed
- Conduct a feasibility study for improvement
- Plan and organize required resources
- Research, analyse and design solutions
- Model, develop and test the solutions
- Identify any resistance during change
- Implement the change for improvement
- Continuation of quality control

- **Quality assurance**

Another part of quality management is quality assurance, focusing on providing confidence that quality requirements will be fulfilled (ISO 9000). Quality assurance includes set of activities and preparation to ensure the promised quality is delivered. Those can be seen as:

- Preparation and documentation of organizational plans for achieving quality
- Establishment of quality assurance plan
- Organization of resources
- Assessment conformities of products/services in comparison with customer needs
- Determination of quality risks through processes
- Assessment of organization's capability in control, elimination and reduction of risks
- Determination of assurance plan's extension
- Verification of products/services quality

In conclusion, quality can hold various concepts depending on the market needs, business strategy and characteristics of products or services. Nevertheless, there are important fundamentals in general quality concepts that businesses need to pay attention when concerning internal quality management. They are key quality management prin-

ciples and activities. Businesses operate in compliance and conformance with those elements results better quality and sustainability.

# 5 QUALITY MANAGEMENT SYSTEM IN SCOPE OF ISO/IEC 17025:2005

## 5.1. Quality management system

In order to deliver quality to customers, an organization needs to build and operate a quality management system. ISO defines quality management system as "a management system to direct and control an organization with regard to quality" (Bergman & Klefsjö 2010).

The quality management system combines of relative and interactive factors to create quality policy and quality objectives for an organization and to achieve them. The combination of internal factors includes organizational structure and responsibilities, processes related to products and services, policies, control procedures and resources, including infrastructure and human resources (ISO 9001:2008). Those attribute to the design process of a quality management system. The quality policies, goals and objectives of a quality management system, in the other hand, are also dependent on external factors. Those could be seen as international standards, industry's instructions and regulations, guidelines, customer requirements, code of ethics and governmental legislations or other institutional requirements.

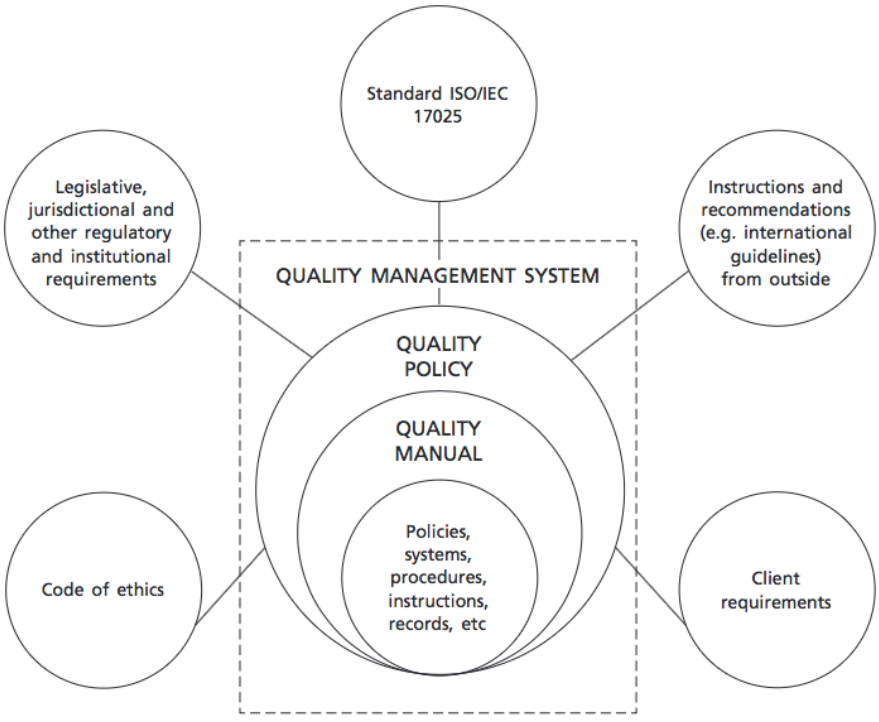


**Figure 5. Hierarchy of the quality management system**

In order to build the quality management system, firstly, the management of an organization decides if they want to commit to quality and if this matter is suitable to the organization. The employees need to be informed and also agree to commit to the process. In most of the case, the international standard acts as the most influential factor in building the quality system. Depending on the nature and the field of business, a general or specific standard is chosen to be a guideline for implementation of quality management system, for example ISO 17025 standard is designed for laboratories, but ISO 15189 standard is specified for medical laboratories. The organization is then binding to its industry's detailed requirements and specifications on the products or services.

As the quality management system is constructed and implemented, the organization continuously reflects itself and internal performance with the external factors changes and requirements to deliver matching quality.

### 5.2. The ISO/IEC 17025:2005 Standard

The ISO standard for laboratory quality systems was first issued in 1999, setting an international foundation for quality systems accreditation in laboratories (UNIDO, 2009.) The standard refers to testing and calibration laboratories work including sampling identification, labelling, testing, analysis and documenting test results.

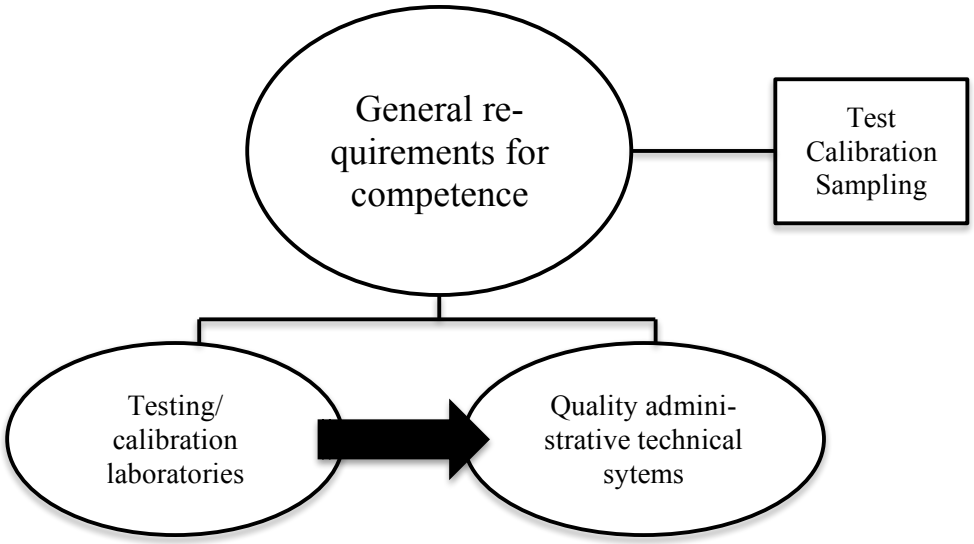


**Figure 6. Scope of ISO/IEC 17025:2005**

There has not been any major difference between ISO 17025:1999 and 17025:2005, especially when concerning technical requirements (UNIDO, 2009.) The changes focused more on management requirements, including control and commitment from management to the quality and customer feedback for improvement.

### 5.2.1 ISO 17025 standard and ISO 9001 standard

In comparison, ISO 17025 and ISO 9001 standards have relevant requirements to be fulfilled. Therefore, when ISO 17025 certified laboratory works as a sub-contractor for another ISO 9001 certified organization, the client organization can treat the laboratory as an ISO 9001 certified body and does not need to perform sub-contractor quality audits on the laboratory (UNIDO, 2009.)

However, a laboratory wants to use accreditation for promotion of their testing services must implement ISO 17025 standard instead of ISO 9001. This is because the requirements in ISO 17025 are set more specifically for the technical quality, and the audit for this standard is also done by technical assessors who are specialists in the field. In this case, they are different because ISO 9001 external auditors are not required to be technical specialists and thus they do not perform review upon technical aspects of an organization (UNIDO, 2009.)

### 5.2.2 Benefits and barriers

Implementation of a quality management system brings different benefits and barriers to the business. As discussed in the previous chapter, the benefits could be seen as industry and international recognition, reduction and prevention from defects, scraps, work failures, increase of test accuracy, reduction of waste and cost savings, as well as improvement of the system continuously (PJLA, 2009).

First of all, implementation of the quality system raises quality awareness among staff, thus, work defects or scraps or failures are reduced and prevented. This makes the test results become more accurate and reliable. Time and money are also saved since there would be a decrease or elimination of product retest. Secondly, the processes are controlled in a systematic way with all the procedures are well defined and documented. The system is then continuously improved for better quality. Finally, a laboratory im-

plements and certified with ISO 17025 also received international recognition for technical competence. This creates a competitive edge over other competitors, and gain better customers confidence and trust in the market. For the case company, another impact of quality management system implementation is the access to global marketplace (PJLA, 2009.)

Despites the benefits, there are also barriers that shall be concerned when implementing quality management system. In small and medium businesses, the challenge presents in the operation process after the implementation. Some companies found it difficult to maintain the quality activities as a lack of commitments from the employees, or lack of management involvement in the system. In some companies operate with different departments, the division could be a reason that causes inconsistency in quality levels between the departments (Srinidhi, 1998.) This problem, however, is less severe in companies with no subsidiaries or departmental units. Another barrier is that the documentation and recording activities could also be a burden in lean-approach technology companies, prolonging the processes and causing extra workforce and time to maintain the system as the requirements. Employees have to learn about new organizational reporting structures when implementing the quality system and very often it is found to be difficult to adapt to them.

### 5.3. Elements of quality management system

Quality management system is built up with quality documentation and quality system records (UNIDO, 2009.) They are different documents and records, organized in a hierarchical level.

The top level includes business strategic documents, quality policy. Quality policy expresses the top management objectives and commitment to business' quality. In large firms, quality policy is distributed as independent item and marketing material. Quality policy is always a part of quality manual, along with a series of other policy statements for each process and element of the ISO 17025 standard.

