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Designing ISO / IEC 17025: 2017 – Based Laboratory Quality Manual : A Case of Laboratory of Environmental Engineering in Andalas University

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Abstract – Testing Laboratory of the Department of Environmental Engineering at Andalas University in maintaining the quality and trust of customers will carry out accreditation. One of the requirements in the accreditation process is the existence of a laboratory quality manual. However, the Testing Laboratory of the Department of Environmental Engineering at Andalas University does not yet have a quality manual that is following ISO / IEC 17025: 2017. Therefore the research aims to design a quality manual for ISO / IEC 17025: 2017 based laboratories in the Testing Laboratory of the Department of Environmental Engineering at Andalas University. The method used in this study is the PDCA framework (Plan, Do, Check, Action). The results showed that the design results of each of the requirements contained in each ISO / IEC 17025: 2017 clause were appropriate.

Keywords- Quality Manual, Laboratory, PDCA.

I. INTRODUCTION

University is a teaching and research institution that aims to qualify human resources and produce knowledge (Alkhafaji, 2003). To qualify human resources and create knowledge, a university must be of high quality. The quality of a university is not only determined by the number of students and the age of university but also determined by the competence of the university. One of the criteria for assessing the quality of a university is its laboratory competence. The competency can be tested if the laboratory has accredited (Kanitvittaya et al., 2016).

Laboratory accreditation is an activity which adjusts technical and general requirements based on ISO / IEC 17025 with related accreditation institutions (Silva and Ribeiro, 2019). Accreditation is also an important mechanism to overcome the limited knowledge, budget, planning, policies, and staff needed to improve laboratory services (Kanitvittaya et al., 201 6). Standards serve as tools to help laboratory staff achieve accreditation (Malkoc and Neuteboom, 2007). However, introducing System Management M utu and obtained the ISO / IEC 17025 is not easy, especially for institutions of learning and research (Grochau and Dan Caten, 2012). Accreditation granted by the government through the National Accreditation Committee (KAN) as a formal recognition of the competence of LPK. Laboratory competency assessment is carried out based on SNI ISO / IEC 17025: 2008, general requirements for testing and calibration laboratory competencies (Dina and Wastra, 2013).

According to International Committee of a national crediting Program, accreditation International Committee of a crediting n national Program provides several significant benefits, such as: (1) by adjusting policies and procedures KAN has recognized internationally regularly so that the laboratory is focused on improving the competence in conducting the assessment conformity, (2) demonstrate independent laboratory for accreditation emphasizes the independence of the LPK in carrying out the assessment,

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and (3) gain recognition internationally for international Committee of a crediting n national Program has been recognized formally by some organizations, international accreditation, including the international accreditation Forum (IAF), the Pacific Accreditation Cooperation (PAC). Asia Pacific Laboratory Accreditation Cooperation (APLAC) and International Laboratory Accreditation Cooperation (ILAC) (Dina and Wastra, 2013).

The application of ISO/IEC 17025 is a mandatory requirement for obtaining laboratory accreditation. Requirements needed in fulfilling laboratory accreditation by auditing eight elements, namely organization, observation systems, documents, quality system records, relationships with customers and colleagues, laboratory work, quality research, and laboratory personnel (ISO/IEC 17025: 2017). An accredited laboratory will receive recognition related to laboratory competencies, advantages in marketing, laboratory capabilities, and international recognition to the laboratory (Pobkeeree, 2012). Previous research has carried out the application of ISO / IEC 17025. Honsa et al. (2003) concluded that the implementation of ISO / IEC 17025 would speed up work in technical matters, and the sequencing of work will become easier. Ratseou et al. (2014) found that the implementation of ISO/IEC 17025 would increase consumer confidence in standard laboratories.

