ASSESSMENT OF FACTORS THAT CONTRIBUTE TO NON-COMPLIANCE DURING SANAS AUDITS IN THE MIDLANDS BUSINESS UNIT FROM 2020 TO 2023

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DECLARATION

I, S'nenhlanhla Nonjabulo Zondi hereby declare that the dissertation entitled "Assessment of Factors That Contribute to Non-Compliance During SANAS Audits in the Midlands Business Unit from 2020 to 2023" submitted to the Central University of Technology, Free State; for the degree Master of Health Sciences in Biomedical Technology, is my own independent work and that it has not been previously submitted by myself or any other person in fulfilment (or partial fulfilment) of the requirements for the attainment of any qualification, for a degree at any other university. All sources used or quoted have been acknowledged and referenced according to the required academic conventions.

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Date: _____07 March 2026_____

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DEDICATION

I dedicate this work to my loving family, who have been my constant source of strength, joy, and inspiration.

To my husband, for his unwavering support, encouragement, and understanding during the long nights and busy days.

To my children, who have been the light of my life and a reminder of why perseverance matters. You are my greatest motivation and my greatest blessing.

To my parents and loved ones, who instilled in me the value of education, hard work, and resilience.

This dissertation is not only a reflection of my academic journey but also a testament to the love, faith, and sacrifice of those who walk beside me.

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ABSTRACT

Accreditation of medical laboratories is a critical requirement for ensuring quality, reliability, and compliance with international standards such as ISO 15189. In South Africa, the South African National Accreditation System (SANAS) evaluates laboratories to maintain standards of competence, accuracy, and patient safety. Despite accreditation, non-conformances (NCs) remain a recurring challenge during audits. This study assessed the factors contributing to non-compliance during SANAS audits in the National Health Laboratory Service (NHLS) Midlands Business Unit from 2020 to 2023.

A descriptive, retrospective, non-experimental quantitative research design was employed. The study population included all SANAS-accredited laboratories in the Midlands BU (N=7). Data were extracted from SANAS audit records, with a focus on NCs raised during the 2020–2023 period, and triangulated with perceptions from purposively selected internal auditors through an online survey. Descriptive statistics were used to analyse trends, and thematic grouping identified recurring NC categories.

Results showed that NCs fluctuated across the period, but persisted in core areas, including documentation and SOP management, training and competency assessment, corrective and preventive action (CAPA) monitoring, and weaknesses in management review meetings. Analytical and post-analytical deficiencies, such as equipment maintenance lapses, QC miscalculations, and inconsistent communication of critical results, were also noted. Survey findings reinforced these themes, with auditors reporting incomplete training records, delayed CAPA implementation, and systemic weaknesses in document control and accountability structures.

The study concludes that non-conformances during SANAS audits in the Midlands BU are driven by systemic quality management challenges compounded by human factors such as SOP non adherence. Strengthening CAPA processes, enhancing training and competency frameworks, embedding SOP discipline, and reinforcing management accountability are recommended to sustain ISO 15189 compliance.

Keywords: audits, ISO 15189, Midlands Business Unit, NHLS, non-conformances, quality management system, SANAS

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LIST OF ABBREVIATIONS

CAPA – Corrective and Preventive Action

CDCP – Centre for Disease Control and Prevention

CLSI – Clinical and Laboratory Standards Institute

EQA – External Quality Assessment

IFCC – International Federation of Clinical Chemistry and Laboratory Medicine

IQC – Internal Quality Control

ISO – International Organization for Standardization

MRM – Management Review Meeting

NC – Non-Conformance

NHLS – National Health Laboratory Service

PDCA – Plan–Do–Check–Act

POCT – Point-of-Care Testing

QMS – Quality Management System

RCA – Root Cause Analysis

SANAS – South African National Accreditation System

SLIPTA – Stepwise Laboratory Improvement Process Towards Accreditation

SOP – Standard Operating Procedure

TAT – Turnaround Time

WHO – World Health Organization

UFS – University of the Free State

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CHAPTER 1: INTRODUCTION

1.1 Background

South Africa has an estimated population of 60.6 million people (Dierks, 2026). Of this population, only 17.4% are covered by a medical scheme, which translates to approximately 9.5 million South Africans with access to private healthcare (Ellis, 2026). This is due to high unemployment and poverty rates in South Africa. The South African public healthcare system is primarily supported by the National Health Laboratory Service (NHLS). For over a decade, the NHLS has provided health laboratory services, conducted medical research, and offered training for health sciences education through a network of 265 laboratories across all nine provinces (NHLS, 2021).

In South Africa, laboratories are required to be accredited by the accreditation body known as South African National Accreditation System (SANAS) (Khadambi-Morokane et al., 2021). Established in 1999, SANAS conducts annual audits to evaluate the ongoing effectiveness of laboratories' Quality Management System (QMS) and their compliance with ISO 15189 (Datema, 2020). Laboratory accreditation is a formal process through which laboratories are evaluated to verify that they meet the requirements of a specific standard (Guzel and Guner, 2009). To achieve accreditation, laboratories must demonstrate the implementation of a comprehensive Quality Management System (QMS) and possess the technical competence necessary to produce accurate, reliable, and precise results (Akase and Kpera, 2024).

The International Organization for Standardization's ISO 15189 standard is recognised globally as the benchmark for medical laboratory quality and competence, while public health laboratories may also comply with ISO 17025 (de la Villa Porras, 2023; Sciacovelli et al., 2017a). All recognised accreditation bodies are part of the International Laboratory Accreditation Cooperation (ILAC), which ensures consistency in methods and processes when accrediting laboratories. Accreditation confirms that a laboratory's QMS meets international requirements and that its results are recognised and accepted globally (Groenheit et al., 2025). Laboratories that meet all requirements receive an accreditation certificate, which serves as formal recognition

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of quality and technical competence. Accreditation not only boosts confidence among patients, clinicians, and stakeholders but also assures them of the accuracy and reliability of laboratory testing (WHO, 2011a).

Furthermore, accreditation is widely recognised as a driver for health system improvement, enabling long term enhancements to quality systems, cost-effectiveness, and the sustainability of public health programmes (Zima, 2017). It ensures that laboratories maintain high standards of service delivery, positively influencing performance. Research by Sikaris (2017), shows that between 60% and 80% of clinical decisions depend on laboratory test results, highlighting the critical role of laboratory accuracy and reliability in effective patient care, particularly in resource limited settings. Reliable and actionable test results are essential to providing high-quality healthcare services.

Public health medical laboratories play a vital role in performing clinical pathology testing on patient samples to aid in diagnosis, treatment, and monitoring of disease (Olver et al., 2023). Given their influence on patient management, it is essential for these laboratories to comply with internationally recognised standards. ISO 15189, developed specifically for medical laboratories, outlines both management and technical requirements to ensure quality and competence (ISO, 2022). Other relevant standards include those from the Clinical and Laboratory Standards Institute, the Good Clinical Laboratory Practice (GCLP) guidelines, and World Health Organization (WHO) programme-specific standards (CLSI 2019; CLSI, 2020).

When SANAS audits identify gaps in compliance, these are recorded as non-conformances (NCs) and categorised by severity (Dhatt et al., 2005). Minor NCs have no impact on patient care, medium NCs indicate repeated issues without causing harm, and major NCs represent significant adverse impacts on patient outcomes, requiring immediate corrective action (Plebani, 2014; NHLS, 2025b).

The NHLS provides diagnostic services to approximately 80% of the South African population through a network of laboratories distributed across all nine provinces (NHLS, 2026). These laboratories encompass disciplines such as Clinical Microbiology and Infectious Diseases, Chemistry, Haematology, Histology, Cytology,

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Virology, Genetics, and Immunology (NHLS, 2026). In the Midlands Business Unit, there are seven SANAS accredited laboratories.

This study aims to investigate the factors contributing to non-compliance during SANAS audits in the Midlands Business Unit between 2020 and 2023. By identifying and addressing these factors, the study seeks to support continuous quality improvement, ensuring that laboratories consistently produce accurate and reliable results. The findings will also contribute to the limited body of research on SANAS audit compliance in the South African public health sector.

1.2 Problem Statement

Although all seven laboratories in the Midlands Business Unit are SANAS accredited, audit records from 2020 to 2023 reveal that NCs are still being raised during external and internal audits. These NCs threaten the reliability of laboratory outputs and raise concerns regarding adherence to ISO 15189 standards. There is a need to identify and understand the underlying causes of these non-compliances to ensure corrective and preventive actions are implemented. This study will fill this gap by quantifying NCs, analysing trends, and collecting internal auditor insights to map contributory factors to non-compliance.

1.3 Purpose of the Study

The purpose of this study is to assess the factors contributing to non-compliance during SANAS audits in the NHLS Midlands Business Unit from 2020 to 2023.

1.4 Research Questions

- What are the factors contributing to non-conformances raised during SANAS audits?
- Which departments are the most frequently associated with non-compliances?
- What are the recurring types and severities of NCs?
- What practices or systems support successful compliance and can be leveraged for improvement?

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1.5 Objectives

- To determine the factors contributing to raised NCs in the laboratories.
- To identify frequent NCs across all laboratories.
- To identify which department contributes the highest number of NCs.
- To identify positive factors that facilitate compliance and can be leveraged for improvement.

1.6 Significance of the Study

This study will contribute to improving quality management systems in public laboratories by identifying recurrent issues and enablers of compliance. The findings will provide data-driven recommendations to reduce non-conformances, thereby supporting accurate and reliable diagnostic services in resource constrained environments. Furthermore, it will enhance internal audit processes and strengthen the NHLS's ability to sustain ISO 15189 compliance.

1.7 Scope and Delimitations

The study is limited to SANAS-accredited laboratories within the Midlands Business Unit of the NHLS during the 2020–2023 period. It does not include laboratories outside the Midlands Unit or those without SANAS accreditation. The study focuses on audit-related data and survey responses from internal auditors, excluding patient data and other clinical performance metrics.

1.8 Operational Definitions

- Non-conformance (NC): Any deviation from ISO 15189 requirements or internal quality standards identified during an audit.
- SANAS Audit: An external quality audit conducted by SANAS to assess laboratory compliance with accreditation standards.
- ISO 15189: The international standard that outlines the requirements for quality and competence in medical laboratories.
- Internal Auditor: A trained staff member who conducts internal audits to assess quality system compliance before external assessments.

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1.9 Chapter Summary

This chapter introduced the context of medical laboratory accreditation in South Africa and the importance of compliance with ISO 15189. It presented the problem of ongoing non-conformances despite SANAS accreditation, and outlined the study's purpose, research questions, objectives, and significance. The next chapter will review existing literature relevant to laboratory accreditation and non-compliance.

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CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter reviews relevant literature on medical laboratory accreditation, the ISO 15189 framework, the importance of quality management systems (QMS), and the factors that contribute to non-compliance during accreditation audits. It further explores the role of internal audits, the impact of non-conformances, and both global and local challenges experienced in achieving and maintaining accreditation in public health laboratories. The discussion integrates international perspectives with a focus on the South African context, particularly in relation to the South African National Accreditation System (SANAS) and National Health Laboratory Service (NHLS) facilities.

2.2 Theoretical Framework

The Quality Management System (QMS) framework, which integrates technical competence, management responsibility, and risk-based quality assurance to guarantee the accuracy and dependability of laboratory results, is the foundation of this study. It is required for medical laboratories to be accredited in accordance with standards created by the International Organization for Standardisation (ISO), specifically ISO 15189 (Plebani et al., 2015). Implementing a QMS offers an organised method for handling documentation, employee competency, equipment maintenance, process validation, occurrence management, and continuous improvement in licensed laboratory settings. Recognising that laboratory quality failures may have serious clinical and public health repercussions, these components work together to reduce mistakes and improve patient safety outcomes (Plebani, 2007). Within the South African context, compliance with accreditation requirements monitored by the South African National Accreditation System (SANAS) requires of laboratories to demonstrate sustained adherence to both managerial and technical clauses, making QMS maturity a critical determinant of audit performance (Tsheola, 2022).

In order to assess and resolve non-compliance in clinical laboratories, the QMS framework places a strong emphasis on evidence driven decision-making, leadership responsibility, risk-based thinking, and continuous improvement (Owino, 2023). In

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laboratory workflows, risk-based thinking promotes the proactive identification of vulnerabilities, such as deficiencies in equipment performance monitoring, documentation control, training, and internal auditing procedures, all of which are commonly linked to audit non-conformances (Qamar et al., 2024). Akase and Kpera (2024) confirm that laboratories with strong quality cultures exhibit better execution of remedial actions and lower recurrence of findings, indicating that organisational culture, communication frameworks, and staff participation are crucial in maintaining compliance (Akase and Kpera., 2024).

Embedded within ISO 15189 is the Plan–Do–Check–Act (PDCA) cycle, which serves as a conceptual lens for understanding patterns of non-conformance and quality improvement responses across laboratory departments (Akase and Kpera, 2024). Firstly, the “Plan” phase involves risk assessment and establishment of quality objectives aligned with accreditation requirements. Secondly, the “Do” phase focuses on the implementation of standard operating procedures and competency-based practices. Thirdly, the “Check” phase evaluates performance through internal audits, quality indicators, and management reviews. Lastly, the “Act” phase drives corrective and preventive actions to eliminate root causes of identified deficiencies. This cyclical approach ensures that identified gaps are systematically addressed, monitored, and re-evaluated to prevent recurrence and promote organisational learning.

Within large public laboratory networks such as the NHLS, Owin clearly showed that the PDCA framework is particularly relevant due to the complexity of multi-disciplinary departments operating under shared governance structures (Owino, 2023). While Vijayanti and colleagues warned that variability in staffing levels, workload pressures, resource allocation, and adherence to standardised procedures may influence audit outcomes across business units (Vijayanti et al., 2025). Applying the QMS and PDCA principles therefore provides an appropriate theoretical foundation for analysing the root causes, frequency, and distribution of non-conformances in the Midlands Business Unit between 2020 and 2023, while also identifying positive compliance practices that can be leveraged to strengthen quality performance and sustain accreditation status.

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2.3 Quality Management Systems (QMS) in Medical Laboratories

A QMS is a structured framework of policies, processes, and procedures designed to ensure that an organisation consistently delivers services that meet both customer requirements and regulatory standards (WHO, 2019). Within the context of medical laboratories, the QMS aligns with the principles of ISO 15189:2022, which integrates management requirements with technical competence to guarantee reliable and accurate patient results.

As aforementioned, QMS encompasses all aspects of laboratory operations, including personnel competence, equipment management, document control, records management, internal audits, occurrence management, and continual improvement. Furthermore, Asif and Qwidai echo that QMS functions as a holistic system that not only ensures compliance with accreditation standards, but also fosters a culture of accountability and patient-centred service delivery (Asif and Qwidai, 2026).

2.3.1 Core Principles of a Laboratory QMS

Adekoya reports that a QMS is founded on several interrelated principles that collectively ensure the delivery of reliable and clinically relevant laboratory services (Adekoya et al., 2025). Central to the system is customer focus, which prioritises the production of accurate and timely laboratory results that meet the needs of patients, clinicians, and other healthcare stakeholders (Akase and Kpera, 2024). In support of this objective, Mekonnen showed that leadership and governance play a critical role, as laboratory management is responsible for establishing quality policies, ensuring impartiality, and allocating adequate resources to sustain compliance and operational effectiveness (Mekonnen, 2004). Furthermore, the QMS adopts a process approach, whereby all laboratory activities from specimen collection and handling to analysis and result reporting are managed as interconnected processes that collectively influence the quality of outputs (Pillai and Fox, 2025).

In addition, Mammadov indicated that risk-based thinking enables laboratories to proactively identify, assess, and mitigate risks that may compromise analytical accuracy, operational efficiency, or patient safety (Mammadov, 2025). Decision-making within this framework is strengthened through evidence-based practices, where data generated from internal audits, quality indicators, incident reports, and

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corrective or preventive action trends guide strategic and operational improvements. These principles converge to support continuous improvement, which is facilitated through structured quality tools such as the PDCA cycle (Gomaa, 2025). This iterative approach promotes ongoing monitoring, evaluation, and refinement of laboratory practices, thereby enhancing compliance, reducing recurrence of non-conformances, and sustaining overall quality performance.

2.3.2 Relevance to ISO 15189 and SANAS Accreditation

Under ISO 15189:2022, QMS serves as a fundamental framework for governance and technical competence in medical laboratories, ensuring accurate and reliable diagnostic results (Tembo et al., 2026). In South Africa, SANAS applies these standards through audits assessing governance, risk management, and patient confidentiality. The most recent update emphasises risk-based thinking by mandating that labs recognise and reduce risks in order to keep their accreditation (Pereira, 2023).

Personnel competence is crucial, necessitating evidence of qualifications and ongoing development, while document control systems must ensure compliance with approved procedures (Guzel and Guner, 2009). Corrective action management and root cause analysis (RCA) are vital for addressing systematic issues rather than attributing failures to individual error. In addition, ISO 15189 fosters continual improvement through structured audits and performance monitoring, with well-performing laboratories showing reduced non-conformances (NCs) (Nah et al., 2017). Assessing weaknesses in QMS implementation is essential for understanding SANAS audit findings, allowing for the identification of compliance drivers and the adoption of effective practices to enhance quality governance.

2.3.3 Role in the NHLS Context

For the NHLS, a robust QMS is especially critical due to the scale of operations, high patient volumes, and resource constraints. The NHLS operates a network of more than 260 laboratories throughout South Africa that process more than 114 million diagnostic tests annually, serving over 80% of the country's population. This highlights the importance of systematic quality management in ensuring consistent, accurate, and reliable results at scale (Enterprise Africa, 2025). Standardised QMS practices

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across laboratories ensure consistency, comparability of results, and resilience against errors. Unresolved risks and persistent process vulnerabilities are exacerbated by incomplete or delayed CAPA deployment. Management Review Meetings (MRMs) are sometimes carried out to assess the overall effectiveness of QMS (Rodriguez-Perez, 2022).

While the QMS provides the overarching framework for ensuring quality and competence in medical laboratories, its practical implementation is best understood through the Quality System Essentials (QSEs) (Pillai et al., 2022). The QSEs translate the principles of ISO 15189 into twelve interconnected components that cover every aspect of laboratory operations, from leadership and personnel to safety and continual improvement. This structure not only guides laboratory practice, but also forms the basis on which SANAS auditors assess compliance (Plebani and Sciacovelli, 2017). Understanding the QSEs is therefore critical for analysing audit outcomes and interpreting the root causes of non-conformances in the Midlands business unit.

2.4 Quality System Essentials (QSEs)

2.4.1 Organization and Management

This essential establishes the governance structure, leadership, authority, and accountability within the laboratory. ISO 15189:2022 emphasises that management must demonstrate commitment to quality, provide adequate resources, and establish clear roles and responsibilities (ISO, 2022). Strong leadership ensures that quality objectives are communicated and integrated into daily practice. In South African public health laboratories, management oversight has been critical in addressing systemic challenges such as staff shortages and equipment procurement delays (SANAS, 2022).

2.4.2 Personnel

The personnel essential is foundational to ensuring laboratory competence and impartiality. ISO 15189:2022 requires policies for training, supervision, competence assessment, and continuing professional development (ISO, 2022). In South Africa, the Health Professions Council of South Africa (HPCSA) enforces CPD compliance as a requirement for medical technologists, aligning with this QSE (HPCSA, 2022). Non-

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conformances often arise from incomplete CPD records or unsigned confidentiality agreements, as observed during SANAS audits (SANAS, 2022).

2.4.3 Equipment

Equipment management covers procurement, calibration, maintenance, and decommissioning. ISO 15189 requires evidence that instruments are validated, calibrated, and fit for purpose (ISO, 2022). Equipment failures or overdue maintenance can result in inaccurate test results. SANAS audit reports frequently cite missing calibration certificates, inadequate maintenance logs, or delayed service contracts as sources of NCs (SANAS, 2022).

2.4.4 Purchasing and Inventory

This QSE ensures timely procurement of reagents, kits, and consumables. Laboratories must implement robust inventory management systems to prevent stock-outs, expired reagents, or unreliable suppliers (WHO, 2011a). SANAS audits often highlight gaps in inventory monitoring, with expired reagents contributing to compromised patient results. Effective inventory systems enhance continuity of service delivery (Pillai et al., 2022SANAS, 2022).

2.4.5 Process Control

Process control ensures test accuracy and reliability through validated SOPs, specimen handling, QC, and EQA. ISO 15189 mandates rigorous process validation and adherence to SOPs (ISO, 2022). SANAS frequently identifies NCs in this area where SOPs are outdated or not followed. For example, incomplete verification studies or inconsistent QC chart reviews weaken confidence in laboratory results.

2.4.6 Information Management

Information management addresses data integrity, confidentiality, and traceability. Laboratories are required to maintain secure and reliable laboratory information systems (ISO, 2022). Breaches such as the NHLS 2023 cyberattack expose vulnerabilities in this area. Common NCs include poor record traceability, inadequate LIS validation, and failure to protect patient confidentiality (WHO, 2011c).

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2.4.7 Documents and Records

This essential ensures proper document control, accessibility, and archiving. Laboratories must establish a document control system that tracks revisions, approvals, and distribution (ISO, 2022). SANAS audits frequently highlight unsigned temperature logs, outdated SOPs, or misfiled records. Such findings emphasise the role of documentation in demonstrating compliance and traceability (SANAS, 2022).

