
**EVALUATION OF EXTERNAL AUDIT ON THE IMPLEMENTATION OF
SNI ISO 17025:2017 IN PROVIDING ADDED VALUE TO THE ORGANIZATION**
*Evaluasi Audit Eksternal Pada Penerapan SNI ISO 17025:2017 dalam Memberikan Nilai
Tambah bagi Organisasi*

Ratna Mayasari¹, Robby Marlon Brando¹, Sari Andarwati¹

¹ Directorate of Laboratory Management, Research Facilities and Science and Technology Areas, National
Research and Innovation Agency for Indonesia
Puspiptek, Serpong, South Tangerang, Banten, Indonesia

e-mail: ratn010@brin.go.id

Diterima: 20 September 2022, Direvisi: 13 Februari 2023, Disetujui: 3 Oktober 2023

Abstract

XYZ Laboratory has main tasks and functions to carry out technology service activities in the field of machine tool technology, production and automation. One kind of technology service to the industry is as a testing laboratory. SNI ISO/IEC 17025:2017 is a testing laboratory standard that is suitable to support the XYZ Laboratory in carrying out technology service tasks in the field of testing. Because the XYZ Laboratory has been accredited by KAN (National Accreditation Body) as a testing laboratory, the XYZ Laboratory has an obligation to participate in an external audit conducted by KAN. This needs to be done to maintain the quality of testing laboratory services so that they remain in accordance with applicable standards. Considering that this external audit will be carried out routinely as long as it is accredited as a testing laboratory, it is necessary to carry out an analysis regarding the findings that often appear at the XYZ Laboratory. This will be useful for formulating preventive and corrective actions in the future. The research used descriptive qualitative with the research subject was a testing laboratory, which consisted of laboratory management and implementer. Data collection is used in this study through semi-structured interviews with employees who have been directly involved in accreditation at the XYZ Laboratory for the formulation, management and application of SNI IEC/ISO 17025: 2017 and non-conformance sheets from 2019 to 2021 from the results of an external audit by the Accreditation Committee. Evaluation of the results of external audits conducted by KAN during 2019, 2020 and 2021, shows that clause 6.4 Equipment, clause 6.2 Personnel, and clause 7.2 Selection, verification and validation of methods, are clauses that often encounter discrepancies. The discrepancy between clauses 6.4 and 6.2 intersects where frequent employee turnover makes employee competence management not run optimally, as evidenced by the discovery of the competence of several employees who do not comply with competency requirements causing equipment maintenance to be hampered.

Keywords: ISO 17025, testing laboratory, external audit

Abstrak

Laboratorium XYZ mempunyai tugas pokok dan fungsi untuk melaksanakan kegiatan pelayanan teknologi dalam bidang teknologi mesin perkakas, produksi dan otomasi. Salah satu bentuk layanan teknologi terhadap industri adalah sebagai laboratorium pengujian. SNI ISO/IEC 17025:2017 adalah standar laboratorium pengujian yang sesuai dalam mendukung Laboratorium XYZ dalam melaksanakan tugas pelayanan teknologi di bidang pengujian. Karena Laboratorium XYZ sudah terakreditasi oleh KAN (Komite Akreditasi Nasional) sebagai laboratorium pengujian, maka Laboratorium XYZ memiliki kewajiban untuk mengikuti audit eksternal yang dilakukan oleh KAN. Hal ini perlu dilakukan untuk menjaga mutu layanan laboratorium pengujian agar tetap sesuai dengan standar yang berlaku. Mengingat, audit eksternal ini akan rutin dilakukan selama terakreditasi sebagai laboratorium pengujian, maka perlu dilakukan analisis terkait temuan yang sering muncul pada Laboratorium XYZ. Hal ini akan bermanfaat untuk melakukan perumusan tindakan pencegahan dan perbaikan ke depannya. Penelitian ini menggunakan deskriptif kualitatif dengan subjek penelitian adalah laboratorium pengujian yang terdiri dari pengelola dan pelaksana laboratorium. Pengumpulan data yang digunakan dalam penelitian ini melalui wawancara semi terstruktur dengan pegawai yang telah terlibat langsung dalam akreditasi di Laboratorium XYZ untuk penyusunan, pengelolaan dan penerapan SNI IEC/ISO 17025:2017 dan lembar ketidaksesuaian tahun 2019 sampai dengan tahun 2021 hasil audit eksternal oleh Komite Akreditasi. Evaluasi terhadap hasil audit eksternal yang dilakukan KAN selama tahun 2019, 2020, dan 2021, menunjukkan bahwa klausul 6.4 Peralatan, klausul 6.2 Personel, serta klausul 7.2 Pemilihan, verifikasi dan validasi metode, merupakan klausul yang sering memperoleh ketidaksesuaian. Ketidaksesuaian antara klausul 6.4 dan 6.2 beririsan dimana turnover pegawai yang sering terjadi menjadikan pengelolaan kompetensi pegawai tidak berjalan maksimal, terbukti dengan ditemukannya kompetensi beberapa pegawai yang tidak sesuai dengan syarat kompetensi sehingga menyebabkan pemeliharaan peralatan menjadi terhambat.