The central of quality documentation is quality manual, or also known as other names such quality book or quality handbook. Quality manual must have the strongest authori-

ty within the system, and also shows commitment from top management level to the quality system (UNIDO, 2009).

The next level of quality includes standard operation procedures (SOPs). Standard operation standards are more specified documents created for each section of the quality management system. They outline responsibilities and actions related to the processes, defining detailed organization's policy and system functions in terms of who, what, and where.

Following SOPs are step-by-step operating procedures and work instructions, as well as any other necessary external guidelines, manuals, specifications required for the business activities. Those documents conform to the policies stated in quality manual and SOPs. Besides defining specific steps to for the employees to accomplish work tasks, the instructions also serve as a direct tool to ensure quality is practiced during all the processes of operation.

In the bottom of the documentation system are checklists, forms, records resulted from the quality management system. There are supporting documents to see how the system is implemented. The classification of documents can be seen in a pyramid shape as in the figure below.

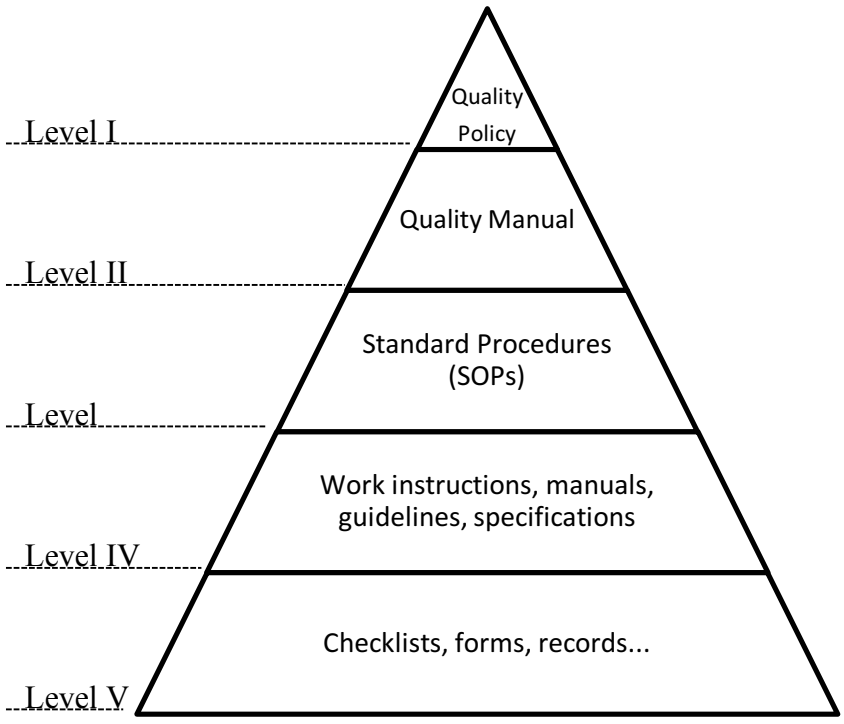


**Figure 7. Quality documentation system.**

# 6 REQUIREMENTS OF ISO/IEC 17025:2005 STANDARD

ISO 17025 standard requirements are divided into two sections: the management requirements and the technical requirements. The management requirements, focusing on organizational activities and management, have similar elements with the quality requirements in ISO 9001. The technical requirements section, in the other hand, focus in giving detailed technical instructions and quality requirements needed in a laboratory to produce quality test/calibration results and services. The quality handbook structure is also based on these requirements. There are 15 clauses in management requirements part and 10 clauses in the technical requirements part, presented as below.

| | |
|---|---|
| Management Requirements | Clause 4.1: Organization and Management |
| | Clause 4.2: Quality system |
| | Clause 4.3: Document control |
| | Clause 4.4: Review of requests, tenders and contracts |
| | Clause 4.5: Sub-contracting of tests and calibrations |
| | Clause 4.6: Purchasing services and supplies |
| | Clause 4.7: Service to the client |
| | Clause 4.8: Complaints |
| | Clause 4.9: Control of non-conforming testing and/or calibration work |
| | Clause 4.10: Improvement |
| | Clause 4.11: Corrective action |
| | Clause 4.12: Preventive action |
| | Clause 4.13: Control of records |
| | Clause 4.14: Internal audits |
| | Clause 4.15: Management reviews |
| Technical Requirements | Clause 5.1: General |
| | Clause 5.2: Personnel |
| | Clause 5.3: Accommodation and environmental conditions |
| | Clause 5.4: Test and calibration methods and methods validation |
| | Clause 5.5: Equipment |
| | Clause 5.6: Measurement of traceability |
| | Clause 5.7: Sampling |
| | Clause 5.8: Handling of test or calibration items |
| | Clause 5.9: Assuring the quality of test and calibration results |
| | Clause 5.10: Reporting the results |

**Figure 8. Required clauses in ISO/IEC 17025:2005**

As the quality handbook is the core of a quality management system, updates and control of relating quality documents are also as important and therefore the company needs to assign staff in responsible or to create a specific system to update on these changes.

The next part of this chapter focuses on the detail of each requirements and briefly explains what shall be done to fulfil each of the requirements of the standard. The author has been studying the standards and benchmarking the implementation process between ISO/IEC 17025:2005 and other standards. When studying the ISO/IEC 17025:2005 standard's requirements, the data and instructions are also collected from different valid guidance sources. Therefore, an interpretation of the standard was created in aim to help the staff in understanding, building and implementing the quality management system easier and faster.

## 6.1. Management Requirements

### 6.1.1 Clause 4.1: Organization and Management.

Clause 4.1 in the standard contains six sub-clauses and requires the general management in the organization.

First of all, the laboratory shall be able to describe its legal status (ISO 17025). For example, this could be articles of corporation, tax ID, partnership agreements or similar documents.

Secondly, the standard requires that the company shall fulfil all the requirements of the standards, and serves the needs of clients (ISO 17025).

Thirdly, all the activities that are in scope of accreditation shall be covered within the quality management system, even if those activities are located in different facilities.

In the next sub-clause, 4.1.4, the conflict of interests is addressed. Since the standard only gives a subjective guide, this could be understood that in large organization, the quality person should not be influenced by any other departments such as financial or marketing in making judgement. In small organization, it is clear that the quality person shall not report to the head of manufacturing. To have an effective and clear system, the

person in charge of quality management shall be able to give independent technical judgement. (ISO 17025).

The fifth sub-clause, in brief, requires that the company shall have an organization chart, and that shall be included in the quality manual (ISO 17025). It is important to successfully express the authority and resources from management related to the control of quality system. All the personnel's authority and responsibilities for implementation, maintenance and improvement of the system shall be described in job description, as well as appointed deputies. In regard of conflict of interests, it is suggested that the company shall have either a training/orientation sessions for new employees or an agreement on this subject that clearly defines the company's policy. Furthermore, a procedure to protect the customer's information and rights shall be established and maybe included in a new employee's training/orientation (ISO 17025). Even though quality management and technical management shall be both presented in the system, it is acceptable in small organizations like the case company, that is the technical manager could also be the quality manager.

Finally, the last sub-clause requires the management to have effective and appropriate communication processes (ISO 17025). This could be expressed through management reviews and meetings records.

### 6.1.2 Clause 4.2: Quality system

Clause 4.2 about quality system contains seven sub-clauses, in which requires the organization to have a well-documented and well-functioned quality management system. The requirements impose on the documentation of quality manual, quality policies, system, programs, procedures and instructions (ISO 17025). To fully satisfy the requirements, it is to be noted to the management in the company that those documents shall be reviewed and updated regularly. The requirements also stress on management's commitment to the quality system, which can be executed through effective communication with the employees and customers (ISO 17025).

A range of activities and methods for maintenance of a quality management system is suggested, for example, the company can conduct training sessions for the employees to understand the quality system and its policies. Furthermore, regular records of internal

audits, management reviews, maintenance of equipment are good evidence to show the quality system are being maintained.

### 6.1.3 Clause 4.3: Document control

Clause 4.3 in the requirements covers three sections: request for document control system, document approval and issues, and management in document changes (ISO 17025). The requirements are stated clearly in the standard, however, there is still missing clarification.

The documents defined in the requirements vary in all kind of forms and contexts (ISO 17025). This means that the documents shall include the quality manual, quality policies, procedures, work instruction and test methods. When the document control system covers all the necessary documents that are related to the quality system, the document approval and issues shall be fulfilled. A signature is evidence of approval, and so does any electronic systems that define the approval in this way. Besides, in order to fulfil this requirement, the company shall be able to prove that all the employees have access to the documents when needed, and those documents are being kept updated regularly with records of changes (ISO 17025).

### 6.1.4 Clause 4.4: Review of requests, tenders and contracts

Clause 4.4, review of requests, tenders and contracts, relates to presale activities with the clients. The company shall be able to keep on documentation during quotation process. Documents includes but not limited to records of review and any changes make between the company and the client's contract. The company shall make sure that it has the capability to perform tests and those test methods meet the client's requirements (ISO 17025).

### 6.1.5 Clause 4.5: Sub-contracting of tests and calibration

As the case company doesn't perform sub-contracting of tests and calibration, a review in this clause is waived.

### 6.1.6 Clause 4.6: Purchasing services and supplies

Clause 4.6 contains the requirements regarding the processes and procedures of purchasing activities. There are two main points in this clause.

First, all the activities, from receiving the equipment or items, shall be documented and strictly followed the policies in an established purchasing procedure. Records of purchasing, receiving inspection and items descriptions shall be made.

Second, the company is required to keep an approved supplier list (ISO 17025). Approved suppliers assure that the all the items coming to the company and the laboratory meet ISO's requirements and therefore correspond with the company's quality management system. Different methods can be used to define an approved supplier. Using an accredited supplier, perform an audit, or having the supplier to declare its conformity to the standard are all valid methods.

