

PrimusGFS General Regulations - Appendix 1 Remote Activities Guidance

Used in conjunction with the PrimusGFS v3.1 & v3.2

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1. Introduction:

- a. The use of remote activities are authorized when used in accordance with the International Accreditation Forum's MD-4:2018 "Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes". As detailed below these remote activities include the use of a remote documentation desk review (herein referred to as a desk review). This audit approach will allow an auditor to review all applicable documents related to the organization's PrimusGFS program prior to arriving on-site for the physical inspection.
- b. The PrimusGFS General Regulations and this document must be used in conjunction with each other when conducting a desk review.

2. Application:

- a. A desk review option can only be requested for announced or pre-assessment audits.
- b. The organization must select the PrimusGFS desk review option when completing the PrimusGFS application with their Certification Body (CB).
- c. The CB has the authority to reject an organization's desk review request depending upon the specific risks associated with the organization.
 - i. Risks may include complaints or recalls related to the organization; history and maturity of the organization's PrimusGFS food safety management system; pending compliance or legal related issues; significant changes to their management or operation system, for example, a change of physical location, a change in the scope of activities, etc.

3. Execution:

- a. After the application has been reviewed and approved by the CB, the organization must complete a self-assessment and submit the required documents following the document: *PrimusGFS Documentation and/or Visual Observations Requirements*.
 - i. The auditee's self-assessment and required documents should be submitted through the use of a method or program meeting the requirements of MD-4:2018-IAF such as:
 - The PrimusGFS 1st party audit tool in the PrimusGFS Auditee System
 - The Azzule Supply Chain Program Compliance Grid
 - Or another secure ICT method for the use of sharing documents between the CB, Auditee, and Auditor.
- b. The CB will assign an auditor to conduct the desk review and conduct the on-site audit. The same auditor must be assigned for both the desk review and the on-site audit.
 - i. The auditee's self-assessment and the CB's selection of an auditor may occur simultaneously.
- c. Once an auditor is assigned and the organization's self-assessment and applicable documents are submitted, the auditor must be granted access to review the information, prior to the on-site audit.
- d. The CB must verify the organization and the auditor have an agreed audit plan to ensure the desk review will be finalized prior to the on-site audit.
- e. There shall be no more than thirty (30) days between the use of desk review and the completion of the on-site audit.
 - i. Under specific circumstances where the 30-day requirement cannot be met, the CB should have a process in place to analyze and identify any risks associated with the organization (e.g., risk assessment as per Section 2, c. i.) prior to granting the extended period between the desk review and on-site audit. Due to GFSI v2020.1 Part II 5.34.1, the time period cannot be extended more than ninety (90) days.

- f. The onsite audit includes the physical inspection of the operation(s) including verification of the FSMS, GAP, GMP, HACCP polices, SOPs, and records assessed during the desk review.
- g. The non-conformances found during the desk review should not be discussed with the organization until the auditor arrives on-site to complete the audit process.
- h. Once the desk review and on-site audit are completed, the auditor must submit the preliminary report in the PrimusGFS system within 15-calendar days of the on-site audit. The preliminary audit report must not be submitted until the desk review and the on-site audit(s) are completed.
- i. The organization has thirty (30) calendar days from the on-site audit date to review and respond to their non-conformances. This stipulation follows the PrimusGFS General Regulations section 12 Non-conformances and Corrective Actions.

Document Revision History

Date	Rev. No.	Description
Jan 2021	2	Updates to Address GFSI v2020.1 remote activities, including use if IAF MD-4:2018, applicability to announced and pre-assessment, and the time period from desk review and on-site audit.
Apr 2021	3	Updates to address what is included in the on-site portion of the audit. updates included in 3. e