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Impact of SAAC accreditation on laboratories in Saudi Arabia according to ISO/IEC 17025:2017

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This study evaluates the impact of Saudi Accreditation Center (SAAC) accreditation on laboratories in Saudi Arabia according to the ISO/IEC 17025:2017 standard by analysing nonconformities observed in 44 laboratories, namely, 7 calibration laboratories and 37 testing laboratories. Each laboratory was assessed by comparing nonconformities identified during initial versus periodic assessments, providing insights into the impact of accreditation on the quality of the laboratory system. Statistical analysis was conducted using descriptive statistics, paired t tests, and effect size calculations to evaluate pre- and postaccreditation nonconformities. The results revealed a significant reduction in nonconformities for both laboratory types following accreditation. The calibration laboratories exhibited a 46% reduction in nonconformities, while the test laboratories demonstrated a 41% reduction. These findings affirm that SAAC accreditation significantly improves laboratory compliance, reduces nonconformities and enhances quality and reliability. The study concludes that SAAC accreditation plays a pivotal role in increasing operational excellence in laboratories across Saudi Arabia, supporting quality infrastructure and regulatory compliance.

Keywords Accreditation, Laboratories, ISO/IEC 17025:2017, Quality, Calibration

The ISO/IEC 17025:2017 standard is at the heart of laboratory accreditation processes. First introduced by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), the ISO/IEC 17025 standard outlines the "general requirements for the competence of testing and calibration laboratories"[1]. As an internationally recognized benchmark, the ISO/IEC 17025 standard sets the requirements for laboratory management systems and technical competencies, including aspects such as personnel qualifications, equipment calibration, and the quality of testing activities[2]. Laboratories accredited to the ISO/IEC 17025 standard are recognized as having robust systems in place that support precise, traceable, and reproducible results, which is critical for laboratories aiming to serve industries and communities with high regulatory demands. The ISO/IEC 17025 standard not only enhances laboratory credibility but also provides a framework for continuous improvement and consistency in laboratory operations[2].

In the modern landscape of quality assurance and regulatory compliance, laboratory accreditation has become an essential tool that ensures reliable and high-quality laboratory results. Accreditation serves as a formal testimony by an authoritative, impartial third party, confirming that a laboratory meets defined quality and competence standards. This assurance of quality is especially critical for laboratories that perform testing and calibration work that directly impacts public health and safety, the quality of products, and international trade. By achieving accreditation, laboratories demonstrate their commitment to providing accurate, reliable, and consistent testing and calibration activities that meet both customer expectations and regulatory requirements. In turn, accreditation contributes to greater public trust in laboratory-generated data, which influences sectors such as public health, construction, food, and the environment[2]. In Saudi Arabia, the importance of ISO/IEC 17025 standard accreditation is highlighted by the country's rapid industrial and economic growth, which demands high standards in laboratory services. Laboratories seeking accreditation must undergo comprehensive assessment processes, wherein expert assessors evaluate the laboratory's compliance with the ISO/IEC 17025 standard requirements. Tasked with this mandate, the Saudi Accreditation Center (SAAC) acts as the national accreditation body for Saudi Arabia and is recognized globally by the International Laboratory Accreditation Cooperation (ILAC) to provide accreditation services within its economy. As part of its mission, the SAAC has four key goals that are used to enhance its impact. First, the SAAC aims to ensure confidence in the services of conformity assessment bodies (CABs), encouraging private sector participation in providing these services. Second, it focuses on improving the quality and competence of CABs to ensure that their services and products

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meet the highest standards, thereby increasing customer confidence. Third, the SAAC is dedicated to ensuring the competence and impartiality of CABs, reinforcing their credibility in delivering reliable conformity assessment services. Finally, it strives to protect customers and uphold safety and public health, emphasizing the societal value of its accreditation activities. These objectives align with the SAAC's ambitious vision to strengthen the kingdom's quality infrastructure and support economic development[3].

In addition to providing accreditation services, the SAAC facilitates training and qualification services for assessors, participates in international and regional organizations, and enables mutual recognition of accreditation certificates with other accreditation bodies. Moreover, the SAAC represents Saudi Arabia both regionally and internationally, coordinates with government entities on regulating conformity assessment activities, proposes relevant regulations, and conducts research, seminars, and conferences[3].

