

2. Literature Review

2.1 Overview of ISO 15189

ISO 15189 is an international standard developed by the International Organization for Standardization (ISO) specifically for medical laboratories [1]. It provides a framework for quality management systems (QMS) and specifies requirements for competence in laboratory practices. The standard aims to ensure that laboratories provide accurate, reliable, and timely test results to support patient care, diagnosis, and treatment [2].

2.2 Key Components of ISO 15189

The standard comprises two main sections: management requirements and technical requirements [1]. Management requirements focus on the QMS and include aspects such as document control, internal audits, management reviews, and corrective and preventive actions [3]. Technical requirements address laboratory competence, including personnel qualifications, equipment maintenance, method validation, quality control, and reporting of results [4].

2.3 Benefits and Challenges of Implementing ISO 15189

Implementing ISO 15189 can lead to several benefits, including improved laboratory performance, increased credibility, and enhanced patient safety [5]. It also promotes a culture of continuous improvement and fosters international recognition of laboratory competence [6]. However, challenges in implementing the standard may include resource constraints, lack of awareness, resistance to change, and the need for ongoing staff training and development [7].

2.4 Previous Case Studies on ISO 15189 Implementation in Educational Laboratories

A review of existing case studies on ISO 15189 implementation in educational laboratories reveals

mixed findings [8];[9]. Some studies have reported improvements in laboratory quality and competence following the adoption of the standard, while others have highlighted challenges related to resource allocation, staff training, and institutional support [10];[11]. These findings underscore the importance of context-specific factors in determining the success of ISO 15189 implementation in educational laboratories.

2.5 Factors Affecting the Implementation of ISO 15189 in Educational Laboratories

Several factors can influence the success of ISO 15189 implementation in educational laboratories, including institutional commitment, resource availability, staff training and development, and the alignment of the standard's requirements with the laboratory's specific needs and goals [4];[12]. Additionally, the effectiveness of the implementation process may be influenced by the laboratory's existing QMS and the extent to which laboratory personnel are engaged in and committed to the process [9].

2.6 Impact of ISO 15189 on Student Learning Experiences

While the primary focus of ISO 15189 is on improving laboratory quality and competence, its implementation in educational laboratories can also have implications for student learning experiences [8]. Improved laboratory quality can lead to more accurate and reliable results, which can enhance students' understanding of scientific concepts and principles [13]. Furthermore, exposure to a well-functioning QMS can help students develop essential professional competencies, such as critical thinking, problem-solving, and teamwork skills [14].

In conclusion, see researchers the literature on ISO 15189 implementation in educational

laboratories highlights the potential benefits and challenges associated with the adoption of the standard. Further research is needed to understand the specific factors that contribute to successful implementation in different contexts and to determine the extent to which ISO 15189 can positively impact the quality of educational laboratories and enhance student learning experiences.

Several case studies have shown improvements in laboratory quality, competence, and overall performance following ISO 15189 implementation, but there are also reports of obstacles and limitations. These challenges can vary depending on the institution, resource availability, existing quality management systems, and the level of staff engagement and commitment.

Moreover, the impact of ISO 15189 on student learning experiences remains an essential area of investigation. Improved laboratory quality and

competence can lead to a more comprehensive understanding of scientific concepts and principles for students. Additionally, exposure to a well-functioning QMS may help students develop essential professional competencies that can be useful in their future careers.

By conducting further research and case studies, institutions can gain a better understanding of the best practices for implementing ISO 15189 and how to overcome potential challenges. This knowledge can contribute to the ongoing improvement of educational laboratories, ultimately benefiting students, educators, and institutions as a whole. It is crucial to recognize the importance of context-specific factors in shaping the outcomes of ISO 15189 implementation and to adapt strategies and approaches accordingly to ensure the maximum benefit which is derived from the adoption of the standard, Figure (1) also shows the transitional stages of these releases.

