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1.0 Introduction

1.1 Purpose Remote auditing activities are considered as standard auditing processes. Remote auditing is referred to in various international standards (ISO), IAF Informative Documents (ID) and IAF Mandatory Documents (MD). This IAF guidance explains specifically how these documents fit together, and how these can be applied for accredited food safety certification.

1.2 Scope Remote auditing activities are designed to support the existing accredited certification process. The scope includes audit methods defined in published documents for Certification Bodies (CBs) providing audits and certification under both ISO/IEC 17021-1:2015 and ISO/IEC 17065:2012. In addition, for Accreditation Bodies (ABs) accrediting conformity assessment bodies under ISO/IEC 17011:2017. When a scheme owner and/or regulator determine the requirements for remote audits and remote assessment, this document is superseded by these requirements and/or regulations.

1.3 Objective For many industry sectors, remote audits/assessments have been a normal part of the process for many years. Sectors include medical devices, food, aerospace, other manufacturing, banking, construction and rail. Example standards and schemes include:

- ISO 9001 Quality
- ISO 13485 Medical Devices
- ISO 14001 Environmental
- ISO 22000 Food
- AS 9100 Aerospace

Remote auditing activities are established to complement the overall audit process, not replace it. Food safety certification scheme owners can call up the relevant reference documentation listed in section 4.1 for provisions on remote auditing activities.

Product or process certifications may also require specific testing or inspection activities that may not be possible to be undertaken

remotely. Taking this into consideration, the objective of this document is to explain remote auditing activities.

1.4 Acronyms

Term	Definition
CPO	Certification Programme Owner
AB	Accreditation Body
CB	Certification Body
ISO	International Organization for Standardization
ID	Informative Documents
MD	Mandatory Documents
IAF	International Accreditation Forum (IAF)
CAB	Conformity Assessment Body
ICT	Information and Communication Technology
GAP	Good Agricultural Practices
GFP	Good Farming Practices
GHP	Good Hygiene Practices
PRP	Pre-requisite program

1.5 Definitions

Term	Definition
Audit	Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. (ISO/IEC 17000:2004)
Conformity assessment	Conformity assessment demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (ISO/IEC 17000:2004)
Effectiveness	Extent to which planned activities are realized and planned results achieved (ISO 9000:2015, 3.7.11)
Remote audit activities	Remote audit activities are performed at any place other than the location of the auditee regardless of the distance. (ISO 19011:2018)
Extraordinary event	A circumstance beyond the control of the organization, commonly referred to as “Force Majeure” or “act of God”. (IAF ID3:2011)

On-site audit activities	On-site audit activities are performed at the location of the auditee. (ISO 19011:2018)
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1.6 Roles and Responsibilities

CPOs, ABs, CBs are recommended for operating within the guidance provided in this document.

If any food safety certification scheme owner and/or regulator specifies the requirements on remote audits and remote assessment, such requirements should take precedence over this document.

The IAF is responsible for providing clarifications of existing IAF documentation. ISO is responsible for providing clarifications regarding ISO standards.

2.0 Remote Auditing Activities for Accredited Certification

2.1 Rationale Remote audit methods were introduced with guidance in ISO 19011:2011 Guidelines for auditing management systems (second edition) and updated with ISO 19011:2018 (third edition). Remote audit methods are further defined in IAF MD 4:2018 The Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes, which is applicable for its use in relation to ISO/IEC 17021-1 and ISO/IEC 17065 based schemes. In addition, remote assessments are referenced in IAF ID 12:2015 Principles on Remote Assessment which is used for AB assessment of CABs.

2.2 Risk Assessment Where a CB wishes to undertake a remote audit activity, as per IAF MD4:2018 clause 4.2.1, a risk assessment shall be undertaken to determine if audit objectives can be achieved. If only part of the objectives can be achieved and the remote activity proceeds, the CB shall document other activities required to complete the audit and meet the objectives, specifying the method to do so and considering an additional on-site visit when feasible.