2.4.8 Occurrence Management

Occurrence management includes error reporting, NC documentation, complaint handling, and root cause analysis. ISO 22367:2020 highlights the importance of risk management in addressing NCs (ISO, 2020). Weak RCA and CAPA processes often result in repeat NCs, undermining continuous improvement (SANAS, 2022). Strengthening this area ensures that lessons are learned and systemic gaps are closed.

2.4.9 Assessment

Assessment covers internal audits, external audits, and management review meetings (MRMs). These processes provide a structured mechanism for monitoring compliance and identifying gaps (ISO, 2022). SANAS requires of laboratories to conduct regular internal audits and MRMs, while SANAS external audits serve as independent evaluations (SANAS, 2022). Repeated NCs highlight the need for more rigorous follow-up and management accountability.

2.4.10 Process Improvement

Process improvement involves corrective actions, preventive actions, benchmarking, and innovation. Laboratories are expected to identify opportunities for quality enhancement beyond immediate compliance (Akase and Kpera, 2024). This proactive approach ensures sustainability of accreditation and prevents recurrence of NCs.

2.4.11 Customer Service

Customer service addresses clinician needs, turnaround time, and effective communication. Although often overlooked, ISO 15189 emphasises that laboratories must engage with service users to ensure satisfaction (ISO, 2022). Poor

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communication or delayed results can erode trust and lead to complaints. Strengthening these essential supports patient cantered care.

2.4.12 Facilities and Safety

Facilities and safety cover infrastructure suitability, biosafety, and occupational safety. ISO 15190 provides detailed guidelines in this domain (ISO, 2020). SANAS audits frequently highlight inadequate storage conditions, poor biosafety practices, or incomplete safety training records. Strengthening safety culture is essential for both staff wellbeing and audit compliance.

2.4.13 Integration into the Study

Understanding the QSEs is crucial for interpreting non-conformances raised in SANAS audits. Each NC observed in the Midlands business unit can be mapped to one or more of these essentials, providing a systematic lens to analyse root causes and identify areas for improvement. By aligning audit findings with QSEs, this study not only contextualises observed trends, but also highlights areas for targeted quality improvement across laboratories.

2.5 Overview of SANAS Accreditation and ISO 15189

Accreditation of medical laboratories is an essential process that ensures the reliability, accuracy, and comparability of test results across different settings (Peter et al., 2010). The international standard ISO 15189:2022 titled, ‘Medical Laboratories Requirements for Quality and Competence’ provides the benchmark for medical laboratory accreditation worldwide (ISO, 2022). It integrates both management and technical requirements, with a strong emphasis on risk management, impartiality, continual improvement, and patient-centred care. Laboratories accredited to ISO 15189 are expected to demonstrate competence, generate valid results, and operate within a structured quality management system. In South Africa, the South African National Accreditation System (SANAS) is the sole national accreditation body, established in terms of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (Act No. 19 of 2006). SANAS operates under the Department of Trade, Industry and Competition (the DTIC) and has the statutory

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mandate to accredit laboratories, certification bodies, and inspection bodies (Peet and MacCurtain, 1997).

For medical laboratories, SANAS is responsible for assessing compliance with ISO 15189 and awarding accreditation where standards are met. Importantly, SANAS is a full member of both the International Laboratory Accreditation Cooperation (ILAC) and the African Accreditation Cooperation (AFRAC), which ensures that SANAS-accredited laboratories in South Africa are recognised internationally (Khadambi-Morokane et al., 2021). This global recognition enhances trust in laboratory results, facilitates cross-border patient care, and strengthens South Africa's participation in international health programs. A key mechanism by which SANAS enforces compliance is through its suite of policy documents (P-documents) and requirements documents (R-documents), which provide laboratories with guidance on implementation (SANAS, 2015).

For instance, SANAS R-03 outlines the requirements for the accreditation of laboratories, detailing how ISO 15189 should be interpreted and applied within the South African context. In addition, SANAS P-32 provides the transition policy for ISO 15189:2022, clearly specifying the timelines and expectations for laboratories migrating from the 2012 to the 2022 version of the standard. SANAS P-10 further governs the use of the SANAS accreditation symbol, ensuring that laboratories apply the accreditation mark correctly and consistently in reports and certificates. Moreover, SANAS TR 81-04 sets out specific technical requirements for medical laboratories, with particular emphasis on traceability of calibrations, the use of reference materials, and equipment verification.

The revision of ISO 15189:2022 has introduced several new requirements that laboratories must integrate into their systems. These include alignment with ISO/IEC 17025:2017, an enhanced focus on risk-based thinking and patient safety, and the incorporation of requirements for point-of-care testing (POCT) that were previously covered under ISO 22870 (HCI, 2022). This revision places greater responsibility on laboratories not only to detect errors, but to identify risks to patient outcomes and implement preventive controls proactively.

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For NHLS laboratories, including those in the Midlands Business Unit, SANAS accreditation has both operational and reputational implications. Accreditation assures clinicians and patients that test results are valid, reliable, and fit for clinical decision-making (Al-Worafi, 2024). It also signals compliance with national regulations and international best practice, enhancing the credibility of the NHLS as the primary provider of public sector laboratory services in South Africa. However, achieving and maintaining SANAS accreditation requires significant investments in infrastructure, human resources, and continuous quality improvement. Laboratories are expected to demonstrate not only technical competence, but also robust documentation, impartiality safeguards, and evidence of continual improvement through regular internal audits and management reviews (Kaur et al., 2025).

Overall, SANAS accreditation is more than a technical compliance exercise. It represents a structured approach to quality that reinforces accountability, transparency, and patient-centred laboratory practice (Groenheit et al., 2025). Yet, sustaining compliance remains a challenge, particularly in resource-constrained environments such as the public sector, where high staff turnover, equipment downtime, and funding limitations can undermine the stability of quality management systems.

2.6 Categories and Grading of Non-Conformances

During SANAS accreditation audits, non-conformances (NCs) are raised when a laboratory fails to comply with specific requirements of ISO 15189 or SANAS policy documents (Khadambi-Morokane et al., 2021). Non-conformances highlight weaknesses in the laboratory's quality management system or technical processes and must be corrected before accreditation can be granted or maintained. SANAS categorises NCs into major, minor, and observations (opportunities for improvement), with each category carrying different implications for laboratories (Dhatt et al., 2005).

A major NC represents a serious failure that compromises the validity of laboratory results, undermines confidence in the management system, or poses a direct risk to patient safety (Tsheola, 2022). Examples include the absence of critical QMS components, repeated failures in EQA participation, or falsified records. SANAS requires urgent corrective action, and failure to close such NCs may result in

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suspension or withdrawal of accreditation. However, a minor NC is less severe, but still reflects weaknesses in compliance, often involving isolated incidents or documentation issues such as outdated SOPs or incomplete training records (ISOQAR Africa, 2025). SANAS requires corrective action within 30 days, and repeated minor NCs may escalate to major.

Lastly, observations highlight areas for potential improvement without formal non-conformance status. While optional, unaddressed opportunities for improvement (OFIs) often evolve into NCs in future audits (Bharathan, 2025). SANAS requires of laboratories not only to correct NCs, but also to provide evidence of root cause analysis (RCA), preventive measures, and verification of CAPA effectiveness. Failure to comply results in consequences such as additional audits, suspension, or withdrawal of accreditation.

2.7 Common Areas of Non-Compliance in South African Laboratories

Audit findings from SANAS and NHLS internal assessments reveal recurring non-compliance patterns across the pre-analytical, analytical, and post-analytical phases, as well as systemic QSEs (Tsheola and Kruger, 2022).

Firstly, in the pre-analytical phase, common NCs include incomplete request forms, inadequate specimen labelling, and improper transport protocols (Alcantara et al., 2022; Nordin et al., 2024). These indicate gaps in staff training and documentation. Post the preanalytical phase comes the analytical phase. In this phase, the frequent issues involve poor calibration and maintenance records, expired reagents, SOP deviations, and incomplete IQC logs (Westgard et al., 2018; Hawkins, 2012). These undermine result validity and attract major NCs. The last phase is the post-analytical phase. NCs here include delayed report release, transcription errors, and inconsistent retention of QC and patient records (Moore, 2025).

Quality System Essentials (QSEs) frequently present systemic weaknesses that undermine sustained accreditation compliance. In particular, deficiencies are commonly identified in document control, personnel competence, internal audits, and corrective and preventive action (CAPA) processes. These elements form the structural foundation of a laboratory quality management system. Therefore,

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weaknesses within them tend to have far-reaching implications across multiple operational areas. Supporting this observation, a Gauteng study reported that 57.6% of NCs originated from QSE-related gaps rather than from purely technical processes (Tsheola et al., 2024). Similarly, these systemic deficiencies reflect patterns observed within the Midlands Business Unit, where resource constraints, high staff turnover, and lapses in documentation further compound compliance challenges (NHLS, 2024). Collectively, this evidence suggests that strengthening core QSE components is critical to reducing recurrent non-conformances and promoting sustainable quality improvement.

2.8 ISO 15189 Implementation Challenges

Implementation of ISO 15189 poses significant challenges, particularly in resource constrained environments such as many public-sector laboratories in Africa. A Ghanaian public health laboratory navigating ISO 15189 accreditation identified major obstacles including inadequate documentation, laboratory safety measures, insufficient management support, and reagent shortages (Attoh et al., 2022). Notably, personnel attrition, workload pressures, and unclear understanding of accreditation requirements also impeded progress.

Systematic reviews of QMS implementation in LMICs highlights that preparing for change, ensuring resource availability, and strong project management are fundamental. Across 32 studies covering 280 laboratories, the most frequently cited key success factors (KSFs) were mentorship (84% of labs) and adequately trained staff (81%), with institutional commitment identified as the foundational driver of QMS implementation success (Tanasiichuk et al., 2023).

Reflecting broader challenges, a Ghanaian Pathology Division's journey to accreditation further highlighted the importance of leadership engagement and technical assistance (Stalsberg et al., 2008). Recommendations emphasised the necessity of national-level strategic direction, consistent laboratory management support, and structured mentorship and training systems to bolster QMS efforts (Attoh et al., 2022).

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Beyond Africa, a review of QMS outcomes in healthcare institutions revealed that accreditation programs lead to quality improvements by enabling better resource utilisation, process optimisation, and error reduction (Adekoya et al., 2025). This highlights that, while accreditation poses implementation difficulties, it also fosters systemic quality improvements when executed effectively (Al-Worafi, 2024).

2.9 Accreditation and Patient Safety

ISO 15189 accreditation aligns closely with patient safety priorities by embedding stringent quality and competence standards in medical laboratories. The 2022 revision of the standard emphasises risk-based, patient-centred approaches and continuous improvement, with provisions integrated directly into laboratory QMS frameworks to minimise risks to patient safety (Kao, 2025).

The revised requirements introduced in the 2022 edition of International Organization for Standardization ISO 15189 reflect a shift towards a more integrated and risk-based quality management approach within medical laboratories (Akase and Kpera, 2024). Key updates include the formal incorporation of point-of-care testing (POCT) into the accreditation framework, recognising the expanding role of decentralised testing and the need to ensure equivalent quality oversight across all testing environments (Linko et al., 2025). The revision also places greater emphasis on structured risk management practices aligned with ISO 22367 principles, requiring laboratories to proactively identify, evaluate, and mitigate risks that may affect patient safety and examination reliability (David, 2022). In addition, strengthened requirements relating to equipment lifecycle management, document and record control, and measurement accuracy were introduced to enhance traceability, standardisation, and analytical reliability (Thelen et al., 2019). Collectively, these changes aim to promote safer and more dependable laboratory services through improved governance, operational consistency, and continual quality improvement (Akase and Kpera, 2024).

ISO 15189 also addresses sample handling and pre-examination processes, establishing strict criteria for sample integrity, traceability, and reporting in cases of compromised specimens which directly influences patient safety protocols and clinical decision-making quality (Bogusz and Hassan, 2011).

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Even earlier versions of the standard recognised the role of accreditation in reducing laboratory errors across the testing phases. It promoted systems-based improvements over individual responsibility, emphasising that most errors stem from flawed processes rather than staff fault (Zima, 2017). By fostering performance improvement strategies across the total testing process, ISO accreditation supports error reduction and improved outcomes for patients (Serteser et al., 2012).

2.10 Role of Internal Audits

Internal audits are mandated by ISO 15189:2022 (Clause 4.14) and serve as proactive mechanisms to identify weaknesses before SANAS assessments (Tsheola, 2022). They must cover all QMS elements annually, be performed by competent and objective auditors, and result in documented CAPAs verified for effectiveness.

In NHLS laboratories, internal audits identify weaknesses in calibration traceability, staff competence, and QC processes (Tsheola et al., 2024). They enhance accountability by ensuring that findings are escalated and addressed before external audits. However, challenges include auditor skill gaps, inconsistent documentation, inadequate follow-up, and resource constraints that limit audit depth (Freya, 2024). SANAS emphasises that internal audits should not be checklist exercises but should generate meaningful insights that feed into management reviews (Clause 4.15). Failure to demonstrate robust internal audit processes often results in SANAS raising NCs against the audit programme itself.

2.11 Factors Contributing to Non-Compliance

This chapter reviews key factors that contribute to non-compliance in medical laboratories, with a focus on their relationship to non-conformances (NCs) observed during SANAS audits. These factors are consistently highlighted in the literature as systemic weaknesses, rather than isolated technical errors. The following subsections expand on human, organisational, and resource-related issues that directly undermine ISO 15189 compliance.

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2.11.1 Human Resources: Training and Competency

Gaps personnel are appropriately trained, assessed for competency, and supported through continual professional development (CPD) (ISO, 2022). Staff competence is central to ISO 15189, which requires of laboratories to ensure that personnel are appropriately trained, assessed for competency, and supported through continual professional development (CPD) (ISO, 2022). Inadequate training records, incomplete competency assessments, and lack of refresher training are frequent NCs reported in SANAS audits. High staff turnover compounds this challenge, leaving laboratories with skill gaps and overburdened teams (Akoma et al., 2025).

Furthermore, poor training of laboratory personnel contribute to errors in QC interpretation, incorrect use of SOPs, and inconsistent application of CAPA processes (Fan and Wang, 2021). This is significant, because such deficiencies directly compromise the reliability and validity of laboratory results, increase the likelihood of non-conformances during audits, and weaken the overall effectiveness of the QMS. Studies in South Africa and other LMICs show that targeted training and mentoring programmes reduce audit findings and strengthen compliance (Yao et al., 2010).

Table 1: Mapping of Human Resources gaps to SANAS non-conformances

HR Gap	Practical Consequence	Typical NC Category
Incomplete training records	Staff not assessed for competence	Training & competency
High staff turnover	Skill gaps, overburdened teams	Resource/HR management
Lack of CPD	Outdated skills, errors in QC	Competency assessment

2.11.2 Documentation Gaps

Documentation underpins every element of the QMS. ISO 15189 requires of laboratories to maintain controlled documents that are regularly reviewed, updated, and accessible to staff (Mtotela, 2020). However, uncontrolled SOPs, missing revision histories, and inconsistent QC records are among the most common NCs in SANAS audits (Tsheola, 2022). In addition, documentation failures weaken traceability, create inconsistencies in testing processes, and increase the likelihood of repeat errors.

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Globally, documentation lapses are identified as one of the top contributors to NCs (Parikh and Rupani, 2025). Therefore, digital document control and scheduled reviews are key strategies to mitigate these risks.

Table 2: Mapping of Documentation Gaps to SANAS non-conformances

Documentation Gap	Practical Consequence	Typical NC Category
Outdated/obsolete SOPs	Staff follow wrong procedures	Document control
Missing revision histories	No traceability of updates	Document control
Inconsistent QC records	Cannot verify compliance	Analytical records

2.11.3 Ineffective CAPA

Corrective and Preventive Action (CAPA) processes are designed to address root causes of errors, prevent recurrence, and demonstrate continuous improvement (Arunagiri et al., 2024). However, ineffective CAPAs that are closed without verification fail to address underlying causes, or are repeatedly delayed, remain a persistent source of NCs (WHO, 2020). Repeat findings across audit cycles often indicate weak CAPA systems, where issues recur with no lasting resolution (Rodriguez-Perez, 2022). Root Cause Analysis tools such as fishbone diagrams and 5-Whys are often underutilised. Embedding CAPA as a genuine learning process with effectiveness checks is critical for sustained ISO 15189 compliance.

Table 3: Mapping ineffective CAPA gaps to SANAS non-conformances

CAPA Weakness	Practical Consequence	Typical NC Category
CAPA closed without verification	Same issue repeats	CAPA monitoring
Superficial root cause analysis	Underlying issues persist	Occurrence management
Delayed CAPA closure	Risks unresolved	Corrective action

2.11.4 Cultural Challenges: Quality Culture and Staff Morale

Organisational culture strongly influences QMS performance. Laboratories with poor morale, resistance to change, and lack of accountability are prone to NCs even when technical resources are available (Schneidman et al., 2014). Staff who view audits as

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punitive may avoid reporting errors, reducing the effectiveness of CAPA and MRMs (Rodriguez-Perez, 2022). Conversely, laboratories that cultivate a positive quality culture with leadership commitment, open communication, and recognition of staff contributions are more likely to sustain accreditation (Yao et al., 2010).

Table 4: Mapping of Cultural Challenges gaps to SANAS non-conformances

Cultural Barrier	Practical Consequence	Typical NC Category
Low staff morale	Poor engagement with QMS	Management responsibility
Resistance to change	SOPs and CAPAs ignored	Continual improvement
Fear of reporting errors	Issues hidden from audits	Occurrence reporting

2.11.5 Communication and Collaboration in Medical Laboratories and Their Relationship to Non-Conformances

This section reviews evidence on how communication and collaboration within and around medical laboratories influence Quality Management System (QMS) performance and non-conformances (NCs) identified during accreditation audits. The discussion aligns with ISO 15189's emphasis on clearly defined responsibilities, controlled documents, effective result communication, competence, occurrence management, and management review (ISO, 2022), and considers lessons from WHO's Laboratory Quality Management System (LQMS) guidance and related programmes.

2.11.5.1 Definitions and Scope

In this review, communication refers to the timely, accurate, and complete exchange of information needed to perform and verify testing activities across the total testing process (pre-analytical, analytical, and post-analytical). Collaboration refers to coordinated, cross-functional work among laboratory staff (technologists, quality officers, supervisors, pathologists) and with external stakeholders (clinicians, couriers, programme managers, suppliers, and accrediting bodies) (Alruways et al., 2025). Effective communication and collaboration are foundational to a functioning QMS and are repeatedly implicated positively or negatively in audit outcomes.

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2.11.5.2 Communication Across the Total Testing Process

Effective communication across the total testing process is essential to maintaining quality, patient safety, and operational continuity within medical laboratories (Carter, 2023). During the pre-analytical phase, communication systems must ensure that test requests are clear, legible, and supported by complete patient and specimen identifiers to prevent misidentification errors. Standardised specimen collection and transport instructions should be agreed upon between laboratories and clinical areas to minimise pre-analytical variability. Structured handover protocols between wards or clinics, courier services, and laboratory accessioning personnel are equally important to maintain specimen integrity and traceability. In addition, laboratories should implement feedback mechanisms that communicate specimen rejection criteria and pre-analytical errors to submitting healthcare providers, thereby promoting corrective action and continuous improvement (Hawkins, 2012).

Within the analytical phase, communication plays a critical role in sustaining testing reliability and workflow efficiency. Shift handovers must include comprehensive documentation of outstanding equipment maintenance activities, quality control (QC) performance status, pending repeat analyses, and instrument alerts to ensure continuity between personnel (Hawkins, 2012). Clearly defined escalation pathways are required for QC failures and troubleshooting processes to enable timely corrective actions and prevent the reporting of unreliable results. Laboratory staff should also have real-time access to controlled standard operating procedures (SOPs) and documented change notifications to ensure consistent adherence to approved methods. Effective interdepartmental communication is particularly important when laboratory sections share equipment, utilities, or laboratory information systems, as service disruptions or system outages may affect multiple testing areas simultaneously (FasterCapital, 2025).

During the post-analytical phase, structured communication processes support accurate result reporting and clinical decision-making. Verification and authorisation workflows must be clearly defined to ensure that only validated results are released. Critical or alert results require documented read-back procedures and time-stamped communication with clinicians to confirm receipt and reduce the risk of delayed patient management (Hawkins, 2012). Laboratories should also maintain transparent

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processes for issuing amended or corrected reports when errors are identified after release. Furthermore, feedback mechanisms that facilitate interpretive discussions and responses to clinical queries enhance collaboration between laboratory professionals and healthcare providers, supporting improved patient outcomes and service quality (Adekoya et al., 2025).

2.11.5.3 Collaboration Mechanisms Embedded in the QMS

ISO 15189 requires strong leadership commitment, clearly defined roles and responsibilities, personnel competence, and coordinated planning to ensure the effective functioning of the laboratory quality management system (Akase and Kpera, 2024). Within this framework, collaboration serves as a key mechanism through which these requirements are operationalised in routine laboratory practice. Structured collaborative processes facilitate communication, accountability, and coordinated problem-solving across laboratory teams.

