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TRAINING ACADEMY

Beginner 2

Course 4.2

STANDARDISATION TRAINING ACADEMY

Topic:

THE ROLE OF STANDARDISATION IN QUALITY INFRASTRUCTURE

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Module Objectives

After completing this module, you should be able to:

1. understand that the World Trade Organisation's Agreement on Technical Barriers to Trade (WTO/TBT) was established to ensure that technical regulations, standards, and technical specifications do not create unnecessary obstacles to international trade;
2. understand that measurement results can be understood by all the parties involved only if the measurement units in which they are expressed are also standardised;
3. understand that accreditation is generally based on regional and international standards and technical specifications/guidelines relevant to the specific laboratory;
4. understand that National Quality Infrastructure (NQI) must have the resources to engage in standards development at the national, regional, and international levels; and
5. understand that although the use of standards as a basis for technical regulations may be seen as highly efficient, this may attract some serious criticism for mixing two separate activities that should operate completely separately from each other.

Key Terms

ISO 15189:2022, ISO/IEC Guide 68:2002, ISO/IEC 17000:2020, ISO/IEC 17007:2009, ISO/IEC 17011:2017, ISO/IEC 17020:2012, ISO/IEC 17021-1:2015, ISO/IEC 17024:2012, ISO/IEC 17025:2017, ISO/IEC TR 17026:2015, ISO/IEC 17029:2019, ISO/IEC 17030:2021, ISO 17034:2016, ISO/IEC 17040:2005, ISO/IEC 17043:2010, ISO/IEC 17050-1:2004, ISO/IEC 17050-2:2004, ISO/IEC 17060:2022, ISO/IEC 17065:2012, ISO/IEC 17067:2013

About The Author

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Biljana Tošić is a Teaching Assistant and a Research Assistant at the Faculty of Organisational Sciences, University of Belgrade. She earned a B.Sc. and M.Sc. in Quality Management and Standardisation and another M.Sc. in Human Resources Management at the same Faculty. She is currently a Ph.D. Candidate, working on a doctoral dissertation titled ''The significance of the expertise in standardisation for the internationalisation of SMEs''. To date, she has been engaged in teaching several courses at the Faculty: Fundamentals of Quality, Standardisation 1, Metrology with the Fundamentals of Engineering, Normative Regulation of Quality, and Accreditation and Certification. She has been a member of the organisational board of the World Standards Cooperation Academic Day 2019 and the International Cooperation for Education about Standardisation (ICES) WorkShop 2019. She has been a member of the technical board of the International Symposium SymOrg 2020 titled ''Business and Artificial Intelligence'' and the SymOrg 2022 titled ''Sustainable Business Management and Digital Transformation: Challenges and Opportunities in the post-COVID Era''. She has been engaged in project III 47003 ''Infrastructure for technology-enhanced learning in Serbia'', supported by the Ministry of Education, Science, and Technological Development of the Republic of Serbia (2017-2020). She has been Editor in Chief of the Quality Media Station, the first media centre for quality established within the TEMPUS project titled ''Enhancement of Quality Infrastructure in Western Balkan Countries (EQIWBC)'' (2015-2017). She is currently a member of the National Mirror Committee Conformity Assessment & Quality Management KS CASCO at the Institute for Standardisation of Serbia (National Technical Committee related to ISO/CASCO, ISO/TC 176, ISO/TC 176/SC 1, ISO/TC 176/SC 2, ISO/TC 176/SC 3, ISO/TC 283, CEN/SS F20, CEN/TC 279, CEN/TC 379, CEN/TC 381, CEN/TC 389, CEN/CLC/JTC 1, and CEN/CLC/JTC 4).