The risk assessment shall include the ability of the organization to receive a remote audit, including:

- Availability of staff for remote activities
 - Availability of documentation and records in electronic form
 - Activities needed to verify implementation of systems, i.e. audit, inspection, product testing etc
 - Access to IT system that both, the CB and organization, will be able to use
 - Capability of organization staff to utilize technologies used in remote audit techniques
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2.3 Audit Planning

There is a need for effective planning for the remote audit to ensure that it effectively achieves stated objectives and minimum audit time. As per ISO 22003:2013 Annex B, Minimum audit time, both the remote audit and the on-site audit contributes towards the audit duration.

The types of issues to be considered in the planning phase are explained in guidance from ISO 19011 clause 6.2.3 Determining feasibility of audit:

The feasibility of the audit should be determined to provide confidence that the audit objectives can be achieved.

The determination of feasibility should take into consideration factors such as the availability of the following:

- a) Sufficient and appropriate information for planning and conducting the audit;*
- b) Adequate cooperation from the auditee;*
- c) Adequate time and resources for conducting the audit*

NOTE: Resources include access to adequate and appropriate information and communication technology

Technologies and methodologies utilized to undertake the audit must be agreed with by the auditee. As per IAF MD4:2018, clause 4.2.1, where the remote technologies and methodologies are not feasible, an alternative shall be proposed to the auditee, and in agreement with the auditee.

In reference to IAF MD4:2018, clause 4.1, the CB needs to also consider local data protection and privacy laws. It is important that if ICT such as video is utilized that relevant consents have been sought from individuals involved, so as to ensure compliance with local privacy regulations. Assigning work to audit team members should take into consideration their ability to utilize remote technologies.

Risk-based approach to planning is explained in ISO/IEC 17021-1:2015 clause 4.8 and supported in guidance from ISO 19011:2018 clause 6.3.2.1. The plan for a remote audit should still reflect the scope and complexity of the audit, as well as the risk of not achieving the audit objectives.

ISO 19011:2018 clause 6.3.2.1 subclauses a) to e) to be considered – and where objectives cannot be achieved remotely this should be

declared through the planning phase, and other monitoring activities replaced, or these activities deferred to when an on-site assessment can be undertaken.

2.4 Remote Audit

Examples of remote audits for accredited food safety certification could be:

- Remote 'off-site' audit for part of stage 1 as allowed for food as per ISO/TS 22003:2013, clause 9.2.3.1.3. Examples of what could be part of a remote audit are provided in Appendix B of this document
- Any food safety requirements reviewed by an auditor in the on-site office location of the organization, could be replicated or replaced with a remote audit e.g. documentation review
- Auditing facilities and processes using streaming video and audio footage through mobile or other technology

Examples of what could be part of a remote audit are also provided in Appendix B of this document.

IAF MD4 clause 0.3 provides some examples of the use of ICT during audits, which includes:

- Meetings; by means of teleconference facilities, including audio, video and data sharing
- Audit/assessment of documents and records by means of remote access, either synchronously (in real time) or asynchronously (when applicable)
- Recording of information and evidence by means of still video, video or audio recordings
- Providing visual/audio access to remote or potentially hazardous locations.

Apart from the above, it should also be noted that there may be different types of ICT that may be more applicable to some industry sectors. These may include:

- Seasonal Production e.g. drones for farm audits. Such remote access could complement an on-site audit to confirm continued implementation of GAP or GFP.
- Smart phones or wearable video technology for manufacturing processes. This can allow confirmation of continued implementation of GHP or PRPs and allow observation of practices.
- Reporting from in-line data monitoring systems.

IAF MD4 clause 4.2.3 considers to what extent ICT will be used e.g. for audit of documentation and records meetings held using video conferencing and online meeting platforms which are easily accessible and most often utilized.

A remote audit must be executed by auditors and other involved persons (e.g. drone pilots, technical experts) who have the competency and ability to understand and utilize the technology for the remote audit. For guidance for auditors planning and conducting remote audits, refer to ISO 19011:2018 Guidelines for auditing management systems, A.1 Applying audit methods. Refer to Annex A for ISO 19011:2018 Table A.1.

The responsibility of the effective application of remote audit methods for any given audit is with the CB planning the audit and the lead auditor.

In the case of an organization request to postpone an audit, there shall be a review and a deeper dive to look at data from the previous 12 months food safety performance of an organization.

