sanas
South African National Accreditation System

The SANAS Assessor Newsletter

The A-news

Issue 1: Summer 2012

IN THIS ISSUE:

Your contributions are welcome

Help us to make this a true assessor newsletter by sharing your experiences, case studies, technical articles, photos and jokes.

You can e-mail your contributions to:
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(Please use *A-news* as the reference)

Letter from the CEO

Ron Josias

Welcome to the first edition of *The A-news*. The need for this publication has been evident for some time now, and was highlighted again during the 2011 Assessor Conclave.

This newsletter fills an important void in terms of communication between SANAS and its assessors, and the intention is to use it as a vehicle to facilitate regular communication. The aim of *The A-news* is threefold, namely to:

1. Create a platform for assessors to contribute and share their knowledge with others
2. Update assessors on developments in accreditation and to ensure that they are equipped with the necessary knowledge to efficiently and effectively execute their responsibilities, and
3. Ensure the continued development of both full-time SANAS staff and assessors.

Various forces in both the voluntary and regulatory domain require SANAS to continuously evaluate its competencies in order to effectively respond to the increasing demand for accreditation. This increase in demand is the result of the greater recognition and acceptance of accreditation as a tool that can assist government in achieving its health, safety, environmental and economic objectives. The Industrial Policy Action Plan 2 (IPAP2), published by the Department of Trade and Industry, also identifies the importance of SANAS accreditation in key development sectors of South Africa. The implication for you, as the assessor, is that you need to continue to be the authority in your specific field of expertise.

SANAS hosted the 2012 Assessor Conclaves on 16 February in Gauteng and on 23 February in the Western Cape. During these conclaves, the following key areas that SANAS and its assessors need to work on were highlighted:

- The need to harmonise the application of relevant requirements by sharing assessment knowledge and experiences
- The requirements for preparation for a re-assessment (this was highlighted at the ILAC/IAF SANAS peer evaluation conducted in August 2011), and
- The need to understand what should be assessed and accepted as evidence of calibration traceability.

This edition of *The A-news* focuses on providing a summary of the 2012 Assessor Conclave discussions and conclusions. It will also provide some valuable updates on issues of concern that impact on assessors.

I hope that this newsletter will contribute towards the SANAS objective of building a closer relationship between SANAS and its assessors and strengthening its knowledge-base by effectively sharing knowledge and experiences.

I would like to invite and encourage you to actively contribute articles on your knowledge and assessment experience, as this newsletter belongs to all of us. You are also welcome to send us any feedback you might have on improving the newsletter.

Lastly, I would like to thank all the assessors that provided input on our understanding of the SANAS values. Your contributions were used to re-align the values, which will direct everything SANAS will be doing in the future. The SANAS "purpose" and "values" will be launched once the process has been finalised.

Enjoy the read!

Ron Josias
Chief Executive Officer

Harmonising

The Assessor Conclave attendees and the ILAC/IAF peer evaluation team identified a need to harmonise the understanding and interpretation of relevant requirements and the way SANAS operates.

During the Conclave, Mr Steve Sidney from the National Laboratory Association (NLA) demonstrated an online tool that can be used by SANAS to advance the interpretation and application of its various requirements by both assessors and its personnel.

Thank you to all who participated in this process, as it made the demonstration much more practical.

SANAS has benchmarked the need for harmonisation with its peer accreditation bodies and produced its first draft information and guidance document. This is the first in a series of documents that will be known as the Assessor Resource Kit (ARK).

SANAS is exploring the use of this tool as part of a continuous development programme, and is seeking the input of its assessors on this important document.

Assessors at the conclave

Please send any comments to:
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Updated SANAS documents

All new and updated SANAS documents are now available on its website, www.sanas.co.za. Since these documents have an impact on the assessor's function, SANAS urges all assessors to ensure that they familiarise themselves with the documents, since implementation and verification forms part of their upcoming assessments.

Preparation for re-assessment

Following findings raised during the ILAC/IAF peer evaluation, SANAS reviewed its process and requirements for conducting a re-assessment in compliance with the international ISO/IEC 17011 standard.

All accreditation bodies must comply with ISO/IEC 17011 and are assessed against this standard by ILAC, IAF or their recognised regional accreditation co-operations such as the European Accreditation (EA), APLAC or IAAC.

According to ISO/IEC 17011 par. 7.6, read together with par. 7.9 and clauses 7.2.1, 7.2.2 and 7.11.1, a re-assessment is similar in nature to an initial assessment and requires SANAS and its assessment team to review all the organisation's documents in preparation for the assessment. More specifically, par. 7.6.2 states that:

"The assessment team shall review all relevant documents and records supplied by the CAB (as described in 7.2.1 and 7.2.2) to evaluate its system, as documented, for conformity with relevant standards and other accreditation requirements.