Kata kunci: ISO 17025, laboratorium pengujian, audit eksternal

1. INTRODUCTION

XYZ Laboratory has main tasks and functions to carry out technology service activities in the field of machine tool technology, production and automation. One kind of technology service to the industry is as a testing laboratory. SNI ISO/IEC 17025:2017 is a standard for testing laboratories that are appropriate to support XYZ Laboratory in carrying out its duties on technology service tasks in the field of testing. XYZ Laboratory is a testing laboratory that received an accreditation certificate from KAN and implements SNI ISO 17025:2017 starting in 2018.

The implementation of a quality system on SNI ISO 17025 and accreditation are completely achievable, and are helpful activities to put members in touch with the real world and broaden their minds (Garcia, et al., 2007)

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 (Putri, et al., 2019)

The purpose of accreditation of the test and calibration laboratory is to guarantee the validity of R&D results by using accredited test and calibration equipment and in addition to providing science and technology services to the community and industry (Oktari, et al., 2019)

One way to measure the performance and quality of laboratory test results in accordance with applicable standards is to apply laboratory accreditation that involves external assessment (Elfriede et al., 2019). Adjustment of SNI IEC/ISO 17025:2017 from SNI IEC/ISO 17025:2008 carried out the adjustment reassessment process at the same time as the XYZ Laboratory re-accreditation process which ended in 2018.

Accreditation is an acknowledgment of the competence of a conformity assessment agency. Obtaining SNI ISO/IEC 17025:2017 accreditation can provide benefits including:

1. developing personnel competence in accordance with competency requirements to perform testing services, ensuring personnel are protected from all forms of conflict of interest, including commercial interests that can affect the quality of test results;
2. can use test equipment that is traceable, reliable and always ready to use;

3. always committed to improving service quality on an ongoing basis so that it can provide maximum service to customers based on the scope of SNI ISO/IEC 17025:2017 accreditation testing (Anggraini et al., 2021).

In accordance with SNI ISO/IEC 17025:2017 clause 8.1.1 which says that the laboratory must establish, document, implement and maintain a management system that is able to support and demonstrate consistent achievement of the requirements of this document and ensure the quality of its laboratory results, this is done as a form of commitment from XYZ Laboratory management to maintain a laboratory management system for the implementation of SNI ISO/IEC 17025:2017. This commitment is carried out by conducting periodic internal audits and external audits/ field surveillance (Zamrudi et al., 2014).

The Internal Audit was conducted to find out how far the consistency of the implementation of the SNI ISO/IEC 17025:2017 quality management system at the XYZ Laboratory was based on laboratory requirements including laboratory activities and document requirements (Subekti, 2018). External audits/field surveillance is carried out regularly and periodically by KAN based on the provisions in the terms and rules for the accreditation of the conformity assessment agency KAN U-01 and the results are followed up and documented.

Considering that this external audit will be carried out routinely as long as it is accredited as a testing laboratory, it is necessary to carry out an analysis regarding the findings that often appear at the XYZ Laboratory. This will be useful for formulating preventive and corrective actions in the future. In addition to conducting external audits, XYZ Laboratory is also required to conduct internal audits. The internal audit process is the same as the external audit, the only difference being that the auditors come from within the XYZ Laboratory.

From the results of the internal audit and external audit, the management reviews the results in order to determine steps to improve the quality of its implementation and to improve the quality management system at XYZ Laboratory. In fact, after an external audit conducted by a competent institution, in this case KAN, several non-compliances were found with the requirements set out in SNI ISO/IEC 17025:2017 (BATAN, 2020).

Evaluation Of External Audit On The Implementation Of SNI ISO 17025:2017 In Providing Added Value To The Organization

(Ratna Mayasari , Robby Marlon Brando, Sari Andarwati)

This study will evaluate the results of an external audit at the XYZ Laboratory with the scope of accreditation being Positioning Accuracy Test, Cutting Accuracy Test, Circular Movement Accuracy Test and 3D Optical Measurement Test for Vertical Type CNC Milling Machines, CNC Lathes, CNC Boring Machines and Artifacts in 2019 – 2021. Its can determine the factors that influence organizational performance with parameters from the clause approach in SNI ISO / IEC 17025: 2017 as seen from the results of external audits so that Laboratory can decide contiounos improvement for future organization

2. LITERATURE REVIEW

The Indonesian National Standard SNI ISO/IEC 17025:2017 with the title General requirements for the competence of testing and calibration laboratories, is an identical adoption of ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories, with a bilingual translation method. This SNI revises SNI ISO/IEC 17025:2008, General requirements for the competence of testing laboratories and calibration laboratories.