A remote audit should also consider impacts to the organization if it is based on an extraordinary event. Examples provided in Appendix C of this document (refer to 3.0 Using Remote techniques during an 'extraordinary event').

If a remote audit indicates the specific food safety processes reviewed are under control, records and documentation reviewed as part of the remote audit are used as an input to the subsequent on-site audit and do not need to be duplicated and replicated again.

This would be the same principle as a stage 1 input to a stage 2 audit, defined in ISO/TS 22003:2013 clause 9.2 and ISO/IEC 17021-1:2015 clauses 9.3.1.2 and 9.3.1.3. Remote audit could be seen to be an evaluation activity as referred to in ISO/IEC 17065:2012 clause 7.4.

2.5 Non-conformities

Remote audit activities follow the same principles of the on-site audit activities and where non-conformities are identified, these are documented as per standard procedures (see ISO/IEC 17021-1:2015 clause 9.4.5 and ISO/IEC 17065:2012 Clause 7.4.6 and 7.4.7).

If a remote audit indicates the specific food safety processes that were reviewed were not fully under control, with documented audit findings, the auditor must follow up to determine effectiveness of any corrective action as defined in the scheme requirements. This may include on-site verification.

Documented findings for remote audit activities cannot conclude approval for certification or recertification but can lead to suspension for critical food safety findings.

2.6 On Going Monitoring

If the conclusion of the remote audit was to allow the certification to be maintained, the organization must continue to demonstrate the ability to produce safe food and to comply with certification requirements. The outcome of the remote audit is used as part of the subsequent on-site audit. If the organization is required to initiate a recall, they must inform their CB, who in turn must fulfill the normal CPO integrity program requirements (if applicable).

2.7 Accreditation Governance

ABs apply ISO/IEC 17011:2017 Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies, IAF ID 12:2015 Principles on Remote Assessment and IAF MD 4:2018 The Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes.

3.0 Remote Auditing Activities for an ‘extraordinary event’

3.1 Extraordinary Event

As per IAF ID3:2011, the “CAB to assess risk for continuing certification and understand the certified organization’s current and expected future situation.”

IAF ID3:2011 is primarily applicable for management systems certification, which is supported by ISO/IEC 17021-1:2015. It can also be applied to all the accreditation and conformity assessment activities for ISO/IEC 17065:2012.

For example, 36,105 sites globally are certified against ISO 22000:2005 Food Safety Management System (as per ISO Survey data, 2018). CBs who certify Food Safety Management Systems according to ISO 22000 requirements can perform remote auditing activities as part of the standard auditing process during any extraordinary event.

Regulators also demonstrate that on-site inspections can be replaced with off-site inspections during an extraordinary event e.g. US FDA conducting remote importer inspections under Food Supplier Verification Program (FSVP).

3.2 Risk Assessment

A risk assessment is required by IAF ID3:2011 to determine whether the need for postponement is justified or not. The risk assessment may be used to determine the risk of continuing certification and justify the recommendation regarding the applicability of performing a remote audit (see section 2.3).

The risk assessment shall include the ability of the organization to receive a remote audit, including:

- To what extent has operations been affected? Whether the organization remains operational. In the case an organization is not operational, a remote audit is not an option
- Availability of staff for remote audit activities during the ‘extraordinary event’
- Will the organization need to use alternative manufacturing and/or distribution sites? If so, are these currently covered under the current certification or will they need to be evaluated?

- Are there issues around supply of raw materials, including packaging materials, which may require re-validation of processes? Or does the organization have enough stored raw materials to get through the event?
- Has a contingency plan been established by the organization with assigned deputies in critical areas/ departments? If so, provide details to ensure remote interviews can be conducted

The risk assessment can also inform the parts of the organization's systems which should be monitored to have confidence in the continuing compliance of the system. In a food safety context these could include:

- HACCP system implementation and verification, in particular the outcomes of verification activities
- Raw material procurement, including supplier assurance programs
- Validation processes where raw materials supply has been significantly affected
- Handling of emergencies and incidents
- Handling of potentially unsafe products (nonconforming products)
- Management system related requirements that are indicators of an organizations control e.g. internal audit and management review, corrections and corrective actions etc

3.3 Extension Approval Decision

The outcome of the risk assessment must be documented by the CB with conclusions and evidence the organization's systems remain under control, and confirmation of the conformity assessment activities e.g. surveillances and/or recertification audits.