### 6.1.7 Clause 4.7: Service to the client

Clause 4.7 requires the company to have procedure in response to any client's requests (ISO 17025). It is usually that client's requests are received in the

Moreover, the company must gain customer feedback in order to improve the quality management system and this shall be done in an annual basis. Another suggestion would be that the company asking for feedback from the customers immediately after every test done.

### 6.1.8 Clause 4.8: Complaints

Clause 4.8 requires an established procedure to handle complaints from the client. The company shall be able to relieve the client's concerns and if there's a problem, there shall be a process that leads to corrective actions.

### 6.1.9 Clause 4.9: Control of non-conforming testing and/or calibration work

Clause 4.9 requires the company to have policies and procedures regarding non-conforming testing work (ISO 17025). The procedures may include investigation activities, evaluation of changes and effects, correction, or even termination of non-conforming work. The authority and responsibility of the personnel who handle non-conformances shall be stated clearly in the job descriptions. All records shall be made during the procedures, and in essential cases, there should be a policy for notification made to the clients regarding non-conformances (ISO 17025).

### 6.1.10 Clause 4.10: Improvement

Clause 4.10 requires the company to have different activities in order to make improvement within the quality management system. The activities could be management reviews, internal audits, training sessions, or corrective and preventive actions (ISO 17025). All the activities shall be regulated in an established procedure and carefully recorded as evidence.

### 6.1.11 Clause 4.11: Corrective action

Clause 4.11 states the standard's requirements of corrective action when a problem emerges in the system. Corrective actions can address any part of the quality management system: non-conforming work, internal or external audits, management reviews, feedback from clients, and so on (ISO 17025). There should be an established procedure for the staff to follow when making corrective action. In addition, the clause imposes that all the actions shall be recorded. The company shall be able to present the evidence proving the procedures are being followed strictly and correctly.

There are four steps the requirement suggests company to follow, including:

- Cause analysis
- Selection and implementation of corrective actions
- Monitoring of corrective actions
- Additional audits. (ISO 17025)

### 6.1.12 Clause 4.12: Preventive action

Clause 4.12 addresses that the company shall keep looking for improvement opportunities with clear action plans when the preventive action is needed (ISO 17025). This shall be made into policy and procedures to follow. There are many forms of action can be done in the preventive action process. For example, the company can perform risk and data analysis or review of current operation processes to find room for improvement. Internal audits, reviews and evaluations are ways to measure the effectiveness of preventive actions taken. Those activities therefore shall always be recorded (ISO 17025).

### 6.1.13 Clause 4.13: Control of records

Clause 4.13 is about control of records, one of the most important elements in the quality system. The records, according to the standard, shall be kept safely to prevent loss, damages, changes, and are accessible when needed. There should always be a backup version of those electronically. The company shall be able to give evidence that the records are access-only to related authorized staff (ISO 17025).

There is recommendation of what shall be included in a record:

- Equipment
- Original and derived data
- Staff performed the test
- Method of test
- Results

For laboratories that also perform calibration and sampling, it is necessary to have calibration report and sampling method. However, in this case, the company doesn't have to worry about these because they are irrelevant to their field of testing.

### 6.1.14 Clause 4.14: Internal audits

Clause 4.14 requires the company to have an established procedure for internal audits. Audit performances can be done either at once to cover the whole quality management system, or separately in periods, depending the cases. It is recommended by the standard that audits are to be done yearly, and all the data acquired shall be documented in records (ISO 17025).

In small laboratories like the case company, the author would suggest to use an external auditor to maintain independence of results.

#### 6.1.15 Clause 4.15: Management reviews

Clause 6.15, the final clause in management requirements of the standard, suggests the company to perform management review at least once per year and on an annual basis (ISO 17025).

The quality manager shall be the responsible person in preparing the meetings with agenda and relevant documents from the quality management system. Minutes shall be taking during the meeting as an evidence of management review. In management reviews, top management goes through list of topics, for example; internal audits, quality manual, reports and records, staff training, customer feedback and so on as instructed in the standard. From management reviews, it is essential that the company does make an action plan upon those.

### 6.2. Technical Requirements

#### 6.2.1 Clause 5.1: General

Clause 5.1 emphasizes on factors that might have effect on the test results within a laboratory. Those factors are not limited, as long as they are linked with the testing activities.

#### 6.2.2 Clause 5.2: Personnel

Clause 5.2, Personnel, is an important clause that deals with a factor which has direct effect on the testing activities: human resources. The clause requires the company to have control on working staff through management of training programs and records.

All the personnel working in the laboratory shall be competent, trained and supervised (ISO 17025). In order to show evidence of staff's competence, the company shall be able to present related documents such as job descriptions, personnel records, training records, certifications, and so on.

### 6.2.3 Clause 5.3: Accommodation and environmental conditions

Clause 5.3 refers accommodation and environmental conditions of the laboratory. It is required that all the environmental factors that might affect test results shall be monitor, controlled, and recorded by the laboratory (ISO 17025).

The most important task to fulfil this requirement is to keep records of the controlled environment in areas that needed. Since there is no specific description in the standard regarding the conditions, the requirements can be referred from regulations depending on field of testing. In case that the field of testing doesn't require specific control of environment conditions, the company shall still keep the all the areas clean as a sign of good housekeeping. Another part required by the clause is the company shall be able to control access to the testing areas.

### 6.2.4 Clause 5.4: Test and calibration methods and methods validation

Clause 5.4 specifies in methods used in laboratory for testing and how to ensure their validity. In general, the laboratory is required to have documented procedures for all of its activities: sampling, handling, transport, storage and preparation of tested items (ISO 17025). Even though procedure documentation is highly recommended, any missing procedure between the process that is proved not affecting validity of the test result can be waived.

It is common and is usually recommended in laboratories, that the methods selected for testing are adapted from international guidelines and instructions. The ISO 17025 standard states that "methods published in international, regional or national standards shall preferably be used" (ISO 17025). Therefore, the laboratory shall be able to present all documentation used as instructions for testing methods. Other documents can be presented to laboratory's customers to demonstrate selection of methods' validity are contract reviews, training records, and test demonstrations.

During the study of standard requirements, the author found out that in digital TV testing laboratory, sometimes the methods are developed upon customer requests. This is valid due to the nature of the testing in the field, as some items require specific parameters evaluation. The laboratory shall be able to prove through records and documents

that all the laboratory-developed methods are planned with a clear starting and ending stage, and are executed by suitable personnel. The sub-clause 5.4.4 also has quite clear instructions on non-standard methods for laboratories.

It was given clearly in the standard how validation of methods shall be done with certain techniques (ISO 17025). It is obvious that the need for validation of methods raise when the laboratory is having activities out of the normal scope. For example, if there are new equipment or new laboratory-developed methods of testing to be used, then there shall be validation on those to assure the quality is maintained.

### 6.2.5 Clause 5.5: Equipment

Clause 5.5 refers to control of equipment used during testing. Equipment used for performing tests shall be available for assessment of accreditation regardless of ownership. Therefore, the company shall be able to prove that any outside equipment used with temporary control matches with ISO 17025 standard through documentation.

Another requirement from this clause is equipment shall be calibrated, and the company shall be able to give evidence that equipment used in the laboratory can perform tests and the test results are valid. Calibration or checks are ways to assure that the equipment meets the requirements prior usage. Thus, all the information and data regarding equipment's calibration status shall be well recorded according to the standard's requirement.

Besides, the staff using equipment shall always be authorized (ISO 17025). The best way to demonstrate this is to include it in the training/personal records. To assist staff, equipment's manuals/ operation guides shall be available to use upon request. When the standard requires equipment and testing programs to be uniquely identified (ISO 17025), the company can take advantage of usage of serial numbers or code to fulfil the requirements.

The standard specifies clearly of what shall be included in equipment's records. Those requirements can be found in the standard, section 5.5.5. In addition, the company shall make sure that all changes happen to equipment are recorded and trackable. Obviously, established procedures for handling, transport, storage, use and maintenance of equipment and/or faulty equipment will help the company in complying to the standard (ISO

17025). After all, the main idea of this clause is to assure the equipment are suitable for use in the whole testing process, through a range of activities including checking, calibrating and verification.

### 6.2.6 Clause 5.6: Measurement of traceability

Clause 5.6 in the standard requires laboratories to have all equipment related to testing activities calibrated (ISO 17025). Besides, it is highlighted that any program and procedure designed for calibration shall be documented (ISO 17025).

Usually, the programs and the procedures contain tracking elements of the equipment. These includes information about intervals and history of calibration, labels, methods, process of calibration, results and so on. This meant to create an uninterrupted chain of measurement traceability.

### 6.2.7 Clause 5.7: Sampling

As the company performs tests based on items sent directly to the laboratory, this clause is not applicable and therefore review for this clause is waved.

### 6.2.8 Clause 5.8: Handling of test and calibration items

Clause 5.8 are requirements about handling of test items of the laboratory. The clause states clearly processes, included but not limited to transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, shall be included in the procedure (ISO 17025).

To fulfil the requirements of identifying of tests and/or calibration items, there are different methods the company can utilize. Identification of items can be made by marking, labelling, tagging, or even arrange certain items for certain areas to prevent wrong results. Depending on the characteristics of the items and the nature of testing methods, the company will decide the most suitable system for item identification.

In case of deterioration, lost or damage of items during the whole process, the standard requires laboratory to have procedures for following actions. Records are also required

in those cases. Usually, the procedures shall give clear instructions from contacting the clients, reports to technical manager to storing the items to make sure all the parties reach mutual agreement on the next step.