In practice, collaboration is implemented through several recurring organisational structures. These include daily huddles or briefing sessions where laboratory staff discuss workload distribution, operational risks, and QC status (Alsubaihi, 2025). Cross-functional CAPA review meetings further support collaborative problem-solving by bringing together personnel from different sections to evaluate non-conformities and implement corrective strategies. In addition, MRMs provide a formal platform where leadership and technical staff collectively review quality indicators, risk registers, audit findings, and progress on corrective actions (Alexander, 2022). Inter-laboratory and EQA debriefing sessions also promote shared learning by enabling laboratories to analyse performance outcomes and identify improvement opportunities. Furthermore, supplier and service provider review meetings contribute to preventive quality management by ensuring the reliability of reagents, equipment maintenance, and service delivery (Sisay, 2019).

Evidence from the World Health Organization Laboratory Quality Management System (LQMS) handbook and programme indicates that strengthening leadership engagement and team-based processes significantly improves laboratory audit scores and enhances the sustainability of quality system compliance (Owino, 2023). Collectively, these structured collaborative mechanisms support the continuous

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improvement principles embedded within ISO 15189 and contribute to maintaining accreditation readiness (Sciacovelli, 2024).

2.11.5.4 How Communication Breakdowns Generate Non-Conformances

Breakdowns at any stage of the laboratory communication chain can directly contribute to common NC categories identified during accreditation audits (FasterCapital, 2025). Ineffective communication often manifests through several typical pathways within the quality management system. Firstly, document control failures may occur when laboratory personnel continue to use obsolete SOPs or do not receive timely notification of document revisions (Garcia et al., 2003). Secondly, gaps in personnel competence and training can arise when procedural updates are poorly communicated, resulting in incomplete training records or missing competency signoffs (Akoma et al., 2025). Thirdly, CAPA processes may be delayed when agreed actions are communicated verbally, but not formally documented, or when responsibility for implementation is not clearly assigned (Rodríguez-Pérez, 2022).

In addition, QC or equipment maintenance issues may fail to be escalated effectively during shift handovers, leading to unresolved technical problems (Akase and Kpera, 2024). Failures in the communication of critical results can also occur when essential procedures, such as read-back verification or accurate time documentation, are not consistently followed (Hanna et al., 2005). Furthermore, weak follow-through during MRMs may result in action items not being monitored or tracked to completion (Jayamani et al., 2022). Collectively, these communication breakdowns contribute to recurring audit findings and may escalate from minor to major non-conformities when the associated risks to patient safety and quality of care increase.

Table 5: Mapping Communication/Collaboration Failure Modes Mapped to Typical Audit Findings

Failure Mode (Communication/Collaboration)	**Likely Consequence in Practice**	**Typical NC Category in Audits**
Obsolete/on-paper SOP updates not cascaded to staff	Staff follow outdated steps; inconsistent practice across shifts	Document control; SOP implementation

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No structured shift handover (no QC/maintenance status)	Missed QC alarms; repeats not performed; instruments left with pending faults	Analytical phase control; equipment/maintenance; QC interpretation
Verbal CAPA agreements without action logs/owners	Actions forgotten or delayed; same issue recurs	Corrective and preventive action (CAPA) monitoring
Critical result calls without read-back/time stamp	Clinicians not reliably notified; risk to patient safety	Post-analytical reporting; critical value communication
Irregular Management Review Meetings or no action tracking	KPIs and risks not reviewed; systemic issues persist	Management responsibility; continual improvement
Soloed sections; poor Cross-section collaboration	Dependencies missed (e.g. LIS outage impact); TAT slippage	Risk management; service continuity
Inadequate feedback to specimen submitters	Repeated pre-analytical errors; high rejection rates	Pre-analytical quality; client communication

Internationally, similar challenges occur. Studies in Ghana (Attoh et al., 2022) and Europe (Dehouck et al., 2019) report document control, calibration, and QC deficiencies. In South Africa, Mashamba-Thompson et al., (2018) emphasise the compounded effect of workload and funding limitations. For the Midlands Business Unit, these systemic pressures highlight the need for targeted interventions. Effective communication is vital for maintaining laboratory standards and ensuring patient safety (Carter, 2023; Lippi and Mattiuzzi, 2016)

2.12 Lack of Continuous Improvement in Medical Laboratories and Its Link to Non-Conformances

Continuous improvement is a central principle of ISO 15189, requiring laboratories to demonstrate not only initial compliance but also sustained efforts to identify risks, address deficiencies, and enhance performance over time (Alali et al., 2024). This section explores how the absence of continuous improvement mechanisms

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undermines Quality Management System (QMS) effectiveness and contributes directly to non-conformances (NCs) raised during SANAS audits.

2.12.1 Concept and Relevance of Continuous Improvement

ISO 15189 embeds continuous improvement through clauses on internal audits, management review, occurrence management, risk management, and CAPA (ISO, 2022). The philosophy aligns with established quality models such as Deming's Plan-Do-Check-Act (PDCA) cycle, Juran's quality trilogy, Lean, and Six Sigma (WHO, 2011). In laboratories, this means constantly identifying gaps, implementing solutions, and verifying outcomes. Practical examples include regular SOP updates, monitoring of IQC and EQA trends, timely closure of CAPAs, and integration of lessons from audits into training and system design.

A strong culture of continual improvement is fundamental to the effectiveness of a QMS. In its absence, organisational stagnation may occur, allowing NCs to persist across multiple audit cycles (Johnson, 2024). Laboratories frequently experience recurring findings where CAPAs are administratively closed, but fail to address underlying systemic causes in practice (Rodríguez-Pérez, 2022). Unresolved risks and persistent process vulnerabilities are exacerbated by incomplete or delayed CAPA deployment. MRMs are sometimes carried out to assess the overall effectiveness of QMS (Alam, 2024).

Similarly, risk assessments may be performed as compliance exercises without meaningful proactive planning or integration into operational workflows. Opportunities for improvement identified through EQA programs and internal audits are also sometimes inadequately translated into preventive strategies, limiting organisational learning (Pitt, 2014). Collectively, these deficiencies not only increase the likelihood of repeated NCs during audits but may also negatively affect staff morale, weaken accountability structures, and reduce stakeholder confidence in the accuracy and reliability of laboratory results (Walvekar et al., 2024).

2.12.2 Evidence from Literature

Studies across Africa, particularly from the SLMTA/SLIPTA programmes, highlight that laboratories embracing continuous improvement practices achieve higher audit scores

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and sustain accreditation more effectively (Yao et al., 2010). These facilities reported improvements in document control, CAPA effectiveness, and staff engagement. In contrast, laboratories viewing accreditation as a one-time exercise often fail to maintain standards, leading to repeat NCs and, in some cases, suspension of accreditation (Bogusz et al., 2011). In the South African context, SANAS audit reports frequently identify ineffective CAPA systems and inadequate MRM follow-up as recurring issues (SANAS, 2024).

2.12.3 How Lack of Continuous Improvement Links to NCs

The absence of continuous improvement mechanisms can be mapped directly to common NC categories. For instance, ineffective CAPA processes lead to repeat NCs in subsequent audits, while inactive MRMs result in weak management accountability (Rodriguez-Perez, 2022). Similarly, failure to use QC and EQA data proactively can result in analytical and post-analytical NCs.

Table 6: Mapping Continuous Improvement Failures Mapped to Typical Audit Findings

Continuous Improvement Gap	Practical Consequence	Typical NC Category
CAPAs closed without verification	Problems recur in subsequent audits; ineffective corrective action	CAPA monitoring; repeat findings
Delayed CAPA implementation	Risks remain unresolved; accreditation jeopardised	Corrective and preventive action
Management Review Meetings not driving change	KPIs and risks not tracked; systemic weaknesses persist	Management responsibility; continual improvement
No proactive risk assessments	Emerging risks not mitigated; reactive responses dominate	Risk management; preventive action
Lessons from EQA/IQC not integrated	Same analytical errors repeat; poor learning culture	Analytical quality; post-analytical reporting

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2.12.4 Good Practices for Embedding Improvement

Sustaining accreditation requires laboratories to embed continual improvement as an integral component of routine operations rather than treating it as an activity driven solely by audit requirements (Dwivedi, 2024). Effective implementation involves recognising corrective and preventive action (CAPA) processes as opportunities for organisational learning, with documented effectiveness evaluations conducted prior to formal closure to ensure that root causes have been adequately addressed. Maintaining time-bound CAPA registers that clearly assign responsible individuals and incorporate escalation mechanisms supports accountability and timely resolution of identified risks (ClinicalStudies.in, 2025).

MRMs should be conducted using structured agendas supported by action registers and systematic follow-up evaluations to ensure that decisions translate into measurable improvements (Abdallahi, 2025). In addition, comprehensive risk assessments should inform quality objectives, staff competency development, and targeted training programmes to promote proactive risk mitigation. Trend analysis of EQA and IQC data should be actively linked to preventive improvement initiatives and refresher training activities to strengthen analytical performance (Keppens et al., 2020). Recognising and celebrating successful quality improvement initiatives further promote staff engagement and ownership of the QMS, thereby reinforcing a positive quality culture that supports sustained accreditation compliance (Sharma, 2025b).

2.12.5 Conceptual Linkage to the Present Study

The Midlands BU has faced recurring NCs across audit years (SANAS, 2024). By exploring how continuous improvement is or is not embedded into CAPA systems, MRMs, and quality monitoring, this study will provide insights into why systemic issues persist and how they can be addressed. Highlighting these gaps will support practical recommendations for strengthening QMS resilience and sustaining ISO 15189 accreditation.

2.13 Lack of Resources and Its Impact on Laboratory Accreditation

Resource availability is a critical determinant of laboratory performance and accreditation outcomes. ISO 15189 requires of laboratories to demonstrate access to

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adequate facilities, equipment, consumables, and staffing to support reliable testing (ISO, 2022). However, in many low- and middle-income countries, including South Africa, resource constraints remain a persistent challenge, undermining compliance and contributing to NCs (Tanasiichuk et al., 2023).

2.13.1 Financial and Infrastructure Constraints

Public health laboratories often operate under constrained budgets, with limited funding for infrastructure upgrades and expansion. Challenges such as unreliable electricity, inadequate cold storage, insufficient laboratory space, and outdated facilities compromise the ability to maintain controlled environments required for accurate testing (Homauni et al., 2023). These limitations are frequently highlighted as NCs during SANAS audits (WHO, 2020).

2.13.2 Equipment and Maintenance

Limited resources affect the procurement, calibration, and maintenance of laboratory equipment. Delayed servicing, lack of spare parts, and reagent stock-outs compromise analytical quality (WHO, 2011a). Limited resources can delay equipment calibration and maintenance, cause reagent stock-outs, and increase equipment downtime, thereby compromising test accuracy, delaying results, and affecting the reliability of laboratory diagnostic services. Laboratories with constrained budgets often adopt reactive maintenance approaches, which result in extended downtime and increase the likelihood of major NCs during accreditation audits (Getahun et al., 2019).

2.13.3 Human Resources

Staff shortages remain a significant barrier to sustained compliance. High workloads limit the ability of medical technologists and quality officers to review IQC data, close CAPAs, and attend management review meetings (De Lanerolle et al., 2024). Inadequate staffing also undermines training and competency assessments, leading to recurring NCs related to staff competence and continual professional development (Akoma et al., 2025).

2.13.4 Supply Chain Challenges

Inefficiencies in procurement and supply chain management further compound resource limitations. Delays in acquiring reagents, consumables, or proficiency testing

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materials interrupt laboratory workflows and compromise quality assurance processes (Sisay, 2019). Poorly coordinated supply chains contribute to lapses in QC and EQA participation, which are frequently cited as NCs in public health laboratories (Tanasiichuk et al., 2023).

2.13.5 Link to Non-Conformances

Resource limitations were reflected in multiple audit findings across the laboratory quality system (Odhiambo et al., 2023). Equipment maintenance NCs were frequently attributed to overdue calibrations and delayed servicing, indicating insufficient technical or financial capacity to maintain instrumentation according to prescribed schedules (Tsheola, 2022). Stock management NCs arose when essential reagents or quality control (QC) materials were unavailable, thereby compromising continuity of testing and adherence to quality assurance protocols. Furthermore, training and competency related NCs were observed as a consequence of staff shortages, which limited opportunities for structured training, supervision, and competency assessments (Akoma et al., 2025). Facility related NCs were also reported, linked to inadequate workspace, insufficient safety infrastructure, and unreliable utilities. Collectively, these deficiencies underscore the direct relationship between resource constraints and systemic weaknesses in the effective implementation and sustainability of the QMS.

Table 7: Mapping Resource Gaps Mapped to Typical Audit Findings

Resource Gap	Practical Consequence	Typical NC Category
Limited funding and outdated facilities	Poorly controlled environments; interruptions in workflow	Facilities and safety; infrastructure compliance
Delayed equipment Servicing and calibration	Extended downtime; unreliable analytical results	Equipment maintenance; analytical quality
Staff shortages and high workload	Training delays; incomplete IQC and CAPA follow-up	Competence and training; CAPA monitoring
Stock-outs of reagents/consumables	Interrupted testing; delayed Turnaround times	Stock management; QC/EQA participation
Weak supply chain coordination	Frequent disruptions in QA materials and reagents	Procurement and supply chain management

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2.13.6 Good Practices in Resource-Limited Settings

Despite these challenges, some laboratories have successfully sustained accreditation by adopting innovative approaches to resource optimisation. Examples include pooled procurement across sites to reduce stock-outs, implementation of strict inventory monitoring systems, and use of solar or generator backups to mitigate power disruptions (Odhiambo et al., 2023). Partnerships with donors and international organisations have also supported EQA participation and staff development initiatives (Yao et al., 2010). These strategies demonstrate that resource constraints can be mitigated with careful planning and collaboration.

2.13.7 Conceptual Linkage to the Present Study

The Midlands Business Unit operates within the realities of resource limitations common to public sector laboratories. By investigating the extent to a which lack of resources contributes to NCs during SANAS audits, this study aims to highlight practical interventions that could support sustained ISO 15189 compliance. Findings may inform resource allocation strategies within the NHLS and guide targeted improvements in laboratory infrastructure, staffing, and supply chain systems.

2.14 Enablers and Good Practices

Laboratory quality management systems should methodically include evidence-based procedures that improve teamwork and communication while lowering the risk of NCs. The implementation of standardised communication tools, such as SBAR for clinician communication, structured checklists for shift handovers, and mandatory read-back procedures for critical results, promotes clarity, consistency, and accountability in information exchange (Alanazi et al., 2024). Visual management systems, including whiteboards or digital dashboards displaying QC status, instrument downtime, CAPA due dates, and daily operational priorities, further enhance transparency and team situational awareness (Qamar et al., 2024).

Clear delineation of roles and responsibilities using RACI matrices in CAPA processes and quality improvement projects ensures explicit ownership, defined timelines, and structured escalation pathways when deadlines are not met (Hurley and Sharkey, 2026). To ensure that staff members accept new SOPs before they are implemented,

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digital document management systems with automated change-notification protocols are crucial. This should be complemented by competency linkage processes, whereby training signoffs and direct observation of practice are conducted immediately following SOP revisions to confirm understanding and compliance (Olutobi, 2025).

Routine, time-bound MRMs should be conducted using structured agendas supported by action registers, clearly assigned responsible individuals, and formal closure verification to ensure accountability. EQA debrief sessions should incorporate root cause analysis methodologies, such as fishbone diagrams and the 5-Whys technique, with multidisciplinary participation to translate findings into preventive interventions (Sharma, 2025a). Finally, the monitoring of communication-related key performance indicators (KPIs), including timely critical value notification, read-back compliance rates, on-time CAPA closure, and handover checklist completeness, provides measurable indicators of system effectiveness and continuous quality improvement (Cerkl Research Team, 2025).

2.15 Evidence from Low- and Middle-\ Income Settings (Including South Africa)

Evaluations of laboratory strengthening programmes in Africa (e.g. SLMTA/SLIPTA) report that facilities improving leadership engagement, team communication, and routine use of quality tools show significant gains in audit scores and sustain improvements over time (Beyena, 2015). In the South African public sector context, similar themes appear in accreditation and internal audit reports. Recurrent findings often reflect gaps in document control, competence, CAPA follow-through, and management oversight issues tightly coupled to communication and collaboration. While resource constraints and workload are contributing factors, the literature demonstrates that structured communication practices are a pragmatic, low-cost lever for reducing NCs and improving patient safety (Pandya et al., 2025).

2.16 Conceptual Linkage to the Present Study

This review therefore motivates the inclusion of communication- and collaboration-sensitive indicators in the analysis of SANAS audit findings and the perceptions of internal auditors within the Midlands Business Unit. In particular, the study will examine

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whether the observed NCs are associated with several key operational processes. These include communication related to document control and change management, the maintenance of personnel competence records following updates to SOP, the documentation of CAPA ownership and the timeliness of their implementation; the effectiveness of shift handover practices that influence QC and equipment maintenance; compliance with critical-value notification procedures; and the conduct as well as follow-through of MRMs. Collectively, the assessment of these indicators will provide insight into how communication and collaborative practices may influence the occurrence of NCs within the laboratory quality management system.2.16 Regional Progress and Implications

Across Africa, initiatives such as SLMTA and SLIPTA have strengthened laboratory systems and expanded ISO 15189 accreditation coverage (Odhiambo et al., 2016). Participating laboratories demonstrate improved QMS implementation, particularly in documentation and internal auditing (WHO, 2011b). Countries such as Kenya, Uganda, and Nigeria have increased their accredited laboratories, while South Africa leads the continent due to NHLS and SANAS efforts (Musuka et al., 2025).

SANAS plays a regional role through AFRAC, mentoring other accreditation bodies and ensuring international recognition via ILAC (Peet and MacCurtain, 1997). This facilitates cross-border recognition of results for diseases such as HIV and TB. Despite these gains, challenges persist in sustaining accreditation, including limited funding, supply chain disruptions, and shortages of trained staff. These developments highlight how crucial it is for the Midlands Business Unit to solve systemic issues in order to preserve SANAS accreditation, improve patient safety, and maintain stakeholder confidence, especially in light of the ISO 15189:2022 transition date.

2.17 Laboratory Quality Standards and Human/Organisational Factors

Beyond the technical requirements of ISO 15189, several studies emphasise the critical role of human and organisational factors in sustaining accreditation. In a KwaZulu-Natal study by Ngubo (2021), human resources, training, and leadership commitment as decisive contributors to accreditation outcomes were identified. NCs were often traced not to technical failure, but to lapses in staff competence, communication breakdowns, and inadequate supervisory oversight. These findings

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support the argument that QMS succeed only when staff at all levels are actively engaged in implementation and management demonstrates visible accountability (Turusbekova et al., 2007).

Tsheola and Kruger (2022) examined non-conformances in Gauteng's non-accredited laboratories between 2015 and 2019, highlighting recurring weaknesses in document control, training, and QMS implementation. Internal auditors cited systemic barriers, such as limited resources, inconsistent training on QMS standards, and a lack of commitment from senior leadership as primary obstacles to achieving accreditation. Furthermore, the majority of NCs occurred in quality system essentials (QSEs), particularly CAPA, document control, and staff competency (Tsheola and Kruger, 2022).

These findings emphasise the centrality of management and systemic processes in sustaining compliance. Kruger et al. (2022) further contributed by capturing auditor perspectives, revealing that staff shortages, low morale, and poor resource allocation were major contributors to persistent non-compliance. Auditors also noted that limited mentorship and inadequate auditor development weakened the effectiveness of internal audits, perpetuating recurring findings (Kruger et al., 2022). Their recommendations for structured auditor training and mentorship resonate with broader calls for capacity-building initiatives in public health laboratories.

International perspectives also highlight similar challenges. In Saudi Arabia, insufficient training, leadership gaps, weak infrastructure, and workload pressures were identified as consistent contributors to non-compliance across institutions (Alkhurayji et al., 2023). Therefore, this emphasises that achieving and sustaining compliance requires strong leadership accountability, investment in human resources, and a culture of continuous training and quality improvement.

Taken together, these studies demonstrate that laboratory accreditation is as dependent on human and organisational enablers as it is on technical systems. The Midlands Business Unit's experiences of recurring deficiencies in CAPA, document control, and training mirror both national and international patterns, reinforcing the conclusion that systemic, people centred strategies are essential to long-term ISO 15189 compliance (Mtotela, 2020).

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2.18 Summary and Research Gap

This chapter reviewed the literature on ISO 15189 and SANAS accreditation, integrating global, regional, and local perspectives. Key themes include the importance of accreditation, common NCs, contributing factors, enablers, and strategies for sustaining compliance. While South Africa leads the continent in accreditation coverage, NHLS laboratories, including those in the Midlands Business Unit, face persistent challenges in documentation, staff competence, equipment calibration, and CAPA effectiveness.

Existing literature provides valuable insights into accreditation trends, yet there is limited research focused specifically on the Midlands BU between 2020 and 2023. This represents a critical gap, especially given the pressures of high patient volumes, staff shortages, and the looming ISO 15189:2022 transition deadline. The present study addresses this gap by assessing the factors contributing to non-compliance during SANAS audits in the Midlands BU, thereby generating evidence to inform targeted interventions for sustained accreditation and improved patient safety.

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CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the research design and methodology used to investigate factors contributing to non-compliance during SANAS audits in the Midlands Business Unit from 2020 to 2023. The chapter details the research approach, study setting, population, sampling strategy, data collection methods, analysis plan, and ethical considerations. It also outlines the limitations of the study.

3.2 Research Design

A descriptive, retrospective, non-experimental quantitative research design was employed. This design was chosen to allow for the systematic analysis of existing audit data and survey responses without manipulating any variables. The approach facilitates the objective assessment of patterns, frequency, and trends of non-conformances (NCs) in SANAS-accredited laboratories.

