

PrimusGFS General Regulations- Appendix 3

Guidance for the Closure of Non-conformances and Corrective Actions

Used in conjunction with the PrimusGFS v3.2

PrimusGFS (owned by Azzule Systems, LLC)

Contact Us:
PrimusGFS@azzule.com

Santa Maria, California, U.S.A. +1-805-862-4219
Culiacan, Sinaloa, Mexico +52-667-716-5037
Viña del Mar, Chile +56-32-332-5045

The questions in the PrimusGFS program are categorized into one of the following four types:

1. Automatic Failure Level – These questions are of critical importance to food safety and/or applicable government regulations and a deficiency/down score will result in an automatic failure of the audit.

2. Essential Level – These questions are of essential importance to food safety and/or applicable government regulations due to the potential concerns regarding conformity of a product/process or statutory requirements. These are identified with a caution symbol (⚠) throughout the PrimusGFS v3.2 Question & Expectations and Checklist.

3. General Level – these are questions that do not have any critical or essential food safety and/or applicable government regulations issues related to the product/process or statutory requirements.

4. Information Gathering – these are questions that have no points given and are used to gather additional information.

All non-conformities must be addressed with corrective actions or corrective action plans submitted by the auditee within 30 calendar days from the date of the audit. Closure of nonconformities shall be handled through the guidance for each category as stated below.

Corrective Action – the action taken to correct a deficiency found during an audit. The corrective action documentation shall include a determination of the cause (i.e., root cause analysis), actions taken to mitigate any immediate issues due to the deficiency (e.g., placing product and/or field on hold, recall, etc.), corrective actions taken and preventive actions to avoid recurrence if needed.

Corrective Action Plan – the documented plan of actions to be taken to correct the deficiency, this shall include a determination of the cause, evidence of the intent to complete (e.g., purchase orders, service requests, etc.), the expected timeframe for completion, actions taken to mitigate any immediate issues due to the deficiency (e.g., repairs, training, placing product and/or field on hold, recall, etc.), and/or a documented risk assessment with evidence of mitigation measures in place which show that the identified issue or non-conformance is controlled.

Corrective action evidence can be in the form of documents, records and/or photographs and it must show that the non-conformance has been adequately addressed.

The non-conformance closure process with the four categories is defined as:

1. Automatic Failure Level Questions

The status of the corrective action will be shown on the Corrective Action report as “CA Accepted - Yes or No” and the corrective action will be designated as “Closed” in a RED box whether the CA was accepted or not, until a new on-site audit of the entire operation by the CB can be completed. (see below scenario section for example of this box image from a final corrective action report).

Note: There are a number of questions that result in an automatic failure of the audit if and only if the question is scored as NC – 0 points. These questions are notated with the following statement, **A ZERO POINT DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.** In this case the questions shall be handled as shown above for Automatic Failure Questions. If scored with a Major or Minor Deficiency, then they shall be addresses as an Essential Level Question below.

2. Essential Level Questions

Major and Minor Deficiencies

a. The CB and/or auditor will review the corrective actions and/or corrective action plans submitted. If they accept

the evidence as submitted it will be indicated on the Corrective Action report as "CA Accepted – Yes" and the corrective action will be designated as "Closed" in a GREEN box. (see below scenario section for example of this box image from a final corrective action report). The CB and/or auditor's acceptance of the corrective actions taken will upgrade the question score (e.g., from a Major to a Minor/ Total Compliance) and additional points will be awarded that coincide with the upgraded score.

b. If the CB and/or auditor determines that the submitted corrective actions are unacceptable or that the auditee chose not to submit a corrective action, this will be indicated on the Corrective Action report as "CA Accepted – No" and the corrective action will be designated as "Closed" in a RED box. (see below scenario section for example of this box image from a final corrective action report). This will result in the audit not being certified.

Non-Compliance Deficiencies

a. The CB and/or auditor will review the corrective actions and/or corrective action plans submitted. If they accept the evidence as submitted, it will be indicated on the Corrective Action report as "CA Accepted – Yes" and the corrective action will be designated as "Closed" in a GREEN box. (see below scenario section for example of this box image from a final corrective action report).The CB and/or auditor's acceptance of the corrective actions taken will upgrade the question score (e.g., Non-Compliance to partial scoring or Total Compliance) and additional points will be awarded that coincide with the upgraded score.

b. If the CB and/or auditor determines that the corrective actions are unacceptable or that the auditee chose not to submit a corrective action, this will be indicated on the Corrective Action report as "CA Accepted – No" and the corrective action will be designated as "Closed" in a RED box. (see below scenario section for example of this box image from a final corrective action report).This will result in the audit not being certified.

