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The Quality of Educational Laboratories According to the International Standard ISO 15189 - A Case Study at Kut University College

Ali Saad Alwan¹, Balsam Saad Esmail², Ali hameed abd³, Ali A. Al-khattawi⁴

Abstract

This case study explores the implementation and effectiveness of the ISO 15189 standard in the teaching laboratories of Kut University College, with a focus on medical and health sciences. The study aims at identifying areas for improvement, evaluating the effectiveness of the standard, and making recommendations to improve laboratory quality. Data collection methods include document analysis, interviews, and direct observation of laboratory practices. The results will reveal the status of implementation of ISO 15189, the strengths and weaknesses of the process, and its impact on laboratory quality and efficiency. As the results appeared in the first (Management) requirement, with a percentage of application (75.83%), and the second (technical) requirement. They also showed a percentage of application (66.66%). This study is considered as a basis for developing strategies to enhance the quality of educational laboratories at Kut University College. The study contributes to existing knowledge about the implementation of ISO 15189 in educational laboratories, and offers a unique perspective within the context of an educational institution. The results can support improved learning experiences for students, the development of skilled professionals, and the advancement of medical and health sciences education respectively.

Keywords: ISO 15189, Educational Laboratories, Quality Management, Laboratory Performance, Kut University College

جودة المختبرات التعليمية على وفق المواصفة الدولية ISO 15189 - دراسة حالة في كلية الكوت 4 م. علي سعد علوان 1 ، م. م. بلسم سعد إسماعيل 2 ، على حميد عبد 3 ، على عبد الكريم الخطاوى

المستخلص

تستكشف دراسة الحالة هذه تنفيذ وفعالية معيار ISO 15189 في المختبرات التعليمية لكلية الكوت الجامعة، مع التركيز على العلوم الطبية والصحبة. تهدف الدر اسة إلى تحديد مجالات التحسين، وتقييم فعالية المعيار ، وتقديم توصيات لتحسين جودة المختبر . تشمل طرق جمع البيانات تحليل الوثائق والمقابلات والمراقبة المباشرة للممارسات المختبرية. ستكشف النتائج عن حالة تنفيذ ISO 15189 ، ونقاط القوة والضعف في العملية ، وتأثير ها على جودة المختبر وكفاءته. اذ ظهرت النتائج في المتطلب الأول (الإداري) بنسبة مئوية للتطبيق (%75.83), والمتطلب الثاني (الفني). كما ظهرن بنسبة مئوية للتطبيق (66.66%). وتعد الدراسة هذه بمثابة أساس لتطوير استراتيجيات لتعزيز جودة المختبرات

Affiliation of Authors

^{1,3,4} Kut University College, Iraq, wasit, 52001 ² Al-Karkh, University of science, Iraq, Baghdad, 10011

¹ali.s.al-musawi@alkutcollege.edu.iq

- ² Balsam.altameme72@gmail.com
- ³ ali.h.abid@alkutcollege.edu.iq
- ⁴ ali.a.hasan@alkutcollege.edu.iq

¹Corresponding Author

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> انتساب الباحثين ^{4,3,1} كلية الكوت الجامعة، العراق، واسط، 52001 ² جامعة الكرخ للعلوم، العراق، بغداد، 10011

¹ali.s.al-musawi@alkutcollege.edu.iq ² Balsam.altameme72@gmail.com ³ ali.h.abid@alkutcollege.edu.iq ⁴ ali.a.hasan@alkutcollege.edu.iq

التعليمية في كلية الكوت الجامعة. أذ تساهم الدراسة في المعرفة الموجودة حول تنفيذ ISO 15189 في المختبرات التعليمية ، وتقدم منظورًا فريدًا ضمن سياق مؤسسة تعليمية. يمكن أن تدعم النتائج خبرات التعلم المحسنة للطلاب، وتطوير المهنيين المهرة، والنهوض بتعليم العلوم الطبية والصحية.