According to the SNI ISO/IEC 17025:2017 document which is an identical adoption of ISO/IEC 17025:2017 published by the National Standardization Agency, it contains general requirements for competence, impartiality and consistent laboratory operation. SNI ISO/IEC 17025:2017 applies to all organizations that carry out laboratory activities, regardless of the number of personnel.

Laboratory customers, government authorities, peer-assessment organizations and schemes, accrediting bodies, and others use this document to confirm or acknowledge laboratory competence. XYZ Laboratory is a testing laboratory accredited by National Accreditation Committee that received accreditation in 2013 and has reaccredited twice in 2018 and 2022. The first re-accreditation in 2018 was carried out based on SNI ISO/IEC 17025:2008 and in 2020 based on SNI ISO/IEC 17025:2017 which was adjusted in 2019. The scope of accreditation is Positioning Accuracy Test, Cutting Accuracy Test, Movement Accuracy Test Circular and 3D Optical Measurement Test for Vertical Type CNC Milling Machines, CNC Lathes, CNC Boring Machines and Artifacts.

As an organization that has a function as a testing laboratory, XYZ Laboratory must have competent human resources. This is a demand that must also be fulfilled in the SNI ISO/IEC

17025:2017 clause. The role of human resources in testing laboratories is very large, because it is directly related to the organization's goal of producing reliable and trustworthy test results. For that, as an organization, XYZ Laboratory has the obligation to maintain the competence of its human resources according to the requirements in the SNI ISO/IEC 17025:2017 clause. In his research (Triharto et al., 2022) states that in order to prevent the recurrence of non-compliance, the organization must prepare personnel resources to meet the requirements for ensuring the validity of test results as required in SNI ISO/IEC 17025:2017.

In addition to the clauses in SNI ISO/IEC 17025:2017, maintenance and improvement of human resource competencies is one of the programs that has become an area of change in bureaucratic reform made by the Ministry of Administrative Reform and Bureaucratic Reform especially in the working group Arrangement of Apparatus Human Resource Management System (PermenPAN NOMOR 16 TAHUN 2015, 2015).

Change management is the management of resources in order to achieve organizational goals with better performance. Change is an organizational shift from the current state to the desired state. Within the organization, these changes include structure, process, people, mindset, and work culture. Changes to the previous organizational structure need to be made to adjust the business processes to SNI ISO 17025: 2017 in order to make it easier for personnel to carry out their work which must coordinate with each other (Gunawan & Rahardjo, 2022).

For this reason, it is important for XYZ Laboratory to be able to maintain and improve the integrity and competence of its human resources. Because the competency of human resources is a valuable asset for the organization to be able to continue to carry out its services in the face of today's rapid technological developments. The success and failure of an organization depends on success in managing its human resources, so how important human resources are to the organization.

The stages carried out by the laboratory in developing personnel competence are determining the position map, position analysis, position competency gaps and in the final stage there is the implementation of training according to the existing gaps. The need for the number of personnel and positions needed will be known when compiling the position map

3. RESEARCH METHODS

The research used descriptive qualitative with the research subject was a testing laboratory, which consisted of laboratory management and implementers. Data collection is used in this study through semi-structured interviews with employees who have been directly involved in accreditation at the XYZ Laboratory for the formulation, management and application of SNI IEC/ISO 17025: 2017 and non-conformance sheets from 2019 to 2021 from the results of an external audit by the Accreditation Committee. National where data is viewed based on the number of non-conformities per clause.

Furthermore, data processing is carried out by reducing data, namely sorting out the data used for research, check sheets, Pareto diagrams and fishbone diagrams. The next step will be to evaluate and analyze the results of the non-conformance of the external audit assessment. Furthermore, the researcher will continue the analysis based on the author's experience and direct observation. Result the parameters to be analyzed in this study consist of three parameters, namely:

1. Highest non-conformance for 3 years from 2019 to 2021;
2. The trend of increasing non-conformance in the clause in 2021;
3. The trend of decreasing non-conformance in the clause in 2021.

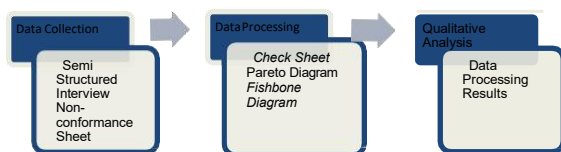


Figure 1 Research Method.

