SCIENTIFIC CULTURE
www.sci-cult.com

SCIENTIFIC CULTURE, Vol. 12, No. 4, (2026), pp. 10975-10980
Open Access. Online & Print

DOI: 10.5281/zenodo.20557681

DETERMINANTS OF NON-COMPLIANCE IN SANAS AUDITS: A RETROSPECTIVE ANALYSIS OF PUBLIC SECTOR LABORATORIES (2020–2023)

S'nenhlanhla Nonjabulo Zondi[1,2,3]*, Pakiso Moses Makhoahle[2,3]

[1]Midlands Business Unit, National Health Laboratory Service (NHLS), KwaZulu-Natal, South Africa
[2]Center for Quality of Health and Living
[3]Department of Health Science, Faculty of Health and Environmental Sciences, Central University of Technology, Free State, South Africa
snezondi1993@gmail.com and P Makhoahle: pmakhoahle@cut.ac.za
PM Makhoahle ORCID id: 0000-0001-6131-9419

Corresponding Author: S'nenhlanhla Nonjabulo Zondi (snezondi1993@gmail.com)

ABSTRACT

Accreditation of medical laboratories is essential for ensuring quality and compliance with ISO 15189 standards. This study assessed factors contributing to non-compliance during SANAS audits in the regional business unit of a national public laboratory service from 2020 to 2023. A retrospective quantitative design was used, analysing audit records from seven laboratories and survey data from internal auditors. Non-conformances persisted in documentation, training, CAPA systems, and management reviews. Analytical and post-analytical gaps were also identified. Findings highlight systemic quality management weaknesses influenced by human and organisational factors. Strengthening CAPA, training, and management oversight is recommended to sustain compliance.

KEYWORDS: Audits, ISO 15189, SANAS, Non-Conformances, Quality Management

Copyright: © 2026. This is an open-access article distributed under the terms of the Creative Commons Attribution License. (https://cre-ativecommons.org/licenses/by/4.0/).

Introduction

The accreditation of medical laboratories is a critical requirement for ensuring quality, reliability, and compliance with international standards such as ISO 15189 (ISO, 2022). In South Africa, the South African National Accreditation System (SANAS) evaluates laboratories to maintain standards of competence, accuracy, and patient safety (SANAS, 2022). Within the regional business unit of a national public laboratory service, which serves approximately majority of the South African population, laboratories must demonstrate the implementation of a comprehensive Quality Management System (QMS) and technical competence to produce reliable results (NHLS, 2026). This is particularly vital as 60% to 80% of clinical decisions depend on laboratory data (Sikaris, 2017). A robust QMS is founded on twelve Quality System Essentials (QSEs), including organization, personnel, equipment, and process control (Pillai et al., 2022). These essentials translate the principles of ISO 15189 into interconnected components that form the basis for SANAS audits (Datema et al. 2020). Central to this framework is the Plan-Do-Check-Act (PDCA) cycle, which drives continuous improvement by identifying risks and establishing corrective actions (Akase and Kpera, 2024). Despite the rigorous requirements of these standards, non-conformances (NCs) remain a persistent and recurring challenge during laboratory audits (Plebani, 2007). Existing literature suggests that successful implementation is frequently hindered by several systemic weaknesses, most notably in the area of human resources, where high staff turnover and incomplete competency assessments undermine consistency (Akoma et al., 2025). Furthermore, significant documentation gaps, such as the use of outdated or uncontrolled Standard Operating Procedures (SOPs), often lead to procedural inconsistencies (ISOQAR Africa, 2025). These issues are compounded by ineffective CAPA management, where corrective and preventive action processes fail to address underlying root causes or lack the necessary verification to ensure long-term resolution (Rodriguez-Perez, 2022; WHO, 2020). Regional studies, particularly in low and middle income settings, highlight that while SLIPTA and SLMTA programs have expanded accreditation coverage, sustaining compliance requires strong leadership and a positive quality culture (Odhiambo et al., 2016). In South Africa, recurrent findings often reflect gaps in management oversight and document control (Pandya et al., 2025). This study assesses the factors contributing to non-compliance within the regional business unit of a national public laboratory service from 2020 to 2023. By identifying recurring types and severities of NCs and mapping them to systemic challenges, this research seeks to provide data-driven recommendations to strengthen QMS resilience, ensure accurate diagnostic services, and sustain ISO 15189 compliance in a resource-constrained environment.