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1 STANDARDISATION

The World Trade Organisation's Agreement on Technical Barriers to Trade (WTO/TBT) was established to ensure that technical regulations, standards and specifications required to assess conformity with them, do not create unnecessary obstacles to international trade. [1] Successive reviews of the WTO/TBT Agreement have noted the usefulness of ISO/IEC conformity assessment standards and guides in harmonising conformity assessment activities and as benchmarks for the technical competence of conformity assessment bodies so that adequate credibility and confidence in the obtained results may be achieved. [2] The use of ISO/IEC conformity assessment standards helps to overcome trade barriers and promotes the international recognition of conformity assessment, market surveillance, and related activities, as well as, the worldwide acceptance of the results of these activities. [3]

QI Diagnostics and Reforms Toolkit (Module 3), jointly developed by the World Bank Group and the National Metrology Institute of Germany, explores in detail both standards and standardisation as the components of QI, and may be accessed freely via the following link:

- https://thedocs.worldbank.org/en/doc/480511553265329688-0090022019/original/Part2.Module3Standards.pdf

1.1 Standardisation & Metrology

The need for measurement standards aimed at assisting trade and commerce within and between countries became apparent during the Industrial Revolution. [4] These needs were mostly based on military requirements, especially those of large maritime powers, such as Great Britain and the United States (US). [5] The need of ensuring that measurements were standardised led to the early stages of a metrology system with measurement standards, laboratory calibrations, and comparisons. [6] Over time, as measurements became standardised within countries, the need arose to standardise measurements between countries. [7] During this time, there was a significant expansion of discoveries in quantum mechanics and molecular, atomic, nuclear, and particle physics and these laid the foundation for the International System of Units (SI). [8]

[1] ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf, p. 3.
[2] Ibid.
[3] Ibid.
[4] Bucher, J., et al. (2004). The Metrology Handbook. The Measurement Quality Division, ASQ Quality Press., p. 7.
[5] Ibid.
[6] Ibid.
[7] Ibid.
[8] Ibid.

Nowadays, it is well known that SI units have been accepted internationally and are the basis of all modern measurements conducted by governments, academia, and industries. [9] This means that an item that is calibrated at one lab should be able to make a like measurement anywhere within that measurement system. [10] This is because measurement systems that use standards traceable to a national or international standard will be a basis for all measurements within that system. [11] Measurement results can be understood by all the parties involved only if the units in which they are expressed are standardised, meaning that a standardised measurement unit ensures that everybody concerned with a measurement result understands it the same way. [12]

1.2 Standardisation & Accreditation

Accreditation is generally based on regional or international standards, e.g. **ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories** [13], and technical specifications and guidelines that are relevant to the specific laboratory. [14] Generally speaking, the ISO/IEC 17000 series has become imperative, although national standards (not harmonised with the ISO/IEC 17000 series) are still used in some countries. [15]

Other international systems related to the QI that require accreditation are: [16]

- *Good Manufacturing Practices (GMP)*, defined by the World Health Organisation (WHO) and used by pharmaceutical regulators or the pharmaceutical industry; and
- *Principles of Good Laboratory Practice (GLP)*, defined by the Organisation for Economic Co-operation and Development (OECD), applicable to nonclinical studies conducted to assess the safety or efficacy of chemicals.

International Standards which are developed by the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) and are dealing with accreditation are given in Table 1.

[9] Ibid., pp. 34.
[10] Ibid., pp. 71.
[11] Ibid., pp. 71.
[12] Ibid., pp. 73.
[13] ISO/IEC. (2017). General requirements for the competence of testing and calibration laboratories.
[14] Howarth, P., Redgrave, F. (2008). Metrology – In Short (EURAMET, 3rd ed.), Accessed on 20.02.2025. Retrieved from: https://www.euramet.org/publications-media-centre/documents/metrology-in-short/?L=0, pp. 34.
[15] Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf, pp. 93.
[16] Ibid., pp. 94.

Table 1. Standards used for accreditation of different types of Conformity Assessment Bodies (CABs) [17]