4. RESULTS AND DISCUSSION

XYZ Laboratory has personnel, in addition to its other duties, the necessary authority and resources to perform its duties, including:

- a) Implementation, maintenance & improvement of management system
- b) Identification of deviations from the management system or procedures
- c) Initiation of actions to prevent or minimize deviations
- d) Reporting to laboratory management, related to management system performance & any improvement needs
- e) Ensuring the effectiveness of laboratory activities

Laboratory personnel are divided into 2 groups, namely the technical team and the quality team. The technical team is in charge of laboratory operations in terms of ensuring availability, quality assurance, equipment management personnel. While the quality team is in charge of ensuring documentation and managerial systems for the implementation of SNI ISO / IEC 17025

Competency management of laboratory XYZ personnel determining competency requirements are personnel selection, personnel training, personnel supervision, personnel authorization, and personnel competency monitoring.

In the implementation of testing, methods and procedures that have been established as SNI (Standar Nasional Indonesia) are used. The methods and procedures referred to here include those needed for the purposes of estimating the uncertainty of measurement results and analyzing test data.

XYZ Laboratory has procedures and work instructions for safe handling, transport, storage, use and maintenance to ensure the proper functioning of equipment

In the external audit in 2019 there were 11 non-conformities, in 2020 there were 11 non-conformance sheets and 16 non-conformities in 2021 based on the SNI ISO/IEC 17025:2017 clause. (Putri et al., 2019). The non-conformance is mapped based on the clauses as shown in Table 1.

Evaluation Of External Audit On The Implementation Of SNI ISO 17025:2017 In Providing Added Value To The Organization
(Ratna Mayasari , Robby Marlon Brando, Sari Andarwati)

Table 1 Number of External Audit Non-conformities per XYZ Laboratory clause 2019-2021

Clause 17025:2017	2019	2020	2021	Sum	%
4.1 Impartiality	1	1		2	5%
4.2 Confidentiality	1			1	3%
5 Structural Requirements	1	1	1	3	8%
6.1 General – Resource Requirements				0	0%
6.2 Personnel		1	3	4	11%
6.3 Facilities and Environmental Conditions				0	0%
6.4 Equipment	5	4	1	10	26%
6.5 Metrological Traceability		1		1	3%
6.6 Externally Provided Products and Services			1	1	3%
7.1 Review of Requests, Tenders, and Contracts				0	0%
7.10 Nonconforming Work				0	0%
7.11 Control of Data and Information Managements				0	0%
7.2 Selection, Verification, and Validation of Methods			4	4	11%
7.3 Sampling				0	0%
7.4 Handling of Tests or Calibration Items				0	0%
7.5 Technical Records			1	1	3%
7.6 Evaluation of Measurement Uncertainty			1	1	3%
7.7 Ensuring the Validity of Results		1	1	2	5%
7.8 Reporting of Results		1	2	3	8%
7.9 Complaints				0	0%
8.1 Options Management System Requirements				0	0%
8.2 Management System Documentation (Option A)				0	0%
8.3 Control of Management System Documents (Option A)	1		1	2	5%
8.4 Control of Records (Option A)				0	0%
8.5 Action to Address Risks and Opportunities (Option A)	1			1	3%
8.6 Improvement (Option A)				0	0%
8.7 Corrective actions (Option A)				0	0%
8.8 Internal audits (Option A)				0	0%
8.9 Management reviews (Option A)	1	1		2	5%

In Table 1 there are non-conformance in several clauses, not all of them have non-conformance. The pareto diagram shows the priority of the causes of events or problems that need to be addressed. Pareto diagrams can help to focus attention on the main issues that must be

addressed in the improvement effort. Based on the non-conformity data, pareto diagram can be made which illustrates the non-conformity per clause contained in Figure 2 as follows: (Utami & Suryawardani, 2018).