In order to obtain laboratory accreditation, Andalas University has made various efforts, including collaborating with PT. Sucofindo and the Educational Development and Quality Assurance Institute (LP3M) of Andalas University in carrying out the Pre Audit stage in 2015 as an initial evaluation stage for laboratory readiness towards the implementation of Laboratory Quality Systems based on ISO/IEC 17025: 2008 standards, which focus on evaluating the competency of personnel to five laboratories namely: Biomedical Laboratory of the Faculty of Medicine, Biotech Laboratory of the Faculty of Animal Husbandry, Chemical Laboratory of Natural Biota in Sumatra, Central Instrumentation Laboratory of the Faculty of Agricultural Engineering, Environmental Engineering Laboratory of the Faculty of Engineering, and Biotech Laboratory of the Faculty of Agriculture. Based on the results of the Pre Audit, it is concluded that all laboratories involved in the pre-audit process were declared not ready to be accredited because the competence of laboratory staff members did not meet the requirements. In 2017, the University conducted another Pre Audit, which only focused on laboratory facilities and management systems. Pre audits were conducted based on ISO/IEC 17025: 2008 standard, and the results show that the quality management system of laboratory for the accreditation process is not following ISO/IEC 17025 standards. It obtained that only the Testing Laboratory of Environmental Engineering has achieved document readiness up to 50%.

The SNI ISO/IEC 17025: 2008 should also be updated into ISO/IEC 17025:2017. In ISO/IEC 17025:2017, there are several solutions from technical requirements and management requirements to 5 requirements, namely: general requirements, structure requirements, resource requirements, process requirements, and management requirements. These will undoubtedly change from the requirements that have been carried out pre-audit at the instrumentation laboratory at Andalas University. The suggestions for the laboratory quality management system of implementation program based on the requirements of SNI ISO/IEC 17025: 2017 and recommended by PT Sucofindo in 2017 for accreditation are structuring the quality system which consists of determining the scope, starts from the preparation of level I documents that contain policies and laboratory commitments in implementing quality systems according to ISO/IEC 17025: 2017, and then proceed to level II documents that explain implementation of commitments in the form of documents containing implementation procedures at ISO/IEC 17025: 2017. After the level II is revised, then proceed to level III documents that explain supporting documents for the implementation of level II documents such as work instructions, testing methods, and recording activities. Finally, level IV documents that explain supporting documents for the implementation of level III documents such as forms, decrees, and forms incompatibility. Tool calibration, spatial planning, method verification and validation, comparative test/proficiency testing, and personnel preparation with training and evaluation programs.

One of the documentation requirements required for laboratory accreditation is a quality manual. The quality manual is a specific document and is very important for each laboratory and must be able to cope with situations such as place, staff, organization, national standards, methods, equipment, quality system, demand, and always updated according to the latest model (Velho, 2001). In designing quality manuals in laboratories, of course, a particular approach is needed to facilitate the preparation of quality manuals. *Plan-Do-Check-Action* (PDCA) is one approach that can solve problems in the quality field

(Yonatan and Palt, 2015). Therefore PDCA is quite comprehensive in solving problems in the quality field. At the moment, Andalas University does not yet have a quality manual for the laboratory. Therefore, further research is needed to make a quality manual at the Testing Laboratory of the Department of Environmental Engineering, Andalas University.

II. METHOD

At this stage, the preparation of laboratory quality guidelines is made based on ISO / IEC 17025: 2017. This study uses systematics with the PDCA framework, namely *Plan, Do, Check*, and *Action*, but in this study only carried out up to the stage Do. The steps are as follows:

A. Plan (Planning)

Planning at this stage is to set goals and processes needed to deliver results that are following specifications in the selection of environmental indicators. Following are the steps in the planning stage:

1. Identification of General Requirements
   Identification of general requirements is also a requirement of a code of ethics, namely impartiality and confidentiality.
2. Identification of Structural Requirements
   Identification of organizational structure requirements
3. Identification of Resource Requirements
   Identification of personnel, laboratory facilities, and environmental conditions, equipment, metrological traceability, providers of external goods and services.
4. Identification of Process Requirements
   The identification of process requirements includes:
   a. Review requests, tenders and contracts.
   b. Selection, verification, and validation of methods.
   c. Sampling.
   d. Handling of test items.
   e. Technical Records.
   f. Evaluation of measurement uncertainty.
   g. Quality assurance of test results
   h. Result of test
   i. Complaint
   j. Incompatible work
   k. Information management data control.
5. Identify Management Requirements
   Identification of management requirements includes management system documentation, management control system documents, records, actions aimed at risks and opportunities, improvement, corrective actions, internal audits, management reviews.

