



Accreditation during a pandemic

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ILAC AIC chair

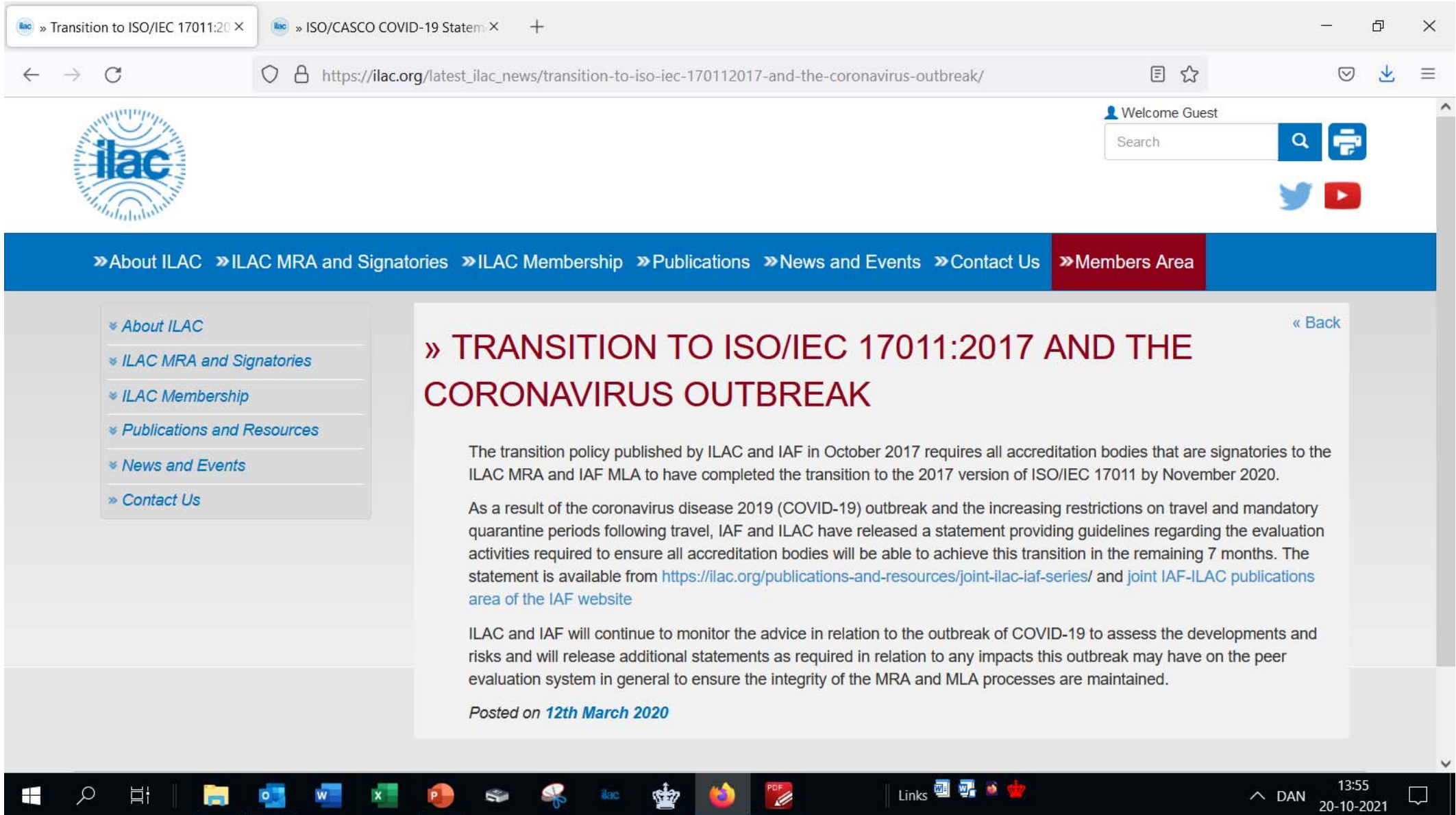
Processes in accreditation



When the pandemic hit hard March 2020 most members of ILAC have had to adapt and overcome challenges never experienced in accreditation:

- Staff working from at home
- Cancelling on site assessments
- Delays in processing applications and changes to accreditation
- International cooperation restricted/troubled
- Peer evaluation system with international teams operating remotely.
- Travel restrictions for assessors
- Health authority restrictions

