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NEW ISO/IEC 17025:2017

By Shadrack Phophi

The review of the ISO/IEC 17025 was started in February 2015 and culminated into the publication of the new version on the 01 December 2017. The last revision was published in 2005, consequently, there was a pressing need for the standard to be revised. Chief amongst the many reasons why the standard needed to be revised were:

- Developments in Information Technology (IT)
- Changes in market conditions
- Alignment to ISO 9001

Format of the New Standard

The setup of the new standard has been significantly altered to be more in line with new ISO formatting guidelines. The basic format is similar to other new standards such as ISO/IEC 17020 and ISO/IEC 17065. The new standard is now structured as follows:

1. Scope
2. Normative references
3. Terms and definitions
4. General requirements
5. Structural requirements
6. Resource requirements
7. Process requirements
8. Management requirements
    - Annex A – Metrological Traceability (Informative)
    - Annex B – Management System (Informative)
    - Bibliography

A quick glimpse into the new standard

1. Scope

The new ISO/IEC 17025:2017 scope has been revised to embrace three laboratory activities, namely: Testing; Calibration and Sampling, associated with subsequent calibration and testing. Thus, the new standard makes it possible for sampling activity to be accredited as a standalone provided the sample will end up being tested either by a testing or calibration laboratory. I must, however, hasten to mention that the Accreditation Body (AB) has the sole prerogative to decide whether it accredits sampling as a standalone or not.

The current SANAS position regarding sampling is that sampling will be accredited only if the organization responsible for sampling will also perform the test or analysis. The advent of the new version has put back the sampling issue on the agenda for SANAS to reconsider its position and the outcome will be communicated to all and sundry as soon as the decision has been made.

2. Terms and definitions

Guide 99 ISO/IEC, *International vocabulary of metrology — basic and general concepts and associated terms (VIM)*, is referenced in the standard as a normative reference. The definitions also given in ISO/IEC 17000 are applicable. In addition, the standard provides the detailed definitions of the terms *impartiality, complaint, interlaboratory comparison, intra-laboratory comparison, proficiency testing, laboratory and decision rule*.

3. General Requirements (Clause 4)

This clause is dedicated to Impartiality (4.1) and Confidentiality (4.2). Laboratories are required to identify and eliminate or minimize risks related to impartiality, on an on-going basis. It is also expected of laboratories to inform their customers in advance of information they are planning to release or put on public domain. In addition, the standard requires that information obtained or created during the

performance of laboratory activities (i.e. testing, calibration or sampling) by personnel, committees, contractors and people acting on behalf of the laboratory to be kept confidential. This clause also addresses how confidentiality must be handled in the case the laboratory is obliged by law to disclose certain information.

4. Structural Requirement (Clause 5)

Under this clause, the following requirements are defined: Legal status of the laboratory, organization and management structure, identification of management, range of laboratory activities, documenting its procedures, availability of personnel responsible for the implementation and maintaining the integrity of the management system. It is important to note that the new standard is less prescriptive, for example: it is no longer required for laboratory management to appoint a "Quality Manager", however, the laboratory management must have personnel who have authority and resources needed to carryout their duties which include:

- implementation, maintenance and improvement of the management system
- identification of deviations from the management system or from the procedures for performing laboratory activities
- initiations of actions to prevent or minimize such deviations
- ensuring the effectiveness of laboratory activities

5. Resource Requirements (Clause 6)

This clause requires laboratory to have resources (i.e. facilities, personnel, equipment, systems and support services) necessary to manage and perform its laboratory activities. It is expected that all internal or external personnel of the laboratory shall be competent and act impartially. The standard doesn't refer at this clause to ALL personnel, but only to personnel who could have influence on the results of laboratory activities. This is not only personnel who are directly involved in testing/calibration/sampling activities, but also personnel who are indirectly involved, like technical personnel. For example, it can be personnel that perform maintenance of the equipment, or management system personnel, who evaluate suppliers and/or maintain the management system including internal auditing activities.

6. Process Requirements (Clause 7)

Clause 7 covers all process related requirements, namely: Review of requests, tenders and contracts (7.1); Selection, verification and validation of methods (7.2); Sampling (7.3); Handling of test or calibration items (7.4); Technical records (7.5); Evaluation of measurement uncertainty (7.6); Ensuring the validity of results (7.7); Reporting of results (7.8); Complaints (7.9); Nonconforming work (7.10) and Control of data and information management (7.11). The revised standard puts the emphasis on the results of a process instead of the detailed description of its tasks and steps. Importantly, the revised standard introduces a risk-based thinking which involves identifying the areas of high risk within the laboratory and take the appropriate mitigation measures in accordance with the level of risk. This approach permeates throughout the standard.

7. Management System requirements (Clause 8)

The laboratory can choose between implementing a management system in accordance with option A or option B. Option A lists the minimum requirements for implementation of a management system in a laboratory. Option B allows laboratories to establish and maintain a management system in accordance with the requirements of ISO 9001. Laboratories that implement option B will therefore also operate in accordance with ISO 9001. Conformity of a laboratory to the requirements of ISO 9001 does NOT, by itself, demonstrate the competence of the laboratory to produce technically valid data and results. This is accomplished only through compliance to ISO/IEC 17025.

