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A CRITICAL ANALYSIS OF ISO/IEC 17025 PRACTICES AT UNIKL MITEC LABORATORY TOWARDS IMPROVEMENT OPPORTUNITIES

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ABSTRACT

This research critically examines UniKL MITEC laboratories' compliance with ISO/IEC 17025:2017 accreditation standards. The laboratories have not achieved full accreditation for an extended period, necessitating a comprehensive assessment of their practices. A qualitative and quantitative approach involving interviews, observations, and gap analysis was employed. The self-assessment checklist, designed by the researcher, measured the laboratory's readiness for accreditation certification. Descriptive statistics revealed that the laboratory's compliance with clause 8, focusing on management requirements, is currently at a modest 40%. This signifies a significant gap between their current practices and the minimum compliance level. The study further assessed specific clauses within clause 8, ranging from 8.1 to 8.9, revealing that the least compliance observed was at 37.5%, while the highest was only 42.5%. A Pareto analysis highlighted that clause 8.2 and 8.5 are the major contributors to non-compliance, accounting for over 30% of the cumulative gap percentage. Notably, clause 8.2 exhibited the most significant gap, with 59 individual gap levels identified. The research delves into a detailed cause-and-effect analysis, investigating the root causes of non-compliance within the laboratory's current practices concerning clause 8. Proposed improvements align with management concepts and ISO/IEC 17025 standards. In essence, this research serves as a valuable contribution to enhancing laboratory practices, ensuring alignment with international standards, and identifying opportunities for improvement in management requirements.

1.0   Introduction

The most recent version of this standard, ISO/IEC 17025:2017, has been revised. The standard was established due to the combined efforts of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO). According to the Ministry of International Trade and Industry, Malaysia has 54 accredited public Institutes of Higher Learning laboratories and 7 private Institutes of Higher Learning laboratories [1]. In total, there are 840 active accredited laboratories, both government and private, while 253 laboratories have been withdrawn under SAMM. In the education sector, other universities have fully complied, and some have also started the practice of achieving the accreditation system under SAMM. This is because UniKL needs a laboratory that is recognized as competent in testing activities, quality management and reliable and credible results.

Based on a study of the implementation of ISO/IEC 17025 accreditation in other countries, the Korean certification body said that the four-year variance index score was significantly different between labs with and without accreditation [2]. Their results were like those of other studies that found a link between lab standards and accurate test results. [3]. In other studies, researchers investigated food testing labs and found similar results [4]. Within a few years of getting hospital laboratory accreditation, four measures of success in Nairobi, Kenya, showed improvements [5]. Another study included 26 accredited labs in India, 25 central and
110 regionals. The percentage of accredited labs is 19%, indicating that many are still unaccredited. The ministry or interested parties may question test data from unaccredited labs so that they may apply for accreditation [6].

This research aims to thoroughly examine UniKL MITEC laboratory's adherence to ISO/IEC 17025:2017 standards. It will identify existing problems in the laboratory, assess how well the laboratory complies with these standards, and propose recommendations for practices. According to the laboratory, organizations are struggling to comply with ISO/IEC 17025:2017. The laboratory had long planned to be certified in accreditation but has not yet reached a level that meets compliance standards. In the latest revision of ISO/IEC 17025, not all laboratory personnel fully understand these new standards and it is difficult to apply the standard.

An analysis plays a crucial role in formulating an organization's implementation strategy and enhancing its effectiveness in various organizational aspects [7]. The critical component of doing a gap analysis is figuring out the specific actions that need to be taken to close the gap [8]. The ISO standard establishes an extensive framework of criteria and guidelines that educational institutions need to adhere to for certification purposes. Performing a gap analysis can be a valuable tool in clarifying improvement objectives, particularly when those objectives lack specificity. Accreditation guarantees a higher probability that laboratories' test results and analysis reports are accurate. After getting ISO/IEC 17025 accreditation, the study showed some signs of better compliance from a lab in a less-resourced setting. As a result, the accreditation procedure improved the laboratory's work [9].

2.0   Overview of the Study

Problem Statement	Breakdown of Problem	Research Objective	Research Question	Research Methodology	Result
The laboratory had long planned to be certified in ISO17025 Laboratory Accreditation Standard. Currently, it is not clear to what extent the current system and practices in managing UniKL labs are complying with the standard. The current practices are not standardized and vary from one lab to the other, following individual initiatives from the lab owner.	RP1: Problem on laboratory's practices and procedures	RO1: To conduct a review of the current practices in laboratory	RQ1: What is current practice used to ensure preventing or addressing problems in laboratories?	MT1: Interviews and observation.	RS1: Understood of the laboratory's practices and potential areas for improvement
	RP2: Laboratory compliance performance has not been evaluated based on current practice	RO2: To evaluate the current practices and performance in UniKL MITEC Laboratory against ISO/IEC 17025:2017	RQ2: What is the value of compliance's level and the gap's level in the laboratory with the standard ISO/IEC 17025:2017 in its current practice?	MT2: Evaluate using Self-Assessment Checklist Standard. The Gap Analysis Method and find root causes.	RS2: Identified any gaps or areas of non-compliance between the organization's current practices and the requirements outlined in the standard
	RP3: Lack of ensuring that the laboratory will facilitate future improvement	RO3: To propose guideline towards an effective practice of ISO/IEC 17025:2017 in UniKL MITEC Laboratory	RQ3: What are the benefits of implementing effective practices in UniKL MITEC laboratory?	MT3: Recommend for improvement opportunities.	RS3: Laboratory performance is well optimized by following best practices

Table 1: Summary of Problem Statement, Breakdown of Problem, Research Question, Research Methodology and Result.

