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SRLA
SADC REGIONAL LABORATORY ASSOCIATION

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FACILITATING TRADE AND REGIONAL INTEGRATION

Assessment of laboratory competencies in the Southern African Development Community (SADC) region

BACKGROUND

Trade has long been recognized as a potential engine for growth and wealth creation. Many developing countries continue to face difficulties in demonstrating compliance with quality requirements and trade rules, thus hindering them from accessing international markets.

Southern Africa's trade diversification from primary product exports into higher value manufacturing exports is limited, except for South Africa. To ease this, the Southern African Development Community (SADC) Industrial Development Policy Framework 2013-2018 acknowledges the crucial role of quality and quality infrastructure in enhancing manufacturing capabilities and international competitiveness within the region, especially in relation to small-and-medium enterprises (SMEs).

The effective coordination of trade related initiatives on quality infrastructure in the SADC region are key conditions to achieve development, social economic growth and poverty reduction.

The United Nations Industrial Development Organization (UNIDO) is determined to contribute to the Agenda 2030 and the Sustainable Development Goals (SDGs) by promoting and accelerating Inclusive and Sustainable Industrial Development (ISID). UNIDO is a key player in the fight to end poverty - while its activities contribute to numerous goals relating to people, prosperity, planet, peace and partnerships, its mandate is embedded in SDG 9: build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation.

Setting up a Quality Infrastructure System is one of the most positive and practical steps that a developing nation can take on the path forward to developing a thriving economy as a basis for prosperity, health and well-being. Within the quality infrastructure system, conformity assessment services are used to demonstrate that a product, process or service, meets specified requirements. Such services are usually performed by organizations specialising in certain activities, of which the main ones are testing, inspection and certification.

The requirements for conformity assessment activities themselves are also given in international standards, ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories. The standard is for use by laboratories in developing their management system for quality, administrative and technical operations and covers aspects such as general management requirements as well as technical requirements of personnel and equipment. This helps to ensure consistency worldwide, and cross-border acceptance of results.

Recognizing the value of quality infrastructure for economic development, many Southern African countries requested UNIDO's assistance for facilitating global trade and regional integration. As the quality culture improves in Africa, tested and certified products are winning consumers' confidence and they demand better and safe products. To prove and verify the quality of goods, conformity assessment certificates are sought for.

However, these certificates from the SADC region are often not nationally/internationally recognized, creating a barrier to trade. From the 175 laboratories assessed, only 31 are accredited against ISO/IEC 17025. 138 laboratories are not accredited, meaning they cannot provide internationally recognized services. Although 67% of the laboratories claim that they use the laboratory management standard ISO/IEC 17025, 73% of those laboratories have not been appropriately trained to deploy these standards.

Thus, there is a need to increase the capacity of Southern African countries to verify compliance to standards and quality requirements. One way of doing this is to strengthen the laboratories in the SADC region to offer high quality and reliable testing services for enterprises and regulators to facilitate trade. In order to do so, UNIDO has developed a holistic approach to strengthen conformity assessment bodies in developing countries, in a step-by-step approach.

11 COUNTRIES

175 LABORATORIES

35 Swaziland
27 Zimbabwe
26 Zambia
23 Mozambique
18 Malawi
17 DR Congo
12 Zanzania
9 Botswana
5 Namibia
2 Mauritius
1 Seychelles

124 Testing laboratories
32 Medical laboratories
19 Calibration laboratories

APPROACH

UNIDO approach to strengthening conformity assessment bodies in developing countries:

1. Mapping of existing conformity assessment services and scopes
2. Compile information in a directory
3. Identify technical gaps through a questionnaire
4. Visit laboratories on-site to identify specific areas of technical assistance required
5. Strengthen conformity assessment services through capacity building activities
6. Develop business plans and marketing tools to assure sustainability of interventions
7. Support laboratories towards accreditation

The SADC Regional Laboratory Association (SRLA) is a non-profit stakeholder body that represents the voice of Southern African laboratories that perform activities related to testing and calibration. Following UNIDO's approach on strengthening conformity assessment bodies in developing countries, UNIDO and the SRLA developed a Laboratory Assessment Tool to identify the technical gaps of testing laboratories in the SADC region. On a larger scale, the tool measures the readiness to implement a quality management system of testing laboratories (i.e. ISO/IEC 17025) and has the ability to measure progressively, over time, the efforts of the laboratory towards meeting the requirements of this standard.