During the next audit the auditor must verify that the corrective actions/corrective action plans implemented/submitted adequately addressed the original issue and that these actions were effective. When the corrective action/corrective action plan has been found to be ineffective or not have adequately addressed the issues, questions 1.01.03 and 1.03.03 should be evaluated by the auditor to determine if a non-conformance should be raised during that audit.

3. General Level Questions

Major and Minor Deficiencies

a. The CB and/or auditor will review the corrective actions and/or corrective action plans submitted. If they accept the evidence as submitted it will be indicated on the Corrective Action report as "CA Accepted – Yes" and the corrective action will be designated as "Closed" in a GREEN box. (see below scenario section for example of this box image from a final corrective action report). The CB and/or auditor's acceptance of the corrective actions taken will upgrade the question score (e.g., from a Major to a Minor/ Total Compliance) and additional points will be awarded that coincide with the upgraded score.

b. If the CB and/or auditor determines that additional on-site verification of the corrective action is necessary this will be indicated on the Corrective Action report as "CA Accepted – Pending Verification Next Audit" and the corrective action will be designated as "Closed" in a RED box. (see below scenario section for example of this box image from a final corrective action report). This does not result in a failed audit.

Non-compliance Deficiencies

a. The CB and/or auditor will review the corrective actions and/or corrective action plans submitted. If they accept the evidence as submitted it will be indicated on the Corrective Action report as "CA Accepted – Yes" and the corrective action will be designated as "Closed" in a GREEN box. (see below scenario section for example of this box image from a final corrective action report).The CB and/or auditor's acceptance of the corrective actions taken will upgrade the question score (e.g., Non-Compliance to partial scoring or Total Compliance) and additional points will be awarded that coincide with the upgraded score.

b. If the CB and/or auditor determines that the corrective action/ corrective action plans are unacceptable or that the auditee chose not to submit a corrective action, this will be indicated on the Corrective Action report as "CA Accepted – No" and the corrective action will be designated as "Closed" in a RED box. (see below scenario section for example of this box image from a final corrective action report).This will result in the audit not being certified.

During the next audit the auditor must verify that the corrective actions/corrective action plans implemented/submitted adequately addressed the original issue and that these actions were effective. When the corrective action/corrective action plan has been found to be ineffective or not have adequately addressed the issues, questions 1.01.03 and 1.03.03 should be evaluated by the auditor to determine if a non-conformance should be raised during that audit.

4. Information Gathering Questions

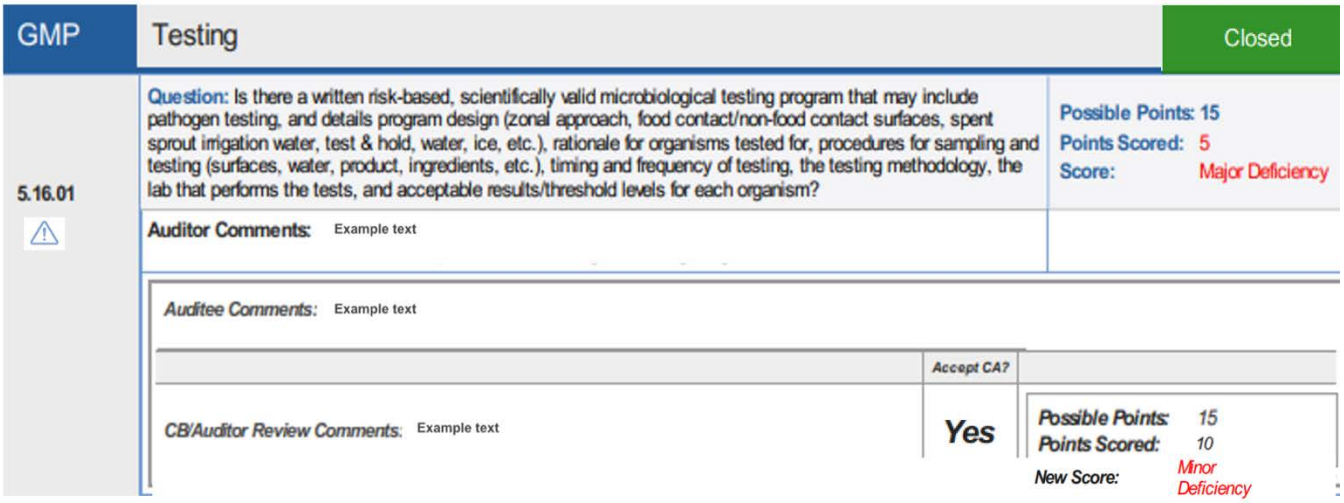
Used only for gathering information and no points are awarded for these questions. Corrective actions or corrective action plans are not required for this category.

