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CONFORMITY ASSESSMENT

The Lithuanian system of accreditation

The present document has been submitted by the Lithuanian National Accreditation Bureau and is presented for information to delegations. It is reproduced in the form in which it was received by the secretariat.

THE LITHUANIAN SYSTEM OF ACCREDITATION

1. The Lithuanian system of accreditation forms part of the Lithuanian system for conformity assessment. This system encompasses government institutions which issue statutory technical regulations identifying products that are subject to mandatory conformity assessment procedures, the Lithuanian National Accreditation Bureau, product certification agencies, quality systems, environmental management systems, personnel management systems and inspection bodies.
2. The legislative basis for the Lithuanian conformity assessment system is the Conformity Assessment Act, which lists the participants in the Lithuanian conformity system and specifies their principal functions and obligations, items subject to conformity assessment and aspects of conformity assessment in the regulated and unregulated fields, as well as other issues.
3. The standards underpinning the Lithuanian conformity assessment system are: international standards (ISO) transposed into Lithuanian national standards (LST ISO), ISO/IEC guides, European standards (EN 45000 series) transposed into Lithuanian national standards (LST EN), documents of the European Accreditation (EA) organization, documents of the International Laboratory Accreditation Cooperation (ILAC) organization, documents of the International Accreditation Forum (IAF) and documents of the Lithuanian National Accreditation Bureau (AD).
4. The functions of a Lithuanian national accreditation bureau are performed by the Lithuanian National Accreditation Bureau, which under the Conformity Assessment Act is authorized to accredit testing and calibration laboratories, product certification bodies, quality systems, environmental management systems, personnel management systems and inspection bodies. As a financially independent organization statutorily authorized to adopt, suspend and cancel decisions relating to accreditation in an independent manner, the Bureau was established on 1 January 1988 under the auspices of the Ministry of Public Administration Reforms and Local Authorities.
5. Until 1 January 1998 the accreditation bureau operated under the Lithuanian Standardization Department. Standardization and accreditation functions were separated in pursuance of a recommendation by the European Commission aimed at ensuring the impartiality and independence of the accreditation body.
6. From 1 January 2001 the National Accreditation Bureau has been operating as a financially independent organization under the Ministry of the Environment with the same independent status in relation to the adoption of all decisions on accreditation.
7. The accreditation bureau has a permanent staff of 11 specialists. Over 70 qualified specialists from research institutes, universities, testing laboratories and other organizations who possess the appropriate skills participate in the work of groups of experts which are contracted to assess conformity assessment bodies.

8. The permanent staff of the bureau, who have the required technical knowledge in the relevant areas and have been trained in accreditation and quality issues by specialists from the Netherlands, Germany, Sweden and Norway, participate in the work of the groups as senior experts.
9. The Lithuanian system of accreditation also includes five consultative sectoral committees - on metrology; construction elements and materials; mechanical, electronic and information technology; chemical analysis; and microbiological analysis. The main functions of these committees are to provide the bureau with advice and proposals on matters of accreditation in special technical fields, on the drafting of documents on accreditation, on the selection of technical experts and the relevant requirements, on the organization of interlaboratory comparisons, etc.
10. The Lithuanian National Accreditation Bureau reports to the Accreditation Board, which is composed of 15 representatives of various parties such as State institutions, associations of industrialists, businessmen, conformity assessment bodies, etc., with an interest in accreditation-related activities. The membership of the Board is organized in such a way that none of the participating groups is dominant. The Director of the Bureau is not a member of the Board: she participates in Board meetings as an observer, and supplies all requisite information.
11. The principal functions of the Board are to oversee the accreditation policy pursued by the Accreditation Bureau, to ensure that it is fully in line with the interests of those with a stake in accreditation; to participate in shaping policy and strategic goals relating to accreditation; and to consider matters related to the drafting of legislation and other documents in the field of accreditation.
12. One of its tasks is to set up a commission to handle appeals relating to the activities of the Lithuanian National Accreditation Bureau and conformity assessment bodies accredited by it.
13. The activities of the Lithuanian National Accreditation Bureau are guided by LST EN 45003, LST EN 45010 and ISO/IEC TR 17010, which set out requirements in respect of laboratory accreditation bodies, certification bodies and inspection bodies.
14. In complying with the criteria set out in these standards, the Bureau has created an internal quality system. The system is documented in the form of quality guidance and corresponding procedures. Special attention is paid to the continuous improvement of accreditation services, using continuous feedback from accredited conformity assessment bodies, analysing their proposals, and also the proposals made by the technical experts and the permanent staff of the Bureau during the conduct of analyses, and taking the necessary corrective action. Internal audits of the quality system constitute a valuable input for improving the work of the Bureau.
15. The principal aim of the Lithuanian accreditation system is to secure international recognition, in the first place in the countries of the European Economic Community, so as to enable technical barriers to trade to be removed and facilitate exports by Lithuanian manufacturers to the countries of the European Union and the European Free Trade Association.

16. In the process of Lithuanian integration into the European Union in pursuance of the association agreement, special emphasis in the section on “free movement of goods” was placed on the system of conformity assessment, its infrastructure, operating principles harmonized with the requirements of the European Union’s legislation and regulations, and also the international recognition of the system.