### 6.2.9 Clause 5.9: Assuring the quality of test and calibration results

Clause 5.9 brings requirements about the quality of test and calibration results. Assuring a steady performance in testing and delivery of test results is important to both the laboratory and the customers. There are a few suggestions to fulfil the requirements, such as the laboratory participates in inter-laboratory comparison or proficiency testing programs (ISO 17025). Repeat of tests is also another way to measure variation in testing results. Although there is no certain task that the laboratory is obliged to do, those mentioned methods above helps to assure the quality to be delivered.

### 6.2.10 Clause 5.10: Reporting the results

Clause 5.10, reporting the results, provides clear guidance for the laboratories on the methods of reporting test results. It requires certain information to be presented on the report. Some of them, but not all, can be seen as methods of testing, laboratory information and address, customer information and address, descriptions, test results and so on. The clause also specifies on test certificates, report formats, and electronic transmission of the result (ISO 17025).

# 7 DEVELOPING THE QUALITY MANAGEMENT SYSTEM

## 7.1. General

The quality management system implementation starts with study of current internal and external situation. After the quality personnel or quality committee is assigned, the responsible person begins with investigation process. In the case company, firstly the interview with company's top level management and technical personnel was made to understand the aims and objectives of the leaders when establishing the quality management system. It was also made clear during the interviews what scope of work should be included in accreditation application. When discussing with the top-level management, the thesis worker starts learning about the company's current market position. This is important as it decides how the following plan could be done to improve current situation of the company.

The process of implementation was mentioned above in the flowchart. Within the assigned scope of work, the tasks below were conducted in order:

- **Study of clauses and requirements**: The aim of study of clauses and requirements is to fully understand the contents of ISO 17025 and its requirements. All staff is engaged in this process, as this will help the thesis worker and other staff to have a vision on what to be included in the quality management system. Result of this study is utilize for the construction of a quality handbook, an essential part to be delivered to the company.
- **Self-assessment**: Laboratory activities conformance and applicability to ISO 17025 standard requirements. Self-assessment activities are divided into two phases, preliminary study and post documentation study. The aim of this self-assessment is to prepare to the fullest company's readiness for audits. The results between two assessments are compared to see the improvements in the implementation for quality management system.
- **Prepare and modify required documents**: From the results of self-assessment, the author reviews current documents available within the system and prepare the missing documents. It is very common that a lot of organizations have the procedure but no official documents established.

### 7.2. Standard-familiarization workshops

To introduce the quality management requirements to staff in the laboratory, short meetings were conducted with managers. During the first meeting, the manager explained about ISO/IEC 17025:2005 and gave reasons why he thought the laboratory should implement it. There were discussions about quality and how the employees as well perceive their current quality performance within the laboratory.

The training session starts with briefing the requirements of quality system according to the ISO 17025 standard. The staff then went through each clause in the standard to reach a common understanding of required and elements. This step was important because there were many small details included in the standard. All the employees needed to have a consensus on each procedure and solid agreement on what shall be done and what shall not, in order to not overlapping or doubling work. At the end of the first workshop, staff was also provided with related guidelines to conform with ISO/IEC 17025:2005 standard and some audit samples from other firms to have a better view about the quality system and official audit process.

After the first workshop which was designed to help the employees get familiar with the standard, the second workshop was conducted after the preliminary study to define missing procedures and prepare cornerstone elements for the quality book. During this workshop, different tasks were assigned to employees depending on their responsibility and availability. As the laboratory is heavily technical based, a large amount of work from the quality book needed to consult from the laboratory's technical specialists. After the workshop, it was clear what the next step should be in the implementation process.

### 7.3. Preliminary study

The first self-examination session on quality readiness was conducted as a questionnaire delivered to the management in the laboratory. The questions given were based on UNIDO's guidebook, covering all the sections in the system. There are 73 questions or statements in total to check the company's readiness. Designed as a ticking-questionnaire, there are 4 answer options for the questions. During the session, manag-

ers went through each sub-category in the requirement and answer whether the procedure for that subject was met or not, and to what extend it was met.

The answer options also give the opportunities to eliminate unnecessary procedures by assessing the applicability of that subject to the current situation. For example, the laboratory doesn't do any calibration work, and therefore all the requirements and procedures regarding calibration could be eliminated from the quality management system.

Below are the results of preliminary study:

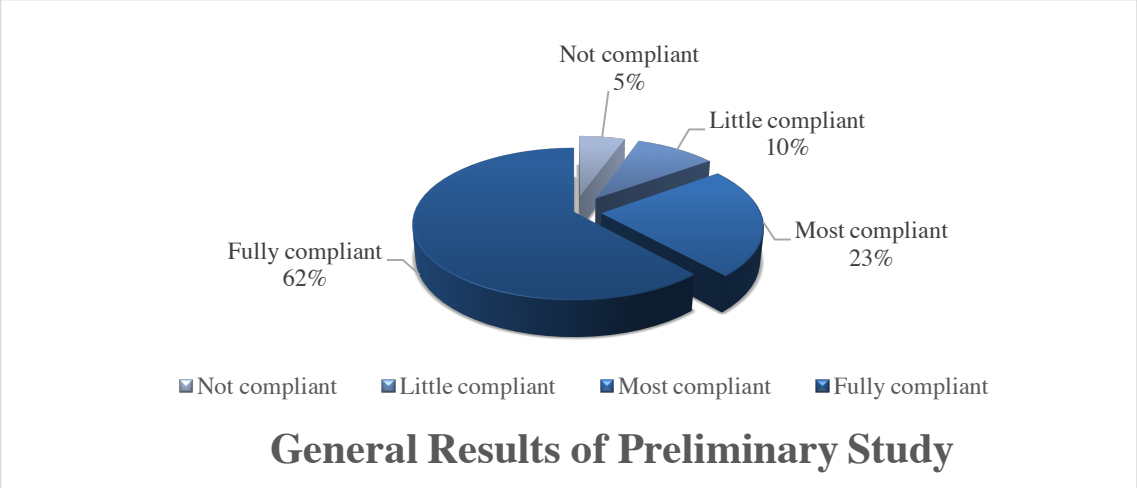


**Table 1. General results of Preliminary Study.**

From the preliminary study, the company has complied to many of the requirements. This table shows that the company is 62% fully compliant (45 clauses out of 73 clauses). A fully compliant mark in a clause means that the company has fulfilled the requirements and has an existed procedure for that. 23% of the result (17 clauses out of 73 clauses), shows those sections where the company might be compliant to the requirement, but has no official and established procedure to fulfil the requirements. 10% of the result (7 clauses out of 73 clauses) is marked as little compliant, in which the company has very little established resources to match with the requirements. About 5% of the results is not compliant (4 clauses out of 73 clauses). This is because the company doesn't perform sub-contraction and works as an independent laboratory.

The collected data was analysed deeper to study which part of the requirements are missing from the company's quality management system.

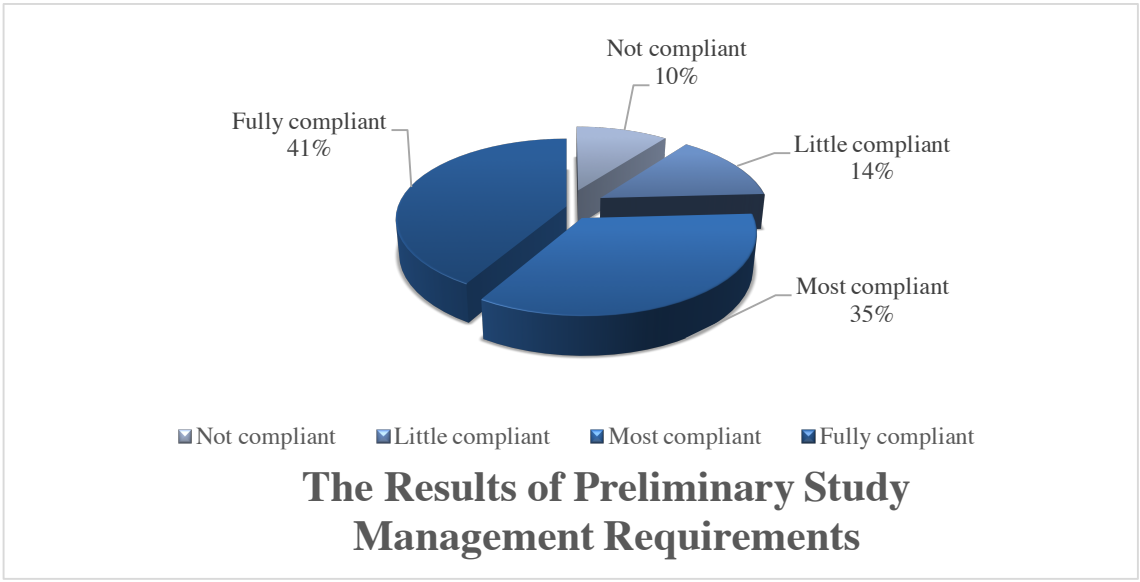


**Table 2. The results of Preliminary Study-Management requirements.**

When measuring the compliance with management requirements from the standard, it is shown in the table 2 that only 41% of the system is fully compliant (12 clauses out of 29 clauses). There are 35% of the system is mostly compliant (10 clauses out of 29 clauses), while 14% is little compliant (4 clauses out of 29 clauses). 10% of the system is not compliant to the requirements (3 clauses out of 29 clauses). Those 10% falls into section 4.5, which is understandable because the company doesn't perform sub contraction as mentioned above.