Type of CAB	Standard used for accreditation of the CAB	Requirements and standards for Clients of the CAB
Calibration laboratories	ISO/IEC 17025:2017	Various measurement- and instrument-specific requirements
Testing laboratories (general)	ISO/IEC 17025:2017	Various measurement- and product-specific requirements
Proficiency testing providers	ISO/IEC 17043:2010	Providers of proficiency testing schemes
Producers of Certified Reference Materials (CRMs)	ISO 17034:2016	The production and assignment of property values of CRMs
Medical laboratories	ISO 15189:2022	Various diagnostic tests
Inspection bodies	ISO/IEC 17020:2012	Various product and regulatory requirements
Certification bodies:		
a) QMS certification	ISO/IEC 17021-1:2015	ISO 9001:2015
b) EMS certification	ISO/IEC 17021-1:2015	ISO 14001:2015
c) FSMS certification	ISO/IEC 17021-1:2015	ISO 22000:2005, HACCP
d) Product certification	ISO/IEC 17065:2012	Various product-specific requirements
e) Service and process certification	ISO/IEC 17065:2012	Various service- and process-specific requirements
f) Certification of persons	ISO/IEC 17024:2012	Various skill-specific requirements

[17] Ibid., pp. 95.

g) Validation and verification	ISO/IEC 17029:2019	Various validation and verification requirements

* Note: As these are continuously updated, the latest versions should be obtained from the ISO.

1.3 Standardisation & Conformity Assessment

National Quality Infrastructure (NQI) is responsible for providing the resources and capabilities to engage in standards development at the national, regional, and international levels. [18] When it comes to conformity assessment, two aspects of standardisation shall be considered. [19] First, ''the availability of national, regional and international standards that may be used by suppliers, purchasers, conformity assessment bodies, and regulators for setting the specified requirements for an object and assessing its conformity with them'' and, second, ''the availability of standards which set out requirements for best practice of conformity assessment and the bodies which carry it out''. [20] Accordingly, these standards aim to ensure that ''there are consistent and internationally harmonised practices'' amongst conformity assessment bodies and different bodies with which they work, such as accreditation bodies. [21] Also, conformity assessment activities must be as consistent as possible internationally, as they play such a significant role in the global trade of both goods and services. [22]

[18] ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf, pp. 17.
[19] Ibid.
[20] Ibid.
[21] Ibid.
[22] Ibid.

1.4 Standardisation & Market Surveillance

Compared to more developed countries, developing countries endure serious obstacles when establishing or maintaining a regulatory market surveillance authority. [23] The necessity to protect consumers from unsafe products ''is just as pressing and valid'' as in developed countries, but the lack of resources and capabilities required to do so is exacerbated. [24] To overcome these constraints, some countries have established a market surveillance authority within an already established conformity assessment or national standards body. [25] Although the use of standards as a basis for technical regulations may be seen as highly efficient, this may attract serious criticism for mixing two separate activities that should operate separately from each other. [26]

Although there are some similarities between standards and technical regulations, there are also some major differences. [27] While it is a good practice to base the requirements of technical regulations on standards, it is significant to limit the requirements that should be regulated. [28] Technical regulations are ''used by the state to regulate and control products that may be deleterious to the health and safety of the population, … and the environment''. [29] Standards are developed and published by public or private standards bodies and based on ''internationally recognised principles, such as transparency, openness, and consensus''. [30] Standards are voluntary instruments and it is up to the users of standards to decide if the benefits of using standards justify the costs of implementing them. [31] Non-conformance (or non-compliance) with standards ''may limit market opportunities and result in relinquishing a lucrative contract, or impose civil-law consequences for non-compliance'', but non-compliance with standards is not, by itself, an offence, punishable by the state. [32] Technical regulations must be complied with by all parties, regardless of how big or small, foreign or local, and regardless of the costs, because non-compliance with technical regulations is punishable by the state. [33]

The standards and other documents developed by the ISO/CASCO that should create a basis for market surveillance and related activities are given in Table 2.

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[23] ISO. (2012). A Guide to Good Practice: Principles and Practices in Product Regulation and Market Surveillance. Accessed on 20.02.2025. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_guide.pdf, pp. 14.
[24] Ibid.
[25] Ibid., pp. 15
[26] Ibid., pp. 15.
[27] Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf, pp. 143.
[28] ISO. (2012). A Guide to Good Practice: Principles and Practices in Product Regulation and Market Surveillance. Accessed on 20.02.2025. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_guide.pdf, pp. 17.
[29] Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf, pp. 143.
[30] Ibid.
[31] Ibid., pp. 144.
[32] Ibid., pp. 144.
[33] Ibid., pp. 144.

