Document Type: Procedure Manual		Department: C S	
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 1 of 17

1. THE MANAGEMENT SYSTEMS CERTIFICATION PROCESS

1.1 **Purpose**: The purpose of this procedure is to ensure that the Certification process of

FSSC 22000 management systems and subsequent surveillance audits of organizations are done consistently in accordance with: - ZWS ISO/IEC 17021, ZWS ISO/TS 22003 & FSSC 22000 Requirements for

Certification Bodies.

1.2 **Scope**: This procedure covers the whole Certification process, i.e. from the inquiry

stage through to actual Certification and the ongoing surveillance audits of organizations' FSSC 22000

management systems as per QA/FD/1, QA/FD/2.

1.3 **Responsibility**: The **Manager** CS is responsible for implementing,

maintaining, improving and revising this procedure.

1.4 **Relevant Documents**: Forms

QA F/1b, QA F/2b, QA F/3, QA F/4, QA F/5, QA F/6, QA F/7, QA F/8, QA F/10, QA F/11, QA F/16, QA F/32, QA F/34, QA F/35, QA F/37, QA F/44, QA F49, QA F/11a, QA F/60 or 60a, QA F/70, **QA F/71**, QA F/50, QA F/51,

QAF 57b,

Standards

ZWS ISO 9001, ZWS ISO 22000, ZWS ISO/TS 22003, & ESSC 22000, ZWS ISO 10011, ZWS ISO 17021

FSSC 22000, ZWS ISO 19011, ZWS ISO 17021

IAF DOCUMENTS

IAF MD 5: IAF MD 1: IAF MD 2: IAF MD 3: IAF MD 4

Procedures

PR 17, PR19, PR/20, PR/21, PR/32, PR/44, PR 47b

Flow Charts

QA FD/1, QA/FD/2

Other Documents

Audit Program, Audit Plan (QAF 100)

Proforma Invoice, Tax Invoice

Credit Application Form

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 2 of 17

1.5 **Activity Description**:

The description of the management system certification process is in the form of a flow diagram QA FD/1 and QA FD/2 (attached). In order to clarify what happens at some of the stages during the Certification process, an outline of those chosen activities is given below; therefore, this document should be read together with QA/FD/1 and QA/FD/2, Certification process flow charts.

1.5.1 <u>General Guidance</u>

- 1.5.1.1 The Director CS, Manager CS, Management Systems Auditors or any delegated personnel to offer general guidance on the requirements of the various standards on offer for certification and the certification process.
- 1.5.1.2 An information pack (FD1, Certification process questionnaire, Guidance to certification process and PM 31) on the Certification process and the series of standards on offer is given to those prospective applicants who express their serious wish to implement any or a combination of the management systems.
- 1.5.1.3 It is important to note that CS does not offer consultancy services to organizations implementing management system standards.
- 1.5.1.4 It is necessary that at enquiry stage, the organization furnishes the Lead Audtor with adequate information for the auditor time to be determined. This information is used to complete the **Determination of Auditor Time Form (QA F/57b)**according to PR38b Procedure Determination of Auditor Time for FSSC/ISO 22 000 FSMS Certification.

Enquiries shall be captured on Form (QAF 14b) or Certification questionnaire by the client or by anyone who receives enquiry from a client. The enquiry shall be forwarded to the relevant **Lead auditor or Trainee Auditor** who shall ensure that audit time has been determined. The Audit Time Calculations shall be approved by the Manager CS or Director CS.

1.5.2 **Quotation for Certification**

1.5.2.1 When an organization makes an enquiry for a **Quotation for Certification or Proforma Invoice**, the Auditor goes through with the prospective client organization, the Determination of Auditor Time Form (**QA F/57b**), following

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 3 of 17

procedure **PR38b** and PR 39 in order to determine the auditor days for the Stage 1 and Stage 2 Audits. The audit time shall be conducted with a person with competence as approved by the CS Manager. The CS Manager shall approve the audit time forms and ensure a quotation is prepared is sent to the client by the respective Lead auditor.