Audit Scenarios For Non-Conformances And Corrective Action Closures

Scenario A:

Operation receives a Major Deficiency down score for the Essential Level question 5.16.01 – Module 5 GMP. The operation provides the action taken to correct the deficiency found in their environmental program, which included the determination of the cause (i.e., root cause analysis) and actions taken to update their program, and a future date of training the workers on the procedural updates.

The auditor/CB accepts the corrective action and awards partial points, because a future date for employee training was provided and there is not immediate evidence that applicable workers have been trained on the updated program, a Minor Deficiency is given rather than Total Compliance.

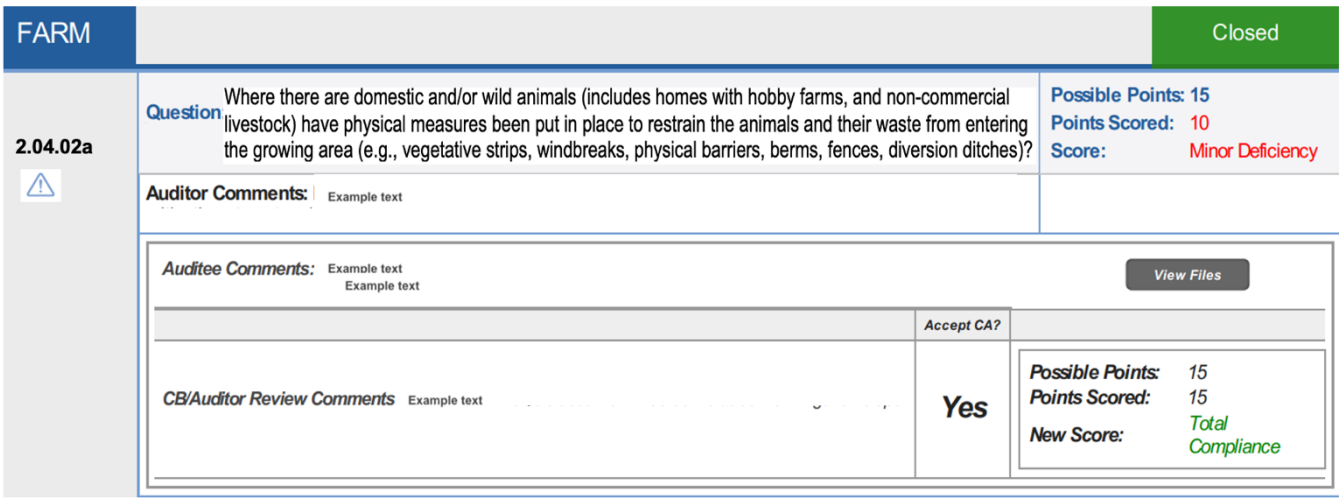


Scenario B:

Operation receives a Minor Deficiency down score for Essential Level question in Farm 2.04.02a – Module 2 Farm

The operation provides corrective actions and corrective action plan evidence. For example, the corrective action included determination of the cause (i.e., root cause analysis), the immediate actions taken to mitigate the immediate issue due to the deficiency, expected timeframe for completing their full corrective action plan, and their risk assessment for the issue and situation identified. Perhaps, the operation even provided training on certain topics related to the deficiency.