3.0   Research Methodology

This research was conducted using a quantitative method supported by qualitative data. The qualitative approach was chosen because it matches the study's goals and needs, making information easier to organize.
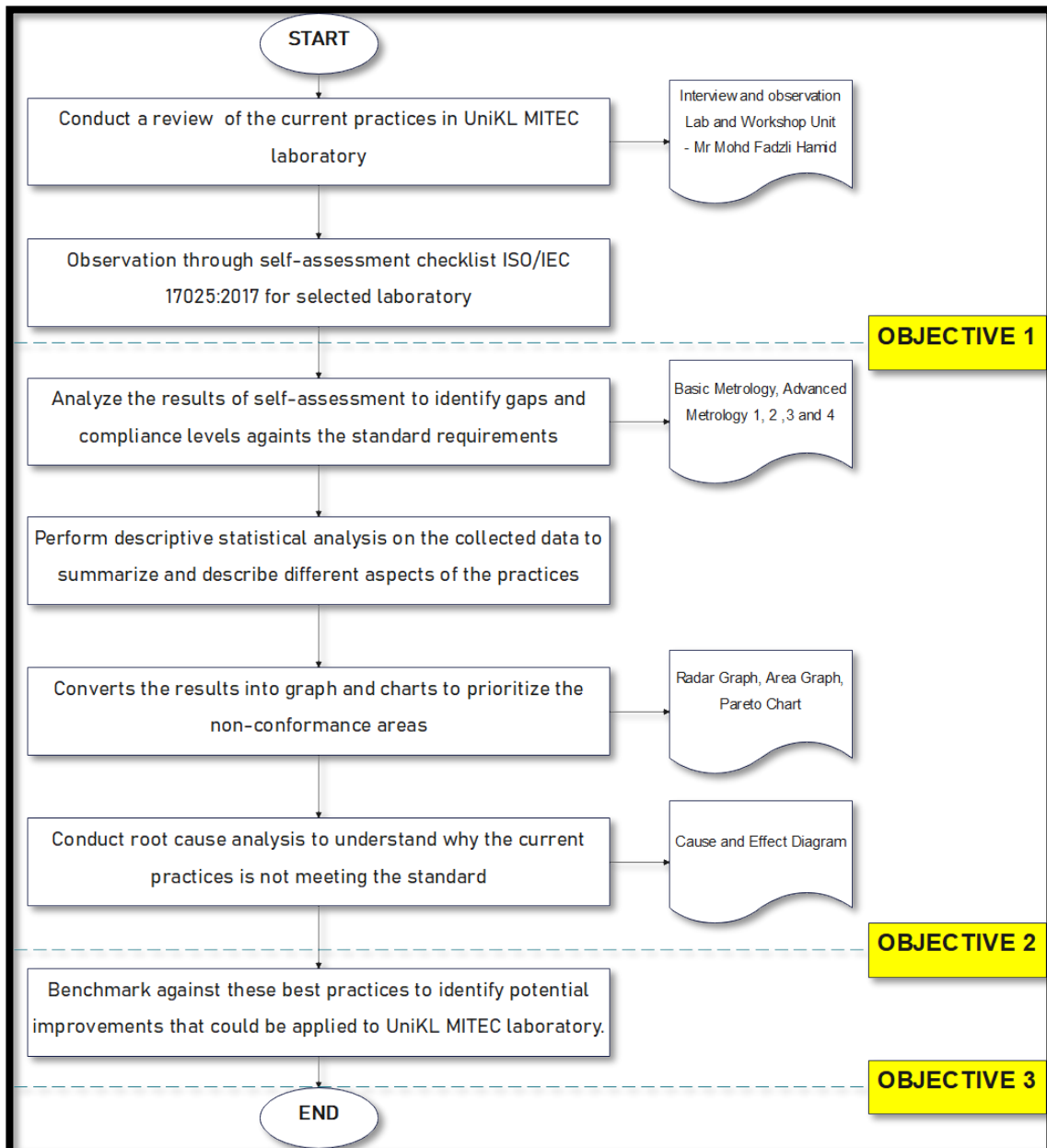

Figure 1: Research Methodology

In order to obtain the necessary study results, the researcher plans to conduct interviews and observation sessions with Mr. Mohd Fadzli bin Hamid and a technician from the selected laboratories. The quantitative method in this study objectives to measure how far the laboratory readiness is in applying ISO / IEC 17025:2017. Though the qualitative data method generates a broad picture of the readiness of the laboratory in implementing ISO / IEC 17025 [12]

