Register of EA resolutions for use by EA, National Accreditation Bodies and EA evaluators

PURPOSE

This publication provides a register of all relevant EA resolutions, which have not been transferred in EA documents, but which are still valid, for the use by EA, National Accreditation Bodies and EA evaluators.
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INTRODUCTION

1 GENERAL RESOLUTIONS

2 RESOLUTIONS RELATED TO EN ISO/IEC 17011

3 RESOLUTIONS RELATED TO CALIBRATION

4 RESOLUTIONS RELATED TO TESTING (INCLUDING MEDICAL EXAMINATIONS)

5 RESOLUTIONS RELATED TO INSPECTION

6 RESOLUTIONS RELATED TO PRODUCT CERTIFICATION

7 RESOLUTIONS RELATED TO MANAGEMENT SYSTEM CERTIFICATION

8 RESOLUTIONS RELATED TO CERTIFICATION OF PERSONS

9 RESOLUTIONS RELATED TO VALIDATION AND VERIFICATION

10 RESOLUTIONS RELATED TO PROFICIENCY TESTING PROVIDERS

11 RESOLUTIONS RELATED TO REFERENCE MATERIAL PRODUCERS

12 RESOLUTIONS RELATED TO BIOBANKING
**INTRODUCTION**

The decision-making process is defined in the EA Articles of Association and in EA-1/17 *EA Rules of Procedures*.

According EA-1/17 Rules of Procedure paragraph 5 e) the EA members are obliged to abide by the decisions of the General Assembly and the Multilateral Agreement Council (MAC).

Most of the decisions taken by the General Assembly - expressed as EA resolutions - are implemented in EA documents, but some of the decisions are only set out in the EA resolutions itself.

Decisions/requirements set out in EA documents are published on EA’s website. EA-INF/01 *List of EA Publications and International Documents* includes all documents, relevant for EA and its members.

The EA resolutions are published on EA’s website too.

The EA system ensures through the peer evaluation system that the implementation of these decisions/requirements is monitored. But this system is (presumably) focused on decisions/requirements set out in EA documents. There is a risk that decisions/requirements covered in single EA resolutions, which are not transferred into an EA document, will not be implemented by the EA members and will not be covered in the monitoring system.

An EA member doesn’t implement (relevant) EA’s decisions/requirements deliberately, but it may happen that an EA member will not follow all EA resolutions, if not covered in EA documents. Furthermore, it is very difficult for peer evaluators to ensure that all EA decisions/requirements, which are not covered in EA documents, are monitored in the peer evaluation of an EA member, because that would mean that the peer evaluator would have a list with all relevant EA decisions/requirements.

In order to ensure that all EA decisions/requirements, which are not covered in EA documents, will be implemented by the EA members and that will be covered in the peer evaluation system, EA has created this register of all relevant EA resolutions, which have not been transferred in EA documents but which are still valid.

Relevant resolutions are those resolutions, which shall be followed in the accreditation of conformity assessment bodies, even if not covered in an EA document.

But this document covers also resolutions, which are relevant for EA only. These resolutions have been marked with a disclaimer that this resolution is not relevant for the NABs and EA peer evaluators.

Mandatory IAF and ILAC documents adopted by EA and endorsed level 3 and 4 standards, including applicable transition periods, are listed in EA-INF/01.

This document covers the relevant EA resolutions from 2010 up to the present day.
1 GENERAL RESOLUTIONS

EA Resolution 2019 (44) 11
The General Assembly adopts the following IAF resolution(s) approved at the IAF 33rd Annual General Assembly in Frankfurt on 28-30 October 2019, as applicable to EA and its members:

IAF Resolution 2019-15 – (Agenda Item 9) Accredited Certification Only Issued Against Normative Documents That Contain Requirements - The General Assembly, acting on the recommendation of the Technical Committee, resolved that accredited certification shall only be issued against documents/standards that contain requirements.

EA Resolution 2018 (42) 18
The General Assembly approves the following IAF resolutions adopted at the IAF 32nd Annual General Assembly in Singapore on 31 October 2018, as applicable to EA and its members:

IAF Resolution 2018-17 – (Agenda Item 9): Transition date for ISO and IEC publications - The General Assembly, acting on the recommendation of the Technical Committee, resolved to endorse the start date and end date of all future IAF Transition periods be the last day of the month of publication, as outlined on the ISO and IEC standard.

