

Guidance on non conformity grading, time frame to close NCs and certification conditions

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This document provides **Clarification and Guidance on the grading of the severity of potential non conformities (NCs)** arising from an FSSC 22000 Certification audit and **defines the time frame required to close NCs.**

While the grading of NCs remains the responsibility of the CBs, the aim of this document is to achieve a more uniform agreement between the Foundation and FSSC 22000 licensed CBs in the definition of what constitutes a Minor or Major NC.

Definitions

Additional clarification on the definition of NCs is taken up in the [Features of the FSSC 22000 scheme documents](#).

- **Minor Non Conformity:**

A failure in a requirement of the Management system which does not impact the capability to achieve the expected outcomes.

- **Major Non Conformity:**

A failure to fulfill one or more requirements of the Management System that raises doubt about the capability of the management system to achieve the expected food safety outcomes in the Food chain or to effectively control the process for which it was intended.

NOTE 1: in the context of a FSMS, the expected outcome is typically a safe product.

NOTE 2: a number of minor non conformities associated with the same requirement or issue could demonstrate a systematic failure and thus constitute a major non conformity.

NOTE 3: definition adapted from draft revision of the ISO 17021.

Audit findings that could lead to a Major NC

1. Failure to document and implement FSMS requirements effectively.
2. FSMS failure with a direct impact on the safety of the food.
3. Multiple minor failures that cumulatively indicate that the capability of the FSMS to achieve the expected outcomes is in doubt.
4. Failure to resolve any food safety relevant issues in a timely manner.
5. Unresolved minor NCs within the agreed timeframes.
6. Evidence of situation which raises a doubt as to the safety of the food and/or unsafe product without any measure taken to control the concerned potentially unsafe product.

Time frame to close NCs

If a **Minor NC** is identified in an audit a proposed corrective action plan is **required within 3 months of the audit**. Corrective actions should be completed within 12 months after the audit. Implementation / completion of the corrective plan should be reviewed, at the latest, at the next on-site audit.

If a **Major NC** is identified in an audit, the client must provide objective evidence of a root cause analysis and proposed corrective action plan, agreed on by the CB. This should be provided **within 14 days of the audit** and the MNC closed within a further 14 days.

The implementation of the corrective actions might take more time depending on the potential severity of the NC. In such cases the corrective action plan must include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented.

A Major NC is automatically raised (on management responsibility & resource allocation) in the event of non-completion of the approved action plan.

When food safety is at risk this should be reflected in both the wording and grading of the NC and the corrective action plan provided by the client.

If food safety is at risk, a certificate should be withdrawn within 5 working days (max).

Certification conditions

An FSSC 22000 Certificate will only be achieved when

- all action plans related to the Minor non-conformities have been accepted;
- all Major non-conformities have been completed.

A repeat audit is required in cases where any non-conformities are not resolved and the certificate not issued within 3 months of the original audit date.