3.1 Research Framework

The framework outlines a methodical process for assessing laboratory readiness, starting with the creation of a questionnaire focused on various requirement. Respondents, including laboratory personnel and managers, provide data that is analyzed and depicted using tools like Radar, Area and Pareto charts. This analysis leads to findings that highlight the laboratory preparedness and inform subsequent recommendations for improvement
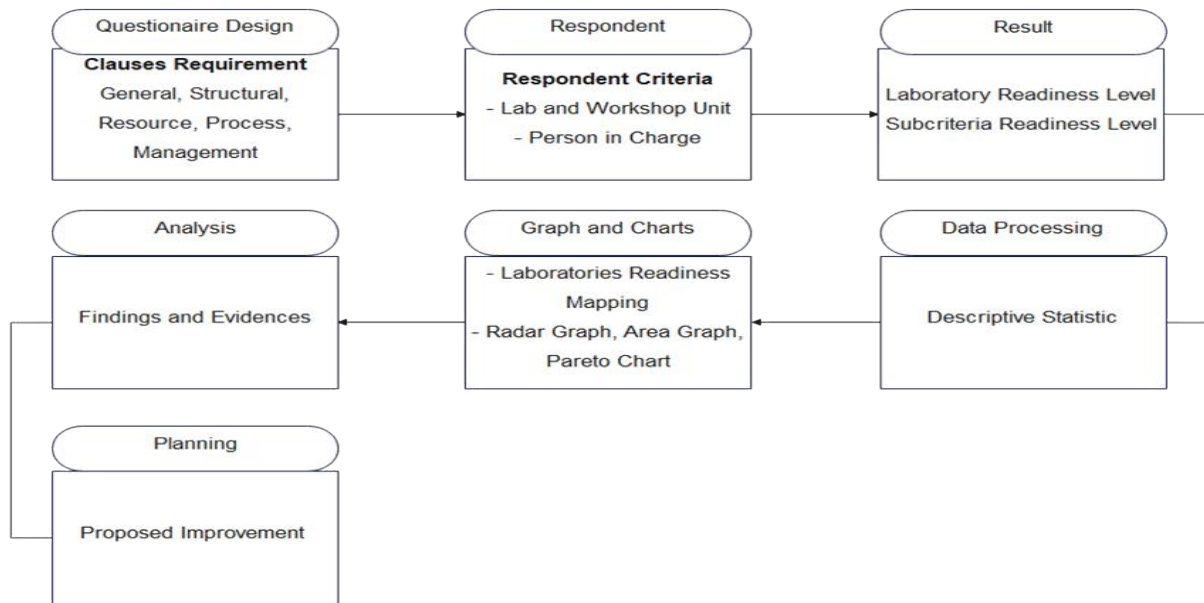

Figure 1: Research Framework

3.2 Data Collection

The gap analysis process, data collection is done by conducting an assessment checklist by distributing questionnaires and in-depth interviews to key informants. Key-informant were selected based on their knowledge and involvement in the preparation process for implementing ISO / IEC17025. Figure 3.2 shows the framework questionnaires [10]:
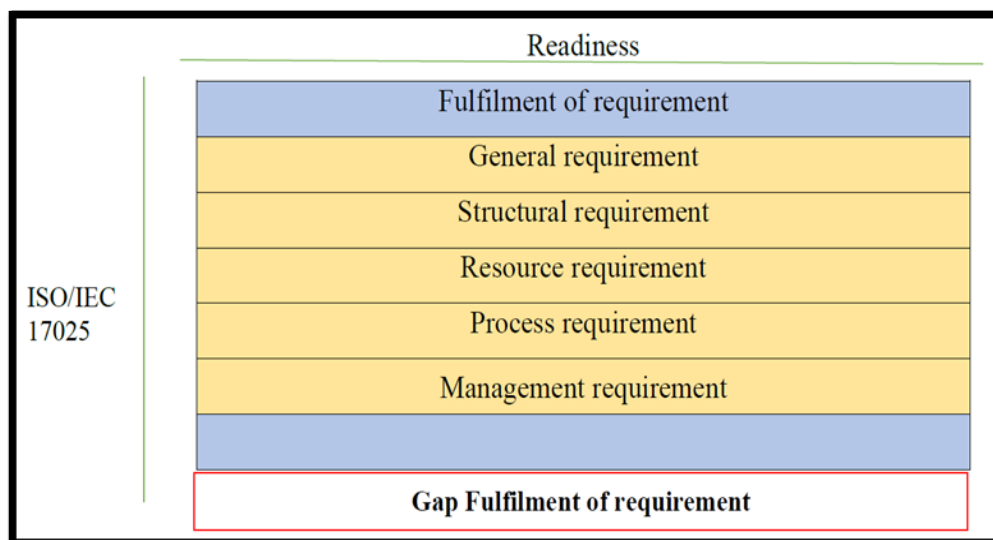

