# ABC 200 Management system assessment and certification procedure



Trust Quality Progress

# **ABC 200**

Management system assessment and certification procedure

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# Changes made to the previous (15th) edition

- Updated table of contents
- Updated the text of the first paragraph of "1 Introduction"
- The name of the standard has been added to Annex 3,4,6,8,10 and 11
- Updated Annex 5, paragraph 2, first sentence
- Updated Annex 7 Food safety management systems
- Added Annex 12 Quality management systems in the field of medical devices
- Added annex 13 Business continuity management systems



# Management system assessment and certification procedure

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#### 1 Introduction

These regulations apply to the procedure of Inspecta Sertificianti Oy, hereafter certifier, for assessing and certifying management systems of organisations. The organization applying for certification is required to commit to the requirements of this guide.

Management systems of organisations are certified based on standards listed in Annexes 3 - 13. An organisation can apply for the certification of more than one management system simultaneously. Certificates are issued to each management system individually but their audits can well be integrated.

All organisations have equal rights and possibilities applying for certification from the certifier. The conditions for certification are equal to all applicants and certificate holders.

The certifier complies with the international requirements and instructions set for certification bodies in order to guarantee the competence, impartiality, confidentiality and independence of the certification activity.

#### 2 Terms and definitions

The terminology used in these regulations in addition to the definitions given in the management system standards, includes the following terms:

<u>An applicant</u> is an organisation that has submitted its application and commissioned the certifier to perform an assessment of its management system.

<u>A certificate</u> is the confirmation on the fact that the system of the organisation has been audited by a third party and found to be in conformance with set of specific standard requirements.

<u>A lead auditor</u> is a person competent for organising and leading an assessment of one or more systems, to report on observations and to issue statements on an organisation's system and on changes made to such a system.

<u>An auditor</u> is a person competent to assess one or more systems in cooperation with a lead auditor and to be in charge for the assessment of certain specific areas of the activity.

<u>The certification committee</u> is a body whose members are chosen by the certifier among its different interest parties. The committee safeguards the impartiality of the certification activity and acts as a panel of experts of certification. The committee's tasks are listed more in detail in its operational directives.

<u>The appeals board</u> is a body whose task is to handle the complaints concerning certification. Its members are appointed by the Certification Committee.

## 3 Management system certification procedure

In the following list are the steps taken once an organisation has requested the certification of its system. The applicant pays the costs accrued of the procedure.



Information meeting optional mandatory Pre-audit optional Initial Certification audit stage 1 mandatory Initial Certification audit stage 2 mandatory Additional audit freesesary Surveillance audits optional mandatory mandatory

Recertification audit mandatory at regular intervals

Audit focusing optional

## 3.1 Information meeting

The information meeting is generally held at the customer's premises for the purpose of providing information on the different phases of the assessment of the customer's system. For example, the following aspects may be covered:

- main features of the organisation's system and its readiness for certification
- eventual pre-audit
- assessment and certification procedure
- areas and phases of audit requiring special expertise (for the purpose of selecting the audit team)
- basis of payment
- steps and procedures to be taken prior to the audit.

#### 3.2 Application information

An organisation wishing to be certified shall forward the necessary application information in the signed contract or using a form created for this purpose. The forms can be obtained from the certifier or from its website www.kiwa.com/fi. The organisation will be sent The Management System Assessment and Certification procedure ABC 200, basis of payment and eventual supplementary instructions for audit preparation.

The certifier will nominate a team of auditors to carry out each audit, comprising a lead auditor and additional auditors as necessary.

Prior to the audit, the organisation is entitled to reject any proposed auditor on valid grounds. In such a case the certifier will appoint a new auditor for the task.

No application is needed for the continuation of certificate validity in connection with the recertification audit.

#### 3.3 Pre-audit

A pre-audit is optional and carried out like the certification audit but on a smaller scale. The extent is agreed upon with the organisation. The corrective actions for non-conformities found at the pre-audit do not need to be sent to the certifier. A pre-audit does not replace the certification in any extent.