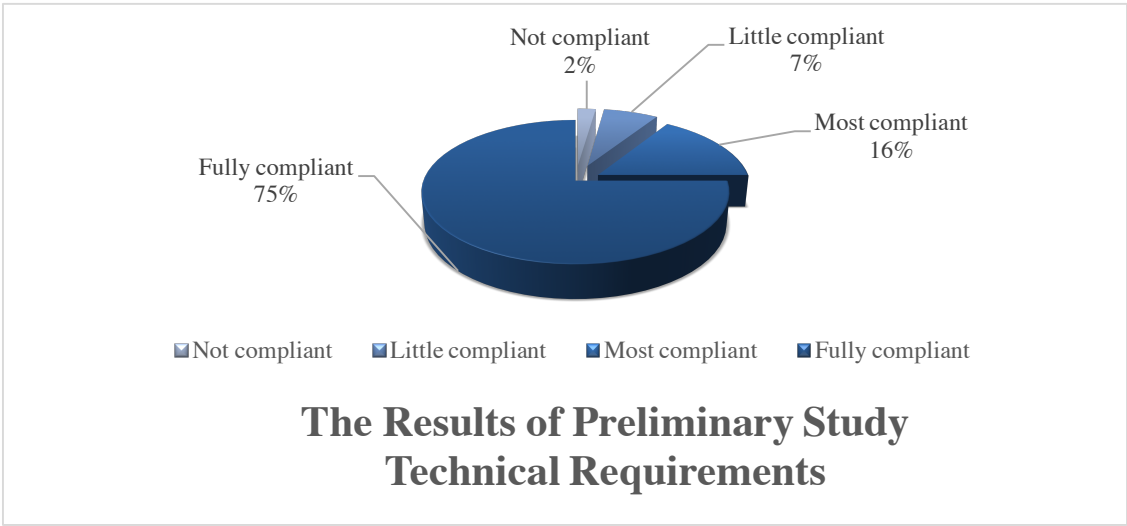


**Table 3. The results of preliminary study -Technical requirements.**

The result of preliminary study based on technical requirements shows that the company has fully complied to 75% (33 clauses out of 44 clauses). This is a positive sign that the company was having a systematic and correct control of technical procedures. 16% of the system (7 clauses out of 44 clauses) is mostly meeting the technical requirements, and 7% of the system (3 clauses out of 44 clauses) barely meet the requirements. The 2% (1 clause out of 44 clauses) doesn't meet the requirement, which can be explained that is because the company works as an independent laboratory and doesn't exchange samples or compare results.

The collected data from the first study also displays some other important information. The table below, Table 4, expresses in detail the conformity of the company quality management system by each of the requirements from standard ISO/IEC 17025:2005. The table shows number of clauses asked in each of the requirements, and the conformity level in correspondent to the clause. From this table, the author can understand which parts from the system needed to be done and define the next steps.

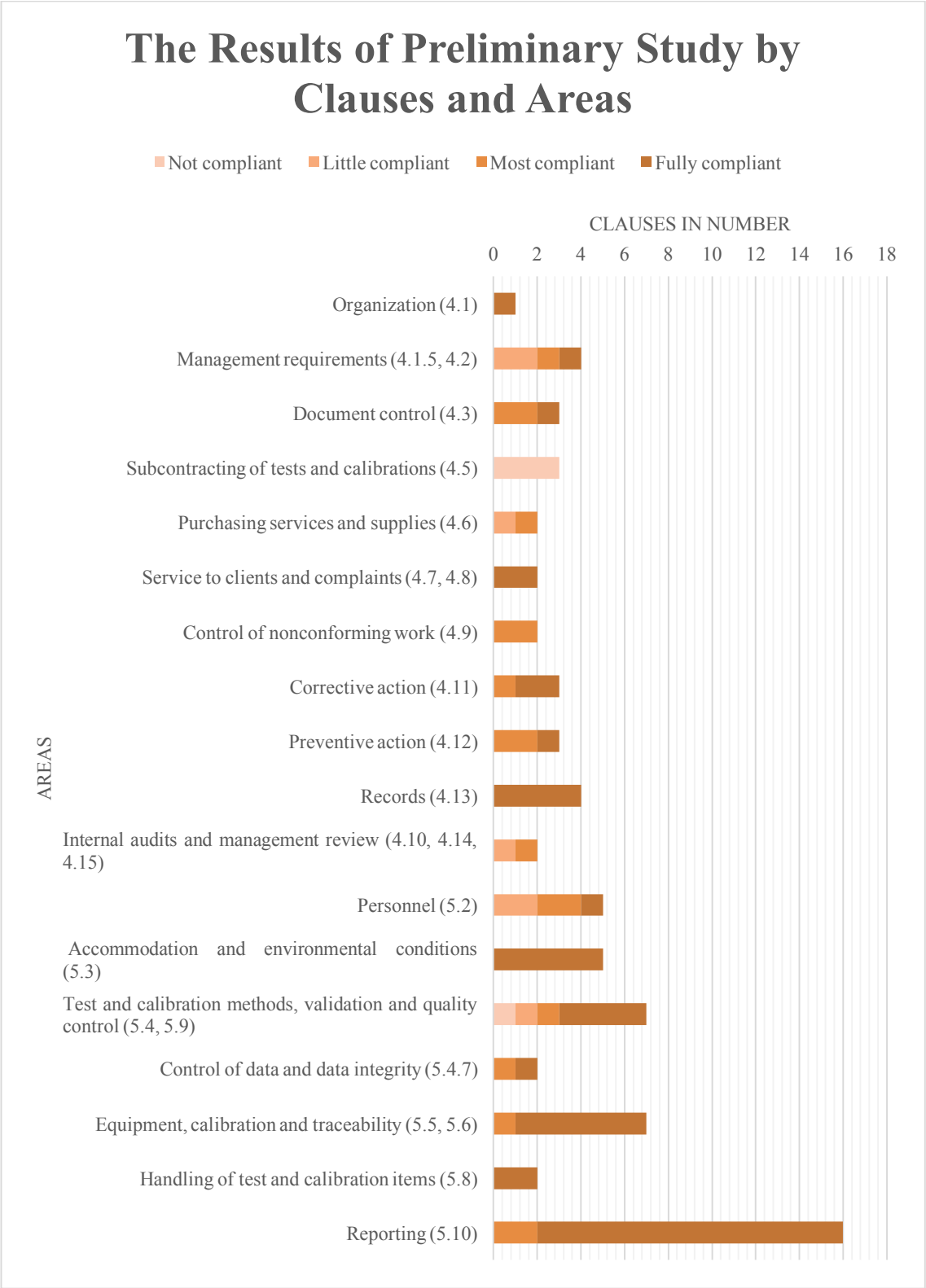


**Table 4. The Results of Preliminary Study by Clauses and Areas**

From the graph, the team was provided with useful information, that mostly the laboratory is missing either a procedure or established documentation those clause:

- Management requirements
- Purchasing and service supplies

- Internal audits and management review
- Personnel
- Test and calibration methods, validation and quality control.

Those were marked as “mostly compliant”, or “little compliant” to the standard. The information is important to decide what elements shall be added to the quality management system.

From the preliminary study, it can be concluded that the company has most of its procedures being compliant to the general requirements. The results showed that a larger part of the technical parts are compliant to the standard, in comparison with the management requirements. After the preliminary study, author made the second step to deeper investigate what are still missing from the quality management system. The second study was conduct right after the result of the first study. In this one, a meeting was organized and the author, together with the staff and managers went through the elements and procedures needed. The result is a list of documents required in the next part.

### 7.4. Building documentation system

There are a few requirements for the standard electronic documents created within the quality management system. Firstly, the document shall be easily accessed by staff at any time. Secondly, the documents shall not be easily modified by unauthorized personnel. Thirdly, all the changes in the documents shall be tracked and notified to the authorized manager.

After the preliminary analysis, the thesis worker has learnt that the company’s internal document sharing system has built-in functions that could serve the requirements of quality management system quite well. For example, it automatically records update and changes with time on each document by the specific person who made that change. However, the person in charge still needs to specify inside the document what and where the changes were made. It was also noticeable that even though there were many processes recognized as “conforming” to the requirements, the official documentation for those were still under-developed. It is important in a good quality system that both of the elements are needed, the actual work conforms the standard, and the documentation system is set up appropriately.

### 7.4.1 Quality Handbook

From the laboratory's point of view, the quality handbook serves as a general guide for staff and customers about company's quality procedures and policy. The thesis worker was assigned to draft the first version of quality handbook with other staff and under the supervision of the manager.

The quality handbook drafting started with review of the company's organizational structure and roles. Through this, the organization chart was created and quality management roles were added to the first section of the quality handbook. The first three chapters of the quality handbook introduce the company, its laboratorial services, scope of activities, main purpose of the quality handbook and reference sources.

From the fourth chapter onwards, the quality handbook concentrates on policies that the laboratory was following and guidelines for operating testing activities to staff. The structure of quality handbook, as mention in previous chapters, strictly follows the structure of clauses in the ISO/IEC 17025:2005 standard.