Materials and Methods

Study Design and Setting

A descriptive, retrospective, non-experimental quantitative study was conducted within the regional business unit of a national public laboratory service in KwaZulu-Natal, South Africa. This design facilitated the objective analysis of historical patterns and trends in non-conformances (NCs) across seven SANAS-accredited public sector laboratories between 2020 and 2023.

Population and Sampling

The study utilized two distinct populations:

Laboratory Audit Data: A total population sampling approach was applied to all seven qualifying SANAS-accredited laboratories within the business unit.

Internal Auditors: Purposive sampling was used to recruit internal auditors with experience auditing these specific facilities during the study period. Participation was voluntary and contingent upon informed consent.

Data Collection

Data were gathered through a dual-modality approach to ensure triangulation:

Audit Review: Historical NC data were extracted from the regional business unit of a national public laboratory service centralized audit log. Key variables included audit year, type (Internal vs. SANAS), classification (Technical vs. Management), severity (Minor, Medium, Major), and affected testing phase (Pre-analytical, Analytical, Post-analytical).

Online Survey: A structured survey was administered via the REDCap platform to capture auditors' perceptions regarding root causes, systemic challenges, and laboratory readiness.

Data Analysis

Descriptive statistics (frequencies and percentages) and trend analyses were performed using Microsoft Excel to summarize NC distribution and evaluate quality improvement progress over time. Comparative analysis was conducted using cross-tabulations to identify statistically significant

associations between NC types, departments, and testing phases. Quantitative audit findings were triangulated with qualitative survey insights to provide context-rich results.

Reliability and Validity

Internal validity was maintained through the use of verified, standardized SANAS audit records. Reliability was ensured by applying consistent coding and categorization for all NCs across the four-year period and utilizing a structured, uniform survey format.

Ethical Considerations

The study was approved by the University of the Free State Ethics Review Board (approval reference number: UFS-HSD2025/0575/290; Date:11 August 2025). Institutional permission to access audit records was granted by NHLS AARMS (Ref number: PR2559108). Implied consent was obtained from internal auditor participants: a cover letter displayed at the beginning of the REDCap survey explained that returning a completed survey constituted voluntary agreement to participate. All participants were informed of the study's purpose and their right to withdraw at any time. No personal identifiers were collected during data collection, and all information was anonymized to protect participant confidentiality. Audit records were accessed only with the necessary permissions and were stored securely in accordance with institutional data protection policies. Participation in the study was entirely voluntary, and no incentives were offered. The study posed minimal risk to participants and maintained full compliance with applicable ethical and data protection standards.

Results

Overview of Non-Conformance (NC) Trends

A total of 61 non-conformances were recorded across the seven laboratories in the regional business unit of a national public laboratory service between 2020 and 2023. The distribution of NCs was highly uneven over the study period, showing a significant surge during the mid-period. In 2020, compliance was stable with only 11.5% (n=7) of the total NCs. However, this figure tripled in 2021 to 39.3% (n=24) and remained high in 2022 (n=24), before declining sharply in 2023 to 9.8% (n=6).

