Gap Analysis in Implementation Of ISO/IEC 17025:2017 Accreditation Programme in Selected Microbiological Laboratory

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Abstract- *ISO/IEC Guide 17025 is a universal guideline that comprises benchmarks for product testing service laboratories. This instruction will assure the testing laboratory to carry out testing services consistently and reliably. Implementation and improvement of the quality management system is an objective of many companies. Having a quality management system is part of strategic business development. A company with good quality practices simply increases faith and interest from existing customers and also from potential customers. Quality is a comprehensive topic, and it indeed cannot be covered thoroughly within this project, therefore focused on three significant angles that could help the process of implementing quality systems become easier. Those are the requirements of ISO/IEC 17025:2017 standard, the construction of a quality manual, and also the company's readiness for accreditation. The main objectives of this study are to identify and analyze the gaps and also implement the ISO/IEC 17025:2017 quality management system in conformance with the standard. The key data was collected through questionnaires, interviews, observations and study of internal documents. The secondary data was collected from reliable sources of information, including guidebooks and standards linked to the study. As well as this study use gap analysis techniques compare to the existing situations with the expected conditions. It gives a quantitative approach to the research. According to the outcomes, the company was mostly compliant with the standard, and there was a need for slight modifications or updates in the system to be fully conformed.*

Keywords: ISO/IEC 17025, Accreditation, Gap analysis, Readiness

I. INTRODUCTION

A quality system is a unified global system of quality standards universally agreed to be a global document to guarantee the quality of management and also it is a system of checking on what their works conform to procedures and rules that have been written and adopted (Sadikoglu and Temur, 2012).

International Organization for Standardization (ISO) is a non-governmental, international, independent organization and it has 162 national standard bodies' members and it was officially established in 1947. Today ISO has 785 technical committees and subcommittees for standard development, Including, ISO 9001 (Quality Management System), ISO 14001 (Environment and Management System), OHSAS 18001 (Occupational Health and Safety Management System), ISO 22000 (Food Safety Management System), ISO/IEC 17025 (General Requirements for the Competence of Testing and Calibration Laboratories) Among them, ISO/IEC 17025 is a family of international standards which addresses the general requirement for the competence and calibration laboratories and assists laboratories to produce precise and accurate tests results and calibration data.

Laboratory accreditation can help laboratories to produce reliable results through implementing the framework of a documented quality system (Beckett and Slay, 2007). Accreditation of the testing and calibration laboratories as per ISO/IEC 17025 standard is the only means to guarantee the reliability of testing laboratories, laboratory management system as per international standard is that the way to give assurance to their customers and also comprising exporters and the business community by providing quality testing and calibrating activities (Okezue, et al, 2020). Through a laboratory management system, a customer understands that laboratories are showing technical competency for the issuance of authentic, reliable and precise results. Laboratory accreditation enhances the trust and confidence of the customer and they offer the best analytical services to its customers (Memon *et al*., 2020).

After the implementation of the revised international standard, the laboratory will be able to demonstrate that it works with a new framework using modern technology and information technology techniques. Furthermore, the format of this standard has been significantly changed to be more in line with modern ISO formatting guidelines. The standard takes into consideration the newest version of the ISO 9001 standard, to help the implementation of ISO/IEC 17025 in laboratories that have already met the requirements of ISO 9001 (Grochau and Caten, 2012)

Laboratories practice ISO/IEC 17025 to implement a high-quality system expected at improving their ability to consistently produce valid results and it's also the premise for accreditation from an accreditation body (Honsa and Mclntye, 2003). Since quality is about competence, accreditation is the official recognition which is an indication of competence. A prerequisite for a laboratory to become accredited is to own a documented quality management system and also the typical contents of the standard operational manuals (SOPs) follow the outline of the ISO/IEC 17025 standard. National accreditation bodies are liable for accrediting laboratories to ISO/IEC 17025. Laboratories can use either an area organization or another universally recognized body in cases where the local organization ‘’has either no international recognition or where it lacks recognition in parts of the planet appropriate to the laboratory’s operations’’ Laboratories usually select a variety of common and sometimes used methodologies that might readily advantage and demonstrate a comprehensive quality system that those methodologies run under.

