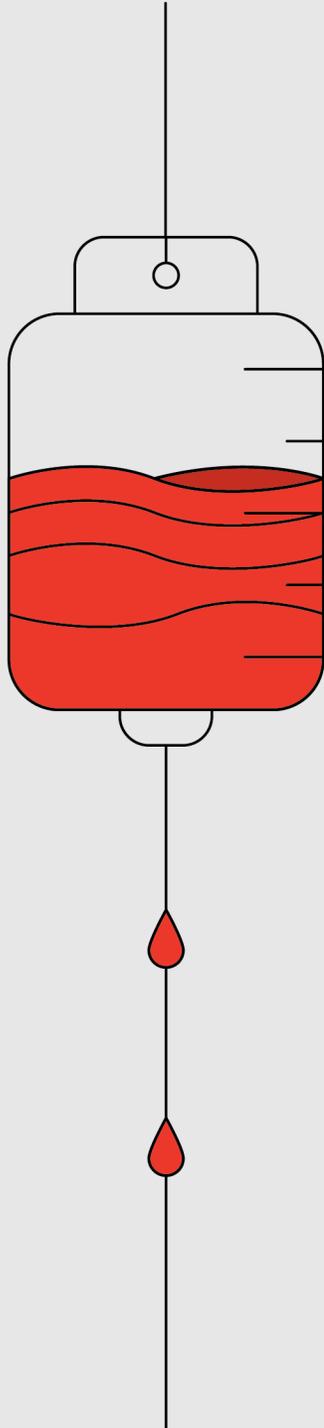




**36th South African
NATIONAL BLOOD
Transfusion Congress**

22 – 25 August 2022 - Durban

SHAPING A SUSTAINABLE FUTURE



ISO 15189

Implementation in SANBS

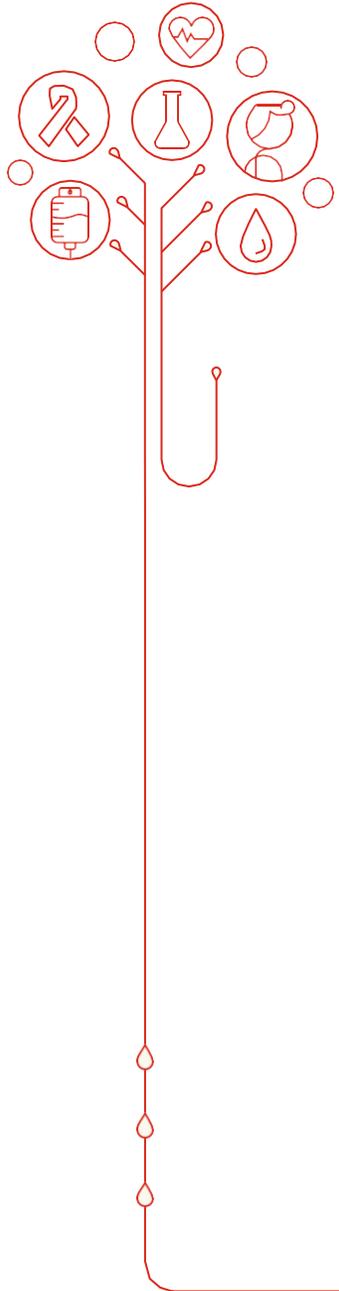
Presenter:

Feroza Tree
Accreditation Specialist, SANBS

Contributor:

Hazel Bell
Senior Manager: Quality Management Systems,
SANBS

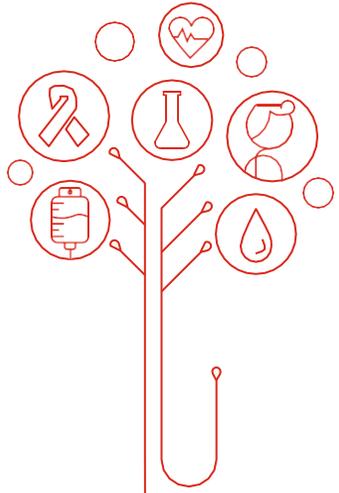




BACKGROUND



- SANBS previously self-regulated and wrote the Standards of Practice for Blood Transfusion together with the Western Cape Blood Service.
- Self-regulation was a conflict of interest and harmonising to an international standard was of vital importance.
- The most appropriate standard identified was the ISO 15189 standard for Medical Laboratories.

