



**To:** Independent Communications Authority of South Africa (ICASA)  
**Subject:** ICASA THE DRAFT CONFORMITY ASSESSMENT FRAMEWORK FOR EQUIPMENT AUTHORIZATION: SABS's RESPONSE  
**Date:** 27 February 2019

### **THE CONSTITUTION OF THE SABS**

The SABS is the peak national standardisation institution in South Africa, established by the Standards Act, 1945 (Act No. 24 of 1945), and continues to exist under the Standards Act, 2008 (Act No. 8 of 2008). The objectives of the SABS are as follows:

- Develop, promote and maintain South African National Standards (SANS)
- Promote quality in connection to commodities, products and services
- Render conformity assessment services and matters connected therewith

The SABS is a Schedule 3B public entity under the Public Finance Management Act, 1999 (Act No. 1 of 1999)

The following is the SABS's comments on ICASA's Draft Conformity Assessment Framework for Equipment Authorisations, Government notice No.42108 published in the Government Gazette on 13 December 2018 refers.

## GENERAL COMMENTS

### 1. COMMENT - 01

In the Executive Summary – The SABS proposes that a statement be included to mention the number of pages that are in this document. Furthermore – The page numbering must be also indicate the number of pages in this document (Example: *Page 01 of 45*).

### 2. COMMENT - 02

On Figure 3 (Page 10) – The SABS will require more clarity about the roles of the National Standards Bodies, Regional Bodies and International Standards Bodies.

### 3. COMMENT - 03

On Page 11 – The SABS recommends that the word EMC/EMI should be changed to only EMC.

### 4. COMMENT - 04

On Figure 7 (Page 22) – The SABS proposes that more information must be included to clearly specify the functions of each block in this diagram.

### 5. COMMENT - 05

On page 43 – The SABS proposes that the Relevant State Organs be mentioned – For example: SABS, NRCS, SARS, Department of Health (for certain category of Medical Equipment).

### 6. COMMENT - 06

The SABS suggests that the Updated List of Regulated Standards is included in this document.

### 7. COMMENT - 07

On Page 44 – The SABS suggests that the criteria used to determine Low Level Risk, is clearly defined and explained.

### 8. COMMENT - 08

On Page 45 – The SABS proposes that the exact period should be stipulated instead of using the word Prescribed Period. Furthermore – The Authority's prescripts must be clearly defined.

SABS COMMERCIAL SOC Ltd. Reg. No. 2000/013581/30

Website: [www.sabs.co.za](http://www.sabs.co.za) E-mail: [info@sabs.co.za](mailto:info@sabs.co.za) Call Centre: 0861 277 227

Page 2

## RESPONSES TO QUESTIONS

### RESPONSE 01

Conformity assessment is the primary way to ensure that health, quality, safety or environmental requirements are met as per specifications/standards. Conformity assessment is often made obligatory through government regulations. Without appropriate assessment and approval and subsequent surveillance, products are stifled from accessing the markets timeously, may be banned from sale, or suppliers could be disqualified from submitting tenders for government procurement contracts.

The SABS supports ICASA in this endeavour as conformity assessment related to the proposed changes in the conformity assessment framework for equipment authorisation would need to be aligned to those products/equipment classified as High Risk. It would be prudent to understand the principles applied when determining how Risk is defined within the framework.

### RESPONSE 02

Yes. The SABS's view is that it will depend on the application of the equipment. ICASA will need to ensure due diligence is applied in this process taking into consideration South African manufacturers, which may not be in a position to equip fully operational laboratories and bear the costs of accreditation. Therefore, there may be extra costs associated when compared to international manufacturers who, due to the nature of their global operations already possess much of the required infrastructure. It is the view of SABS that further stakeholders such as *the dti* needs to be consulted on the potential impacts of initiatives such as local content verification and Industrial Policy Action Plan, etc., as well as *the dti's* Technical Infrastructure Entities of NRCS, NMISA and SANAS.