Impact to transition to ISO/IEC 17011:2017



The screenshot shows a web browser window displaying the ILAC website. The address bar shows the URL: https://ilac.org/latest_ilac_news/transition-to-iso-iec-170112017-and-the-coronavirus-outbreak/. The page features a blue navigation bar with the following menu items: » About ILAC, » ILAC MRA and Signatories, » ILAC Membership, » Publications, » News and Events, » Contact Us, and » Members Area. On the left side, there is a sidebar with a list of links: » About ILAC, » ILAC MRA and Signatories, » ILAC Membership, » Publications and Resources, » News and Events, and » Contact Us. The main content area has a heading: » TRANSITION TO ISO/IEC 17011:2017 AND THE CORONAVIRUS OUTBREAK. Below the heading, there are three paragraphs of text. The first paragraph states that the transition policy published by ILAC and IAF in October 2017 requires all accreditation bodies that are signatories to the ILAC MRA and IAF MLA to have completed the transition to the 2017 version of ISO/IEC 17011 by November 2020. The second paragraph explains that as a result of the coronavirus disease 2019 (COVID-19) outbreak and the increasing restrictions on travel and mandatory quarantine periods following travel, IAF and ILAC have released a statement providing guidelines regarding the evaluation activities required to ensure all accreditation bodies will be able to achieve this transition in the remaining 7 months. The statement is available from <https://ilac.org/publications-and-resources/joint-ilac-iaf-series/> and joint IAF-ILAC publications area of the IAF website. The third paragraph states that ILAC and IAF will continue to monitor the advice in relation to the outbreak of COVID-19 to assess the developments and risks and will release additional statements as required in relation to any impacts this outbreak may have on the peer evaluation system in general to ensure the integrity of the MRA and MLA processes are maintained. At the bottom of the article, it says 'Posted on 12th March 2020'. The browser's taskbar at the bottom shows various application icons, including Windows, File Explorer, Microsoft Office, and Firefox, along with the system clock showing 13:55 on 20-10-2021.

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» TRANSITION TO ISO/IEC 17011:2017 AND THE CORONAVIRUS OUTBREAK

The transition policy published by ILAC and IAF in October 2017 requires all accreditation bodies that are signatories to the ILAC MRA and IAF MLA to have completed the transition to the 2017 version of ISO/IEC 17011 by November 2020.

As a result of the coronavirus disease 2019 (COVID-19) outbreak and the increasing restrictions on travel and mandatory quarantine periods following travel, IAF and ILAC have released a statement providing guidelines regarding the evaluation activities required to ensure all accreditation bodies will be able to achieve this transition in the remaining 7 months. The statement is available from <https://ilac.org/publications-and-resources/joint-ilac-iaf-series/> and joint IAF-ILAC publications area of the IAF website

ILAC and IAF will continue to monitor the advice in relation to the outbreak of COVID-19 to assess the developments and risks and will release additional statements as required in relation to any impacts this outbreak may have on the peer evaluation system in general to ensure the integrity of the MRA and MLA processes are maintained.

Posted on 12th March 2020

Impact to transition to ISO/IEC 17025:2017



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» TRANSITION PERIOD FOR ISO/IEC 17025 EXTENDED

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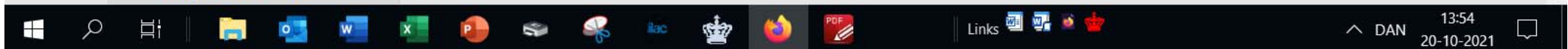
As a result of the recent ILAC ballot the transition period for ISO/IEC 17025:2017 adopted as part of the ILAC Resolution GA 20.15 (November 2016) has been extended from 30 November 2020 to 1 June 2021.

This extension has been granted to ensure all accreditation bodies and the accredited laboratories are able to achieve the remaining transitions in a robust manner under the restrictions imposed as a result of the global coronavirus disease 2019 (COVID-19) outbreak.

At the end of the transition period, the accreditation of a laboratory to ISO/IEC 17025:2005 will not be recognised under the ILAC Arrangement.

The ISO/ILAC ISO/IEC 17025:2017 Transition Communique available from <https://ilac.org/about-ilac/partnerships/international-partners/iso/> has been updated to reflect this extension to the transition period.