## 3.4 Certification audit stage 1

The certifier holds a certification audit stage 1 meeting with the representatives of the organisation. Prior to the meeting, the organisation shall send the certifier a description of its system. The certifier checks the material delivered and gives the organisation written feedback on the description including



eventual deficiencies compared to the requirements set by the standard and on other matters to be clarified.

At this point, if not earlier, the extent and the scope of the system to be certified, such as processes and sites included in the system, shall be clearly defined.

The procedures and situation of management reviews and internal audits are assessed at this first stage of the certification. On agreement, also other parts of the system can be assessed. Should the organisation already have another management system certified by the certifier, this also serves as an assessment point for which parts of the new system have already been audited. Such parts can be given less attention only ensuring their functional connection with the new system.

The organisation's readiness for certification, the time of audit and a draft of the audit programme are settled together at the certification audit stage 1.

# 3.5 Certification audit stage 2

The certification audit stage 2 is conducted according to the audit programme sent to the organisation in advance.

The purpose of the certification audit is to get sufficient evidence on the compliance of the organisation's activities with the organisation's own descriptions and the requirements of the standard.

A daily progression meeting is held with the organisation representatives whenever possible. At this meeting, the observations of auditors as well as eventual unclarities are dealt with.

Should it be found at the audit that the development of the system is still incomplete, the organisation may discontinue the audit or change its status to a pre-audit. Incompleteness of the system means the occurrence of several major non-conformities.

In conclusion of the certification audit the results of the audit are stated. The lead auditor responsible for the assessment states the results and also whether the issue of a certificate can be recommended, is there a need for corrective actions or an additional audit. The organisation is also given a written audit report with eventual non-conformity reports

Non-conformities are classified as minor or major. For FSSC 22000 also critical non-conformities are used, for FSSC non-conformity grading and corrective actions see annex 7.

A major non-conformity is written if

- a basic matter required by the standard lacks description or is missing
- several minor non-conformities against a same standard clause or in a same function are found
- the system is found fundamentally incomplete
- the organisation does not fulfil its responsibilities described in these regulations.

A minor non-conformity is an individual deficiency in a procedure or an operation.

The organisation shall send the certifier an analysis of the root cause(s) regarding the non-conformities as well as a description or a plan for corrective actions within a defined time.

The certifier needs a clarification on the following matters:



- analysis of the root cause of the non-conformity
- the matter changed
- how the instructions have been changed (enclosing the new ones)
- date for the implementation of the change
- how the change has been communicated
- how such a change will prevent the re-occurrence of a similar non-conformity
- who, and when, has controlled that the implementation of the change or correction has taken place.

The certifier will verify the implementation of the corrective actions' effectiveness. Depending on the nature of corrective actions the verification will either be effected on the basis of the written material forwarded, or in connection with an additional audit.

#### 3.6 Additional audit

An additional audit consists of the verification of corrective actions taken against the major non-conformities found but it can also be carried out, should the certifier find it necessary for other reasons. The implementation and effectiveness of the corrective actions as well as the areas possibly affected by the changes are assessed during the additional audit. If the system was found incomplete at the certification audit, the additional audit will be conducted on a larger scale.

#### 3.7 Surveillance audit

After the issue of a certificate, surveillance audits are carried out at least once a year in accordance with the following methods, of which the organisation chooses one.

- 1. Surveillance audits once a year: the most crucial points and changes of the system are audited. The first follow-up audit is conducted 12 months after the certification decision at the latest.
- 2. Surveillance audits twice a year: the contents of the audits are annually agreed upon together with the organisation. The first surveillance audit is conducted within 6 months after the certification audit.
- Continuous surveillance: the contents of the audits are annually agreed upon with the
  organisation. Particularly suitable for large organisations where the annual audit effort is
  extensive

An additional surveillance audit may be carried out, should the certifier deem it necessary or the organisation request one.

If other management systems of the organisation have been certified by the certifier, the surveillance audits of all of them may well be integrated.