EA Resolution 2017 (40) 13
The General Assembly, acting upon the recommendation of the Horizontal Harmonisation Committee, agrees with the HHC position paper on CERTIF 2015-02 Rev03 (document EAGA(17)67 HHC Position paper on CERTIF 2015-02 rev 03) and endorses the following position on consultancy activities provided by Notified Bodies: “Given that Article R17(4) of Decision 768/2008 refers to the activity for which a body is notified, this means that the notified body may not provide consultancy services (such as technical assistance or provide advice on how to pass conformity assessment procedures) to any manufacturers of the kind of products it assesses, as described in the accreditation scope. Otherwise, the independence provisions in relevant harmonized standards used to accredit NBs would be undermined or even contradicted.

EA Resolution 2017 (40) 15
The General Assembly, acting upon the recommendation of the Executive Committee based on the advice from the Horizontal Harmonisation Committee, agrees that: - issues related to the non-technical implementation and interpretation of EA-1/22: EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members are for the HHC to discuss; - technical issues concerning the schemes are for the relevant technical committees to address; - scheme owners shall have only one contact point for their questions to EA. It is the role of the “home AB” to be that unique contact point.

EA Resolution 2016 (38) 10
The General Assembly, acting upon recommendation from the Executive Committee, agrees to mandate Cabinet DELOITTE to be: - the commissaire aux comptes of EA for the period and financial years 2016-2021; and-the financial auditor for the verification and certification of eligible costs under the FPA and operating grant with the European Commission/EFTA.

Note: This resolution is not relevant for NABs and EA peer evaluators.
EA Resolution 2015 (35) 22
The General Assembly recognises that Option B in standards on CABs (17000 series) is included to enable a CAB which operates a management system in accordance with ISO 9001 to use that management system to achieve the same result as they would by implementing the ISO 17xxx management system. NAB must check that during its assessments.

EA Resolution 2012 (29)16
The General Assembly confirms that formal positions of EA are agreed through decisions made at the General Assembly, normally on the recommendation of an EA committee. Where issues are discussed within a committee that do not lead to a Resolution being proposed for endorsement at the General Assembly, it is for individual accreditation bodies to make their own decision, suitably informed by the technical or general discussions that have taken place within the committee.

2 RESOLUTIONS RELATED TO EN ISO/IEC 17011

EA Resolution 2017 (40) 24
The General Assembly approves the following resolution adopted at the 17th IAF-ILAC Joint General Assembly in Vancouver, Canada in October 2017, as applicable to EA and its members: JGA Vancouver Resolution 2 - Implementation of transition to ISO/IEC 17011:2017 The Joint General Assembly endorses the recommendation of the Joint Executive Committee, to ensure JGA Delhi Resolution 1 – Transition to ISO/IEC 17011:2017 is fully implemented, that all peer evaluation activities carried out from 1 July 2018 will use ISO/IEC 17011:2017 as the requirements document. Details of this transition plan are described in the document entitled “ISO/IEC 17011:2017 Transition Plan” dated 29 October 2017.

EA Resolution 2016 (38) 24
The General Assembly approves the following resolution adopted at the 16th IAF-ILAC Joint General Assembly in New Delhi, India in November 2016, as applicable to EA and its members:

JGA Delhi Resolution 1 - Transition to ISO/IEC 17011:2017 The Joint General Assembly endorses the recommendation of the Joint Executive Committee, that the transition period for the revised ISO/IEC 17011:2004 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies due for publication in August 2017 will be three years from the date of publication of the revised standard.

3 RESOLUTIONS RELATED TO CALIBRATION
No entries

4 RESOLUTIONS RELATED TO TESTING (INCLUDING MEDICAL EXAMINATIONS)

EA Resolution 2019 (43) 25
Consequently, the General Assembly resolves to amend accordingly EA-1/06: EA Multilateral Agreement. Criteria for signing, Policy and Procedures for Development.

**EA Resolution 2016 (38) 23**

The General Assembly approves the following ILAC resolution adopted at the 20\(^{th}\) ILAC General Assembly in New Delhi, India in November 2016, as applicable to EA and its members:

**ILAC Resolution GA 20.15** As the revised version of ISO/IEC 17025 is scheduled for publication in 2017, the General Assembly endorses the recommendation of the AIC that a transition period of 3 years from the date of publication be adopted. At the end of the transition period, accreditation of a laboratory to ISO/IEC 17025:2005 will not be recognised under the ILAC Arrangement.