III. RESULT

3. 1 Plan

The Plan is the initial stage in designing the laboratory quality manual of the Department of Environmental Engineering, Faculty of Engineering, Andalas University based on ISO/IEC 17025. The steps of the planning stage are 1). Identification of the requirements of ISO/IEC 17025: 2017, and 2). Determining the specifications of the requirements of ISO/IEC 17025: 2017.

3 .1.1 Identification Requirements Achievement of ISO/IEC 17025: 2017

The first step of the planning stage is to identify the achievement of the requirements for designing laboratory quality manuals based on ISO/IEC 17025: 2017. This identification is carried out to determine whether the laboratory quality manual of the Environmental Engineering Department of the Andalas University Faculty of Engineering has fulfilled the requirements of the laboratory quality manual based on ISO/IEC 17025: 2017. Besides, a part of the quality manual that has not been fulfilled or changed according to the requirements of ISO/IEC 17025: 2017 is the current laboratory quality manuals of Department of Environmental Engineering, Faculty of Engineering, Andalas University designed using ISO/IEC 17025:2008 standard. Therefore some parts do not meet the requirements of ISO/IEC 17025: 2017. Identification of the achievement of the requirements was carried out through discussions with two Laboratory analysts from the Department of Environmental Engineering at Andalas University, where this analyst was given full responsibility in the preparation and preparation of laboratory quality manual documents.

There are five requirements in designing a laboratory quality manual based on ISO/ IEC 17025: 2017 consist of general requirements, structural requirements, resource requirements, process requirements, and management requirements. While according to ISO/IEC 17025:2008, it only two requirements, namely requirements management and technical requirements. The difference between

ISO/IEC 17025: 2008 and ISO/IEC 17025: 2017 can be seen in Table 1.

Table 1 Differences between ISO/IEC 17025: 2008 and ISO/IEC 17025: 2017

ISO / IEC 17025: 2008	ISO / IEC 17025: 2017
4. Management Requirements	**4 General Requirements:**
4.1. Organization	4.1 *Impartiality* (Mandatory)
4.2. Management system	4.2 *Confidentiality* (Mandatory)
4.3. Document Control	**5 Organizational structure requirements**
4.3.1. General	**6. Resource requirements**
4.3.2. Ratification and Issuance of Documents	6.1 General
	6.2 Personnel (new format)
	6.3 Laboratory facilities and environmental conditions
4.3.3. Changes to Documents	6.4 Equipment
	6.5 Metrological traceability
4.4. Review Requests, Tenders and Contracts	6.6 Providers of external goods and services
	7 Process Requirements
4.5. Subcontracting Testing	7.1 Review requests, tenders and contracts
4.6. Purchasing Services and Supplies	7.2 Selection, verification, and validation of methods (Contents changed)
4.7. Services to *Customers*	
4.8. Complaint	7.3 Sampling
4.9. Improper Analysis of Control Work	7.4 Handling of test and calibration items
4.10. Enhancement	7.5 Technical records
4.11. Corrective action	7.6 Evaluation of measurement uncertainty (contents change)
4.11.1. General	
4.11.2. Additional audit	7.7 Quality assurance of test results (Contents changed)
4.12. Preventive measure	
4.13. Control of Records	7.8 Report on test results
4.14. Internal Audit	7.9 Complaints
4.15. Management Review	7:10 Woorkerd incompatible
5.1 Technical Requirements	7.11 Data control - Information management (New)
5.1. General	
5.2. Personnel	**8 Management Requirements**
5.3. Accommodation Conditions and Environmental Conditions	**Option A**
	8.1 Option
5.4. Method of Analysis and Validation of Methods	8.2 Management system documentation
	8.3 Control of document management systems
5.4.1. General	8.4 Quality Records
5.4.2. Method Selection	8.5 Actions aimed at risks and opportunities (New)
5.4.3. Nonstandard Method	
5.4.4. Method Validation	8.6 Improvement
5.4.5. Estimation of Measurement Uncertainty	8.7 Corrective action
	8.8 Internal audit
5.4.6. Data Control	8.9 Review management
5.5. Equipment	**Option B**
5.6. Measurement traceability	Implement the latest ISO 9001 quality management system relevant to clauses 4 to 7 ISO / IEC 17025: 2017
5.6.1. General	
5.6.2. Reference standards and	