الكلمات المفتاحية : ISO 15189، المختبرات التعليمية، إدارة الجودة، إداء المختبر، كلية الكوت الجامعة

Introduction

Educational laboratories are essential components of academic institutions, particularly in the fields of medical and health sciences. These laboratories provide students with the opportunity to apply theoretical knowledge and develop practical skills in a controlled environment. Ensuring the quality and competence of these laboratories is critical for effective learning outcomes, student satisfaction, and the development of skilled professionals who can face the demands of the healthcare sector. To achieve and maintain high-quality performance in educational laboratories, many institutions adopt international standards, such as ISO 15189. ISO 15189 is a globally recognized standard specifically designed for medical laboratories. It outlines requirements for quality and competence, emphasizing the importance of a robust quality management system (QMS), appropriate personnel qualifications, equipment maintenance, and process validation. By implementing ISO 15189, institutions can improve laboratory performance, increase credibility, and enhance the overall learning experience for students. Kut University College, a leading educational institution. maintains educational laboratories that provide essential practical training for students in various medical and health science disciplines. Ensuring the quality of these laboratories is crucial for the success of the institution and the development of competent professionals who can contribute effectively to the healthcare sector.

1.1 Research Problem

The research problem of this case study revolves around the challenges and opportunities associated with the implementation of ISO 15189 in educational laboratories at Kut University College, specifically those related to medical and health sciences. While ISO 15189 has been widely adopted in medical laboratories worldwide, its application in educational laboratories remains less explored. As a result, there is a limited understanding of the effectiveness of this standard in enhancing the quality and competence of educational laboratories and its impact on the learning experiences of students.

The research problem can be summarized in the following question:

To what extent has the implementation of ISO 15189 improved the quality and competence of educational laboratories at Kut University College, and how can the implementation process be optimized to maximize the benefits of the standard?

Addressing this research problem will provide valuable insights into the practical application of ISO 15189 in educational laboratories and help identify potential areas of improvement. The outcomes of this case study can serve as a basis for the development of strategies to enhance the quality and competence of educational laboratories, ultimately contributing to improved learning experiences and the development of skilled professionals in the medical and health sciences fields.

¹ المؤلف المراسل

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1.2 Research Objectives

This case study aims at:

- Assessing the current implementation status of ISO 15189 in the educational laboratories at Kut University College, particularly those related to medical and health sciences.
- 2. Identifying the strengths and weaknesses in the implementation process, highlighting any gaps or areas that require improvement.
- Evaluating the impact of ISO 15189 on laboratory quality and competence, determining its effectiveness in promoting high-quality performance and learning experiences for students.
- 4. Providing recommendations for improvement based on the findings of the study, suggesting strategies to enhance the quality management systems and competence of the educational laboratories at Kut University College.
- 5. Contributing to the existing body of knowledge on ISO 15189 implementation in educational laboratories, offering a unique perspective from the context of an educational institution.

1.3 Significance of the Study

The significance of this case study lies in its potential contributions to the understanding and optimization of ISO 15189 implementation in educational laboratories, particularly those related to medical and health sciences. The outcomes of this study hold several important implications; They are as follows:

 Practical insights: By assessing the current implementation status of ISO 15189 in educational laboratories at Kut University College, this study provides practical insights into the challenges and opportunities associated with adopting the standard in an educational setting. These insights can be helpful for other institutions considering the adoption of ISO 15189 in their laboratories.

- 2. Quality improvement: Identifying strengths, weaknesses, and areas of improvement in the implementation process can lead to the development of targeted strategies for enhancing the quality management systems and competence of educational laboratories, ultimately resulting in improved learning experiences for students.
- Benchmarking and best practices: The findings of this case study can serve as a benchmark for other institutions seeking to implement ISO 15189 in their educational laboratories. By comparing the implementation process and outcomes at Kut University College with other institutions, best practices can be identified and shared.
- 4. Contribution to the literature: This case study adds to the existing body of knowledge on ISO 15189 implementation in educational laboratories, providing a unique perspective from the context of an educational institution. The findings can potentially support future research on the impact of ISO 15189 in promoting high-quality laboratory performance and student learning experiences.
- 5. Professional development: The outcomes of this study can contribute to the development of skilled professionals in the medical and health sciences fields, as improved laboratory quality and competence can lead to more effective and efficient training of students, preparing them for careers in the healthcare sector.

