

Analysis Implementation Effectiveness of ISO / IEC 17025 on Testing Laboratory

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Abstract

In improving the quality management system, the testing laboratory uses the ISO / IEC 17025 standard as a benchmark for the general requirements of testing / calibration competence, including sampling. This standard is also used for quality, administrative and technical activities. Customer laboratories, regulators and accreditation bodies may also use them to confirm or acknowledge the competence of the laboratory. The application of standards in laboratory testing is closely related to achieving the quality objectives contained in the laboratory. By using the standard ISO / IEC 17025 then the resulting product is guaranteed security, reliable and certainly has a quality that no doubt. Testing laboratory can be said to run effectively when it can manage or manage flexibility, customer, production, value-oriented, and the main job of its employees. Therefore, the analysis of the effectiveness of ISO / IEC 17025 implementation takes an important role for the testing laboratory. The Focus Group Discussion (FGD) method consisting of several competent assessors is instrumental in assessing any clauses related to the effectiveness of ISO implementation.

Keywords

ISO/IEC 17025, Effectiveness, Focus Group Discussion, Testing Laboratory

1. Introduction

1.1 Background

The improvement of national competitiveness of Indonesian products in the era of the ASEAN Economic Community (MEA) is currently quite rapid, this is closely related to the three matters mandated by Law No.20 of 2014 which is the development of standards by stakeholders, the application of SNI to protect the people of Indonesia and increasing national product competitiveness in their own country so it is expected to compete in global market (Badan Standardisasi Nasional, 2015). National industries compete with each other to feature their products. Therefore, the National Standardization Agency develops three pillars of infrastructure that facilitate the competition of national products, namely: Standardization, Conformity Assessment and Metrology (Badan Standardisasi Nasional, 2011). Voluntary standards are a strong pillar in improving the quality of an industry so that some regulations require certain industries to implement standards (Badan Standardisasi Nasional, 2016). In addition, with the development of the global economy the standards that affect it, change the pattern and time (Thema, 2016). Competition in the global economy and the market today also demands that service companies create well-designed Quality Management Systems (QMS) and implement them effectively (Psomas, L, Pantouvakis, A and Kafetzopoulos, P, 2013). Socio-economic activities can not be separated from the measurement (Khodabocus, F & Balgobin, K, 2011). Food safety, health and environmental protection depend on chemical measurement analysis, so that laboratory accreditation is required based on ISO / IEC 17025 standards to obtain accurate measurements (Khodabocus, F & Balgobin, K, 2011).

International Standards become a reference in the application of industry standards. Many industries implement quality management standards based on ISO 9001 (Sumaedi, S & Yarmen, M 2015). Based on a survey conducted by the standardization agency, most organizations apply the management system standard is the Testing Laboratory (Komite Akreditasi Nasional, 2016). This is because the test results provided by the testing laboratory is the determinant of the acceptability of a product in a particular market (ISO/IEC 17025,2005). One of the goals of applying ISO/IEC 17025 is to prove reliability and capability to clients and regulators (Vlachos, N, Michail, C & Sotiropoulou, 2002). Almost every region in Indonesia has an accredited testing laboratory (Komite Akreditasi Nasional, 2016) (figure 1).

In the improvement of the quality management system, the testing laboratory uses the ISO / IEC 17025 standard as the reference of general requirements of competence to perform the test / calibration, including sampling test (ISO/IEC 17025,2005). This standard is also used for quality, administrative and technical activities. Customer laboratories, regulators and accreditation bodies may also use it in confirming or recognizing laboratory competence (ISO/IEC 17025, 2005).

The application of standards in laboratory testing is closely related to achieving the quality objectives contained in the laboratory. By using the ISO / IEC 17025 standard, the resulting product is secure, reliable and certainly has undoubted quality (ISO, 2017). Testing laboratory can be said to run effectively when it can manage or manage the flexibility, customer, production, value-oriented, and main job of its employees (Bien, M, Marion, R, McKelvey, B, 2007).