Facilities or laboratories that will opt for option B, it is important to note that during assessments SANAS assessors will not be auditing their management system for compliance to ISO 9001 but rather assess them to determine if the ISO 9001 system meet the option A requirements.

TRANSITION

A three-year transition period has been agreed upon, thus, by 30th November 2020, all accredited laboratories must have successfully been assessed to the new standard. Of course, this doesn't mean that laboratories should wait for action until the end of

the three-year period. It is, therefore, incumbent upon all accredited laboratories to plan and initiate the transition process much earlier.

What are the expectations?

There is a popular adage often attributed to **Benjamin Franklin**, the father of time management, "Failing to plan is planning to fail". Therefore, it is important that we all plan on how we are going to approach this transition so that we can bit the cut-off date. All accredited laboratories will be required to come up with transition plans (i.e. implementation plan with dates and timelines for implementation) informed by a GAP analysis done against the new standard to determine shortfalls. Transition plans must be submitted to SANAS and they will be used by assessment teams to assess implementation of requirements of the new version.

To assist laboratories, SANAS has put together a transition schedule (See table below) with key important activities and dates. This schedule will be reviewed in the coming months depending on when the new standard will become available locally. The process of adopting the new version in the country is currently underway and the entire process is expected to take at least two months. In the interim, facilities/ laboratories can purchase a copy of the new standard directly from ISO.

Activity	Date	Comment
Publication of the standard	01 December 2017	A **three-year transition period** commencing 01 December 2017 and ending 30 November 2020
Transition Plans by CABs	TBC	Date to be announced once the standard is available locally
Cut-off date of receiving **ISO/IEC 17025:2005** new applications	30 June 2018	From 01 July 2018, only **ISO/IEC 17025:2017** new applications to be accepted
2018/2019 Assessments	01 April 2018 – 31 March 2019	Assessments to be done against **ISO/IEC 17025:2005**. However assessors will still check the implementation of the **2017** version and non-conformances against the new standard will be regarded as observations
2019/2020 Assessments	01 April 2019 – 31 March 2020	Assessments to be done against **ISO/IEC 17025:2017**. Non-conformances against the new standard will be addressed as per the SANAS normal procedure
Assessments for all accredited laboratories	30 June 2020	All assessments to have been conducted against **ISO/IEC 17025:2017** for all accredited laboratories
Clearing backlog	01 July 2020 – Nov 2020	Focusing on clearing outstanding non-conformances
Transition Cut-off date	30 November 2020	CABs that were unable to transit successfully will be automatically suspended after the 30 November 2020

UNSCHEDULED ASSESSMENT

By Rebecca Ramabulane

A QUICK GLIMPSE INTO SANAS R 76 DOCUMENT – EXTRAORDINARY / UNSCHEDULED ASSESSMENT

SANAS ensures the on-going competence by accredited Conformity Assessment Bodies (CABs) through different types of assessments, and one of these is the unscheduled/ and or unannounced/ extraordinary assessment.

SANAS reserves the right to conduct such extraordinary assessments over and above scheduled assessments at any time during an accreditation cycle and at the premise(s) of the CAB, this can be done under the following circumstances:

- Follow up on the investigation and resolution of a complaint against a CAB;
- Follow up on significant changes in relation to a CAB which may influence the CAB's accreditation / compliance status; or
- For any other reason that SANAS may deem necessary to confirm on-going compliance to
- accreditation requirements.

SANAS will, at its discretion, notify the CAB at least one (1) hour prior to the assessment, informing the CAB of the purpose and scope of the assessment and the name of the assessor(s).

Extraordinary assessments will be conducted by an assessor(s) appointed by the applicable Accreditation Manager (AM) or Executive, who shall ensure there's – No conflict of interest and that the visit is Scheduled during normal working hours of the CAB.

The assessor(s) will be provided with clear guidance as to the purpose and scope of the assessment.

Upon arrival at the CAB the assessor will, introduce him/herself as a representative from SANAS, Inform top management of the purpose and scope of the assessment.

Extraordinary assessments are as extensive as is required by the scope of the assessment.

The CAB shall comply with the "Access and Cooperation" requirements as specified in the Terms and Conditions of Accreditation (F147) or the Terms and Conditions of GLP/GCP Compliance (F199), as applicable.

After the assessment, the assessor prepares a short report on the purpose and extent of the assessment, record any findings or observations identified during the assessment and attach additional supporting documentation as evidence of non-compliance.

SANAS will take appropriate action depending on the outcome of the assessment – i.e. either handle as a complaint (P12), suspension or withdrawal of accreditation (R51).

The extraordinary assessment will be at the cost of the CAB should SANAS confirm any transgression/ contravention of the accreditation requirements.

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