Posted on **11th June 2020**

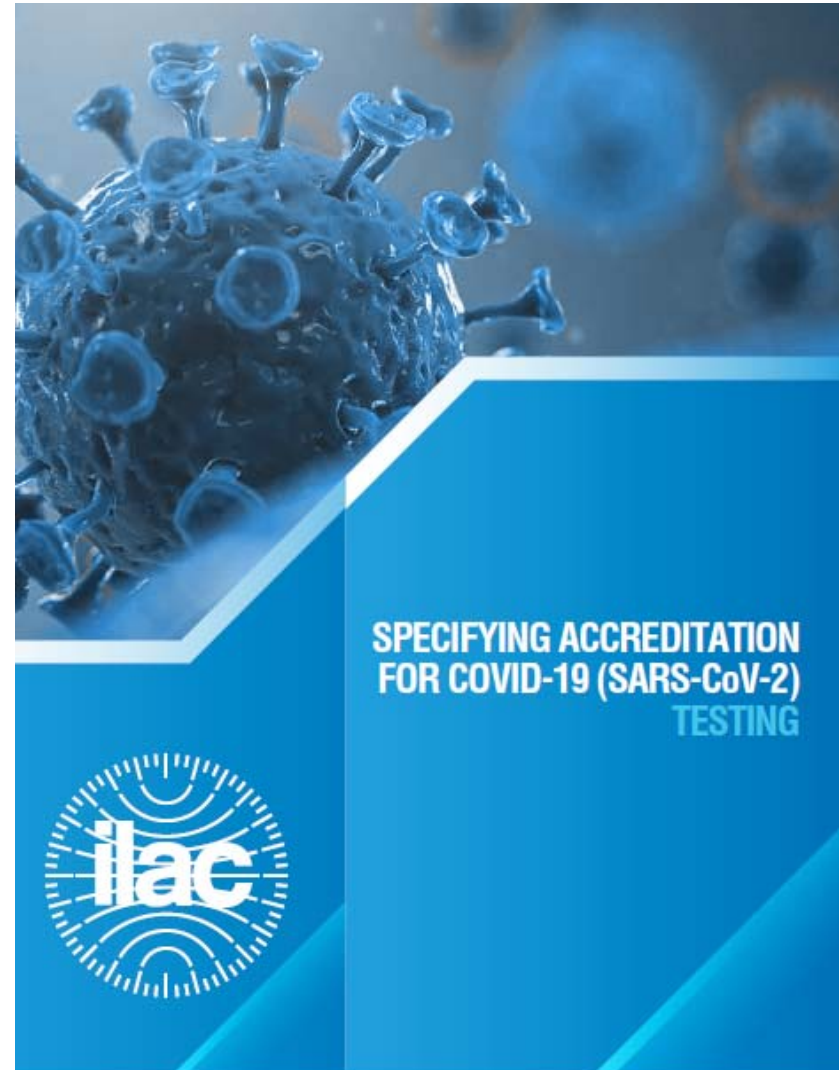


Covid-19 testing



29th July ILAC issued a brochure to address the testing needs based on ISO 15189:2012 for medical examination.

Brochure updated to cover all kinds of covid-19 testing using ISO/IEC 17025:2015, ISO 15189:2012 as well as ISO 22870 (Point of care testing) for humans, animals and food/feed, sewage, swaps,...





Replacement of assessments during the COVID-19 pandemic

During the current COVID-19 pandemic, where a mandatory scheduled on-site/remote assessment cannot be performed, by the AB or, whenever relevant, by a sub-contracted AB which is an IAF MLA/ILAC MRA signatory, that assessment may be replaced, in extraordinary circumstances, by an off-site review of documentation.

The review of documentation should only be considered if the justifications for not being able to conduct the on-site or remote assessment are traced back to the exceptional situation due to COVID-19 (e.g.: travel restrictions, social distancing, workplace health and safety decisions including health risk categories for both assessors and CAB personnel).

The impact of the replacement on the accreditation program for the current accreditation cycle needs to be considered.

If either a remote assessment or an on-site assessment has not been conducted within 12 months from the review of documentation, for reasons not attributable to the AB, the AB shall normally initiate the process for suspension or withdrawal of the accreditation of the CAB.

For an initial assessment, review of documentation only, is not sufficient.



IAF/ILAC Approach to Remote Peer Evaluations of Regions and Single Accreditation Bodies during the COVID-19 Pandemic

Some facts/(personal) experiences



- Some AB's have for more than 1½ year not done any on-site assessments.
- Some AB's have done 95 % of all assessments partly or in full as normally.
- Plans have been changed numerously times.
- Remote assessments and peer evaluations occupies more workdays in the calendar.
- International meetings e.g. in ISO WG's developing standards have been hardly impacted as a normal 3 day meeting now occupies 6 or more days due to the international "time window" 13.00 – 16.00 UTC.

Regions reaction to peer evaluation e.g. EA MAC committee



https://european-accreditation.org/new-calendar-for-the-2020s-peer-evaluations-due-to-the-covid-19/

> How Quality Infrastructures support transition to Industry 4.0
30 September 2021

> Cybersecurity Act: Candidate EUCC scheme
14 September 2021

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EA FAQs

regarding the operation of the peer-evaluation system under the COVID-19 outbreak.

As a consequence, even though the preparation and document review activities were carried out in 2020, for 7 peer evaluations (COFRAC, EGAC, INAB, NA, PCA, SWEDAC, UKAS), the on-site activities have been postponed to 2021, while 3 evaluations (DANAK, IPAC, OLAS) have been postponed to Autumn 2020.

Although the postponements of parts of the evaluations from 2020 to 2021 have a major impact on the program of peer evaluations for 2021, no postponements from 2021 to 2022 have been scheduled for the time being.

Further dispositions will be developed by the MAC MG for considering a combination of alternative approaches that, while not dispensing an on-site visit, will assist in keeping the confidence in the accreditation infrastructure by the interested parties. Such alternative approaches which could be considered are the following:

- Remote evaluation of horizontal management system elements;
- Remote evaluation of NAB's assessment files (that are files which contains all information and records about the assessment of a Conformity Assessment Body by the NAB);
- Remote witnessing of the assessment of Conformity Assessment Bodies.

The COVID-19 pandemic outbreak also influenced the decision-making process which moved entirely online. Hence, the MAC made 27 decisions in the period May - July 2020 by on-line ballots.

For more information about the peer evaluation of NABs and the MLA signatories:
<https://european-accreditation.org/mutual-recognition/the-ea-mla/>

Regions reaction to peer evaluation e.g. EA MAC committee

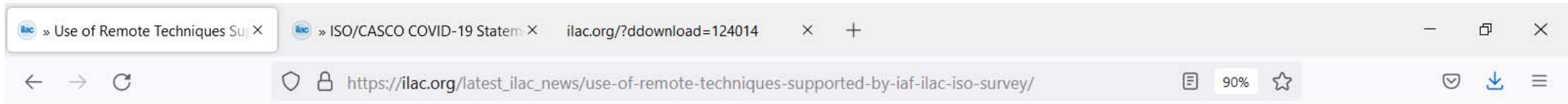


October 20th 2021: Please be informed that the EA Multilateral Agreement Council (EA MAC) has made the decision to start the on-site peer evaluations in 2022. The Decision of the MAC is transcribed below:

“MAC decides, in principle, to start the on-site peer evaluations from January 2022 considering the following aspects:

- *In case it is not possible for the TL to be on-site, due to travel restrictions, at least DTL to be on-site;*
- *If there are travel restrictions applicable in the country of the NAB under evaluation, the MG will decide on a case-by-case basis the deviation from the above principle;*
- *It is accepted for TMs not to be on-site if there are travel restrictions by their countries.”*

Report for IAF/ILAC/ISO Survey on Remote Audit/Assessment/Evaluation (Reference Report)



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» USE OF REMOTE TECHNIQUES SUPPORTED BY IAF/ILAC/ISO SURVEY

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A joint IAF/ILAC/ISO survey on the use of remote assessment techniques has shown that a large majority prefer remote or blended audits, assessments and/or evaluations. Furthermore, respondents felt that remote activities provide as much confidence as on-site activities and would like to see continued or an increased use of remote activities in the future. A cross-section of the conformity assessment community were invited to participate and over 4000 surveys were returned!

There are many benefits to remote working including, reduced travel time and costs, efficient use of time during assessment, and a reduced carbon footprint. In addition to providing a snapshot of attitudes towards the use of remote techniques, the survey received hundreds of suggestions, ideas and proposals from users, CABs, auditors and assessors.

With this in mind ILAC will work alongside IAF and ISO and consider next steps in order to incorporate the outcomes in the relevant documents and processes as appropriate, and support our members.

For more information:

[Full article](#)

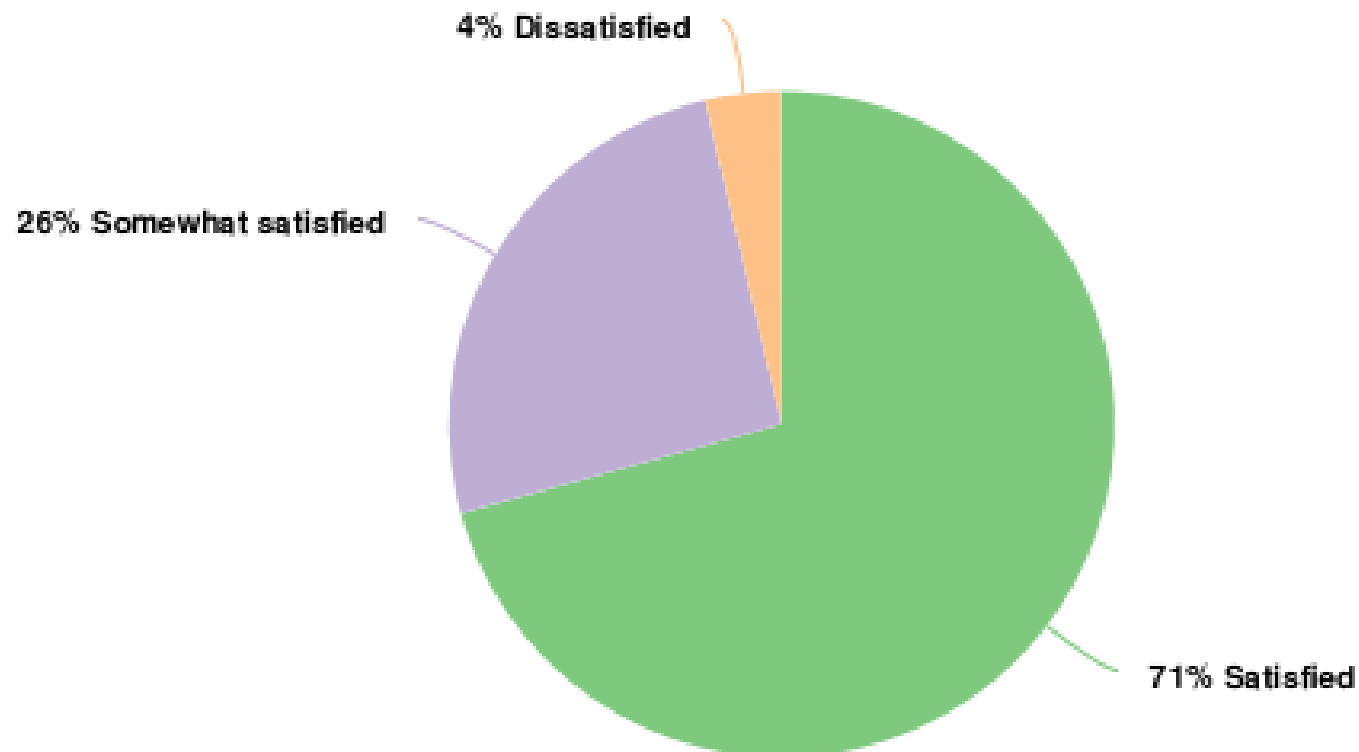
[Survey Report](#)

Posted on **12th October 2021**
















All in all, how satisfied are you with the remote audit/assessment/evaluation experience?