Figure 1. Map of the Distribution of Accredited Test Laboratory

1.2 Research Purposes

Analysis of implementation effectiveness of ISO / IEC 17025 is expected to provide a description of what factors affect the achievement of the objectives of the laboratory and how it relates to the clause contained in ISO 17025, whether the implementation of the standard has been effective. Analysis of the relationship between each clause that has a role to the effectiveness of the achievement of the objectives become the basis in improving the quality of laboratory quality management system.

1.3 Literature Review

Effectiveness can be defined in terms of productivity, employee and customer satisfaction and managerial assessment (Campion, M, Medsker, G, 1993). In addition, the effectiveness can also be divided into 3 dimensions, namely the fulfillment of quality standards, group ability to work in the future, and grow in a team (Tohidi, H. 2011). Organizational effectiveness plays an important role in organizational development, and this organization is effective when it is able to manage ambiguity, flexibility, customer-oriented, production, value oriented and structured learning and know the key areas of employment and employee empowerment (Bien, M, Marion, R, McKelvey, B, 2007). According to Hunter, S, Bedell-Avers, K, Mumford, M (2007), experts have defined organizational effectiveness toward the level of goal attainment.

In measuring the effectiveness of an organization, Focus Group Discussion (FGD) can be one of the methods used. FGD is an empirically qualitative data collection methodology comparing data from two sessions, FGD and interviews one by one to ensure consistency of data taken from respondents using both data collection (Boateng, W, 2012). Focus Group Discussion (FGD), also referred to as group interviews, is basically qualitative in nature based on structured, semi-structured or unstructured interviews, allowing researchers to interview multiple respondents systematically and simultaneously (Babbie, 2011).

The application of standards to improve the quality of management systems is a way to show that the quality of test results is reliable. The existence of quality assurance through the use of appropriate procedures and management methods, ensuring that mistakes will be minimal. In addition, with a quality management system standard, the laboratory has measurement traceability, error prevention, and corrective actions when an error occurs. (Khodabocus, F & Balgobin, K, 2011). International Standards Organization (ISO) is an independent organization, not a government

with members of 162 standardization bodies (ISO, 2017). International standards with a slogan "make things work", they provide specifications for products, services and systems to ensure quality, safety and efficiency (ISO, 2017). The ISO / IEC 17025 standard can be applied to all laboratories regardless of the number of personnel or the extent of the scope of testing and / or calibration activities (ISO/IEC 17025, 2005).

The ISO / IEC17025 standard has 15 management clauses and 10 technical clauses as shown in Table 1, which are used as reference by testing or calibration laboratories. Each clause contained in the management aspect requires clear procedures, policies, programs and instructions to maintain the management system. While in the field of technical itself, set various factors that determine the truth and reliability testing and / or calibration performed by the laboratory. (ISO/IEC 17025, 2005).

Table 1. Management and Technical Requirements ISO/IEC 17025

Clause	Management and Technical Requirements
4.1	Organization
4.2	Management system
4.3	Document control
4.4	Review of request, tenders, and contracts
4.5	Subcontracting of tests and calibrations
4.6	Purchasing services and supplies
4.7	Service to the customer
4.8	Complaint
4.9	Control of nonconforming testing and/ or calibration work
4.10	Improvement
4.11	Corrective action
4.12	Preventive action
4.13	Control of records
4.14	Internal audits
4.15	Management review
5.1	General
5.2	Personnel
5.3	Accommodation and environmental conditions
5.4	Test and calibration method and method validation
5.5	Equipment
5.6	Measurement traceability
5.7	Sampling
5.8	Handling of test and calibration items
5.9	Assuring the quality of test and calibration results
5.10	Reporting the results