- 1.5.2.2 A Quotation is then drawn up according to the auditor days determined. In some cases, it is possible to do a quotation after receiving application forms from the potential client.
- 1.5.2.3 If the Quotation is accepted, the organization completes an application form **QAF/01b** which is reviewed as in Section 1.5.3 of this procedure. On acceptance of the application, the client and the CS Director or CS Manager sign a legally binding agreement/contract, **QA F/02b**
- 1.5.2.4 Quotations must be processed as per Certification Services' turnaround timeframes.
- 1.5.2.5 The processing of the organization's application can only commence after they have formally confirmed by completing and submitting the application form, **QA F/1b**, which the Director CS has to either accept or reject.
- 1.5.2.6 Quotations shall be revised on request, whenever there are changes in operating charges.

1.5.3 **Application Review**

- 1.5.3.1 The organization shall fill in the application form i.e. **QA F/1b** preferably when their documentation is ready for evaluation.
- On receipt of the application form, the Auditor shall review the application and propose an audit team; and a technical advisor where such competence is not available in the Registration Approval Board (RAB). If competency is available or if it can be made available within 12 months, the Manager CS accepts the application. If there is no competency and it cannot be made available within 12 months, the application is rejected and the client is made aware of the reasons. When the application has been reviewed, the Executive Secretary opens an RaFSSC file for the organization with a unique identification and forwards the file to the Manager CS.
- 1.5.3.3 The Manager CS shall assess the application form and confirm acceptance or rejection.

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C S	
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 4 of 17

- 1.5.3.4 The **Manager CS** shall also verify whether the **Scopes** on the application form is already covered on the Southern Africa Development Community Accreditation Services(SADCAS) or FSSC/ISO 22 000 Schedule.
- 1.5.3.5 If the scope is not covered, the Manager CS shall formally make an application to the accreditation body for the relevant scope. For critical scopes, the accreditation body shall be invited to witness the stage 2 audit followed by office file assessment. A certificate with the accreditation body shall only be issue to the client after the accreditation body has formally communicated to SAZ CS that the extension of scope has been granted. This shall also have been communicated to the applicant that their scope is not yet under the scope of accreditation and that the accreditation body will have to witness their stage 2 audit. For noncritical scopes, the CS Manager shall make application to the accreditation body for scope extension and either invite the accreditation body assessment of the file or the file can be send to the accreditation body for scope extension consideration. SAZ CS shall not issue any FSSC 22000 certificates without prior licensing of the scope/category by the FSSC Foundation.

SAZ CS can alternatively accept the application for non-accredited scopes and proceed to certify the client but they will be issued with a certificate that does not bear the accreditation body symbol and the client will have been informed of this at application review. The CS Manager shall apply to the accreditation body for scope extension where witnessing (for critical scopes) assessment of the file may be carried during scheduled surveillance assessments.

- 1.5.3.6 The Organization reserves the right to object to an audit Team Member(s) and **Procedure PR34** shall be followed.
- 1.5.3.7 In the event that a client requests for a Preliminary Audit /Gap analysis audit, this shall be carried out in line with procedure **PR 48.**

1.5.4 Stage 1 Audit

1.5.4.1 **Purpose**

- To verify the physical address and Certification status of organization;
- To check from discussions, the organization's status and understanding of the standard requirements (system documentation, planning, operational control, management reviews, internal audits, corrective and risk assessment processes);

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department C S	
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 5 of 17

status concerning the identification of key performance or significant aspects, processes, objectives, and operation of the management system;