Figure 2: Readiness of ISO/IEC 17025:2017

3.3 Question Design

This section outlines how the questionnaire for assessing a laboratory's readiness to implement ISO/IEC 17025 was designed. The process involved identifying the key factors that impact readiness. Determining the requirements is outlined in ISO / IEC 17025 clause and identifying the documents required in the standard. Furthermore, the level of fulfilment is measured. Figure 3.4 below is the framework for how to design the questionnaire [10].
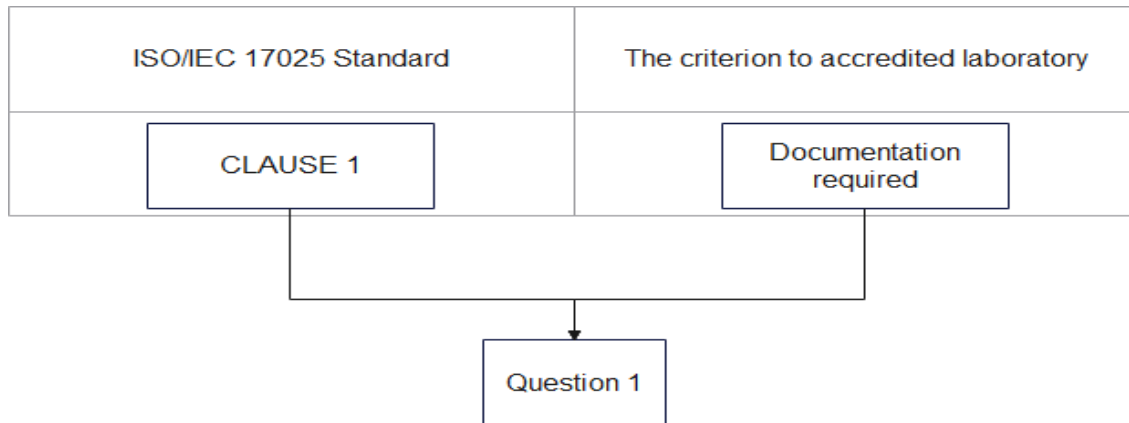

Figure 3: Questionnaire Design

3.4 Scoring Criteria

The level of laboratory readiness in implementing ISO/IEC 17025 is done by measuring the level of compliance with the requirements contained in ISO/IEC 17025. The measuring tool used is a questionnaire based on identifying clauses and documents required in ISO/IEC 17025. Then, the system scoring is carried out using the smallest scale that is better with a range of 0-5. The primary step of this tool is developing a gap analysis checklist that proposes recognising gaps among written requirements, resources, and the actual process carried out [10]. The detailed criteria for each score are described in Table 3.2 below [11]:

Score	Criteria
0	Do not comprehend the requirement, not implementing the requirement and do not have the essential document and resource
1	Comprehend the requirement but do not implement the requirement and do not have the essential document and resources.
2	The requirement is implemented but does not have the all-essential document and resources.
3	The requirement is not implemented, but having the essential document and resource.
4	The requirement is implemented inconsistently, and having the essential document and resource.
5	The requirement is implemented consistently, and having the essential document and resource.

Table 2: Scoring Criteria

3.5   Instrument Testing

The researcher carried out a assessment using the instrument to collect data from section of quality engineering laboratories in UniKL MITEC. The respondents chosen to fill out the questionnaire were the technician of each laboratory. The technician of the laboratory was chosen because they knew the best about their laboratory conditions including the management and technical aspects. The respondents were asked to check off the requirement which they had fulfilled [12]

No.	Respondent	Laboratory
1	Mr. Mohd Fadzli Hamid	Executive
2	Mr. Abdul Aziz Atan	Basic Metrology, Advanced Metrology 3
3	Madam Syuhada Shahul Hameed	Advanced Metrology 4
4	Mr. Haffizan Abbas	Advanced Metrology 1, Advanced Metrology 2

