

CHALLENGES ACHIEVING AND MAINTAINING ISO/IEC 17025 ACCREDITATION FOR STACK TESTING LABORATORIES – A SOUTH AFRICAN PERSPECTIVE

Presented by:
Gerald Woollatt



LEVEGO ENVIRONMENTAL SERVICES
www.levego.co.za

OVERVIEW

- Introduction - The State of Air Quality In South Africa
- Legislative requirements
- What is ISO 17025 accreditation?
- Why Insist on accreditation
- APHL study and findings
- Challenges facing the industry
- Conclusion and way forward



Introduction – the state of air quality in South Africa

- Managing air quality effectively has been an ongoing challenge for several decades
- All listed process operators require an air emission license to operate
- All South Africans have a duty to uphold the bill of rights to ensure every citizen right to clean air
- World class regulations need to be supported by consistent and strict enforcement of the regulatory requirements



LEGISLATIVE REQUIREMENTS

- National Environmental Management: Air Quality Act (Act No. 39 of 2004)
- Listed activities and minimum emission standards in terms of section 21 of the NEMA
- The national framework for air quality management in the republic of South Africa
- Applicable national ambient air quality standards
- Permit to operate - Air Emission Licenses (AELs)
- Since 2018 - Specific license requirement that all sampling and analysis conducted by 17025 accredited laboratory



WHAT IS ISO 17025 ACCREDITATION?

- It is the global quality standard for testing and calibration laboratories
- The standard covers two main clauses
 - management requirements: operation and effectiveness of the quality management system similar to ISO9001:2015
 - Technical requirements: competence of staff, testing methodology, equipment and quality, reporting of test and calibration results