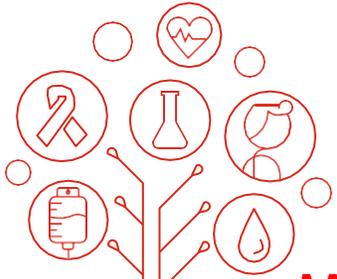


Aim of the Study



The aim of this study was to determine whether the change to the new standard was implemented successfully, according to the project plan and if it had a positive impact within SANBS.

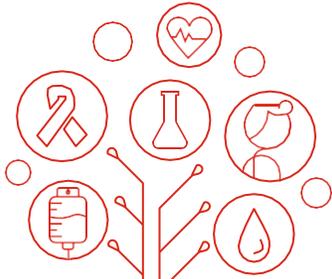




Method

- In the implementation phase of the standard, a gap analysis was performed to identify the shortcomings and opportunities for improvement in compliance to ISO 15189.
- A project plan based on the results of the gap analysis was developed.
- Both was presented to Management and relevant stakeholders.
- The final project plan included the following;
 - Draw up Transition plan for the South African National Accreditation System
 - Training
 - Addressing gaps identified
 - Implementing corrective action
 - Updating the Quality manual in line with the ISO 15189 Standard
 - Internal audits
 - Accreditation





Method



- The transition plan was developed and submitted to SANAS (South African National Accreditation System).

- Training was sourced from an external service provider. It was planned in a phased approach from Senior Managers down to Supervisors in conjunction with the SANBS Learning and Development department.



- Gaps identified in the GAP Analysis was addressed and corrective action implemented.



- The Quality Management Systems Manual was updated.

- Internal audits, concentrating specifically on the ISO 15189 specifications, was conducted across the zones.

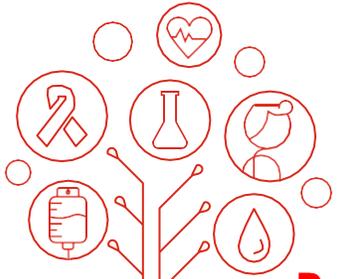




Results

- The SANAS application was submitted in December 2018 for the Pinetown and Constantia Kloof sites and included the Quality management system, SANBS laboratories and Processing centers.
- The first SANAS assessment was done in September 2019.
- It had to be done in a phased approach coinciding with the expiry of SANAS certificates for the blood banks and donor centers in the rest of the areas.
- Due to COVID-19 most of the assessments was performed remotely.

