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Implementation of PDCA Cycle in Calibration and Testing Laboratory Based on ISO/IEC 17025:2017

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Abstract. ISO/IEC 17025:2017 is an international reference standard for calibration and testing laboratories to improve their competence, to promote confidence in the operation of laboratory, and to generate valid results. Implementation of ISO/IEC 17025:2017 is also related to the implementation of ISO 9001:2015 standard which contains a process-based PDCA cycle (Plan-Do-Check-Act). The PDCA cycle is commonly used in terms of improving quality of services that is in line with the objective of the implementation of ISO/IEC 17025:2017. Therefore, this research discusses the concept of PDCA which is used in ISO 9001:2015 based on ISO/IEC 17025:2017's clause to provide convenience in understanding the implementation of ISO/IEC 17025:2017 in the transition period. This research is conducted by reviewing clause by clause on ISO/IEC 17025:2017 standard which is connected with PDCA concept. The result of this research is obtained PDCA model which contains clauses on ISO/IEC 17025:2017 standard accompanied by its implementation in calibration and testing laboratories

1. Introduction

The ISO/IEC 17025:2017 standard is a guide for testing laboratories and calibration laboratories to improve their competence. The ISO/IEC 17025:2017 can increase confidence in operation on the laboratory and provide validity of measurement and calibration results. The ISO/IEC 17025:2017 is also used by the National Accreditation Body in Indonesia to carry out accreditation specifically for calibration laboratories and testing laboratories[1]. At the beginning of 2019, there are 278 calibration laboratories and 1306 testing laboratories have been accredited by the National Accreditation Body in Indonesia. Calibration laboratories and testing laboratories are also part of National Quality Infrastructure in Indonesia.

The purpose of this research is to provide a point of view to the related parties that apply the ISO/IEC 17025:2017 standard, especially for calibration laboratories and testing laboratories. The clauses in ISO/IEC 17025:2017 are used to improve the competence of calibration laboratories and testing laboratories which in connection with this research are carried out through a process approach principle found in ISO 9001:2015. The relationship between ISO/IEC 17025:2017 and ISO 9001:2015 is very close. In the introduction part of ISO/IEC 17025:2017, there is a statement that testing laboratories and calibration laboratories that meet this standard will also operate in accordance with ISO 9001:2015 standard[2]. So that it can be



said if a laboratory implements ISO/IEC 17025:2017 then in principle it also applies ISO 9001:2015 standards.

ISO 9001:2015 standard employs the process approach, which incorporates the PDCA Cycle (Plan-Do-Check-Act) [3]. The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined, and acted on [3]. Every step earlier, will be the input for the next step. By implementing PDCA cycle in laboratory management system, it will create harmonization and integration between one activity and other activities starting from upstream step to downstream step. So that it can provide convenience in understanding, and it can be a tool to equalize perceptions and perspective in implementing ISO/IEC 17025:2017 especially in the transition period of this standard which will be end in 2020. In addition, with PDCA cycle concept, the harmonization between the ISO/IEC 17025:2017 and ISO 9001:2015 is more unified, making it easier for the body/company that implement both of them simultaneously. Many publications have discussed the achievements of implementing the PDCA concept in their institutions/companies. The achievement of success can be proven by the increase in company income, increased productivity of personnel, and decrease in work accident rates.

2. Study Literature

According to ISO 9001:2015 standard, there are 7 quality management principles[3], i.e.: customers focus, leadership, engagement of people, process approach, improvement, evidence-based on decisions making and relationship management. In the quality management principle associated with the process approach, one of the methods used is the PDCA cycle (Plan-Do-Check-Act). This method was developed by Walter Shewhart and popularized by Dr. William Edward Deming[4]. PDCA method is commonly used by body/companies to improve service quality, minimize errors, and improve customer satisfaction. In a research conducted by Liu et al., The concept of PDCA was used for the safety and security factors of workers in mining companies in China to overcome with high rates of accident for mining workers[5]. According to Wang et al., although mining contributes greatly to the Chinese economy, it holds the degree of the worst occupational safety and security in the world, so it requires certain solutions to overcome this problem[6]. The results of Liu et al.'s research that sparked the modern safety management system have an impact on the decline in work accident rates in mining companies in China[5]. The following figure is a the PDCA cycle whose concept was used in this research:

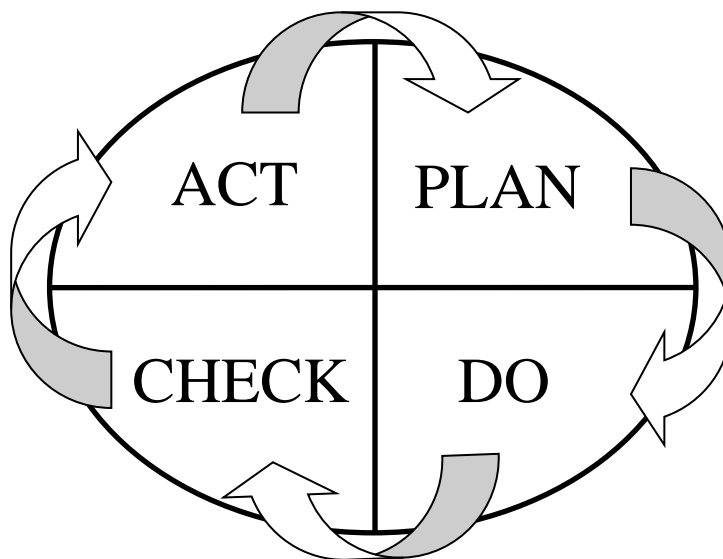


Figure 1. PDCA Cycle (Plan-Do-Check-Act)

In another research Conceicao et.al applied PDCA to the assembly part of an automotive company in Portugal[7]. From the results of his research, the PDCA concept approach was successfully implemented because it can optimize the production process, and achieve production capacity according to customer demand. According to Prashar, in general there are 4 steps taken in one PDCA cycle that consists of "PLAN" (making plans and strategies), "DO" (implementing and operationalizing), "CHECK" (monitoring and evaluating) and "ACT" (ensuring and improving quality) [8].

As we know, the ISO/IEC 17025:2017 standard consists of 8 clauses, those are: (1). Scope, (2). Normative references, (3). Terms and definitions, (4). General Requirements, (5). Structural Requirements, (6). Resource Requirements, (7). Process Requirements, and (8). Management System Requirements. The ISO/IEC 17025:2017 standard is applied to an organization from a calibration/testing laboratory called the quality management system. According to ISO 9000:2008 standard, the definition of a quality management system is a management system for directing and controlling organizations in terms of quality[9]. Therefore the context of the quality management system based on ISO/IEC 17025:2017 is related to calibration/testing activities and supporting activities carried out by a laboratory to issue a measurement certificate, calibration certificate and test report.

3. Methodology

This ISO/IEC 17025:2017 (3rd edition) standard began to be implemented by calibration laboratories, testing laboratories, accreditation bodies, suppliers and other interested parties in early 2018, replacing the previous edition of ISO/IEC 17025:2005 (2nd edition). In the introduction part of that standard, edition changes occur because of 3 reasons, those are: (1). the application of the concept of risk-based thinking, (2). high flexibility, and (3). there are additional new definitions. The relevance of the changes to ISO/IEC 17025:2017 to this research is that this standard is more flexible, represented by the structure of clauses that apply a process approach which is one of the quality management principles of the ISO 9001:2015 standard. In its implementation, the activities carried out first are placed in a clause with an earlier number, so that in general the next clause can be implemented if the previous clause has already been done. The concept of the process approach at ISO/IEC 17025:2017 can be explained in the following figure 2:

8. Management System Requirement	<u>maintenance</u>	<u>ensuring of consistency and</u>
7. Process Requirement	<u>appliances</u>	<u>main activities, implementation steps</u>
6. Resources Requirement	<u>frame and system</u>	<u>main component of implementation</u>
5. Structural Requirement	<u>foundation</u>	<u>organization, legal basis</u>
4. General Requirement	<u>building code</u>	<u>commitment, ethical code, intention</u>

Figure 2. Process Approach on ISO/IEC 17025:2017

From Figure 2, it can be explained that clause 4 concerning General Requirements is an ethical code in implementing the ISO/IEC 17025:2017 standard where all elements of the quality management system need to have the intention to always be impartial and maintain confidentiality. Compliance with the requirements in clause 4 is essentially the essence of achieving results in the form of quality calibration/testing results. After the ethical code stipulated in clause 4 is accommodated and set forth in the form of

procedures or forms, the next step is to build the foundation of the laboratory in the form of organizational structure, job description, legal basis, etc. which are entities of clause 5 concerning Structural Requirements. In addition, it is necessary to determine the width of scope that can reflect the resources needed (clause 6), the process carried out (clause 7) and the laboratory management system (clause 8). Therefore this research is conducted by analyzing the clause per clause in the ISO/IEC 17025:2017 standard which is related to the PDCA concept in accordance with the principle of the process approach. The results of this research resulted a PDCA cycle model related to the implementation of ISO/IEC 17025:2017 as seen in figure 3.

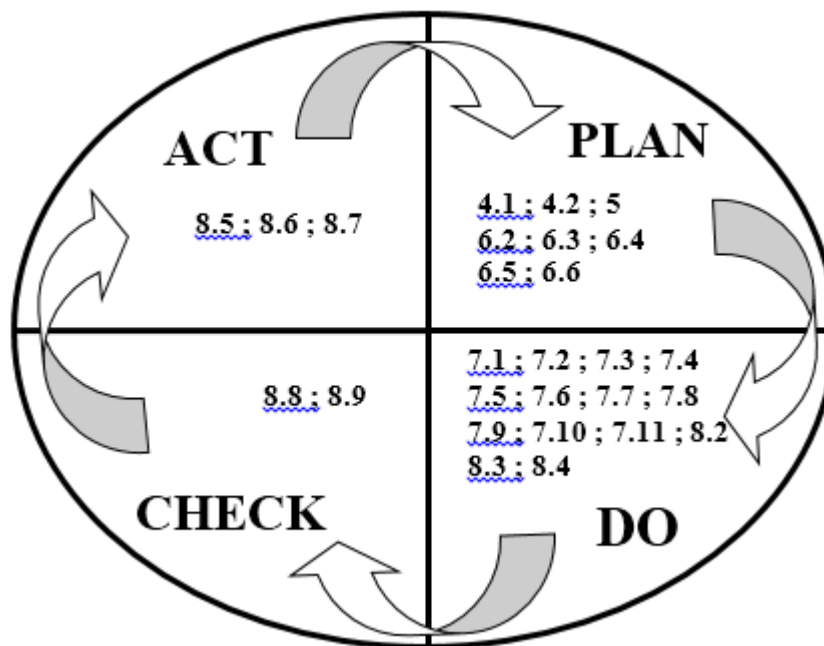


Figure 3.PDCA modeling based on ISO/IEC 17025:2017 standard

4. Results

In Figure 3, the PDCA model consists of clauses in the ISO/IEC 17025:2017 standard. The "PLAN" step is the basis and requirements for the laboratory to be established. This step is the most essential main foundation where the seriousness of the laboratory to achieve goals is determined by its readiness to carry out this step. In the context of the ISO/IEC 17025:2017 standard which is included in the "PLAN" step are clauses related to Impartiality (4.1), Confidentiality (4.2), Structural requirement (5), and Personnel (6.2), Facilities & environmental conditions (6.3), Equipment (6.4), Metrological traceability (6.5) and, External provided products & services (6.6). This step is the basic foundation for carrying out activities in the laboratory in relation to the competence and validity of the calibration/testing results. The first foundation is the intention and awareness of each individual in the laboratory management system to always impartiality and keep confidentiality. Impartial attitude means being free from conflicts of interest^[2]. This impartiality is the main foundation so that every personnel in the laboratory management system is always neutral so that every action taken does not affect the validity of calibration/testing results. In addition, each individual is expected to keep confidentiality, both for internal or external parties. Clause 4 is aethical code of applying ISO/IEC 17025:2017 so it is necessary to commit.

