

## **SANAS AND SAHPRA SIGNS MEMORANDUM OF UNDERSTANDING**

*By Mr Tumelo Ledimo, SANAS Project Manager*

SANAS Acting CEO, Mr Tumelo Baleni and South African Health Product Regulatory Authority (SAHPRA) CEO, Dr Boitumelo Semete-Makokotlela signed an extension of the Memorandum of Understanding (MoU) on the 28<sup>th</sup> of June 2022 at the SAHPRA office in Pretoria. The initial SANAS and SAHPRA MoU signed in 2017, was for the implementation of the Medical Devices and In-Vitro Diagnostics regulations that was promulgated on the 9<sup>th</sup> December 2016. This MoU was limited to SANAS assisting SAHPRA with the accreditation of Conformity Assessment Bodies (CABs) in medical devices quality management system.



The Medical Devices and In-Vitro Diagnostics regulations makes provision for the certification bodies to be accredited in order to provide certification to the manufactures, importers, wholesalers, and distributors in accordance with ISO 13485 “Medical Devices – Quality Management System – Requirements for regulatory purpose”. The certification bodies will be accredited to ISO 17021-1, International Accreditation Forum (IAF) mandatory documents and any additional requirements that the SAHPRA might publish.

The new MOU was extended to include the following accreditation programmes:

- Calibration and Testing Laboratories against ISO/IEC 17025;
- Blood Transfusion Services against ISO 15189; and
- Inspections and Testing of Diagnostic X-ray Imaging Systems against ISO/IEC 17020.

Inspections and Testing of diagnostic X-ray imaging systems had a separate MoU, that was signed with the directorate of the Radiation Control under Department of Health. That particular MoU was to support the licence conditions for Diagnostic X-ray Imaging Systems, this function is now under the auspice of SAHPRA.

Calibration, Testing and Blood Transfusion Services are included as part of the work that SANAS do in support of streamlining health and safety process and system of SAHPRA.

The recently signed MOU outlines the roles and responsibilities of SANAS and SAHPRA, this partnership and collaboration will assist with the streamlining of process in the interest of healthcare products and services safety and performance in South Africa.

<https://www.sanas.co.za/Attachments/SANAS%20and%20SAHPRA%20MoU.pdf>