The question on what were the key causes for implementing ISO 17025 solicited the following answer categories; improving the quality of the goods and services, to streamline procedures and simplify work processes, decreasing client complaints and getting access to more work contracts (Shaltout and Gad, 2019). Respondents acknowledged the fact that there is pressure to get ISO 17025 accreditation because it provides the access to more contracts as some holding organizations prefer using accredited laboratories but improving the quality of the products and services was the key cause stated by respondents. The conclusion from the responses was most of the reasons furnished are somehow interconnected. Better services would lead to fewer client complaints (Cebekhulu and Mugova, 2017).

Reduced client complaints, enhanced testing productivity, enhanced quality of services and increased efficiency of projects are the key benefits of the implementation of ISO 17025 (Wierzowiecka, 2013). The benefits of applying ISO 17025 stated by interviewees, survey respondents and what is normally found in literature was more or less the same (Zapata-García *et al*., 2007). The significance of each of those benefits varied from one organization to another. One organization might have product enhancement as their key benefit were another organization might have reduced client complaints as theirs. The possibility of achieving other benefits is an added incentive (Cebekhulu, 2012).

II. RESEARCH METHODOLOGY

This research was conducted using a quantitative method supported by qualitative data. The quantitative method in this study objectives to measure how far the laboratory readiness in applying ISO / IEC Guide 17025. Though the qualitative data method generating a broad picture of the readiness of the laboratory in implementing ISO / IEC Guide 17025 (Aqidawathi *et al.*, 2019)

A. Gap analysis

This study uses the gap analysis method (Gap Analysis) for assessing the readiness of microbiology laboratory in Silvermill Group of Companies to applying ISO / IEC 17025.

B. Data Collection

For the gap analysis process data collection was done by conducting an internal audit by distributing questionnaires and in-depth interviews to main informants (General Manager, Assistant General Manager, Quality Assurance Manager, Quality Assurance Executive,) at the microbiology laboratory of Silvermill Groups of Companies. Figure 1 shows the framework questionnaires,

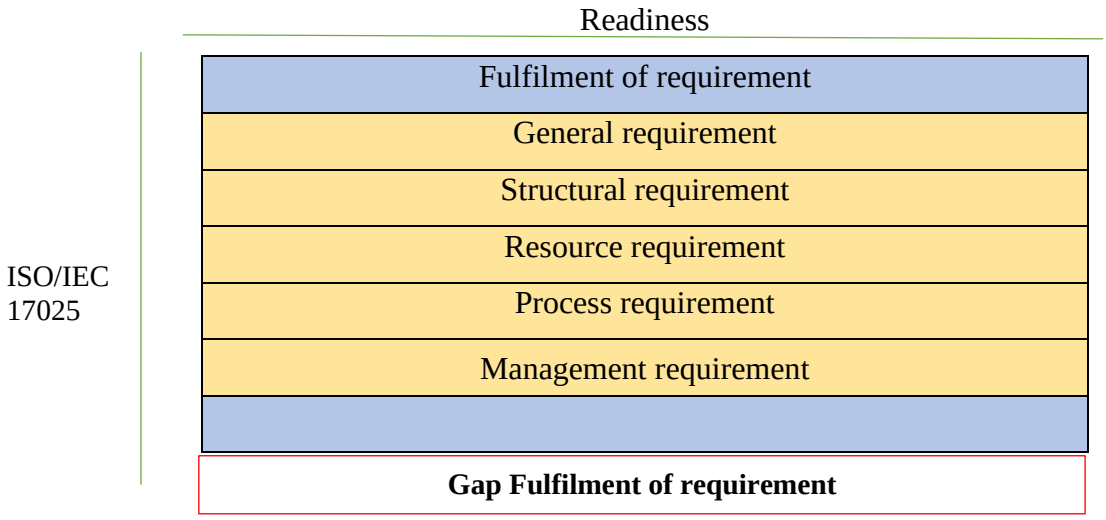

Figure 01: Framework questionnaires

Table 01: Scoring Benchmarks

Score	Criteria
0	The requirement is implemented consistently and having the essential document and resource
1	The requirement is implemented inconsistently and having the essential document and resource
2	The requirement is not implemented, but having the essential document and resource
3	The requirement is implemented, but don't have the all essential document and resource
4	Comprehend with the requirement, but not implementing the requirement and don't have the essential document and resource
5	Don't comprehend the requirement, not implementing the requirement and don't have the essential document and resource

The primary step of this tool is developing a gap analysis checklist that purposes to recognize gaps among written requirements, resources, and the actual process carried out (Putri *et al.*, 2019). This checklist was made based on the requirements of ISO17025. To facilitate the analysis of each clause, scoring for assessment was given in Table 01

C. Questionnaire Design

The designing of the questionnaire was carried out by determining the variables that are influencing the readiness of the microbiology laboratory. Determining the variables was done by deriving the clause contained in ISO / IEC 17025 and identifying the documents and resources required in ISO / IEC 17025. Furthermore, the level of fulfillment was measured.