2. Research Methodology

In conducting the research, the authors divide the process into 5 stages of the initial stages of research, literature review stage, the stage of data collection and processing, analysis stage of the results and the final stage of the study. And here's an explanation of each stage:

a) **The Initial Stage**

Determining the topic of research is the initial stage of the study, followed by formulating and adding problems that will be discussed more deeply. In determining the topic of research, the authors conducted discussions with several lecturers related to the field of industrial management.

b) **Literature Review Stage**

The literature used as a reference or reference comes from journals, articles, both national and international. This is done to facilitate the authors in understanding the basic concepts and implementation of the research to be discussed. The literature study focused on concepts and methods of effectiveness, standardization in general and ISO/IEC 17025.

c) **The Stage of Data Collection and Processing**

The data used in this study is taken from the object of research in this case is the Assessors of National Accreditation Committee that has competence in the field of management and technical. Data is the result of the Focus Group Discussion from the assessors in discussing the clause in ISO/IEC 17025 related to the determination of the effectiveness of ISO/IEC 17025 implementation in the testing laboratory.

d) **The Stage of Result Analysis**

After obtaining the factors that affect the effectiveness, then the analysis to get a recommendation result can be done. This is a solution in improving an organization's system.

e) **The Final Stage**

At this stage the conclusions are drawn from the research conducted and suggestions for further research.

3. Result and Discussion

In conducting research on the effectiveness of ISO/IEC 17025 implementation using Focus Group Discussion method, the researcher conducted a discussion with 5 respondents who have competence as described in table 2. The respondent is an experienced assessor who has experience in performing field visits to assess the quality management system of the testing laboratory. The discussion was conducted to analyze any clause that became the main key of successful laboratory effectiveness in applying ISO/IEC 17025 standard.

Table 2. Focus Group Discussion Respondent

Respondent Name	Areas of Expertise	Background Study	Experience
Respondent A	Agriculture and Management	S2 Agriculture	7 years
Respondent B	Chemistry and Management	S2 Chemistry	5 years
Respondent C	Construction and Management	S1 Mechanical Engineering	7 years

Respondent D	Civil Construction and Management	S1 Physics	5 years
Respondent E	Management	S1 Management	5 years

From the discussion with 5 respondents, different results were obtained in formulating the effectiveness clause in accordance with table 3, but there are 6 clauses that have the same opinion in assessing the effectiveness as follows:

Table 3. Result of Focus Group Discussion for each Respondent

Respondent	Clause	Effectiveness Clause of ISO/IEC 17025	Description of Effectiveness
A	4.14	Internal Audit	Laboratory description can be seen from how the results of internal audits conducted periodically
	4.15	Management Review	In a good management system it is necessary to review the management and technical aspects to assess the success of the laboratory
	5.2	Personnel	The system will not work effectively if the personnel do not understand ISO/IEC 17025
	5.4	Test and calibration method and method validation	Method verification and validation must be performed to produce accurate test results
	5.9	Assuring the quality of test and calibration results	The quality assurance program should be designed to maintain the quality of the test results
B	4.2	Management System	Describes expected system design including documentation, policy or commitment structure, system integrity
	4.14	Internal Audit	Tool to verify that laboratory activities are in compliance with ISO 17025
	4.15	Management Review	It is the key of monitoring the implementation of ISO/IEC 17025 periodically to ensure continuity of compatibility and effectiveness
	5.2	Personnel	Competency assurance of all human resources that greatly affect lab operational and its effectiveness
	5.4	Test and calibration method and method validation	Relates directly to how the laboratory conducts tests