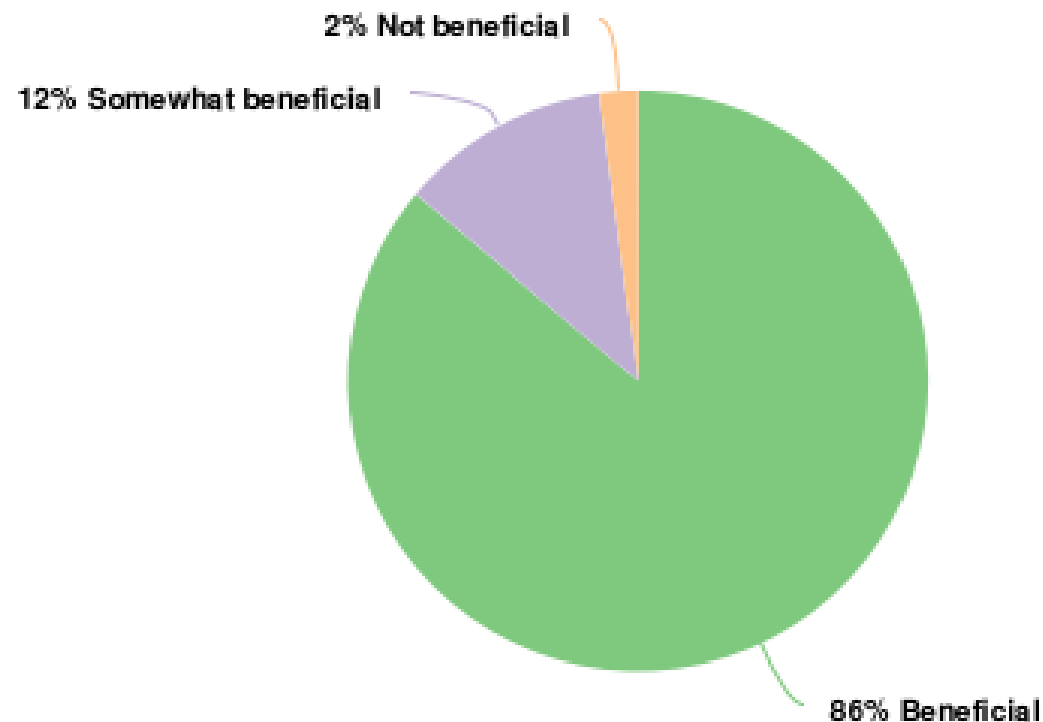




Value		Percent	Responses
Standards-developer		6.6%	287
Regulator		2.0%	88
Conformity assessment body - having undergone a remote assessment		23.8%	1,028
Conformity assessment body - undertaking a remote audit (i.e. certification body)		21.1%	910
Accreditation Body - having undergone an evaluation		10.9%	470
Accreditation Body - undertaking assessments		13.0%	563
Regional Accreditation Group - having undergone an evaluation		1.4%	60
Regional Accreditation Group - undertaking evaluations		1.9%	80
User (e.g. a certified organisation)		40.3%	1,743
Consultant/expert		17.2%	744
Other - please specify		9.1%	393

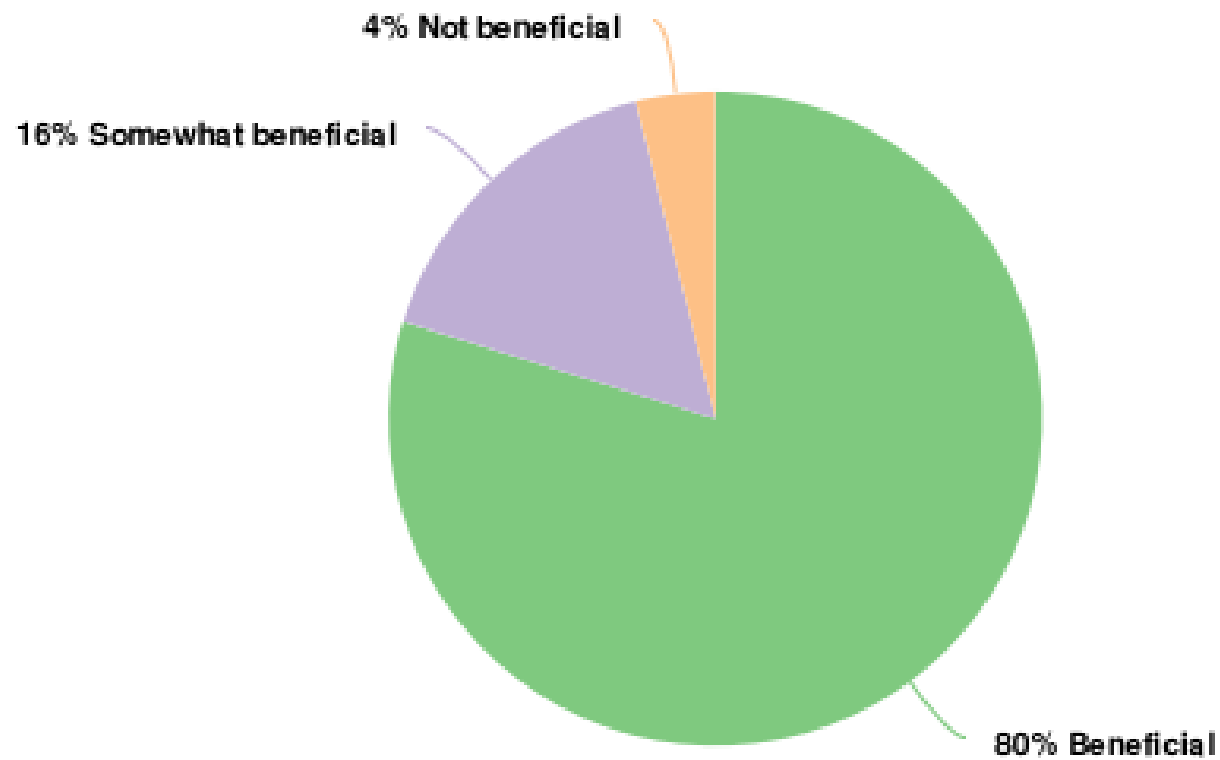


e. Possibility to keep the certificate/accreditation/recognition and conduct the audit/assessment/evaluation despite the pandemic