- Products classified as Low-risk, will largely benefit the manufacturers with an accredited laboratory and SDOC (1<sup>st</sup> party) will be advantageous. ICASA is aware that such a framework will require it to ensure that sampling and testing of live equipment in the market is conducted. Cognisance may also be required to educate and ensure consumers have a platform to log defective products, which could be used to determine sampling rationale and programs.
- Products classified as Moderate-risk will therefore require assessment of the product application (e.g.; Medical Equipment) which may require a 3<sup>rd</sup> party conformity assessment process, aligned to SANS 17065, Type 5 conformity assessment.

Whereas a moderate risk product where the application of the product is not used in provision of e.g.; Medical equipment, SDOC may be sufficient combined with sampling and testing of live equipment in the market. The SABS again is well positioned to support ICASA in these activities due to our National footprint and infrastructure.

- Products classified as High-risk will require 3<sup>rd</sup> party conformity assessment aligned to SANS 17065 Type 3 and or Type 5 conformity assessment due to the inherent risk profiling.

## **RESPONSE 03**

The SABS fully supports the Process shared by ICASA and all the steps and suggestion as depicted in figure 10.

## **RESPONSE 04**

The SABS supports ICASA's vision to introduce SDOC (Supplier Declaration of Conformity), special attention will be required when risk profiling equipment, taking into consideration the application and strategic importance of the equipment. See response 2, further detail can be provided on request.

## **RESPONSE 05**

The SABS's view is that there is a need to ensure better collaboration between regulators (e.g., ICASA and NRCS) to improve the experience of manufacturers, lower cost and improve turnaround times of type approvals which will ultimately result in equipment in the market to potentially be more cost effective for consumers. The further benefit is that spare parts will become more accessible to consumers as product ranges will be aligned to global rollouts. The SABS proposes a One-Stop-Shop applications process for regulatory approvals - this may reduce costs, improve knowledge sharing, skills development as well as to ensure a far more efficient application process, from application to issuance of certificates. The SABS is ready to support our colleagues at ICASA in reaching their intended milestones.

## **RESPONSE 06**

The SABS supports ICASA and SDOC 1

See Response 2 for further response

## RESPONSE 07

The SABS understands that risks associated with the use of an IT resource can be mapped to one of three different risk categories, namely high-risk, moderate-risk and low-risk, depending on the outcome of equipment risk profiling assessment. It is the SABS view that risk assessment should be considered according to the purposes of use of the IT resource and or equipment. Risk assessment should be closely related to purposes of use, therefore harmonization between regulatory bodies will be advantageous. Consideration for defining risk profiling of IT resources and or Equipment can be mapped against existing risk profiling methodologies, eg; European Union.

## RESPONSE 08

There might be risks associated with the usage of the exempted ICT equipment in cases where the equipment is used in hospitals and other critical support and state functions of a strategic importance. Furthermore – There may be some low-risk equipment that were exempted that might start to radiate, caused by the high usage of the equipment and or the ageing of the equipment.

## RESPONSE 09

The SABS's view that ICASA consider using on-going Consumer Communication Awareness Campaigns to all the relevant stakeholders, Whistle Blower Mechanisms, Policing Ports of Entry (Harbours and Airports) and Border Posts.

## RESPONSE 10

The biggest issue is time-frame to get their equipment into the market, lack of market surveillance and the enforcing of the type approval requirements at Ports of Entries (Harbours and Airports) and Border Posts.

Regards



**Garth Strachan**

**Acting Chief Executive Officer**

T: +27 12 428 6002 | [garth.strachan@sabs.co.za](mailto:garth.strachan@sabs.co.za)

**SOUTH AFRICAN BUREAU OF STANDARDS | HEAD OFFICE**

1 Dr Lategan Road, Groenkloof, Pretoria | Private Bag x191, Pretoria, 0001