Table 3: Section of Quality Engineering Laboratory

4.0   Result and Discussion

4.1 Result for All Requirement with Executive Laboratory

The score value was gained from the outcomes of the questionnaire assessment. The maximum score is the maximum compliance value where if it reaches the values, it means that the laboratory has comprehended and the laboratory system ready to complete ISO/IEC 17025 [13]. Then the calculation of the score divided by a maximum score will show the compliance level value. From the results of the gap, it can be seen that the percentage does not meet the requirements of ISO/IEC 17025. The first meeting was conducted with Mr. Mohd Fadzli, the executive to measure the existing situation of the laboratory. Table 4.2 show the results of the first assessment
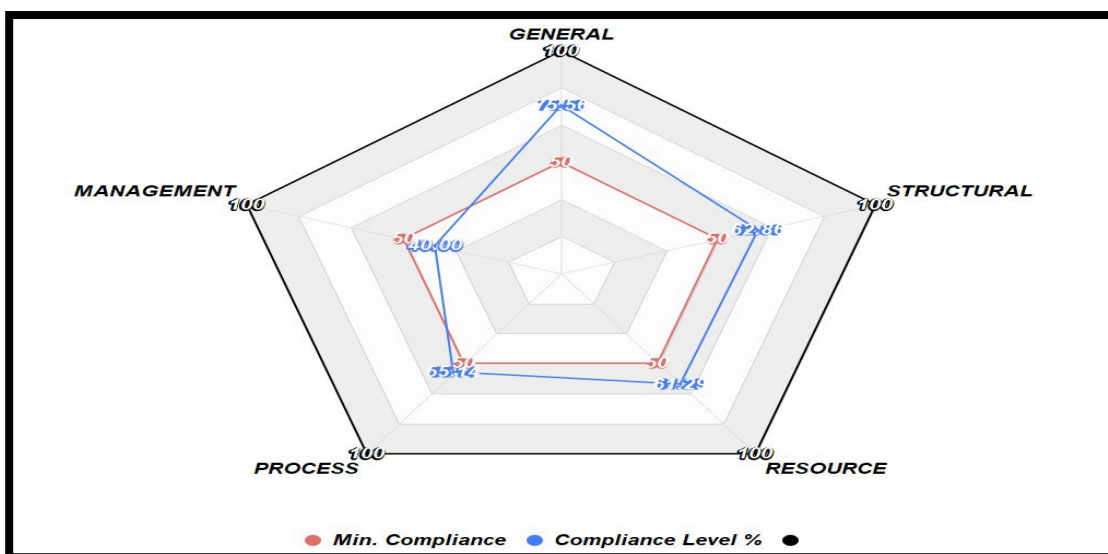

Figure 4: Radar Graph of Labortory Readiness Mapping

Clauses	Question Code	Max Score	Total Score	Compliance level (%)	Gap level (%)
Clause 4: General Requirement	1-9	45	34	75.56%	24.44%
Clause 5: Structural Requirement	10-16	35	22	62.86%	37.14%
Clause 6: Resource Requirement	17-47	155	95	61.29%	38.71%
Clause 7: Process Requirement	48- 117	350	193	55.14%	44.86%
Clause 8: Management Requirement	117 - 140	120	48	40.00%	60.00%

Table 4: Result of Laboratory Readiness

The research findings reveal significant gaps in compliance with ISO/IEC 17025:2017 requirements across various clauses. Notably, Clause 4 (General Requirement) demonstrates a strong start with a 75.56% compliance rate, indicating a solid foundation. However, a 24.44% gap still needs to be addressed to fully meet the standards.

In terms of structural requirements (Clause 5), the laboratory scores 62.86% in compliance, indicating commitment to infrastructure standards. Yet, a 37.14% gap implies room for improvement in laboratory facilities.

Resource management (Clause 6) reflects a similar compliance rate of 61.29%, emphasizing the importance of resource optimization. However, a 38.71% gap underscores the need for better resource allocation.

Process requirements (Clause 7) exhibit a 55.14% compliance rate, suggesting potential enhancements in lab workflows. The 44.86% compliance gap highlights the necessity for process optimization.

The most significant compliance gap appears in Clause 8 (Management Requirement) with a critical 60.00% gap and a compliance level of 40.00%, falling below the minimum requirement. This signals a substantial need for improvement, with an in-depth analysis of each laboratory's management practices to uncover factors contributing to non-compliance with this crucial clause in ISO/IEC 17025.

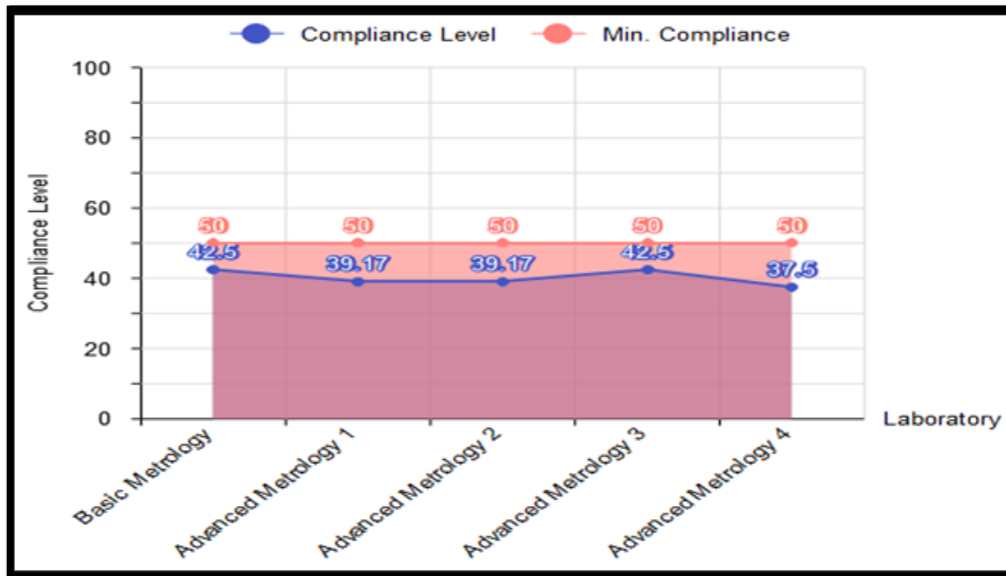**4.2   Result for Selected Laboratory Readiness Level in Clause 8 Management Requirement**

Figure 5: Area Graph of Compliance Level of each Laboratory

The graph presents the outcomes of a checklist assessment focusing on ISO/IEC 17025 Clause 8, addressing management requirements. The evaluation involved individuals responsible for laboratory management at UniKL MITEC. The results clearly indicate a significant shortfall in compliance with laboratory management requirements, falling well below the ISO/IEC 17025 standards.

