

## Beginner 2

Course 4.3

### STANDARDISATION TRAINING ACADEMY

Topic:

# THE ROLE OF ACCREDITATION IN QUALITY INFRASTRUCTURE

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#### **Module Objectives**

After completing this module, you should be able to:

- understand that two key international organisations for accreditation are the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) and both have the aim of facilitating trade;
- 2. understand that Regional Accreditation Bodies (RABs) have been established in some regions as the ones that provide accreditation services at the regional level;
- 3. understand that the European co-operation for Accreditation (EA) has been
- 4. officially appointed by the EC as the European organisation for the accreditation;
- 5. understand that member states may establish National Accreditation Focal Points (NAFPs) to act as the liaison mechanisms between the RAB and entities wishing to be accredited; and
- 6. understand that National Accreditation Bodies (NABs) offer accreditation services mostly within their countries, although some operate outside the national borders, as well.

#### **Key Terms**

accreditation, European co-operation for Accreditation (EA), International Accreditation Forum (IAF), International Laboratory Accreditation Cooperation (ILAC), Regional Accreditation Bodies (RABs), National Accreditation Focal Points (NAFPs)







#### **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 ACCREDITATION

According to the ISO 17000:2020, Conformity Assessment – Vocabulary and general principles, accreditation is defined as "a third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality, and consistent operation in performing specific conformity assessment activities". <sup>1</sup> Additionally, attestation is defined as "the issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated". <sup>2</sup> Accordingly, "accreditation as such is applicable in the case of laboratories, inspection bodies, certification bodies, validation and verification bodies, and bodies that certify personnel". <sup>3</sup> Additionally, the use of the ISO/IEC 17000 standards series (Conformity Assessment) by the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) has recently become imperative, but sometimes national standards (not harmonised with the ISO/IEC 17000 standards series) are also used in some countries.

At the international level, two key international organisations for accreditation are **the International Laboratory Accreditation Cooperation (ILAC)** and **the International Accreditation Forum (IAF)** both having the aim of facilitating international trade through enhanced confidence. <sup>5</sup> The ILAC was established in 1977 to promote good practice solutions within testing and calibration and to promote the international acceptance of the activities of the laboratories conducting these activities. <sup>6</sup> The IAF was established in 1993 with similar aims related to quality management systems certification (e.g. mostly conforming to ISO 9001). <sup>7</sup> Since 2001, the ILAC and the IAF have been cooperating to achieve "improved alignment of their work programmes, as this contributes to the effectiveness and efficiency of both organisations, their mutual members and delivery of value to their stakeholders". <sup>8</sup> These two organisations have established and managed MRAs among their members, whereby each member, by signing the MRA, accepts the inspection and test reports and certificates issued by another party in the system as being equal to the one issued by itself. <sup>9</sup>

<sup>&</sup>lt;sup>9</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: <a href="https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf">https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf</a>, pp. 101.





<sup>&</sup>lt;sup>1</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: <a href="https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf">https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf</a>, pp. 93.

<sup>&</sup>lt;sup>4</sup> Ibid., pp. 93.

<sup>&</sup>lt;sup>5</sup> ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\_building-trust.pdf, pp. 25.

<sup>&</sup>lt;sup>6</sup> Ibid., pp. 25.

<sup>&</sup>lt;sup>7</sup> Ibid., pp. 25.

<sup>&</sup>lt;sup>8</sup> ILAC/IAF. (2023). ILAC/IAF Partnership. Accessed on January 23, 2023. Retrieved from: <a href="https://ilac.org/about-ilac/partnerships/international-partners/iaf/">https://ilac.org/about-ilac/partnerships/international-partners/iaf/</a>



To learn more about the ILAC, please visit the following link:

https://ilac.org/

To learn more about the IAF, please visit the following link:

ttps://iaf.nu/en/home/

At the regional level, **Regional Accreditation Bodies (RABs)** are the ones that provide accreditation services to smaller countries in a region established by a trade agreement – have been established in some regions and have been paid special attention through ILAC and the IAF, such as Southern African Development Community Accreditation Services (SADCAS). <sup>10</sup> These are usually some non-profit commercial entities and not membership organisations, but their governance may also comprise the representatives of the region (e.g. they may be funded by the member states at the beginning or at least until they become self-sufficient). <sup>11</sup> A country without **a National Accreditation Body (NAB)** may sign a formal agreement with a RAB to act as the de facto or the de jure NAB. <sup>12</sup>

At the European level, **the European co-operation for Accreditation (EA)** has been officially appointed by the European Commission (EC) as the European organisation for accreditation. <sup>13</sup> The establishment of the EA follows the adoption of Regulation (EC) 765/2008 by the European Parliament and the European Council which establishes the legal framework for accreditation in the EU and sets the requirements for accreditation.