**EA Resolution 2016 (37) 47**

The General Assembly, acting upon recommendation from the Laboratory Committee, endorses the mandatory application of:

- ISO 22870:2006 Point-of-care testing (POCT)- Requirements for quality and competence;
- ISO 15195:2003 Laboratory medicine - Requirements for reference measurement laboratories

**EA Resolution 2015 (35) 20**

The EA General Assembly, taking into consideration that ISO/IEC 17000 A1.1, A2.1 and A2.2 identify selection (which includes sampling) as one of the three key functions of conformity assessment determines that accreditation of sampling as a stand-alone activity is appropriate and does fall within the remit of accreditation bodies. The EA General Assembly determines that both ISO/IEC 17025 and ISO/IEC 17020 are appropriate as accreditation standards for sampling as a stand-alone activity. The fact that ISO/IEC 17025 contains a specific section on sampling, it lends itself very well to assessment of sampling as a standalone activity. The criteria included within this shall form the basis for all accreditation for sampling and hence if it is decided that ISO/IEC 17020 is the most appropriate standard then the requirements for sampling in ISO/IEC 17025 shall be included in the assessment.

**EA Resolution 2014 (33) 31**

Reissuance of test reports when the trade name / trademark of the tested product has changed (clause 5.10.9 of ISO/IEC 17025) Test reports shall be reissued only for the correction of errors and the inclusion of omitted data available at the time of test. The unique identification of the sample shall be given and any manufacturers branding or labelling may also be shown and marked as such. The practice which consists for an accredited laboratory in reissuing a test report under accreditation when the trade name / trademark of the tested product has changed (without testing it again) is not permitted, even with a clear reference to the initial report that it replaces. The product tested has been clearly identified both in the contract review and in the test report. The laboratory shall not assume the responsibility for declaring that the product with the new trade name / trademark is strictly identical to the one tested; this responsibility belongs to the client. A transition period of one year for the complete application of the resolution is defined in order to allow the market to adapt to the change.
EA Resolution 2010 (25) 24
The General Assembly resolves that an accreditation body, when accrediting laboratories for Point of Care Testing (POCT) activities, shall use ISO 22870 in combination with ISO 15189 as the accreditation criteria. The accreditation of POCT against ISO 22870 in combination with ISO 15189 is covered under the EA-MLA for testing. This supersedes Resolution 2009 (23)26.

5 RESOLUTIONS RELATED TO INSPECTION

EA Resolution 2015 (35) 20
The EA General Assembly, taking into consideration that ISO/IEC 17000 A1.1, A2.1 and A2.2 identify selection (which includes sampling) as one of the three key functions of conformity assessment determines that accreditation of sampling as a stand-alone activity is appropriate and does fall within the remit of accreditation bodies. The EA General Assembly determines that both ISO/IEC 17025 and ISO/IEC 17020 are appropriate as accreditation standards for sampling as a stand-alone activity. The fact that ISO/IEC 17025 contains a specific section on sampling, it lends itself very well to assessment of sampling as a standalone activity. The criteria included within this shall form the basis for all accreditation for sampling and hence if it is decided that ISO/IEC 17020 is the most appropriate standard then the requirements for sampling in ISO/IEC 17020 shall be included in the assessment.

6 RESOLUTIONS RELATED TO PRODUCT CERTIFICATION

EA Resolution 2019 (43) 27
EA disagrees with the answer of ISO CASCO to the CASCO clarification request (dated 07 December 2018) to ISO/IEC 17065:2012 clause 4.2.6 dealing with impartiality requirements. EA and its members will not take into account the CASCO answer on the request.

EA Resolution 2017 (40) 16
The General Assembly, acting upon the recommendation of the Horizontal Harmonisation Committee, endorses the mandatory application of the ERA Technical Document (MNB – Assessment scheme 000MRA1044 ver.1.1) Requirements for CABs seeking Notification as Level 4 document for all EA members. The transition period for transferring accreditation of existing CABs already accredited for IOD/2008, to the scheme will end on 1st July 2020. By 1st July 2020, all accreditations will have to be granted according to the scheme. Applications received from 1st January 2018 on shall be processed according to the ERA Technical Document. 23 November 2017 3 / 6

EA Resolution 2018 (42) 18
The General Assembly approves the following IAF resolutions adopted at the IAF 32nd Annual General Assembly in Singapore on 31 October 2018, as applicable to EA and its members:

IAF Resolution 2018-13 – (Agenda Item 9) Non-Accredited Product Certification where the CAB is accredited for the same scope - The General Assembly acting on the recommendation of the Technical Committee resolved that IAF Accreditation Body members shall have legally enforceable arrangements with their accredited CABs for product certification that prevents the CAB from issuing non-accredited product certification in scopes for which they are accredited. The enforceable arrangements shall require full implementation within three years from 31 October 2018.
Additionally, CABs for product certification must transition certification documentation to include the accreditation symbol and/or must make reference to the accreditation status of the CAB including the identification of the AB, no later than 31 October 2021.

