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A Framework to Measure Readiness Level of Laboratory for Implementing ISO/IEC 17025: A Case Study

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Abstract. ISO/IEC Guide 17025 is an international guideline which contains criteria for product testing service laboratories. This guideline will guarantee a testing laboratory to carry out testing services consistently and reliably also guarantee its acceptance either in national or international forums. Currently, Sebelas Maret University have a testing and calibration laboratory that had been accredited by National Accreditation Committee (KAN) Indonesia, named "Integrated Testing Laboratory Unit Sebelas Maret University. Besides that, Sebelas Maret University also has many laboratories spread across 10 faculties with 151 study programs. But until now these laboratories have not been certified by KAN (National Accreditation Committee) and have not performed their functions optimally. This study aims to see the readiness of potential laboratory at Sebelas Maret University in implementing ISO/IEC 17025. This study using quantitative approach through surveys with gap analysis techniques to see currently conditions with the desired conditions.

1. Introduction

At the present time, one of the driving forces for education at every country is universities. Higher education is an institution that have duties in education, research, and community service. The development of globalization has changed the paradigm of higher education, from what was originally held in competition within a single country, became a competition in the global scope. By these conditions, every university is required to improve its quality in order to survive and compete globally.

Sebelas Maret University is one of the state universities in Indonesia organized by the Indonesian Ministry of Education and Culture. Sebelas Maret University have the task of organizing academic education and vocational education in various clusters of science and/technology. Currently, Sebelas Maret University has 11 faculties [1]. In order to support various educational and research activities of students/lecturers in each faculty, Sebelas Maret University has provided adequate facilities and infrastructure such as libraries, studios, workshops, and laboratories. All laboratories/studios/workshops are academic facilities and infrastructures that are used to support the implementation for education, research, and community service, both by lecturers and students [2].



Laboratories in universities are used by lecturers and students to conduct learning, practicum, and research activities. However, there are laboratories that also have function as testing laboratories service. Laboratories that can have a very beneficial impact on students, lecturers, and the community must of course be supported by quality and accredited laboratory conditions. In order to be accredited, the laboratory must apply ISO / IEC 17025 and accredited by National Accreditation Committee (KAN) Indonesia [3]. ISO/IEC 17025:2005 is a specific requirement for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods [4].

We are not the first university to make efforts to implement ISO 17025 in the laboratory. In 2005, Rodima et al. [5] decided to implement the ISO 17025 quality system at Tartu University in Estonia. They made a laboratory central unit that supervises other laboratories at the university. They concluded that this system would facilitate consumer testing services and they were sure to provide significant added value to the university. Two years later in 2007, Zapata-García et al. [6] recounts their experience in implementing ISO / IEC 17025 at the University of Barcelona. They considered that it was a difficult task, but it could still happen. Based on their experience, it is evident that the application of ISO 17025 gives positive impact because it helps the university to get to know the real world more closely and impacted in the results of their academic research.

Laboratory accreditation will provide many benefits and become one of the keys to the promotion of the latest laboratories at the international level. Hence, even though it is not a written regulation, the application of ISO/IEC 17025 is crucial and compulsory for testing laboratory. The General Chemical State Laboratory in its experience of implementing ISO 17025, stated that the obvious benefits after accreditation were increasing competitiveness and reliability of test results, increasing laboratory awareness of quality, and build work efficiency and a better culture of cooperation. [7]. Whereas in the scope of research / research of students and lecturers, the application of ISO 17025 will facilitate students / lecturers in understanding the testing process because of the availability of standardized technical procedures for each process. In addition, the available equipment has been calibrated so that it will provide valid and reliable testing results. This will train students' responsibility to be able to carry out the testing / research process while still paying attention to the quality of testing and the results [8].