SANAS concluded that to meet these requirements, the following will have to be reintroduced by the appointed lead assessor:

1. Reviewing the applicant's scope of accreditation as applied for with the relevant field manager
2. Reviewing the applicant's documents, including the quality manual and relevant associated documents and records, such as the participation in proficiency testing. Where required, also requesting team members to provide input
3. Submitting a review to the relevant field manager within 10 working days from the date of receipt of the documentation
4. Liaising with the field manager regarding the cycle assessment planning of the facility and advising them on the resources and time required for the assessment.

SANAS management has addressed concerns regarding compensation for the preparation for reassessment in a separate letter to all registered lead assessors.

Update of 2012 assessor fees

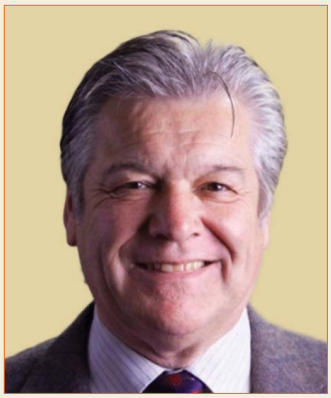
With the Gauteng toll fees taking effect on 30 April 2012, SANAS has had to take into account the impact this will have on the costs incurred by SANAS assessors. Various options were investigated on how to include this cost, while taking into account the need to minimise the tax and administrative burden. As a result, SANAS has resolved to increase the R/km rate for assessors working in Gauteng.

As from 30 April 2012, the R/km rate for assessors working in Gauteng will be R3.70/km. This takes into consideration the 60 cent/km rate as currently prescribed by SARS as well as the possible tax that might be levied.

The 2012 assessors' fees have already been sent out. To avoid any delays in payment, SANAS encourages all assessors to submit their claims as soon as they have submitted all required information and documentation to the relevant programme administrator.

Whose non-conformances are they anyway?

By John Peart



At the recent Assessor Conclave the need for the proper recording of non-conformances was emphasised once again. This is not only for the sake of the facility being assessed, but also for the approvals committee and for the effective closure of follow-up assessments.

The main reason for recording non-conformances is for the assessed facility to be able to implement effective corrective action. If the facility does not fully understand the non-conformance, it may have difficulty in getting to the root of the problem, especially if it does not have additional information such as the completed vertical assessment or witnessing forms.

It is accepted that non-conformances are recorded at 10:00 on the first morning of a three day assessment. This is recommended because the details of the non-conformance are still top of mind for the facility personnel involved, whereas two to three days later they become 'hazy'.

A clearly recorded non-conformance should at least indicate the objective evidence and relate back to an activity, a requirement or facility documentation. It is important to keep in mind that a different assessor may have to verify the clearance of the non-conformance, and a lack of clarity could end up being an unnecessary waste of time.

It is important that facilities take ownership of their non-conformances. SANAS has often found that when faced with an unclear non-conformance record, facilities refer to the non-conformances as if they belong to SANAS, since they were recorded by a SANAS assessor. Some facilities have even tried to recover courier costs from SANAS when sending through their documentation.

When a facility applies to SANAS for accreditation, the facility essentially confirms that it is competent to carry out what is proposed on its accreditation schedule and has a system to support that competency. SANAS therefore assesses the facility to confirm its conformance to the necessary standards and to confirm that the necessary systems are in place and are effective. Any non-conformances recorded and the clearance thereof are therefore the responsibility of the facility.

This means that the facility should ensure that it understands why the non-conformance is being recorded. Only when these non-conformances are effectively closed can SANAS grant accreditation to the facility. The recoding of non-conformances not only helps the facility to implement the necessary, effective corrective action, but also allows it to improve its systems and processes.

In the early days of accreditation, facilities were asked to indicate their proposed corrective actions at the close-out meeting. This, however, often led to superficial solutions to the problems identified as non-conformances.

Nowadays facilities are asked to investigate the root cause of the non-conformances as soon as possible after the assessment by getting the necessary personnel together to investigate the problem thoroughly and to decide on the best action to be taken to prevent recurrences. By immediately addressing non-conformances, anything that is not clear can immediately be taken up with the accreditation body. This prevents facilities from facing suspension and using lack of clarity on non-conformance as an excuse.

As previously stated, however, all non-conformances should be recorded as clearly as possible at the outset. Therefore, the SANAS assessor training courses emphasise that an accreditation assessment is a peer evaluation, with the assessors and facility personnel carrying out the assessment together. This not only creates a sense of team work, but ensures that the facility's personnel understand any non-conformances. Assessors are also advised to ask the facility personnel to assist in recording the non-conformance, as they are ultimately responsible for resolving it.

Facilities on the other hand are urged to properly train all personnel involved in the assessment process. Personnel should be aware that they are not simply signing the non-conformance as a witness, but that by signing it they are also confirming that they clearly understand the problems identified as stated in the non-conformance in order for them to address the issues.