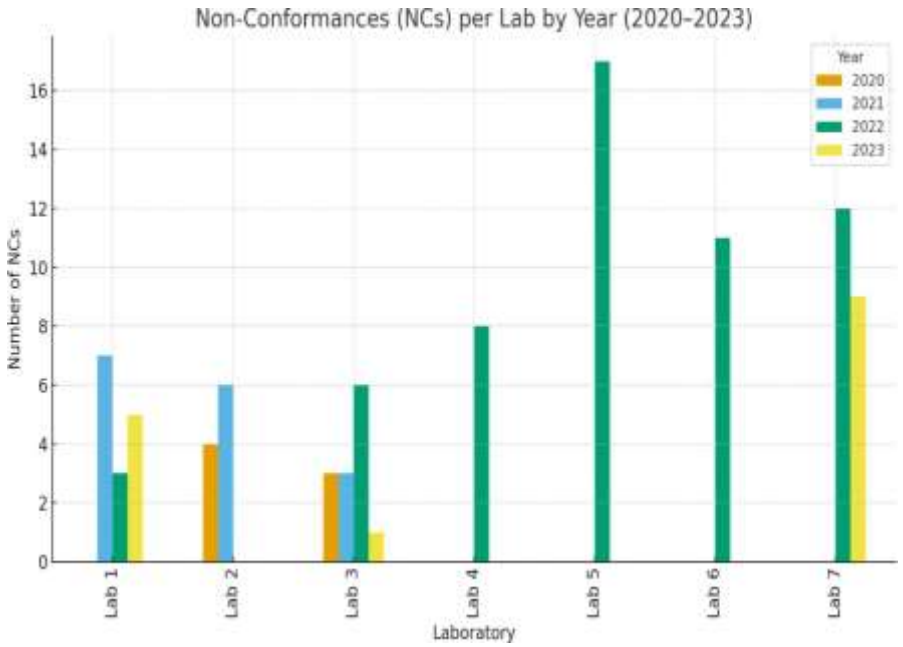

Figure 1: Non-conformances (NCs) per Lab by Year (2020–2023)

Classification and Severity of Findings

The majority of audit findings were categorized under Management Requirements (n=38; 62.3%) compared to Technical Requirements (n=23; 37.7%). In terms of severity, Minor NCs were the most frequent (n=44; 72.1%), followed by Medium NCs (n=12; 19.7%) and Major NCs (n=5; 8.2%). Major NCs were primarily linked to the 2021 to 2022 period and involved critical failures in quality control monitoring and CAPA effectiveness.

Recurring Systemic Deficiencies

Three specific areas of the ISO 15189 standard accounted for the highest burden of non-compliance as shown in

table 1. Systemic deficiencies across the study period were primarily concentrated in three critical areas of the ISO 15189 standard. Challenges regarding document control and Standard Operating Procedures (SOPs) remained a persistent issue across all four years, with frequent findings related to version control lapses and overdue document reviews. Similarly, Corrective and Preventive Action (CAPA) management emerged as a significant weakness, characterized by a trend of "repeat non-conformances" where laboratories failed to execute effective root cause analyses, resulting in the recurrence of identical findings in consecutive audit cycles. These technical and management gaps were further exacerbated by personnel and training deficiencies, particularly during 2021, when acute staffing shortages directly correlated with a peak in missing competency records and significant gaps in staff training documentation.

Table 1: Distribution of NCs by ISO 15189

ISO 15189 Clause	Requirement Category	Total NCs (n=61)	% of Total
4.3	Document Control	14	22.9%
4.10	Corrective Action	11	18.0%
5.1	Personnel/Training	9	14.8%
4.15	Management Review	7	11.5%
5.3	Laboratory Equipment	6	9.8%

Internal Auditor Survey Insights

As shown in figure 2, the survey achieved a response rate from experienced auditors (44.4% with >10 years' experience). Auditors identified Staffing/Workload (85.7%) and Lack of Management Oversight (71.4%) as the primary root causes for recurring NCs. Furthermore, 75% (9 of 12 respondents) indicated that while Management Review Meetings (MRMs) were held, the action items were frequently not implemented, creating a "compliance gap" between planning and execution.