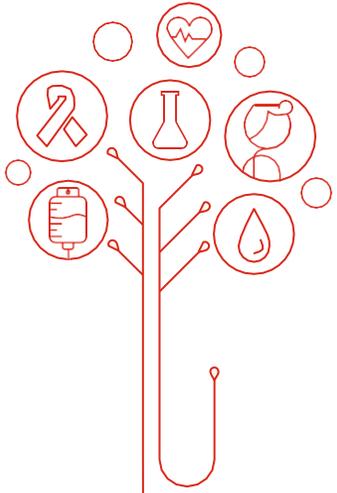




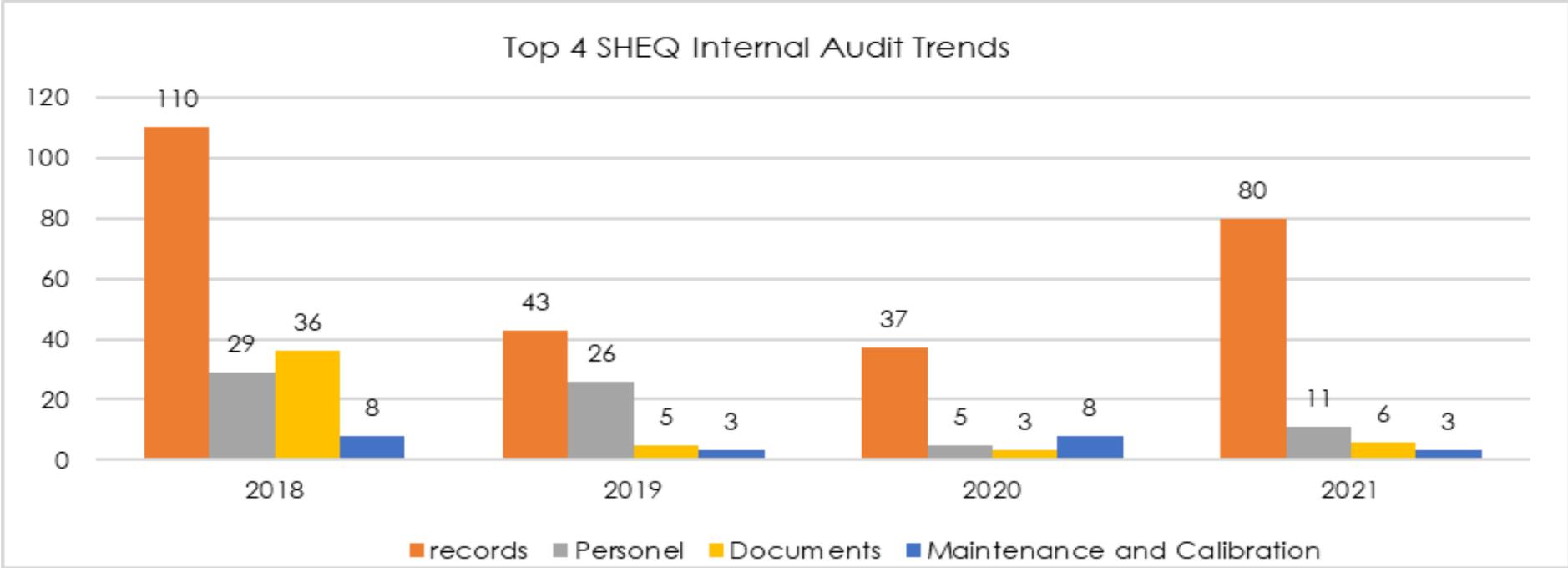
Results

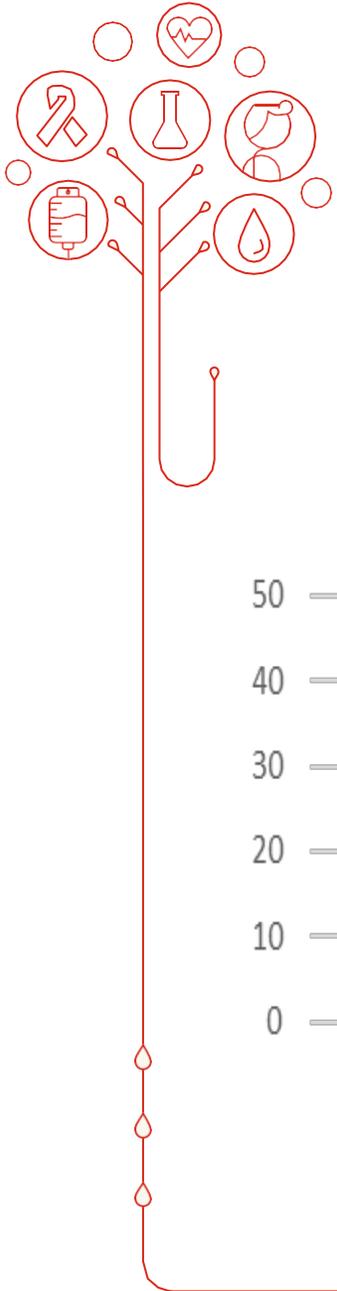
- For the years, 2019, 2020 and 2021, 178 SANBS sites had their initial assessments to the new standard.
- This included the Quality management system, processing centers, specialised laboratories, blood banks and donor centers.
- 128 findings were raised across the sites.
- 120 sites had no findings.