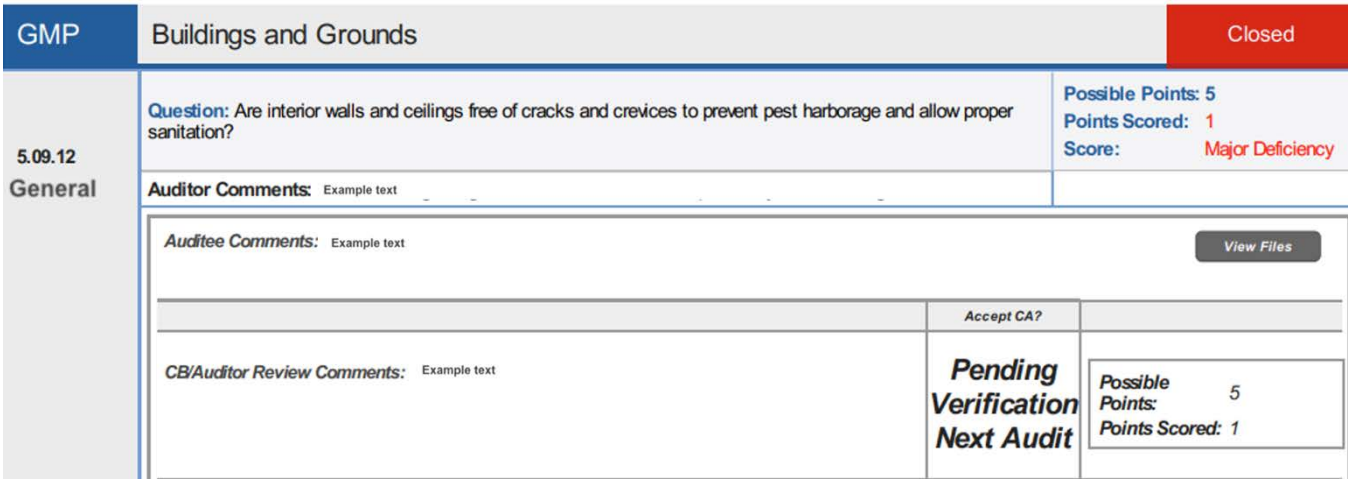
The auditor/CB accepts the corrective action and awards points re-scoring to Total Compliance.



Scenario C:

Operation receives a Major Deficiency for General Level question 5.09.12- Module 5 GMP. The operation provided only a portion of their corrective action and corrective action plan evidence. For example, the corrective action included determination of the cause (i.e., root cause analysis), the immediate actions taken to mitigate the issue, their risk assessment for the issue and situation identified, but their plan did not include the timeframe for completing the maintenance scheduled to fix occurrences of cracks on the interior production floor walls.

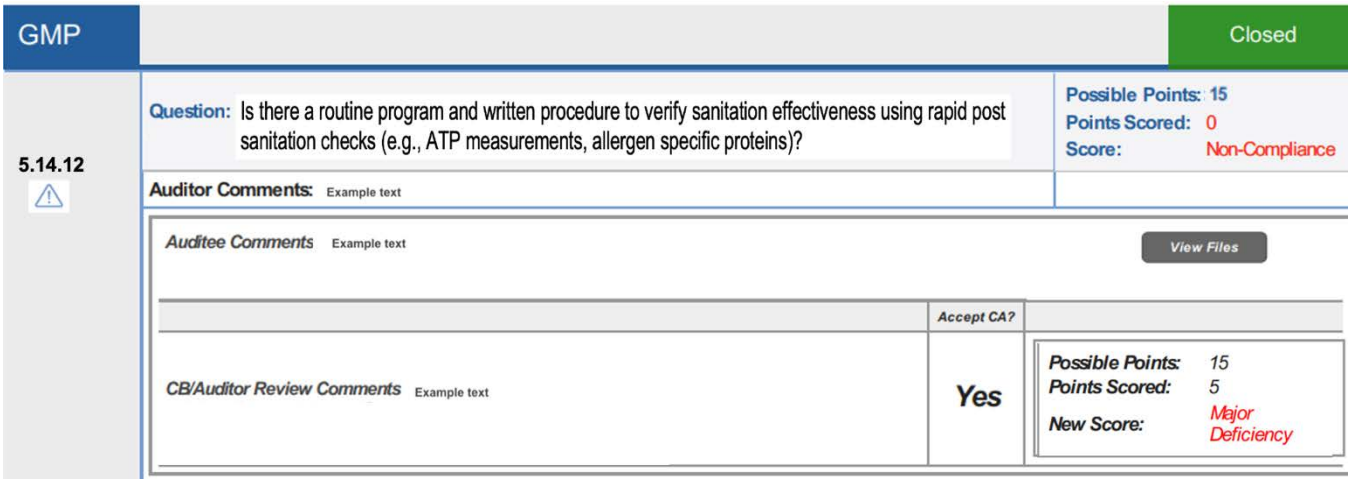
The auditor/CB acknowledges in the comments that actions were taken by the operation but no schedule was provided. The CB makes the decision to close the nonconformance for this audit with the missing corrective action element but the operation must correct the issue completely and it will be reviewed during the next audit.