- To determine the scope of the management system and related statutory and regulatory requirements and compliance;
- To verify whether the documented management system complies with the requirements of the relevant standard;
- To assess the organization's preparedness for stage 2/certification or recertification audit
- To verify and confirm adequacy of information supplied on the application form.
- 1.5.4.2 The **Lead Auditor or Trainee Auditor** shall contact the organization to agree on the date for the audit and the audit shall be conducted on site or offsite upon approval by CS Manager or CS Director. **The Auditor who undertakes the stage 1 shall have the necessary competence for the sector/category.**
- 1.5.4.3 The Auditors shall assess the documentation and interview a representative sample of personnel throughout the structure of the organization to assess the level of awareness of the standard to which certification is being sought. The level of preparedness for the Stage 2 Audit is determined from the findings raised in the documentation and the concerns raised from the interviews, as well as from the capacity within the SAZ to provide the certification service. The Lead Auditor or Trainee Auditor shall prepare and Audit Programme if Stage 2 has been recommended. A report is prepared on the FSSC Standard Report (QA F/60b) on which the organization and the Auditor also agree on the estimated time the organization and CS need to prepare for the Stage 2 audit. The applicant shall be required to institute corrective action on issues of concern raised during stage 1 and request SAZ CS to come for stage 2 when they are satisfied that the issues have been addressed. The Stage 1 issues can be resolved before the Stage 2 audit or can be cleared at the Stage 2 audit. The Stage 2 Audit shall be conducted within 6 months after Stage 1 Audit and there shall be no any extension. Where the document evaluation does not meet the minimum requirements, a reaudit of the full documentation shall be done at the client's expense.
- 1.5.4.5 The Lead Auditor or Trainee Auditor shall return the Stage I Audit Report, QA F/60b, to the Technical Reviewer for review and to the Manager CS for approval. There might be need to send back the Stage I Audit Report, QA F/60b the Lead Auditor or Trainee Auditor for Corrections or Amendments before the Final Report is Approved. The report is passed on to the Auditor to review the requirements of CS for readiness for the Stage II audit. The review shall include (i) availability of competent auditors, (ii) the actual auditor time required for Stage II

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 6 of 17

and (iii) decision on how much time **SAZ CS** needs to prepare for this audit and (iv) availability of competence within the RAB to make the certification decision.

- 1.5.4.6 The time spent by the auditor at the organization's premises for the audit will be charged for, using the costing form QA F/11 which is completed by the relevant Team leader. A Proforma Invoice shall be raised and approved by the Manager Cs and forwarded to Accounts.
- 1.5.4.7 The output of the Stage 1 audit is a completed Stage 1 audit report, QA F/60a for the management system and an invoice for the audit. Relevant checklists shall be used for each system. Within QA F/60 and/or 60a and the follow-up there is a declaration by the organization of any consultants that may have been used in between audits. Both the organization and the auditor are also supposed to declare any gifts that may have been issued to the auditor(s) after the audit to ensure the impartiality of the auditor during the audit process. An auditor shall not accept any gift whose price exceeds US\$20,00
- 1.5.4.8 For multi-site organizations, the same audit team should be maintained as much as possible throughout the audit period and where this is not possible, the audit team leader shall at least be maintained throughout the audit of all sites. The team leader shall consolidate the audit findings and the report from his/her team and any other teams involved. The audit findings including issues of concern and comments shall be made on the FSSC Standard Report (QAF/60b)
- 1.5.4.9 The Stage I audit results shall be recorded on QA F/60(a). If the organization requests a typed audit report, the respective **Lead Auditor or Trainee Auditor** shall ensure that such a report has been provided within **2 weeks** of audit date.
- 1.6 <u>Preparation for the Stage 2/Certification/Recertification/Surveillance,</u> Unannounced Audits:
- 1.6.1 As part of preparation for the Stage 2 audit ensure that:
 - The Determination of Auditor Time Form QA F/57b was completed
 - A quotation was issued to organization.
 - Application form was completed in full.
 - Certification Contract (QAF/02b) is signed by both parties, C S Director or C S Manager & the Organization
 - All Stage I/IDE & aspects/hazards/impact/legal & other requirements identification were done and report issued.

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedu	ure Manual	Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 7 of 17

- Scope and boundaries were determined (QA F/01b, QA F/57b, and/or QA F/50) form.
- The client has confirmed that IDE issues of concern were addressed.
- Competent auditors were identified.
- All invoices were paid for, and
- Record the above on the relevant checklist, QA F/71, Qualification for Stage II audit checklist.
- Submit the IDE report and the above together with the initial audit programme, agenda etc to the Manager CS for approval.