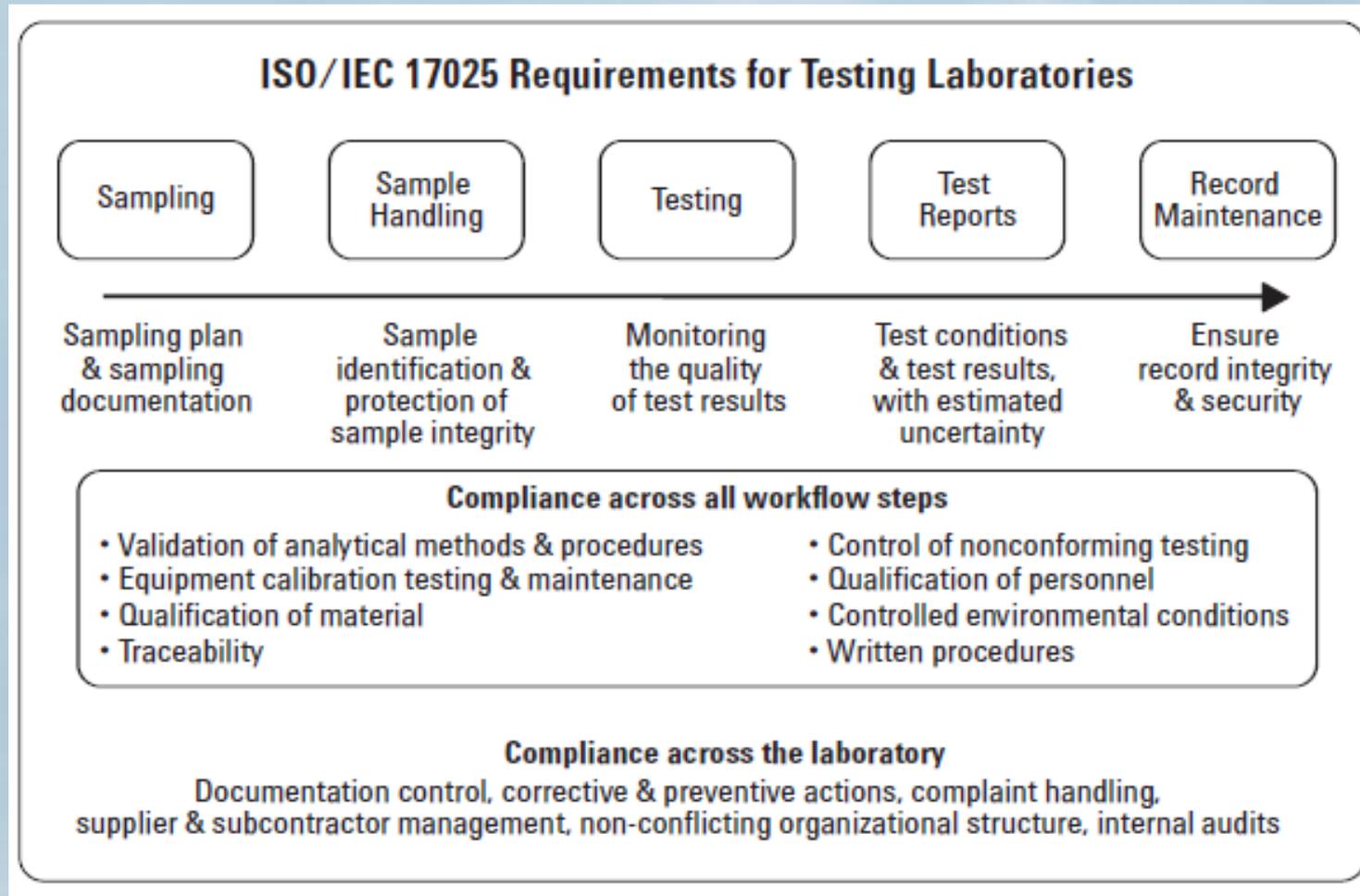


WHAT IS ISO 17025 ACCREDITATION?

- The ISO 17025 Accreditation process
 - ISO17025 accreditation is a rigorous and ongoing assessment of Emission Testing and Ambient Air monitoring activities to establish that:
 - The organisation is impartial
 - The organisation employs technically competent staff
 - The organisation uses technically suitable sampling methods as prescribed by the Air Quality Act, 2004(Act No. 39 of 2004)
 - The organisation has the appropriate resources, equipment and facilities
 - The organisation meets the requirements of 17025



WHAT IS ISO 17025 ACCREDITATION?



WHY INSIST ON ISO 17025 ACCREDITATION



- You can not manage what you cannot measure
- The quality of decision making is only as good as the quality of data utilised
- Tested once accepted everywhere!



WHY INSIST ON ISO 17025 ACCREDITATION

- UNINTENDED CONSEQUENCES



WHY INSIST ON 17025 ACCREDITATION

- **Ensures Technical competence**

- The organisation must demonstrate that the individuals carrying out Emission testing and Ambient Air Monitoring are technically competent to do so and that methods and equipment are valid and fit for purpose these include;
 - Competent staff authorised and fully trained in all relevant stack monitoring activities
 - Robust internal training
 - Routine competence monitoring
 - Regular technical internal auditing by qualified auditors



