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South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

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ISO 13485 Conformity Assessment Body

This guideline is intended to provide recommendations for ISO 13 485 to conformity assessment bodies (CAB), license holders and Holders of Certificates of Registration (HCR) of medical devices. It represents the Authority's current thinking on the quality management system of medical device establishment license holders. It is not intended as an exclusive approach. Conformity assessment bodies (CABs) operating in South Africa shall be accredited by the South African National Accreditation System (SANAS) according to the applicable accreditation scheme, medical device regulations and additional requirements as determined by SAHPRA.

Document History

Final Version	Reason for Amendment	Effective Date [dd Month yyyy]
1	New guideline	Draft for comment March 2023

General Comments:

Updated Regulations not yet published.

Definitions to be in line with new Regulations once published.

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

Contents

Glossary

Abbreviation/ Term	Meaning
Authorised representative	means a natural person, resident in the Republic of South Africa, who— (a) has the written mandate to represent a manufacturer, distributor or wholesaler in the Republic; and (b) acts on behalf of a manufacturer, distributor or wholesaler, in whose name the licence in terms of section 22C(1)(b) of the Act or certificate of registration is issued;
Conformity assessment	means relevant testing, calibration, inspection or certification of a medical device or a quality management system;
Conformity assessment body (CAB)	means a local or international body corporate or other legal entity, recognised by the Authority as competent to carry out conformity assessments;
Designation	The process to designate local / Non International Laboratory Accreditation Cooperation (ILAC) CAB's
ISO	Internal organization for standardization
ISO 13485	means the International Standard "Medical devices — Quality management systems — Requirements for regulatory purposes"; reference number ISO 13485; International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support)
Medical device regulations	Medicines and Related Substances Act 1965, Act No. 101 of 1965- Regulations relating to Medical Devices and IN VITRO Diagnostic Medical Devices (IVDs).
Published list	List of approved CAB's to be published on the website
QMS	Quality management system
SAHPRA (The Authority)	Means the South African Health Products Regulatory Authority established under the Medicines and Related Substances Act, 1965 (Act 101 of 1965) , as amended
SANAS	means the South African National Accreditation System (SANAS) established by section 3 of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act No.19 of 2006);

1. INTRODUCTION

The Medicines and Related Substances Act 101 as amended, requires a medical device establishment to hold an establishment license in recognition of the activities conducted by the organization. Such a license is issued upon the fulfilment of the regulatory requirements which include, but are not limited to, managing a (scope-relevant) quality management system which meets the recognized international standard for medical device establishments, i.e ISO 13485.

The international standard, ISO 13485:2016 Medical Devices – Quality Management systems-Requirements for regulatory purposes identifies the requirements for a quality management system that is used by an organisation involved in one or more stages of the life-cycle of a medical device, including the design and development, production, storage, distribution, installation, servicing, final decommissioning and disposal of a medical device, design and development, or provision of associated activities (e.g. technical support). The requirements in this international standard can also be used by suppliers or other external parties providing product and services (e.g., raw materials, components, subassemblies, medical devices, sterilisation services, calibration services, distribution services, maintenance services) to such organizations.

The nature of the QMS implemented by a medical device establishment must be appropriate to the activities conducted by the organization at each site. These activities may for example, include manufacturing, secondary packaging, refurbishing, servicing and distribution or wholesaling of medical devices.

1.1 Purpose

The purpose of the document is to provide regulatory guidance on how SANAS certified Conformity Assessment Bodies (CAB) are recognised by the South African Health Products Regulatory Authority (SAHPRA)

This document provides guidance for:

i) Defining the responsibilities of SANAS and SAHPRA in relation to certification and recognition of ISO 13485 CAB's

ii) Application by the ISO 13485 certified CAB to be recognized by SAHPRA

iii) Submission requirements

The scope of the document is applicable only to medical device (including IVDs) establishment license Quality Management Systems and not product related certification/registration

2. Legal Provisions

a. Medical Device Regulations Government Gazette
b. Memorandum of Understanding (MOU) between the South African Health Products Regulatory Authority and the South African National Accreditation System

3. Responsibilities

3.1 Responsibility of SAHPRA

The South African Health Products Regulatory Authority (SAHPRA) is an entity of the National Department of Health (NDOH), created by the South African Government to ensure that the health and well-being of human and animal health is at its core. SAHPRA is a schedule 3A public entity in terms of the Public Finance Management Act 1 of 1999 and is accountable to and reports to the Minister of Health. The objectives of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials, medical devices, and related matters in the public interest. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973 as amended) and is in accordance with Section 2B of the Medicines and related substance Act (Act No 101 of 1965 as amended) in relation to the functions of the Authority.