The assessment covered labs in Basic Metrology, Advanced Metrology 1, Advanced Metrology 2, Advanced Metrology 3, and Advanced Metrology 4, considering questions aligned with clauses 8.1 to 8.9. Both the researcher and the respondents reviewed this self-asessment checklist evaluation.

The overall compliance level across these labs is notably below the minimum requirement of 50%. Among them, Advanced Metrology 4 shows the lowest compliance rate, standing at just 37.5%. Conversely, Basic Metrology and Advanced Metrology 3 exhibit the highest compliance, each at 42.5%. These results underscore the need for significant improvement, particularly in Advanced Metrology 4, which requires an additional 12.5% adherence to meet the minimum compliance threshold.

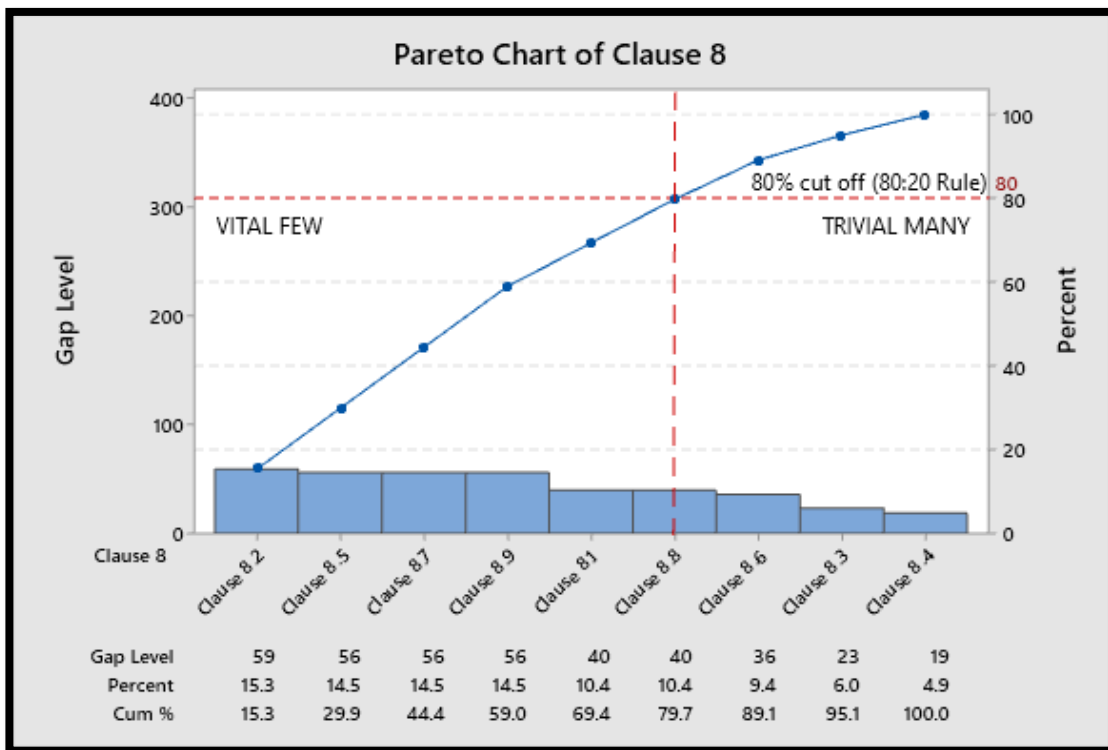### 4.3 Pareto Chart for Each Clauses Gap Level

Figure 6: Pareto Chart of Laboratories Readiness in Clause 8 Management Requirement

The chart indicates that the most significant gaps in compliance are associated with Clauses 8.2 and 8.5, which together account for approximately 30% of the total gap levels. Clause 8.2 has the highest individual gap level at 59, and Clause 8.5 also has a gap level of 56.

Conversely, Clauses 8.3 and 8.4 have the smallest gap levels, contributing the least to the overall gap levels at 23 and 19 respectively. These figures suggest that these areas are closer to meeting the standard or requirements being assessed.

All clauses showing gap levels that contribute to a cumulative total of 100%, it's clear that none of the clauses reach the 50% minimum compliance level required. In summary, this Pareto Chart would suggest focusing improvement efforts on Clauses 8.2 and 8.5 as they are the largest contributors to the gap. By prioritizing efforts on these clauses, it could lead to significant improvements in the overall compliance level.