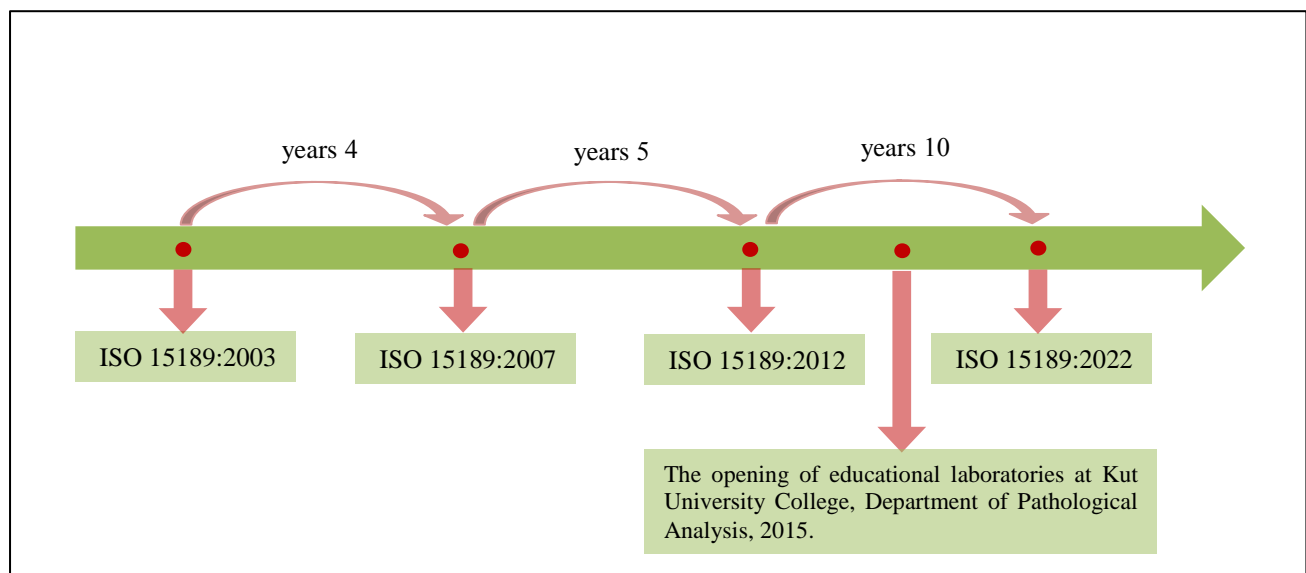


Figure (1): The Time Frame for the Transfer of the International Specification Medical Laboratories

Source: Prepared by the Researcher.

3. Methodology

3.1 Research Design

This study adopts a qualitative case study research design to explore the implementation of ISO 15189 in educational laboratories at Kut University College. The case study approach allows for an in-depth investigation of the specific context and provides valuable insights into the unique factors that influence the implementation process and outcomes.

3.2 Data Collection

Data for this study will be collected through multiple sources to ensure a comprehensive understanding of the research problem. The data collection methods include:

1. A checklist: Is a form that is used for quickly and easily recording data or identifying actions or requirements.
2. Document analysis: A review of relevant documents, such as laboratory manuals, standard operating procedures, quality management system documentation, and internal audit reports, will be conducted to gain insight into the laboratory's adherence to ISO 15189 requirements.
3. Semi-structured interviews: In-depth interviews will be conducted with key stakeholders, including laboratory managers, technicians, and university administrators, to gather information on their perspectives, experiences, and challenges in implementing ISO 15189.
4. Focus group discussions: Focus groups with students who have had practical experiences in the laboratory will be organized to

understand their perception of the laboratory's quality and the impact of ISO 15189 implementation on their learning experiences.

3.3 Sampling Strategy

A purposive sampling technique will be employed to select participants for the interviews and focus groups. This sampling strategy ensures that participants have relevant knowledge, experience, or involvement in the ISO 15189 implementation process. Participants will be chosen based on their role and responsibilities within the institution and laboratory.

3.4 Data Analysis

Qualitative data analysis will be conducted by using thematic analysis, which involves identifying, analyzing, and reporting patterns or themes within the data. The collected data from document analysis, interviews, and focus group discussions will be transcribed, coded, and analyzed to identify emerging themes and patterns. The analysis will be guided by the research objectives and existing literature on ISO 15189 implementation in educational laboratories.