2B. Functions of Authority.

(1) The Authority must, in order to achieve its objectives—ensure the efficient, effective and ethical evaluation or assessment and registration of medicines and medical devices that meet defined standards of quality, safety, efficacy and performance, where applicable; ensure that the process of evaluating or assessing and registering medicines and medical devices is transparent, fair, objective and concluded timeously; ensure the periodic re-evaluation or re-assessment and monitoring of medicines and medical devices; ensure that evidence of existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance is being monitored, analysed and acted upon; ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation; and ensure that clinical trial protocols are being assessed according to prescribed ethical and professional criteria and defined standards.

Furthermore,

(2) The Authority may liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of—

(i) matters of common interest; or

(ii) a specific investigation; and enter into agreements to co-operate with any regulatory authority or institution in order to achieve the objects of the Medicines and Related Substance Act.

For SAHPRA to be able to deliver on its mandate especially regarding Medical Devices (IVD and Non-IVDs), one of its oversight responsibilities is to ensure that manufacturers, distributors and wholesalers distribute and or sell products that are safe, perform as intended and of quality. To ensure compliance with existing legislation every organisation which holds a medical device establishment license is required to have a formal quality management system (QMS) in place.

The revised medical device regulations identify that certification to the quality standard *ISO13485 Medical devices – Quality Management Systems – Requirements for Regulatory Purposes* will be

required for a new medical device establishment licence application, renewal of a medical device establishment licence, an amendment to a medical device establishment licence and associated records.

[Prior hereto – the Authorised Representative has been required to make a legal declaration that the requisite quality management system and procedures were implemented within the medical device establishment.]

To achieve certification to the ISO13485 standard for medical devices, the certification process requires each medical device establishment to implement a formal quality management system (QMS) which must be inspected and certified by an independent conformity assessment body (CAB) which has in turn been accredited by SANAS and recognised by SAHPRA as compliant to South African ~~l~~egislation and regulations for medical devices.

3.2 RESPONSIBLITY OF SANAS

South African National Accreditation System (SANAS), is a schedule 3A public entity in terms of the Public Finance Management Act 1 of 1999, established in terms of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act 19 of 2006. SANAS is the only national body responsible for carrying out accreditation in respect of conformity assessment, which includes the accreditation of Testing, Calibration, Verification laboratories, Inspection, and Certification bodies. SANAS is a signatory to the African Accreditation Cooperation (AFRAC) Mutual Recognition Arrangement, and AFRAC is internationally recognised through the International Laboratory Accreditation Cooperation's Mutual Recognition Agreement (ILAC MRA) and International Accreditation Forum's Multilateral Arrangement (IAF MLA).

4. Recognition / Verification / Designation Process

Conformity assessment bodies (CAB) operating in South Africa shall be accredited by SANAS according to the applicable accreditation scheme, medical device regulations and additional requirements as determined by SAHPRA.

Foreign conformity assessment bodies operating in South Africa (which are accredited by signatory members to International Accreditation Forum Multilateral Arrangement (IAF MLA)) and local conformity assessment bodies, shall be recognised by SAHPRA for compliance with the South African regulations in respect of regulatory and any additional South African requirements as determined by the SAHPRA, within the scope of their accreditation.

On meeting the requirements as established by SAHPRA, SAHPRA will publish on the website (https://www.sahpra.org.za/list-of-recognised-conformity-assessment-bodies/) , the name and address of a conformity assessment body recognised by the Authority . The list will be updated monthly .

5. Complaints and Appeals

a. All investigation and disputes arising from a contravention of the medical device regulations will be the responsibility of SAHPRA
b. All investigations and disputes arising from the contravention of the accreditation requirements will be the responsibility of SANAS in accordance with its procedures P12 "Handling of Complaints and Appeals.
c. Where investigations and disputes overlap, the function of SAHPRA and SANAS, both parties will cooperate to resolve the issue(s).