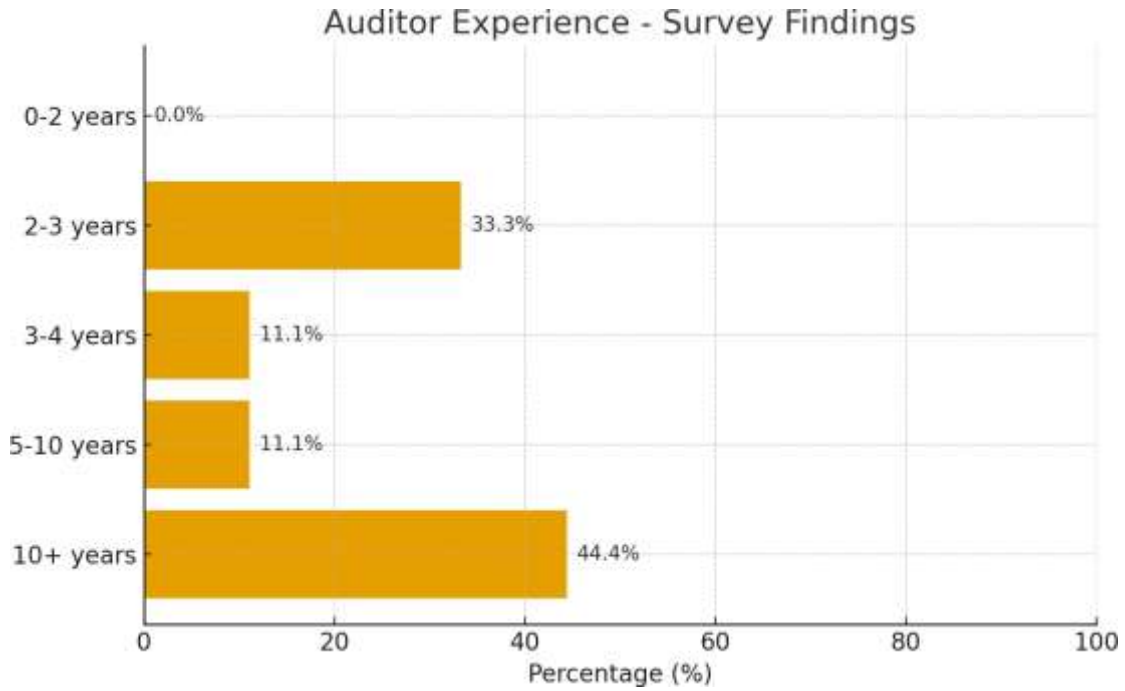

Figure 2: Survey findings on auditor experience among internal auditors in the Midlands BU

Discussion

Overview of Audit Trends (2020–2023)

Longitudinal analysis of audit data revealed a cyclical pattern of compliance. While 2020 served as a stable baseline, 2021 witnessed a significant spike in non-conformances (NCs), attributed to the operational strain of the COVID-19 pandemic. Despite the easing of pandemic pressures, high NC levels persisted into 2022, particularly in newly accredited facilities (Lab 5), confirming international findings

that first-time accreditation typically faces higher initial non-compliance (Alkhurayji et al., 2025). Although a partial recovery was observed in 2023, the recurrence of specific gaps suggests that improvements were reactive rather than systemic.

Triangulation of Systemic Factors

The convergence of audit records and internal auditor survey data identified four entrenched systemic challenges within the Quality Management System (QMS):

Weak Document Control: Inconsistent SOP reviews and unauthorized versioning were frequent. Survey data showed that 50% of auditors noted incomplete implementation of document requirements, mirroring national trends where document control remains a primary weakness in public laboratories (Tsheola and Kruger, 2022).

Ineffective CAPA Management: Corrective and Preventive Action (CAPA) systems were identified as a critical pinch point. Root cause analysis (RCA) was often superficial, citing "staff negligence" rather than systemic failure, leading to a failure in closing the loop on quality improvements (SANAS, 2022).

Training and Competency Gaps: Personnel-related NCs spiked during periods of high workload. The lack of structured mentorship and incomplete competency records poses a direct risk to both ISO 15189 compliance and patient safety.

Leadership and Oversight: A significant disconnect was identified between Management Review Meetings (MRMs) and operational implementation. 75% of auditors reported that MRM outputs were not translated into action, undermining the laboratory's ability to foster a sustainable quality culture (Ngubo 2021).

External Disruptions and Resilience

The study highlighted the vulnerability of the QMS to external shocks, and the COVID-19 pandemic plus other cyber security vulnerability. These events exposed a lack of redundancy in manual processes and highlighted the urgent need for digital infrastructure. The results suggest that laboratories focusing solely on "audit readiness" rather than operational resilience are more susceptible to compliance failure during crises.

Implications for Laboratory Practice

The findings suggest that the regional business unit of a national public laboratory service faces a risk in its accreditation status if repeat NCs are not addressed through system-based interventions. Moving forward, the adoption of the ISO 15189:2022 standard with its increased emphasis on risk-based thinking will require laboratories to shift from checklist compliance to prioritized, high-impact controls (ISO, 2022).

Study Limitations

This study was conducted within the regional business unit of a national public laboratory service, which may limit the generalizability of the findings to other units within the national public laboratory service. As operational structures, resource allocation, and management practices may differ across business units, the results should therefore be interpreted within the specific contextual framework of the Midlands region.

The study further relied on historical data, which may have introduced inaccuracies due to incomplete, inconsistent, or inadequately maintained records. Such limitations in documentation could potentially affect the reliability and comprehensiveness of the data analysed. In addition, the use of survey-based data introduces the possibility of recall bias and subjective interpretation by auditors, which may influence the accuracy of reported findings.