NOTE 1: It must be noted that preparation for an audit is a very essential stage during the Certification process and it determines the quality of the output of an audit.

NOTE 2: Stage 2 audit shall be done within **6 months** of Stage 1 Audit.

- Using the Auditor's Competency Matrix (QA F/37b), the Lead Auditor or Trainee Auditor shall appoint the audit team members according to their competences. The policy of the department is to ensure that appropriately qualified personnel comprise an audit team, The terms of reference for the technical expert are as in the policy document, PM19.1.
- 1.6.3 Audits shall be planned by **allocated or approved Management Systems Auditor** in accordance with PR/19 and PR/17. The **Management System Auditor** shall determine the audit time and the competent audit team and have this approved by the Manager CS before notifying the Organization to be Audited and the Audit team on the Audit dates.
- 1.6.4 The **Lead auditor or Trainee Auditor** shall prepare an audit plan and have it approved by the CS Manager. The audit plan shall also indicate the need to review Stage1/IDE NCs.
- 1.6.5 The **Lead auditor or Trainee Auditor** shall send a notification together with the audit plan to the organization at least 2 weeks before the audit date for confirmed audits.
- 1.6.6 The Lead auditor or Trainee Auditor shall also forward the following documents together with the notification:

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C S	
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 8 of 17

1.6.7 <u>The Organization - 2 weeks before the audit date, for confirmed audits,</u> (except for Unannounced Audits)

- Audit Plan (QA F/100b)
- Opening Meeting Agenda QA F/5
- Closing Meeting Agenda QA F/6
- A letter informing the organization of the audit date and time and requesting that senior management be present during the opening and closing meetings and that the organization's consultant(s) be absent for the time of the audit to uphold the principle of impartiality.

1.6.8 The Team Leader or Trainee Auditor shall have access to updated versions of the following working documents:

- Audit Plan (QA F/100b)
- Attendance List/Register (QA F/4)
- Audit Observation Report (QA F/7)
- Relevant Audit Observation Summary (QA F/44
- FSSC Standard Report (QA F/60b) Template
- Audit Opening and Closing Meeting Aid Memoires Attachments D & E (for new auditors under observation/assessment) (Optional)
- Relevant Generic System Audit Checklist HACCP 35, FSMS 35d, and/or FSSC 35 Audit Notes

1.6.9 Other Audit Team members within 2 weeks of the audit date

- Shall be informed of audit date and time by phone or any other convenient means
- Audit Plan (QA F/100b)
- Opening Meeting Agenda (QA F/5)
- Closing Meeting Agenda (QA F/6)
- Relevant Generic Audit checklist HACCP 35, FSMS 35d, and/or FSSC 35 Audit Notes
- 1.6.10 In addition to the mentioned documents, <u>all</u> audit team members shall have a copy of the standard for relevant audits they are carrying out:
 - ZWS ISO 22 000, ISO/TS 22 002-Part X, FSSC 22000 Additional Requirements, HACCP ZWS 749 etc.
- 1.6.11 The Lead auditor shall make necessary transport arrangements after approval by Manager CS for the audit team in writing in the audit notification to allow the organization time to prepare. If there is a serious problem regarding availability of resources, the Director CS shall be **notified.**

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C S	
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 9 of 17

- 1.6.12 The notification letter shall contain all the necessary information including:
- 1.6.12.1 the names of the Audit Team members to allow sufficient time for the organization to exercise their right to formally object, with valid reasons to the appointment of any of the audit team as soon as they receive the audit notification. The auditor who planned the audit, in consultation with the Manager CS shall ensure that the audit team is reconstituted in response.