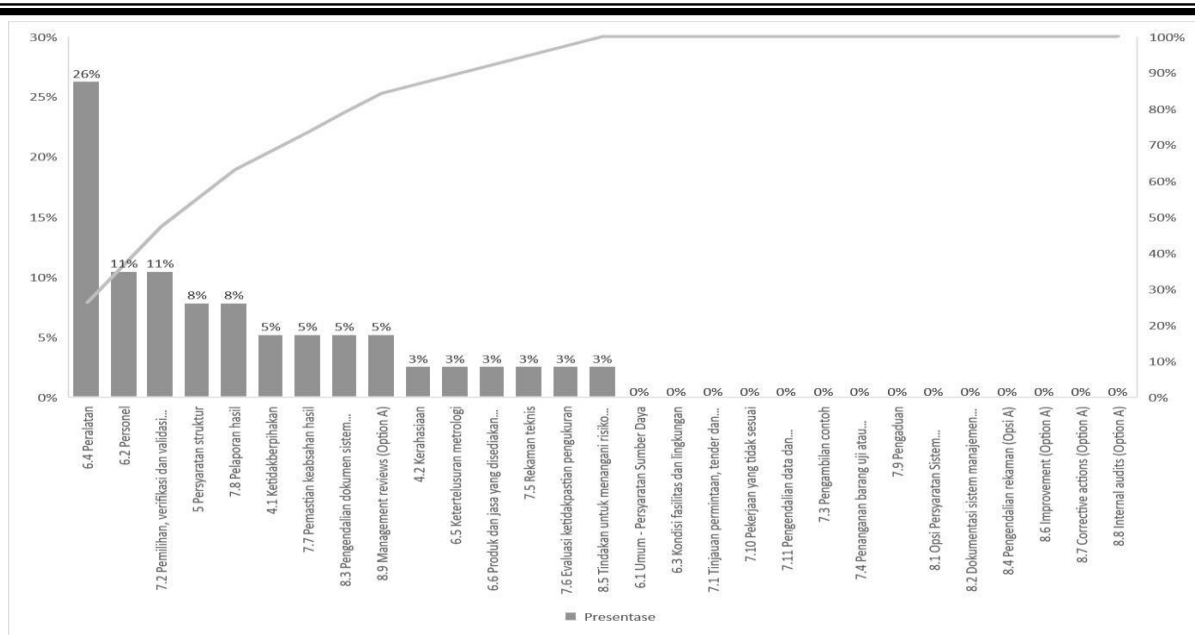


Figure 2 Graph of External Audit Non-conformity per XYZ Laboratory clause 2019-2021.

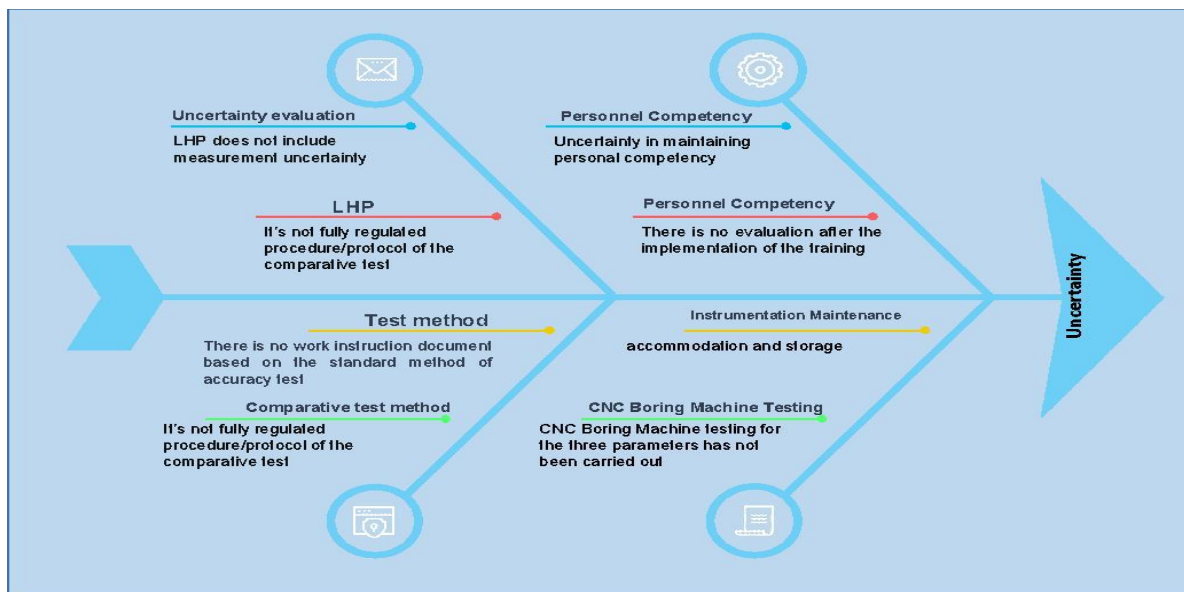


Figure 3 Fishbone diagram of non-conformance in audit results.

The analysis is carried out on each parameter that has been determined. Based on Pareto diagrams (Figure 2), and fishbone diagrams (Figure 3), the following analysis can be drawn:

4.1 Highest non-conformance for 3 years from 2019 to 2021

This research performs an analysis at the highest level of incompatibility to prioritize and focus improvements on it at XYZ Laboratory.