Note: If there is an exception to the above, the CAB must justify the exception to the AB, and if accepted by the AB, the certification is still considered accredited.

**EA Resolution 2014 (34) 22**

**EA Resolution 2012 (29)01**
The General Assembly ratifies the decision by the EA Executive Committee that the ECM (Entity in Charge of Maintenance) certification scheme of ERA (European Railway Agency) is accepted as covered by the EA MLA under EN 45011.

### 7 RESOLUTIONS RELATED TO MANAGEMENT SYSTEM CERTIFICATION

**EA Resolution 2019 (44) 11**
The General Assembly adopts the following IAF resolution(s) approved at the IAF 33rd Annual General Assembly in Frankfurt on 28-30October 2019, as applicable to EA and its members:

IAF Resolution 2019-17 – (Agenda Item 9) Transitional Arrangements for ISO 22301:2019
- The General Assembly, acting on the recommendation of the Technical Committee, resolved that the Transitional Arrangement for the Revision of ISO 22301 Societal security – Business continuity management systems – Requirements be three years from the last day of the month of publication of the revised standard. All ISO 22301:2012 certifications shall expire or be withdrawn at the end of the transition period.

Within this transition timeline:
- ABs shall be ready to carry out transition assessments for ISO 22301:2019 within six months from the last day of the month of publication of the revised standard.
- CABs shall complete the transition with ABs for ISO 22301:2019 within 18 months from the last day of the month of publication of the revised standard.
- CABs shall cease conducting initial and recertification audits to ISO 22301:2012 18 months from the last day of the month of publication of the revised standard.


Within this transition timeline:
- ABs shall be ready to carry out ISO 14065 assessments using 14064-3: 2019 for conformity assessment schemes that reference ISO 14064-3 within18 months from 30 April 2019.
- Where local legislation/regulation requires accredited validation/verification referencing ISO 14064-3:2006 and has not been amended to reference ISO 14064-3:2019, the use of ISO 14064-3:2006 in accredited validation/verification may be extended.
IAF Resolution 2019-19 – (Agenda Item 9) Transitional Arrangements for ISO14065:202x - The General Assembly, acting on the recommendation of the Technical Committee, resolved that the transition arrangement for the revision of ISO 14065 shall be three years from the date of publication of ISO 14065:202x.

Within this transition timeline:
- ABs shall be ready to carry out transition assessment against the new version of ISO 14065 within 12 months from the date of publication.
- All accreditation against the new version of ISO 14065 shall require accreditation to ISO/IEC 17029.
- Where local legislation/regulation requires accredited validation/verification referencing ISO 14065:2013 and has not been amended to reference the new version of ISO 14065, the use of ISO 14065:2013 in accredited validation/verification may be extended.

EA Resolution 2018 (42) 18
The General Assembly approves the following IAF resolutions adopted at the IAF 32nd Annual General Assembly in Singapore on 31 October 2018, as applicable to EA and its members:


All ISO/IEC 20000-1:2011 accredited certificates shall expire or be withdrawn no later than 29th September 2021 (the end of the transition period).

Within this transition timeline:
- ABs shall be ready to carry out transition assessments for ISO/IEC 20000-1:2018 within 8 months from 30th September 2018 (the starting date of transition).
- CABs seeking accreditation to the new standard shall complete the transition with ABs for ISO/IEC 20000-1:2018 within 18 months from 30th September 2018 (the starting date of transition).
- CABs shall cease conducting initial and recertification audits to the ISO/IEC 20000-1:2011 18 months from 30th September 2018 (the starting date of transition).

IAF Resolution 2018-15 – (Agenda Item 9) Transitional Arrangement for ISO 22000:2018 - The General Assembly, acting on the recommendation of the Technical Committee, resolved that the period for the transitioning of accredited certifications to ISO 22000:2018 Food safety management systems -- Requirements for any organization in the food chain be three years, with the transition deadline being no later than 29 June 2021.