The retrospective nature of the study allows for the review of historical audit data from 2020 to 2023. Descriptive analysis will enable the quantification and comparison of audit outcomes across laboratories. Additionally, the use of an online survey with internal auditors will provide contextual insights that complement the numerical audit data.

3.3 Study Setting

The study was conducted in the Midlands Business Unit of the National Health Laboratory Service (NHLS), located in KwaZulu-Natal, South Africa. The business unit consists of seven SANAS-accredited laboratories, serving both urban and rural populations. All laboratories are public sector facilities and operate under the NHLS quality management framework.

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3.4 Study Population and Sampling

3.4.1 Population

The study population comprised two distinct groups. Population 1 included all SANAS-accredited laboratories within the Midlands Business Unit that underwent SANAS audits during the period from 2020 to 2023. Population 2 consisted of internal auditors who conducted audits in these laboratories within the same period and who provided informed consent to participate in the study.

3.4.2 Inclusion Criteria

The study population comprised SANAS-accredited laboratories within the Midlands Business Unit that were audited between 2020 and 2023. In addition, the study included internal auditors who conducted audits within this unit during the specified period and who consented to participate in the survey. These participants were selected to provide relevant insights into audit processes and quality management practices within the accredited laboratories.

3.4.3 Exclusion Criteria

Laboratories that were not accredited SANAS or that fell outside the Midlands Business Unit were excluded from the study. In addition, auditors who did not conduct audits within the specified study period, as well as those who declined to participate, were not included in the research sample.

3.4.4 Sampling Strategy

A total population sampling approach was employed for the laboratories, whereby all seven qualifying laboratories were included in the study. This method ensured comprehensive representation of the study setting and eliminated sampling bias by incorporating the entire eligible population. For the auditors, a purposive sampling strategy was utilised to recruit internal auditors with prior experience auditing the selected laboratories. This approach ensured that participants possessed the relevant knowledge and expertise necessary to provide informed, meaningful, and contextually relevant data for the study. Invitations were sent via email, and participation in the survey was voluntary.

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3.5 Data Collection Methods

3.5.1 Audit Data Review

Audit data were extracted from a centralized audit log maintained by the Quality Assurance Coordinator of the Midlands Business Unit. The spreadsheet includes comprehensive records of NCs logged during both SANAS and internal audits. Data fields extracted included:

- Audit year (2020–2023)
- Type of audit (internal or SANAS)
- Classification of NC (technical vs. management)
- Severity of NC (minor, medium, major)
- Affected department (pre-analytical, analytical, post-analytical)
- Closure time and recurrence patterns

3.5.2 Online Survey

A structured online survey was distributed to internal auditors via a secure platform (RedCap). The survey included:

- Closed-ended questions (multiple-choice)
- Questions addressing root causes of NCs, perceived systemic challenges, and suggestions for improvement
- Sections capturing perceptions of compliance readiness and audit preparedness

The survey responses were anonymised and stored securely.

3.6 Data Analysis

3.6.1 Descriptive Statistics

Frequencies and percentages were used to describe the distribution of non-conformances (NCs) according to type, severity, department, and audit year. These descriptive statistics provided a clear summary of the pattern and magnitude of

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identified NCs across the study period. In addition, trend analysis was conducted to identify recurring non-conformances and to assess changes in audit performance over time, thereby enabling the evaluation of patterns, persistence of specific deficiencies, and overall quality improvement progress.

3.6.2 Comparative Analysis

Cross-tabulations were performed to examine the relationships between non-conformance (NC) type (management versus technical), department, and testing phase. This approach enabled the identification of distribution patterns and potential associations across categorical variables. Where appropriate, Chi-square tests were applied to determine whether the observed associations were statistically significant, thereby providing inferential support for the relationships identified in the analysis.

3.6.3 Triangulation

Data triangulation was employed by comparing quantitative audit data with qualitative insights from the survey. This approach enhanced the credibility and comprehensiveness of findings, ensuring that observed patterns could be contextualized with real-world experiences of the auditors.

3.6.4 Tools and Software

Microsoft Excel was utilised for data cleaning and preliminary analysis of the audit data, enabling the identification of inconsistencies, missing values, and basic descriptive trends prior to formal statistical evaluation. More advanced statistical analyses were conducted using SPSS, which facilitated comprehensive inferential testing and exploration of associations within the dataset. Survey data were collected using REDCap, a secure web-based data capture platform, and subsequently exported for further analysis.

3.7 Validity and Reliability

Internal validity was strengthened through the use of verified audit records and standardized audit classification systems, which ensured that the data analysed accurately reflected documented non-conformances and their respective categories. Reliability was enhanced by applying consistent coding and categorization procedures

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for non-conformances (NCs) across all audit years, thereby reducing variability in data interpretation. In addition, the use of a structured survey format promoted uniformity in data collection, further supporting the consistency and reproducibility of the findings.

3.8 Ethical Considerations

The study adhered strictly to established ethical research principles and institutional guidelines. Ethical clearance was obtained from the University of the Free State (UFS) Ethics Review Board prior to commencement of the study. Informed consent was secured from all participating auditors, ensuring that participation was based on voluntary agreement and adequate understanding of the study's purpose and procedures. 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.

3.9 Limitations

This study was conducted within the Midlands Business Unit, which may limit the generalizability of the findings to other units within the National Health Laboratory Service (NHLS). 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

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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.

3.10 Chapter Summary

This chapter outlined the study's methodology, including the research design, setting, population, sampling strategy, data collection methods, and analysis plan. Ethical considerations and limitations were also discussed. The chosen methodology supports the objectives of the study by providing a rigorous and triangulated analysis of SANAS audit data alongside auditor perspectives. The next chapter will present the results and interpretation of the collected data.

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CHAPTER 4: RESULTS

This chapter presents the SANAS audit non-conformance (NC) findings for five anonymised laboratories (Lab 1–Lab 5) in the Midlands Business Unit for the period 2020–2023. The results are presented on a lab-by-lab basis, highlighting yearly trends, severity, and the recurring nature of NCs. Where data were unavailable, this is noted, and interpretations are made cautiously.

The summary below shows the distribution of NCs across all five laboratories between 2020 and 2023. Lab 1 and Lab 3 recorded higher NC frequencies compared to other labs, particularly in 2021 and 2022, while Lab 5 only began recording NCs from 2022 due to its recent accreditation.

Table 8: Non-conformances (NCs) per Lab (2020–2023)

Lab	2020	2021	2022	2023
LAB 1	0	7	3	5
LAB 2	4	6	-	-
LAB 3	3	3	6	1
LAB 4	-	8	-	-
LAB 5			17	
LAB 6			11	
LAB 7	-	-	12	9

Figure 4.1 illustrates NC trends by lab between 2020 and 2023. The bar chart highlights that NCs were most frequent in Lab 1 and Lab 3, with fluctuating patterns across the years. The visual presentation confirms that while some improvements were achieved in 2023, recurring weaknesses remained evident in SOP adherence, training, and CAPA processes.

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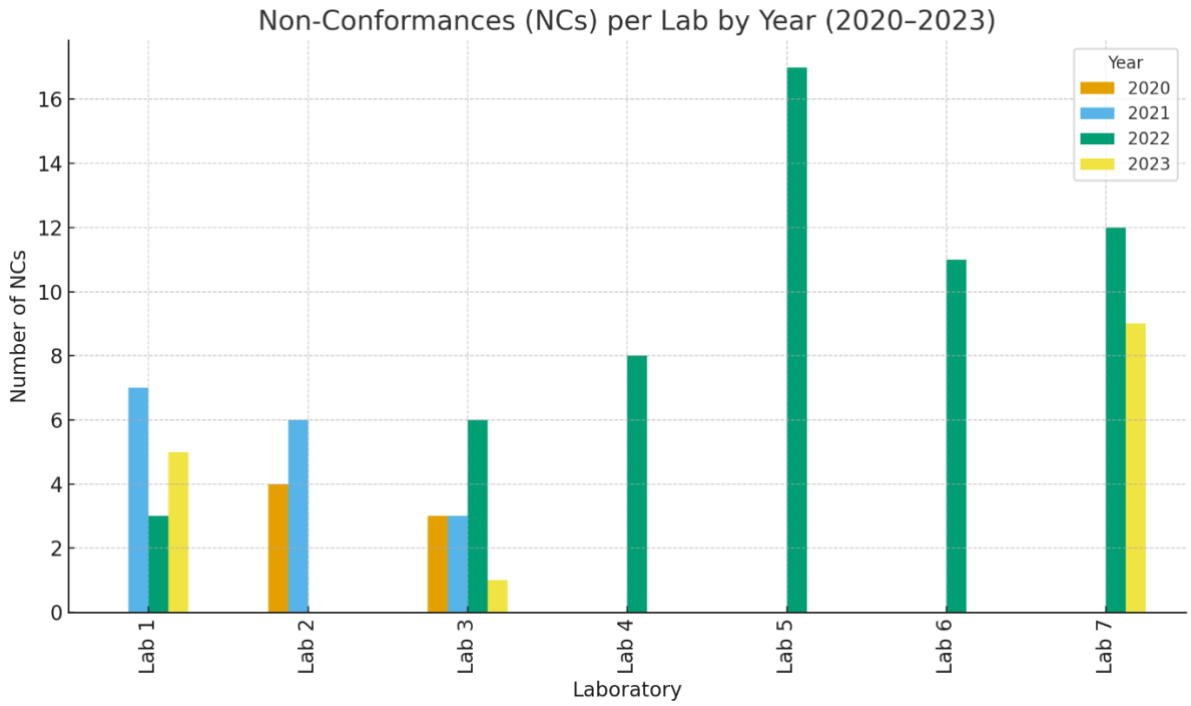


Figure 1: Non-conformances (NCs) per Lab by Year (2020–2023)

4.2 Lab 1 Results

4.2.1 SANAS Audit Findings (2020–2023)

Lab 1 had no non-conformances (NCs) recorded during the 2020 SANAS audit, suggesting a strong compliance baseline at the start of the study period. However, subsequent audits (2021–2023) revealed recurring issues across documentation, verification, equipment maintenance, and staff competency, indicating challenges in sustaining long-term compliance.

4.2.2 Documentation and Record-Keeping

In 2021, NCs were raised regarding misfiled or incomplete records. For example, OTL (Outstanding Test List) reports requested during the assessment period were either missing or unsigned (Clause 5.7). This was attributed to printer problems and an SOP that did not explicitly require signatures. Similarly, in 2022, temperature monitoring records for the storeroom were not consistently completed, with charts being placed behind doors and overlooked (Clause 5.2.6). These findings point to a lack of robust document control and monitoring systems, which compromise traceability and hinder demonstrable compliance with ISO 15189 requirements.

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4.2.3 Verification and Methodological Gaps

A persistent theme across audits was incomplete or omitted verification procedures. In 2022, specific procedures for FBC verification were omitted from reports (Clause 5.5), and MPV verification was not performed despite being a reportable analyte. By 2023, further verification gaps emerged, including missing traceability of laboratory clocks and timers (Clause 5.3.1.4), and incomplete ESR stand maintenance logs (Clause 5.3.1.5). These gaps reflect weaknesses in method verification, which is central to ensuring reliability and reproducibility of results.

4.2.4 Equipment and Resource Issues

Lab 1 also faced challenges related to equipment use and maintenance. In 2023, assessors noted that the ESR stand maintenance log had not been completed since January, highlighting lapses in routine equipment quality checks. Additionally, during test witnessing of peripheral smear procedures, the absence of a documented procedure for quality control (use of a dummy slide) was observed (Clause 5.5.3). These findings suggest that while equipment and processes were available, compliance with required verification and maintenance practices was not embedded into routine operations.

4.2.5 Staff Competency and Training

Staff competency was a recurring factor. In 2021, incomplete method traceability for EQA submissions was attributed to staff not realising the importance of recording method details (Clause 5.6). In 2023, deficiencies in root cause analysis (RCA) were noted (Clause 4.9), with corrective actions and RCAs being inconsistently documented. These findings indicate limited awareness of ISO 15189 requirements and insufficient training in QMS principles, particularly RCA, documentation, and verification standards.

4.2.6 Overall Interpretation

Lab 1 transitioned from having no NCs in 2020 to multiple NCs across 2021–2023. The pattern suggests that initial compliance may not have been sustained due to weak documentation culture, procedural oversight, and inadequate staff training. While corrective actions were implemented including SOP revisions, staff retraining, and

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enhanced supervision these responses were reactive. For long-term improvement, Lab 1 requires a shift toward proactive systems: embedding document control into routine practice, strengthening verification and equipment maintenance logs, and ensuring continuous staff training in RCA and QMS compliance.

4.3 Lab 2 Results

4.3.1 Lab 2 – SANAS Audit Findings (2020–2023)

Lab 2's audit trail during the 2020–2021 period highlighted recurring challenges in management review practices, documentation control, and technical verification processes. No subsequent audits were available for 2022–2023 within the study dataset; thus, the interpretation focuses on the earlier years, which nonetheless provide insight into systemic weaknesses.

4.3.2 Documentation and Record-Keeping

Findings in both 2020 and 2021 repeatedly flagged documentation lapses. In 2020, several Q-Pulse documents (e.g. GPL3963, POLF0014, POL10009) were overdue for review, contravening Clause 4.3. By 2021, further gaps were observed where outdated forms (GPL3346v9, GPL2952v17) continued to be used, reflecting a lack of effective document control and distribution processes.

4.3.3 Quality Indicators and Monitoring

In 2020, FBC turnaround time (TAT) targets were not met across multiple months. Despite investigations, corrective actions were ineffective, as the same reason—results left on verification queues – was repeatedly cited. Rejected samples were recorded but not trended to detect patterns, which limited the ability to address recurring causes. In 2021, a similar weakness appeared when nonconforming events such as mis-logged CSFs and send-away tests were discussed in meetings, but not raised as formal NCs, undermining the feedback and escalation mechanism of the QMS.

4.3.4 Management Review (MRM)

The 2020 audit revealed that the MRM process was ineffective. The last MRM in November 2019 covered data only up to March 2019, leaving an 8-month period

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unreviewed. This was inconsistent with ISO 15189 Clause 4.15.1, which requires reviews at least annually. Such delays reduced the effectiveness of management oversight in identifying and addressing QMS risks.

4.3.5 Method Verification and Technical Issues

Technical NCs were particularly evident in 2021. These included:

- RPR EQA survey: Preventive action ("second checker for titre confirmation") was not implemented.
- RPR verification records: Lot traceability was inconsistent, with mismatched lot numbers.
- Cobas Integra maintenance: Maintenance logs showed incorrect scheduling, with three-monthly checks performed monthly.

These findings indicated poor traceability, weak follow-up on EQA gaps, and inadequate alignment of maintenance schedules with SOPs.

4.3.6 Root Cause Analysis and Corrective Actions

Across both years, RCAs lacked depth. In 2020, sample rejection incidents (clotted or insufficient samples) were logged but not trended, limiting their usefulness for systemic improvement. In 2021, customer survey follow-up logs listed intended corrective measures but did not document actual actions taken, falling short of Clause 4.14.3. Overall, CAPA processes were reactive and superficial, allowing repeat issues.

4.3.7 Overall Interpretation

Lab 2's findings reflect systemic weaknesses in management review, documentation control, and technical verification. The absence of later audit records (2022–2023) prevents assessment of whether improvements were made, but the recurring NCs in 2020–2021 indicate persistent compliance risks. Strengthening trend analysis, enforcing annual MRMs, and embedding preventive action into verification would be critical for long-term compliance.

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4.4 Lab 3 Results

4.4.1 Lab 3 – SANAS Audit Findings (2020–2023)

Lab 3's audit history between 2020 and 2023 shows a consistent pattern of NCs across management reviews, documentation, SOP adherence, equipment verification, and staff competency. While corrective actions were implemented each year, the recurrence of similar findings indicates systemic weaknesses in embedding compliance into daily laboratory practice.

4.4.2 Management and Documentation Gaps

In 2020, NCs were raised concerning overdue management review meetings (Clause 4.15). A management review meeting (MRM) was postponed due to the COVID-19 pandemic without proper documentation, creating a 17-month gap between reviews. This contravened ISO 15189 requirements, which stipulate reviews every 12 months. The same audit also found that NCs and rejected samples were not adequately trended (Clause 4.9). These findings highlight deficiencies in governance and QMS oversight, where external factors such as the pandemic exacerbated already weak documentation practices.

4.4.3 Verification and SOP Non-Compliance

From 2021 onwards, issues shifted towards verification and SOP adherence. Examples include incorrect dates recorded on competency checklists (Clause 5.1), lot number discrepancies in ESR verification (Clause 5.5), and incomplete bin card inventory records (Clause 5.3.2). In 2022, additional NCs were observed around calibration of thermometers (Clause 5.8), incorrect control ranges for triglyceride and phosphate tests (Clause 5.6), and failure to conduct trend analysis for sodium analyte data (Clause 5.6). These findings point to weak internal control systems, where verification procedures were performed inconsistently, and SOP requirements were not consistently followed.

4.4.4 Equipment and Resource Limitations

Lab 3 also struggled with equipment-related NCs. In 2020, overdue test monitoring was not performed due to staff shortages, particularly on weekends when the lab was on call-out (Clause 4.5.2). In 2022, incomplete templates for capturing analyte data

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resulted in missing uncertainty of measurement calculations (Clause 5.5.1.4). In 2023, reagents for the Sysmex XN1000 were not correctly labelled as “in use”, violating SOP requirements (Clause 5.3.2). These resource and compliance gaps suggest that workload pressures, compounded by staff shortages, undermined adherence to routine monitoring and documentation of equipment and reagent usage.

4.4.5 Staff Competency and Training

Several NCs were directly related to staff competency. In 2021, assessors noted errors in competency assessment documentation and data capture. By 2022, training documentation was incomplete for staff retrained after an EQA failure (Clause 5.6.3.4), showing that even when training occurred, it was not properly recorded. This undermines the credibility of corrective actions and raises concerns about the sustainability of competence management systems.

4.4.6 Overall Interpretation

Lab 3’s NCs reflect a recurring struggle with documentation, verification, and staff competency management. The pandemic in 2020 revealed structural vulnerabilities in QMS governance, which continued into subsequent years as lapses in verification, SOP adherence, and training documentation. Corrective actions such as retraining staff, revising SOPs, and recruiting additional staff were implemented, but were reactive by nature. The persistence of similar NCs year after year suggests that systemic solutions, such as embedding QMS compliance into daily routines, strengthening internal audits, and ensuring management accountability, are still lacking. For long-term compliance, Lab 3 needs to move beyond corrective actions and establish proactive, preventive systems supported by continuous monitoring and adequate staffing.

4.5 Lab 4 Results

4.5.1 Lab 4 – SANAS Audit Findings (2021)

Lab 4’s audit in August 2021 revealed multiple NCs across management, documentation, equipment maintenance, and technical practices. The findings highlight systemic weaknesses in QMS implementation and resistance from leadership in supporting accreditation requirements.

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4.5.2 Management Review and Quality Objectives

(Clauses 4.1 & 4.2.1.2)

Two different organograms were submitted, with one uncontrolled version, and neither reflected the micro/serology department. This created uncertainty about the organizational structure and accountability. Additionally, while quality objectives were reviewed during the management review, unmet objectives were not accompanied by evidence of corrective actions, undermining the cycle of continuous improvement.

4.5.3 Documentation and Record Control

(Clauses 4.3 & 4.13)

Several issues were noted with documentation:

- A cytology SOP (GPL4171) omitted reporting guidelines for normal negative non-gynae cases, creating risk of incomplete reporting.
- Maintenance records contained amendments without signatures, violating traceability and accountability requirements.

4.5.4 Equipment Maintenance

(Clause 5.3.1.7)

Evidence of routine maintenance was lacking. For example, no May 2021 Sysmex maintenance record was available, and LH750 monthly maintenance was not documented for June 2021 (Weeks 3 and 4). These lapses compromised equipment reliability and raised concerns over instrument performance monitoring.

4.5.5 Technical Processes and Verification

(Clauses 5.5 & 5.8.3)

- A CSF result (ED02260298) was reported as a cryptococcal antigen latex test, while the actual method in use was lateral flow. This discrepancy undermined the accuracy of result reporting and could mislead clinicians regarding test methodology.

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- Discrepancies were noted between the received time (14h00) and final report time (15h15) on episode ED02239904, suggesting weaknesses in timestamping and data integrity.

4.5.6 External Quality Assessment (EQA)

(Clause 5.6.3.4)

The NHLS chemistry EQA Survey 02 of 2020 had no preventive action (PA) documented, nor was it discussed during review meetings. This reflected inadequate response to external performance evaluations, missing an opportunity to strengthen quality assurance.

4.5.7 Overall Interpretation

Lab 4 in 2021 exhibited serious deficiencies in QMS adherence, particularly in:

- Uncontrolled documentation and weak record integrity.
- Failure to implement actions when objectives or EQA targets were not met.
- Poor equipment maintenance records, creating risks for instrument reliability.
- Technical discrepancies in reporting and verification, directly impacting result accuracy.
- Leadership resistance, which undermined accountability and QMS culture.

Overall, Lab 4's challenges reflect not only procedural non-compliances, but also cultural resistance to QMS principles, which poses a major barrier to sustainable SANAS accreditation.