1.6.12.3 The objectives for the audit

- 1.6.12.4 Attached, shall be the agendas for the opening and closing meeting, with guidelines on the classification of nonconformities
- 1.6.13 The Lead Auditor or Trainee Auditor should meet with audit team member before the audit to prepare and familiarise themselves with processes they will be auditing. The audit team shall also go through the previous audit records to check on past performance as part of their preparations. Records of the preparatory meeting shall be maintained in the form of additional checklists.
- 1.6.14 The Lead Auditor or Trainee Auditor conduct on-site audits in accordance with the requirements of ZWS ISO 17021, ZWS ISO/TS 22003, FSSC Scheme Requirements and CS procedures.
- 1.6.15 In addition to visiting physical locations (e.g. factory and/or offices), on-site audits can include remote access to electronic site(s) which contain(s) information that is relevant to the audit of the management system. Such audits shall be conducted, where appropriate, according to the requirements in the IAF Mandatory Document MD 4: Computer Aided Audit Techniques (CAAT) may be employed during FSSC/ISO 22 000 FSMS and HACCP audits under the condition spelt out in the FSSC Requirements for Certification bodies and as guided by the Accreditation Body requirements

1.7 Terms of Reference for the Audit Team

- 1.7.1 The mandate of an audit team shall be to examine objectively and impartially The structure, policies and procedures of the organization.
 - the audit team shall assess and confirm whether the above meet the requirements of the relevant standard including FSSC Additional Requirements applicable to the scope of Certification;

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C S	
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 10 of 17

- that the system is implemented and is effective by verifying enough records generated during the implementation process;
- the degree of reliance that can be placed on the internal audit process;
- the qualification, authority and experience of the staff encountered;
- the adequacy of the internal structure;
- the actions taken to correct identified non-conformities including those identified in previous audits;

NOTE: The audit team shall assess and comment on the above during the auditors' meeting, closing meeting and in the audit report.

1.8 The Opening Meeting

- 1.8.1 The audit shall begin with the opening meeting between organization's management and the audit team. The agenda for the opening meeting shall be as outlined in Form **QA F/5**.
- 1.8.2 The meeting shall be chaired by the audit team leader making use **of QAF/5**. The rules and the tone of the audit are set during this meeting.

1.9 <u>Conducting the Audit/Collecting Evidence</u>

- 1.9.1 Auditors are to ensure that all the audit checklists are filled in adequately in order to create an audit trail **and proper corroboration**. "Yes" and "No" answers without the supporting evidence are not acceptable.
- 1.9.2 The auditors shall submit all the audit records to the full time auditors who shall review whether all the audit records are completed in full and raise any observations on them to the auditors' attention. The reports are handed over to the Manager CS for approval.
- 1.9.3 Auditors should at all times be critical of issues with the intention to add value during the audit and be careful not to consult.
- 1.9.4 The audit shall always be based on a representative sampling basis, so that the auditors can have a good appreciation of the management system and draw representative, logical conclusions. The auditor shall write nonconformities on **QA F/7b**, which shall be signed by a representative of the auditee; this is just to confirm the finding at the particular time and does not mean that they are responsible for the nonconformity. The audit teams shall be briefing each other on progress as they proceed with the audit.

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C S	
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 11 of 17

<u>NOTE</u>: It is important to note that the auditors will audit the system and not the individuals.

1.10 <u>Audit Findings</u>

There are two types of audit findings that auditors can come across during an FSSC audit:

- a) Nonconformity (Critical, Major or Minor)
- b) Conformity

The nonconformities shall be classified into "Critical, Major and Minor" according to FSSC 22 000 using the following guidelines:

CLASSIFICATION OF AUDIT NON CONFORMITIES CRITERIA:

Nonconformity grading

1. Introduction

In accordance with the definitions in the Scheme and as defined below, the SAZ CS has established and maintained criteria as a reference against which to determine the level of nonconformities resulting in three grading levels: a) Minor nonconformity, b) Major nonconformity, c) Critical nonconformity.

2. **Opportunity for improvement**

The use of opportunities for improvement during a FSSC 22000 audit shall not be allowed.