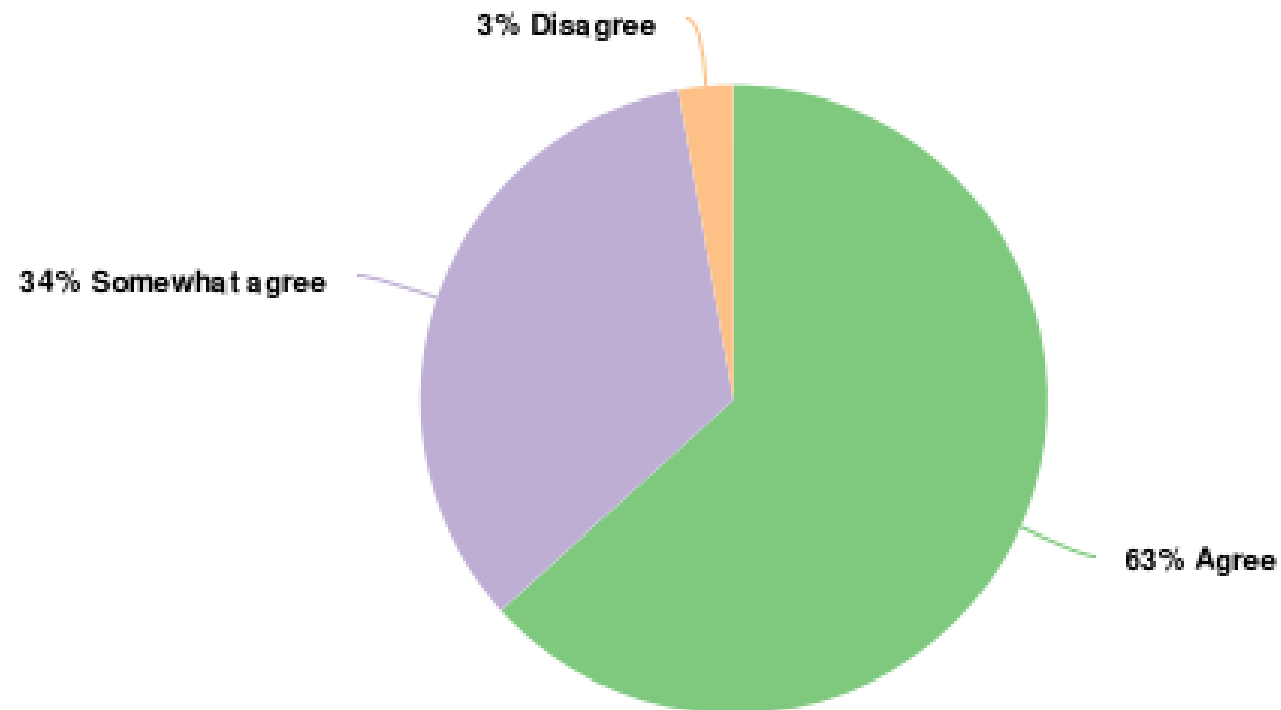


a. Reduced travel time and costs for auditors/assessors/evaluators



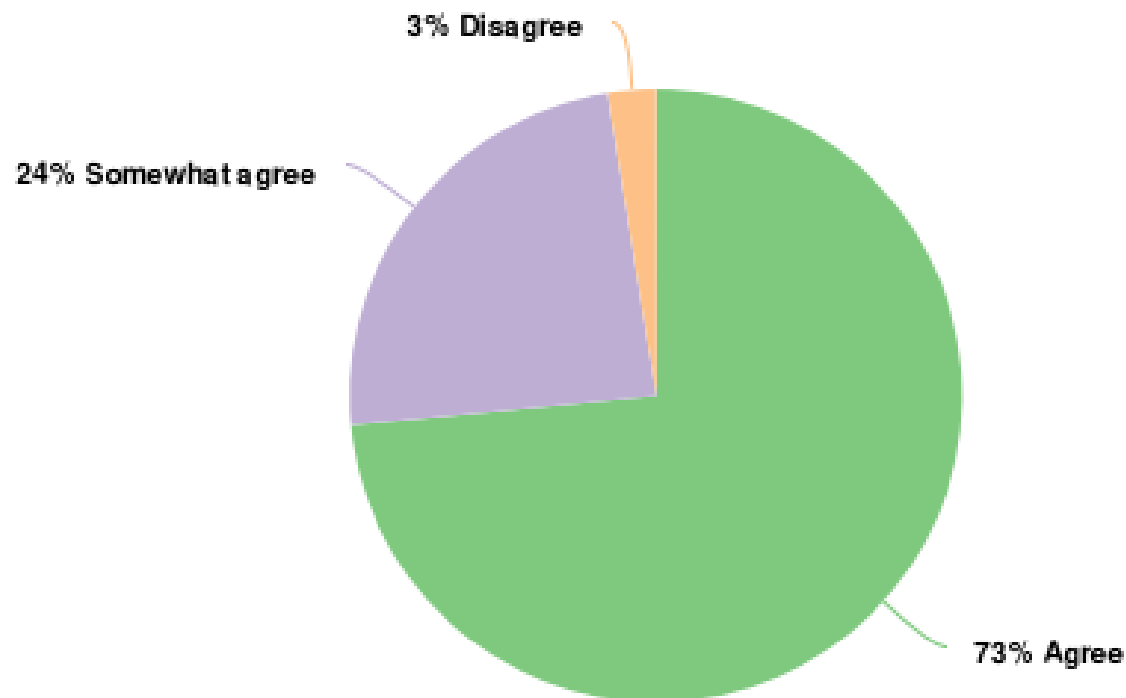


a. the documents available for carrying out audits/assessment/evaluations (e.g. IAF, ILAC, standards, etc.) were appropriate and flexible for remote work?