Based on a survey, Sebelas Maret University has 2 laboratories that have been able to perform testing services at Sebelas Maret University, but have not implemented ISO 17025 yet. Both of these laboratories are Basic Chemical Laboratories in Chemical Engineering and Work System Design and Ergonomics Laboratories in Industrial Engineering. First step that must be done by Sebelas Maret University to be able to optimize the potential of both laboratories at Sebelas Maret University for the expansion of testing parameter by measuring the level of readiness of both laboratories at Sebelas Maret University in applying ISO / IEC 17025. With this measurement result, it will be known the level of readiness of both laboratories in Sebelas Maret University.

2. Research Method

2.1 Research Approach

This research was conducted using a quantitative approach supported by qualitative data. The quantitative approach in this study aims to measure how far the laboratory readiness in applying ISO / IEC Guide 17025. While the qualitative data approach to produce a comprehensive picture of the readiness of the laboratory in implementing ISO / IEC Guide 17025.

2.2 Technical Approach

The study was conducted using questionnaires and in-depth interviews through structured questionnaires.

2.3 Key-Informant

Key-informant were selected based on their knowledge and involvement in the preparation process for implementing ISO / IEC Guide 17025. They're operator of laboratory. The pilot projects of this research are Work System and Ergonomics Design Laboratory and Basic Chemical Laboratories.

2.4 Research Location

The research location is in all laboratories located at Sebelas Maret University.

2.5 Data Collection

Data collection is done by distributing questionnaires and in-depth interviews to key informants at each laboratory in Sebelas Maret University

2.6 Method

This study uses gap analysis technique (Gap Analysis) for measuring the readiness of Sebelas Maret University laboratories to applying ISO / IEC 17025. ISO/IEC 17025 requirement could be summarizing in framework below.

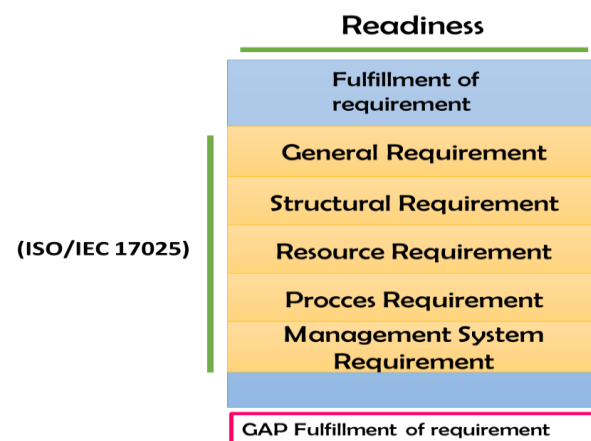


Figure1. Framework questionnaires

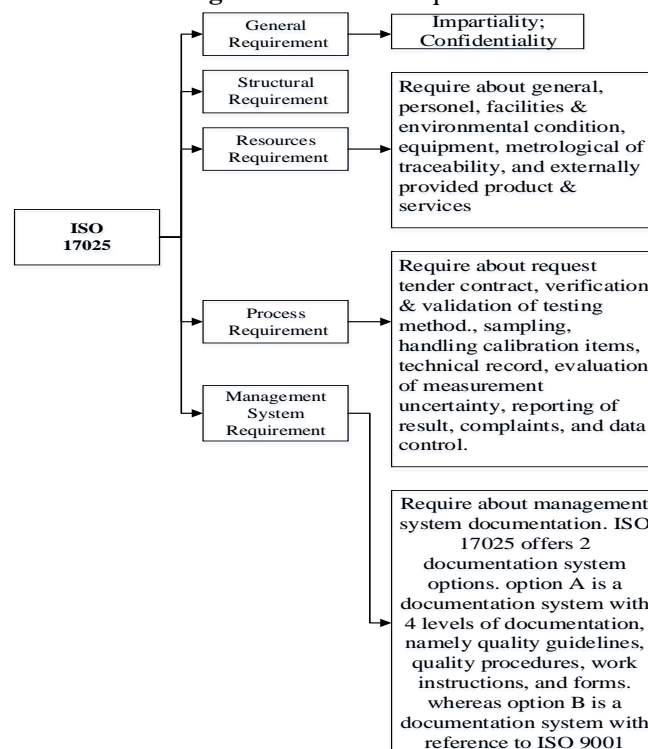


Figure2. Framework ISO/IEC 17025 requirements

The initial step of this tool is developing a gap analysis checklist that functions to identify gaps between written requirement and the real process carried out. This checklist is made based on the requirements of ISO17025. To facilitate the analysis of each clause, scoring for assessment is given below.