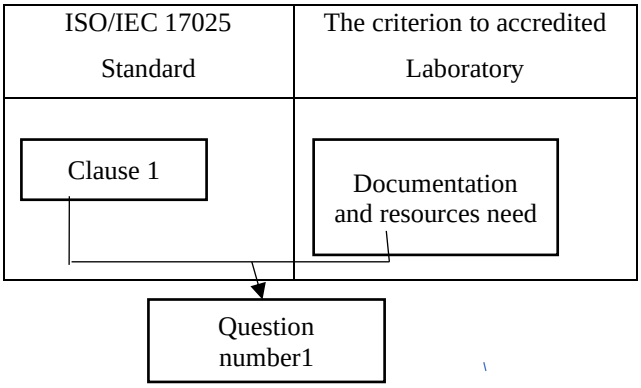

Figure 02: Questionnaire Design

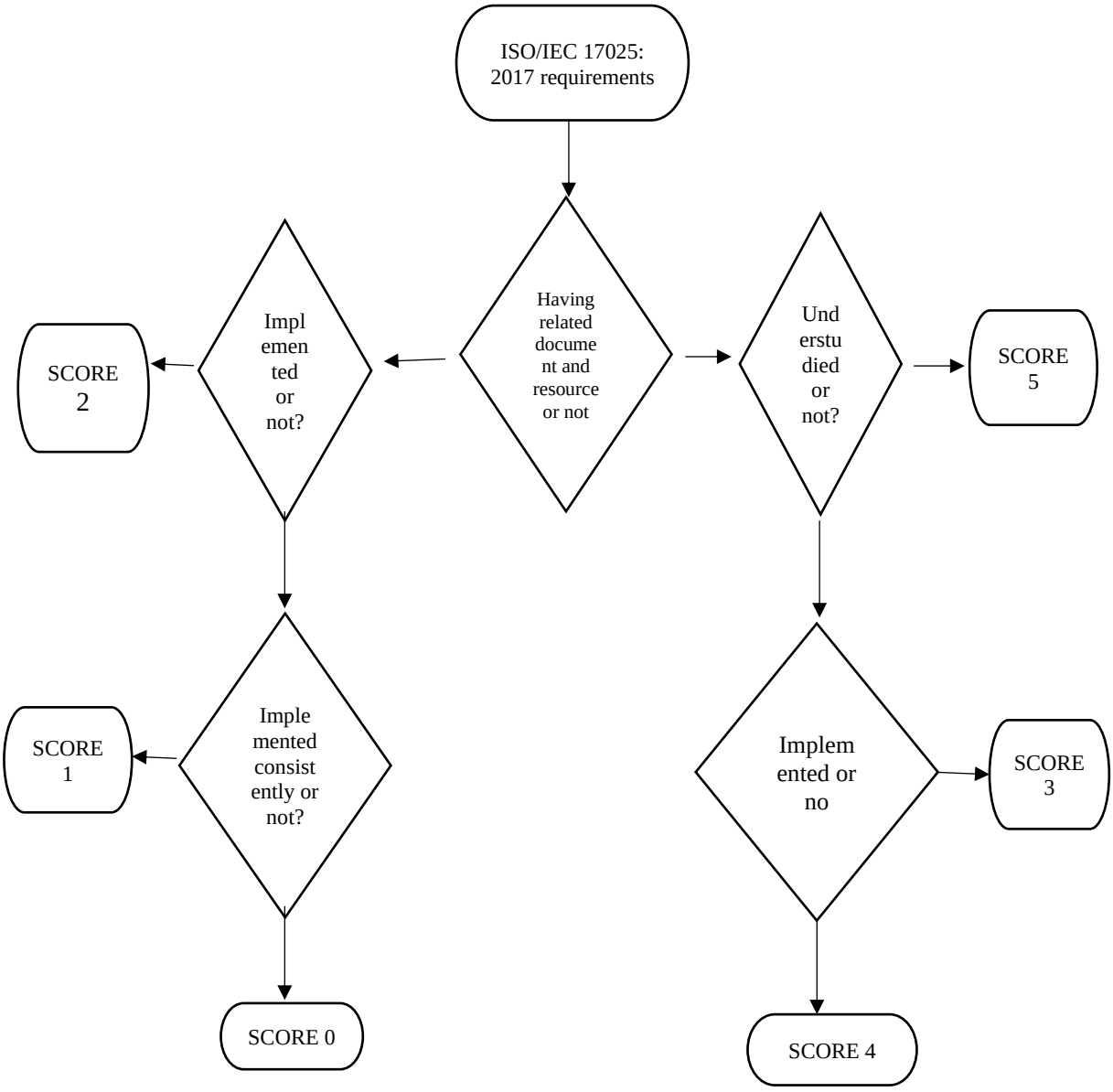

Figure 03: Flow Chart for scoring

Implementation process

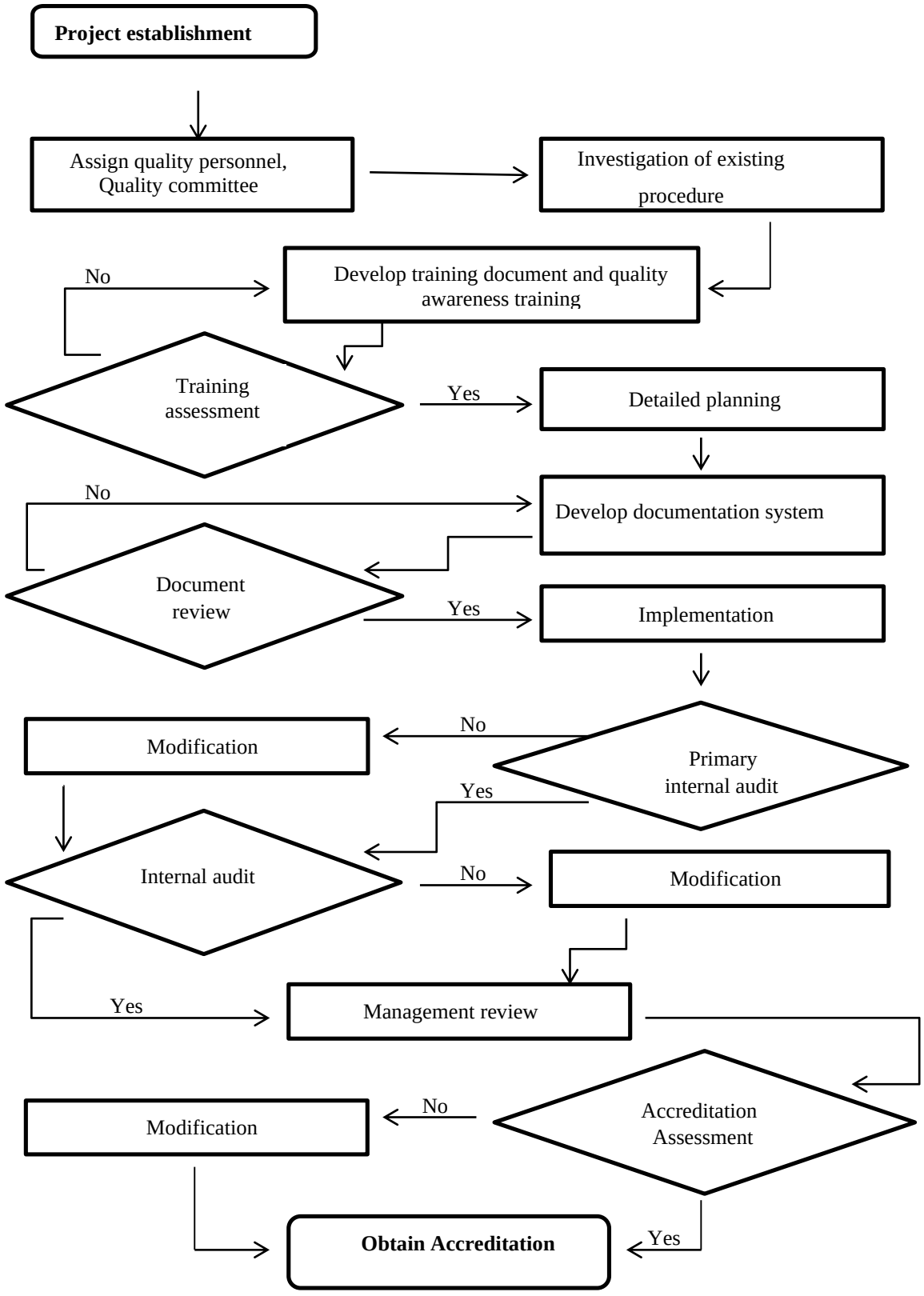

Figure 04: Flow chart for the Implementation process

III. RESULTS AND DISCUSSION

Results of the first audit

The score value was gained from the outcomes of the questionnaire assessment. The maximum score is the maximum gap value where if it reaches that value, it means that the laboratory has not comprehended yet and the laboratory system does not potentially apply ISO / IEC 17025 (Khodabocus and Balgobin, 2011). 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. The first internal audit was conducted to measure the existing situation of the laboratory. Table 2 shows the results of the first internal audit, Question code 1-9 for general requirements comprising of impartiality and confidentiality. In this laboratory, a total score of 0 was created. This shows that a gap value of 0% was created because the laboratory system fulfilled the document, resource requirements and the level of accomplishment of 100% was created because the laboratory has been understood and implementing impartiality and also confidentiality requirements as well as already documented the requirements.

Table 02: Results of first internal audit

Requirement	Question Code	Max Score	Total Score	Gap%	Compliance Level%
General requirement	1-9	45	0	0%	100%
Structural requirement	10-16	35	15	43%	57%
Resource requirement	17-47	155	83	37%	63%
Process requirement	48-114	335	112	33%	67%