3. Minor nonconformity

A minor nonconformity shall be issued when the finding does not affect the capability of the management system to achieve the intended results: 1) When a minor nonconformity is issued during an audit, the organization must provide SAZ CS with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP). This shall be provided to the auditor within three (3) months after the audit. 2) Corrective action (CA) shall be implemented by the organization within 12 months after the audit. 3) SAZ CS shall review the design of the corrective action plan, challenge it and approve it when acceptable. 4) Implementation of the corrective action plan shall be reviewed, at the latest, at the next scheduled on-site audit. SAZ CS shall review the corrective action plan and determine its effectiveness of implementation through recording auditor name and date of review on the CAP. 5) A major nonconformity is raised (on management responsibility and resource allocation) in the event of non-completion of the approved action plan at the next scheduled on-site audit.

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 12 of 17

4 Major nonconformities A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results:

- When a major nonconformity is issued during an audit, the organization must provide SAZ CS with objective evidence of an investigation into causative factors, exposed risks and evidence of effective implementation. This shall be provided to SAZ CS within 14 days after the audit.
- Corrective action shall be implemented by the organization within 14 days after the audit.
- The major nonconformity shall be closed by SAZ CS within a further 14 days after implementation of the corrective action by the organization. The organization shall submit objective evidence of implementation to the CB. 4) SAZ CS shall review the corrective action plan and related objective evidence of implementation, challenge it if necessary and determine its effectiveness and approve the CAP and CA through recording his/her name and date of review on the CAP.
- SAZ CS shall conduct a follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, SAZ CS may decide to perform a desk review.
- The completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causative factors. In such cases the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. A follow-up audit shall be conducted to verify the permanent corrective action and to close the major nonconformity.
- A critical nonconformity is raised in the event of non-completion of the approved corrective action.

5. Critical nonconformity

A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity are at stake:

- When a critical nonconformity is issued at a certified site the certificate shall be immediately suspended for a maximum period of six (6) months.
- When a critical nonconformity is issued during an audit, the organization must provide the CB with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This shall be provided to the CB within 14 days after the audit.
- A follow-up audit shall be conducted by the CB within the six (6) month timeframe to verify the closure of the critical nonconformity.
- The certificate shall be withdrawn when the critical nonconformity is not effectively solved within the six (6) month timeframe.

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C S	
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 13 of 17

• In case of a certification audit, the full certification audit shall be repeated.

From the above guideline, the Audit Team should then be able to decide what constitutes System Failure/System Breakdown

For Certification, Surveillance, Recertification Audits and or Unannounced Audits the Lead Auditor or Trainee Auditor must make a recommendation with guidance from the FSSC Standard Report form QAF 60b1.

Where The audit team note that there is a System Breakdown/Failure, action may include but not limited to the following conditions as stipulated in FSSC Requirements:

Certificate suspension, withdrawal or scope reduction, the following three criteria apply;

- a) SAZ CS shall suspend a certification when there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements within the time frames applicable to the clearance of major nonconformities
- b) SAZ CS shall withdraw a certification when there is evidence that their client is either unable or unwilling to establish and maintain conformity with Scheme requirements, within the timeframes applicable to the clearance of critical nonconformities.
- c) When SAZ CS has evidence that their client holds a certificate whose scope exceeds their capability or capacity to meet, SAZ CS shall reduce the certification scope accordingly. 2) Examples include: a) The organization's certified management system has persistently or seriously failed to meet the Scheme requirements, including requirements for the effectiveness of the management system. b) Immediate risk to the safety of the product impacting consumer health.
- c) The certified organization does not allow surveillance or recertification audits to be conducted at the required frequencies. d) The certified organization has voluntarily requested a suspension.