### 7.4.2 Standard Operational Procedures

Standard Operational Procedures (SOPs) are always part of a quality management system. The procedures and processes to be written were categorized and follow the standard's requirements.

| CATEGORIES | DOCUMENTS |
|---|---|
| Organization | • Description of organization<br>• Scope of operation |
| Management and personnel | • Responsibilities and duties description<br>• Policy and procedures for maintaining personnel's competence<br>• Procedure for training new and temporary workers. |
| Confidentiality | • Confidentiality requirements for personnel. |

| | |
|---|---|
| Management system | • Regular audits and management reviews instructions<br>• Procedure for internal audits and corrective actions: records of results, timetables, appointment of responsible persons and monitoring of implementation of actions. |
| Document control | • Procedures for controlling all the documents, including documents from external sources. |
| Review of requests, tenders and contracts | • Procedure to review of requests, tenders and contracts. |
| Purchasing services and supplies | • Policy and procedures for selection of and purchasing of services and supplies<br>• Procedures to inspect the purchased supplies before use. |
| Service to the client | • Policy and procedures for collecting and handling complaints and feedbacks from clients<br>• Policy and procedures for the resolution of complaints. |
| Control of nonconforming testing and/or calibration work and corrective action: | • Policy and procedures for treating nonconforming testing work<br>• Policy and procedure with defined responsibilities for implementing corrective action. |
| Preventive actions | • Procedures for identifying potential sources of nonconformance<br>• Procedures for needed improvements,<br>• Procedures to ensure the preventive actions are effective. |
| Control of records | • Procedures for the control of records, including electronically stored records. |
| Environment | • Definition for environmental condition requirements<br>• Monitoring of environmental condition to meet the requirements<br>• Access control system to prevent unauthorized persons. |
| Methods and procedures | • Detailed description of procedures for tests<br>• Instructions for internal quality assurance<br>• Assurance of computer-based programs functioning |

| | |
|---|---|
| | • Definition of uncertainty of measurements, list of reference materials and instructions pertaining to their uses. |
| Equipment and calibration | • Instructions for the operation, maintenance, calibration and service of equipment<br>• Calibration plan/substitute procedures to prove the validity of results. |
| Handling of the object to be test-ed | • Instructions for handling, storing, returning and disposal of testing objects<br>• Instructions for the content of test reports. |

### 7.5. Preliminary internal audit

The preliminary internal audit was made to review the quality management system building process. The manager also participated and showed input in the evaluation process. Because it was unnecessary to go through the same questionnaire from the preliminary study as the project has been heavily focused on the documentation system, the audit was conducted as a reflection of the laboratory's documentation system and provided status of each required document depending on the standard.

The laboratory has been following quality standards and most of the work only based on improving the quality documentation system, the result of audit showed positive improvements. For example, most of the procedures were ready by the time of audit, or in the status of 70% completed. Some of them were already integrated into the working system and only needed small updates or modification to conform with the standard. Organization chart, quality policy and quality manual was completed by the time of audit.

The graph below will give a detailed information on result of documentation system based on standard's requirement clauses.

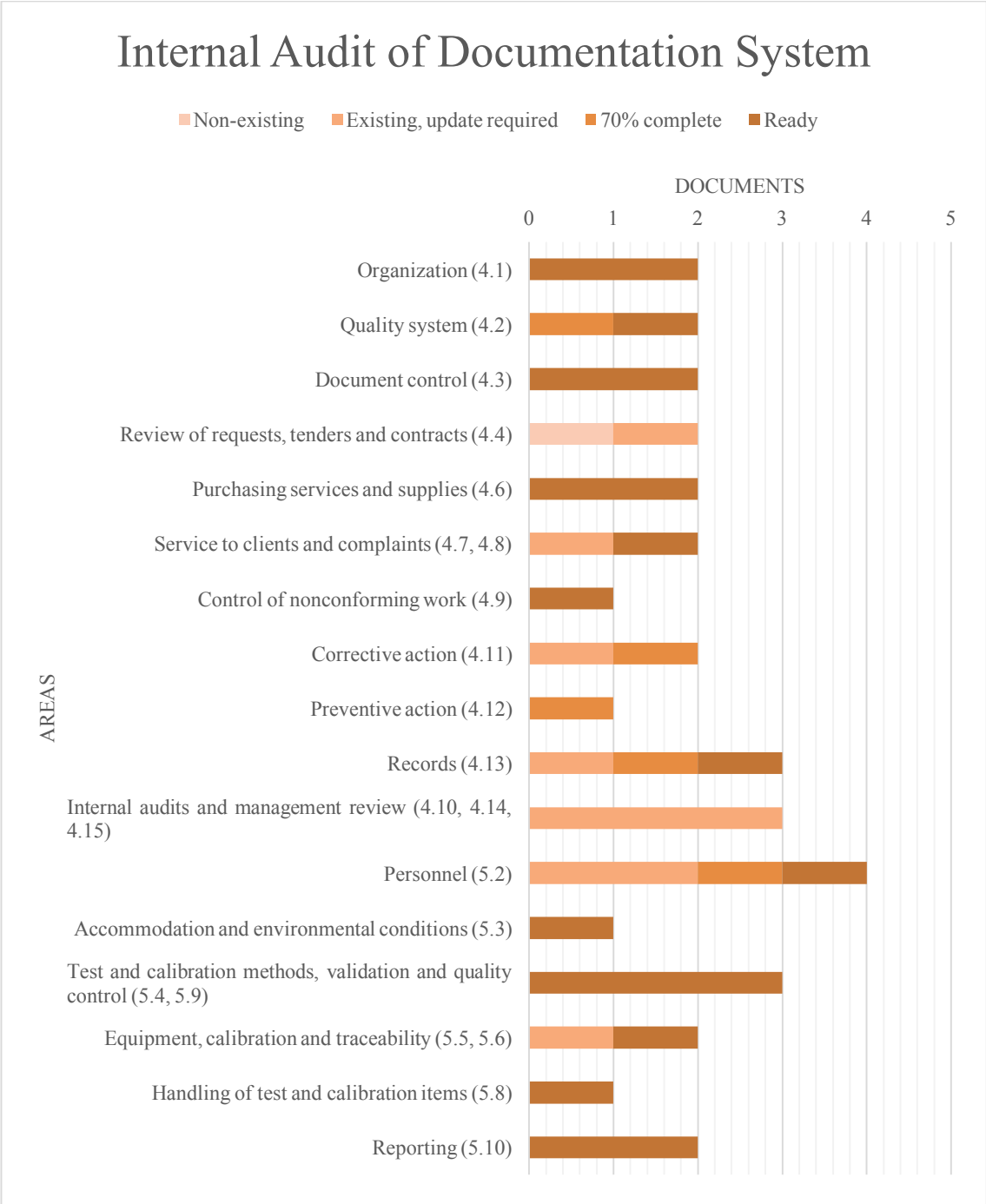


**Table 5. Result of documentation system's internal audit**

From the result of audit, the laboratory still needs to improve its internal audit and management review process, as displayed in the graph under clause 4.10, 4.14 and 4.15. These processes shall be established with clear procedure to all staff and perform annually or semi-annually. In addition, clause 4.4, “review of requests, tenders and contracts” also needs more updates and added procedure to the system, even though the process has been executed without any problem in previous years.

# 8 DISCUSSION

Outcomes of the project are seen as follow:

- Readiness Analysis
- Quality Manual
- Management Procedures

By the end of this thesis work, the outcome has been satisfactory. As the main objective of this project was to help commissioned company implement the ISO/IEC 17025:2005 into quality management system, the answer for this question can be seen through outcomes of the project. The company reached a better point of view of their stance in the quality management and now has a clear framework of steps to walk up the accreditation process.

The readiness analysis helps the top management and staff to understand the requirements from the standard, while an established quality manual fulfil primary need from the manager. A set of management procedures works as guide documents for staff to follow. The study of standard's requirement clauses in this thesis can also serve as a tool and reference for staff in case they need further clarification and/or instructions from the requirements.

After the project, the staff and top management team has a clear view about what are the requirements of the quality management system and how to receive accreditation. The company has achieved quite a satisfactory level of implementing the standard, but through the research, it also proves that there is still room for improvement.

Few of the most important parts that the company misses from the quality management system is the work and records of annual reviews and audits, management reviews, and staff trainings. Even though it is acceptable to prove that the company has started those activities from the date the accreditation application being sent, previous records during the whole business time will increase the image of the company in conforming standard and quality.

Besides, the documentation system might need arrangement and restructuring. Because of the nature of business, a big amount of documents stored in the internal electric doc-

umentation system is in bad navigation. Those can still be improved with implementation of other documentation management system. The company might consider solution from those service providers like M-Files. Another noticeable point is that although the internal SVN system of the laboratory allows staff to access easily to files and track updates by other staff quickly, it does not leave a record of what changes have been done. This limitation can badly affect the audit result as well as accreditation result. However, one of the simple ways to fix the problem is to attach an appendix on each document and manually note down what has been changed as a proof of record.

Every single quality management system requires a different set of documentation, organization and work process. During the project, the author faced difficulties to recognize the missing part in quality system of the commissioned company. The technical nature of the business, which is not the study major of the author, makes it difficult to understand the whole system quickly. Some of the guidelines and work instructions are built in Finnish. which is also a barrier. Another reason is that in quality management system, there was no sample case to help the author benchmark and find the best implementation plan.

In the author's point of view, it is also beneficial for the company to hire an external auditor with experience in ISO/IEC 17025:2005 accreditation to help reviewing the system. He or she will know best what can be left aside and not necessarily has to be implemented. This will help the company from having too many unnecessary documents built up in the procedures. In those small companies, this is very sensitive and essential, as bureaucracy will slow down organization's efficiency and increase costs for the business.

# 9 CONCLUSION

Quality management is always a difficult topic in term of planning, executing and evaluating. One of the reasons is, as mentioned in earlier chapters, because the perception of quality varies between each individual. Each individual in an organization will have a different approach and action towards the quality goal, and therefore it is usually difficult to have a consensus between all staff. Awareness of difference in quality perception will help management team to have more effective concentration and effort on quality training and quality management system.

Another issue raised during the project is that the thesis author notices difficulties to implement a total quality management system in small companies according to standards and rules. The requirements of documentation system are very complex and following those strictly slows down the efficiency in an organization. It increases the bureaucracy at work and sometimes demotivates staff when they have to add extra steps in their work process. A solution has been suggested in the previous chapter, but it does not guarantee a decrease in amount of paper work.

The next step of the project will depend on the top management decision, if they would like commit to the annual activities included in the quality management system, and their plan to acquire ISO/IEC 17025:2005 certification. This will require more involvement from both staff and top management, as well as a more detailed implementation plan.

