L.N. 252 of 2006

MALTA STANDARDS AUTHORITY ACT, 2000 (ACT NO. XIX OF 2000) National Accreditation Board (Malta) (Establishment) Regulations, 2006

IN exercise of the powers conferred by article 21 (i) of the Malta Standards Authority Act 2000, the Minister for Competitiveness and Communications has made the following Order:–

Citation and commencement.

1. (1) The title of these regulations is the 'National Accreditation Board (Malta) (Establishment) Regulations'.

(2) These regulations shall be deemed to have come into force on 1st October 2006.

Definitions.

2. (1) In these regulations, unless the context otherwise requires:

"accreditation" means third-party attestation by a public authority, related to a conformity assessment body, conveying formal demonstration of its competence to carry out specific conformity assessment tasks;

"National Accreditation Board (Malta)" means that board established in terms of regulation of these regulations and which hereinafter in these regulations is also referred to as the "Accreditation Board" or the "Board";

"accreditation body" is the authoritative body that performs accreditation and that is either part of government or operates under the responsibility of, and with authority derived from, government.;

"accreditation certificate" means a formal document or a set of documents, stating that accreditation has been granted for a defined scope;

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

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

"Adverse decisions" includes refusal to accept an application, refusal to proceed with an assessment, corrective action requests, changes in accreditation scope, decisions to deny, suspend or

withdraw accreditation, and any other action that impedes the attainment of accreditation.

"appeal" means a request by an applicant or accredited body for reconsideration of any adverse decision made by the accreditation body related to its desired accreditation status.

"applicant" means any body which has applied for accreditation;

"assessment" means the process undertaken by an accreditation body to assess the competence of a Conformity Assessment Body based on particular standard(s) and/or other normative documents and for a defined scope of accreditation. Assessing the competence of a Conformity Assessment Body involves assessing the competence of the entire operations of such body, including the competence of the personnel, the validity of the conformity assessment methodology and the validity of the conformity assessment results;

"assessor" means a person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a Conformity Assessment Body;

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

"certification" means third-party attestation related to products, processes, systems or persons;

"certification body" is a body that conducts certification;

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

"conformity assessment" means the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. It covers such activities such as testing, calibration, inspection and certification.

"conformity assessment body " means a body that performs conformity assessment services;

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

"expert" means a person assigned by an accreditation body to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed;

"extending accreditation" means the process of enlarging the scope of accreditation;

"Chairman of the NAB-Malta" means the person appointed in terms of Regulation 4 and shall be hereinafter in these regulations referred to as "the Chairman".

"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;

"Minister" means the Minister responsible for accreditation;

"Ministry" shall be construed accordingly.

"normative document" is a document that provides rules, guidelines or characteristics for activities or their results. The term "normative document" is a generic term that covers such documents as standards, technical specifications, codes of practice and regulations."

"reducing accreditation" means the process of cancelling accreditation for part of the scope of accreditation;

"scope of accreditation" means specific conformity assessment services for which accreditation is sought or has been granted; the specific tests, measurements or calibration for which a body is formally accredited by the National Accreditation Board (Malta) , including any qualifications such as range of measurement, test procedures and assigned measurement uncertainties;

"surveillance" means the set of activities, except reassessment, to monitor the continued fulfilment by accredited Conformity Assessment Bodies of requirements for accreditation.The term includes both surveillance on-site assessments and other surveillance activities, such as the following:

(a) enquiries from the accreditation body to the Conformity Assessment Body on aspects concerning the accreditation;

(b) reviewing the declarations of the Conformity Assessment Body with respect to what is covered by the accreditation;

(c) requests to the Conformity Assessment Body to provide documents and records (e.g. audit reports, results of internal quality control forverifying the validity of Conformity Assessment Body services, complaints records, management review records);

(d) monitoring the performance of the Conformity Assessment Body (such as results of participating in proficiency testing).

"suspending accreditation" means the process of temporarily making accreditation invalid, in full or for part of the scope of accreditation;

"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.

"witnessing" means the observation of the Conformity Assessment Body carrying out conformity assessment services within its scope of accreditation.

"withdrawing accreditation" means the process of cancelling accreditation in full.

Establishment of the National Accreditation Board (Malta).

3. (1) There shall be a Board to be known as the National Accreditation Board (Malta) to act on behalf of the Minister in all matters related to accreditation.

(2) The Board shall assume the functions of the Directorate for Accreditation established by means of L.N. 313 of 2001 listed in regulation 3 of same and, the said Directorate for Accreditation shall cease to exercise the said functions with immediate effect.