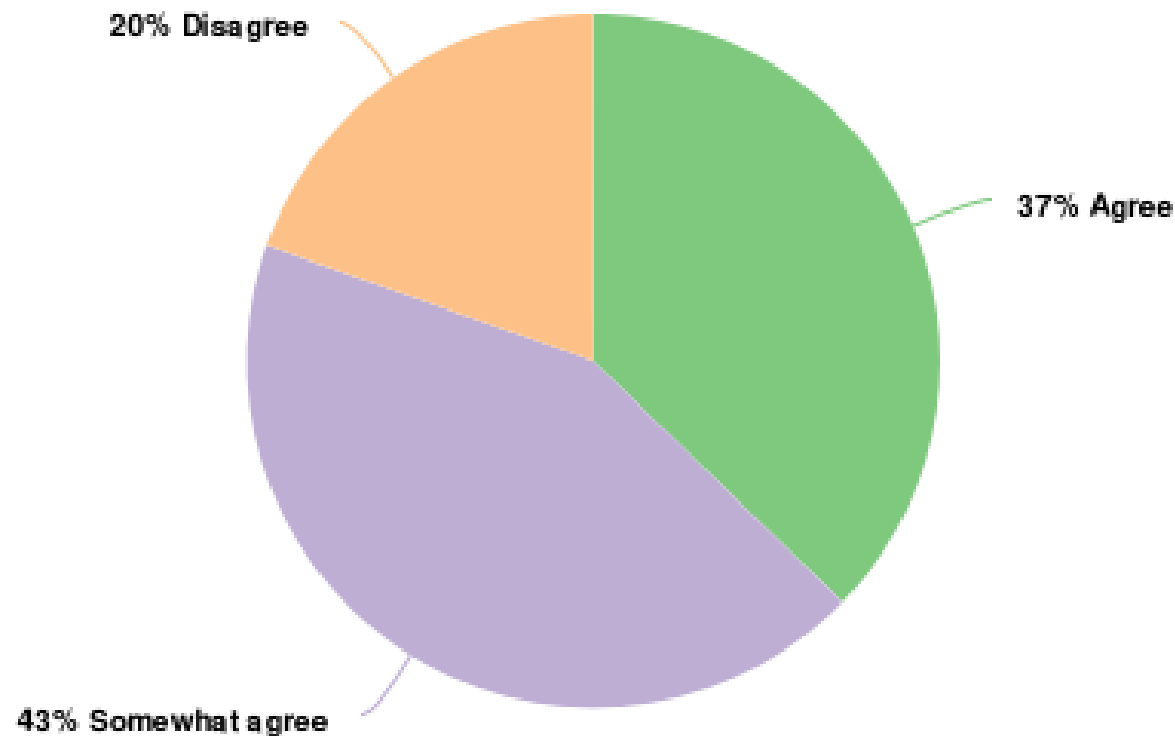


b. new technologies and alternative techniques should be used to ensure continuous improvement, robustness and trustworthiness of audit/assessment/evaluation e.g. real time camera, sensors, data exchange, AI technology, etc.



