

## THE USE OF ALTERNATIVES TO PT / ILC

BY YOLANDA VINNICOMBE

The SANAS Proficiency Testing and other comparison programme requirements for Calibration Laboratories (R48) and the Proficiency Testing and other comparison programme requirements for Testing and Medical Laboratories (R80) documents specifies the mandatory requirements for all applicants and accredited facilities in the participation of proficiency testing or inter-laboratory comparisons (referred to as EQA by Medical Laboratories).

All laboratories are required to participate in appropriate proficiency testing (PT) or inter-laboratory comparisons (ILC), *where these are available*, for the required scope of accreditation. Proof of participation in PT or ILC and satisfactory performance report must be submitted to SANAS together with the application form, whether it is a new application or an application for an extension of scope.

Proficiency testing schemes used should have independently demonstrated compliance with the requirements of ISO/IEC 17043. A database of accredited Proficiency Testing Scheme Providers is available on the SANAS website.

In areas where there are no accredited schemes,

participation in unaccredited schemes will be acceptable until such time that sufficient accredited schemes in the various disciplines exist, however, the laboratory must be satisfied by the competence of the PT providers whose schemes they participates in. The SANAS website has a link to the European Proficiency Testing Information System (EPTIS) database and a register of non-accredited proficiency scheme providers and inter-comparison schemes, however this does not imply that any of these schemes meet the requirements of ISO/IEC 17043.

In instances where there are no formal PT schemes or where it is “not practical” a suitable alternative must be proposed and justified by the laboratory in writing and agreed to by SANAS. These alternatives may include activities such as intra-laboratory comparisons, the use of reference materials or other inter-laboratory activities arranged by the laboratory. The acceptability of the implementation of these alternatives to PT or ILC will be assessed on site during the assessment.

Where it is found that a laboratory has participated in alternative methods for PT or ILC, and where suitable PT or ILC does exist, the test or calibration method will not be accredited.



You may be wondering what “not practical” means. Cost alone is not an acceptable reason for not participating in a PT or ILC activity, the associated risk must also be considered before a decision can be made. An example of a PT or ILC scheme not being practical could include instances where the regulatory authority does not allow for the transport of samples due to their hazardous nature. Other examples could be where the test or calibration method is very rarely performed in the laboratory,

and the associated risk involved is very low, or where the stability, viability or required volume of the sample to be used for PT or ILC cannot be guaranteed due to various factors.

Should you have any queries regarding the acceptability of alternatives to PT or ILC, please contact the relevant programme manager.

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## DOCUMENT UPDATES

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The newly published and revised SANAS documents (period: September to November 2015) are published on the website: [http://home.sanas.co.za/?page\\_id=335](http://home.sanas.co.za/?page_id=335)

**Please ensure that all previous versions of these documents are destroyed.**

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