In the next step of the "PLAN", several components are needed to carry out all activities in the laboratory as inside clause 5 regarding the structural requirements. Components such as the legal basis of laboratory, the organizational structure, personnel,

job description of personnel and effective communication processes. In the "PLAN" step, there are clauses which is concrete and real foundation for laboratory operational activities as stated in clause 6 concerning Resource Requirements. In the PDCA cycle, the laboratory can carry out the "DO" step, if at the "PLAN" step it has:

1. Personnel who are competent to do work in a laboratory management system (6.2)
2. Equipment (measuring standards/measuring instruments) to carry out calibration, testing and monitoring (6.3)
3. Facilities (permanent, semi-permanent, mobile) for calibration or testing activities (6.4)
4. Evidence of traceability of measurements of equipment (6.5)
5. External service providers or products which has competency and acceptable (6.6)

From Figure 3, the second step of the PDCA cycle is "DO". From the laboratory basic foundation which are in the "PLAN" step, it will be an input for "DO" step. "DO" step is all activities carried out related to calibration/testing activities and supporting activities. Most clauses in the ISO/IEC 17025:2017 standard are implemented at this step. The clauses included in the "DO" step are among other: Review of requests, tenders, and contracts (7.1), Selection, verification and validation of methods (7.2), Sampling (7.3), Handling of test or calibration items (7.4), Technical records (7.5), Evaluation of measurement uncertainty (7.6), Ensuring the validity of results (7.7), Reporting of results (7.8), Complaints (7.9), Nonconforming work (7.10), Control of data and information management (7.11), Management system documentation (8.2), Control of management system documents (8.3), and Control of records.

The "DO" step will start when there is a calibration/testing request where the laboratory will respond with a review of the request. The review process is done by looking at the availability of calibration/testing scope, the calibration/testing method used, the measuring range of measurements that can be accommodated, and the value of measurement uncertainty that can be achieved. If the laboratory undertakes a certain type of calibration/testing work with the agreed method, the customer can bring test samples or artifacts that will be calibrated to the laboratory. Samples or artifacts from customers require special treatment in terms of packaging, transportation and handling so that there is no deterioration in quality or value, therefore there are procedure for handling items that will be calibrated or tested. In the "DO" step, a process of evaluating uncertainty of measurement is carried out in the report of the calibration/testing results.

In order for the calibration/test results carried out to have valid values, a quality assurance process that can be carried out internally (intralaboratory) or externally (interlaboratory) is needed. Based on ISO/IEC 17025:2017 standard, which are internal quality assurance process activities such as: the use of Certified Reference Materials, carry out functional check activities on standards/measuring instruments, carry out regular intermediate check processes, use check standards etc. Whereas those that include external quality assurance such as: carry out proficiency testing activities with laboratories that have similar test/calibration scope. At the "DO" step there are clauses to accommodate customer complaints and non-conformity from other sources to improve laboratory performance and the quality of the calibration/testing results. In "DO" step, there is a control process for documented information consisting of documents, data and records. The process of controlling documents is in accordance with clause 8.3, the control process of records is in accordance with clauses 7.5 and 8.4, and the control of data is carried out in accordance with clause 7.11.