4.4   Cause and Effect Diagram of Management Requirement

This research examines a detailed cause and effect diagram analyzing non-compliance issues in laboratory management requirement. The categorizing these issues into the Manpower, Materials and Methods we aim to uncover the root causes. These findings can guide proposed improvements in the research process, ultimately improving the quality and credibility of research.
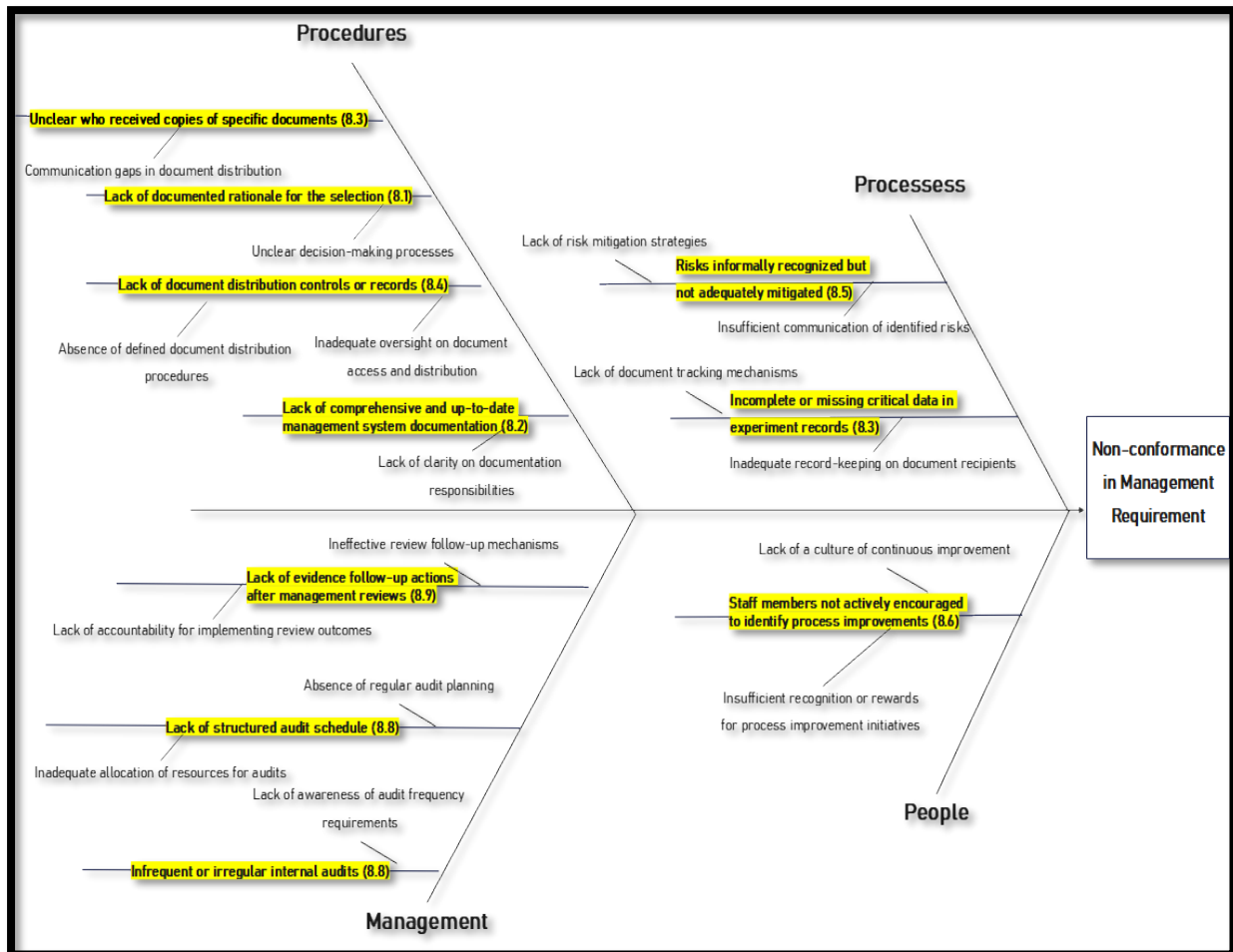

Figure 7: Cause and Effect Diagram of Non-conformance point

The non-conformance points within ISO/IEC 17025:2017 Clause 8 (Management Requirements) highlight several key issues. In Clause 8.1, the chosen options lacked clear documentation and rationale. Clause 8.2 revealed that the laboratory did not maintain comprehensive and up-to-date records of relevant documents, while Clause 8.3 identified a lack of document distribution controls, making it challenging to track document recipients. In Clause 8.4, some experiment records were incomplete or missing critical data. Clause 8.5 exposed a deficiency in addressing recognized risks and opportunities, while Clause 8.6 indicated a lack of encouragement for staff to identify process and operational enhancements. Delays in initiating corrective actions were found in Clause 8.7. Additionally, Clause 8.8 showed that there was no structured audit schedule, leading to infrequent audits, and in Clause 8.9, insufficient evidence of follow-up actions based on management review findings resulted in unresolved operational issues within the laboratory.

