

ANNEX V

EAST AFRICAN COMMUNITY TESTING LABORATORIES DESIGNATION REGULATIONS

(Draft One)

PART I

In exercise of powers conferred by section 12 of the East African Community Standardization, Quality Assurance, Metrology and Testing Act, 2006, the Council of Ministers makes this regulation this ___ day of __ 2008.

Preliminary Provisions

Article 1

These regulations specifies procedures, requirements and conditions for designating testing laboratories to perform conformity assessment of products subject to national or regional technical regulations or mandatory standards.

Article 2

The Minister responsible for trade in a partner state may designate testing laboratories to perform conformity assessment of products subject to national or regional technical regulations or mandatory standards.

Article 3

Definitions

1. **Accreditation** is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.
2. **Designation** is the nomination by a Designating Authority of a Testing laboratory as competent to perform specific test and measurement activities in accordance with the provision of the Standardization, Quality Assurance ,Metrology and Testing Act,2006, Section 12.
3. **Designating Authority** shall be the Minister responsible for trade in the

partner state. The minister shall have authority to designate, monitor, suspend designation, or withdraw designation of Testing Laboratories under his jurisdiction.

4. **Recognition** is the acceptance of test reports from a designated testing laboratory by other member states.
5. **Designated Testing laboratory** means public or private testing laboratory designated by the Minister responsible for trade in a partner states.
6. **Testing laboratory is** a laboratory that performs tests and or measurements according to a defined procedure.

PART II

Conditions and procedures for designation

Article 4

To be eligible for designation, a testing laboratory must:

1. be an entity legally established and operated under the law of a partner state;
2. have the capability and technical competence in performing the tests against the relevant standard ;
3. comply to Standardization, Quality Assurance, Metrology and Testing Act, 2006,Section 12 (2) and 12 (3);
4. demonstrate one or more of the following:
 - a) use of internal quality control;
 - b) participation in at least one relevant proficiency testing scheme where available;
 - c) use of reference materials
 - d) implementation of good laboratory practice according to relevant international standards;

OR

5. be accredited by an internationally recognized accreditation body

Article 5

Applications or enquiries for designation of testing laboratories should be addressed to the Minister responsible for trade in the respective partner states.

Article 6

Approval procedure for laboratories that are not accredited as defined in Article 4.5

1. Approval is based on the evaluation of the application and on site assessment.
2. The Minister may delegate to competent person or group of persons to carry out the evaluation and assessment and make recommendations regarding the laboratory readiness for designation.
3. After completion of evaluation by the Minister, the testing laboratory will be informed of the outcome of the application.
4. Where a laboratory has been approved for designation, it shall be issued with designation certificate and a unique designation number. The certificate shall clearly indicate the relevant technical regulation or mandatory standard for which the designation is valid, including the scope of testing and measurement.
5. The certificate shall be valid for a period of three years. During this time the designated testing laboratory shall be subjected to midterm surveillance assessment.
6. The designated laboratory shall pay applicable fees as determined by each partner states from time to time.
7. The designated laboratory shall be granted permission to use designation logo and number on its test and measurement reports. Where the report includes results outside the scope of its designation these results shall be identifiable.
8. The designated laboratory shall notify the Minister of any changes which might have significant impact on laboratory capacity to provide tests and or measurements for which they are designated.
9. The Minister shall notify the East African Community Secretariat once a laboratory has been designated. The Minister shall be obliged to inform the East African Community Secretariat of any changes in the designation status of a designated laboratory.

10. The East African Community Secretariat shall be responsible for providing updated information regarding the designated laboratories to the partner states and maintain the data base.

Article 7

Procedure for laboratories that are accredited in accordance with Sub-article 4.5

1. Approval is based on the evaluation of the application and on assessment of the accreditation documentation.
2. The Minister may delegate to competent person or group of persons to carry out the evaluation and make recommendations regarding the laboratory for designation.
3. After completion of evaluation by the Minister, the testing laboratory will be informed of the outcome of the application.
4. Where a laboratory has been approved for designation, it shall be issued with designation certificate and a unique designation number. The certificate shall clearly indicate the relevant technical regulation or mandatory standard for which the designation is valid, including the scope of testing and measurement.
5. The certificate shall be valid for as long as the laboratory's accreditation remains valid.
6. The designated laboratory shall pay applicable fees as determined by each partner states from time to time.
7. The designated laboratory shall be granted permission to use designation logo and number on its test and measurement reports. Where the report includes results outside the scope of its designation these results shall be identifiable.
8. The designated laboratory shall notify the Minister of any changes, including changes to its accreditation status which might have significant impact on laboratory capacity to provide tests and or measurements for which they are designated.

The Minister shall notify the East African Community Secretariat once a laboratory has been designated. The Minister shall be obliged to inform the East African Community Secretariat of any changes in the designation status

PART III

Rights and Obligations of the designated testing laboratory

Article 8

1. Test reports from the laboratory designated under the provisions of the Standardization, Quality Assurance, Metrology and Testing Act, 2006, Section 12, shall be accepted by other partner states.
2. The designated laboratory is obliged to adhere to the terms and conditions under which the laboratory is designated.
3. The designated laboratory is also obliged to adhere to the applicable national laws and regulations.
4. The designated laboratory is obliged to provide updates to the Minister in accordance with the provision of article 6(8) of these regulations.

PART IV

Post-designation Surveillance

Article 9

1. As and when required, the Minister will have surveillance assessments and other non-routine assessments conducted by competent persons on the designated laboratories that are not accredited to ensure that standards of practice are maintained or to investigate complaints made against designated testing laboratories on matters related to their designation.

Article 10

The Minister shall notify the partner states through the East African Community Secretariat on the status of the designated testing laboratory regarding the following:

- i) New designation;
- ii) Changes in scope of designation;
- iii) Suspension or withdraw of the designation of the testing laboratory;
- iv) Re-instatement of designation.

PART V

Offences

Article 11

Partner states shall in their approximated regulations provide for penalties for the offences in line with their applicable national laws.

PART VI

Disputes and Appeals

Article 12

Disputes arising from the implementation of these regulations shall be settled in accordance with provision of the Standardization, Quality Assurance, Metrology and Testing Act, 2006, Section 26.

PART VII

Implementation provisions

Article 13

Partner states are obliged to adopt and implement these regulations.

Article 14

These regulations will be reviewed and amended from time to time to reflect the prevailing realities in accordance with provision of the Standardization, Quality Assurance, Metrology and Testing Act, 2006, Section 28 (1).