3.5 Checklist ISO 15189

ISO 15189: "Medical laboratories — Requirements for quality and competence," outlines the criteria for the quality and competence of medical laboratories. It covers both management and technical requirements that contribute to the accurate, timely, and reliable delivery of medical laboratory services. Here is a simplified checklist of the main requirements for medical laboratories as shown in Table (1):

Table (1): A Checklist of the Main Requirements for Educational Medical Laboratories Management Requirements

Serial	Checklist ISO 15189						
	fully Applied fully Documented	fully Applied partially Documented	fully Applied Non-Documented	partially Applied fully Documented	partially Applied partially Documented	partially Applied Undocumented	partially Applied Un Documented
The first requirement. Management Requirements							
1.1 Organization and management responsibility							
1.2 Legal entity, roles, and responsibilities		✓					
1.3 Laboratory director with appropriate qualifications and experience	✓						
1.3 Defined organizational structure	✓						
2.1 Quality management system (QMS)							
2.2 Documentation and implementation of QMS		✓					
2.3 Quality policy and objectives	✓						
2.4 Quality manual	✓						
3.1 Document control							
3.2 Document approval, review, and update procedures		✓					
3.3 Control of external documents						✓	
3.4 Control of document changes						✓	
4.1 Identification and control of nonconformities							
4.2 Process for identifying, evaluating, and correcting nonconformities		✓					
4.3 Documentation of nonconformities and corrective actions		✓					
5.1 Corrective action							
5.2 Procedures for identifying the					✓		

causes of nonconformities							
5.3 Implementation and monitoring of corrective actions		✓					
5.4 Preventing the recurrence of nonconformities			✓				
6.1 Continual improvement							
6.2 Regular assessment and improvement of the QMS	✓						
7.1 Quality and technical records							
7.2 System for maintaining and retaining records	✓						
8.1 Internal audits							
8.2 Regular internal audits of the QMS		✓					
8.3 Documentation of audit findings and follow-up actions			✓				
9.1 Management reviews							
9.2 Periodic management reviews of the QMS			✓				
9.3 Documentation of review findings and actions			✓				
Weights	6	5	4	3	2	1	0
frequencies	6	7	4	0	1	2	0
Output (weight x number of iterations)	36	35	16	0	2	2	0
Weighted average (weighted mean)	4.55						
Percentage of application	%75.83						
The gap size of the requirement	%24.17						

Source: prepared by the researcher.

The ISO 15189 standard provides criteria for the quality and competence of medical laboratories.

Here is a simplified checklist focusing on the technical requirements as shown in Table (2):

Table (2): A Checklist of the Main Requirements for Educational Medical Laboratories Technical Requirements

Serial	Checklist ISO 15189						
	fully Applied	fully Applied	fully Applied	partially Applied	partially Applied	partially Applied	partially Applied
	fully Documented	partially Documented	Non- Documented	fully Documented	partially Documented	-Non Documented	Non- Documented
The second requirement. Technical Requirements							
1.1 Personnel							
1.2 Adequate staffing with appropriate qualifications and experience			✓				
1.3 Continuing education and training programs			✓				
2.1 Laboratory equipment, reagents, and consumables							
2.2 Selection, maintenance, and calibration of equipment		✓					
2.3 Control and monitoring of reagents and consumables						✓	
3.1 Safety and Risk Management							
3.2 Compliance with relevant safety regulations and guidelines							
3.3 Procedures for the identification, assessment, and mitigation of risks		✓					
3.4 Laboratory safety and security measures		✓					
Weights	6	5	4	3	2	1	0
frequencies	0	3	2	0	0	1	0
Output (weight x number of iterations)	0	15	8	0	0	1	0
Weighted average (weighted mean)	4						
Percentage of application	%66.66						
The gap size of the requirement	%33.34						

Source: prepared by the researcher.

By following the ISO 15189 checklist, medical laboratories can ensure that they provide a high level of quality and competence in their services.

4. Results

4.1 Document Analysis

The document analysis revealed that Kut University College has implemented various policies and procedures in line with ISO 15189 requirements. The laboratory manuals, standard operating procedures, and quality management system documentation demonstrated adherence to both the management and technical requirements of the standard. However, some areas required improvement, such as regular equipment maintenance and method validation.

4.2 Semi-Structured Interviews

Interviews with key stakeholders, including laboratory managers, technicians, and university administrators, provided valuable insights into the implementation process, challenges, and benefits associated with ISO 15189 adoption. The participants highlighted the following themes:

1. Institutional commitment: The administration at Kut University College expressed strong support for implementing the standard, which facilitated the allocation of necessary resources and staff training.
2. Resource constraints: Despite the institutional commitment, participants mentioned budgetary and staffing constraints as significant challenges in meeting the ISO 15189 requirements.
3. Staff training and development: The need for continuous staff training and development to maintain compliance with the standard emerged as a critical factor.