Finally, the study focused exclusively on non-compliances related to SANAS accreditation requirements and did not explore other quality performance indicators or associated clinical outcomes. Consequently, the findings may not fully capture the broader impact of quality management practices on overall laboratory performance or patient care outcomes.

Conclusion

Sustained compliance in this resource-constrained environment depends on maturing four interlocking domains: document control, RCA proficiency, competency management, and leadership accountability. Targeted interventions, such as mentored internal audits and the implementation of digital QMS dashboards, are recommended to transition from reactive compliance to a culture of continuous quality improvement.

Acknowledgement

The author expresses sincere gratitude to Professor Pakiso Moses Makhoahle for his invaluable mentorship and guidance throughout this study. Appreciation is extended to the University of the Free State Ethics Committee for providing ethical clearance

and to the National Health Laboratory Service (NHLS) Midlands Business Unit for granting access to the study data. Special thanks are also due to the internal auditors and colleagues at the NHLS for their participation and cooperation during the data collection process. Finally, the author thanks her husband and her sister for the unwavering support throughout the research and writing journey.

References

1. Akase, S. and Kpera, T., 2024. Ensuring accuracy, ensuring life; a crucial role of quality management systems in medical laboratories. *ScienceOpen Preprints*.
2. Akoma, F.V., Oritsebinone, E.I., Ochekwu, E.B., Ebibo, A.T., Selegha, A. and Oyemade, S.A., 2025. A review: personnel management in laboratory practices: challenges and strategies. *Frontline Professionals Journal*, *2*(7), pp.10-27.
3. Datema, T.A., Oskam, L., Broerse, J.E. and Klatser, P.R., 2020. Review of the stepwise laboratory quality improvement process towards accreditation (SLIPTA) version 2: 2015. *African Journal of Laboratory Medicine*, *9*(1), pp.1-7.
4. International Organization for Standardization (ISO), 2022. ISO 15189:2022 – Medical laboratories: Requirements for quality and competence. ISO. Available at: https://www.iso.org/standard/76677.html (Accessed: 1 February 2026).
5. ISOQAR Africa, 2025. Reporting non-conformances and the grading of findings. Available at: https://isoqar.co.za/reporting-non-conformances-and-the-grading-of-findings/ (Accessed: 6 March 2026).
6. National Health Laboratory Service (NHLS), 2026**.** *Diagnostic services.* Available at: https://www.nhls.ac.za/diagnostic-services/ (Accessed: 6 February 2026).
7. Odhiambo, C.O., Van Der Puije, B., Maina, M., Mekonen, T., Diallo, S., Datema, T., Loembe, M.M., Kebede, Y., Ndlovu, N. and Ondoa, P., 2023. Examining 7 years of implementing quality management systems in medical laboratories in sub-Saharan Africa. *Tropical Medicine & International Health*, *28*(2), pp.126-135.
8. Pandya, A., Wadhwa, M., Harshika, K. and Zafar, S., 2025. An integrated communication control system framework for hospital setting – A conceptual framework to streamline healthcare communication. *International Journal for Healthcare Quality, Patient Centeredness & Safety*, *6*(2), pp.59-65.
9. Pillai, S., Calvert, J. and Fox, E., 2022. Practical considerations for laboratories: Implementing a holistic quality management system. *Frontiers in Bioengineering and Biotechnology, 10*, pp. 1-9.
10. Plebani, M., 2007. Errors in laboratory medicine and patient safety: the road ahead. *Clinical Chemistry & Laboratory Medicine*, *45*(6), pp. 700-707.
11. Rodríguez-Pérez, J.P., 2022. *Handbook of investigation and effective CAPA systems*. Quality Press.
12. Sikaris, K.A., 2017. Enhancing the clinical value of medical laboratory testing. The Clinical Biochemist Reviews, 38(3), p.107.
13. South African National Accreditation System (SANAS), 2022. *SANAS Accreditation Toolkit (brochure).* SANAS. Available at: https://www.sanas.co.za/Brochures%20and%20Reports/SANAS%20Accreditation%20Toolkit.pdf (Accessed: 20 November 2025)
14. World Health Organization Regional Office for Africa, 2020. Guide for the stepwise laboratory improvement process towards accreditation in the African region (SLIPTA). WHO AFRO. Available at: https://apps.who.int/iris/bitstream/handle/10665/333129/9789290234418-eng.pdf (Accessed: 20 November 2025).