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**APPENDICES**

Appendix 1. Preliminary study

| Self-examination questionnaire | | Score | | | |
|---|---|---|---|---|---|
| | | Not compliant | Little compliant | Most compliant | Fully compliant |
| **Organization (4.1)** | Is the laboratory managed in such a way that it operates independently and is free from external influences? | | | | 4 |
| **Management requirements (4.1.5, 4.2)** | Is senior management committed to a quality system, including compliance with ISO 17025, and agreed that resources will be provided to establish and maintain it? | | | | 4 |
| | Do staff at all levels recognise that, irrespective of workload and other pressures, the requirements of the quality system must be followed at all times? | | | 3 | |
| | Is there a person who is responsible for establishing and monitoring compliance with the quality system on a day-to-day basis? | | 2 | | |
| | Is there a documented specification of the quality management system, for example in a quality manual, with clear assignment of authority and responsibility such that the managers who supervise work have authority to ensure the quality of the work which they supervise? | | 2 | | |

| | | | | | |
|---|---|---|---|---|---|
| **Document control (4.3)** | Are there documents available that give work instructions so that staff have a source of reference to enable them to conduct their work properly and consistently? | | | 3 | |
| | Are all documents giving instructions or used to record data authorised by defined management personnel? | | | | 4 |
| | Is a record of the issue of all documents kept and procedures adopted so that, when amendments are made, every copy can be retrieved to be updated? | | | 3 | |
| **Subcontracting of tests and calibrations (4.5)** | Do you have a list of approved subcontractors? | 1 | | | |
| | Do you have a record of the accreditations of the subcontractors? | 1 | | | |
| | Where subcontractors are not accredited do you have other evidence that they are competent? | 1 | | | |
| **Purchasing services and supplies (4.6)** | Do you have a list of approved suppliers and a policy for inclusion of a supplier on the list? | | 2 | | |
| | Does this policy ensure that purchased materials and services will be good enough to ensure that the quality of your data is not threatened? | | | 3 | |
| **Service to clients and complaints (4.7, 4.8)** | Do clients know how to contact you and who to speak to about the progress of their work? | | | | 4 |
| | Do you follow up complaints from clients and learn from them so that you can take steps to ensure that the problem does not happen | | | | 4 |

| | | | | | |
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| | again | | | | |
| **Control of nonconforming work (4.9)** | Do you have a procedure for ensuring that work, or release of data, is stopped immediately nonconforming work is identified? | | | 3 | |
| | Do you follow up on nonconforming work in order to learn from it and take action to ensure that the problem cannot happen again | | | 3 | |
| **Corrective action (4.11)** | Where quality problems are identified do you have a procedure for ensuring that prompt corrective action is taken? | | | 3 | |
| | Do you ensure that the corrective action taken addresses the root cause of the problem, i.e. do you think that you normally make it unlikely that the problem will happen again? | | | | 4 |
| | Do you follow up to ensure that the corrective action has been effective, for example after a period of settling in? | | | | 4 |
| **Preventive action (4.12)** | Do you track trends in data so that you can respond to deterioration in quality before it reaches unacceptable levels? | | | 3 | |
| | Do you hold regular meetings of senior technical staff to discuss areas of concern about quality and consider proposals for improvement? | | | | 4 |
| | Do you track measurable items, for example turnaround times, num- | | | 3 | |

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| | bers of re-tests necessary, and respond when performance appears to be deteriorating? | | | | |
| **Records (4.13)** | Where your documentation requires a procedure to be followed do you have records which show whether it was actually done or not? | | | | 4 |
| | Would your records enable you to identify the person who did each piece of work? | | | | 4 |
| | Would your records enable you to identify the equipment used? | | | | 4 |
| | Would your records enable you to prove that the equipment was properly calibrated and functioning correctly? | | | | 4 |
| **Internal audits and management review (4.10, 4.14, 4.15)** | Do you carry out and record regular inspections to check that the procedures which you have defined and documented are, in fact, being followed? | | 2 | | |
| | Does senior management carry out reviews to determine whether the quality system continues to meet the needs of the organisation? | | | 3 | |
| **Personnel (5.2)** | Do you have appropriate numbers and types of staff so that work can be carried out without having to rush so much that quality may be compromised? | | | 3 | |
| | Do you formally check if all persons performing technical functions possess the required educational/professional qualifications and experience? | | | | 4 |

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| | Are there clearly defined job descriptions set out for each of the persons working in the laboratory? | | | 3 | |
| | Do you have a procedure for regular performance evaluation to assess their competence? | | 2 | | |
| | Do you have a procedure for training staff in testing and/or calibration? | | 2 | | |
| **Accommodation and environmental conditions (5.3)** | Does the accommodation provide adequate separation of functions to minimize the possibility of cross contamination? (Give a lab floor plan?) | | | | 4 |
| | Are you confident that the conditions and standard of housekeeping in your laboratory are adequate to ensure that the quality of data is not being compromised? | | | | 4 |
| | Are there measures to provide uninterrupted services (electricity, gas, water)? | | | | 4 |
| | Are there measures to restrict the entry of unwanted materials and persons into the laboratory? | | | | 4 |
| | Are there appropriate storage facilities to provide integrity of samples before and after testing? | | | | 4 |
| **Test and calibration meth-** | Do you use only standard, internationally accepted methods for testing? | | | 3 | |

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| **ods, validation and quality control (5.4, 5.9)** | Are all methods documented to the extent necessary to enable them to be performed properly and consistently? | | | | 4 |
| | Do you have validation data which shows the performance characteristics, for example accuracy and precision, of all of the methods which you carry out? | | | | 4 |
| | Are quality control procedures in place to ensure that the performance characteristics established for the methods continue to be met on a routine basis? | | 2 | | |
| | Is the laboratory staff trained in sampling? | | | | 4 |
| | Where these are available, does the laboratory make regular measurements on certified reference materials to confirm the accuracy of its measurements? | | | | 4 |
| | Where available, does the laboratory participate in interlaboratory comparison exercises, i.e. exchange of samples with other laboratories and comparison of results? | 1 | | | |
| **Control of data and data integrity (5.4.7)** | Is all raw data recorded at the time of observation and traceable, for example by being signed, to the person who made the observation? | | | | 4 |
| | Are transfers of data between documents, or between documents and computers, subject to checks? | | | 3 | |
| **Equipment,** | Are operational procedure charts available with each of the equip- | | | | 4 |

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| **calibration and traceability (5.5, 5.6)** | ments? | | | | |
| | Where the concept is applicable, has equipment been calibrated to ensure traceability to the SI system of units through an unbroken and, if necessary, international chain? | | | | 4 |
| | Are regular cleaning and maintenance checks performed? | | | 3 | |
| | Do you have evidence to show that calibration is carried out often enough to ensure that drift between calibrations is not so large as to undermine data quality? | | | | 4 |
| | Where practicable, is equipment checked between calibrations and records kept to confirm that it has not drifted and lost its calibration? | | | | 4 |
| | Is all equipment which is subject to regular checks or calibrations labelled to show when the next calibration or check is due? | | | | 4 |
| | Is there a record of all equipment and particularly of its cleaning, maintenance and calibration history? | | | | 4 |
| **Handling of test and calibration items (5.8)** | Do you have a system for uniquely labelling and numbering items so that the number remains with all samples and sub-samples as the item moves through the laboratory? | | | | 4 |
| | Do you have procedures for identifying samples which require special storage or preservation and for ensuring that appropriate action is taken? | | | | 4 |

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| **Reporting (5.10)** | Name and address of the laboratory; | | | | 4 |
| | Name and address of client; | | | | 4 |
| | Unique identifier of certificate or report (such as serial number); | | | | 4 |
| | On each sheet of the certificate or report, a unique form of sheet identifier (such as the serial number of the certificate or report, with a unique page number in the form "page -- of -- pages"); | | | | 4 |
| | Date of receipt of calibration or test item, and date(s) of performance of calibration or test, as appropriate; | | | | 4 |
| | Date of issue of certificate or report; | | | | 4 |
| | Signature and legible name of approved signatory or signatories taking responsibility for the content of the certificate or report, or equivalent form of technical authorisation; | | | | 4 |
| | Unambiguous identification of item(s) calibrated or tested (including name of manufacturer of item(s), any model or type designation and any relevant serial numbers, as appropriate); | | | | 4 |
| | Any abnormalities or departures from standard conditions; | | | | 4 |
| | Reference to calibration or test method and procedure used; | | | | 4 |
| | Any standard or other specification relevant to the calibration or test method or procedure, and deviations, additions to or exclusions from the specification concerned; | | | | 4 |

| | | | | | |
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| | Where relevant to the validity or application of the calibration or test result(s), details of any sampling, item preparation, or data analysis; | | | | 4 |
| | Calibration or test result(s); | | | 3 | |
| | Any design or performance specifications met or failed; | | | | 4 |
| | Estimated uncertainty of the calibration or test result (this information need only appear in test reports and test certificates where it is relevant to the validity or application of the test result, where a client's instructions so require, or where uncertainty affects compliance to a specification or limit); | | | 3 | |
| | Any other available information requested by a client relevant to the validity or applicability of the calibration or test result. | | | | 4 |