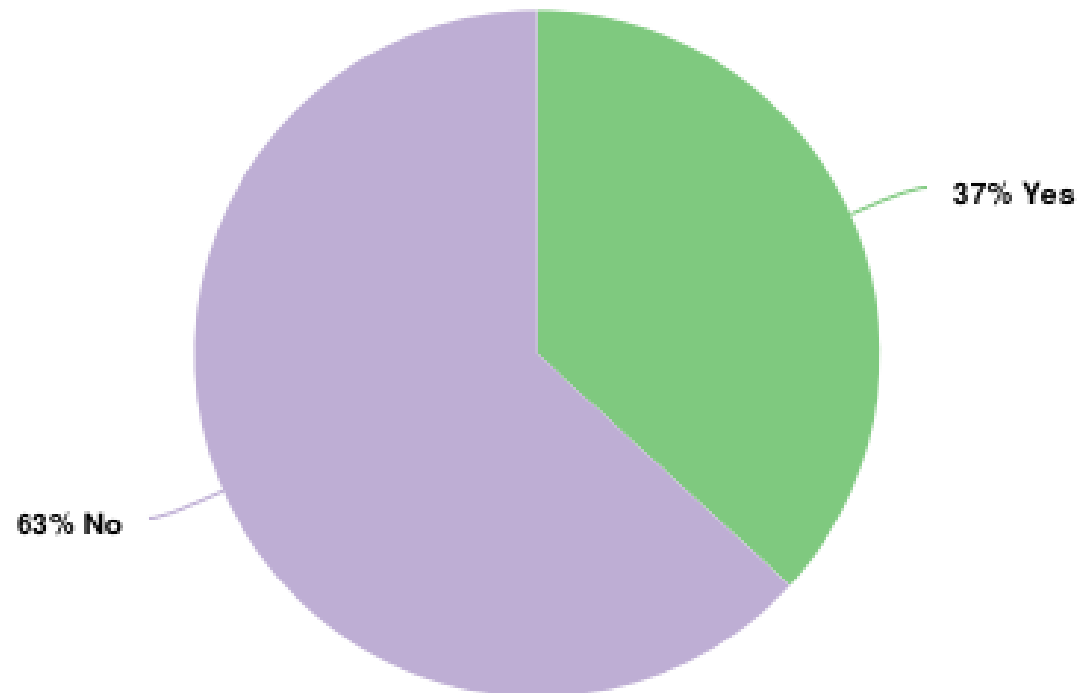


c. assuming an ideal set-up (e.g. preparation, consideration of risks, effective technology including internet connection), a remote audit/assessment/evaluation provides as much confidence as an on-site audit/assessment/evaluation



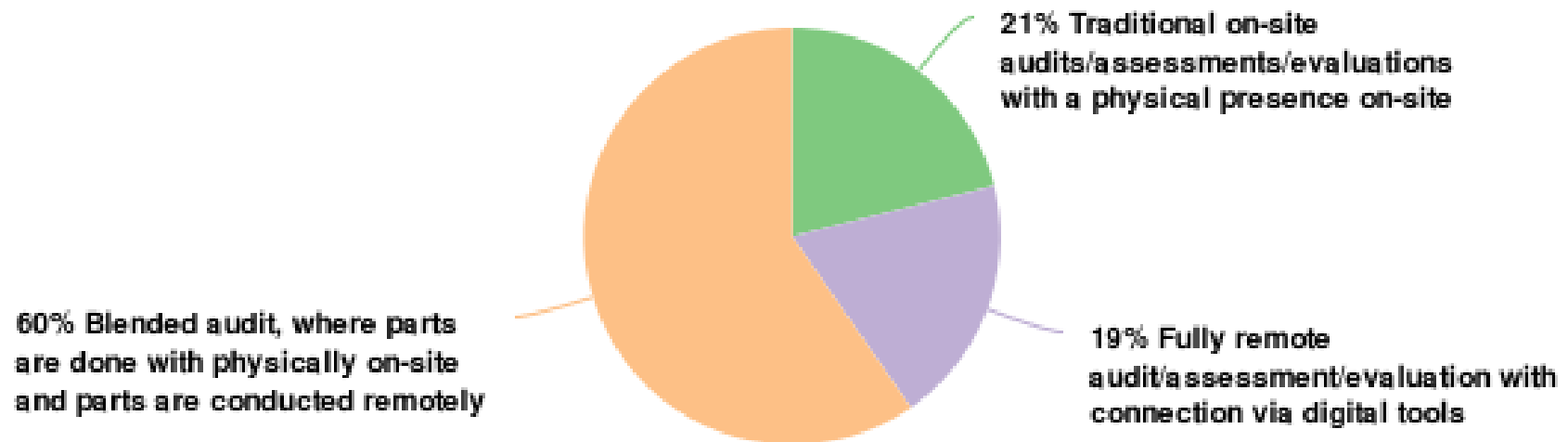


Do you think that the current rules (standards, IAF, ILAC, etc.) should be modified in some way to adapt to the new normal after the end of the pandemic?





Assume there are no longer any pandemic restrictions; what would you prefer



Remote accreditation and remote peer evaluation



- A remote assessment of a certification body doing a remote audit at their client can certainly be a challenge.
- A remote peer evaluation (so called “witnessing” in ISO/IEC 17011:2017) of the above is even more an issue.
- Non electronically documented/recorded information is somehow a showstopper for remote assessments. Similar is specialized systems that are automatized and not connected to the internet (e.g. big analyzers in medical labs).
- Non automatized activities is a larger challenge to assess remotely. Manual activities in particular.
- Confidentially issues (e.g. medical examination with patient details) and remote platforms (Teams/zoom)

Never forget that a lot happened remotely before covid-19



Many processes were also in the past done remotely:

- Document review of QMS.
- Review of MU evaluations and CMC's.
- Review of calibration (or test) procedures.
- Review of key records e.g. Management review and internal audit reports.
- Review of corrective actions to NC's from assessments.
- In the past QMS were printed paper controlled by the page.
- Then we had Latex and Word Perfect and later we got Word.
- And everything was sent by post man.
- We also did assess/communicate by phone.



A look into the future

- Now we have electronic QMS systems.
- We communicate by emails and send most documentation digitally via emails, USB sticks or by sharing drives or in the cloud.
.....
.....
- Remote assessments using Zoom or Teams is “just” another tool. It will not go away and will be a valuable tool for the future.

Is the glass half empty or half full?