Table 2. Standards and other documents used as a basis for market surveillance and related activities [34]

Reference	Title
ISO 15189:2022	Medical laboratories — Requirements for quality and competence
ISO/IEC Guide 68:2002	Arrangements for the recognition and acceptance of conformity assessment results
ISO/IEC 17000:2020	Conformity assessment — Vocabulary and general principles
ISO/IEC 17007:2009	Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment
ISO/IEC 17011:2017	Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17020:2012	Conformity assessment — Requirements for the operation of various types of bodies performing inspection
ISO/IEC 17021-1:2015	Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements
ISO/IEC 17024:2012	Conformity assessment — General requirements for bodies operating certification of persons
ISO/IEC 17025:2017	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17029:2019	Conformity assessment — General principles and requirements for validation and verification bodies
ISO/IEC TR 17026:2015	Conformity assessment — Example of a certification scheme for tangible products
ISO/IEC 17030:2021	Conformity assessment — General requirements for third-party marks of conformity
ISO 17034:2016	General requirements for the competence of reference material producers

[34] ISO. (2012). A Guide to Good Practice: Principles and Practices in Product Regulation and Market Surveillance. Accessed on 20.02.2025. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_guide.pdf, pp. 13.

ISO/IEC 17040:2005	Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies
ISO/IEC 17043:2010	Conformity assessment — General requirements for proficiency testing
ISO/IEC 17050-1:2004	Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements
ISO/IEC 17050-2:2004	Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation
ISO/IEC 17060:2022	Conformity assessment — Code of good practice
ISO/IEC 17065:2012	Conformity assessment — Requirements for bodies certifying products, processes and services
ISO/IEC 17067:2013	Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

* Note: As these are continuously updated, the latest versions should be obtained from the ISO.

SUMMARY

The World Trade Organisation's Agreement on Technical Barriers to Trade (WTO/TBT) was established to ensure that technical regulations, standards and specifications required to assess conformity with them, do not create unnecessary obstacles to international trade. [35] Successive reviews of the WTO/TBT Agreement have noted the usefulness of ISO/IEC conformity assessment standards and guides in harmonising conformity assessment activities and as benchmarks for the technical competence of conformity assessment bodies so that adequate credibility and confidence in the obtained results may be achieved. [36] The use of ISO/IEC conformity assessment standards helps to overcome trade barriers and promotes the international recognition of conformity assessment, market surveillance, and related activities, as well as, the worldwide acceptance of the results of these activities. [37]

[35] ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf, p. 3.
[36] Ibid.
[37] Ibid.

GLOSSARY

ISO 15189:2022

Medical laboratories — Requirements for quality and competence

ISO/IEC Guide 68:2002

Arrangements for the recognition and acceptance of conformity assessment results

ISO/IEC 17000:2020

Conformity assessment — Vocabulary and general principles

ISO/IEC 17007:2009

Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

ISO/IEC 17011:2017

Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17020:2012

Conformity assessment — Requirements for the operation of various types of bodies performing inspection

ISO/IEC 17021-1:2015

Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

ISO/IEC 17024:2012

Conformity assessment — General requirements for bodies operating certification of persons

ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

ISO/IEC TR 17026:2015

Conformity assessment — Example of a certification scheme for tangible products

ISO/IEC 17029:2019

Conformity assessment — General principles and requirements for validation and verification bodies

ISO/IEC 17030:2021

Conformity assessment — General requirements for third-party marks of conformity

ISO 17034:2016

General requirements for the competence of reference material producers

ISO/IEC 17040:2005

Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies

ISO/IEC 17043:2010

Conformity assessment — General requirements for proficiency testing

ISO/IEC 17050-1:2004

Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements

ISO/IEC 17050-2:2004

Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation

ISO/IEC 17060:2022

Conformity assessment — Code of good practice

ISO/IEC 17065:2012

Conformity assessment — Requirements for bodies certifying products, processes and services

ISO/IEC 17067:2013

Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

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ISO. (2012). A Guide to Good Practice: Principles and Practices in Product Regulation and Market Surveillance. Accessed on 20.02.2025. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_guide.pdf.

ISO/IEC. (2017). General requirements for the competence of testing and calibration laboratories.

ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf.

Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf.

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