Accredited certificates issued to ISO 22000:2005 after the date of publication of ISO 22000:2018 shall state an expiry date of 29 June 2021. This resolution replaces IAF Resolution 2017-16.

EA Resolution 2016 (38) 21
The General Assembly approves the following IAF resolutions adopted at the 20th IAF General Assembly in New Delhi, India in November 2016, as applicable to EA and its members:

management systems -- Requirements for bodies providing audit and certification of energy management systems as a Normative reference for the accreditation scope and grouping of sectors for witnessing of energy management systems.

**IAF Resolution 2016-17 – (Agenda Item 9)** Accredited MS Certification Document - Further to Resolution 2015-14, The General Assembly, acting on the recommendation of the Technical Committee, resolved that in order for a management system certification document to be considered accredited, it must display the accreditation symbol, and/or, reference the accreditation status of the CB including the identification of the AB. The General Assembly further agreed that management systems certification bodies: 1. must transition certification documentation to include the accreditation symbol, and/or, reference the accreditation status of the CB including the identification of the AB, at the time of recertification decision; no later than 06 November 2019; 2. when granted initial accreditation (for a standard or scope), as of 06 November 2016, the CB must transition (re-issue) previous unaccredited certification documents, within one year after the accreditation decision; 3. must apply this resolution to all management system standards. Note: If there is an exception to the above, the client must justify the exception to the CB and AB, and if accepted by both the CB and AB, the certification is still considered accredited.

**IAF Resolution 2016-24 – (Agenda Item 10)** General Policy for MLA Scope Extensions under Management System Certification - In Accordance with the amended requirements as provided in IAF ML4:2016 3.1.5 and 3.1.6, the General Assembly, acting on the recommendation of the MLA Committee, resolved that the following principle be applied for the extension to all Sub-Scopes of Management System Certification as follows:

**For Individual ABs:**
For a signatory to the IAF MLA with a Main Scope of ISO/IEC 17021(-1): to provide a self-declaration, that the Sub-Scope has been introduced and relevant requirements as defined by IAF have been met (IAF ML4:2016, 3.1.5.ii, 3.1.6.i)

For a signatory to the IAF MLA but not for the Main Scope of ISO/IEC 17021(-1): full evaluation in accordance with IAF/ILAC A2 (IAF ML4:2016, 3.1.5.i)

**For Regional Accreditation Groups:**
For a signatory to the IAF MLA with a Main Scope of ISO/IEC 17021(-1):
- at least 1 MLA signatory
- document review
  For a signatory to the IAF MLA but not for a Main Scope of ISO/IEC 17021-1: full evaluation in accordance with IAF/ILAC A1 This Resolution supersedes the Note 2 point 3.1.5 of IAF ML4:2016.

**IAF Resolution 2015–14 – (Agenda Item 10)** Non-Accredited Certification Where the MS CB is Accredited for the Same Scope - The General Assembly, acting on the recommendation of the Technical Committee, resolved that IAF Accreditation Body members shall have legally enforceable arrangements with their accredited CABs that prevents the CAB from issuing non-accredited management systems certificates in scopes for which they are accredited. The General Assembly further agreed that the transition period will be one year from the date of endorsement.
EA Resolution 2015 (35) 30
The General Assembly, acting upon recommendation from the Certification Committee, endorses that IAF MD2:2007 - Transfer of Accredited Certification of Management Systems shall be applied to all management systems under the EA MLA and not only to QMS and EMS (current IAF MLA sub-scopes).

EA Resolution 2013 (31) 30
The General Assembly, acting upon recommendation from the Certification Committee, resolves that when accrediting CBs for the purpose of the ‘End of Waste Regulations’ according to ISO/IEC 17021, the certification of the management system of the producers by the CBs shall be against ISO 9001 and the requirements in the applicable ‘End of Waste Regulations’ – this requires that compliance with all the ISO/IEC 17021 requirements, including annual surveillance audits and recertification on the third year, will be fulfilled. The accreditation certificate shall additionally refer to the ‘End of Waste Regulations’ detailing the types of products covered. The certificates issued by accredited CBs to producers shall refer to the relevant End of Waste Regulation(s) and specify the type of products covered by the management system. Moreover, upon request and agreement with the national authorities, the CBs can be accredited under EN 45011 or ISO/IEC 17065 for the certification of the end of waste process, using the appropriate management system requirements and the applicable ‘End of Waste Regulations’ requirements.