4. Continuous improvement: Participants recognized the value of the standard in promoting a culture of continuous improvement and increasing the overall quality of the laboratory services.

4.3 Focus Group Discussions

Focus group discussions with students who had practical experiences in the laboratory revealed that the implementation of ISO 15189 had a positive impact on their learning experiences. The students observed improvements in laboratory procedures, equipment maintenance, and overall quality. They also noted that exposure to a well-functioning quality management system helped them develop essential professional competencies, such as critical thinking, problem-solving, and teamwork skills respectively.

4.4 Summary of Findings

The results of this study suggest that the implementation of ISO 15189 at Kut University College has led to the improvements in the quality and competence of the educational laboratory. However, challenges related to resource constraints and the need for ongoing staff training and development remain. Furthermore, the findings indicate that the adoption of the standard has positively impacted student learning experiences.

5. Discussion

The findings from this study provide valuable insights into the implementation of ISO 15189 in educational laboratories at Kut University College. Several key themes emerged from the data analysis, which contribute to a broader

understanding of the benefits and challenges associated with the adoption of the standard.

5.1 Benefits of ISO 15189 Implementation

The results highlight the positive impact of ISO 15189 on the quality and competence of the educational laboratory. This is consistent with previous studies that have reported improvements in laboratory performance following the adoption of the standard [9] and [12]. The document analysis revealed that Kut University College had implemented policies and procedures in line with the standard's requirements, promoting a culture of continuous improvement.

Furthermore, the focus group discussions with students indicated that the implementation of ISO 15189 had a positive impact on their learning experiences. This finding aligns with previous research suggesting that improved laboratory quality and competence can enhance student learning outcomes [13].

5.2 Challenges in ISO 15189 Implementation

Despite the benefits, the study also identified challenges associated with the implementation of ISO 15189, particularly regarding resource constraints and the need for ongoing staff training and development. Similar challenges have been reported in other studies on the adoption of ISO 15189 in different contexts [14] and [8]. Addressing these challenges requires continued institutional commitment and support to ensure the allocation of necessary resources and the provision of staff training.

5.3 Implications for Practice

The findings from this study have several implications for the implementation of ISO 15189

in educational laboratories. Institutions looking to adopt the standard should be aware of the potential challenges and develop strategies to overcome them. This may include securing funding, investing in staff training, and fostering a culture of continuous improvement. Additionally, institutions should consider conducting regular assessments of their laboratory quality and competence to ensure ongoing compliance with the standard.

5.4 Limitations and Future Research

This study has some limitations, primarily related to its focus on a single case at Kut University College. Consequently, the findings may not be generalizable to other educational laboratories with different contexts and resources. Future research should explore the implementation of ISO 15189 in a broader range of educational settings to gain a more comprehensive understanding of the factors that contribute to successful implementation and the impact on student learning experiences.

In conclusion, this study has contributed to the growing body of literature on ISO 15189 implementation in educational laboratories by providing an in-depth examination of the benefits and challenges at Kut University College. The findings suggest that the adoption of the standard can lead to improvements in laboratory quality and competence, as well as enhancing student learning experiences. However, institutions must address the challenges related to resource constraints and staff training to fully realize the potential benefits of ISO 15189 implementation.

6. Conclusion

This study aimed at exploring the implementation of ISO 15189 in educational laboratories, focusing on a case study at Kut University College. The research provided valuable insights into the benefits and challenges associated with the adoption of the standard, as well as its impact on student learning experiences.

The results indicate that the implementation of ISO 15189 has led to the improvements in the quality and competence of the educational laboratory at Kut University College. These improvements have contributed to a more comprehensive understanding of scientific concepts and principles for students and have helped them develop essential professional competencies. However, the study also identified challenges, such as resource constraints and the need for ongoing staff training and development, which must be addressed to ensure the successful implementation of the standard.

The findings of this study have several implications for educational institutions looking to adopt ISO 15189. Institutions should be aware of the potential challenges and develop strategies to overcome them, including securing funding, investing in staff training, and fostering a culture of continuous improvement. Additionally, regular assessments of laboratory quality and competence should be conducted to ensure ongoing compliance with the standard.

Future research should examine the implementation of ISO 15189 in a broader range of educational settings to gain a more comprehensive understanding of the factors that contribute to successful implementation and the impact on student learning experiences. By doing so, educational institutions can better understand

how to implement effectively the ISO 15189 and how to maximize its benefits for students, educators, and institutions as a whole.

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