L.N. 313 of 2001

MALTA STANDARDS AUTHORITY ACT, 2000 (ACT NO. XIX OF 2000)

Malta Standards Authority (Establishment of the Accreditation Directorate) Order, 2001

IN exercise of the powers conferred by article 3 (14) of the Malta Standards Authority Act 2000, the Minister for Economic Services has made the following Order:–

Citation and commencement.

1. (1) The title of this Order is the Malta Standards Authority (Establishment of the Accreditation Directorate) Order, 2001.

(2) This Order lays down the establishment, organisation and operation of the Accreditation Directorate within the Malta Standards Authority, acting as the only recognised National Accreditation Body in Malta. This Order specifies the fields in which accreditation shall be performed and the application of accreditation in all regulations specifying conformity assessment.

(3) The date of coming into force of this Order is the 1st January, 2002.

Definitions.

2. In this Order, the following definitions shall apply, unless the context otherwise requires:

"accreditation" means the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks;

"Accreditation Advisory Board" means that board established in terms of section 5 of this Order;

"Accreditation Appeals Board" means that board established in terms of section 6 of this Order;

"accreditation body" is a body that conducts and administers an accreditation system and grants accreditation;

"accreditation system" means a system that has its own rules of procedure and management for carrying out accreditation;

"accredited body" is a body to which accreditation has been granted;

"Act" means the Malta Standards Authority Act, 2000;

"assessment" means the examination for competency and for compliance with pre-determined regulations conducted by independent assessors working under the authority of the Accreditation Directorate;

"assessor" means a technical expert who has undergone appropriate training and has a combination of qualifications and experience enabling him to examine and evaluate competently the testing skill of any body and to judge its effectiveness and quality;

"Authority" means the Malta Standards Authority;

"body" means any person or association of persons, whether corporate or unincorporate, private or public;

"calibration" refers to all the operations for the purpose of determining the values of errors of a measuring instrument;

"certification" is the procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements. The term "certification" includes certification of personnel;

"certification body" is a body that conducts certification;

"conformity" means the fulfilment by a product, process or service of specified requirements;

"conformity assessment" means any activity concerned with determining directly or indirectly that relevant requirements are fulfilled;

"conformity assessment body" is a body that conducts conformity assessment;

"conformity assessment procedure" means the procedure by which conformity assessment is attained;

"Head of Directorate" means the person appointed to that post according to the provisions of article 3 (17) of the Act;

"inspection" means the examination of a product design, product, service, process or plant, and the determination of their

conformity with specific requirements or, on the basis of professional judgement, general requirements;

"inspection body" is a body that performs inspection;

"scope of accreditation" means the specific tests, measurements or calibration for which a body is formally accredited by the Accreditation Directorate, including any qualifications such as range of measurement, test procedures and assigned measurement uncertainties;

"test" means the technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure;

"third party" means any person or body that is recognised as being independent of the parties involved as concerns the issue in question.

Establishment of the Accreditation Directorate.

3. (1) There shall be established, within the Authority and as provided for in section 3 (14) of the Act, an Accreditation Directorate, with the following principal functions and responsibilities:

(a) it shall be the National Accreditation Body in Malta responsible for accreditation in accordance with the relevant national, international and European standards and guides, and the applicable national, international and European regulations;

(b) it shall be the National Accreditation Body in Malta responsible for adopting commitments and obligations relating to accreditation arising out of any international agreement, whether bilateral, regional or multilateral.

(2) In particular, the functions of the Accreditation Directorate shall include the following:

(a) to accredit testing and calibration laboratories;

(b) to accredit certification bodies providing certification of products, services, management systems and personnel;

(c) to accredit inspection bodies;

(d) to collaborate with other European and international accreditation bodies, and to represent in them the Maltese interests;

(e) to provide advice to the Government in matters concerning accreditation and other assessments and in the approval or otherwise as to the competence of bodies carrying out conformity assessment activities;

(f) to perform other assessments and approvals of competence for carrying out conformity assessment activities;

(g) to publish accreditation procedures; and

(h) to keep a register of accredited bodies.

The Head of the Accreditation Directorate.

4. (1) The Head of the Accreditation Directorate shall be appointed according to the provisions of article 3 (17) of the Act.