Management requirement	115-137	115	71	62%	38%

Question code 10-16 for structural requirements. In this laboratory, a total score of 15 was created. This shows that a gap value of 43% was created because the laboratory does not have a technical manager accountable for the testing process and also there was no documented organizational structure. Then a fulfillment percentage of 57% was created because the laboratory has already defined the laboratory as a legal entity and it was legally responsible for its laboratory activities and also, they identified and documented the overall responsibility of the laboratory.

Question code 17-47 for resource requirements. In this laboratory, a total score of 83 was created. This displays that 37% is created because the laboratory doesn't have complete documentation and resources even though has been understood the requirements. The reasons for the gaps were, Laboratory did not possess all personnel, facilities, equipment, systems and support services. As well as they had not documented monitoring records of facilities and environmental conditions. The duties and responsibilities of laboratory employees are properly communicated, the laboratory was established and maintained metrological traceability of its measurement results, and also it has ensured measurement results are traceable to the international system of the unit. Therefore, with these requirements, the laboratory creates 63% compliance.

Question code 48-114 for process requirements. In this laboratory, a total score of 112 was created. This displays that the gap value is 33%. The main reason for this gap value is the laboratory does not have complete documentation, as well as laboratory does not keep all methods, procedures and supporting documentation. There are, instructions, standards, manuals, and reference data related to the laboratory activities, laboratory have implemented a proper sampling plan and methods but it hasn't documented well, the laboratory doesn't have a written procedure for transportation, receiving, handling, protection, storage, retention and calibration or disposal item. Most of the requirements were implemented but without any proper documentation. Hence the fulfillment rate was 67% achieved because the laboratory has understood the requirements of ISO / IEC 17025 and carried out some of these requirements. Therefore, the laboratory has a procedure for the review of the request, tenders, and contracts, laboratory use appropriate test methods, laboratory properly validates test methods and also retain a document of validation. The laboratory has documented procedures to

receive, evaluate and make decisions on complaints.

Question code 115-137 for management requirements. In this lab, the total score was 71 created. This displays that the resulting gap value is 62% and the fulfillment percentage is 38% because the laboratory staff understood the requirements of the management system but have not compiled yet the document recording procedure. Figure 5 shows the readiness level of implementing ISO 17025,

The general requirements were fully completed there were no gaps and also have proper documentation.