4.6 Lab 5 Results

4.6.1 Initial SANAS Audit Findings (2022)

Lab 5 underwent its initial SANAS accreditation audit in 2022, and no follow-up surveillance audit was conducted in 2023. The initial assessment identified several non-conformances (NCs) across technical and management requirements, providing insight into the laboratory's baseline compliance challenges.

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4.6.2 Documentation and Record Management

One NC (Clause 4.1.2.6) highlighted a lack of documented feedback from hospital meetings. Although feedback was verbally communicated, the absence of written records meant that evidence of staff engagement was not demonstrable to assessors. Similarly, under Clause 5.6.2, misfiling of EQA results resulted in PT/INR data for three consecutive months (October–December 2021) appearing unavailable (NHLS, 2025a; NHLS, 2025b). These findings emphasise weaknesses in documentation practices, a recurrent issue across laboratories, where verbal or informal practices are not translated into traceable records required for ISO 15189 compliance.

4.6.3 Verification and SOP Compliance

Audit findings also revealed shortcomings in method verification and adherence to standard operating procedures (SOPs). Under Clause 5.5.1.3, the ESR verification was incomplete, with only two out of six required IQC samples performed. In addition, Clause 5.3.2 flagged inconsistencies between the SOP (HAEM1705) and the manufacturer's instructions for reagent reconstitution, leading to misapplication of technical procedures. These NCs highlight the risk of partial compliance where processes are initiated, but not followed through to completion, as well as the dangers of SOPs not being aligned with supplier documentation.

4.6.4 Resource and Equipment Gaps

Clause 5.3.1 identified the absence of an ESR stand with a level indicator, which hindered compliance with verification requirements. Although corrective actions included procuring the required equipment and borrowing a temporary stand, the finding illustrates the role of inadequate resources in driving non-conformance. Such gaps point to systemic issues in procurement and resource allocation within the laboratory network.

4.6.5 Staff Training and Competence

Two NCs directly related to staff performance and competency. Under Clause 5.5, accuracy and precision data were incomplete due to a failure to capture measurements correctly in the spreadsheet, including reporting in the wrong units. Additionally, under Clause 5.6, deficiencies in root cause analysis (RCA) training were

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observed, with staff unable to perform RCAs adequately. Both findings demonstrate the need for continuous staff development in quality management principles, particularly in areas that directly impact the validity of test results and the sustainability of corrective actions.

4.6.6 Overall Interpretation

The NCs observed in Lab 5's initial audit primarily reflects foundational challenges typical of laboratories undergoing accreditation for the first time. Documentation and record-keeping were inconsistent, SOPs were not always aligned with best practice, equipment shortages limited compliance, and staff lacked training in critical quality management competencies such as RCA. While corrective actions were implemented such as retraining staff, realigning SOPs, and procuring equipment, these responses were reactive. For long-term compliance, a shift towards proactive systems for documentation, preventive training, and structured procurement planning is required.

4.7 Lab 6

4.7.1 SANAS Audit Findings (2022)

Lab 6 underwent its first SANAS accreditation audit in 2022. As this was an initial assessment, no prior baseline existed, and there was also no documented audit in 2023. The findings highlighted expected challenges for a laboratory at the beginning of its accreditation journey, particularly around documentation, staff competency, and quality management system (QMS) integration. Corrective actions were submitted but were brief and summarised, limiting the ability to assess their long-term effectiveness.

4.7.2 Documentation and Record-Keeping

The audit revealed weaknesses in document control and record maintenance. Key records, including training files and certain quality control logs, were incomplete or inconsistently maintained (Clause 4.13). For example, staff files lacked updated competency assessments, and equipment calibration records were not consistently signed off. These gaps suggest that systematic documentation practices had not yet been embedded into daily operations, undermining traceability and demonstrable compliance.

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4.7.3 Verification and Methodological Gaps

Verification processes were highlighted as an area of concern. Certain analytical methods had been implemented without adequate verification evidence, and reports did not consistently document verification outcomes (Clause 5.5). The omission of these details suggested a limited understanding of ISO 15189 verification requirements. In particular, the laboratory struggled to demonstrate method performance characteristics and reproducibility, raising questions about reliability of reported results.

4.7.4 Equipment and Resource Issues

The laboratory faced challenges in aligning equipment use with ISO 15189 standards. Equipment maintenance logs were inconsistently updated, and some instruments lacked documented preventive maintenance schedules (Clause 5.3). Resource constraints also affected the ability to sustain routine equipment checks, with reliance on external service providers delaying corrective actions. These findings are common in laboratories undergoing initial accreditation, where resource mobilisation is still developing.

4.7.5 Staff Competency and Training

Staff competency gaps were evident, particularly in quality management principles. Several NCs were raised due to incomplete training records and insufficient evidence of competency assessments across all testing areas (Clause 5.1). Moreover, deficiencies in root cause analysis (RCA) were observed (Clause 4.9). The corrective actions submitted did not reflect in-depth RCA, with responses limited to surface-level fixes rather than addressing systemic issues. This points to a need for enhanced staff training in QMS fundamentals, RCA techniques, and documentation standards.

4.7.6 Overall Interpretation

Lab 6's first SANAS audit in 2022 revealed the typical challenges of a newly accredited laboratory: weak documentation practices, incomplete verification processes, inconsistent equipment maintenance, and limited staff competency in ISO 15189 standards. While corrective actions were provided, their summarised nature raised

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concerns about sustainability and effectiveness. The absence of a 2023 audit further restricts evaluation of whether improvements were achieved.

For Lab 6 to progress toward sustained compliance, proactive systems must be developed. These include embedding document control into daily practice, conducting thorough verification and RCA, strengthening equipment maintenance routines, and prioritising ongoing staff training. Without such measures, there is a risk of recurring NCs in future audits, delaying full integration of ISO 15189 principles into the laboratory's culture and operations.

4.8 Lab 7 Results

4.8.1 Lab 7 – SANAS Audit Findings (2020–2023)

Lab 7 showed fluctuating audit outcomes across the study period, with certain years reflecting better compliance and others highlighting recurring systemic weaknesses. The most prominent issues related to documentation, verification processes, and staff competency tracking.

4.8.2 Documentation and Record-Keeping

Audit reports repeatedly flagged incomplete or mismanaged records (Clause 4.13). In particular, 2021 and 2022 highlighted problems with temperature monitoring logs and calibration records that were either unsigned or inconsistently updated. These lapses undermined the ability to demonstrate traceability and compliance with ISO 15189 requirements.

4.8.3 Verification and Method Validation

In both 2022 and 2023, the laboratory received NCs regarding insufficient verification of new test methods. For example, certain chemistry assays lacked comprehensive verification data, raising concerns about the reliability of reported patient results. This reflects a pattern of reactive rather than proactive method validation practices.

4.8.4 Staff Competency and Training

Several audits found that personnel files lacked evidence of updated competency assessments (Clause 5.1). Staff training records were incomplete, with annual

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refresher courses not consistently documented. This created gaps in proving that laboratory staff remained competent to perform their assigned duties.

4.8.5 Root Cause Analysis (RCA) and Corrective Actions

While RCAs were submitted, they tended to describe the immediate error (e.g. “staff oversight”) rather than probing systemic factors. Corrective actions, such as refresher training or reminders, were put in place, but without a structured follow-up plan, repeat findings persisted in subsequent years.

4.8.6 Overall Interpretation

Lab 7 demonstrated ongoing challenges in sustaining compliance across critical areas. The laboratory often closed NCs with surface-level actions, but recurring findings show that deeper systemic improvements – such as strengthening the QMS, enforcing staff accountability, and implementing robust verification protocols – are needed to achieve long-term compliance.

4.9 Survey Results

This section presents the findings of the survey conducted among internal auditors in the Midlands Business Unit. The survey aimed to capture auditors’ perceptions of non-conformances (NCs), their root causes, and the systemic challenges that contribute to non-compliance during SANAS audits. Responses were collected via REDCap and are presented here using diagrams, accompanied by narrative analysis.

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Survey Results – Figures

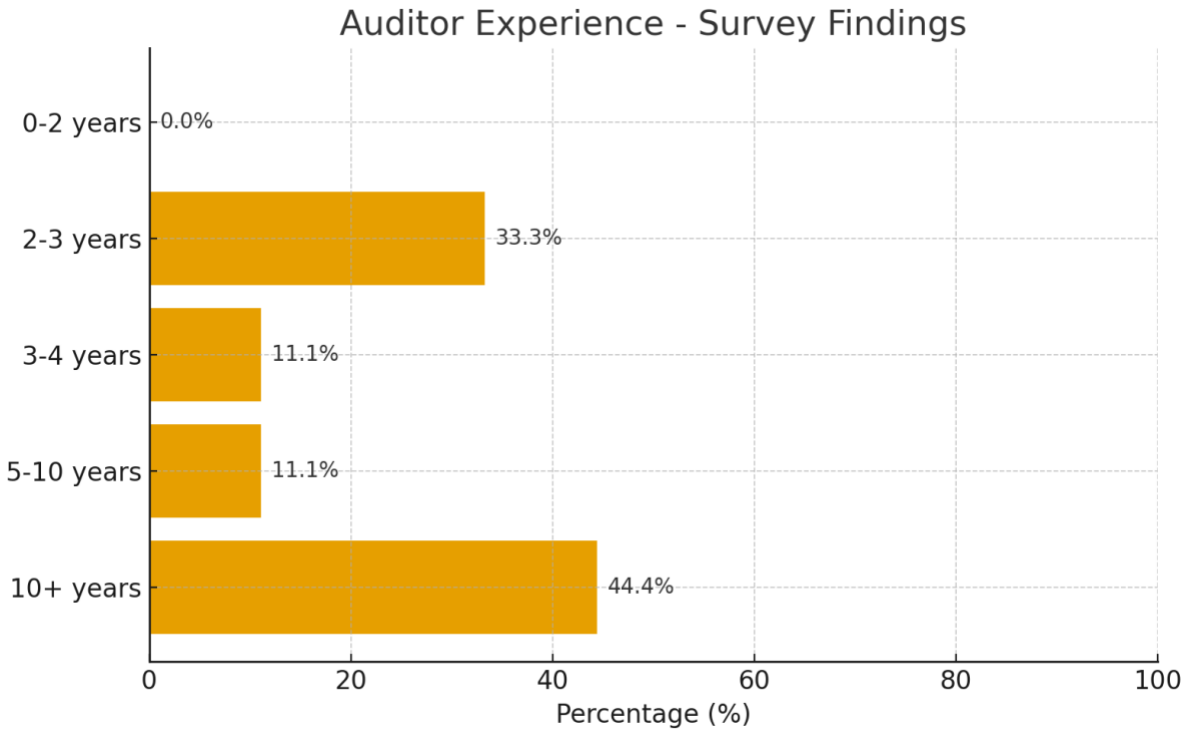


Figure 2: Survey findings on auditor experience among internal auditors in the Midlands BU

Years of Auditing Experience

Nearly half of the respondents (44.4%) reported having 10 or more years of auditing experience, while one-third (33.3%) had 2–3 years of experience as shown in Figure 1. Only a small proportion reported between 3–4 years (11.1%) or 5–10 years (11.1%), and none were in the 0–2 years' category. This distribution indicates that the auditor pool is composed of experienced individuals, which strengthens the credibility of their observations. However, it also highlights a potential succession gap, as fewer newer auditors are entering the system.

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(2020–2023)

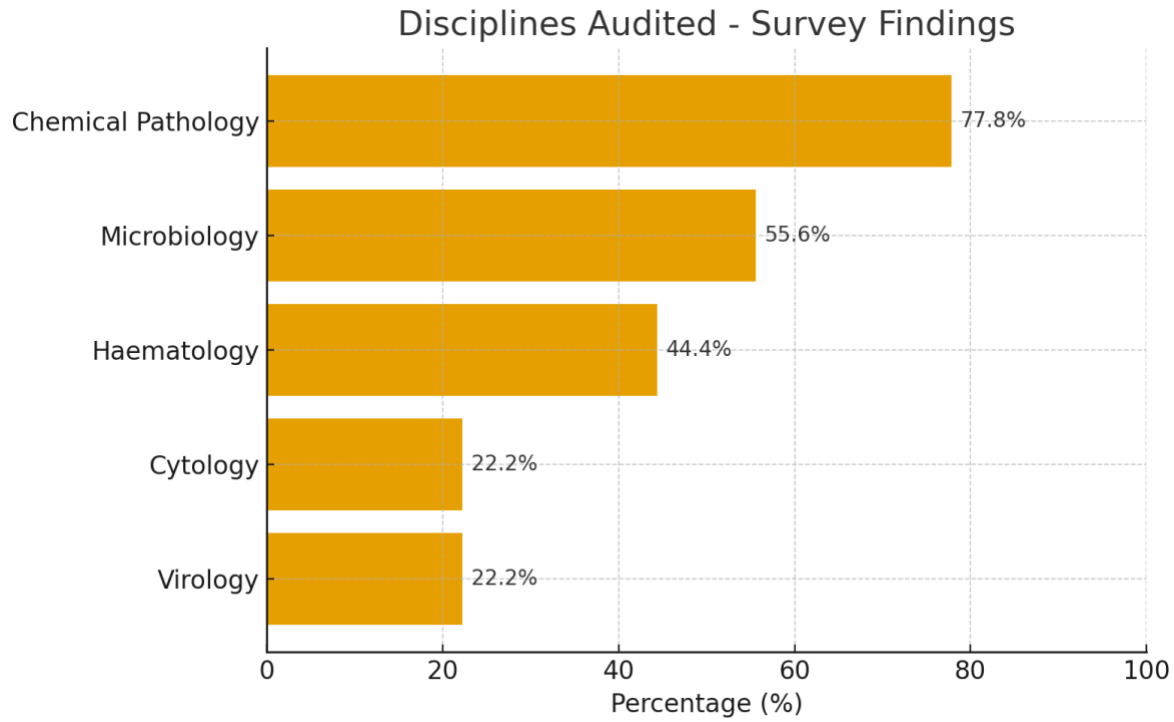


Figure 3: Survey findings on disciplines audited among internal auditors in the Midlands BU (2020–2023)

Disciplines Audited

The majority of auditors (77.8%) had experience auditing Chemical Pathology, followed by Microbiology (55.6%) and Haematology (44.4%). Less commonly audited areas included Cytology (22.2%) and Virology (22.2%). These findings suggest that most auditors had exposure to high-volume diagnostic disciplines, which are traditionally more resource intensive and prone to non-conformances. The low coverage of Cytology and Virology may reflect the smaller number of such laboratories in the Midlands Business Unit.

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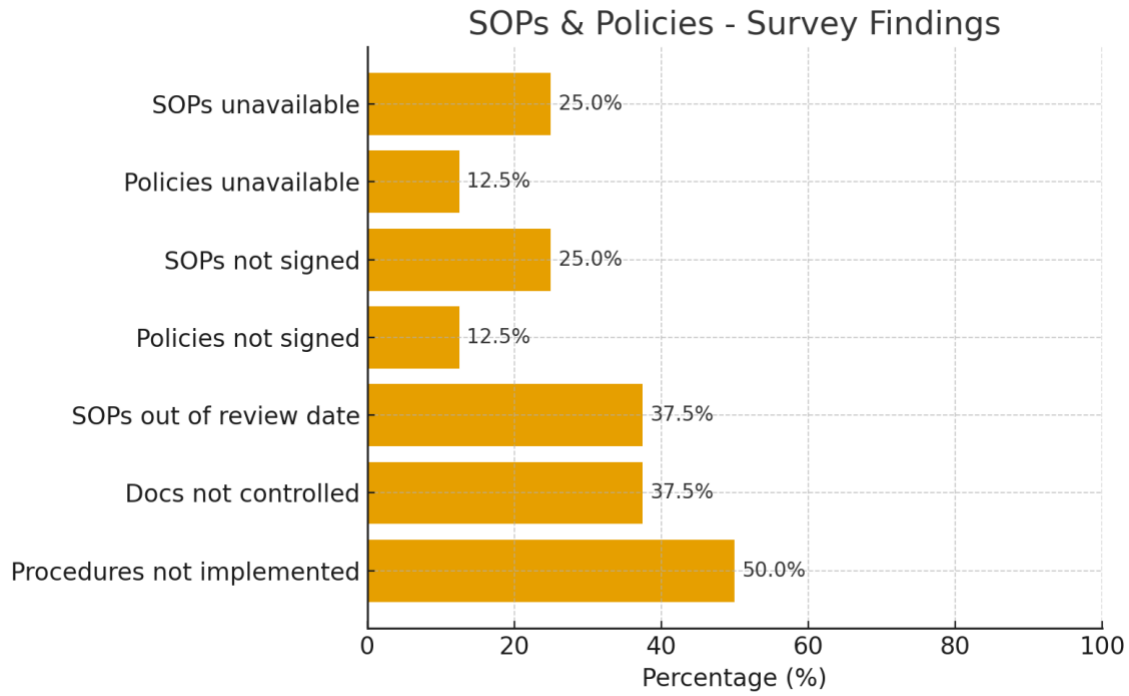


Figure 4: Survey findings on SOPS and Policies among internal auditors in the Midlands BU (2020–2023)

Documents and Records

Auditors highlighted persistent weaknesses in document and record control. Half of the respondents (50%) identified a lack of full implementation of document requirements as a recurring issue. Over one-third observed SOPs out of review date (37.5%) and non-document-controlled procedures (37.5%). Additionally, 25% noted missing SOPs or unsigned SOPs, while 12.5% reported unavailable or unsigned policies. These findings emphasise systemic lapses in document control, which undermine the reliability and consistency of laboratory processes.

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Corrective Action (CAPA) Weaknesses

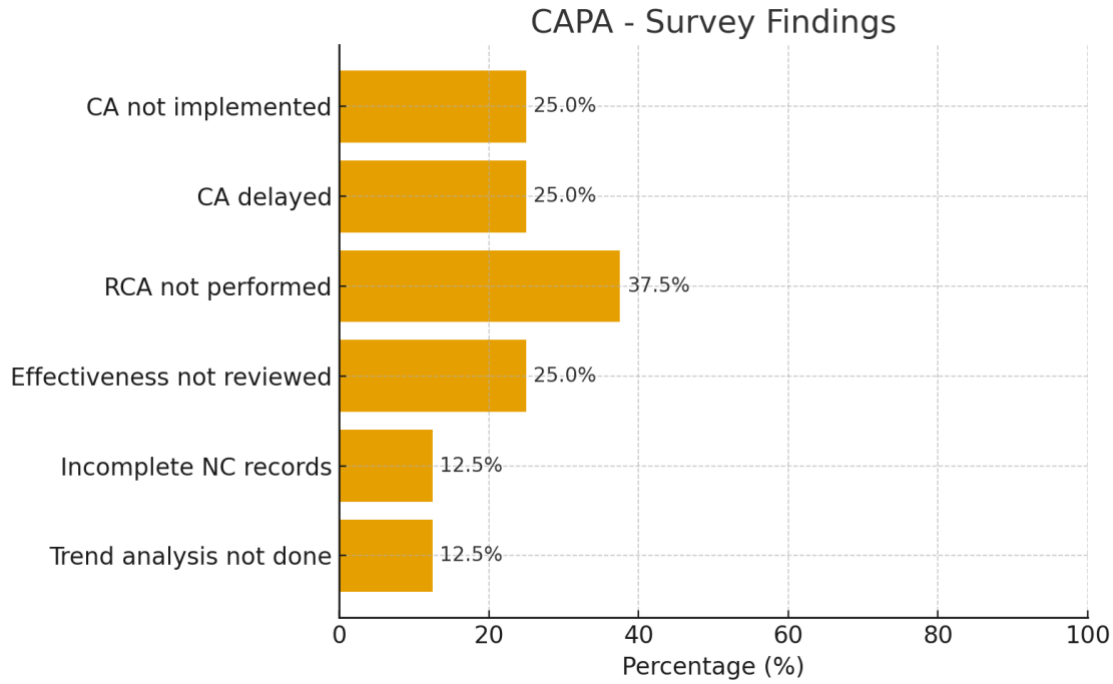


Figure 5: Survey findings on CAPA among internal auditors in the Midlands BU (2020–2023)

CAPA processes were identified as a significant area of weakness. Over one-third of respondents (37.5%) indicated that root cause analysis was not done, while 25% highlighted delayed or incomplete implementation of corrective actions. A further 25% reported that the effectiveness of CAPAs was not reviewed, limiting the ability of laboratories to confirm whether corrective actions addressed underlying issues. Smaller proportions of auditors noted incomplete NC records (12.5%) and a lack of trend analysis (12.5%). Overall, these findings suggest that while CAPAs are initiated, their completion and effectiveness remain major challenges.