Several studies have evaluated the impact of accreditation on various aspects of laboratory operations[4–8]. For example, a study by Okezue et al.[4] examined the influence of laboratory accreditation on the severity of nonconformities and reported a reduction in the number of major nonconformities, as well as a decrease in the severity of nonconformities postaccreditation. Similarly, some studies have assessed the effect of accreditation on laboratories' performance in proficiency testing and reported a positive correlation[5]. Moreover, a study by Elhuni[6] demonstrated that ISO/IEC 17025 standard accreditation significantly enhances company performance, as evidenced by data from 15 accredited laboratories. Additionally, Mahmed et al.[7] identified a statistically significant relationship between accreditation and the performance and efficiency of employees. Furthermore, another study provided empirical evidence supporting a significant relationship between the adoption of the ISO/IEC 17025 standard and the operational performance of testing and calibration laboratories[8].

Accreditation has proven essential in laboratories that conduct testing and generate reports on the quality of results, as well as in laboratories that monitor other critical areas of public health and safety[4–8]. By adhering to the ISO/IEC 17025 standard, laboratories in Saudi Arabia and around the globe can significantly enhance their ability to produce reliable and valid test results, which is a factor that is crucial in public health and safety.

This paper aims to assess the impact of SAAC accreditation on laboratories according to the ISO/IEC 17025 standard in Saudi Arabia through a detailed analysis of nonconformities observed during assessments. By comparing the frequency of nonconformities identified during initial and periodic SAAC assessments, this study also provides insights into how accreditation influences laboratory performance over time and highlights areas where improvements occurred. This analysis is intended to offer valuable information for both laboratories' customers and regulatory authorities, contributing to a deeper understanding of the role of accreditation in advancing laboratory quality and reliability.

Materials and methods

Sample selection

The focus of this study is to perform a comprehensive statistical analysis of nonconformities observed during the initial assessment for laboratories that were not primarily accredited by the SAAC at the time of assessment. All laboratories included in this study were systematically categorized on the basis of their primary field of activity and had successfully undergone the accreditation process, received accreditation certificates, completed surveillance assessment visits, and have completed the full accreditation cycle, additionally, only laboratories that were accredited after SAAC obtained international recognition by ILAC in 2021 were included. Based on these criteria, 44 laboratories were identified for inclusion in this analysis (Table 1). Laboratories that did not meet the selection criteria were excluded.

Statistical analysis

The statistical methodology used in this study involved collecting pre- and postaccreditation data on nonconformities from 44 laboratories, which were mainly categorized as calibration laboratories and testing laboratories. Descriptive statistics, including the mean, median, mode, and standard deviation, were calculated to compare nonconformities before and after accreditation.

To confirm data suitability for further analysis, normality was assessed using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Paired samples t-tests were then conducted to evaluate the statistical significance of differences in nonconformities before and after accreditation. Effect sizes were calculated using Cohen's d and Hedges' g with small-sample correction. All statistical analyses were performed using Python (version 3.11),. This approach enabled a detailed evaluation of the changes observed between the initial and surveillance assessments.

Main field	Number of laboratories
Construction	24
Calibration	7
Food & agriculture	5
Chemical	2
Electrical	2
Mechanical	2
General materials	2
Total	44

Table 1. Classification of laboratories based on their main fields.

	Calibration laboratories		Testing laboratories	
	Preaccreditation	Postaccreditation	Preaccreditation	Postaccreditation
Sample Size	7	7	37	37
Number of nonconformities	159	86	961	541
Mean	23	12	26	15
Median	21	7	26	14
Mode	32	7	23	12
Std. deviation	13.56	11.25	9.30	6.85

Table 2. Frequency of pre- and postaccreditation.

	Kolmogorov-Smirnov[a]			Shapiro–Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Calibration laboratories						
Preaccreditation	0.182	7	0.200*	0.975	7	0.931
Postaccreditation	0.252	7	0.199	0.870	7	0.186
Testing laboratories						
Preaccreditation	0.085	37	0.200*	0.972	37	0.454
Postaccreditation	0.083	37	0.200*	0.980	37	0.712

Table 3. Test of the normality of nonconformities pre- and postaccreditation. *. This is a lower bound of the true significance. a. Lilliefors Significance Correction.