The third step of the PDCA cycle is "CHECK". This step serves to monitor the laboratory management system activities carried out from the previous step and see its effectiveness. In addition, this step is carried out to see conformity in relation to the implementation of the ISO/IEC 17025:2017 standard. The "CHECK" step is done to see the suitability, adequacy and effectiveness of the laboratory. The conformity concept at this step is divided into 2 such as:

1. Conformity between reference documents/standards and documented information

2. Conformity between documented information and practice

The first conformity concept can be interpreted that the documented information from the laboratory must be in line with the reference document (standard). The second concept of conformity can be interpreted that the practice carried out by all laboratory management system personnel must be in accordance with documented information. If there is a difference between documented information with reference documents/standards or with practice, non-conformity (NC) can occur. This non-conformity is usually found in this "CHECK" step. Non-conformity requires corrective actions in accordance with clause 8.7 of ISO/IEC 17025:2017.

The clauses in the ISO/IEC 17025:2017 standard which are included in the "CHECK" step include: internal audit (8.8), and management review (8.9). At this step the checking process is carried out to all elements of the laboratory management system, either the technical, quality or administrative parts. Generally, activities at this step are carried out regularly at least once a year. Implementation of this step will obtain data related to conformity or non-conformity that occur in the operation of the laboratory management system, fulfillment of quality policy, internal and external issues related to the implementation of laboratory activities, corrective actions taken from internal audit and external assessment, changes in the volume and type of the work, etc.

The fourth step of the PDCA cycle is "ACT". At this step there are 3 clauses such as: Action to address risks and opportunities (8.5), Improvement (8.6), and Corrective action (8.7). This step is a proactive response from the laboratory for: eliminate non-conformity (NC), identified the risks that can occur from laboratory activities and identified the opportunities that can be done. A corrective action is needed to eliminate the non-conformity that occur in the laboratory management system so that the credibility of the laboratory is maintained. In addition, at this step there are actions to minimize/eliminate risks and actions to increase the available opportunities. Risk means condition that can reduce the quality of calibration/testing results so that their existence needs to be minimized/eliminated. Opportunities mean condition that can improve the quality of calibration/testing results so that they need to be raised, maintained and upgraded.

The circumstances such as: any deviation in calibration/testing room condition, recalibration due date that has passed, and any delay in completing calibration/testing work can be categorized as risks, so that it requires action to minimize/eliminate it. On the other hand, the condition such as: Exactness of completion of calibration/testing work, improvement of personnel competency, and expansion of the scope of services can be categorized as opportunities, so that action is needed in order to increase laboratory management systems. One of the improvement processes that can be done is by evaluating feedback from customers. All actions (corrective actions, actions to minimize/eliminate risk, actions to realize the opportunity) carried out at the "ACT" step are input to the "PLAN" step for the next cycle. The PDCA cycle on the implementation of ISO/IEC 17025:2017 can lead to customer trust, apply consistency to laboratory operational activities, and produce valid calibration/testing results.

5. Conclusion

From the results of this research, ISO/IEC 17025:2017 standard can be applied using the PDCA cycle (Plan-Do-Check-Act) where the concept is used in applying the ISO 9000:2015 standard regarding the process approach. This aims to provide an overview so as to facilitate understanding the implementation of the clause per clause of the ISO/IEC 17025:2017 standard so that its application can be consistent. In general there are 4 steps in one PDCA cycle, those are "PLAN" step, "DO" step, "CHECK" step, and "ACT" step. All of these steps will form one cycle so that from this research a PDCA model is created based on ISO/IEC 17025:2017 standard. The step of "PLAN" is the basic foundation, and ethical code in order to operate calibration/testing activities that can produce valid results. The "DO" step is the main activity of the laboratory starting from the upstream part such as review of the calibration/testing request up to the downstream part such as issuing calibration/testing certificate which are products from the calibration/testing laboratory.

The "CHECK" step is carried out to see the suitability, adequacy and effectiveness of the laboratory management system. While the "ACT" step is actions taken to eliminate/minimize risk, eliminate non-conformities and realize opportunities so as to create an increase in laboratory performance. The PDCA ISO/IEC 17025:2017 model from the results of this research is expected to be implemented in calibration laboratories and testing laboratories as part of National Quality Infrastructure in Indonesia mainly related to the transition period from edition 2 to edition 3 of the standard which will be end at 2020.

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