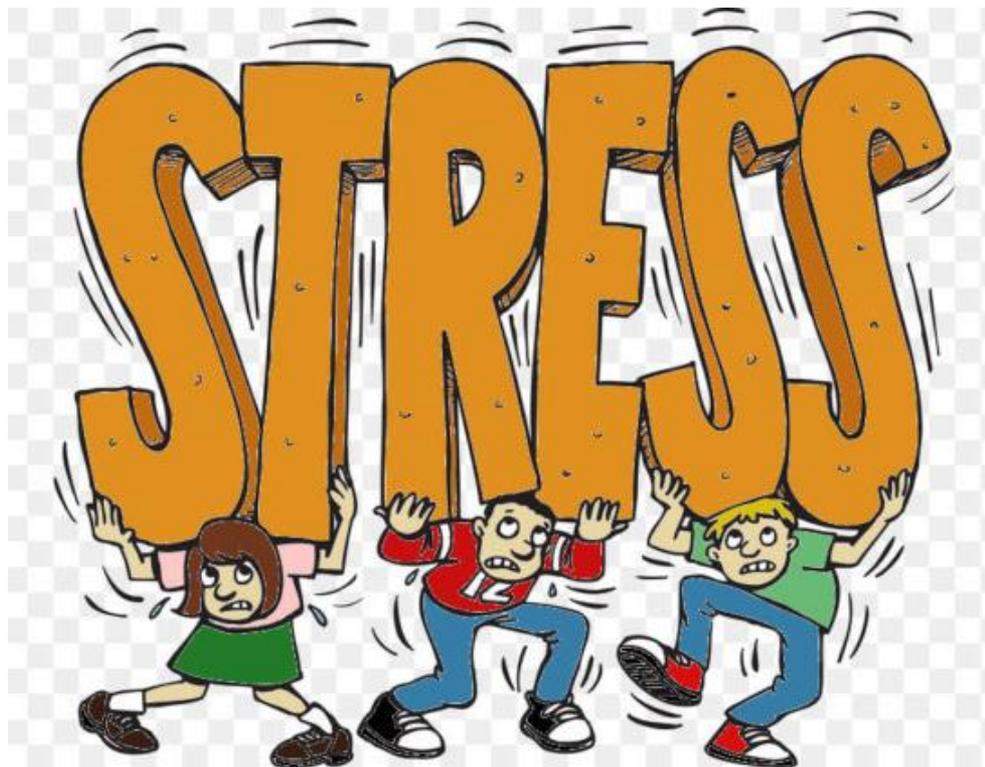
WHY INSIST ON 17025 ACCREDITATION

- **Ensures Technical competence – continued**

- Regular participation in recognised proficiency testing schemes
- Traceability to international reference standards
- Equipment calibrated with traceable standards and meets the EPA, EN BS and ISO standards as per their schedule of accreditation
- Verification and demonstration of ability to perform methods to National, European, International and Environment Agency specific standards



WHY INSIST ON 17025 ACCREDITATION



- **Ensures Independence, impartiality and integrity**
- The Organisation must demonstrate that:
 - All emissions monitoring work is carried out independently and impartially
 - Staff are free from undue financial, commercial or other pressures that may adversely affect the quality of work



ACCREDITATION TO 17025 - AN AMERICAN EXPERIENCE – APHL STUDY AND FINDINGS

- **Background**

- Limited data and few studies conducted globally
- Association of public health laboratories (APHL) –Laboratory costs of ISO/IEC 17025 Accreditation a 2017 Survey Report (published - February 2018) identified as most comprehensive study conducted
- The US food and drug administration (FDA) Identified ISO 17025 accreditation as a critical element for ensuring data integrity
- The FDA setup and implemented the ISO cooperative agreement program with the objective of increasing the number of accredited food laboratories in the United States



ACCREDITATION TO 17025 - AN AMERICAN EXPERIENCE – APHL STUDY AND FINDINGS

- **Background - continued**

- Many laboratories participating in the study recognise that sustaining 17025 accreditation without funding would be difficult
- The costs of accreditation vary substantially from laboratory to laboratory depending on;
 - size, starting point, staffing, location and testing methods of the laboratory,
- additional costs can be;
 - preventative maintenance contracts, Assessment fees, Training, Additional Staff
- A survey was conducted by APHL in 2017 to gain a better understanding of the approximate costs of implementing and maintaining ISO/IEC 17025 accreditation



ACCREDITATION TO 17025 - AN AMERICAN EXPERIENCE

- Assessment Method

- APHL survey was fielded in July 2017 to 30 accredited laboratories involved in the FDA ISO cooperative agreement programs
- Respondents were instructed to include only those costs that related directly to ISO17025 accreditation



ACCREDITATION TO 17025 - AN AMERICAN EXPERIENCE

- Results and analysis
 - The data gathered from the survey was presented in several tables
 - Individual costs included training, assessment fees, consultant fees, supplies and equipment, calibrations, preventative maintenance, proficiency testing, software and monitoring systems and salaries
 - Based on all the costs listed above, table 1 lists the cumulative annual costs for each laboratory that are directly related to becoming ISO/IEC 17025 accredited