The schedules for surveillance audits are agreed upon with the organisation in advance. FSSC 22000 requires that one of the surveillance audits is to be done as un-announced. Further details in annex 7.

A surveillance audit is reported on a similar manner with a certification audit. Should major non-conformities be found, the certifier will handle them case wise and make a decision. This can result in an additional audit, a suspension or a permanent withdrawal of the certificate.



#### 3.8 Recertification audit

A recertification audit is always carried out 36 months after a certification audit or a prior recertification audit at the latest, regardless of which method of follow-up audits stated in clause 3.7, has been chosen.

The purpose of a recertification audit is to ensure that the management system as a whole is continuously in conformance with requirements and effective, permanently appropriate and suitable regarding the scope of certification. If the organisation has multiple sites, the sufficient coverage of onsite assessments is ensured to secure trust in certification.

If the organisation implements several certified management systems, they can all be re-assessed simultaneously considering that a maximum time of 36 months is allowed to have passed since a certification, or a re-certification audit of each management system.

When choosing the date for a recertification audit, it has to be considered that the corrective actions to eventual non-conformities to be found shall be implemented prior to the expiry of certificate.

#### 3.9. Short-notice audits

It might be necessary for the certification body to conduct short-notice audits. The need for these audits may rise from:

- changes in the certified organisations procedures or actions, which may bring reason to doubt the sufficient effectiveness of organisations management system
- complaints to the organisation

The certification body exercises additional care in the assignment of the audit team in short-notice audits.

#### 3.10 Extent and allocation of audits

The extent of audits is based on accreditation requirements, of which at least the minimum ones shall be fulfilled. If similar work is carried out at the different sites of the organisation, sampling can be applied on the number of sites audited taking into account the fulfilment of accreditation requirements.

The organisation and the certifier can plan the surveillance audits and recertification audits together at so called audit allocations. The allocation can be conducted in connection with a prior audit, as a separate meeting or any other way suitable. The objective of an allocation is to improve the effectiveness and implementation of audits, plan the audits in long-term as well as to allocate the assessments to such parts or operations in the system that are found important from the aspects of both the organisation and the certifier in assessing the performance of the system.

#### 4 Issue of certificate and renewal of validity

The certification is issued for the first time on the basis of certification audit once it has been established that the management system of the organisation fulfils the requirements of standard.

The validity of certificate is renewed on the basis of recertification audit if it can be established that there remain no uncorrected major non-conformities or other eventual obstacles for the continuation of certification.



The validity of the certificate and the operations and sites covered by certification are stated in the certificate unequivocally.

The certificate is valid for a certain time limit, 36 months at most, providing that the organisation fulfils the requirements. The organisation may terminate it certificate, the period of notice being three (3) months. The withdrawal of a certificate from the certifier's side is handled in clause 7.

# 5 Duties of the certified organisation

The certified organisation shall

- maintain and develop its system in accordance with the standard
- ensure that all processes, work performed and services related to the certified area are conducted in accordance with the documents of the certified system
- notify the certifier in writing of changes relating to the certified system possibly affecting the extent or validity of certification. The certifier will decide on the action needed case-by-case. Such changes can consist of the following:
  - major changes in the corporate form or ownership
  - changes in the key personnel of the system
  - significant organisational changes
  - changes in the range of products or services within the scope of certificate
  - major changes planned in the system in order to enable the certifier's evaluation of their effects and needs for assessment in advance
  - cease of production or its transfer to another location.
- notify the certifier immediately in writing of any disruptions or other problems possibly causing other than minor consequences to customers or other interest parties, or resulting in e.g. withdrawal of products from the market. The organisation is obliged to take any necessary action in order to solve the disruption or other problem and aim to eliminate the effects of such a disruption or problem. The withdrawal of certificate is agreed upon as described in clause 7.
- ensure that the certifier is indemnified of any financial or other claims for compensation concerning damage caused to the third parties by the certified organisation, its management system and/or the production methods used by the organisation or products/services manufactured or sold by the organisation. The duties and responsibilities of the certifier are exhaustively defined in clause 6 of these regulations. Should the certifier become subject to a claim for compensation or any other corresponding financial claim, the certified organisation is under obligation of informing the certifier immediately and to take necessary action in order to prevent any damage.
- use the certification mark in a manner described in clause 11 and discontinue any use of the certification mark and such reference to the certification deemed unacceptable in a written statement issued by the certifier.
- admit the representatives of the certifier at an agreed time during normal work hours to the organisation's work areas to inspect the system in the extent of the scope of certification