(2) Without prejudice to the functions listed in article 3, the functions of the Head of the Accreditation Directorate shall be:

(a) to provide for assessment visits of applicant bodies, as required by the relevant national, international and European standards and the applicable national, international and European regulations according to the scope of accreditation;

(b) to provide for periodic visits for the assessment of the technical and organisational requisites of the accredited bodies, as required by the relevant national, international and European standards and the applicable national, international and European regulations according to the scope of accreditation;

(c) to publish suspensions and/or revocations of accreditation;

(d) to take part in the work of international and/or supranational bodies operating in the field of accreditation;

(e) to collaborate with the Standardization Directorate of the Malta Standards Authority in order to promote appropriate drafting or updating of technical standards;

(f) to collaborate with the relevant Directorates of the Malta Standards Authority in order to promote appropriate conformity assessment procedures;

(g) to promote studies, meetings and actions in its area of competence in co-operation with national and international associations;

(h) to represent the Authority in relevant national and international activities; and

(i) to carry out such other functions, not conflicting in any way with the provisions of this Order, as the Minister may, from time to time, direct.

(3) In exercising its functions under this Order, the Accreditation Directorate shall be functionally independent from the Authority as regards operational matters and, more specifically, as regards technical matters within its area of competence. In particular, the Accreditation Directorate shall be independent of any other structure or official within the Authority as regards the implementation of the functions listed in article 3 of this Order and in sub-article (2) of this article.

(4) Without prejudice to the immediately preceding sub-article, the Accreditation Directorate shall operate subject to the administrative and financial control of the Authority as provided for in the Act as well as subject to the general policy of the Authority.

Establishment of the Accreditation Advisory Board.

5. (1) There shall be established an Accreditation Advisory Board, the functions of which are:

(a) to provide advice of a technical nature to the Head of Directorate and to provide assistance on general matters of policy and organisation relating to the functions and activities of the Directorate; and

(b) to examine proposals for new accreditation projects and to make recommendations on how to proceed in pursuance of these proposals.

(2) The number of members, manner of procedure of their appointment and their terms of office shall be determined by the Authority, according to the relevant national, international and European standards and guides of the European and international accreditation bodies.

(3) The Accreditation Advisory Board shall draw up its own rules of procedure based on the relevant national, international and European standards and documents of the European and international accreditation bodies.

(4) Administrative matters relating to the Accreditation Advisory Board shall be conducted by the Head of Directorate.

6. (1) There shall be established an Accreditation Appeals Board to hear and decide upon appeals against decisions of the Accreditation Directorate, including those arising from the interpretation of the regulations and the specified criteria of competence or otherwise arising in connection with the operation of the accreditation scheme. Establishment of the Accreditation Appeals Board.

(2) The number of members, manner and procedure of their appointment and their terms of office shall be determined by the Authority, according to the relevant national, international and European standards and guides issued by European and international accreditation bodies.

(3) The Accreditation Appeals Board shall draw up its own rules of procedure based on the relevant national, international and European standards and guides issued by European and international accreditation bodies.

(4) The Accreditation Appeals Board shall have the power to:

(a) examine all documentation relevant to the appeal; and

(b) require the attendance of assessors and/or technical advisors as necessary.

(5) The decisions of the Accreditation Appeals Board shall be final as to the merits of the appeal and shall be binding both on the appellant and the Accreditation Directorate.

7. (1) The Head of Directorate may, with the agreement of the Accreditation Advisory Board, establish technical committees in order to provide scientific and technical advice in their respective areas of competence. Technical Committees.

(2) The Head of Directorate shall chair and co-ordinate the technical committees under his responsibility.

(3) The Head of Directorate may, with the agreement of the Accreditation Advisory Board, disband technical committees and remove, replace or suspend any member of such committees if such action is considered to be necessary in order to maintain their impartiality, transparency and independence.

8. (1) Assessments for the accreditation of any body shall be conducted in accordance with the relevant national, international and Accreditation procedure.

European standards and guides and the applicable national, international and European regulations.

(2) Accreditation shall be carried out upon the request of any body and may be granted for a limited period of time or until suspension or withdrawal.

(3) The Accreditation Directorate shall conclude a contract with any body wishing to obtain accreditation, stipulating the rights and obligations of the parties to the contract.

(4) The Accreditation Directorate shall, upon concluding the contract, provide advice regarding the requirements for obtaining accreditation and the accreditation procedure.

(5) The Accreditation Directorate shall grant a certificate of accreditation to any body who fulfils the requirements of the relevant national, international and European standards and the applicable national, international and European regulations.

(6) The accredited body shall continue to conform with the requirements for accreditation specified in sub-article (1) of this article on a permanent basis. Failure to meet these requirements during the period of accreditation shall result in the suspension, reduction in scope or withdrawal of the accreditation.

Regulations specifying conformity assessment.

9. (1) The regulations laying down conformity assessment may specify the participation of the Accreditation Directorate in designating the bodies carrying out assessment of conformity in line with the requirements of these regulations.

(2) The regulations laying down conformity assessment may specify that the competence of the bodies responsible for assessing conformity in line with the requirements of these regulations can be presumed on the basis of accreditation certificates.