Appendix 2. Internal document audit

| DOCUMENT SYSTEM ACCORDING TO ISO/IEC 17025:2005 REQUIREMENTS<br>HỆ THỐNG TÀI LIỆU THEO YÊU CẦU ISO/IEC 17025:2005 | | |
|---|---|---|
| **ISO/IEC 17025:2005 STANDARD<br>TIÊU CHUẨN ISO/IEC 17025:2005** | **DOCUMENTS<br>TÀI LIỆU** | **STATUS<br>TÌNH TRẠNG** |
| **4 MANAGEMENT REQUIREMENTS<br>CÁC YÊU CẦU VỀ QUẢN LÝ** | | |
| **4.1. Organization<br>Tổ chức** | Organization Chart<br>Sơ đồ tổ chức | *Ready<br>Hoàn thành* |
| | Conflict of Interest Agreement<br>Thoả thuận về Xung đột lợi ích | *Part of the employment agreement<br>Nằm trong hợp đồng lao động* |
| **4.2. Quality system<br>Hệ thống chất lượng** | Quality Manual<br>Sổ tay chất lượng | *In preparation, 70% ready<br>Đang chuẩn bị, 70% hoàn thành* |
| | Quality Policy Statement<br>Chính sách chất lượng | *Part of the Quality Manual<br>Nằm trong Sổ tay chất lượng* |
| **4.3. Document and Data Control<br>Kiểm soát tài liệu** | Document control Procedure<br>Quy trình Kiểm soát tài liệu | *Ready<br>Hoàn thành* |
| | Document Master List<br>Danh sách tài liệu | *Ready<br>Hoàn thành* |
| **4.4. Review of requests, tenders and contracts<br>Xem xét các yêu cầu và đề nghị hợp đồng** | Review of requests, tenders and contracts Procedure<br>Quy trình Xem xét yêu cầu, đề nghị và hợp đồng | *Implemented, needs to be documented<br>Đã áp dụng, cần ghi lại văn bản* |
| | Reliability Test Request<br>Yêu cầu Kiểm tra độ tin cậy | *Needs to be implemented<br>Cần được áp dụng* |

| DOCUMENT SYSTEM ACCORDING TO ISO/IEC 17025:2005 REQUIREMENTS<br>HỆ THỐNG TÀI LIỆU THEO YÊU CẦU ISO/IEC 17025:2005 | | |
|---|---|---|
| **ISO/IEC 17025:2005 STANDARD**<br>**TIÊU CHUẨN ISO/IEC 17025:2005** | **DOCUMENTS**<br>**TÀI LIỆU** | **STATUS**<br>**TÌNH TRẠNG** |
| **4.5. Subcontracting of tests and calibrations**<br>**Hợp đồng phụ về thử nghiệm và hiệu chuân** | Non-conforming<br>Không phù hợp | |
| **4.6. Purchasing services and suppliers**<br>**Mua dịch vụ và đồ cung cấp** | Purchasing Procedure<br>Quy trình Mua dịch vụ và đồ cung cấp | *Ready*<br>*Hoàn thành* |
| | Supplier List<br>Danh sách nhà cung cấp | *Ready*<br>*Hoàn thành* |
| **4.7. Service to the customer**<br>**Dịch vụ đối với khách hàng** | Customer Feedback Form and Record<br>Mẫu và Hồ sơ Phản hồi của khách hàng | *Existing, but need to be updated*<br>*Đã có sẵn, cần cập nhật* |
| **4.8. Complaints**<br>**Khiếu nại** | Complaints Procedure<br>Quy trình Giải quyết phàn nàn | *Ready*<br>*Hoàn thành* |
| **4.9. Control of nonconforming testing and/or calibration work**<br>**Kiểm soát hiệu chuẩn & thử nghiệm không phù hợp** | Nonconforming Product and Test Control Procedure<br>Quy trình Kiểm soát hiệu chuẩn & thử nghiệm không phù hợp | *Ready*<br>*Hoàn thành* |
| **4.10. Improvement**<br>**Cải tiến** | Management Review Procedure<br>Quy trình Xem xét lãnh đạo | *Needs to be documented*<br>*Cần ghi lại văn bản* |
| **4.11. Corrective action**<br>**Hành động khắc phục** | Corrective and Preventive Action Procedure<br>Quy trình Hành động khắc phục, phòng ngừa | *Implemented, documentation is being processed*<br>*Quy trình đã được áp dụng, văn bản đang trong quá trình hoàn thành* |
| | Corrective Action Report<br>Báo cáo Hành động khắc phục | *Existing, but needs to be updated*<br>*Đã có sẵn, cần cập nhật* |

| DOCUMENT SYSTEM ACCORDING TO ISO/IEC 17025:2005 REQUIREMENTS<br>HỆ THỐNG TÀI LIỆU THEO YÊU CẦU ISO/IEC 17025:2005 | | |
|---|---|---|
| **ISO/IEC 17025:2005 STANDARD<br>TIÊU CHUẨN ISO/IEC 17025:2005** | **DOCUMENTS<br>TÀI LIỆU** | **STATUS<br>TÌNH TRẠNG** |
| **4.12. Preventive action<br>Hành động phòng ngừa** | Corrective and Preventive Action Procedure<br>Quy trình Hành động khắc phục, phòng ngừa | *Implemented, documentation is being processed*<br>*Quy trình đã được áp dụng, văn bản đang trong quá trình hoàn thành* |
| **4.13. Control of records<br>Kiểm soát hồ sơ** | Control of Records Procedure<br>Quy trình Kiểm soát hồ sơ | *Built into internal documentation management, needs to be documented*<br>*Đã được xây dựng trong hệ thống quản lý hồ sơ nội bộ, cần ghi lại văn bản* |
| | Quality Management Records<br>Hồ sơ Quản lý chất lượng | *System ready, some documents missing*<br>*Hệ thống hoàn thành, một số tài liệu còn thiếu sót* |
| | Technical records<br>Hồ sơ Kỹ thuật | *Ready*<br>*Hoàn thành* |
| **4.14. Internal audits<br>Đánh giá nội bộ** | Internal Audits Procedure<br>Quy trình Đánh giá nội bộ | *Needs to be documented*<br>*Cần ghi lại văn bản* |
| **4.15. Management reviews<br>Xem xét của lãnh đạo** | Management Review Procedure<br>Quy trình Xem xét lãnh đạo | *Needs to be documented*<br>*Cần ghi lại văn bản* |
| **5 TECHNICAL REQUIREMENTS<br>CÁC YÊU CẦU VỀ KỸ THUẬT** | | |

| DOCUMENT SYSTEM ACCORDING TO ISO/IEC 17025:2005 REQUIREMENTS<br>HỆ THỐNG TÀI LIỆU THEO YÊU CẦU ISO/IEC 17025:2005 | | |
|---|---|---|
| **ISO/IEC 17025:2005 STANDARD**<br>**TIÊU CHUẨN ISO/IEC 17025:2005** | **DOCUMENTS**<br>**TÀI LIỆU** | **STATUS**<br>**TÌNH TRẠNG** |
| **5.2. Personel**<br>**Nhân sự** | Training Procedure<br>Quy trình Đào tạo | *Implemented, needs to be documented*<br>*Đã áp dụng, cần ghi lại văn bản* |
| | Training/orientation Program<br>Chương trình đào tạo/hướng dẫn | *Implemented, needs to be documented*<br>*Đã áp dụng, cần ghi lại văn bản* |
| | Employee personal training/orientation Records<br>Hồ sơ Đào tạo/hướng dẫn nhân sự | *Almost ready*<br>*Gần hoàn thành* |
| | Job Descriptions<br>Bản mô ta công việc | *Ready*<br>*Hoàn thành* |
| **5.3. Accommodation and environmental conditions**<br>**Tiện nghi và điều kiện môi trường** | Specifications<br>Yêu cầu kỹ thuật | *Ready, some minor instructions need to be updated*<br>*Hoàn thành, một số hướng dẫn nhỏ cần cập nhật* |
| **5.4. Test and calibration methods and method validation**<br>**Phương pháp thử nghiệm/hiệu chuẩn và phê duyệt phương pháp** | Lab test methods<br>Phương pháp thử nghiệm phòng thí nghiệm | *Ready*<br>*Hoàn thành* |
| | Normative documents, standards, regulations…<br>Hướng dẫn, tiêu chuẩn và quy định… | *Ready*<br>*Hoàn thành* |
| **5.5. Equipment**<br>**Thiết bị** | Equipment user manuals<br>Hướng dẫn sử dụng, vận hành thiết bị, bảo quản… | *Ready*<br>*Hoàn thành* |

| DOCUMENT SYSTEM ACCORDING TO ISO/IEC 17025:2005 REQUIREMENTS<br>HỆ THỐNG TÀI LIỆU THEO YÊU CẦU ISO/IEC 17025:2005 | | |
|---|---|---|
| **ISO/IEC 17025:2005 STANDARD**<br>**TIÊU CHUẨN ISO/IEC 17025:2005** | **DOCUMENTS**<br>**TÀI LIỆU** | **STATUS**<br>**TÌNH TRẠNG** |
| | Control of Measuring and Monitoring of Equipment<br>Điều khiển giám sát và đo đạc thiết bị | *Built into internal documentation management, needs to be documented*<br>*Đã được xây dựng trong hệ thống quản lý hồ sơ nội bộ, cần ghi lại văn bản* |
| **5.8. Handling of test and calibration items**<br>**Quản lý mẫu thử nghiệm và hiệu chuẩn** | Guidelines<br>Hướng dẫn | *Ready*<br>*Hoàn thành* |
| **5.9. Assuring the quality of test and calibration results**<br>**Đảm bảo chất lượng kết quả thử nghiệm và hiệu chuẩn** | Lab test methods<br>Phương pháp thử nghiệm phòng thí nghiệm | *Ready*<br>*Hoàn thành* |
| | Nonconforming Product and Test Control Procedure<br>Quy trình Kiểm soát hiệu chuẩn & thử nghiệm không phù hợp | *Ready*<br>*Hoàn thành* |
| **5.10. Reporting the results**<br>**Báo cáo kết quả thử nghiệm** | Test Report<br>Báo cáo thử nghiệm | *Ready, automatically generated from the test management system*<br>*Hoàn thành, được ghi chú tự động trong hệ thống quản lý thử nghiệm* |
| | External calibration reports<br>Báo cáo Hiệu chuẩn bên ngoài | *Ready*<br>*Hoàn thành* |

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