- accommodate the presence of observers e.g. accreditation auditors or trainee auditors
- pay the certifier the fees for the assessment and certification as agreed
- discontinue any reference to certification as well as the use of the certification mark once a certificate is withdrawn or its validity expired.

When there are valid ground for doing so, the organisation is entitled to refrain from revealing its trade secrets (e.g. specific production method) and other data classified secret if the performance of the system can otherwise proven.

# 6 Duties and responsibilities of Inspecta Sertificinti Oy

The certifier shall

- attend to the tasks presented to it in these regulations
- maintain the confidentiality of all information concerning the organisation. Thus any individual with the opportunity to obtain any such information shall sign a confidentiality agreement. The representatives of outside accreditation bodies with access to the certifier's records are also under a pledge of confidentiality. Once a certificate has been issued, the organisation's contact information and the information recorded in the certificate are public.
- handle all received appeals regarding a certified system
- withdraw a certificate (see cl. 7) or reduce its scope, should the organisation not answer to the responsibilities described in clause 5. In the case of a complaint by an organisation concerning a system assessment, and if the Appeals Board is to approve such a complaint, the certifier shall, at its own cost choose new auditors to conduct a re-assessment.

The certifier cannot be held liable, if a third party, e.g. the customer, does not acknowledge, or only partly acknowledges a certificate.

The certifier is neither liable for any mistakes made by the client organisation nor for the flawlessness of its production methods, products/services manufactured or sold. The certifier is in no circumstances responsible for any damage caused to a third party by such flaws.

The certifier is not either liable to the certified organisation on the grounds of certification, surveillance or other service in connection with certification. Certification acts as proof that a management system of the organisation has been found to comply with the requirements of a relevant standard, and that the organisation has also been found capable of maintaining its operations accordingly.

# 7 Expiration and withdrawal of certificate

A certificate is valid for a set period of time. Its validity expires at the end of the period stated in the certificate unless the certifier decides to prolong its validity. Regardless of the period of validity of the certificate the certifier can suspend or permanently withdraw a certificate issued to an organisation.

Grounds for withdrawal include i.a. the following:

- one or more major non-conformities observed at a follow-up audit
- the organisation claims that a certificate pertains to operations it does not actually cover, or continues the misuse of the certification mark even after a written notification from the certifier



- misleading or deficient information submitted at an audit
- the organisation fails to notify the certifier of major changes made in its system (see cl. 5)
- the organisation fails to implement corrective actions within an agreed schedule
- the organisation fails to pay the certifier its invoices for assessment and certification procedures
- the organisation goes bankrupt
- the organisation fails to fulfil its other responsibilities stated in clause 5.

The withdrawal can be in force temporarily (suspension) if the organisation is able to implement the corrective actions within an agreed, reasonable time frame. In connection with large organisational or other similar changes, a longer period of suspension may also be applied.

The decision on withdrawal, with grounds for it, will be forwarded to the organisation in writing.

The information on an organisation whose certificate's validity has expired, or whose certificate is withdrawn, is removed from the register of certified organisations. In the case of a suspension, an entry to this effect is added in the register.

During the suspension period any reference to certification is forbidden in marketing.

# 8 Utilisation of certificates issued to the organisation

When issuing a certificate, the certifier may accept either as such, or as a part of its audit, reports drawn by another certification or audit body.

This acceptance is based on consideration case-by-case, or on an agreement made between the certifier and the other certification body.