C	4.1	Organization	Management commitments most affect laboratory activities, if top management does not have a commitment then it will be a major obstacle in the success of a laboratory
	4.15	Management Review	Regular reviews aim to take into account policy-related and procedural compliance with ISO 17025
	5.2	Personnel	Competence of personnel is important because that will run the system is human resources. The system will run smoothly with the existence of qualified human resources
	5.4	Test and calibration method and method validation	The methods used in testing the test scope parameters should be verified and validated for the test results to be accurate and accountable
	5.9	Assuring the quality of test and calibration results	Proficiency test or comparative test or internal quality control is a tool used in maintaining the suitability and validity of test results
D	4.1	Organization	The commitment aspect strongly supports the effectiveness of the entire lab management system
	4.2	Management System	All depends on making the system, whether it will be made complicated or simple
	4.3	Document Control	The principle of ISO is writing that we have done and doing what is written, then control becomes very important in documenting all activities
	4.14	Internal Audit	As a means of self-assess whether the operational laboratory is in accordance with the requirements
	5.2	Personnel	A good system will be run by committed personnel and certainly have competencies
E	4.1	Organization	The organizational structure must be created by mapping the right personnel for the quality management system to be achieved
	4.2	Management System	The management system must be integrated so that the effectiveness of the implementation of 17025 can be seen maximally

	5.2	Personnel	The laboratory personnel must be competent in operating the equipment and supervise all personnel working in the laboratory
	5.4	Test and calibration method and method validation	Use of the selected method, previously verified or validated to generate valid test data
	5.9	Assuring the quality of test and calibration results	Laboratory should be able to ensure that the tests performed produce valid data

From the explanation presented by each respondent, there are 2 management clauses that get the same number of 3 respondents with the same opinion for each clause namely Organization and Internal Audit, from both of this clause Organization become the main assessment because in a management system in laboratory, the establishment of appropriate managerial and technical personnel is a key element in the smoothness and effectiveness of the laboratory. In addition to the policy and commitment of the organization, in this case top management will facilitate the laboratory to achieve specific targets. Therefore, the effectiveness clauses contained in the ISO can be reduced to 6 clauses according to table 4.

Table 4. Effectiveness Clause of ISO/IEC 17025

Clause	Effectiveness Clause of ISO/IEC 17025	Description of Effectiveness
4.1	Organization	The laboratory system can work effectively if there is full support from top management. Commitment in organizing can facilitate business process and minimize obstacles
4.2	Management System	A good management system is a system designed as simple as possible without reducing the things that it must be met, so that the implementation will be easier and the goals and objectives of the laboratory can be realized
4.15	Management Review	Management review is conducted periodically, consistently and applied to all quality documents both management and technical
5.2	Personnel	Each laboratory personnel must meet the applicable requirements, have competence and experience in accordance with the field of test employed. As well as personnel should be managed by providing training that can improve their competence
5.4	Test and calibration method and method validation	Test methods every scope of the test should always be updated, verified and validated so that the test results can be justified

5.9	Assuring the quality of test and calibration results	Each parameters of the scope of the test need to be maintained with a proficiency test program consistently
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The six main clauses obtained from discussions with the 5 (five) Assessor of the National Accreditation Committee related to the effectiveness of ISO/IEC 17025 implementation provide an illustration that a good and effective quality management system cannot be separated from the consistency of the implementation of international standards designated for testing or calibration laboratories

4. Conclusion

Quality management systems in laboratory based on ISO/IEC 17025 will be effectively work when some of the key factors in the effectiveness clause can be well executed, including organization, management system, management review, personnel, testing methods and quality assurance of test results. The management and technical clause becomes the assessment parameter how the laboratory can achieve its operational objectives.

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Biographies

Irma Permata Sari is a graduated student of Physics major, from Diponegoro University, who received a scholarship from the Ministry of Research of Technology and Higher Education to continue her studies in Postgraduate program majoring in Industrial Engineering, University of Indonesia. She is also work as a government employee in the National Standardization Agency (BSN) with the Testing Laboratory and Inspection Body of Accreditation Division, she has an interest in the field of quality management system after 5 years experience in handling the accreditation process of testing laboratories based on ISO/IEC 17025. With experience and competence in the field of quality management system, she also several times get the opportunity to conduct field visits to assess the quality system in testing laboratory and inspection bodies based on ISO/IEC 17020.

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