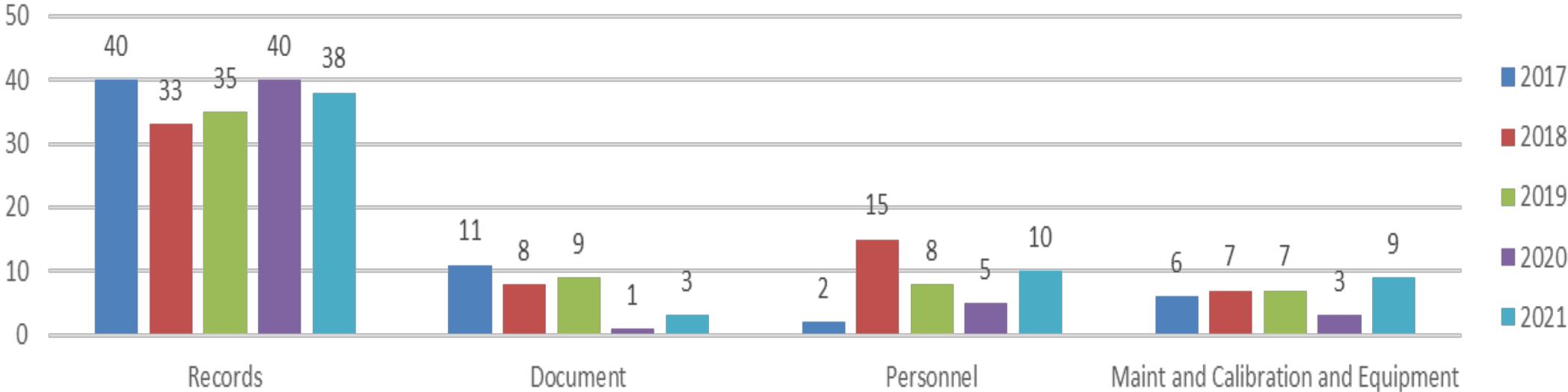
Top 4 SHEQ Internal Audit Trends

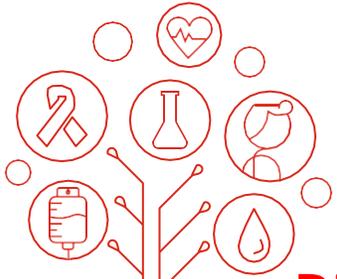




Top 4 SANAS Trends

Top 4 SANAS Trends





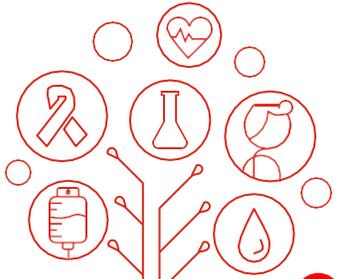
Discussion

The transition from one standard to another did not come without its challenges, however, the strict adherence to the project plan, guaranteed success.

Findings were addressed and corrective action implemented.

All sites were granted unconditional accreditation upon review by SANAS for successful implementation and were converted to ISO 15189 by March 2021.

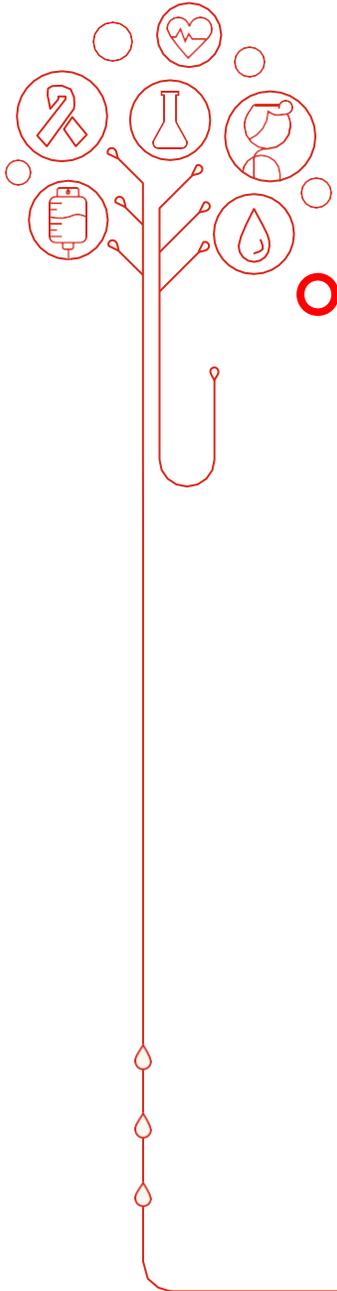




Conclusion

The new standard is more applicable to our environment and has a customer focus. The data supports SANBS' decision to adopt and implement the ISO 15189 standard and the successful implementation and accreditation received.





Other ISO standards currently being implemented in SANBS

- ISO 13485 - Medical devices — Quality management systems — Requirements for regulatory purposes.

ISO 20387 - Biotechnology — Biobanking — General requirements for biobanking

ISO 9001 - Quality management systems — Requirements

Thank you