ACCREDITATION TO 17025 – AN AMERICAN EXPERIENCE

Table 1. Total Annual Cost of ISO/IEC 17025 Accreditation (APHL, 2017)

Laboratory Identifier	Total Annual Costs Due to ISO/IEC 17025 Accreditation	Full-time Employees (Technical Staff Only)	Years Accredited to ISO/IEC 17025	Human Food		Animal Food	
				Samples Per Year	Testing Methods on Scope	Samples Per Year	Testing Methods on Scope
1	\$ 256,177.00	9	2	777	10	0	0
2	\$ 682,151.33	59	6	1558	29	1364	9
3	\$ 119,500.00	10	1	2000	4	700	4
4	\$ 293,546.50	4	1	740	16	0	0
5	\$ 296,488.78	4	1.5	172	19	0	0
6	\$ 431,500.00	14	10	10000	21	200	1
7	\$ 326,483.00	19	10	9510	44	0	0
8	\$ 67,100.00	7	2	0	0	611	8
9	\$ 89,160.00	5	2	700	9	0	0
10	\$ 121,288.00	9	1.5	0	15	0	0
11	\$ 432,759.00	3	5	5623	17	693	10
12	\$ 245,539.00	4	<1	469	5	20	0
13	\$ 495,339.77	15	7	480	6	580	13
14	\$ 337,250.00	7	7	5000	5	1000	3
15	\$ 184,800.00	12	<1	100	5	1500	1
16	\$ 397,150.00	8	<1	1739	5	2449	2
17	\$1,358,064.00	21	9	19715	17	497	7
18	\$ 726,201.00	15	2	385	6	2100	1

Median: \$311,485

Range: \$67,000 - \$1,358,064

ACCREDITATION TO 17025 - AN AMERICAN EXPERIENCE

- Discussion

- The data provide a detailed overview of the laboratory costs associated with 17025 accreditation
- Several respondents found it difficult to separate what costs and interventions were related directly to ISO17025 accreditation
- Not always possible to accurately determine all costs
- Some costs may be understated due to FDA funding



ACCREDITATION TO 17025 - AN AMERICAN EXPERIENCE

- Overall Accreditation Costs
 - From table 1 the costs vary substantially for a host of reasons
 - Noteworthy that the median annual cost was \$311 485.00
 - Equivalent to R 5.4 million
 - Costs of accreditation estimated to be similar to APHL survey results for South African laboratories



ACCREDITATION TO 17025 - AN AMERICAN EXPERIENCE

- Conclusion of APHL Study
 - FDA provided \$50 million over a 5 year period
 - Overall improvement in laboratory quality attributed directly to accreditation
 - Significant interventions could be conducted as a result of improved data quality
 - The benefits of accreditation are significant, however many laboratories will not be able to sustain accreditation without federal funding



CHALLENGES FACING THE INDUSTRY

- South Africa is a middle income country
- Limited number of accredited stack testing laboratories
- Enforcement of legislation - ISO17025 requirements - difficult?
- Quality of data held in NAEIS?
- High Costs
- Lack of Technical expertise



CHALLENGES FACING THE INDUSTRY

- Support and infrastructure – PT schemes, availability of suitable equipment and supplies
- No local certification scheme
- Government funding and support
- Prevailing economic conditions
- Political uncertainty with regards to government policy
- Stable, cost effective power supply



CONCLUSION AND WAY FORWARD

- Under the constitution and bill of rights everyone has the right to an environment that is not harmful to their health or well-being
- Until the law is enforced and process operators operate in a responsible manner and adequate government support and funding is forthcoming we as a country will continue to fall short of ensuring each citizens right to clean air
- Further investigation is needed into the unique challenges facing South Africa
- Adoption of a similar program to the ISO cooperative agreement will go a long way to support the industry
- Various funding models and training programs need to be considered
- Collaboration with all stake holders will be required
- Public and private enterprise participation is essential



Thank You



LEVEGO
Environmental Services

www.levego.co.za