



## Clarification on Risk Assessment for SQF Certified Sites Impacted by COVID-19

The intent of this guideline is to outline SQFI's expectations on when and how to conduct a risk assessment for sites that are unable to undergo an on-site recertification audit in their audit window due to COVID-19. This is not a change to SQF procedures, but a clarification based on the review of risk assessments submitted over the past month.

### 1. When to conduct a risk assessment

The risk assessment applies when a site's recertification audit is due, but the site is inaccessible due to COVID-19 restrictions.

The on-site audit continues to be the preferred option. If the site is accessible during the audit window, then the audit shall be scheduled and conducted as normal. (Note, the three-certification-cycle rule for auditors is waived during the COVID-19 period. If the only available auditor has completed three certification cycles at the site, that auditor can be used to complete a fourth site recertification audit during this period).

If the site's recertification audit is due but the site is inaccessible due to COVID-19 restrictions, the CB is required to conduct a risk assessment to determine the risk to food safety and the site's SQF system by extending the certificate.

Using the risk assessment information and the CB's risk analysis process, a risk level (e.g. low/ high) is assigned for determining certificate extension. Examples of low and high-risk levels are below:

- **Low.** Then the CB must request a six (6) month extension to the recertification audit using the on-line form. The risk assessment must be completed before completing and submitting the request for extension
- **High.** The CB should request additional information and conduct remote activities (see #3 below) to determine if the risk can be lowered to permit an extension

### 2. Conducting a COVID-19 Risk Assessment.

SQF licenced CBs are required to have a documented policy, procedure, and form in place to assess the risk of SQF certification during the COVID-19 pandemic. The policy may be part of their existing crisis management policy or may be a temporary policy implemented to meet the current pandemic.

The CB policy should define and distinguish between a risk assessment and remote activities (as outlined in # 3) and define a risk analysis process with definitions for risk levels and actions to take. The difference is in the purpose and extent of the assessment, although both are based on the IAF informative Guideline: IAF ID 3:2011 *Management of extraordinary events or circumstances affecting ABs, CABs, and certified organisations.*

The risk assessment is to determine the risk to food safety and the site's SQF system by extending the certificate. Note, the risk assessment is NOT intended to determine the risk of COVID-19 to the site, except to the extent that COVID-19 could affect the safety of the product and the integrity of the SQF system.



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The required information should be acquired by survey form and may be supported by interview with the SQF Practitioner if necessary. Each CB should develop their own risk assessment procedure. It is expected that a typical risk assessment would take approximately 1-3 hours. The following questions are suggested but are not mandatory:

- i. When will the site be able to function normally again?
- ii. Is the site able to continue to manufacture (produce, store, as applicable) products or perform the service defined within the current scope of certification?
- iii. If interrupted during the current crisis, when will the site be able to manufacture (produce, store, as applicable) products or perform the service defined within the current scope of certification?
- iv. Will the site need to use alternative raw material, packaging, or ingredient suppliers or service providers? If so, are these currently covered under the SQF system or will they need to be separately evaluated?
- v. Will the site be producing product for emergency situations outside the scope of certification?
- vi. Will some of the processes or products need to be subcontracted to other organizations or sites? If so, how will the other sites' activities be controlled by the certified site?
- vii. Does existing and on-going finished product inventory meet regulatory requirements and customer specifications for food safety (and quality if applicable) or will the certified organization need to contact its customers regarding possible concessions?
- viii. Has the certified site conducted an impact assessment of the COVID-19 pandemic? What impact is experienced or expected in the supply chain and/or site operations?
- ix. To what extent has operation of the SQF management system been affected? Have any activities been suspended?
- x. How has the current crisis impacted the availability of staff who are responsible for food safety, including staff responsible for sampling and testing, monitoring of CCPs, receipt and dispatch, cleaning, and maintenance.
- xi. Since the last recertification audit, have there been any:
  - Changes implemented within the food safety and, if applicable, quality management system?
  - Recalls, withdrawals or regulatory actions arising from the site?
  - Food safety (or quality, as applicable) complaints in the past year that facilitated any changes in the management system?
- xii. Has the facility completed all management review activities as required by the SQF Code?
- xiii. Have all internal audit activities been completed as required by the SQF Code?



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### 3. Remote Activities

Remote activities are an extension of the risk assessment and are only necessary when the risk assessment determines that the site is high risk and that further investigation and action is necessary to lower the risk so that a request for extension can be submitted (refer Attachment: Extraordinary Event Flowchart).

The CB policy should include remote activities. Remote activities are NOT complete recertification audits, and do not include remote GMP audits or inspections.

There is not a prescribed duration for remote activities. The duration will depend on the outcome of the risk assessment and extent of investigation necessary to maintain the integrity of the SQF system.

Areas of concern that are not in compliance may be raised by the CB during the remote activities, and may be addressed by the CB based on corrective action provided. If the CB determines that implemented corrective actions have significantly lowered the risk, then a request for extension can be submitted.

Thr remote activities shall build on the information received during the risk assessment. Only evidence that will lower the SQF system risk shall be requested from the site.

Remote activities may include a detailed review of (as appropriate):

- Site management reviews, internal audit records, site GMP inspections, customer complaints, and corrective action records;
- Records of CCP monitoring, environmental and finished product testing, product release, raw material receipts, pre-production inspections;
- Changes to the SQF system, and in particular the food safety plan (and food quality plan, as appropriate) since the last recertification audit;
- Follow-up on corrective actions raised at the last recertification or surveillance audit.

Remote activities may also include remote interviews with:

- The site manager, departmental managers, SQF Pracioner, and/or key staff as necessary.

Where the CB determines the risk cannot be lowered by remote activities, the site's certificate will expire at it's current expiry date.

## Process Flow for Determining the Risk for Extending the Certificate