Action upon suspension, withdrawal and scope reduction:

- 1) In case of withdrawal or suspension, the organizations' management system certification is invalid. SAZ CS shall:
- a) immediately change the status of the certified organization in the FSSC 22000 database and its own Register of Certified Organizations and shall take any other measures it deems appropriate; b) inform the organization in writing of the withdrawal or suspension decision within three (3) days after the decision was made and confirm the decision;
- c) instruct the organization to take appropriate steps in order to inform its clients through various forms of communication such as advertising and product labelling where applicable.
- 2) In case of scope reduction, the organizations' management system certification is invalid beyond the revised certification scope statement. SAZ CS CB shall:
- a) immediately change the scope of the certified organization in the FSSC 22000 database and its own Register of Certified Organizations and shall take any other measures it deems appropriate. b)

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual		Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 14 of 17

inform the organization in writing of the scope change within three (3) days after the last day of the audit or any other intervention and confirm the decision.

c) instruct the organization to take appropriate steps in order to inform its clients through various forms of communication such as advertising and product labelling where applicable.

In cases where the audit team identify nonconformities, they shall not recommend specific solutions as this is regarded as providing consultancy during an audit. Nonconformities shall be recorded on form QA F/7b.

1.11.2 The Auditors' Meeting

The auditors' meeting is basically to summarise the audit findings to be presented to management in the closing meeting by the Lead Auditor or Trainee Auditor. The Lead Auditor or Trainee Auditor shall chair this meeting.

1.11.2.1 The audit team shall discuss and make their recommendations and observations to the audit team leader who shall take note and make his/her remarks to this effect in the closing meeting. The team encourages and solicits for input from the team members in order to have a balanced view on the status of the management system.

<u>NOTE</u>: The audit team shall recommend or not an organization for Certification to the Registration Approval Board (RAB); the RAB shall, however, have the final approval. Refer to PR/21 clause 21.4.3. The audit findings and any other observations constitute the objective evidence the auditors shall use to make the recommendation to the **Manager CS forward** the organization's file to the RAB for granting or not to grant the certification.

1.12. The Closing Meeting

- 1.12.1 The Closing Meeting is the concluding meeting of the audit and is the formal presentation by the Lead Auditor or Trainee Auditor of the findings and conclusion of the audit to the organization's management. The Lead Auditor or Trainee Auditor chairs the meeting and shall work through the Closing Meeting Agenda (QA F/6).
- 1.12.2. The Lead Auditor or Trainee Auditor circulates around the Attendance register, QA F/4 to be filled in by each attendee.

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedure Manual	Department: C	S
Document No.: PR/1b Subject: Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 15 of 17

- 1.12.3 The Lead Auditor or Trainee Auditor shall ensure that the organization is represented by senior management at the closing meeting.
- 1.12.4 The Lead Auditor or Trainee Auditor shall inform the organization of the requirement to analyze the cause(s) of nonconformities and describe in a corrective action report, the specific correction(s) and corrective action(s) taken or planned to be taken, to eliminate the detected nonconformities. The deadlines for submission of corrective action reports are as set in 1.14.5.
- 1.12.5 The Lead Auditor or Trainee Auditor shall issue a typed FSSC Standard Report (QAF60b1) and Nonconformance Report (QAF7b). Report shall be left on the last day of the audit, which they can use to initiate corrective action.
- 1.12.6 Following submission of the corrective action report by the client, the Lead auditor shall go through the corrective action report to check if the causes of all nonconformities have been determined. If not the organization is informed in writing and the corrective action report shall not be cleared. The organization shall be required to re-submit the corrective action report with root causes within a week of being informed of the state of the corrective action report.
- 1.12.7 For an Initial Audit/Stage 2, if major NCs are not verified for implementation of corrections and corrective actions cleared within 6 months of the audit, the stage 2 audit shall be repeated at the organization's expense.

1.13 The Audit Report

- 1.13.1 The **FSSC Standard Audit Report** shall provide a clear record of the products, audit purpose, findings (if needed) and conclusions. It is the major output of the audit process and shall be read and used by some people who were not at the audit and have no other information about the audit.
- 1.13.2 It is therefore important that the audit report gives a balanced view of the whole audit byway of general comments. Suggestions or recommendations on how to improve the system shall not be made with the comments as this constitutes provision of consultancy by the audit team.
- 1.13.3 The audit report comprises of a typed version (if needed) of, the findings on Forms QA F/7b, and the invoice. The audit report shall bear the name of the organization

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedu	ire Manual	Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 16 of 17

and the physical address of the entities, which were audited, and the audited elements shall be on the audit programme and confirmed on the audit observation summary (QA F/44 for FSMS audits for example).

