Remote Activities in Relation to Accredited Certification of GFSI Certification Programmes

Proposal

There is acknowledgement that an accredited certification audit of a GFSI Certification Programme cannot be performed remotely, nor can a certificate be issued or reissued based on a remote audit (see action #1). The proposal definition "*remote activities*" refers to third party verification activities performed remotely and does not mean a remote audit.

The proposal is to:

- Short term; publish guidance around remote activities in relation to GFSI Certification Programmes to support the extraordinary event i.e. COVID-19, reinforcing confidence in the Programme.
- Longer term; capture the lessons learned from the application of this guidance into a formal guideline document to be used for usual surveillance remote activities that can complement and reinforce normal on-site audit activities, as well as provide a tool for future emergency situations.

It is essential to demonstrate unity during an extraordinary event. Any GFSI guidance published would need commitment and support from all key stakeholders; Conformity Assessment Body (CABs), Accreditation Bodies (ABs) and Certification Programme Owners (CPOs).

Why do we need remote activities guidance?

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

- ISO 9001 Quality
- AS 9100 Aerospace
- ISO 13485 Medical Devices
- ISO 45001 Health & Safety
- ISO 14001 Environmental

As defined in IAF ID3:2011 Management of Extraordinary Events[1] "*The CAB should assess the risks of continuing certification and establish a documented policy and process*". IAF ID3:2011 describes the "WHAT" to do in terms of a risk assessment. Without guidance or a guideline, there

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[1]IAF ID3:2011 asks the following question "Is IAF MD 4 .... applied?". A remote activities guidance can highlight the IAF MD 4 document is not mandatory or applicable in respect to allowing or accepting a remote audit for certification purposes for the food industry. This would demonstrate to regulators and Accreditation Bodies that IAF MD4:2018 has been taken into consideration, comparable to other industry sectors that apply IAF ID3: 2011.

will not be a consistent "HOW" to do in terms of a risk assessment. This could lead to different interpretations of what are the key risk focus areas (see action #2).

The challenge is variation of how each individual CAB, AB and CPO interprets risk. This can lead to variation in the consistency of CAB risk assessments. In addition, variation in risk assessment interpretation with the governance from ABs and risk assessment interpretation related to the various CPO integrity programmes.

A lack of a harmonized approach to risk assessments, focused on food safety principles, during an extraordinary event may result in the production, manufacture or distribution of unsafe food and critical failure e.g. consumer hospitalizations and/or deaths.

Guidance and guideline considerations

Guidance and guideline consideration should be given to remote activities performed by a CAB as part of a documented three (3) step process in order to allow a certificate expiry extension or not:

- Step 1 - Risk Assessment (high level) – based on the outcome of the risk assessment go to Step 2
- Step 2 - Remote Assessment (deeper dive)
- Step 3 - Remote Follow-up Actions (where applicable)

A risk assessment (Step 1) is important to determine whether the need for postponement is justified or not. In addition, to determine risk of continuing certification with a high-level risk rating to decide what is applicable with respect to a more detailed remote assessment.

A remote assessment (Step 2) must be executed by a qualified auditor, but it is not considered as an audit or replacement of an audit. It should be a review and a deeper dive to look at data from the previous 12 months food safety performance of an organization[2] e.g.

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

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[2] Examples provided in guidance must reference specific GFSI Benchmarking requirements

A remote assessment should consider impacts to the organization based on the extraordinary event[3] e.g.

- 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

Ability to assign actions (Step 3) with deadlines goes beyond a risk assessment and allows an organization to continue to operate whilst working to close out food safety related actions. As part of the remote assessment the auditor is permitted to assign actions where applicable to the organization with defined timelines for completion. The auditor will then follow-up remotely as per defined timelines to determine if the actions have been completed or not.

It is acknowledged that assigning actions remotely would be regarded as a new process. This should be considered because a risk assessment is required by IAF ID3:2011 to grant an extension. As part of the risk assessment, if an observation indicates a food safety process is not fully under control, it will mean a certificate extension could not be granted. With no option of an on-site audit, the certificate would expire. The impact to the organization would mean they would not be permitted to deliver to their customers who require a valid certificate to be in place.

Expected Outcomes of a Remote Activities

To reinforce the application of the principles of a certified Food Safety Management System:

- Remote activities are focused on protecting the consumer from harm
- Remote activities are intended to protect the client's brand and performance of food safety programmes in an extraordinary event
- Remote activities are not used the sole purpose of continuing certification.
- Remote activities do not consider criteria regarded as non-critical in protecting the consumer from harm.
- Remote activities determine the organization remains resilient in the production, manufacturing or distribution of safe food.
- Remote activities contribute to ensuring the integrity of the certificate

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[3] Examples related to an extraordinary event need to be aligned with GFSI Benchmarking requirements for crisis management or business continuity planning

Value Add of a Remote Assessment

Remote assessment can be used as an input to the subsequent on-site accredited certification audit:

- If CAB remote assessment indicates the specific food safety processes reviewed were fully under control, records and documentation reviewed as part of the remote assessment are used as an input to the subsequent on-site audit and does not need to be duplicated and reviewed again
- If CAB remote assessment indicates the specific food safety processes that were reviewed were not fully under control, with assigned actions, the auditor must follow up to determine effectiveness of the actions during the subsequent on-site audit

What a Remote Activities Guideline[4] for the Food Industry could look like

A guideline would be a "HOW TO" document with objective to explain what the remote activity process looks like; 1- Risk Assessment, 2- Remote Assessment, 3- Remote Follow-up Actions:

- Examples provided for recommendations what tools to collect, analyze and interpret data
- Examples of what templates could be used for good ways to document remote activities
- Restating remote activities are just like normal parts of the process
- Provide examples of what good CAB procedures, processes, policies and controls in place as to manage remote activities
- Explanation of the limitations, what remote activities are appropriate and what should only be considered as part of an on-site audit
- Provide a list of Frequently Asked Questions to help with a common interpretation
- Flow charts / diagrams to help consistent interpretation of risk

Recommended Actions

#	Action	Responsible
1	Attain consensus that accredited certification audits of GFSI Certification Programmes cannot be performed remotely.	GFSI
2	Publish guidance and a guideline for remote activities in relation to accredited certification of GFSI Certification Programmes.	GFSI

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[4] If a guideline was created, it could be used for future extraordinary events and used for normal day to day remote activities outside of managing an extraordinary event with reference to IAF ID3:2011.