Results

Statistical analysis of nonconformities

Table 2 illustrates the frequency of nonconformities noted before and after accreditation for both the calibration laboratories and testing laboratories. For the calibration laboratories, the average nonconformity decreased from 23 during the granting visit to 12 during the surveillance visit. Similarly, the median nonconformity decreased significantly, moving from 21 to 7. The mode, which indicates the most common nonconformity count, shifted from 32 through the preaccreditation stage to only 7 during the surveillance visit accreditation. Furthermore, the standard deviation for preaccreditation was 13.56, which was reduced to 11.250 at the surveillance visit, thereby reflecting less fluctuation in nonconformities postaccreditation.

For testing laboratories, the mean number of nonconformities before accreditation was 26, which decreased to 15 after accreditation. The median also decreased, from 26 preaccreditation to 14 postaccreditation. The mode before accreditation was 23, whereas after accreditation, it shifted to 12. The standard deviation for preaccreditation was 9.30, reflecting moderate variability in nonconformities across laboratories, whereas for postaccreditation, the standard deviation increased to 6.85, indicating a narrower spread in the number of nonconformities.

Analysis of the normality of nonconformities

The normality of the data was evaluated via the Kolmogorov–Smirnov and Shapiro–Wilk tests, as shown in Table 3. The results for both the calibration ***laboratories*** and testing laboratories across the pre- and postaccreditation assessments indicate that the data follow a normal distribution. This conclusion is supported by p values greater than 0.05 in all the cases, demonstrating no significant deviation from normality. These findings confirm that the assumptions for conducting parametric tests, such as the paired samples t test (2-tailed), are justified, ensuring the robustness and reliability of the subsequent statistical analyses.

Testing the significant difference between nonconformities

Tables 4 and 5 show the sample t tests for both types of laboratories with a confidence interval of 95%, which will be discussed in detail in the discussion section. Tables 6 and 7 show the paired sample effect sizes for calibrating and testing laboratories to identify whether accreditation has a substantial effect on the number of nonconformities.

Discussion

Initially, the data suggest that accreditation has positive effect on reducing nonconformities. In calibration laboratories, nonconformities experience a substantial reduction of approximately 46% following accreditation, indicating a marked improvement in compliance with and adherence to standards. Similarly, in testing laboratories, the incidence of nonconformities decreases by approximately 41%, reflecting enhanced conformity during the surveillance visit.

	Paired differences					t	df	Sig. (2-tailed)
				95% Confidence interval of the difference				
	Mean	Std. deviation	Std. error mean	Lower	Upper			
Preaccreditation - Postaccreditation	10.429	8.264	3.123	2.786	18.071	3.339	6	0.016

Table 4. Paired sample test for calibration laboratories.

	Paired differences					t	df	Sig. (2-tailed)
				95% Confidence interval of the difference				
	Mean	Std. deviation	Std. error mean	Lower	Upper			
Preaccreditation - Postaccreditation	11.351	8.453	1.39	8.533	14.17	8.168	36	0.000

Table 5. Paired sample test for testing laboratories.

		Standardizer[a]	Point Estimate	95% confidence interval	
				Lower	Upper
Preaccreditation - Postaccreditation	Cohen's d	8.264	1.262	0.022	2.502
	Hedges' correction	9.296	1.122	0.020	2.224

Table 6. Paired sample effect sizes for calibration laboratories. a. The denominator used in estimating the effect sizes. Cohen's d uses the sample standard deviation of the mean difference. Hedges' correction uses the sample standard deviation of the mean difference, plus a correction factor.

		Standardizer[a]	Point estimate	95% confidence interval	
				Lower	Upper
Preaccreditation - Postaccreditation	Cohen's d	8.453	1.343	0.883	1.803
	Hedges' correction	8.629	1.315	0.865	0.950

Table 7. Paired sample effect sizes for testing laboratories. a. The denominator used in estimating the effect sizes. Cohen's d uses the sample standard deviation of the mean difference. Hedges' correction uses the sample standard deviation of the mean difference, plus a correction factor.

The paired samples t test results in Table 4 for the calibration laboratories show t value of 3.339 and p value of 0.016 indicate that this reduction is statistically significant. The large effect sizes (Cohen's d = 1.262 and Hedges' correction = 1.122) shown in Table 6 further reinforce the magnitude of this significant effect. These findings confirm the substantial influence that accreditation has on reducing nonconformities in calibration laboratories.

