CASCO/STAR COVID-19 SURVEY

Introduction

A survey was conducted among the members of ISO/CASCO Strategic Alliance and Regulatory Group (CASCO/STAR) to collect their experience of coping with the COVID-19 pandemic. The key findings from the survey are summarized below, focused on two key areas:

- 1. maintaining business continuity, and
- 2. replacing on-site activities with remote activities.

The survey revealed some concerns but also indicated responses that emerged and potential areas for development in both areas.

The survey was conducted in May 2020, therefore some of the issues clearly reflect the current coping with the global pandemic.

Related resources are available on ISO.org.

1 Business continuity

The coronavirus (COVID-19) pandemic has impacted businesses all over the world. Every industry/sector had to adapt in order to maintain business continuity and avoid disruption. Not only the integrity of full supply chains, the individual conformity of the supplied products, provided services but also operating processes and systems were at risk.

The STAR survey revealed challenges with regard to maintaining business continuity in the conformity assessment community. The feedback also indicated responses that emerged, and tools used during the pandemic, to keep the business going.

The pandemic developed rapidly, leaving the market little time to make adjustments. The following examples of challenging situations were identified.

- Reorganizing meetings previously planned to take place face-to-face.
- Ensuring that all employees are equipped to perform their work from home with necessary technological support.
- Maintaining efficient communications with external experts on secured platforms.
- Establishing procedures and permissions to conduct meetings virtually (instead of usual inperson meetings).
- Developing a consistent approach applicable to all customers based in multiple industries and geographical jurisdictions was difficult.

In some cases, the restrictions related to COVID-19 pandemic led to the postponement of audits and assessments and some conformity assessment bodies (CABs) faced difficulties in accreditation renewal, due to the lack of opportunities for witnessing.

New accreditations, or in some cases extensions of scopes of accreditation, were more impacted. In addition, the transition period for the 2017 edition of ISO/IEC 17025 for the laboratories has been extended as a result of the COVID-19 pandemic.

Finally, the key challenge remained providing continued service to support industry (such as assured supplies or conformity assessment services for emergency production), regulatory authorities, market and the public.

Good practices

To maintain business continuity and as a response to the pandemic, the following good practices emerged.

- a. Establishing a coordination mechanism (e.g. a task force for fast response or a bulletin board for decentralised activities.;
- b. Detection and protection measures (e.g. providing equipment, monitoring employees' well-being and resilience.
- c. Timely and clear internal communication to staff about the new measures.
- d. External communication to clients and stakeholders (for example, an FAQ was put in place to respond to questions on how accreditation and certification activities can continue despite the restrictions on the onsite activities).
- e. Prioritise tasks and activities/ adopt a flexible time-planning (e.g. substitute, reduce or postpone activities, adopt audit dates, surveillance cycles, extend expiry of certificates), IAF ID3 and IAF COVID-19 FAQs provided instructions for special treatment for expiry dates of accreditation.
- f. Use alternative approaches (e.g. judging on "equally fit for purpose" rather than determining conformity with detailed requirements, reducing scope of CA statements, implementing 6eyes principle for review and decision).
- g. Use standards for proficiency testing (e.g. ISO/IEC 17043, ISO 13528) to assure competence and results of ad hoc testing and inspection (e.g. for pandemic prevention and protection materials).
- h. Adopt a risk-based approach to impartiality, quality of conformity activities and robustness of results (including probable effect of missed or misjudged nonconformities).
- i. Transparency and clarification of relevant rules and procedures by public authorities and scheme owners (e.g. permissions, acceptable adaptations).

The role of ICT

Business continuity was supported by increased use of ICT, such as remote meetings, webinars, platforms for remote assessments, tele- and videoconferences.

This includes the use of remote techniques in audits (e.g. audits by ICT, document review platforms, imaging by helmet-camera, drone, satellite, or sampling by proxy). In accreditation, IAF MD4 provides guidelines on the use of ICT. Some remote techniques were already well established such as on-line voting module for decisions required as part of the evaluation processes, use of emails to review evaluation reports and process the comments received as part of the review process. The witnessing component of evaluations may require more adaptations in future.

The following good practices can facilitate the use of ICT tools.

- Establish agreed methodology (e.g. develop a protocol for decentralised work, provide guidelines for remote activities).
- Adapt procedures (e.g. explicitly confirm and summarise information in virtual meetings, allow for screenshots or imaging as evidence).

Encourage personnel to become more knowledgeable and more familiar with ICT so that they
can trust and have confidence in using ICT in audits (e.g. develop guidance, training, test
runs).