The structural requirement, before implementation the gap value was 43% but after the implementation process, the gap value decreases to 26%. The compliance level increases 57% to 74%. Because the laboratory was documented the organizational structure of the laboratory and the management of the laboratory were identified and documented overall

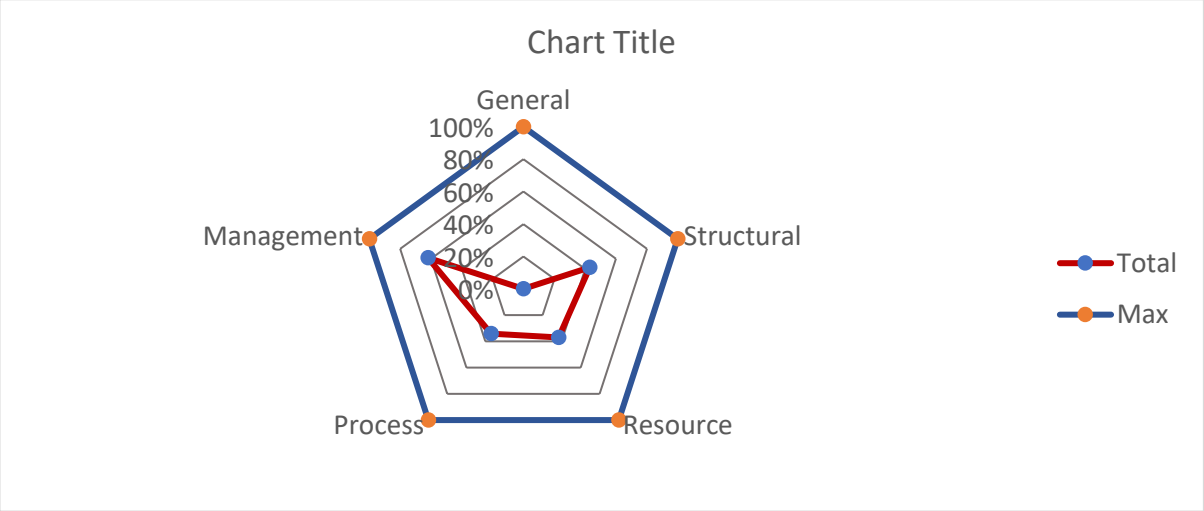

Figure 05: Radar diagram readiness Level of implementing ISO17025

Based on the first internal audit results laboratory have more gaps to fulfill to achieve ISO 17025:2017. The main reason did not have proper documentation. Most of the requirements were already comprehended and implemented but the problem is they were not documented well.

Results of the second audit

After the implementation process, the quality committee was conducted a second internal audit to measure the readiness of the laboratory to achieve ISO 17025:2017. Table 3 shows the results of the second internal audit,

responsibility of the laboratory. But there was a remaining 26% of gaps to fill. The reason was some of the documents were not documented yet. In the resource requirement before implementation, the gap value was 37% but after the implementation process, the gap value decreases to 16%. The compliance level increase to 63%-84%. Because the laboratory fulfills the necessary equipment, personnel, systems, and support services. Before the implementation process, the laboratory there is a shortage of laboratory equipment. Such as a Biosafety cabinet, double door autoclave, digital manometer, automatic pipette washer, loop sterilizer,

Table 03: Results of Second internal audit

Requirement	Question Code	Max Score	Total Score	Gap%	Compliance Level%
General requirement	1-9	45	0	0	100%
Structural requirement	10-16	35	9	26%	74%
Resource requirement	17-47	155	26	16%	84%
Process requirement	48-114	335	30	9%	91%
Management requirement	115-137	115	15	13%	87%

glassware washer, conductivity meter and vortex mixture, etc. the environmental monitoring records are properly documented after the implementation process. Hence increase in the compliance level but there was still a 16% gap is remaining because of some documentation problems of facilities and environmental procedures.

In the process requirement, before implementation, the gap value was 33% but after the implementation process, the gap value has decreased to 9%. The reason for that was the laboratory was kept all methods, procedures and supporting documentation relevant to the laboratory activities. As well as they were prepared a quality manual and standard operating procedures for all equipment and laboratory tests. Because of that, the compliance level was increased to 67-91%.

In the management requirement, the first audit gap value was 38% but after the implementation process, it was decreased to 13%. The compliance level was increased from 62% to 87%.