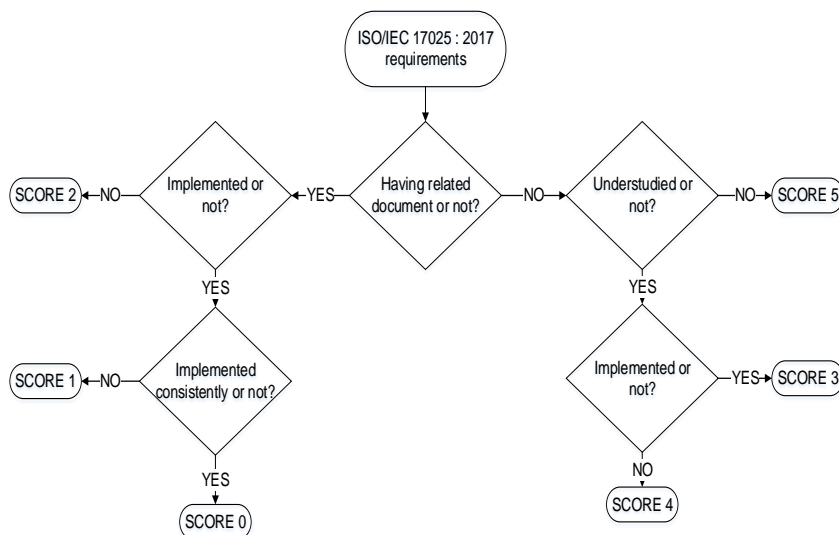


Figure3. Scoring Flowchart

The scoring concept was smallest the better. The smaller the score, make the smaller gap value and its mean laboratory have been comprehended, implementing, and documenting the requirement well. Otherwise, the bigger the score get, they make the bigger gap value and its mean they have not comprehended, implementing and documenting the requirement yet.

3. Result and Analysis

3.1 Questionnaire Design

This section describes the design of the questionnaire for measuring laboratory readiness in applying SNI 17025. The design of the questionnaire was carried out by determining the variables that influence. Determining the variables is done by deriving the clause contained in ISO / IEC 17025 and identifying the documents required in ISO / IEC 17025. Furthermore, the level of fulfillment is measured. Below is the framework how to design the questionnaire.

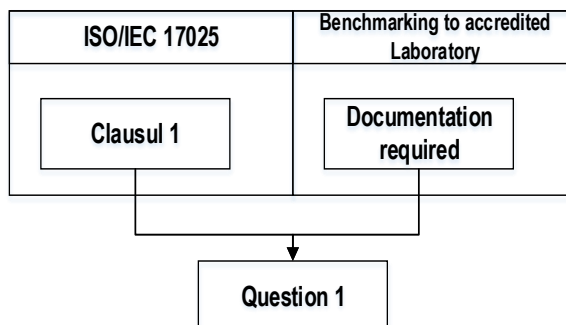


Figure 4. Questionnaire Design

3.2 Work System and Ergonomics Design Laboratory

Work System and Ergonomics Design Laboratory is one of the laboratories in the Industrial Engineering Study Program that have been able to perform 7 testing parameters. The level of fulfillment was rated based on the results from questionnaire dissemination. The result of the assessment is presented in the following table.

Table 1.Assesment of WSED Laboratory

Question code	Score	Max Score	Gap (%)	Compliance Level (%)
A1-A5	17	25	68%	32%
B1-B5	8	115	7%	93%
C1-C18	60	90	67%	33%
D1-D24	82	120	68%	32%
E1-E4	16	20	80%	20%

Score value is obtained from the results of the questionnaire assessment. The maximum score is the maximum gap value where if it reaches that value, it means that the laboratory assistant has not comprehended yet and laboratory system do not potentially apply ISO / IEC 17025. Then the calculation of the score divided by a maximum score will show the gap value. From the results of the gap, it can be seen the percentage of fulfillment of requirements from ISO / IEC 17025.