For 3 years, the highest non-conformance rates based on the highest percentage are as follows:

a. Clause 6.4 Equipment 26%

The non-conformity in maintaining equipment in accommodation and storage by the technical team for the accreditation of SNI ISO/IEC 17025: 2017 at the XYZ Laboratory is something that needs to be improved and paid attention to. Changes in laboratory personnel who take turns and exchange of information that has not been

Evaluation Of External Audit On The Implementation Of SNI ISO 17025:2017 In Providing Added Value To The Organization

(Ratna Mayasari , Robby Marlon Brando, Sari Andarwati)

maximized which causes equipment maintenance that often occurs as a non-conformance.

b. Clause 6.2 Personnel 11%

The non-conformity in maintaining the competence of personnel in the technical team and the quality team for the accreditation of SNI ISO/IEC 17025: 2017 is a non-conformity that often arises when there is an assessment of an external agency of KAN. One form of maintaining the competence of personnel is through training. The non-conformity that is often found is related to the evaluation of the results of the implementation of the training which causes the training that has been carried out cannot be judged to have supported the competence of personnel or not.

c. Clause 7.2 Selection, verification and validation of methods 11%

This non-conformity occurs in that the laboratory does not yet have a Work Instruction document based on the standard test method used for Positioning Accuracy Test (3 testing machines) Error in writing ISO reference for Positioning Accuracy Test.

d. Clause 5. Structural requirements 8%

The non-conformity with the structural requirements occurs related to the organizational requirements of the XYZ Laboratory which have been changed several times and the legal basis underlying the XYZ Laboratory cannot be explained with certainty. In 2019, there was a Decree of the accreditation team that was not in line with the Decree on the Establishment of the XYZ Laboratory. In 2020, there is an authority between administrative managers and technical managers that is out of sync between the XYZ Laboratory Personnel Placement Letter and the XYZ Laboratory Establishment Decree. In 2021, the transition period for organizational fusion, including XYZ Laboratory, resulted in the XYZ Laboratory not getting a clear organizational structure.

e. Clause 7.8 Reporting results 8%.

The non-conformity in reporting the results related to the implementation of the comparative test carried out independently, but the laboratory has not fully regulated the comparative test procedure/protocol regarding the implementation of the comparative test for the stages of the comparative test in accordance with the scope to

be compared, from artifact preparation, testing requirements (such as methods, tools, environmental conditions), evaluation and acceptability of test results, etc. This happens because the documentation of activities in the laboratory has not been done thoroughly.

4.2 The trend of increasing non-conformance in the clause in 2021 are:

a. Clause 6.2 Personnel

In 2020 there is only 1 non-conformity but in 2021 there are 3 non-conformance. This non-conformity is because the implementation of personnel training, both technical and quality, has not been consistent in the implementation, especially in terms of evaluation after the implementation of the training. This can happen because there are no personnel assigned to handle the implementation evaluation on a roto basis.

b. Clause 6.6 Externally provided products and services

In this clause there is a new non-conformity in 2021 in the accreditation validity period. The non-conformity that has arisen is that there has been no updating of evaluation data for equipment procurement service suppliers and review of tender requests and contracts covering the scope of requirements for calibration methods, standard equipment, calibration service time. This can happen that there has not been assigned roto personnel for updating supplier evaluation data and reviewing tender requests and contracts

c. Clause 7.2 Selection, verification and validation of methods

In this clause there is a new non-conformity in 2021 in the accreditation validity period. The assessor considers that the existing Work Instructions are less effective in the implementation process in the laboratory, so it is necessary to check the effectiveness of the work instructions. This can happen that the document review process has not been carried out optimally, it is necessary to make a more effective and efficient implementation method.

d. Clause 7.5 Technical records.

The non-conformity in this clause is that the Laboratory has not been able to show evidence that the Laboratory has tested the CNC Boring Machine for the three proposed parameters. This

happens because there is no request from external parties for this CNC boring machine service.

e. Clause 7.6 Evaluation of measurement uncertainty

In the Circular Movement Accuracy Test (three tools: Vertical Type CNC Milling Machine; CNC Lathe; CNC Boring Machine), the testing result does not include measurement uncertainty.

f. Clause 7.8 Reporting results

The laboratory has an inter-laboratory comparative test procedure related to the implementation of the comparative test which is carried out independently, but the laboratory has not fully regulated the comparative test procedure/protocol related to the implementation of the comparative test for the stages of the comparative test in accordance with the scope to be compared, from preparation artifacts, test requirements (such as methods, tools, environmental conditions), evaluation and acceptability of test results, etc.

4.3 The trend of decreasing non-conformance in the clause in 2021.

The downward trend can be seen from two sides in 2021.

a. First, in 2021 there is no non-conformity at all. The first trend is found in 4.1 Impartiality, Clause 4.2 Confidentiality, Clause 6.5 Meteorological Traceability, Clause 8.5 Measures to address risks and opportunities, 8.9 Management reviews.

Seen by the absence of non-conformance in 2021, it shows that XYZ Laboratory has consistently improved and implemented these clauses so that in 2021, there will be no non-conformance based on the assessment of external bodies.

b. Second, in 2021 there will be a decrease in the number of non-conformities from the previous year.