EA Resolution 2013 (31) 31
The General Assembly, acting upon recommendation from the Certification Committee, resolves that accreditation of CBs providing certification according to EN 15224 can be provided as a standalone activity. In case of an audit to EN 15224 delivering two certificates (ISO 9001 and EN 15224), the CB needs to confirm this with a proper contract review and state on the audit objectives and plan; the CB needs to be accredited for both ISO 9001 and EN 15224 and follow the relevant EA and IAF mandatory documents.

EA Resolution 2011 (27) 35
The General Assembly, acting upon the recommendation from the Certification Committee, resolves that ISO 22005 is not a standard to be used for accreditation.

8 RESOLUTIONS RELATED TO CERTIFICATION OF PERSONS

EA Resolution 2017 (40) 23
The General Assembly approves the following IAF resolutions adopted at the 31st IAF Annual General Assembly in Vancouver, Canada in October 2017, as applicable to EA and its members:

IAF Resolution 2017-19 – (Agenda Item 9) Non-Accredited Personnel Certification where the CAB is accredited for the same scope and Transitional Arrangement - The General Assembly acting on the recommendation of the Technical Committee resolved that IAF Accreditation Body members shall have legally enforceable arrangements with their accredited CABS for personnel certification that prevents the CAB from issuing non-accredited persons certificates in scopes for which they are accredited. 23 November 2017 5
/ 6 The enforceable arrangements shall require full implementation within three years from 30 October 2017. Additionally, CABS for personnel certification shall transition certification documentation to include the accreditation symbol and/or shall make reference to the accreditation status of the CAB including the identification of the AB, at the time of recertification decision; no later than 30 October 2020. When granted initial accreditation (for ISO/IEC 17024), after 30 October 2017, a CAB shall transition (re-issue) previous
unaccredited certification documents and/or make reference to the accreditation status including identification of the AB, within one year of the accreditation decision. Note: If there is an exception to the above, the CAB must justify the exception to the AB, and if accepted by the AB, the certification is still considered accredited.

9 RESOLUTIONS RELATED TO VALIDATION AND VERIFICATION

EA Resolution 2017 (40) 23 The General Assembly approves the following IAF resolutions adopted at the 31st IAF Annual General Assembly in Vancouver, Canada in October 2017, as applicable to EA and its members:

IAF Resolution 2017-15 – (Agenda Item 9) Transitional Arrangements for the revision of ISO 14064-1:2006 and 14064-2:2006 - The General Assembly, acting on the recommendation of the Technical Committee, resolved that the Transitional Arrangement for the Revision of ISO 14064-1:2006 Greenhouse gases -- Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals, and ISO 14064- 2:2006 Greenhouse gases -- Part 2: Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas emission reductions or removal enhancements be three years from the date of publication of the revised standard. Within this transition timeline: • ABs shall be ready to carry out transition assessment for ISO 14064-1:2018 and ISO 14064-2:2018 within 6 months from the date of publication of the revised standard. Note: If there is an exception to the above, the AB shall justify the exception based on valid reasons. • CABs shall complete the transition with ABs for ISO 14064-1:2018 and ISO 14064-2:2018 within 3 years from the date of publication of the revised standard.

10 RESOLUTIONS RELATED TO PROFICIENCY TESTING PROVIDERS

No entries

11 RESOLUTIONS RELATED TO REFERENCE MATERIAL PRODUCERS

EA Resolution 2016(38) 23
The General Assembly approves the following ILAC resolution adopted at the 20th ILAC General Assembly in New Delhi, India in November 2016, as applicable to EA and its members:

ILAC Resolution GA 20.14 As a result of the publication of ISO 17034 in November 2016, replacing ISO Guide 34:2009, the General Assembly endorses the recommendation from the AIC, that accreditation of reference material producers be conducted in accordance with ISO 17034 and that an implementation period of 3 years be adopted.

12 RESOLUTIONS RELATED TO BIOBANKING

EA Resolution 2018 (42) 19
The General Assembly approves the following resolution adopted at the ILAC 22nd Annual General Assembly in Singapore on 31 October 2018, as applicable to EA and its members:
ILAC Resolution GA 22.19: The General Assembly resolves that the standard applicable to biobanks for the purposes of accreditation will be ISO 20387 Biobanking – General requirements for biobanking, to be used as a standalone standard.