(3) In additions to the functions mentioned in the last preceding subregulation, the functions of the Board shall also include the following:

(a) to accredit medical laboratories;

(b) to accredit EMAS Verifiers;

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

(d) to collaborate with organisations of accreditation bodies, and to represent in them the Maltese interests as and when requested;

(e) to perform other assessments and approvals of competence for carrying out conformity assessment activities, including fulfilment of the requirements for conformity assessment bodies pursuant to particular regulations for conformity assessment;

(f) to publish accreditation guidelines.

4. (1) The Board shall be composed of such number of Members, being not less than two and not more than seven as the Minister may deem fit and it shall be chaired by the Chairman.

(2) The Minister shall appoint the Chairman and the members of the Board.

(3) In the performance of its functions the National Accreditation Board (Malta) shall be accountable to the Minister and the Chairman shall be accountable operationally and shall report directly to the Minister.

5. (1) Without prejudice to the functions listed in regulation 3, the functions of the Chairman shall include:

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

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

(c) to make publicly available information about the current status of the accreditations that it has granted to Conformity Assessment Bodies. The information shall include the name and address of each accredited Conformity Assessment Body and the scopes of accreditation, condensed and/or in full;

(d) to prepare an annual business plan and to monitor and manage its implementation;

(e) to consult with the National Accreditation Board (Malta) on the development of the policies related to accreditation, as necessary, and to implement such policies;

(f) to take part in the work of international bodies operating in the field of accreditation;

(g) to collaborate with the Standardization Body in order to develop and promote appropriate drafting or updating of technical standards;

(h) to collaborate with the relevant national and international entities in order to develop and promote appropriate conformity assessment procedures;

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

(j) to represent Malta in relevant national and international activities; and

(k) 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.

(2) In exercising its functions the National Accreditation Board (Malta) shall operate in line with the international standards which define the requirements for accreditation bodies. In addition in exercising its functions under these regulations, the National Accreditation Board (Malta) shall be functionally independent as regards operational matters and, technical matters within its area of competence.

Establishment of the Accreditation Committee.

6. (1) There shall be established an Accreditation Committee, the functions of which are:

(a) to provide advice of a technical nature to the Chairman and to provide assistance on general matters of policy and organisation relating to the functions and activities of the National Accreditation Board (Malta);

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

(c) to make recommendations on the granting and withdrawal of accreditations.

(2) The Accreditation Committee shall be composed of a balanced representation of interested parties as identified by the Chairman with no single party predominating.

(3) The manner of procedure of the appointment of the members and their terms of office shall be determined by the Minister after consulting the Chairman, according to the relevant national regulations and international and European standards and guides of the European and international organisation of accreditation bodies.

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

(5) Administrative matters relating to the Accreditation Committee shall be conducted by the Chairman. The Chairman, or his designate, shall act as the Secretary of the Board.

Appeals.

7. (1) Any person who feels aggrieved by a decision of the Accreditation Committee may appeal such a decision to the national Accreditation Board (Malta) within thirty days from the date when the decision was notified to him or was made public.

(2) The National Accreditation Board (Malta) shall assess the validity of each appeal made from a decision of the Accreditation Committee.

(3) The National Accreditation Board (Malta) shall appoint, as and when necessary, a suitably competent, impartial and independent person, or group of persons depending on the nature of the appeal to report on the merits of the appeal and to make the appropriate recommendations to the National Accreditation Board (Malta)

Staff.

8. The National Accreditation Board (Malta) shall in the performance of its functions use the services of such staff, contract employees or contractors as may be assigned to it by or with the concurrence of the Minister.

Technical Committees.

9. (1) The Chairman of the Board may, with the agreement of the Board, establish technical committees in order to provide scientific and technical advice in their respective areas of competence.

(2) In agreement with the Board, the Chairman shall appoint a competent person to chair and co-ordinate each technical committee.

(3) The Chairman may, with the agreement of the Accreditation Board, disband a technical committee and remove, replace or suspend any member of such committee if such action is considered to be necessary in order to maintain its impartiality, transparency, independence and competence.

Accreditation procedure.

10. (1) Assessments for the accreditation of any body shall be conducted in accordance with the applicable national, international and European regulations, standards and guides.

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

(3) The Board shall conclude a contract with assessors as necessary and as required by the accreditation process.

(4) The Board shall grant a certificate of accreditation to any body which fulfils the requirements of the applicable national, international and European normative documents.

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

(6) All costs associated with assessment of competence, accreditation and surveillance shall be borne by the Conformity Assessment Body.

Rules specifying conformity assessment.

11. (1) Rules regarding conformity assessment may specify the participation of the National Accreditation Board (Malta) in designating the bodies carrying out assessment of conformity in line with the requirements of these regulations.

(2) Such rules may also 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.

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