To learn more about the EA, please visit the following link:

https://european-accreditation.org/

At the national level, member states may establish **National Accreditation Focal Points (NAFPs)** to be liaison mechanisms between the RAB and entities wishing to be accredited. <sup>15</sup> NAFPs may be established within a

<sup>&</sup>lt;sup>15</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: <a href="https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf">https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf</a>, pp. 104.





<sup>&</sup>lt;sup>10</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>11</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>12</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>13</sup> EA. (2022). Relations with the European Commission (EC). Accessed on October 27, 2022. Retrieved from: <a href="https://european-accreditation.org/about-ea/relations-with-european-commission/#european-accreditation-infrastructure">https://european-accreditation.org/about-ea/relations-with-european-commission/#european-accreditation-infrastructure</a>

<sup>&</sup>lt;sup>14</sup> Ibid.





ministry or the national standards body (if there is no potential conflict of interest). <sup>16</sup> The role of NAFPs as liaison mechanisms diminishes given that most organisations aiming to be accredited communicate directly with RABs. <sup>17</sup>

NABs offer accreditation services mostly within their countries, although some operate outside the national borders, as well. <sup>18</sup> At the European level, as of 2010, the EU required all member states to ensure that a single NAB was established (e.g. Germany had to merge almost 20 accreditation bodies into a single NAB). <sup>19</sup> Accordingly, the NAB of one member state must sign an agreement stating that it will not do business within the territory of the NAB of another member state (considering that both are internationally recognised). <sup>20</sup> As most developing countries still do not have the resources and capabilities to establish a single NAB, one of the major decisions for a developing country involves the way in which the conformity assessment activities (and the accreditation requirements) are to be carried out. <sup>21</sup> The use of a combination of domestic and multinational conformity assessment bodies, supported by some regional structures, may be the most reasonable solution, although solutions (to countries' needs) must be tailored to suit these circumstances. <sup>22</sup>

If a NAB or a RAB is a signatory to the relevant ILAC or IAF MRA, the output of the accredited conformity assessment service provider is more likely to be accepted across borders. <sup>23</sup> Contrarily, private-sector certification schemes are constantly being developed although they are based on the same principles as the ISO/IEC 17000 international standards series (e.g. ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17025, or ISO/IEC 17065). <sup>24</sup> Some examples are AS 9100, IATF 16949, GLOBAL G.A.P., SA 8000, and BRC certification schemes.

QI Diagnostics and Reforms Toolkit (Module 5), jointly developed by the World Bank Group and the National Metrology Institute of Germany, explores in detail the significance and applicability of accreditation, especially in countries dependent on global trade, due to its significance for the services of the QI, and may be accessed freely via the following link:

https://thedocs.worldbank.org/en/doc/200921553265346808-0090022019/original/Part2.Module5Accreditation.pdf

<sup>&</sup>lt;sup>25</sup> Ibid., pp. 105.





<sup>&</sup>lt;sup>16</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>17</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>18</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>19</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>20</sup> Ibid., pp. 105.

<sup>&</sup>lt;sup>21</sup> ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: <a href="https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco">https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco</a> building-trust.pdf, pp. 25.

<sup>&</sup>lt;sup>22</sup> Ibid., pp. 25.

<sup>&</sup>lt;sup>23</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: <a href="https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf">https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf</a>, pp. 105.

<sup>&</sup>lt;sup>24</sup> Ibid., pp. 105.



#### **SUMMARY**

According to the ISO 17000:2020, Conformity Assessment - Vocabulary and general principles, accreditation is defined as "a third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality, and consistent operation in performing specific conformity assessment activities". <sup>26</sup> Additionally, **attestation** is defined as "the issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated". 27 Accordingly, "accreditation as such is applicable in the case of laboratories, inspection bodies, certification bodies, validation and verification bodies, and bodies that certify personnel". 28 Additionally, the use of the ISO/IEC 17000 standards series (Conformity Assessment) by the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) has recently become imperative, but sometimes national standards (not harmonised with the ISO/IEC 17000 standards series) are also used in some countries. <sup>29</sup> At the international level, two key international organisations for accreditation are the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) both having the aim of facilitating international trade through enhanced confidence. 30 At the regional level, Regional Accreditation Bodies (RABs) are the ones that provide accreditation services to smaller countries in a region established by a trade agreement - have been established in some regions and have been paid special attention through ILAC and the IAF, such as Southern African Development Community Accreditation Services (SADCAS). <sup>31</sup> At the national level, member states may establish National Accreditation Focal Points (NAFPs) to be liaison mechanisms between the RAB and entities wishing to be accredited. 32 NAFPs may be established within a ministry or the national standards body (if there is no potential conflict of interest). 33 As most developing countries still do not have the resources and capabilities to establish a single NAB, one of the major decisions for a developing country involves the way in which the conformity assessment activities (and the accreditation requirements) are to be carried out. <sup>34</sup> The use of a combination of domestic and multinational conformity assessment bodies, supported by some regional structures, may be the most reasonable solution, although solutions (to countries' needs) must be tailored to suit these circumstances. 35