Scenario D:

Operation receives a Non-Compliance down score for the Essential Level question 5.14.12 - Module 5 GMP. The operation provides corrective actions and corrective action plan evidence. For example, the corrective action included determination of the cause (i.e., root cause analysis), the immediate actions taken to mitigate the immediate issue due to the deficiency, expected timeframe for completing their full corrective action plan, and their risk assessment for the issue and situation identified. Perhaps, the operation provided evidence the ATP device was purchased, their program was updated to include ATP thresholds and there was evidence indicating ATP checks are beginning to take place.

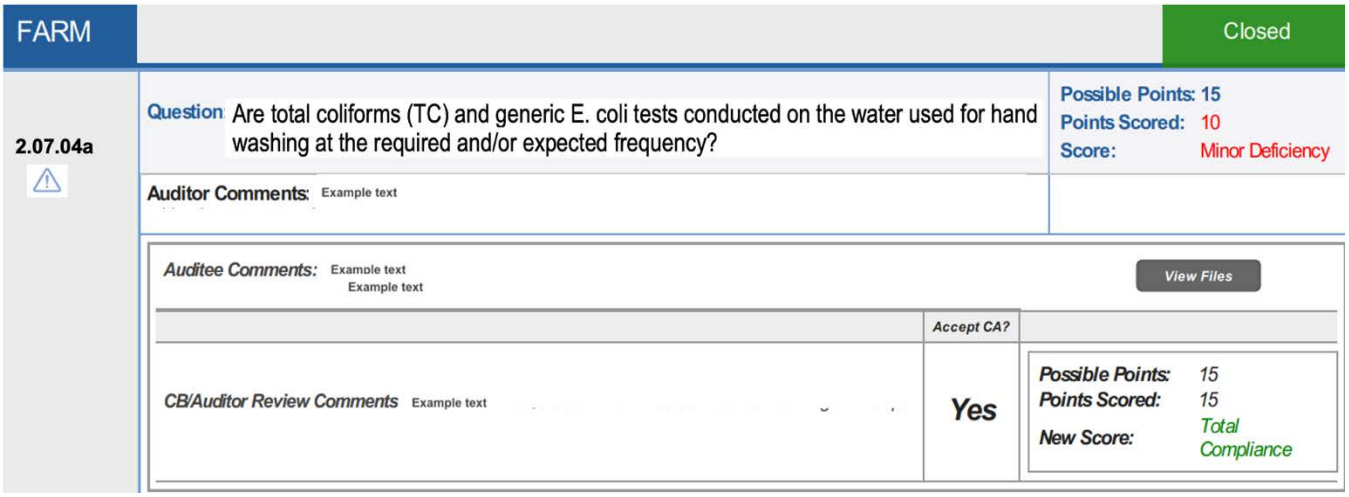
The auditor/CB accepts the corrective action and awards partial points, re-scoring the question to a Major Deficiency because more time is needed to ensure full implementation of the programs completed.



Scenario E

Operation receives a Minor Deficiency down score for the Essential Level question 2.07.04a – Module 2 Farm. At the time of audit the hand washing water testing did not account for one of the two water sources used. The Operation provided a corrective action, perhaps the evidence was a suitable test result for the second water source, the evidence provided included the determination of the cause (i.e., root cause analysis), the immediate actions taken to mitigate the immediate issue due to the deficiency, expected timeframe for completing their full corrective action plan, and their risk assessment for the issue and situation identified.

The auditor/CB accepts the corrective action and awards points re-scoring to Total Compliance .



Document Revision History

Date	Rev. No.	Description
9/24/21	0	Initial