5.0 Recommendation

Based on findings from data analysis, an initial framework model for management review flow chart has been developed. There have four main point which is management review meeting, review of documentation, report of management and new objectives for improvement. Based on information, below is the framework have been recommended in Figure
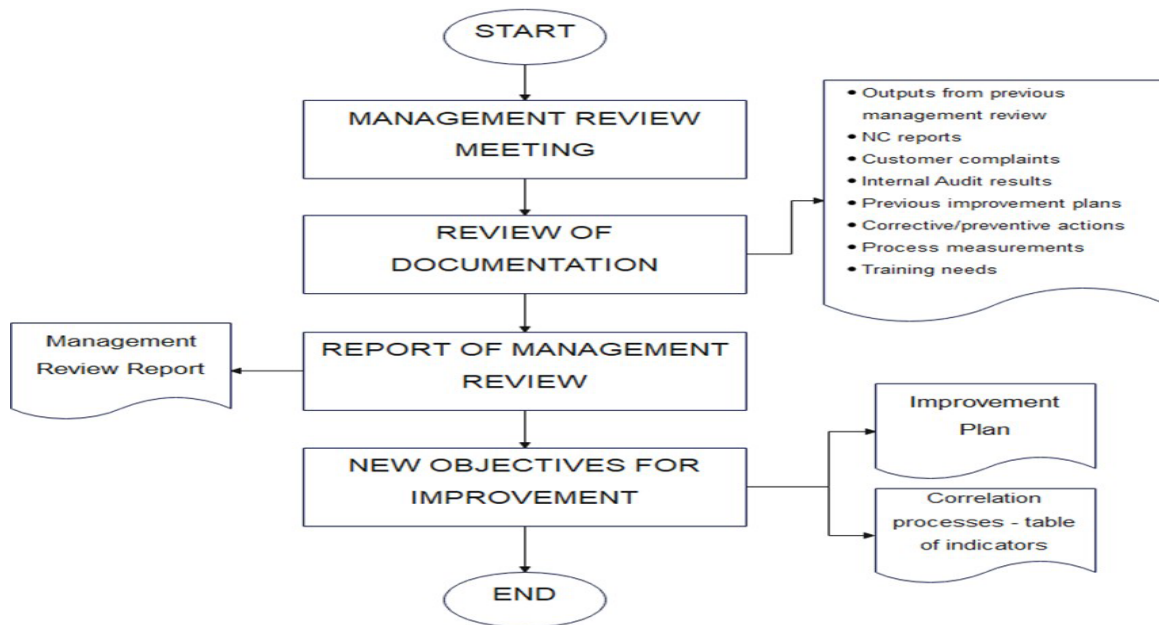

Figure 8: Framework Model for Management Review Flow Chart

The management review process involves several key steps and outputs. Initially, it includes meetings where agendas and contributions from different levels within the laboratory are considered, typically led by the top laboratory manager. These meetings should occur at least annually to review the entire management system.

Following the meetings, there is a review of documentation, ensuring completeness and accuracy of records and reports discussed. The outputs from previous management reviews play a crucial role, serving as a baseline for assessing progress, maintaining focus on goals, and identifying trends. Non-conformance reports, customer complaints, internal audit results, previous improvement plans, corrective/preventive actions, process measurements, and training needs are among the sources of data used for analysis during these reviews.

A report summarizing findings, discussions, and decisions is then generated. New objectives for improvement are identified, and an improvement plan is formulated, including specific actions, responsibilities, and timelines. Additionally, a table of indicators may be utilized to measure the effectiveness of these improvements against the new objectives. This comprehensive approach ensures continual improvement and adherence to ISO/IEC 17025:2017 standards.

6.0 Conclusion

The study assessed the readiness of Laboratory and Workshop Units in meeting the ISO/IEC 17025:2017 requirements, particularly focusing on Management Requirements (Clause 8). The research revealed that Clause 8 was significantly below compliance, with a 60% gap. To address this, the researcher analyzed sub-clauses in five metrology laboratories, highlighting areas of concern.

The analysis indicated that Clause 8.2 had the highest gap level (59), followed by Clauses 8.5, 8.7, and 8.9 (56), while Clause 8.1 and Clause 8.8 had a gap level of 40. On the positive side, Clause 8.6 (36), Clause 8.3 (23), and Clause 8.4 (19) had lower gap levels.

Additionally, a cause-and-effect diagram was created to identify root causes for non-conformance points. Recommendations for improvement in sub-clauses 8.1 to 8.9 were provided to enhance the Management Requirement (Clause 8) of ISO/IEC 17025 and guide the Lab and Workshop Unit at UniKL MITEC.

Furthermore, the paper introduced a framework for assessing university readiness to become a testing laboratory. This framework generated a radar chart mapping laboratory readiness levels and proposed improvements to facilitate accreditation. It highlighted the need to address gaps in ISO/IEC 17025 compliance before certification and emphasized the role of upper-level management commitment.

In conclusion, this research project successfully met its objectives and laid the groundwork for potential improvements in laboratory management systems, ultimately benefiting the academic institution.

7.0 Acknowledgement

8.0 References

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