sanas South African National Accreditation System

Report

Report 6 of 2011

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Blood Transfusion Certificates

Prepared by Shadrack Phophi

During the recent Peer Evaluation that SANAS underwent in August, it was noted by the team that Blood Transfusion certificates (for facilities accredited against the national standard) did not state the exact standard against which these facilities are accredited. Accordingly, all Blood Transfusion certificates will be updated stating the applicable standard i.e. "Standards of practice for blood transfusion in South Africa, 4th Edition".

Reasons why Specimen Collection Sites should be Assessed

Prepared by Nombuso Ndlovu

ISO 15189 Clause 5.4 (Pre-examination procedures) is a requirement for assessments of specimen collection.

It is for this reason that Conformity Assessment Bodies (CABs) should supply SANAS with a list of all specimen collection sites during the application stage. Depots will be assessed as part of the assessments during the cycle.

Letters have been issued requesting laboratories to submit this information to SANAS by 14 October 2011. SANAS will evaluate their competency in handling samples during collection and transportation. All new applicants will have to submit this information at the time of application.

What is required?

- Contact Person
- Physical address
- Activity: (e.g. collection and arterial puncture or sample collection with the exception of sampling by arterial puncture)

CABs need to ensure that the information relating to pre-examination procedure is readily available at each specimen collection site during the assessment.

Inspection Bodies – Changes to Schedule of Accreditation

Prepared by Eben Smit

SANAS is in the process of reviewing all the Inspection Body Schedules of Accreditation in terms of layout and wording.

During the SANAS Peer Evaluation it was brought to our attention that some of the Type B Inspection Body Schedules contain the wording "*Third Party inspection of…*" This is incorrect and SANAS is in the process of correcting and re-issuing the affected Schedules of Accreditation.

Pressure Equipment Regulation Inspection Bodies (LVUP)

The incorporation of In-service Inspection Bodies will be reflected as Annexure B on the Schedule of Accreditation, listing the Competent Persons in terms of Pressure Vessels (PV) and Boilers (B) as technical signatories. It is expected that the review will be completed by December 2011.

Gas Test Station Inspection Bodies (IGS)

The layout of the Gas Test Station Schedule of Accreditation will be aligned with SANS 1825: XX to reflect the Service Rendered in more detail. Some of the Accredited Gas Test Stations will notice the changes on their Schedules and it is expected that the review will be completed by April 2012.

Proficiency Testing Requirements

Prepared by Neville Tayler

Perhaps ISO/IEC 17025 fails to do justice to the importance of Proficiency Testing, and the role it plays as a quality control measure within a laboratory. Proficiency Testing is included within clause 5.9 as an option that a laboratory may adopt in order to assure the quality of test and calibration results. This does little to highlight its significance.

All accreditation bodies are guided by the requirements of ISO/IEC 17011 and ILAC P9 for participation in Proficiency Testing (PT) by both applicant and accredited facilities, and the role PT must play in the accreditation decision making process.

The terminology and acronyms – PT (Proficiency Testing), EQA (external quality assessment or assurance) and ILCs (inter-laboratory comparisons) – are often used interchangeably, depending on the scope of application, but ultimately all refer to the same activity. In addition the metrology community often refers to a Measurement Audit to describe PT activity undertaken specifically on behalf of the accreditation body (AB).

ISO/IEC 17011 makes it incumbent on the AB to establish procedures that:

(1) take PT into account during both the assessment and decision making process;
(2) ensure that accredited facilities undertake appropriate corrective action where necessary; and
(3) establish the minimum amount and frequency of participation.

ILAC P9:2010 'ILAC Policy for participation in Proficiency Testing Activities' specifies the policy to which any AB wishing to maintain international recognition must adhere, and additionally provides guidance for ABs on the use of PT as part of the accreditation process.

In essence, ILAC P9 requires ABs to:

(1) ensure that there is evidence of satisfactory performance in PT prior to granting of accreditation;
(2) ensure that there is evidence of on-going participation consistent with a PT plan;
(3) ensure that the minimum amount and frequency of PT activity is specified;
(4) define how PT performance, including poor performance is reviewed and used during the decision making process; and
(5) define how PT activity plans are to be reviewed.