Based on the above results most of the requirements of ISO 17025: 2017 standard were reached a 75 %compliance level because of that the laboratory is suitable for applying to get ISO 17025:2017 to the laboratory. This analysis was done by the quality department internal audit team but needs to confirm exactly by Industrial Technology Institute (ITI) audit results to verify the company has succeeded in meeting these standard's requirements

As the key objective of this project was to support the company to implement the ISO/IEC 17025:2017 into a quality management system. The company reached a better point of view of its stance in quality management. Now it has a clear framework of steps to walk up the accreditation process. As well as the readiness analysis supports the top management and also staff to comprehend the requirements from the standard. The establishment of a quality manual achieves the main requirement from the manager. A set of Standard Operation procedures (SOP) works as guidance documents for staff to follow. The learning of standard requirement clauses can also serve as a tool and reference for staff in case they want additional explanation or guidelines from the requirements. At the end of the project, the top management team and staff have a clear sight about what are the requirements of the quality management system and how to obtain accreditation. The company has reached quite a satisfactory level of implementing the standard, but the research, also proves that there is still have for enhancement. A few of the greatest significant parts that the company misses from the quality management system are the work and records of annual reviews and audits, management reviews, and staff training. Even though it is adequate to prove that the company has started those activities from the date the accreditation application being sent, earlier records during the whole business time will increase the image of the company in compliant standard and quality. Besides, the documentation system might want preparation and rearrangement. Because of the nature of business, a large quantity of documents stored in the internal electronic documentation system is in not proper

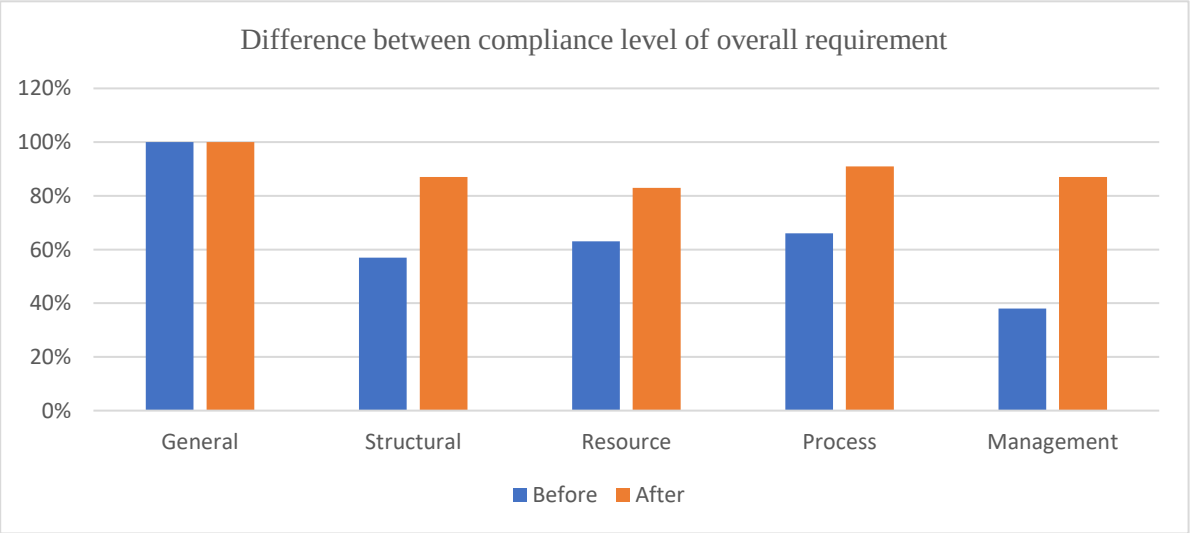

Figure 06: Difference between compliance level of overall requirements in first internal audit and second internal audit results

state. Those can still be improved with the implementation of other document management systems. This restriction can seriously affect the audit result as well as the accreditation outcome. But, one of the simple methods to fix the problem is to attach an appendix to each document and the other method is manually note down what has been changed as proof of record. Each single quality management system needs a different set of documentation, organization and also work procedures.

IV. CONCLUSION

Quality management is always a challenging topic in terms of planning, implementing and evaluating. The perception of quality differs between each individual is one of the reasons for challenges. Each individual in an organization will have a diverse method and action towards the quality objective. Therefore, it is generally tough to have a compromise between all staff. Awareness of variances in quality perception will support the management team to have more effective concentration and effort on quality training and quality management system. The readiness analysis of ISO 17025.2017 in the case company was broad and covered the processes. Some of the teams were resistant to the transformation during the readiness analysis, which might have affected the outcomes. If the person would have been more committed to the alteration from the beginning, the readiness analysis might have been more precise and the ultimate outcomes in the internal audit would have been better. Implements the gaps of requirements to achieve ISO 17025:2017 is the main goal of the study. Overall, the project reached its goals in the restricted schedule and the theory covered each important area.

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