Audits may be postponed and/or the certificate validity extended by 6 months as per the definitions in IAF ID3:2011, '*for a period not normally exceeding 6 months beyond the original expiry date*'.

This should only occur where there is evidence that the organization's systems remain under control.

3.4 Post event activities If the organization has ceased to operate during the event, and will not return to operation, normal suspension and withdrawal procedures should be applied. If the organization has ceased to operate during the event, but intends to restart operations after the event, then start-up processes should be reviewed before certification can continue.

Once the event has passed and audit activities can return to normal the CB shall undertake the following analysis:

- Review the remote audit activities that have been undertaken
- Review any analysis that the organization has undertaken of the effects of the event on the operations of the organization.
- Review the audit program and remaining activities that are outstanding.

Based on this review determine the audit activities and the timeframe within which the activities should be undertaken.

4.0 Documentation

4.1 Reference Documents

Standard	Title
ISO/IEC 17021-1:2015	Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirement
ISO/IEC 17065:2012	Conformity assessment — Requirements for bodies certifying products, processes and services
ISO 19011:2018	Guidelines for auditing management systems
ISO 22000:2018	Food safety management systems — Requirements for any organization in the food chain
ISO/TS 22003:2013	Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems
ISO/IEC 17011:2017	Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

Informative Documents	Title
IAF ID 3:2011	Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations
IAF ID 12:2015	Principles on Remote Assessment

Mandatory Documents	Title
IAF MD 4:2018	The Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

<u>IAF MD 12:2016</u>	Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries
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5.0 Revision History

Version #	Description of Change
1.0	Initial Document Publication

Appendix A

Remote Audit Methods

From Annex A, ISO 19011:2018 Guidelines for auditing management systems

Table A.1 — Audit methods¹

Extent of involvement between the auditor and the auditee	Location of the auditor	
	On-site	Remote
Human interaction	Conducting interviews Completing checklists and questionnaires with auditee participation Conducting document review with auditee participation Sampling	Via interactive communication means: — conducting interviews; — observing work performed with remote guide; — completing checklists and questionnaires; — conducting document review with auditee participation.
No human interaction	Conducting document review (e.g. records, data analysis) Observing work performed Conducting on-site visit Completing checklists Sampling (e.g. products)	Conducting document review (e.g. records, data analysis) Observing work performed via surveillance means, considering social and statutory and regulatory requirements Analysing data

On-site audit activities are performed at the location of the auditee. Remote audit activities are performed at any place other than the location of the auditee, regardless of the distance.

Interactive audit activities involve interaction between the auditee's personnel and the audit team. Non-interactive audit activities involve no human interaction with individuals representing the auditee but do involve interaction with equipment, facilities and documentation.

The responsibility of the effective application of audit methods for any given audit in the planning stage remains with either the individual(s) managing the audit programme or the audit team leader. The audit team leader has this responsibility for conducting the audit activities.

¹ Table A.1 – Audit methods taken from *ISO 19011:2018*, Guidelines for auditing management systems, is reproduced with the permission of the International Organization for Standardization, ISO. This standard can be obtained from any ISO Member and from the Website of the ISO Central Secretariat at the following address: www.iso.org . Copyright remains with ISO.

Appendix B

Examples of potential activities suitable for remote audit

- Production records; CCP, OPRP, PRP, cleaning, maintenance, pest control
- Training records
- Changes to Food Safety Plan and HACCP System
- Corrective actions/NCP/Complaints/Recall
- Traceability and mock recall
- Allergen Control
- Environmental pathogen monitoring programme
- Management Review and Internal audit
- Food defense and food fraud vulnerability assessments

Appendix C

Examples of potential activities suitable for audit criteria in response to an extraordinary event

- Absence of key outsourced services e.g. pest control, cleaning
- Absence of key personnel
- Hiring new hourly employees to backfill absent employees
- Changes to ingredient and packaging materials; suppliers, specifications
- Changes to sanitization processes and mandatory protective clothes
- Documented deviations or exceptions to policies and procedures
- Potential impact in food defense or food fraud