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Management Review (MRM)

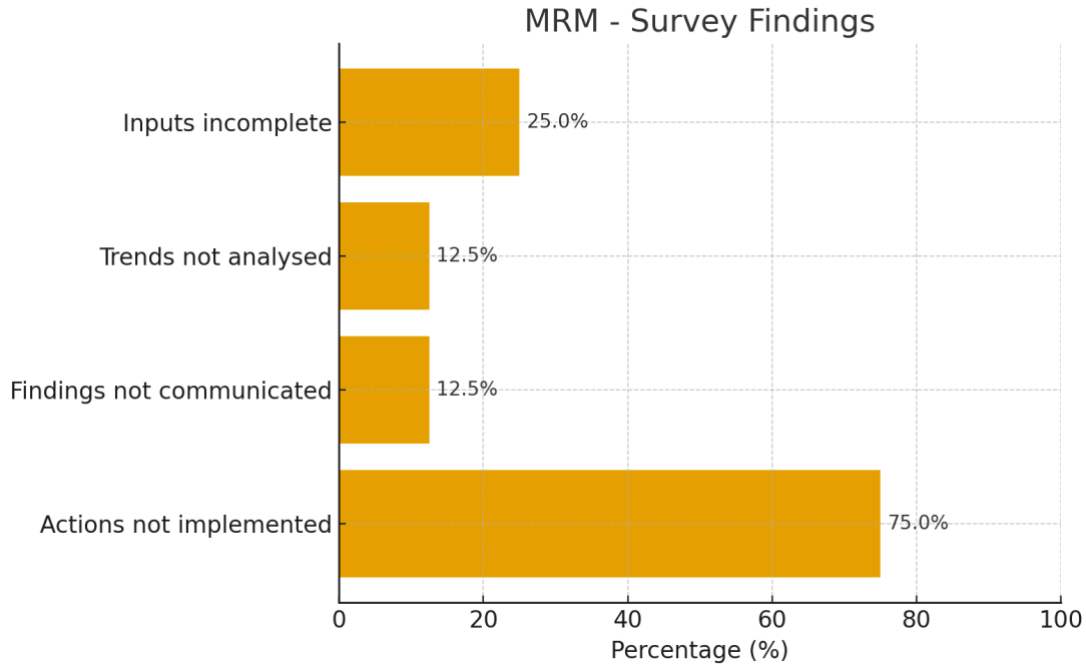


Figure 6: Survey findings on MRM among internal auditors in the Midlands BU (2020–2023)

Management review processes were also found to be problematic. The majority of auditors (75%) observed that actions arising from MRMs were not implemented, representing a critical weakness in leadership oversight. One-quarter of auditors (25%) noted incomplete review input, while smaller proportions identified poor trend analysis (12.5%) and a lack of communication of findings (12.5%). Although all laboratories had conducted MRMs within the required period, the lack of follow through on outcomes reduced their effectiveness as a quality improvement tool.

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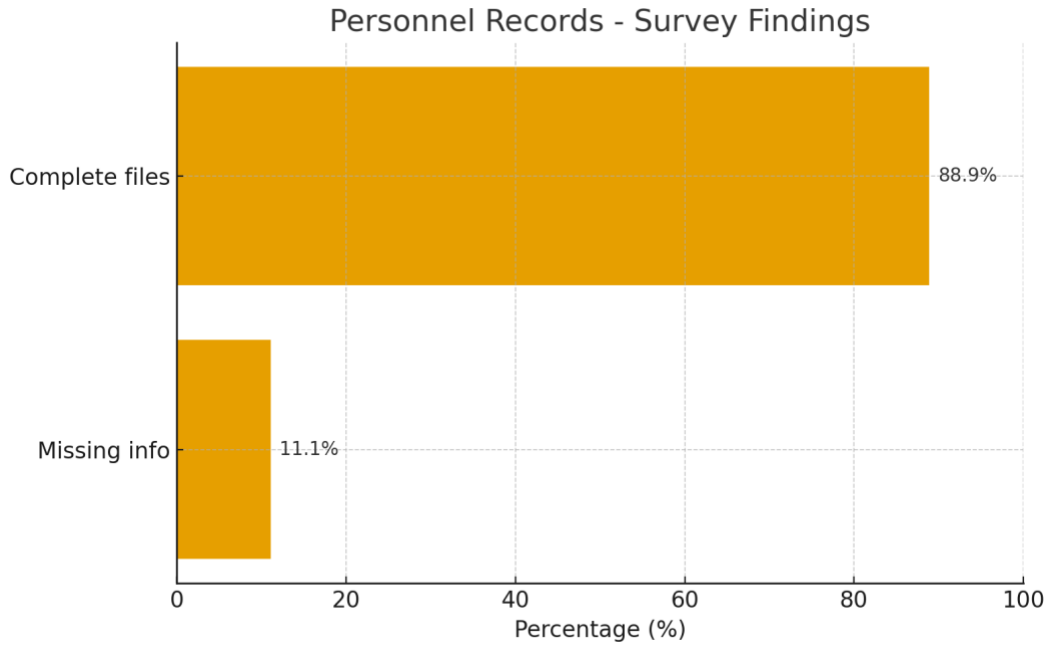


Figure 7: Survey findings on personnel records among internal auditors in the Midlands BU (2020–2023)

All auditors (100%) confirmed that personnel files were available in the laboratories. However, 11.1% indicated that these files did not include all the required information. This suggests that while the documentation framework exists, lapses remain in maintaining complete and updated personnel records. Even small gaps in personnel documentation can compromise compliance with ISO 15189, particularly in demonstrating staff competence and training during SANAS audits.

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Training and Competency

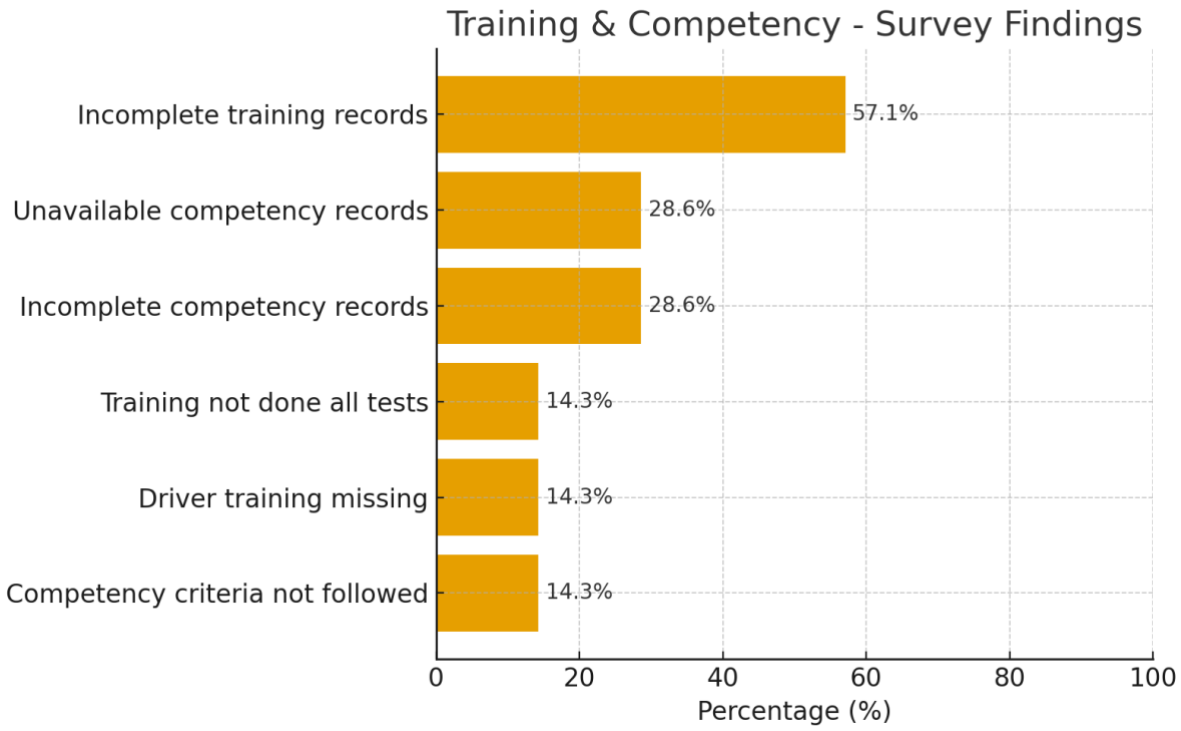


Figure 7: Survey findings on training and competency among internal auditors in the Midlands BU (2020–2023)

Training and competency records emerged as a recurring source of NCs. More than half of the respondents (57.1%) reported incomplete training records, while 28.6% observed unavailable or incomplete competency records. Smaller, but significant proportions highlighted gaps such as training not being performed for all tests (14.3%), missing training records for drivers (14.3%), and non-adherence to competency criteria (14.3%). These findings confirm that personnel-related deficiencies, particularly in training documentation and competency assessments, remain a persistent barrier to compliance.

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Pre-Analytical

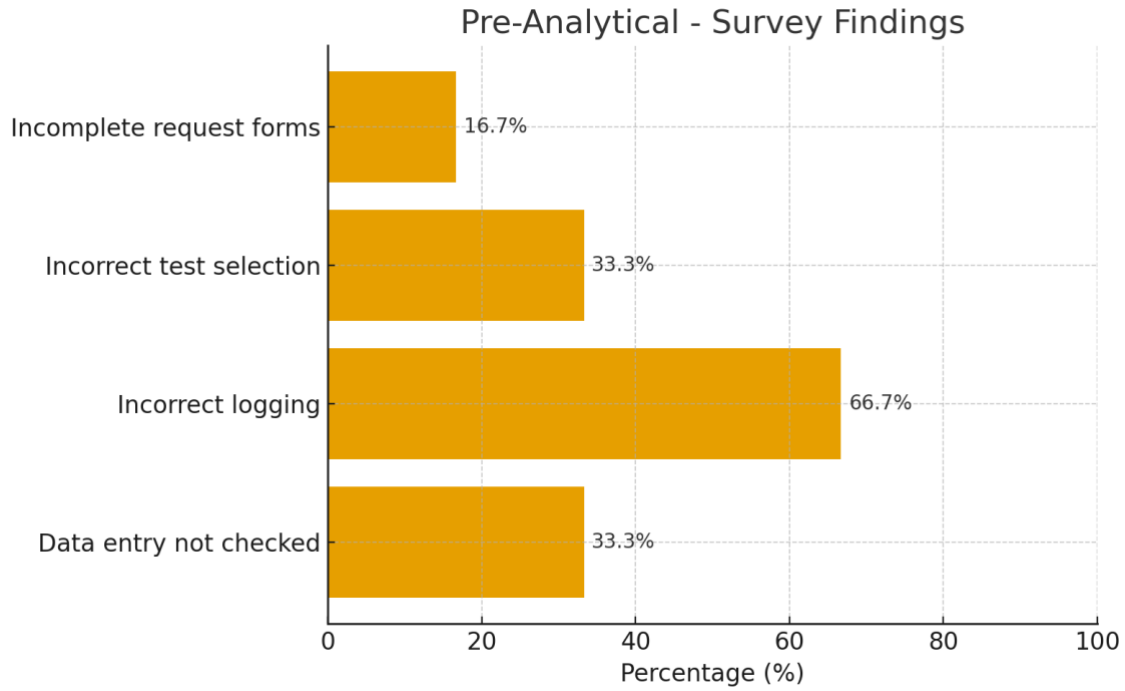


Figure 8: Survey findings on pre-analytical among internal auditors in the Midlands BU (2020–2023)

Two-thirds of auditors (66.7%) reported incorrect logging of information in laboratory records, making it the most frequent pre-analytical weakness. Additionally, one-third noted incorrect test selection (33.3%) and data entry not being checked regularly (33.3%), while 16.7% observed incomplete laboratory request forms. These findings show that errors at the pre-analytical stage, particularly in data capture and request handling, pose significant risks to result reliability. Strengthening staff training and routine verification checks are essential to reduce such recurring issues.

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(2020–2023).

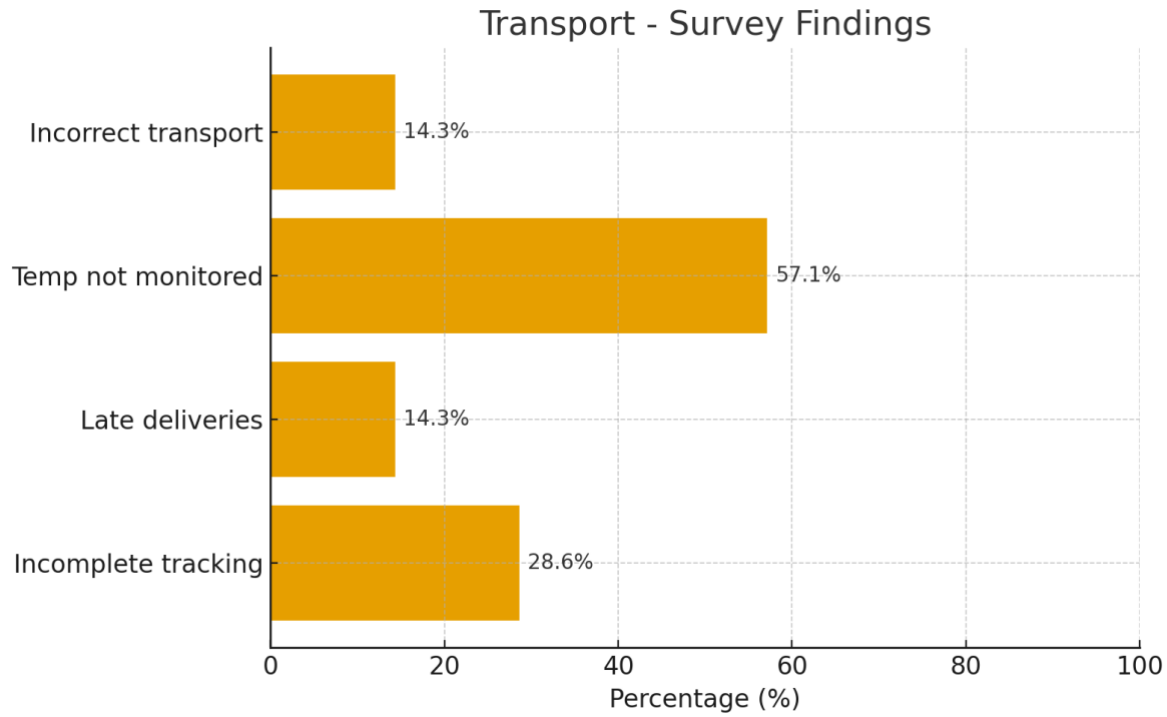


Figure 9: Survey findings on transport among internal auditors in the Midlands BU

The majority of auditors (57.1%) highlighted that transportation temperatures were not monitored consistently. Other challenges included incomplete tracking sheets (28.6%), delayed specimen deliveries (14.3%), and incorrect transportation methods (14.3%). Since sample integrity begins with correct handling during transport, these gaps expose a vulnerability that may compromise result accuracy even before analysis begins. Implementing stricter monitoring systems, such as temperature loggers and standardised transport protocols, would help to address these weaknesses.

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(2020–2023).

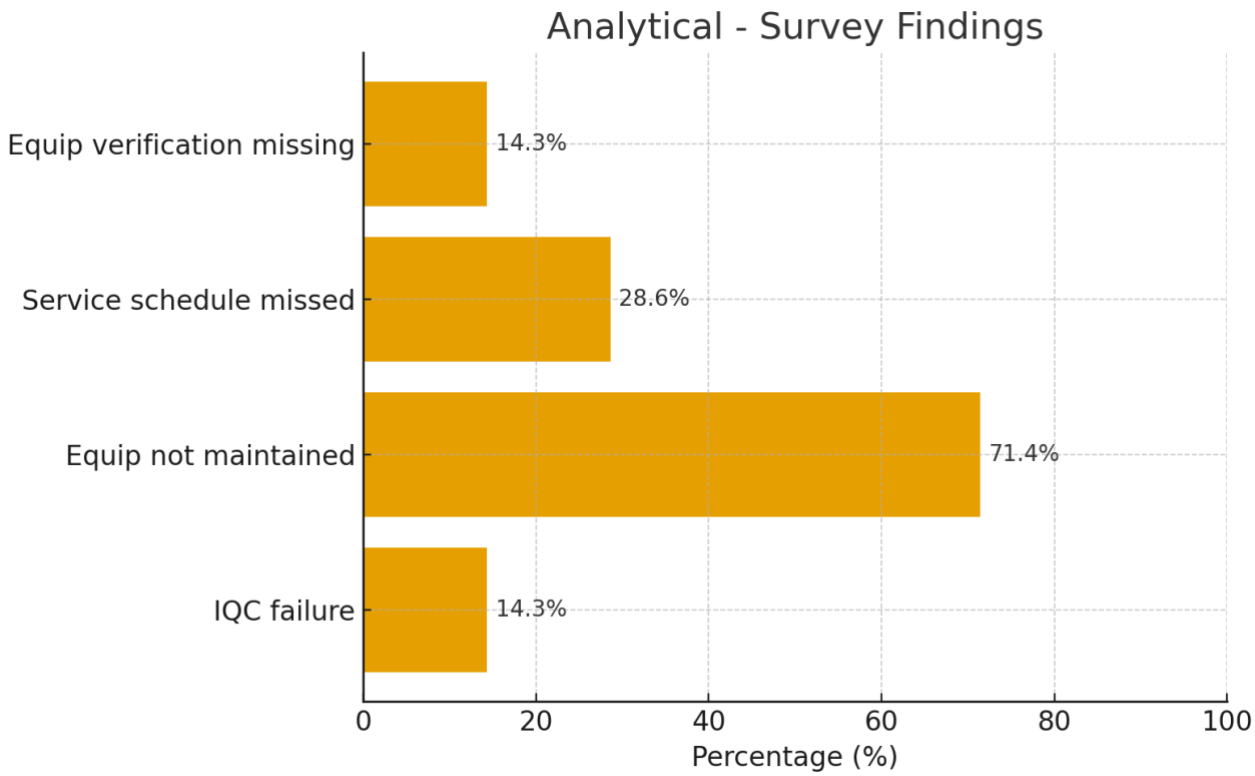


Figure 10: Survey findings on analytical among internal auditors in the Midlands BU

More than two-thirds of respondents (71.4%) reported that equipment was not consistently maintained as per SOPs. Smaller, but still notable proportions cited missed equipment service schedules (28.6%), missing verification records (14.3%), and internal quality control (IQC) failures (14.3%). This highlights that while equipment availability may not be the issue, adherence to maintenance protocols remains inconsistent. Such lapses threaten analytical reliability, reinforcing the need for structured preventive maintenance schedules and closer oversight of IQC practices.

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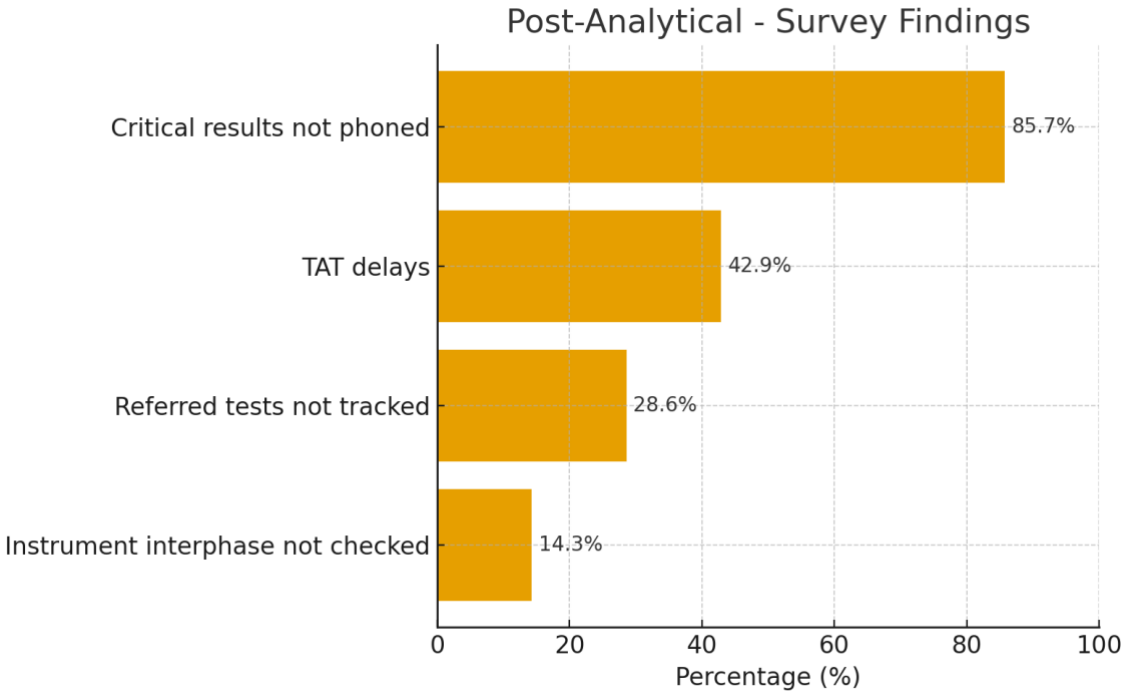


Figure 11: Survey findings on post-analytical among internal auditors in the Midlands BU (2020–2023)

The most frequently reported issue in the post-analytical phase was inconsistency in phoning critical results, noted by 85.7% of auditors. Delays in turnaround times were reported by 42.9%, while 28.6% highlighted that referred tests were not consistently tracked, and 14.3% observed instrument interphase checks not performed regularly. These findings suggest that communication and reporting remain weak points, directly affecting patient care. Improving turnaround monitoring, strengthening communication channels, and automating tracking systems for referred tests are critical to ensuring reliability in the post-analytical stage.

Open Comments and Recommendations

Respondents highlighted documentation, CAPA effectiveness, and staff training as areas needing urgent attention. Recommendations included more structured RCA, refresher training, and stronger management involvement in addressing NCs.