The second trend is found in clause 6.4 Equipment. In 2021 there was a decrease from 2 non-conformance in 2020 and 4 non-conformance in 2019. The XYZ Laboratory made continuous improvements for this clause so that it was seen that in 2021 it had decreased.

Recommendations in applying the results of the analysis of non-conformance to external audits show that XYZ Laboratory has not implemented ISO 17025 comprehensively. It can

be seen that there are repeated findings in several clauses.

Zamrudi stated that the way to determine the fulfillment of the requirements in SNI IEC/ISO 17025: 2017 is to conduct discussions between laboratory staff to resolve non-conformance from external audit results. Based on research by (Elfriede et al., 2019), recommendations for meeting the requirements of SNI IEC/ISO 17025: 2017 include equipment quality assurance (calibration and intermediate testing), equipment maintenance (logbook writing, compliance with Work Instructions, and equipment recording).

Based on the discussion above, a preventive and corrective action plan can be made in the future. The results of this discussion also reflect the description of the XYZ Laboratory other than just a testing laboratory. Therefore, the preventive and corrective action plans developed apply to the entire laboratory. The preventive and corrective actions that can be carried out by the XYZ Laboratory by considering the results of the non-conformity analysis found in the testing laboratory are as follows:

1. Personnel

Competence of personnel must be maintained in accordance with the requirements that have been set and an evaluation of the implementing staff in the testing laboratory is carried out. To ensure this, management must be committed to maintaining the competence of the implementing staff in the testing laboratory. This form of commitment can be in the form of assignments to employees who meet the competencies, increasing competence for employees who carry out testing, all employees implementing the quality system testing laboratory need to master the requirements of SNI IEC/ISO 17025: 2017 comprehensively and provide punishment or reward to implementing employees in testing laboratory. The reward and punishment system is the optimal way to improve employee performance (Wijaya, 2021).

XYZ laboratory has a good concept in personnel management but from the result of external audits it can be seen that there are still weakness in terms of personnel. Repeated personnel replacements cause personnel competencies take longer to get competent personnel in the implementation of the SNI ISO / IEC 17025 quality management system.

The laboratory is part of PT XYZ which focuses on testing activities. The establishment of a position map in the organization can provide an overview of the position, the number of personnel, needed in laboratory management. The next

Evaluation Of External Audit On The Implementation Of SNI ISO 17025:2017 In Providing Added Value To The Organization

(Ratna Mayasari , Robby Marlon Brando, Sari Andarwati)

stage is the process of improving personnel competence based on the results of the competency gap from the analysis of current positions and personnel competencies. One way this can be done can be through training.

2. Quality assurance

Equipment quality assurance, calibration, comparative tests and intermediate tests must be carried out periodically according to the planned schedule. So that if the quality assurance results are declared not to meet the acceptability limit, the test equipment can be repaired.

Validation/verification of methods according to clause 7.2 must be reviewed periodically. This is to ensure the range and accuracy of the values obtained from the test method are appropriate and consistent with the specified requirements. Both internal and external audit systems must be carried out periodically to ensure continuous improvement is implemented (Zapata-García et al., 2007).

Records during the use and maintenance of test equipment in accordance with the prerequisites, both equipment labels, software used, brand and type, specifications, serial numbers, maintenance plans and details of test equipment deviations must always be ensured to be recorded. This relates to the understanding of the testing laboratory staff that records of use and maintenance are important for tracing the history of test equipment.

5. CONCLUSION

Qualitative data from the assessment results show that XYZ Laboratory in implementing SNI IEC/ISO 17025 : 2017 still has recurring non-conformance. Evaluation of the results of external audits carried out by the National Accreditation Committee during 2019, 2020, 2021 on the application of SNI IEC/ISO 17025: 2017 shows that the results of clause 6.4 Equipment, clause 6.2 Personnel, clause 7.2 Selection, verification and validation of methods are clauses that often contain many clauses. discovered during an external audit of KAN

The non-conformity between clause 6.4 Equipment and clause 6.2 Personnel overlaps where the high level of employee turnover makes the management of employee competence not run optimally, as evidenced by the discovery of the competence of several employees who are

not in accordance with the competency requirements so that equipment maintenance is hampered.

To answer the problem statement of the study, XYZ Laboratory should focus more on continuous improvement in equipment management and handling methods where the main factor that must be addressed as a downstream cause is to ensure minimal or non-existent laboratory employee turnover. XYZ Laboratory must determine the strategy realized in the action plan

Recommendations for improvement of non-compliance with the requirements of SNI IEC/ISO 17025: 2017 can be input for other testing laboratories in implementing SNI IEC/ISO 17025: 2017.