Similarly, for testing laboratories, the t test results shown in Table 5 show t value of 8.168 and the p value of 0.00 highlight that this reduction is statistically significant. The effect sizes (Cohen's d = 1.343 and Hedges' correction = 1.315) shown in Table 7 indicating robust evidence of a meaningful reduction in non-conformities postaccreditation.

In laboratories, all major clauses of the standard ISO/IEC 17025:2017 saw a reduction in nonconformities, the reduction in general and structural requirements (Clauses 4 and 5) signifies enhanced compliance with basic principles and structural frameworks, providing a solid foundation for laboratory operations. The reduction of nonconformities in resource requirements (Clause 6) reflects the benefits of accreditation in improving the allocation and management of resources, including calibration equipment, personnel competency, and facilities. Moreover, the reduction of nonconformities in process requirements (Clause 7) directly enhance the technical

performance and reliability of laboratory operations. By strengthening areas such as method validation, sampling, result reporting, and ensuring validity of results. Finally, reduction of non-conformities under management system requirements (Clause 8) points to substantial advancements in management systems, such as better document control, management reviews, and corrective action processes.

The results from the statistical analysis of nonconformities for both the calibration laboratories and testing laboratories support the hypothesis that accreditation would lead to a reduction in the number of nonconformities. In calibration laboratories, the reduction is found to be both statistically significant and substantial, as indicated by the large effect size. In testing laboratories, even though the reduction is statistically significant, the effect size was also very large, reflecting a notable impact and strong improvements in quality management systems.

Moreover, a study on the ISO/IEC 17025 accreditation of the Quality Control Laboratory in Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) demonstrated that accreditation significantly improved quality compliance. After accreditation, the laboratory showed enhanced adherence to the same ISO/IEC 17025 standard, a reduction in nonconformities, and greater reliability in test reports, highlighting the value of accreditation for strengthening quality systems, even in low-resource settings[4]. Moreover, a study by the Canadian Association for Environmental Analytical Laboratories (CAEAL) explored whether accreditation leads to better performance in environmental laboratories. Through a joint accreditation program with the Standards Council of Canada (SCC) based on the ISO/IEC 17025 standard, the CAEAL assessed laboratories' quality systems and technical capabilities. The results indicated that accredited laboratories demonstrate enhanced performance, reinforcing the value of ISO/IEC 17025 accreditation in maintaining high-quality standards in Canadian environmental testing laboratories[5]. Moreover, some studies have reported a strong correlation between accreditation status and laboratory performance in proficiency testing programs, where accredited laboratories present more satisfactory results than nonaccredited counterparts do[9,10].

In conclusion, SAAC accreditation plays a pivotal role in increasing operational excellence in laboratories across Saudi Arabia, supporting quality infrastructure and regulatory compliance. To the best of our knowledge, no previous research has evaluated the effects of accreditation on laboratories in Saudi Arabia Nevertheless, more research should be done to better understand the role of accreditation in laboratory performance. Despite its contributions, this study has certain limitations that should be acknowledged. First, the relatively small sample size of calibration laboratories may restrict the applicability of findings to this specific sector. Second, the study only assessed outcomes up to the first surveillance assessment, and thus longer-term effects of accreditation could not be evaluated. Future research should therefore expand the sample size and investigate long-term impacts across multiple assessment cycles. The findings of this study provide valuable insights for laboratories, customers, and regulatory authorities, underscoring accreditation's essential role in fostering continuous improvement. Although laboratories demonstrated significant improvements following accreditation, SAAC continues to identify nonconformities during surveillance visits. This highlights the importance of sustained compliance efforts. Laboratories are therefore encouraged to focus on preventive actions, strengthen internal audits, and provide targeted training on frequently observed ISO/IEC 17025 clauses to ensure lasting improvements and reduce recurrence of nonconformities.

Data availability

The data that support the findings of this study are available from SAAC but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the corresponding author upon reasonable request and with permission of SAAC.

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Author contributions

A.A. and M.A and M.F wrote the main manuscript text M.F performed all the statistical analysis A.M and M.A prepared the tables. All authors reviewed the manuscript.

Competing interests
The authors declare no competing interests.

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