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4.10 Challenges Encountered During Data Collection

4.10.1 Challenges in Quantitative Audit Data Collection

The retrieval of quantitative data on non-conformances (NCs) from SANAS audit reports between 2020 and 2023 was significantly affected by the cyber-attack on the NHLS in 2024. Although the attack occurred after the study period, it disrupted access to the central electronic databases where audit data were stored. As a result, some historical records could not be retrieved electronically, and several laboratories had incomplete audit spreadsheets available.

To address this gap, the researcher relied on hard-copy records maintained at laboratory level and on data provided directly by Business Managers (BMs). This alternative approach introduced challenges, including delays due to multiple follow-ups, variation in how NCs were documented across laboratories, and occasional missing or illegible entries. The cyber-attack therefore introduced unanticipated obstacles in consolidating a complete dataset for the 2020–2023 audit period.

This incident highlights how external digital disruptions can impact retrospective research, even when the study period predates the event. It also emphasises the importance of robust data backup, redundancy, and disaster recovery systems within the NHLS to protect the continuity of quality management records.

4.10.2 Challenges in Survey Data Collection

The administration of the survey to internal auditors also presented several difficulties. Despite the use of an online platform (REDCap) to facilitate accessibility, the response rate was initially low. Many auditors did not respond within the initial period, due to heavy workloads and competing priorities. To improve participation, the researcher had to send daily reminders via email and WhatsApp, encouraging auditors to complete the survey. In some cases, individual follow-ups were necessary to assure respondents of confidentiality and the importance of their contribution.

While these reminders eventually increased the number of responses, the process highlighted the risk of response bias, as some auditors may have felt pressured to participate or to provide cautious answers. The low initial response rate and the

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repeated follow-ups also extended the survey data collection period beyond the original period.

4.10.3 Impact of Challenges

Although these challenges created delays and required additional effort, they did not compromise the validity of the data collected. Risks were mitigated by triangulating data sources, standardising NC data, and ensuring strict anonymity and confidentiality in survey administration. However, the challenges underscore the realities of conducting research within a large public health service, where logistical and systemic barriers can hinder smooth data collection.

4.11 Discussion

The survey results reinforce and contextualize the NC data from the SANAS audits:

4.11.1 Recurring Themes Across Both Data Sets

Both the audits and survey responses point to SOP/document control lapses, training and competency gaps, and weaknesses in CAPA management. This consistency suggests that these are systemic challenges across the Midlands BU.

The survey highlights end-to-end process vulnerabilities. Pre-analytical issues (incorrect logging, incomplete request forms) compromise accuracy from the start, while analytical gaps (equipment not maintained, IQC failures) threaten reliability, and post-analytical failures (critical results not consistently phoned, TAT delays) directly affect patient care.

4.11.2 CAPA and MRM Gaps

The fact that 75% reported MRM actions not being implemented on time mirrors the audit NCs where delayed corrective actions and poor RCA were frequently raised. This suggests that management-level accountability mechanisms need strengthening.

4.11.3 Human vs Systemic Factors

Auditors identified a mix of human error (failure to follow SOPs, incomplete records) and systemic shortfalls (document control systems, CAPA follow-up, monitoring of transport conditions). This balance shows that improvement requires both capacity

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building (training, accountability) and structural reinforcement (digital systems, automated monitoring, and policy enforcement).

4.11.4 Implications

The triangulation between survey findings and audit data confirms that recurring NCs are not isolated events but reflect broader systemic and cultural issues in quality management. Addressing them requires not only corrective actions, but also preventive, sustainable strategies embedded into daily practice.

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CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter discusses the findings of the study in relation to the research objectives, existing literature, and the broader context of ISO 15189 accreditation. The purpose is to interpret the results presented in Chapter 4, identify the underlying factors contributing to non-compliance, and explore their implications for the Midlands Business Unit of the NHLS. The discussion integrates audit data (2020 to 2023) with insights from the internal auditor survey, providing a triangulated perspective on systemic challenges. The chapter also situates the study within national and international literature to highlight similarities, differences, and lessons for improving compliance.

5.2 Interpretation of Audit Findings

The analysis of SANAS audit outcomes between 2020 and 2023 revealed both improvements and persistent deficiencies in compliance.

5.2.1 2020: Baseline Compliance with Isolated Gaps

The year 2020 recorded the lowest number of NCs (n=7). Most findings were minor, relating to incomplete staff training records, SOPs past review dates, and unmonitored equipment logs. Although these issues reflected weaknesses in document control and training oversight, the overall low number of NCs suggested that laboratories were operating at a stable level of compliance at this time. However, the lack of trend monitoring for rejected samples and ineffective corrective action planning for turnaround time delays indicated that systemic risks already existed within the QMS.

5.2.2 2021: Spike in NCs and COVID-19 Disruptions

In 2021, NCs increased sharply (n=24), representing the highest audit burden in the study period. This coincided with the COVID-19 pandemic, which placed extraordinary strain on laboratory operations. Findings included unmonitored overdue test lists, incomplete CAPA closures, SOPs out of date, and gaps in QC reruns. A key observation was that staff shortages and workload pressures undermined adherence to SOPs, with some laboratories operating with minimal personnel. CAPA weaknesses

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and document control failures became more pronounced, suggesting that the crisis exposed vulnerabilities already present in the QMS.

5.2.3 2022: Persistence of Systemic Weaknesses

Audit findings in 2022 (n=24) mirrored the high levels observed in 2021, even though pandemic pressures had eased. This indicated that systemic deficiencies were not fully addressed. Document control problems, repeat NCs related to CAPA closure, and incomplete internal audits were frequently reported. Lab 5, undergoing its first SANAS accreditation audit, contributed a significant proportion of NCs (n=15), consistent with international literature that shows newly accredited laboratories often face high initial non-compliance. The persistence of similar NCs from previous years highlighted the ineffectiveness of corrective actions, particularly in CAPA management and documentation practices.

5.2.4 2023: Partial Recovery but Persistent Challenges

In 2023, NCs declined (n=6), suggesting some recovery and improvements in compliance. Laboratories demonstrated stronger audit readiness and fewer systemic lapses compared to prior years. Nevertheless, familiar issues persisted, including overdue SOP reviews, incomplete training records, and unresolved CAPAs. This suggests that while improvements were evident, long-term solutions to recurring NCs had not been fully embedded into daily laboratory practice.

The year-by-year analysis reveals a cyclical pattern of NCs, with temporary improvements not fully sustained across the business unit. Recurring issues in documentation, training, and CAPA systems suggest that root causes were not consistently addressed. These findings point towards systemic weaknesses in QMS resilience, particularly in maintaining compliance during periods of external disruption (e.g. COVID-19, staff shortages).

5.3 Interpretation of Survey Findings

The internal auditor survey provided complementary insights into the challenges observed during SANAS audits. The responses confirmed many of the recurring themes from the audit data and helped to contextualise why certain non-conformances persisted across multiple years.

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The survey showed that nearly half of auditors (44.4%) had more than 10 years' auditing experience, and one-third (33.3%) had 2 to 3 years' experience. This indicates that the majority of respondents were highly experienced, strengthening the credibility of the findings. At the same time, the limited number of newer auditors suggests a potential succession gap, with few opportunities for mentoring and capacity building. This aligns with audit findings that showed inconsistent audit quality and lack of escalation of repeat NCs, potentially linked to uneven distribution of auditing responsibilities.

More than one-third of auditors highlighted SOPs that were out of review date (37.5%) and procedures that were not document controlled (37.5%). Half (50%) reported incomplete implementation of document requirements. These findings mirror the audit results from 2020 to 2023, where documentation lapses were consistently raised as NCs. The persistence of outdated SOPs across multiple years suggests that document control systems were not only weak but also not systematically reinforced through training and accountability mechanisms.

The survey revealed that 37.5% of auditors had encountered situations where root cause analysis was not performed, and 25% noted delays in implementing corrective actions. These findings reinforce the audit data, which highlighted CAPA inefficiency as one of the most frequent and unresolved sources of NCs. The lack of CAPA effectiveness reviews reported in the survey also explains why repeat NCs continued across multiple audit cycles, as underlying causes were not being addressed comprehensively.

Survey findings showed that 75% of auditors observed that actions arising from MRMs were not implemented, despite the meetings being conducted. This reflects the disconnection observed in audit reports, where management reviews were formally documented but their outputs did not translate into effective corrective measures. This weakness in leadership oversight perpetuates systemic challenges and limits the ability of the QMS to improve sustainably.

More than half of auditors (57.1%) reported incomplete training records, while 28,6% noted unavailable or incomplete competency records. This resonates with audit findings where training and competency gaps were repeatedly raised as NCs,

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especially in 2021 and 2023. These deficiencies are particularly concerning, as they directly affect staff performance, compliance with SOPs, and the reliability of laboratory results. Inadequate supervision and lack of structured training plans contributed to these findings, suggesting the need for more robust personnel development systems.

The convergence of survey and audit data confirms that the major systemic issues within the Midlands Business Unit revolve around:

- Weak document control systems.
- Ineffective CAPA implementation and follow-up.
- Insufficient training and competency monitoring.
- Incomplete implementation of management review outcomes.

By aligning both datasets, the study provides strong evidence that these factors are not isolated observations but represent entrenched systemic challenges within the QMS of the business unit.

5.4 Factors Contributing to Non-Compliance

The findings from both audit data (2020–2023) and survey responses point to a set of recurring systemic factors that contribute to non-compliance during SANAS audits in the Midlands Business Unit. These factors are interrelated and highlight the complexity of sustaining ISO 15189 accreditation in a resource-constrained public health context.

5.4.1 Staffing and Workload Challenges

Staff shortages and workload pressures emerged as significant contributors to non-compliance, particularly during the COVID-19 pandemic. In 2021, several laboratories reported delays in monitoring overdue test lists and verification queues due to limited personnel. At times, a single technologist was required to perform both technical and clerical duties, compromising compliance with SOPs. Even beyond the pandemic, staff turnover and open posts continued to strain laboratory operations, resulting in delays in training, incomplete competency assessments, and lapses in daily QMS monitoring.

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5.4.2 Weak Corrective and Preventive Action (CAPA) Systems

CAPA-related findings were among the most persistent across the study period. Audit data revealed delayed closure of CAPAs and repeated findings from previous years, while the survey confirmed that root-cause analysis was often incomplete and effectiveness checks rarely performed. This indicates a systemic weakness in CAPA culture, where corrective actions were initiated, but not embedded into routine practice. Without proper RCA and follow-up, laboratories were prone to repeat NCs, undermining the credibility of their QMS.

5.4.3 Document Control Failures

Inconsistent document control was a recurring theme across all years of the study. Laboratories frequently failed to review SOPs within stipulated timeframes, maintained outdated procedures, or lacked proper document version control. The survey reinforced these issues, with 50% of auditors reporting incomplete implementation of document requirements. These failures point to insufficient accountability and monitoring mechanisms for document management, which are fundamental to ISO 15189 compliance.

5.4.4 Training and Competency Gaps

Audits and surveys consistently highlighted deficiencies in staff training and competency records. Incomplete training files, missing driver training records, and inconsistent competency assessments were frequently reported. These gaps not only jeopardise compliance with ISO 15189 clauses, but also pose risks to patient safety by undermining staff readiness to perform critical tasks. Inadequate supervision and lack of structured training plans contributed to these findings, suggesting the need for more robust personnel development systems.

5.4.5 Leadership and Management Oversight

Management review processes, though conducted, often failed to result in meaningful follow-up actions. Both audits and survey results showed that MRM outputs were not implemented in practice, weakening the laboratory's ability to close the loop on quality management. Leadership engagement in quality objectives was also inconsistent, as evidenced by unmet quality goals and lack of improvement planning in some

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laboratories. Weak oversight reduces accountability and perpetuates systemic compliance failures.

5.4.6 External Disruptions (COVID-19 Pandemic and Cyberattack)

The COVID-19 pandemic had a profound impact on compliance, particularly in 2021, when staff absenteeism, increased test volumes, and reprioritisation of resources towards pandemic testing led to a surge in NCs. These findings are consistent with global literature documenting the strain of COVID-19 on laboratory systems. In addition, the NHLS cyberattack in 2024 disrupted access to electronic records and delayed retrieval of audit data for this study. Such external shocks highlight the vulnerability of QMS processes that lack redundancy and resilience mechanisms.

5.5 Comparison with Literature (Expanded)

The findings of this study align closely with national and international literature on ISO 15189 implementation in public-sector laboratories, particularly regarding recurring weaknesses in document control, CAPA systems, training and competency, and leadership oversight and how these are exacerbated by staffing pressures and external shocks.

5.5.1 Human and Organisational Factors

Similarly, Owino (2023) identified human resource shortages, poor communication, and inadequate leadership involvement as central drivers of non-compliance. These findings mirror the Midlands Business Unit's challenges, where staff turnover, insufficient training, and weak management oversight were repeatedly raised. Both studies highlight that accreditation is not merely a technical exercise, but one fundamentally dependent on human factors and organisational culture.

5.5.2 Document and Record Control

The persistent presence of out-of-date SOPs, uncontrolled documents, and incomplete implementation mirrors findings from Gauteng laboratories. Tsheola and Kruger (2022) documented recurring NCs in documentation and highlighted the systemic difficulty of maintaining up-to-date records in resource-limited environments. Their later work (Tsheola et al., 2024) confirms that documentation-related NCs

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accounted for a significant proportion of findings across pre-analytical, analytical, and post-analytical phases. This consistency suggests that document control remains a national weakness within NHLS laboratories, not just a localised problem in the Midlands BU.

5.5.3 Corrective and Preventive Actions (CAPA)

International and national analyses repeatedly identify CAPA as a systemic pinch point. In the Midlands BU, repeat NCs and delayed CAPA closures echoed similar findings in Gauteng, where Tsheola et al. (2024) note that CAPA inefficiency was among the most frequent sources of NCs. Auditor perspectives (Owino, 2023) further stressed that weak root cause analysis and lack of follow-up perpetuated these issues. Literature emphasises that sustainable CAPA requires proper RCA skills, clear accountability, and effectiveness checks elements that remain underdeveloped in the Midlands BU.

5.5.4 Training, Competency, and Auditor Development

The study's recurrent findings on incomplete training files and competency assessments resonate strongly with both national and international literature. Tsheola and Kruger (2022) highlight inadequate QMS training as a barrier to accreditation in Gauteng laboratories, while Owino (2022) underscores the lack of mentorship and auditor capacity-building as limiting factors. At global level, Alkhurayji et al. (2025) similarly found that insufficient training and staff workload were critical barriers to compliance in Saudi healthcare facilities. Together, these studies reinforce the conclusion that training and competency management are not isolated challenges, but widespread and persistent gaps in healthcare accreditation.

5.5.5 Leadership and Management Oversight

The Midlands BU's weak follow-up on management review outputs is also consistent with broader literature. Ngubo (2021) found that leadership disengagement undermined quality improvement efforts in KZN laboratories, while Kruger et al. (2022) report that low morale and limited leadership accountability constrained auditor effectiveness in Gauteng. This pattern highlights a systemic issue across both

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provincial and international contexts: without strong leadership commitment, quality objectives remain poorly implemented, and accreditation risks persist.

5.5.6 External Shocks: COVID-19 and Resilience

Globally, the COVID-19 pandemic disrupted routine QMS activities, leading to documentation lapses, delayed CAPA closures, and training interruptions. The Midlands BU's 2021 spike in NCs mirrors international reports of staff absenteeism, increased workload, and reprioritisation of resources towards pandemic testing. The cyberattack in 2024 similarly highlights vulnerabilities in IT resilience, echoing Alkhurayji et al. (2023), who note that poor infrastructure and system-level weaknesses undermine compliance in healthcare accreditation globally.

5.5.7 Summary

Across sources, the literature corroborates this study's central conclusion: sustained ISO 15189 compliance depends on mature systems in four interlocking domains—document control, CAPA/RCA, training and competency, and leadership oversight—while resilience to staffing and IT shocks is equally critical. The Midlands BU's trajectory (2021–2022 spike, 2023 partial recovery) reflects known patterns both nationally and internationally. Addressing these entrenched weaknesses will require evidence-based interventions, such as risk-based internal audits, RCA skills training, digital document and competency systems, and stronger leadership accountability.

The findings of this study align closely with national and international literature on ISO 15189 implementation in public-sector laboratories, particularly regarding recurring weaknesses in document control, CAPA systems, training and competency, and leadership oversight – and how these are exacerbated by staffing pressures and external shocks.

5.5.8 First-Time Accreditation Trajectories

The concentration of NCs during Lab 5's first SANAS assessment matches international experience: newly accredited laboratories typically register higher initial NC loads as they operationalize full ISO 15189 requirements. The literature suggests mentorship, phased scope, and pre-assessment readiness checks as effective mitigations measures that map directly onto the needs inferred from our 2022 findings.

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5.5.9 ISO 15189:2022 Risk-Based and Patient-Centred Emphases

Recent updates to ISO 15189 emphasize risk management, patient-centred processes, and integrated oversight (including point-of-care testing). The persistent findings in CAPA, document control, and competency in this study indicate areas where the risk-based mind set is not yet fully embedded. Literature recommends moving from checklist compliance to risk-prioritized controls (e.g. focusing reviews, internal audits, and CAPA on high-impact steps like critical result communication, specimen integrity, and equipment states of control). Our results reinforce this shift as crucial for sustained improvement.

5.5.10 African and SANAS Contexts

Regional laboratory quality-improvement initiatives such as Strengthening Laboratory Management Toward Accreditation (SLMTA) and Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) have consistently demonstrated improvements in documentation practices, internal auditing capacity, and leadership engagement when programs incorporate mentorship and practical quality-improvement projects (African Society for Laboratory Medicine, 2023). The SLIPTA process provides a framework for stepwise laboratory improvement in the African region (Ndihokubwayo et al., 2016; Njukeng, 2010).

However, the pattern observed in this study characterised by initial improvements followed by recurring systemic non-conformances suggests that similar capacity-building approaches may be necessary within the context of South African National Accreditation System (SANAS) and the National Health Laboratory Service (NHLS). Specifically, mentored internal audits, structured coaching in root cause analysis, and the use of management dashboards to monitor quality indicators may strengthen institutional capacity and sustain quality gains. This alignment between literature and the study findings indicates that the persistent challenges highlighted in previous research correspond closely with the dominant non-conformance patterns identified in this study.

The literature reviewed supports the central conclusion of this study that sustained compliance with ISO 15189 depends on well-developed and integrated systems across four key domains: document control, CAPA and root cause analysis (RCA),

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staff training and competency management, and effective leadership oversight. In addition, laboratories must maintain operational resilience to disruptions such as staffing shortages and information technology failures. The pattern observed in the Midlands Business Unit, with increased non-conformances during 2021 to 2022 followed by partial improvement in 2023, reflects trends reported in the literature where systemic pressures affect quality management performance. Consequently, targeted interventions including risk-based internal audits, strengthening RCA skills, implementing digital systems for document and competency management, and improving management review meeting action tracking are identified as critical strategies for achieving sustained improvements in accreditation compliance.

5.6 Implications for the NHLS Midlands Business Unit

The convergence of audit and survey findings has several important implications for the Midlands Business Unit.

5.6.1 Risk to Accreditation Status

The recurrence of major NCs, particularly in CAPA, document control, and training, highlights vulnerabilities that could place laboratories at risk of suspension or withdrawal of SANAS accreditation. While improvements were noted in 2023, the persistence of repeat NCs indicates that systemic issues remain unresolved, necessitating urgent and sustained interventions.

5.6.2 Impact on Patient Safety and Service Delivery

Laboratory non-compliance does not only affect accreditation outcomes but also directly impacts the quality of diagnostic services. Incomplete training and poor document control increase the risk of laboratory errors, delayed results, and compromised patient care. The inability to implement CAPA effectively also undermines the principle of continual improvement, which is central to ISO 15189 and essential for ensuring patient safety.

5.6.3 Organisational Culture and Leadership

The finding that MRM outcomes were not implemented consistently underscores a gap in leadership accountability and organisational culture. Without active

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management engagement, laboratories risk perpetuating a compliance culture focused on “audit readiness” rather than embedding quality practices into daily operations. The business unit must strengthen leadership involvement in QMS processes, ensuring that quality objectives are not only set, but actively pursued and monitored.

5.6.4 Resource Allocation and Resilience

The COVID-19 pandemic and the 2024 cyber-attack exposed the fragility of QMS systems under stress. These events highlighted the need for contingency planning, redundant systems, and adequate resourcing of staff and IT infrastructure. The Midlands BU requires investments in digital solutions for document management, competency tracking, and CAPA follow-up to reduce dependence on manual systems that are prone to error and disruption.

5.6.5 Capacity Building and Skills Development

The reliance on a small pool of highly experienced auditors, with limited entry of new personnel into the system, raises sustainability concerns. Continuous professional development, mentorship of new auditors, and broader staff training on QMS principles are needed to ensure long term compliance capacity.

5.7 Discussion of Non-Conformance Categories and Root Cause Analysis

The analysis of non-conformance (NC) categories across the seven SANAS-accredited laboratories within the Midlands business unit revealed recurring patterns that provide insight into systemic challenges faced by public health laboratories. The majority of NCs were concentrated in the management requirements of ISO 15189, particularly documentation control, quality management review, and internal audit follow-up. In the technical requirements, frequent NCs related to equipment calibration, reagent management, and external quality assessment (EQA) participation. These findings align with international literature, where laboratories in low and middle income countries have also struggled to maintain consistency in document control, training, and equipment verification (Sayed et al., 2018; Dacombe et al., 2016).