17. Recognition of the activities of accredited bodies in conformity assessment in the unregulated sphere (where there is no provision for mandatory conformity assessment) in Western Europe is achieved through signature by national accreditation bodies of multilateral recognition agreements prepared by the European Accreditation (EA) organization.

18. A prerequisite for signing these agreements is that all participants in the conformity system - the national accreditation body and the conformity assessment bodies accredited by it - should fully conform with the requirements set out in international and European standards (which specify criteria applying to such bodies), and with the requirements appearing in EA documents. This is assessed by international groups of EA experts.

19. A very important factor in securing international recognition of accreditation systems is the traceability of measurements, that is, their linkage with national and international standard units of physical magnitudes by means of calibration throughout the unbroken chain of transfer of the unit of physical magnitude, with measurement uncertainties specified.

20. The primary standards should be linked with the standards of the corresponding national metrological institutions which participate in interlaboratory comparisons organized by the European Metrology Cooperation organization (EUROMET) and in the activities of the Bureau International des Poids et Mesures (BIPM) (directly or through regional groups).

21. In February 2001, as the Lithuanian National Accreditation Bureau worked towards signing the multilateral recognition agreements in respect of testing and calibration laboratories and product certification bodies, its activities were assessed by an EA group of experts from the United Kingdom, France, Finland and Norway. The group of experts evaluated how the Bureau meets the requirements of European standards EN 45003 and EN 45010, which set out requirements in relation to accreditation bodies - i.e., it appraised the operation of the internal quality system, as well as a number of other aspects of its activities, and observed how the Accreditation Bureau’s groups of experts assessed laboratories and product certification bodies.

22. The findings of the evaluation of the Accreditation Bureau were positive: the group of experts recommended that the Lithuanian National Accreditation Bureau should sign the EA multilateral agreements after a few areas of non-compliance had been eliminated.

23. Under established EA procedure, decisions on signature by national accreditation bodies are taken by the EA MLA Committee on multilateral agreements.

24. At its session held in Brussels on 15 and 16 October 2001, this Committee adopted a favourable decision on signature by the Lithuanian National Accreditation Bureau of the EA multilateral agreements in the fields of accreditation of testing and calibration laboratories and product certification bodies. The agreement was officially signed during the EA General Assembly, held in Budapest on 21 and 22 November 2001. This means that the activities of the

Lithuanian National Accreditation Bureau are now on a par with the activities of the accreditation bodies in Germany, France, Sweden and other Western European countries which are signatories of the agreements; the activities of conformity assessment bodies accredited by the accreditation bureau are recognized in the countries of the European Union.

25. Lithuania has become the third of the countries which have signed association agreements with the European Union (after the Czech Republic and Slovakia) to accede to the EA multilateral agreements.

26. Recognition of the activities of the Lithuanian National Accreditation Bureau and the conformity assessment bodies accredited by it in the European Union was a favourable factor in the signature of the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (PECA).

27. Following settlement of the question of the free movement of goods between the EU associated States and the member countries of the European Union in the regulated sphere composed of products subject to regulation under the so-called New Approach directives (only essential requirements - basically related to safety - are stipulated for these products), the EU associated States have been granted an opportunity to sign protocols on conformity assessment and acceptance of industrial products with the European Union.

28. This will enable producers in countries which have signed such protocols and export their products to the countries of the European Union to supply goods to Western markets on terms which are identical to those enjoyed by producers in those countries. In other words, products which have undergone conformity assessment procedures that have confirmed their compliance with the New Approach directives, and are marked "CE", must enjoy free access to the markets of the European Union countries.

29. The signing of such protocols involves the fulfilment of a number of criteria: adoption of the appropriate technical regulations transposing the provisions of the New Approach directives; operation of an accreditation system which corresponds to the principles accepted in the European Union; and creation of conditions for the application of conformity assessment procedures by the competent designated (notified) conformity assessment bodies. Competence is recognized by means of their accreditation or their corresponding assessment by national accreditation bodies.

30. Lithuania signed a protocol of this type in June 2002. The protocol covers products in six groups which are subject to regulation under the corresponding directives: machinery (directive on safety of machinery), lifts, personal protective equipment, simple pressure vessels, products subject to regulation under the directive on electromagnetic compatibility and products subject to regulation under the directive on low-voltage equipment.

31. The corresponding Lithuanian legislation on the procedure for designation (notification) of conformity assessment bodies provides for the designation of conformity assessment bodies which have already been accredited (and are additionally assessed in terms of the requirements of the appropriate directives). The designation is carried out by the ministries responsible for the introduction of the corresponding technical regulations.

32. The fact that the assessment of the competence of designated (notified) conformity assessment bodies will be carried out by the accreditation body which is the signatory of the EA multilateral recognition agreements offered an opportunity to sign the protocol on more favourable terms for Lithuania, i.e. it rendered unnecessary any assessment of the competence of the designated (notified) conformity assessment bodies by experts from the European Commission.

33. At present the National Accreditation Bureau is engaged in evaluating the competence of a number of conformity assessment bodies.

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