2 Remote activities

Remote activities are understood as activities within the process of conformity assessment or accreditation, which do not require the physical presence of the assessing personnel at the site of the object of assessment.

Remote activities are mainly used as determination activities, but can contribute to all functions of conformity assessment, such as

- virtual meetings (with internal staff or with external clients and stakeholders),
- web-based document review.
- remote auditing, assessing and evaluating by ICT,
- review and decision making by electronic communication (e.g. by circular emails, web-based voting), and
- e-learning, webinars (e.g. for competence management and training of personnel).

Conditions and good practices for remote activities

Any remote activity relies on **electronic tools**, mainly information and communication technology, such as for exchange, virtual meetings, or interactive training.

Imaging can support interviews by video conferencing in audits or assessments, examination activities in inspection, and transferring test results obtained remotely.

Web-platforms with secure access, privacy protection and documentation functions are required for activities such as remote reviews of documents or results, online decision making, and electronic issues of conformity statements.

Remote activities require a high level of **awareness and oversight** by the conformity assessment body or accreditation body.

The risk-based approach of the body needs to take into account the particular threats when activities are not performed on site. Suitable applications and appropriate measures to minimise the risk can be based on a feasibility questionnaire.

Applicable requirements and relevant rules by public authorities and scheme owners (e.g. permissions, acceptable adaptations) need to transparent and clarified with regard to activities performed remotely instead of on-site.

Establishing a coordination mechanism (e.g. bulletin board for decentralised activities) as well as consistent approaches (e.g. organisation of headquarter visit and remote audits of sites, centralised decisions of decentralised activities standards for remote activities) help in providing reliable results consistently. However, the continued fulfilment of the applicable requirements and rules has to be evaluated and ensured.

When preparing for and **organising remote activities**, functionality of the technical resources and familiarity of the personnel with the electronic tools are essential. These should be ensured by technological support as well as training, coaching and supervision of personnel (e.g. technical competence, behaviour in virtual meetings, online learning management systems). Guidance and information should be provided, as well as conducting drills and test runs competent personnel and functional equipment. Back-up systems (e.g. fall-back methods, emergency and alternative contacts) further minimise the risk of failed remote activities.

When conducting determination activities remotely, plans and schedules need to be adapted, such as allowing for breaks, postponing process steps, providing for follow-up in enhanced surveillance. Likewise, procedures need to be adapted to be applied remotely, including explicitly confirming and summarising information in virtual meetings and allowing screenshots or imaging as evidence.

Limitations and threats regarding remote activities

Limitations to remote activities, and considerable threats, depend on the individual situation and can relate to a variety of reasons.

The STAR survey revealed the following concerns with regard to replacing on-site with remote activities. On the other hand, the feedback indicated potential areas for development of remote alternatives.

Limitations to remote activities according to STAR members

- Admissible adaptations of requirements and activities unclear or not granted by authorities, scheme owners or clients (e.g. local jurisdictions regarding privacy and data protection).
- Alternative methods (e.g. remote, virtual) are complicated due to lack of protocols, organisation, preparation and experience.
- Decentralised opinion formation and decision making requires procedures (e.g. for bilateral coordination and reporting system) and is time consuming.
- Decentralised work, lacking exchange and shared information, can lead to isolated views and results.
- Accumulation of actions when making up for postponed activities.
- Determination activities are impossible when time-sensitive (e.g. food) or physical Examination required (e.g. for installations).
- Launch of new services or taking up new clients are impossible without direct communication.
- Assuring conformity in a high-risk context is difficult or not possible.
- Auditing of sites with complex activities is difficult or not possible.
- Managing remote activities with large scopes are difficult or not possible.
- Monitoring personal performance is difficult or not possible.
- Observing situations is difficult/impossible (e.g. with trainees, for witness audits).
- Experiencing the atmosphere is difficult or not possible (e.g. the culture on-site of an organisation, non-verbal communication, behaviour in meetings).
- Authentication is difficult (e.g. of persons, documents).
- Cheating and fraud are less likely to be detected.
- Technical equipment and infrastructure (e.g. camera, internet bandwidth and security) govern the ability for remote activities.
- Evidence and documents need to be available for ICT-based exchange and sharing.
- Confidentiality, security and data protection issues with ICT-based exchange and sharing need to be resolved (e.g. consent by both sides, relevant legislation regarding recording).

CASCO/STAR COVID-19 survey Page 5

- Familiarity and skills with the equipment and the practice influence the ability for remote activities.
- Different time zones need to be taken into account.
- Local working environments may influence the activities (e.g. working from home).
- Misunderstandings are more likely.