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 ISO15189

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 ISO15189 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]. the effectiveness of Additionally, 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, problemsolving, and teamwork skills [14].

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

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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 ISO performance following 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, the level and 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 wellfunctioning 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.
- 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):

and corrective actions

5.2 Procedures for

identifying the

Requirements Checklist ISO 15189 fully fully fully partially partially partially partially Serial Applied Applied Applied Applied Applied Applied Applied fully partially Nonfully partially Undocumented Un Documented Documented Documented Documented Documented 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 1 organizational structure 2.1 Quality management system (QMS) 2.2Documentation and 1 implementation of QMS 2.3 Quality policy 1 and objectives 2.4 Quality manual **3.1 Document control** 3.2 Document approval, review, / and update procedures 3.3 Control of 1 external documents 3.4 Control of 1 document changes 4.1 Identification and control of nonconformities 4.2 Process for identifying, / evaluating, and correcting nonconformities 4.3Documentation of nonconformities /

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

/

5.1 Corrective action

causes of											
nonconformities											
5.3Implementation											
and monitoring of											
corrective actions											
5.4 Preventing the											
recurrence of											
nonconformities											
6.1 Continual improvement											
6.2 Regular											
assessment and	1										
improvement of	•										
the QMS											
	7.1 Quality and technical records										
7.2 System for	1										
maintaining and	\checkmark										
retaining records											
	8.1 Internal audits										
8.2Regular											
internal audits of		✓ ✓									
the QMS											
8.3Documentation											
of audit findings			1								
and follow-up			•								
actions											
		9.1	l Manageme	ent reviews			·				
9.2 Periodic											
management			1								
reviews of the			•								
QMS											
9.3Documentation			1								
of review findings											
and actions											
Weights	6	5	4	3	2	1	0				
frequencies	6	7	4	0	1	2	0				
Output (weight x	3-		4.5	6			-				
number of	36	35	16	0	2	2	0				
iterations)											
Weighted											
average				4.55							
(weighted mean)											
Percentage of	0/75.92										
application	%75.83										
The gap size of		%24.17									
the requirement											

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):

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			Requirem									
	Checklist ISO 15189											
	fully	fully	fully	partially	partially	partially	partially					
Serial	Applied	Applied	Applied	Applied	Applied	Applied	Applied					
	fully	partially	Non-	fully	partially	-Non	Non-					
	Documented	Documented	Documented	Documented	Documented	Documented	Documented					
						Documented	Documented					
The second requirement. Technical Requirements												
1.1 Personnel												
1.2 Adequate												
staffing with												
appropriate			v									
qualifications and												
experience 1.3 Continuing												
education and			1									
training programs												
2.1 Laboratory equipment, reagents, and consumables												
2.2 Selection,												
maintenance, and		1										
calibration of		•										
equipment												
2.3 Control and												
monitoring of						\checkmark						
reagents and												
consumables												
		3.1 Saf	ety and Risk	Managemen	nt							
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			0	0	0		0					
number of iterations)	0	15	8	0	0	1	0					
Weighted average	4											
(weighted mean)												
Percentage of	0/777											
application	%66.66											
	0/ 22 24											
The gap size of the requirement	%33.34											
the requirement												

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

Requirements

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:

- 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.
- Resource constraints: Despite the institutional commitment, participants mentioned budgetary and staffing constraints as significant challenges in meeting the ISO 15189 requirements.
- Staff training and development: The need for continuous staff training and development to maintain compliance with the standard emerged as a critical factor.

 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

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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 wellfunctioning 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. challenges However, related to resource constraints and the need for ongoing staff training development remain. Furthermore, and 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 а 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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