6. APPLICATION REQUIREMENTS FOR A CONFORMITY ASSESSMENT BODY (CAB)

Specific Requirements for a Medical Device Conformity Assessment Body (CAB)

1. A CAB shall demonstrate:

    - compliance to South African regulatory requirements (including, but not limited to the understanding of the Medicines and Related Act 101, as amended and the Hazardous Substances Act 15, as amended);
    - Proof of training regarding compliance to South African regulatory requirements
    - certification of a quality management system as per standard *ISO 17021: Requirements for Certification Bodies,* and
    - compliance to the relevant International Accreditation Forum, Inc. (IAF) mandatory document(s) for medical devices [e.g., MD9 Application of ISO 17021-1 in the Field of Medical Device Quality Management System (ISO 13485)].; and

      A CAB shall make available to SAHPRA information about the organisational structure, ownership and the legal and natural persons exercising control over the CAB.

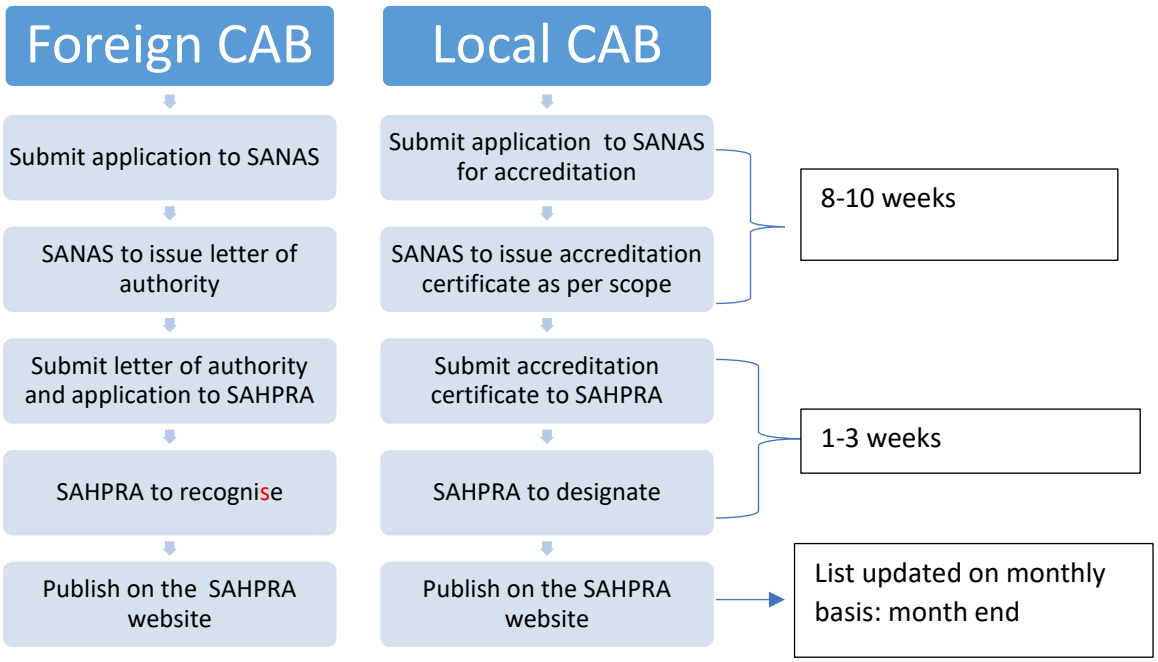
2. In addition, a CAB that maintains multiple offices that perform any part of the regulatory review process, shall ensure that the roles and responsibilities of the CAB and each of the locations are defined and implemented.

3. Documents to be submitted to the authority for approval for local and foreign CAB's:

    - Completed Declaration indicating compliance with South African regulatory requirements and what the scope of work of the CAB will include:
    - Valid **ISO 17021** Conformity Assessment — Requirements for bodies providing audit and *Certification of Management Systems* Certificate
    - Scope of work (include Act and Regulations) – copy
    - Certificate indicating that the CAB is a member of ILAC (IAF MLA)
    - SANAS Letter of Authority

7. Process flow

The following related documents are referenced:



8. REFERENCES

The following related documents are referenced:

a. 16.03 Guideline for a license to manufacture, import, export or distribute medical devices and IVDs

b. SANAS P 05-1 THE ASSESSMENT OF CERTIFICATION BODIES
c. IMDRF GRRP WG/N61 FINAL:2020- Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews
d. IMDRF GRRP WG/N59:2020 – Requirements for Medical Device Conformity Assessment Bodies for Regulatory Authority Recognition
e. ISO 17021: Requirements for Certification Bodies
f. ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

9. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision. It will be reviewed on this timeframe or as and when required.