<sup>&</sup>lt;sup>35</sup> Ibid., pp. 25.





<sup>&</sup>lt;sup>26</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>&</sup>lt;sup>27</sup> Ibid

<sup>&</sup>lt;sup>28</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: <a href="https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf">https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf</a>, pp. 93.

<sup>&</sup>lt;sup>29</sup> Ibid., pp. 93

<sup>&</sup>lt;sup>30</sup> ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: <a href="https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\_building-trust.pdf">https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\_building-trust.pdf</a>, pp. 25.

<sup>&</sup>lt;sup>31</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: <a href="https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf">https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf</a>, pp. 104.

<sup>&</sup>lt;sup>32</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>33</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>34</sup> ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: <a href="https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\_building-trust.pdf">https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\_building-trust.pdf</a>, pp. 25.

#### **GLOSSARY**

#### accreditation

"a third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality, and consistent operation in performing specific conformity assessment activities" <sup>36</sup>

#### **European co-operation for Accreditation (EA)**

European organisation for accreditation has been officially appointed by the EC as the European organisation for accreditation <sup>37</sup>

#### **International Accreditation Forum (IAF)**

was established in 1993 with similar aims related to management systems certification (e.g. conforming to ISO 9001) 38

#### International Laboratory Accreditation Cooperation (ILAC)

was established in 1977 to promote good practice solutions within testing and calibration and to promote the international acceptance of the activities of the laboratories conducting these activities <sup>39</sup>

#### **Regional Accreditation Bodies (RABs)**

are the ones that provide accreditation services at the regional level 40

<sup>&</sup>lt;sup>40</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: <a href="https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf">https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQlToolkitReport.pdf</a>, pp. 104.





<sup>&</sup>lt;sup>36</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>&</sup>lt;sup>37</sup> EA. (2022). Relations with the European Commission (EC). Accessed on October 27, 2022. Retrieved from: <a href="https://european-accreditation.org/about-ea/relations-with-european-commission/#european-accreditation-infrastructure">https://european-accreditation.org/about-ea/relations-with-european-commission/#european-accreditation-infrastructure</a>

<sup>&</sup>lt;sup>38</sup> ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: <a href="https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco">https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco</a> building-trust.pdf, pp. 25.

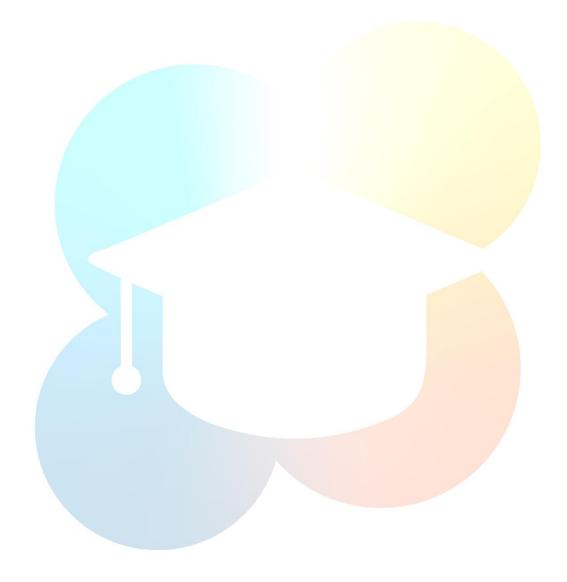
<sup>&</sup>lt;sup>39</sup> Ibid., pp. 25.

#### **National Accreditation Bodies (NABs)**

offer accreditation services mostly within their countries, although some operate outside the national borders, as well  $^{\rm 41}$ 

#### **National Accreditation Focal Points (NAFPs)**

are established at the national level to be liaison mechanisms between the RAB and entities wishing to be accredited  $^{42}$ 



<sup>&</sup>lt;sup>41</sup> Ibid., pp. 104.

<sup>&</sup>lt;sup>42</sup> Ibid., pp. 104.





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