reference materials 5.7. Sampling 5.8. Handling of items tested 5.9. Quality assurance of Testing results 5.10. Reporting the results	

Table 1 shows the differences between ISO / IEC 2008 and ISO / IEC 2017, where general requirements are new requirements in ISO / IEC 17025: 2017, which consist of two items, namely impartiality and confidentiality. The organizational structure requirements previously existed in ISO / IEC 17025: 2008, which were in the item management requirements. The resource requirements for personnel items have changed in the form of a new format in ISO / IEC 17025: 2017 and previously were in the technical requirements items in ISO/IEC 17025: 2008. In the process requirements, three items have changed the content in ISO/IEC 17025: 2017, namely the selection of verification and validation methods, evaluation of measurement uncertainty, as well as quality assurance of test results and previously were technical requirements of ISO/IEC 17025: 2008. Information management data control is a new item in the process requirements of ISO/IEC 17025: 2017. In the management requirements of ISO/IEC 17025: 2017, there are new items, namely actions aimed at risks and opportunities.

The results of identifying the achievement of the requirements of ISO/IEC 17025: 2017 in the quality manual of the Laboratory of the Department of Environmental Engineering, Faculty of Engineering, Andalas University, can be seen in Table 2.

Table 2 Results of Identification of Achievements of ISO/IEC 17025: 2017 Requirements in the Laboratory Quality Manual of the Department of Environmental Engineering, Faculty of Engineering, Andalas University

No	Requirements Type	Requirements Section	Achievement		
			Fulfilled	Less	Not fulfilled
1	General requirement	Impartiality			v
		Confidentiality			v
2	Structure Requirement			v	
3	Resource Requirements	General	v		
		Personnel		v	
		Laboratory Facilities and Environmental Conditions		v	
		Equipment		v	
		Metrology Traceability		v	
		Provider of External Goods and Services	v		
4	Process Requirements	Review, Request, Tender and Collaboration	v		
		Selection of verification and validation methods		v	

		Sampling		v	
		Handling of Test and/or calibration goods		v	
		Technical Records	v		
		Evaluation of measurement uncertainty		v	
		Quality assurance of test results		v	
		Result of test	v		
		Complaint	v		
		Incompatible work	v		
		Information management data control			v
5	Management Requirements	Management system documentation	v		
		Document management system control	v		
		Recording	v		
		Actions are aimed at risks and opportunities			v
		Enhancement	v		
		Corrective action	v		
		Internal audit	v		
		Review management	v		

Table 2 shows the results of identifying the achievement of the requirements of ISO/IEC 17025: 2017 for the quality manual of the Department of Environmental Engineering, Faculty of Engineering, Andalas University. Based on the identification results, there are still shortcomings and not fulfilling the requirements of ISO/IEC 17025: 2017 in the quality manual of the Environmental Engineering Laboratory, Faculty of Engineering, Andalas University. Weaknesses and non-fulfillment of the requirements contained in the quality manual are then revised and improved by conducting a laboratory quality manual for the Department of Environmental Engineering, Faculty of Engineering, Andalas University based on ISO/IEC 17025: 2017.

IV. CONCLUSION

Based on the results of data design and analysis, it is known that the proposed quality manual based on ISO/IEC 17025: 2017 is in accordance with the requirements for the accreditation process, but these results still need to be validated by an expert.

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