

SANAS Accreditation: Delivering confidence in Health Care

The 9th June 2015 was World Accreditation Day. The South African 2015 theme focuses on how accreditation can support the improved delivery of health care in South Africa.

This year the South African National Accreditation System (SANAS) World Accreditation Day celebrations took place at Capital Moloko Hotel in Sandton, Johannesburg. The attendees included representatives from the Departments of Trade and Industry and Health, NRCS, NMISA, industry and stakeholders within the health care sector as well as related industries.

A distinguished panel consisting of Dr Demana from **the dti**, Mr Prags Governder the Chairperson of the SANAS BoD, Mr Ron Josias CEO of SANAS, Ms Leslie Bust, Ms Jane Rogers and Dr Elsabe Steyn talked on various topics relevant to the theme of Accreditation: Delivering confidence in Health Care.

Mr Ron Josias highlighted the fact that effective provision of health care is one of the greatest challenges facing South Africa and the world today. Due to an every growing population and increased life expectancy, together with the need to supply consistent and cost-effective health care, the industry will only grow in scale and complexity. To this end, the health care sector strives for excellence through achieving a balance of quality, economic, social and environmental outputs. Health and social care excellence is driven by the need to provide confidence in the delivery of a competent service to patients, families, regulators and commissioners.

He confirmed that accreditation within the health care sector supports this assurance. It provides an essential tool enabling healthcare providers to demonstrate that they have completed a rigorous process; ensuring patients consistently receive high quality services, delivered by competent staff working in safe environments.

The Chairperson of the SANAS BoD, Mr Prags Governder, emphasized the fact that SANAS is one of many globally recognised accreditation bodies that serve to accredit conformity assessment bodies in their respective countries. The international landscape is defined by the activities the International Laboratory Accreditation Corporation (ILAC) and the International Accreditation Forum (IAF). SANAS is a signatory to various multilateral recognition agreements (MLAs) thereby ensuring the global acceptance of South Africa's products and services. These MLAs remove technical barriers to trade (TBTs), which in turn locks out poor quality imports and locks in high quality exports

Dr Demana shared **the dti's** plan with the medical device industry in South Africa. According to the IPAP the South African medical devices sector (which includes medical diagnostics) was estimated at US \$ 1.3 bn (R 14.3 bn) in 2013. It involves over 200 companies, most of them with only sales / marketing and servicing operations. The import penetration of the South African medical devices sector is over 90%. Domestic manufacturing of medical devices ranges from simple products such as condoms and "medical textiles" – bandages, plasters and sterile wound dressings -through wheelchairs, stents and implants for head and limb surgery – to the world's technologically most advanced full-body X-ray scanner ("Lodox").

Key opportunities for growing the medical devices sectors include:

- Increasing participation in Health Department tenders -
- Expanding regional co-operation and exports of medical products to SADC and Africa

A key action programme in the IPAP for the next 3 year is the development of industrial strategy for the medical devices sector

Ms Leslie Bust from the Western Province Blood Transfusion Service (WPBTS) pointed out that the advantage of SANAS accreditation is that it provides an external review that the management systems are effective and robust. SANAS assessments are conducted regularly and in a professional manner by experienced and knowledgeable assessors.

Ms Jane Rogers draw the attendees attention to the fact that the Medicines and Related Substances Act, 1965 (Act 101 of 1965) makes provision for the Minister of Health, in consultation with the Medicines Control Council, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), to make regulations. In terms of the Medicines Act, the Medicines Control Council (MCC) is mandated to facilitate access to safe and appropriate diagnostics of good quality with high performance and therefore improving pre- and post-market regulatory oversight of diagnostics and IVDs. The Department of Health is currently working on draft regulations for regulatory oversight of Medical Devices and IVDs.

Dr Steyn talked about the current SANAS programmes that are in place that support the proficient delivery of health and social care within the country. Currently there is a pool of 311 medical laboratories, 106 blood transfusion services and several inspection bodies that inspect diagnostic imaging machinery such x-rays and MRI, Ultrasound and CT scan equipment. This pool of competent conformity assessment bodies supports health and social care excellence in South Africa, with the ultimate goal of ensuring confidence in the delivery of services to patients, families, regulators and government. This, in turn, ensures that healthcare providers can operate with confidence within the system.

SANAS is currently working with the Department of Health to develop an accreditation programme for certification of medical devices. This will ensure support for the South African medical device industry in future.

SANAS 2015 World Accreditation Day panel members:



From left: **Ms Jane Rogers** (from Strategic Healthcare Solutions); **Mr. Prags Govender** (Chairperson of the SANAS BoD); **Ms. Leslie Bust** (from Western Province Blood Transfusion Services); **Dr Tshenge Demana** (from Department of Trade and Industry); **Dr Elsabe Steyn** (SANAS Senior Manager, Research and Development) and **Mr Ron Josias** (SANAS CEO).