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The Independent Communication Authority of South Africa

The draft conformity assessment framework for equipment authorisation

The South African National Accreditation System (SANAS) is the sole body in the Republic responsible for carrying out accreditation in respect of conformity assessment, calibration and good laboratory practices as mandated through the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practices Act, 2006 (Act 19 of 2006). The objectives of SANAS are to accredit or monitor:

- For GLP compliance purposes, organisations falling within its scope of activity;
- Promote accreditation as a means of facilitating international trade and enhancing the Republic's economic performance and transformation;
- Promote the competence and equivalence of accreditation bodies; and
- Promote the competence and equivalence of GLP compliant facilities

Thank you for the extension granted through the dti, to provide further comments from the South African Technical Infrastructure Institutions on ICASA's draft Conformity Assessment Framework for Equipment Authorisations. The South African National Accreditation System (SANAS) wishes to acknowledge the challenges facing the ICASA in fulfilling its mandate concerning equipment authorisation. SANAS furthermore appreciates the effort to normalise the equipment authorisation and the associated risk the country is exposed to in the absence of a cost-effective conformity assessment framework for equipment authorisation. Lastly, SANAS recognises the authority of ICASA to develop and implement a mechanism to effectively execute its mandate and the role assigned to SANAS within the framework. With this understanding, SANAS wishes to contribute to improving the proposed framework to allow for a cost-effective and efficient and internationally recognised conformity assessment framework for equipment verification, testing and certification.

In summary, SANAS wishes to comment on:

- The optimisation of the existing technical infrastructure to support ICASA to achieve its stated conformity assessment objective;

- Clarification on the roles and responsibility of SANAS and the Technical Infrastructure Institutions, SABS, NRCS and NMISA.
- Clarification on who the regulator is
- The use of SDoC to minimise market surveillance

Firstly, SANAS will address some general comments.

- i. **Definition of Testing Laboratory (Page viii):** SANAS proposed that “accredited “to be added to the definition, i.e. *means an accredited testing laboratory.....*
- ii. **Page 15:** Please note accreditation cover all of conformity assessment. It includes certification activities. Please amend the first paragraph to include certification.
- iii. Please note in the definitions, the International Accreditation Forum (IAF) also needs to be acknowledged. Furthermore, **page 15** the second paragraph should include the IAF Multilateral Arrangement (MLA) for certification. SANAS, for example, had been evaluated for certification by IAF and is a signatory to the IAF MLA.

Risk-based assessment for conformity assessment procedure selection

The document needs to spell out what is considered high or low risk to ensure a harmonised approach to conformity assessment. It might require a review of all the product specification/standards or identification and documentation of the risk exposure for each product

Paragraph 2.1; Accreditation and testing

It should be noted that SANAS also accredit certification bodies of which the SABS is one. SANAS is an MLA signatory of the IAF. The IAF scope covers, management systems certification, environment management system, product and food safety management certification.

Paragraph 2.2: 30 March 2016 MoU with SABS

Witnessing testing of an accredited laboratory entrenches on SANAS' mandate.

Paragraph 3

Please note that certification is not a substitute for accreditation. Please remove the word “or” between certification and accreditation, and replace it with: and”

Accreditation bodies and Peer assessment (pg. 32)

The international standard changed now **ISO/IEC 17011:2017**. The last sentence, please change accreditation bodies assess and accredit test facilities. It should read "...accredited conformity assessment bodies which include, test, certification and inspection facilities.

Third party claims of conformity (pg. 34)

Most standards refer to here are outdated.

Supplier's declaration of conformity pg. 42

It should be noted, that for suppliers declaration to work effectively, strong liability and recall laws, as well as effective market surveillance, is required. It appears from the text, that SDoC is proposed to minimise market surveillance. SDoC I highly dependent on an effective market surveillance system.

Specific comments**The optimisation of the existing technical infrastructure to support ICASA to achieve its stated conformity assessment objective**

Although the draft framework recognise the importance of accredited laboratories the role of certification bodies is no clear recognised. Furthermore the role of NMISA and NRCS as the regulator for compulsory specifications is not evident. In principle, the South African Technical Institutions was established to support government in the exercising it mandate of health, safety and environment protection. As such it is recommended that ICASA considers the use of the TI to support its mandate.

Clarification on who the regulator is

Although the document provides a definition of "regulator", it is unclear who the regulator is. It is recommended that NRCS be considered as part of this regulatory function already resided with the NRCS.

SANAS thanks ICASA for the opportunity.

Kind regards



Ron Josias