Steps taken to develop laboratory assessment tool:

1. Define target laboratories
2. Develop questionnaire to measure the capacity of laboratories in terms of infrastructure, human capital, quality management system and quality of testing, and assess the needs in view of potential for accreditation against ISO/IEC 17025
3. Identify coordinators at the national laboratory associations who will review and pre-test tool
4. Based on results, improve tool and collect data through web-based application
5. Apply tool in the region
6. Analyze, evaluate and interpret data and results
7. Identify collective gaps encountered and propose activities to overcome gaps at national and regional levels

In 2016, the survey was conducted in **11 Southern African countries** and generated responses from **175 laboratories** out of which there were 124 testing laboratories, 32 medical laboratories and 19 calibration laboratories.

KEY RESULTS

HUMAN SKILLS

6 out of 10 laboratories have no system of assessing training needs

The best equipment is useless, if personnel do not have the capacity and capability to use it. For the provision of technical services, it is important to ensure the competence of all who operate scientific equipment, perform test or calibrations, evaluate results or issue reports. Personnel performing specific tasks should be qualified and receive appropriate training, ideally based on pre-assessed needs.

From the 175 generated responses, only 62 laboratories assess training needs through audits and provide training by certified trainers. 104 laboratories have no system in place to assess training needs. 29 laboratories provide no formal training courses at all and 9 provided no answer.

INFRASTRUCTURE AND TECHNICAL EQUIPMENT

39% of the laboratories have less than 10 pieces of fully functional equipment

68 less than 10 pieces of fully functional equipment

46 10 to 30 pieces of fully functional equipment

32 more than 30 pieces of fully functional equipment

In order to perform accurate test and calibrations, functional technical equipment is key. The laboratory needs appropriate technical equipment to assure the provision of services that its customers can rely on. Regular checks, calibrations and procedures for safe handling are needed to maintain the equipment and assure its functioning over time. Maintenance of high-tech equipment is often costly and can become a financial burden to laboratories in developing countries, who often struggle with tight budgets.

From the 175 laboratories assessed in the region, only 32 of them have more than 30 pieces of functioning equipment. 68 laboratories have less than ten pieces of functioning equipment. 26 laboratories provided no answer.

TEST METHODS AND VALIDATION

3 out of 5 laboratories have some validated methods

60 most methods are validated (› 70%)

82 some methods are validated (‹ 50%)

24 no methods are validated

Within its scope and as part of quality control, the laboratory should ensure that it uses appropriate methods and procedures for all tests and/or calibrations performed. In order to make sure that a certain procedure is appropriate, it is necessary to validate the method used.

Looking at the assessed laboratories in the SADC region, only 60 (out of 175) validate most of their methods (more than 70%) according to a procedure and uncertainty of measurement estimated. 82 laboratories validate some (less than 50%) of their procedures, 24 perform no validation of their methods at all and have no documented procedures for methods validation. 9 laboratories did not respond to the question.

INTERMEDIATE VERIFICATION

1 out of 2 laboratories perform some verification checks

76 most intermediate verification checks performed

56 some intermediate verification checks performed

30 no intermediate verification checks performed

While validation is the process of assuring that a method meets the needs and thus fulfills its purpose, verification is the process of checking whether a product or service meets the predefined specification.

Verification can be done against a certain standard or reference material and should be always carried out in accordance with defined procedures.

From the 175 responses generated, 76 laboratories indicated that they perform most intermediate verification checks (meaning more than 70%), while 56 laboratories perform some (less than 50%) and 30 none. 13 laboratories provided no answer.

DOCUMENTED MANAGEMENT SYSTEM

30% of the laboratories have no documented management system

119 most of the quality system is documented

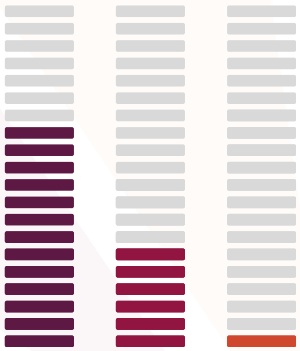
43 some procedures and policies are documented

9 no procedures and policies are documented

In order for laboratories to carry out quality

QUALITY CONTROL

65% of laboratories implement most quality control procedures



113 most quality control procedures implemented

49 some quality control procedures implemented

7 no quality control procedures implemented

Quality control in laboratories is designed to detect