This study only analyzes the results of external audits while XYZ Laboratory applies SNI IEC/ISO 17025: 2017, for further research in order to deepen the analysis results, it can be added by including the results of internal audits as well or other external audits such as from customers

This result of study as a consideration for the laboratory in having an assessment system that is referenced from international standards so that XYZ Laboratory has guidelines in terms of which ones need to be improved to get optimal performance

AKNOWLEDGEMENT

The authors thank Ellia Kristiningrum who has provided guidance on the implementation of research and feedback on this paper.

REFERENCES

- Anggraini, L. D., Purnamasari, E. D., & Melinda, M. (2021). Evaluasi Implementasi Audit Internal Berbasis Iso 9001: 2008 Untuk Meningkatkan Manajemen Mutu Pada Rumah Sakit. *Mega Aktiva: Jurnal Ekonomi dan Manajemen*, 10(1), 39-47. <https://doi.org/10.32833/majem.v10i1.152>
- BATAN, L. S. P. (LSP). (2020). Pedoman Mutu. 251.
- Elfriede, D. P., Kusumaningrum, H. D., & Lioe, H. N. (2019). Kajian Persyaratan Teknis Laboratorium Pengujian Di Industri Susu Terhadap Produk Infant Formula Sesuai Iso 17025: 2017. *Jurnal Standardisasi*, 20(3), 219. <https://doi.org/10.31153/js.v20i3.725>

- Gunawan, K. S., & Rahardjo, J. (2022). Perancangan Dokumen SNI ISO 17025: 2017 untuk Laboratorium Beton dan Konstruksi di Universitas Kristen Petra. *Jurnal Titra*, 10(2).
- Triharto, M., Fadila, M., Pramukti, S. R., & Oktari, Z. (2022). Penilaian Efektivitas Penerapan Sistem Manajemen Kompetensi Laboratorium Uji dan Kalibrasi Sesuai ISO/IEC 17025: 2017. *Reaktor: Buletin Pengelolaan Reaktor Nuklir*, 19(2), 26-33.
- Kementerian Pendayagunaan Aparatur Negara dan Reformasi Birokrasi. (2015). Peraturan Menteri Pendayagunaan Aparatur Negara dan Reformasi Birokrasi Nomor 16 Tahun 2015 tentang Road Map Reformasi Birokrasi Kementerian Pendayagunaan Aparatur Negara Dan Reformasi Birokrasi 2015-2019.
- Oktari, Zaidi., Masripah, Septi Rizkine Pramukti, & Mustika Fadila (2023). Peningkatan Mutu Laboratorium Uji dan Kalibrasi LBBN Melalui Uji Profisiensi / Uji Banding Sesuai Persyaratan ISO/IEC 17025:2017. *Jurnal PENJAMINAN MUTU Volume 9 Nomor 1 2023*. ISSN : 2407-912.
- Putri, Z. T., Fahma, F., Sutopo, W., & Zakaria, R. (2019, April). A framework to measure readiness level of Laboratory for Implementing ISO/IEC 17025: a case study. In *IOP Conference Series: Materials Science and Engineering* (Vol. 495, No. 1, p. 012011). IOP Publishing.
<https://doi.org/10.1088/1757-899X/495/1/012011>
- Subekti, A. T. (2018). Analisis Kualitas Penerapan SNI ISO/IEC 17025:2008 Melalui Audit Internal di Laboratorium Pengujian UPTD Balai Pengujian dan Sertifikasi Mutu Barang (BPSMB) Disperindag Provinsi Jambi. *Teknik Industri Sekolah Tinggi Teknologi Nasional (STITEKNAS) Jambi*, 53(9), 1689–1699.
- Utami, S. S., & Suryawardani, B. (2018). ANALISIS TINGKAT KEPUASAN PELANGGAN MENGGUNAKAN FISHBONE DAN PARETO CHART (Studi Kasus pada Toyota Auto 2000 Cabang Cibiru Bandung Tahun 2017). *Jurnal Teknologi Informasi Dan Manajemen (JTIM) Edisi 1, 1*, 1–11. www.kompas.com,
- Wijaya, L. F. (2021). Sistem Reward dan Punishment sebagai Pemicu dalam Meningkatkan Kinerja Karyawan. *JIKEM: Jurnal Ilmu Komputer, Ekonomi Dan Manajemen*, 1(2), 1-11.
- Zamrudi, J., Kusumaningrum, H. D., & Nuraida, L. (2014). Analisis Pemenuhan Persyaratan Food Savety System Certification 22000 di Industri Kemasan Pangan. *Jurnal Mutu Pangan: Indonesian Journal of Food Quality*, 1(2), 124-131.
- Zapata-García, D., Llauradó, M., & Rauret, G. (2007). Experience of implementing ISO 17025 for the accreditation of a university testing laboratory. *Accreditation and Quality Assurance*, 12(6), 317–322.
<https://doi.org/10.1007/s00769-007-0274-5>