SANAS has drafted and implemented two technical requirements documents, namely R 48 and R 80 which describe the minimum requirement for PT activities undertaken by Calibration and Testing laboratories respectively. These documents address the requirement for laboratories to participate in PT activities that cover their scope of accreditation, to prepare and approve a PT activity plan, to evaluate the PT results, conduct root cause analysis and to investigate poor measurement results and take appropriate corrective and preventative actions where necessary. Testing Laboratories includes any ISO/IEC 17025 or ISO 15189 testing laboratory, such as General Testing Laboratories (mechanical/physical/chemical/microbiological), Medical, Veterinary, Pharmaceutical or Forensic laboratories. Both of these SANAS documents are subject to periodic review.

In line with the growth in both the number and type of inspection bodies worldwide, PT has not been exempted as a requirement for inspection bodies, but has rather been qualified in ILAC P9 as being limited to those instances where it is relevant.

Both the ISO standards and ILAC Policy documents recognise that there may be instances where PT activity does not exist or is not practical. Only in such instances, are alternative methods of demonstrating technical competence accepted as an alternative to PT participation. These alternatives must, however, be discussed and agreed with the accreditation body, and will form part of the PT activity plan.

In essence SANAS requires of its accredited facilities:

(1) regular participation in ILC or PT activities;
(2) a documented and approved participation plan covering the full scope of accreditation;
(3) review of PT results and the preparation of a report where one has not been provided;
(4) investigation and appropriate corrective action when results are not satisfactory; and
(5) making all of the necessary PT activity plans and results available for review either during the assessment, or when requested.

In order to assist applicant and accredited facilities with access to suitable providers of PT, SANAS has a dedicated webpage which includes a list of the SANAS accredited PT schemes, and access to the EPTIS database of international PT providers. In addition the NLA has implemented a number of ILC schemes to assist laboratories in meeting their PT obligations.

Calibration Certificates

Prepared by Neville Tayler

It is inevitable that the majority of accredited facilities will at some stage be the customer of a service provider who has been contracted to calibrate the standards and instruments used in their laboratory or facility. Often the selection of a suitable service provider is the responsibility of the organization's buyer. With little to substantiate his or her decision, price often becomes the overriding factor. Many service providers claim to offer 'traceable calibration certificates', indicating that their own equipment has been calibrated by either NMISA or a SANAS accredited laboratory.

ISO/IEC 17025 clause 5.6.2 includes the following requirement 'when using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability, and traceability'.

From the above statement it is evident that the traceability is established not only through access to standards calibrated by an accredited facility or NMI but through the associated competence and capability as well. In addition the standard requires the issue of a calibration certificate which includes the measurement results and uncertainty of measurement, or a statement of compliance. The standard also notes that calibration laboratories fulfilling the requirements of this standard (ISO/IEC 17025) are considered to be competent.

To determine the legitimacy and suitability of a calibration certificate, a quick perusal of the certificate should be sufficient. Start by looking for the accreditation symbol (SANAS, UKAS, NATA, A2LA, etc.) If the accreditation symbol is present it can be safely assumed that the certificate is legitimate, and will be acceptable for the measurement traceability requirements within your facility, provided the appropriate measurement ranges have been calibrated. It should be noted that certificates issued by accredited laboratories without the necessary accreditation symbol are considered to have been issued outside of their accreditation scope.

The next item to check is the description of the item calibrated. It should include pertinent information such as the name of the manufacturer, the Model and serial numbers. Certificates issued without this relevant information invalidate any calibration that may or may not have been done. Certificates of this nature are often issued by the manufacturer, and may include broad statements such as 'traceable to NIST' and 'calibration valid for 10 years'. These certificates do not satisfy the requirements for traceability as required by ISO/IEC 17025, and will therefore not be acceptable.

The calibration certificate must include the measurement results, including a statement of the measurement uncertainty (or a statement of compliance). This information is essential as it will be required within your own facility for the evaluation of the measurement uncertainty for the test or measurement you are performing. The lack of the measurement uncertainty on the certificate received from the calibration service provider is often a tell-tale sign that the supplier is not accredited and is not capable or competent to either estimate or calculate the measurement uncertainty.

SANAS TR 25 has recently been revised. The document now defines the circumstances under which the services of a non-accredited calibration service provider may be used and, as a general rule, the use of non-accredited calibration service providers is not permitted when accredited service providers are indeed available. The TR 25 document also includes the requirements for in-house calibrations. In both cases the onus for the maintenance of suitable records to confirm the competence of the persons or supplier is on the user of the equipment.

In summary, the choice of a calibration service provider selected solely on price may result in additional expenses when the certificates are found not to satisfy the requirements for measurement traceability. Use the SANAS website www.sanas.co.za to identify suitable calibration service providers.