This eliminates any misunderstanding of non-conformances by, for example, the QA Manager who might not have been present at the time the non-conformance was recorded. By training the relevant personnel, facilities also eliminate the situation where only management, such as the Laboratory Head or the QA Manager, are allowed to sign for non-conformances. Such a situation gives the accreditation body the impression that a further non-conformance should be recorded pertaining to management not making sure that all appropriate personnel are aware, and have an understanding of, the systems implemented at the facility.

When it comes to non-conformances, SANAS assessors are responsible for clearly recording the non-conformance so that the facility can implement corrective actions and the Approvals Committee is able to understand the team's recommendations. At the end of the day, though, it is the responsibility of the facility to clear the non-conformances so that they can continue to live up to the competence claims they have made on their accreditation schedule and to maintain or improve their systems or processes.

Please forward your comments on this article to:
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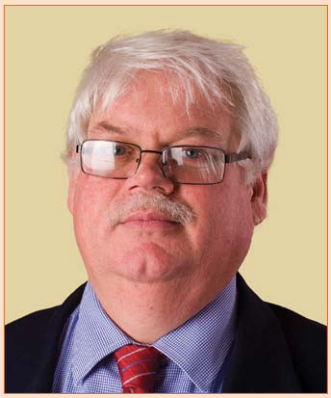
Acceptance of calibration certificates

By Neville Tayler



In commercial and legal proceedings, calibration certificates issued by SANAS-accredited conformity assessment bodies (CABs) are considered as evidence of the facts contained therein. This highlights the importance of the integrity and thoroughness of the assessor's evaluations.

During the recent ILAC/IAF peer evaluation, the evaluator raised the following finding:

"It was observed during the witness assessments of certain laboratories that the technical assessors were accepting unaccredited calibration certificates without verifying traceability, and that these assessors were not knowledgeable enough concerning what is mandatory content of a calibration certificate, namely ISO/IEC 17025, section 5.10 and ISO/IEC 17011, section 6.2.4a."

The above findings, together with the importance of the calibration certificates, require assessors to fully understand what evidence is necessary to underpin any recommendation they make.

Metrological traceability has been defined in the International Vocabulary of Basic and General Terms in Metrology (VIM) as being the property of a measurement result whereby the result can be related to a reference through a documented or unbroken chain of calibrations, each contributing to the measurement uncertainty.

Five major sources of calibration certificates

Principally there are five major sources of calibration certificates that may be accepted as proof of metrological traceability, each with its own set of specific requirements that must be satisfied before it can be accepted. These are issued by:

1. A SANAS accredited calibration laboratory
2. A laboratory that has been accredited by a full member of the ILAC arrangement *(Note: A full list of arrangement members is available on the SANAS website)*
3. The National Metrology Institute of South Africa (NMISA)
4. A member of the CIPM arrangement whose calibration and measurement capabilities (CMCs) have been accepted into the BIPM Key Comparison Database (KCDB)
5. NMIs whose CMCs have been submitted, but not yet accepted into the KCDB (these are only accepted under specific circumstances, and require further evaluation).

Principally there are five major sources of calibration certificates that may be accepted as proof of metrological traceability. Each of the sources also have its own set of specific requirements that must be satisfied before it can be accepted.

Before we discuss the five major sources let's just remind ourselves again that Metrological traceability is defined in the VIM as "being the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".

In the majority of cases, a calibration certificate identifying the originator as one of the above should be acceptable. It remains the responsibility of the assessor, however, to verify the suitability of the calibration, namely that:

- The instrument has been calibrated over the applicable range in which it is being used, and
- The accuracy and measurement uncertainty is suitable for its intended purpose.

In-house calibrations

In house calibrations, performed by testing laboratories, may be accepted where the following minimum criteria have been met:

1. A documented calibration procedure or method is available
2. A suitable method of recording the results, such as a calibration certificate or report, is used
3. The competence of the personnel performing the calibration has been established
4. Training and educational records are available
5. Certificates confirming the metrological traceability are available
6. Calibration intervals have been established and adhered to
7. The uncertainty of measurement has been calculated according to a defined procedure.

In-house calibrations refer only to instances where the facility performs the calibration with its own testing and measuring equipment, and not to instances where it engages the services of a non-accredited service provider.

SI System of unit traceability

It is not always possible to show traceability to the SI system of units, for example when the traceability is to a consensus standard or certified reference material (CRM).

Where the traceability is to a CRM, it should be traceable to the BIPM KCDB or to an accredited producer of CRMs. Such an accreditation will be to ISO Guide 34, in combination with ISO/IEC 17025. The BIPM recognising the requirement for traceability in medicines has established the Joint Committee for Traceability in Laboratory Medicine (JCTLM). This committee is in the process of recognising organisations that provide traceability in the field of laboratory medicine.

ILAC has recognised that there are instances where no CRMs available that originate from accredited producers. In such cases, it requires that these CRMs are treated as critical consumables.

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