- 1.13.4.1.1 The audit report shall be confirmed and dated by the signature of the audit team leader. The report shall refer to the assessed **FSSC or ISO/TS 22003 Scopes** and the relevant standard or other normative documents applied.
- 1.13.5 The organization shall declare on the Audit Report, if they have used a Consultant for training and/or system development since the last audit.
- 1.13.6 Both the audit team and the organization's representative shall declare gifts given to the audit team for CS to monitor impartiality of the auditors.
- 1.13.7 In the case where a hand written report was issued on the last day of the audit, the Lead auditor or Trainee Auditor shall ensure the typed the report gets to the customer within 2 weeks of audit date.
- 1.13.8 The Lead auditor or Trainee Auditor shall return the client's file to the Document Controller for onward transmission and Technical Review. The Technical Reviewer shall review the audit records and sign as "checked by". Any observations made on the audit records should be noted for the Manager CS's attention. The performance of the audit team shall be recorded on QAF 36c. The Manager CS shall make conclusions and approve the audit report. Communication shall be made with the client in cases where immediate attention is required.

1.14 Conclusions and the Audit Report

- 1.14.1 A comment on the status of the previous audit report i.e. whether or not all the nonconformities raised in the previous audit were cleared
- 1.14.2 The total number of nonconformities raised, including the number of major and minor nonconformities, a summary of these and the clauses of the standard under which they fall shall be stated on the relevant forms.
- 1.14.3 State that "It is not possible to audit all documentation and activities and therefore where no nonconformities are reported it does not follow that none exist".

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Proced	ure Manual	Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 17 of 17

- 1.14.4 State whether the audit covered all the areas on the **audit plan** and the relevant requirements.
- 1.14.5 Inform the organization that a Corrective Action Report with cause(s), distinct correction and corrective action) on in accordance to deadlines stipulated on the Nonconformance Form (QAF 7b) and FSSC Standard Report (QAF 60b1)
- 1.14.6 The Lead Audit and Trainee Auditor shall ensure that the Audit Report is composed of what was reported during the closing meeting.
- 1.14.7 All follow-up audit shall be conducted on site or offsite based on the recommendation by the Lead Auditor and Trainee Auditor. Refer to the procedure PR44 on Follow-up audits and as per FSSC scheme requirements.
- 1.14.8 After all has been said, state whether the management system **conforms** or not with the requirements of the relevant standard and whether the organization is to be recommended for certification or not and where applicable, any useful comparison with the results of previous audits of the organization. The audit team leader should make it clear to the client that the audit team only recommends but RAB has the final say on the certification decision.

1.15 **Follow-up Audits**: Refer to procedure PR44.

1.16 <u>The Certification Decision</u>

1.

- 1.16.1 After all the Major Nonconformities have been cleared and an action plan for Minor Nonconformities have been accepted after a Certification, Transfer or Recertification Audit, the Manager CS recommends the organization to the RAB for certification and Procedure PR/21 is followed to make this decision.
- 1.16.2 On Certification, the organisation is included on the Annual Schedule. It is possible that an unannounced Audit may be conducted any time after 4 months of the Surveillance, Certification, Recertification or Transfer Audit. The first surveillance audit shall be conducted not more than 12 months from the date of certification decision (Procedure PR/32), Surveillance Activities, Surveillance Audits and Re-Certification). An Audit programme (QAF 90) shall be prepared by the lead auditor responsible for the file.

END OF PROCEDURE

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	

Document Type: Procedu	re Manual	Department: C	S
Document No.: PR/1b	<u>Subject:</u> Management Systems Certification Process for FSSC 22 000	Revision No 03	Page 18 of 17

Prepared by:	Authorized by:	Supersedes	Effective Date 2021-07-06
CS Manager	CS Director	Document: 02	