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A trend analysis demonstrated that NCs often clustered within the pre-analytical and analytical phases. Pre-analytical NCs included incomplete specimen reception records, inadequate labelling, and poor chain-of-custody documentation. Analytical phase NCs were more technical, such as expired calibrations, failure to verify new lots of reagents, and insufficient maintenance of instruments. Post-analytical NCs, although less frequent, were still notable, with issues such as delayed turnaround time reporting and incomplete EQA corrective action documentation. This distribution of NCs suggests that both human factors and systemic resource constraints contribute to audit non-compliance.

The review of root cause analyses (RCAs) showed varying levels of depth and effectiveness. In some laboratories, RCAs were superficial, citing “staff negligence” or “lack of training” without adequately exploring systemic factors. In others, the RCAs demonstrated a more structured approach, linking NCs to process weaknesses, such as inadequate SOP reviews, insufficient supervisory oversight, or the absence of formalised retraining schedules. According to ISO 15189 and SANAS guidelines, effective RCAs should identify the underlying system failures rather than attributing blame to individuals (SANAS, 2022).

Corrective actions implemented also varied in effectiveness. In certain cases, repeat NCs were observed in consecutive years, highlighting that corrective actions were not sufficiently sustained. For example, documentation-related NCs often reappeared, despite action plans that included SOP updates and refresher training. This indicates a possible lack of monitoring mechanisms or failure to integrate corrective actions into broader quality management reviews. However, there were also positive trends: in some laboratories, corrective actions targeting EQA participation and instrument calibration were associated with a measurable reduction in repeat NCs in subsequent audit cycles.

Overall, the analysis suggests that while RCAs and corrective actions are being performed, their depth, consistency, and sustainability vary across laboratories. Laboratories that adopted a system-based corrective action strategy (addressing processes and policies) demonstrated greater improvement than those relying on reactive, short-term interventions. These findings underscore the importance of

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capacity building in RCA methodology and continuous monitoring of corrective action effectiveness to ensure long-term compliance.

5.8 Chapter Summary

This chapter has discussed the findings of the study in light of existing literature and highlighted the systemic factors contributing to non-compliance during SANAS audits in the Midlands Business Unit. The results demonstrated that while 2020 reflected a stable compliance baseline, the COVID-19 pandemic in 2021 precipitated a sharp increase in NCs, exposing weaknesses in staffing, CAPA, documentation, and training. These challenges persisted into 2022, particularly with the accreditation of a new laboratory, and although improvements were observed in 2023, persistent deficiencies indicated that systemic solutions had not yet been fully embedded.

Survey results confirmed these trends, revealing that auditors consistently observed weaknesses in CAPA follow-up, document control, and training records. The triangulation of findings underscores that these are entrenched, not incidental, challenges.

A comparison with the literature showed that the Midlands BU's experience is consistent with broader patterns observed in other resource-constrained health systems, particularly in Africa, and aligns with known global challenges of ISO 15189 implementation. External disruptions, such as COVID-19 and the cyberattack, further demonstrated the need for resilient and risk-based QMS approaches.

The implications of these findings are profound: sustaining ISO 15189 accreditation requires addressing systemic weaknesses, embedding leadership accountability, investing in capacity building, and adopting resilient digital solutions. The next chapter will present targeted recommendations and the overall conclusions of the study.

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CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

This chapter presents the conclusions of the study and outlines recommendations for practice, policy, and future research. The analysis was focused on identifying factors that contribute to non-compliance in SANAS audits across the Midlands Business Unit between 2020 and 2023. Building on the results and discussion chapters, this chapter synthesises key findings, provides practical recommendations, and identifies areas for future study.

6.2 The study revealed several important trends

- Lab-specific patterns: NC counts fluctuated over time, with Lab 1 showing cycles of deterioration and improvement, Lab 2 and Lab 3 experiencing persistent documentation and competency issues, Lab 4 recording high NCs in 2021, and Lab 5 reporting 17 NCs during its initial accreditation in 2022.
- Cross-cutting issues: Documentation and traceability, equipment verification, QC/EQA follow-up, competency gaps, and weak RCA processes were consistent challenges across multiple sites.
- ISO 15189:2022 impact: The transition to the new standard was associated with heightened assessor scrutiny and transitional challenges in 2022–2023.

The findings demonstrate that NCs were not isolated events, but indicators of systemic weaknesses in quality management systems. While some improvements were achieved following CAPA implementation, these were often not sustained, with similar NCs recurring in subsequent audits. The study confirms that documentation, RCA, and equipment monitoring remain the most vulnerable areas, consistent with both local and global literature. Resource constraints, staff turnover, and gaps in training were additional contributory factors influencing compliance in the Midlands Business Unit.

6.3 Recommendations

Based on the study findings, the following recommendations are proposed:

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- For Laboratory Management: Strengthen document control through electronic document management systems, enhance management review dashboards to include NC recurrence and CAPA follow-up, and ensure timely closure of NCs.
- For Laboratory Staff: Improve competency assessments, implement structured mentorship programmes, and integrate training outcomes into staff appraisals.
- For NHLS Policy and Governance: Allocate resources to support equipment verification and MoU training, and conduct targeted ISO 15189:2022 workshops to prepare staff for evolving audit requirements.
- For Future Audits: Conduct proactive, risk-based internal audits aligned with ISO 15189:2022 requirements to identify and correct issues before SANAS assessments.

6.4 Limitations

The study was limited by incomplete data for some laboratories, particularly in 2023, and the absence of NC data for certain years. Severity classifications were inconsistently captured across labs, limiting detailed analysis of trends. The reliance on secondary audit data, without triangulation from other performance indicators such as workload or turnaround times, also restricted the scope of findings.

6.5 Future Limitations

Although this study provides valuable insights into the factors contributing to non-compliance during SANAS audits in the Midlands business unit, several limitations must be acknowledged, which may affect the interpretation and generalisation of the findings.

Data availability posed a major limitation. The central non-conformance spreadsheet was incomplete, and some historical data were irretrievably lost following the cyber-attack experienced by the National Health Laboratory Service. As a result, certain NC records and associated corrective actions for the period 2020–2023 could not be fully captured. The analysis therefore relied on the data available at the time of collection, which may not represent the complete picture.

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The scope of the study was restricted to seven SANAS-accredited laboratories within a single business unit. While this allowed for a detailed regional analysis, the findings may not be directly generalizable to other NHLS business units or to private sector laboratories in South Africa. Furthermore, laboratories with recent accreditation histories, or those not audited every year, contributed fewer data points, limiting the ability to make consistent year-to-year comparisons.

The use of surveys with internal auditors introduced potential response bias. Despite assurances of confidentiality, auditors may have provided overly cautious or “socially desirable” responses to avoid perceptions of criticism toward their employer. This risk of bias could have influenced the accuracy of self-reported challenges and perceptions of the audit process.

The study employed a retrospective design, which inherently relies on the quality and completeness of existing records. The researcher was unable to influence the manner in which NCs and RCAs were originally documented, and some entries were incomplete or lacked sufficient detail to allow for a fully comprehensive analysis. Additionally, the retrospective nature precluded the opportunity to verify the prospective implementation and sustainability of corrective actions.

The COVID-19 pandemic also posed contextual challenges. Audit schedules were disrupted in 2020 and 2021, and some laboratories experienced resource shortages, staff rotations, and increased workload pressures. These factors may have contributed to unusual audit findings that do not reflect typical operational performance.

Finally, while the findings provide useful insights into compliance challenges, generalisation must be approached with caution. The study’s results are most applicable to SANAS-accredited public health laboratories within the NHLS system. Further research across multiple provinces and including private sector laboratories would be valuable in establishing whether the identified trends are nationally representative.

By recognising these limitations, the study highlights the need for ongoing research, improved data management practices, and continuous strengthening of RCA and

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corrective action monitoring processes to ensure sustainable compliance with ISO 15189 standards.

6.6 Future Research

Future studies should expand on these findings by incorporating additional datasets, including EQA outcomes, IQC records, staff turnover, and workload indicators. Research that evaluates the link between NC recurrence and patient safety outcomes would provide valuable insights. Additionally, longitudinal studies tracking the impact of ISO 15189:2022 implementation on compliance would enhance the understanding of transitional challenges and opportunities.

6.7 Final Conclusion

In conclusion, this study highlights the systemic nature of non-compliance in SANAS audits within the Midlands Business Unit. Recurring NCs, particularly in documentation, RCA, and equipment monitoring, demonstrate that corrective actions were often insufficiently sustained. By addressing these areas through stronger CAPA processes, investment in staff development, and proactive alignment with ISO 15189:2022 requirements, laboratories can achieve more consistent compliance and improve the quality of diagnostic services delivered to patients. The study contributes practical insights to the drivers of non-compliance and provides actionable recommendations for strengthening laboratory quality systems.

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APPENDIXES

Appendix 1

NATIONAL HEALTH LABORATORY SERVICE

Academic Affairs and Research
1 Modderfontein Road, Sandringham, 2031
Tel: +27 (0)11 555 0367/0406
Email: babatyi.kgokong@nhls.ac.za
academic.research@nhls.ac.za
Web: www.nhls.ac.za

11 August 2025

Applicant: Snenhlanhla Zondi
Institution: NHLS
E-mail Address: Snenhlanhla.Zondi@nhls.ac.za
Tel: 031 205 6810 **Cell:** 084 063 0868

Project Title: Assessment Of Factors That Contribute to Non-Compliance During SANAS Audits In The Midlands Business Unit From 2020 To 2023.

Reference Number: PR2559108

Research Application Type(s):
1. Request for Data

RE: APPROVAL LETTER: REQUEST TO ACCESS NHLS RESOURCES FOR RESEARCH PURPOSES

This letter serves to advise that the application requesting permission to conduct the above-mentioned research using the listed NHLS resources has been reviewed and **"Approved"**. Please note that the approval is granted on the condition that you comply with the NHLS Research Material and Data Access Policy and requirements stated below.

1. All material and data requested shall be used as per the research protocol submitted to the NHLS and as approved by the relevant Health Research Ethics Committee (HREC) in South Africa.
2. Access to the NHLS material and/or data shall be limited to the minimum required for successful completion of the approved study and shall be made available ***without patient names and other patient identifiers (including, but not limited to, national identity numbers, hospital/clinic file numbers, addresses and telephone numbers)***.
3. Confidentiality shall be maintained at the participant and institutional level and there shall be no disclosure of personal information or confidential information.
4. Data and/or material shall not be shared with other parties unless approved by the NHLS
5. The material and/or data obtained from the NHLS shall be anonymised and not, for any reason, be used to track or recruit patients as no pre-approval/consent is obtained from patients.
6. Processes shall be discussed with the relevant NHLS departments (i.e. Corporate Data Warehouse (CDW), NHLS Laboratory Management, Operations Office, etc.) and agreed upon.
7. Any amendments to the study requirements, including the use of the material and/or data for purposes not initially disclosed to the NHLS) shall be cleared by an approved HREC and submitted to the NHLS for approval via the AARMS system – https://aarms.nhls.ac.za.
8. The NHLS shall be acknowledged as a source of material and/or data in any output, such as abstracts and journal articles, emanating from the project.
9. A final report of the research study and any published output resulting from this study shall be submitted to the NHLS via AARMS

Please note that this letter constitutes approval by the NHLS Academic Affairs and Research Office. The NHLS entities tasked with providing the material and/data may have additional requirements for access. Data related queries may be directed to NHLS CDW, email: zarina.sabat@nhls.ac.za; contact number: 011 386 6074.

Dr Babatyi Malope-Kgokong
National Manager: Academic Affairs and Research

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Appendix 2

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS HEALTH SCIENCES

Health Sciences Research Ethics Committee

11-Aug-2025

Dear **Miss Snenhlanhla Zondi**

Ethics Clearance: **Assessment of Factors That Contribute to Non-Compliance During SANAS Audits in The Midlands Business Unit from 2020 To 2023.**

Principal Investigator: **Miss Snenhlanhla Zondi**

Department: **CUT - Central University of Technology**

Submission Page

APPLICATION APPROVED

Please ensure that you read the whole document.

With reference to your application for ethical clearance with the Faculty of Health Sciences, I am pleased to inform you on behalf of the Health Sciences Research Ethics Committee that you have been granted ethical clearance for your project.

Your ethical clearance number, to be used in all correspondence is:**UFS-HSD2025/0575/2907**

The ethical clearance number is valid for research conducted for one year from issuance. Should you require more time to complete this research, please apply for an extension.

We request that any changes that may take place during the course of your research project be submitted to the HSREC for approval to ensure we are kept up to date with your progress and any ethical implications that may arise. This includes any serious adverse events and/or termination of the study.

A progress report should be submitted within one year of approval, and annually for long term studies. A final report should be submitted at the completion of the study.

Research conducted in any Department of Health facility: Researchers are required to sign and return the HSREC approval letters to the provincial Department of Health where they applied. It is also a requirement for researchers to submit electronic copies of their final research findings, and/or make a presentation of their findings and recommendations at departmental research days when and where indicated.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2020); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; International Council for Harmonisation (ICH) Harmonised Guideline, Integrated Addendum to ICH E6(R1), Guideline for Good Clinical Practice (GCP) E6(R2), 2016, SAHPRA Guidelines as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

The Principal Investigator (PI) bears final responsibility for the RIMS application. In the event of any misconduct or improper activities perpetuated by a third party, the PI will be held vicariously liable. The HSREC will bear no responsibility or liability for any actions of a PI and/or third party or breach of confidentiality caused by the PI and/or third party.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4012650/9860 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this proposal for ethical clearance and we wish you every success with your research.

Yours Sincerely

Dr. C. Armour (Barrett)
Chairperson: Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
T: +27 (0)51 401 2650/9860 | E: ethicsfhs@ufs.ac.za
IRB 00011992; REC 230408-011; IORG 0010096; FWA 00027947

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Appendix 3

Central University of Technology, Free State

FACULTY OF HEALTH AND ENVIRONMENTAL SCIENCES

29 November 2023

ATTN: NHLS Ethics /Committee

Re: Scientific Review; Snenhlanhla Nonjabulo Zondi
Topic: Assessment of Factors That Contribute to Non-Compliance During South African National Accreditation System Audits in The Midlands Business Unit from 2020 To 2023

To Whom it may concern

This letter serves to confirm that the research protocol, titled, "***Assessment of Factors That Contribute to Non-Compliance During South African National Accreditation System Audits in The Midlands Business Unit from 2020 To 2023***" has been reviewed by the Faculty Research and Innovative Committee (FRIC) of the Faculty of Health and Environmental Sciences, Central University of Technology and has been judged to be relevant, designed in accordance with accepted scientific practices and norms.

Student: **Snenhlanhla Nonjabulo Zondi**
Student number: **224126070**

Should you require additional information, please contact Prof TJ Makhafola at jmakhafola@cut.ac.za

Sincerely;

Tel: +27 51 507 3369
Prof TJ Makhafola
Assistant Dean; Research, Innovation and Engagement
Faculty if Health and Environmental Sciences

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Appendix 4

Central University of Technology, Free State

FACULTY OF HEALTH AND ENVIRONMENTAL SCIENCES

6/2/2025

To whom it may concern

Collaboration letter

I, Pakiso Moses Makhoahle (Prof.) working at Central University of Technology-Frees State, registered as medical laboratory (MW001071) scientist with the HPCSA confirm that I will be supervising the student Ms SN Zondi, student number: 224126070 for her masters project title:
Assessment of Factors That Contribute to Non-Compliance during South African National Accreditation System Audits in the Midlands Business Unit from 2020 To 2023

I confirm that the student Ms SN Zondi adjusted the proposal to the satisfaction of the panel review committee comments.

Hope you find this in order.

Yours sincerely

PM Makhoahle
Assoc Prof: Biomedical Technology/Medical Laboratory Sciences

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Appendix 5

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Assessment Of Factors That Contribute to Non-Compliance During SANAS Audits In The Midlands Business Unit From 2020 To 2023.

Good day, my name is Snenhlanhla Zondi. I am inviting you to take part in a research study that looks at non-conformances in SANAS-accredited laboratories in the Midlands Business Unit from 2020 to 2023. This study is part of my Master's Degree at the Central University of Technology and aims to explore the causes of non-compliance with ISO 15189 and suggest improvements.Participation involves completing a short (10-15 minute) anonymous online survey. Your involvement is voluntary, and you can withdraw at any time before submitting your responses. There are no risks or costs involved, and while there is no payment, your input may help improve quality systems and patient safety in the future.If you have any questions, please feel free to contact me. By completing the survey, you confirm that you understand the purpose of the study and agree to participate voluntarily.

Once again, we assure you that your identity will remain anonymous when results are published. Your co-operation is appreciated.

PLEASE ANSWER THE FOLLOWING QUESTIONS BY SELECTING THE RELEVANT BLOCK OR TYPING YOUR ANSWER IN THE SPACE PROVIDED.

1	Background information Which of the following disciplines have you audited in the Midlands Business unit from 2020-2023?	○ Chemical Pathology ○ Haematology ○ Microbiology ○ Cytology ○ Virology
2.	If you answered none of the above, please do not answer the rest of the survey. Please indicate years of experience as an internal auditor:	○ 0-2 years ○ 2-3 years ○ 3-4 years ○ 5-10 years ○ 10 years and above
3.	Management and Personnel Requirements Please select any relevant statement/s. You may choose more than one answer where applicable. Note: Your responses are to be based on your experience following all audits conducted in the Midlands BU. What were the non-conformances related to standard operating procedures (SOP's) and policies in the laboratories?	☐ SOP/s not available ☐ Policy/s not available ☐ SOP/s not signed by relevant staff ☐ Policies not signed by relevant staff ☐ SOPs out of review date ☐ Internal documents not document-controlled ☐ Lack of full implementation of documented procedures
4.	4. What were the non-conformances (NC'S) related to management of non-conformances and corrective actions?	☐ Corrective actions not implemented ☐ Corrective actions not implemented as per stipulated timeframes ☐ Root cause analysis not performed ☐ Effectiveness of corrective actions not reviewed ☐ NC records do not include all occurring non-conformances ☐ Trend analysis not performed as per stipulated time frame

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5	What were the non-conformances related to management review meetings (MRM)?	☐ Management reviews not conducted as per stipulated timeframes ☐ Review input did not include all of the required information ☐ Trends and patterns that indicate process problems not analysed ☐ Findings and actions of the review not communicated to staff ☐ Actions arising from MRM not implemented as per stipulated timeframes
6.	PERSONNEL REQUIREMENTS Were personnel files for laboratory staff available?	○ Yes ○ No
7.	If yes, did the personnel files include all required information?	○ Yes ○ No
8.	What were the non-conformances related to training and competency of staff?	☐ Unavailable training records ☐ Incomplete training records ☐ Unavailable competency records ☐ Incomplete competency records ☐ Training not done for all tests performed ☐ Training records for drivers not available ☐ Competency criteria not followed
9.	PRE ANALYTICAL REQUIREMENTS: What were the non-conformances related to the request form?	☐ Incomplete laboratory request forms ☐ Incorrect test selection ☐ Incorrect logging of information in the laboratory ☐ Data entry not regularly checked
10.	What were the non-conformances related to the transportation of samples to the laboratory?	☐ Incorrect transportation of samples ☐ Transportation temperature not monitored ☐ Specimens not delivered to the laboratory as per stipulated time frames ☐ Specimen tracking sheets not available ☐ Incomplete specimen tracking sheet
11.	ANALYTICAL REQUIREMENTS: What were the non-conformances documented on the analytical processes?	☐ Unavailable equipment verification records ☐ Non adherence to equipment service schedule ☐ Equipment not consistently maintained as per SOP's ☐ Internal quality control failure ☐ Incorrect storage of reagents
12.	POST ANALYTICAL REQUIREMENTS: What were the non-conformances in the post-analytical phase?	☐ Inconsistency in phoning critical results ☐ Instrument interphase not regularly checked ☐ Tests requested not all completed ☐ Referred tests not consistently tracked ☐ Referred tests not indicated on the final report ☐ Non adherence to results turnaround time
13.	Do you have any other comments about the reasons for the non-compliances with ISO 15189 that are raised during SANAS audits? If YES please provide comments :	_____
14.	What are your recommendations for improvement if applicable, that can be applied to assist laboratories to fully comply with the ISO 15189 standard?	

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10 OCTOBER 2023

DECLARATION

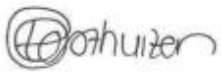
I hereby declare that I am a qualified and professional language practitioner with the following qualification from the Central University of Technology, Free State:

- MTech Language Practice (2013)

In this capacity, I have linguistically revised (in English) the following title:

TITLE:	**Assessment of Factors That Contribute to Non-Compliance During SANAS Audits in The Midlands Business Unit from 2020 To 2023.**
EDITED TITLE:	**Assessment of factors that contributed to non-compliance during South African National Accreditation System audits in the Midlands Business Unit from 2020 to 2023**
DEGREE:	**Master of Health Sciences in Biomedical Technology**
STUDENT:	**SN Zondi (student number: 224126070)**
INSTITUTION:	**Central University of Technology, Free State Faculty of Health and Environmental Sciences**

Signed:



.....

TANIA OOSTHUIZEN
SENIOR LANGUAGE PRACTITIONER
CENTRAL UNIVERSITY OF TECHNOLOGY, FREE STATE

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