A1-A5 is a question code for general requirements consisting of impartiality and confidentiality. In this lab an average score of 3.4 is generated. This shows that a gap value of 68% is produced because the laboratory system does not fulfill the document requirements and the level of fulfillment of 32% is produced because the laboratory assistant has been comprehended and implementing about impartiality and confidentiality requirements even though those requirements do not been documented yet.

B1-B5 is a question code for structural requirements. In this lab an average score of 1.6 is generated. This shows that a gap value of 7% is produced because the laboratory does not have a quality and technical manager responsible for the testing process. Then a fulfillment rate of 93% is generated because the laboratory has a complete organizational structure document that shows the position and responsibilities of laboratory personnel as required by ISO / IEC 17025.

C1-C18 is a question code for technical requirements. In this lab an average score of 3.3 is generated. This shows that a gap value of 67% is produced because the laboratory assistant does not have complete documentation even though has been comprehended with the requirements. Then the fulfillment level of 32% is generated because the laboratory assistant has comprehended with the requirements of ISO / IEC 17025 and carried out some of these requirements, such as personnel training and handling of equipment maintenance.

D1-D24 is a question code for process requirements. In this lab an average score of 3.4 is generated. This shows that the gap value is 68% because the laboratory does not have complete documentation. Then the fulfillment rate of 32% is generated because the laboratory assistant has comprehended with the requirements of ISO / IEC 17025 and carried out some of these requirements.

E1-E4 is a question code for system management requirements. In this lab the averages score is 4. This shows that the resulting of gap value is 80% and the fulfillment rate is 20% because the laboratory assistant has been comprehended with the requirements of the management system but not compiled yet with document recording process.

From the measurement results, it can be analyzed that overall, Work System and Ergonomics Design Laboratory assistant has been comprehended with ISO / IEC 17025 and for some requirements it been carried out even though it not fulfilled with document recording.

3.3 Basic Chemical Laboratory

Basic Chemical Laboratory is one of the laboratories in the Chemical Engineering Study Program that been able to perform 6 testing parameters, those are density testing, ash level test, water content test, industrial wastewater test, dissolved oxygen test, and dried total residue test. The level of fulfillment was rated based on the results from questionnaire dissemination. The result of the assessment is presented in the following table.

Table 2. Assesment of Basic Chemical Laboratory

Question code	Score	Average Score	Max Score	Gap (%)	Compliance Level (%)
A1-A5	25	5	25	100%	0%
B1-B5	22	4.4	115	19%	81%
C1-C18	76	4.2	90	84%	16%
D1-D24	108	4.5	120	90%	10%
E1-E4	20	5	20	100%	0%

Average result for question code A1-A5 is 5. This makes the laboratory get 100% of GAP value that means laboratory assistant has not comprehended and do not implement the requirement about impartiality and confidentiality yet at all. Average result for question code B1-B5 is 4.4. This produce 88% GAP value and it's because of laboratory not having a proper organization structure yet. Besides that, laboratory also doesn't have quality and technical manager yet. In other hand, laboratory get 12% fulfillment value because of they already understood about the requirement although they have not been implemented yet.

Average result for question code C1-C18 is 4.2. This produce 84% GAP value and it's because they haven't implementing requirements well even, they have been comprehended. While, 16% of compliance level produced because they had been doing personnel training and documenting the calibrated tool.

While, for D1-D24 and E1-E4, each they get average 4.5 and 5 because they almost have not comprehended yet with the requirement and they haven't implementing the requirement yet automatically. That's why the produced 90% gap value for D1-D24 and 100% for E1-E4.

From the measurement results, it can be analyzed that overall, Basic Chemical Laboratory assistant has not comprehended with ISO / IEC 17025 in whole term and they only implement 21% of requirement.

4. Conclusion

The readiness level of laboratory in implementing ISO / IEC 17025 is done by measuring the compliance level of requirements that contained in ISO / IEC 17025. The measuring instrument used is a questionnaire that made based on identification from clauses and documents required in ISO / IEC 17025. Then, the scoring system is carried out using smallest the better scale with range 0-5. The details criteria of each score are describe in table below.

Table 3. Scoring Criteria

SCORE	CRITERIA
0	The requirement is implemented consistently and having the required document
1	The requirement is implemented inconsistently and having the required document
2	The requirement is not implemented, but having the required document
3	The requirement is implemented, but don't have the required document
4	Understand with the requirement, but not implementing the requirement and don't have the required document
5	Don't understand with the requirement, not implementing the requirement and don't have the required document

Based on the measurement result, Work System and Ergonomics Design Laboratory is more ready than chemical basic Laboratory because they more understand about ISO/IEC 17025 and some of requirement have been implemented. Also, they have been able doing testing service for customer. While, in chemical basic Laboratory, they are a new laboratory that still on their way to upgrade their laboratory to be able doing testing services. They still prepare for fulfill their technical needs and basic needs.

Comparison of both readiness can be seen on the following radar chart.

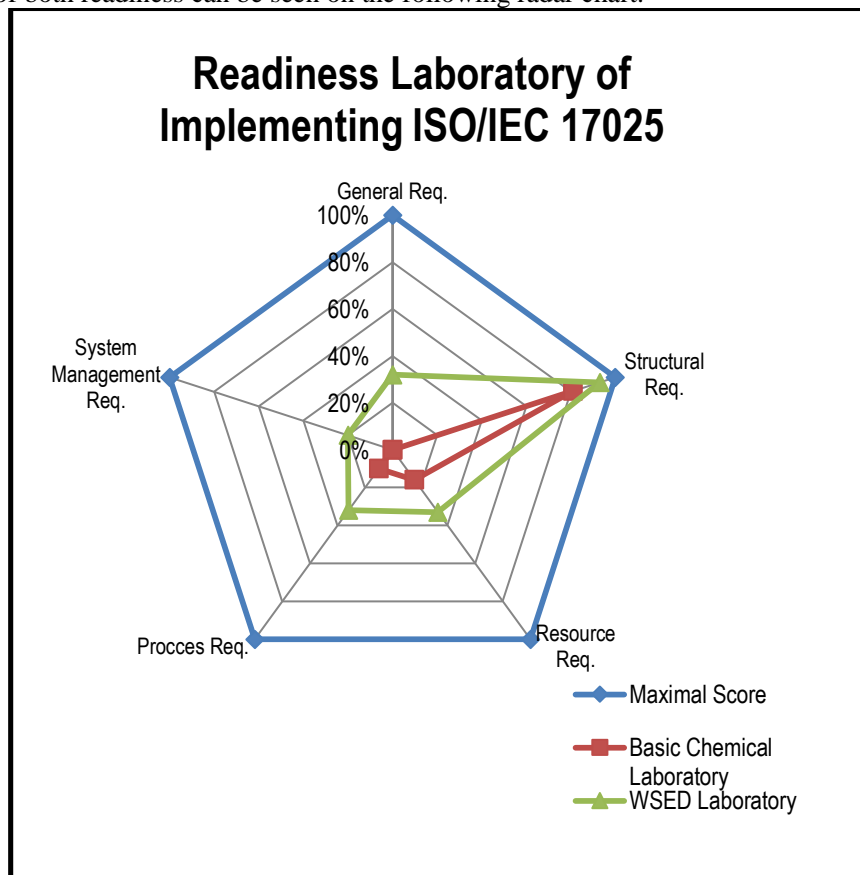


Figure 5. Radar Chart Readiness Level Laboratory of Implementing ISO/IEC 17025

The recommendation that can be given is that the Laboratory that been selected can be truly fostered by the University and the UNS UPT Laboratory to conduct accreditation. Coaching can take the form of training to fulfill requirements, especially general, technical, process and management requirements where the fulfillment level does not reach the 50% level.

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