#### 9 Appeal procedure and handling of complaints

If an organisation applying for certification or already having been issued one, wishes to appeal against a decision made by the certifier concerning a system audit or certification, it shall forward its appeal to the certifier in writing within 14 days from the receipt of the decision.

The Certification Committee nominates an impartial, qualified Appeals Board comprising a chairman and two members for each complaint.

The Appeals Board will convene within 21 days from the receipt of an appeal. The appellant will be informed of the date, place and composition of the Board at least seven (7) days in advance.

The certifier's decision remains in force until the meeting of the Appeals Board. At this meeting both the organisation registering the appeal as well as a representative of the certifier have the right to be heard in confidence. A majority decision of the Appeals Board is final. Should it be contrary to the certifier's original decision, the re-assessment referred to in clause 6 will be conducted at the certifier's cost.

An unfavourable decision does not affect the organisation's right to re-apply for a certificate.

Should a customer, or other party trusting the certificate, make a complaint on the performance of the system or unfulfilled certification requirements, the certifier will handle the complaints independently,



excluding any persons who have made the decision on certification or taken part in the audit, from the complaint handling or decision on actions. The certifier also presents the complaint at a moment suitable for the certified organisation. The appellant is forwarded a notification on the receipt of the appeal considering, however, the confidentiality of certification as well as the date for the organisation's next audit.

## 10 Changes in the assessment and certification procedure

The certifier reserves the right to amend these regulations. The amendments can be necessitated by

- changes in the requirements set by the accreditation body
- requirements of reciprocal agreements
- the certifier 's membership in international bodies
- changes in system standards. The amendments do no affect the organisation's right to use the certification mark or to refer to certification for the duration of a transition period set by the certifier with the announcement of any amendments. A transition period is normally six (6) months at least. Revised regulations are immediately sent to all certificate holders, applicants and the accreditation body. Other parties are informed via the website of the certifier (www.kiwa.com/fi). The implementations of the amendments will be inspected, when possible, at surveillance audits.

#### 11 Use of the certification mark

An organisation that has been issued a certificate has the right to refer to the certification and use the appropriate certification mark during the validity of the certificate.

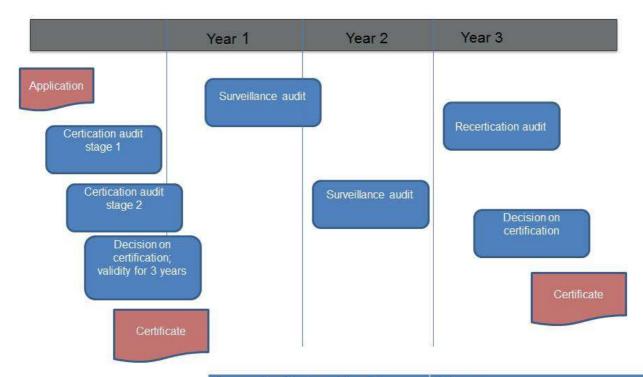
The text belonging to the mark is given in English. An organisation that has been issued an accredited certificate also has the right to use the mark of the accreditation body in connection with the certification mark. Also the certification mark of IQNet can be used when the organisation has been issued an IQNet certificate. Exact models of the marks are available from the certifier.

- 1 The name of the organisation shall be stated in connection with the certification mark.
- 2 The mark may be used in stationery, catalogues and brochures and other marketing material. Should the afore-mentioned material also include products or services not certified, the scope of the certificate shall be clearly stated.
- 3 In no circumstances shall the mark be used directly on products in such a way that the products themselves could be considered certified by the certifier. If the mark is used on packaging or similar, a definition of what the certified system actually covers is to be clearly stated (the product inside, packaging material, label manufacturer etc.).
- 4 The certification mark shall not be used on the test, calibration and inspection reports of laboratories belonging to the certified organisation.
- 5 Upon withdrawal of certificate any use of the mark shall be discontinued.
- 6 For technical information on the mark, please see annex 2.
- 7 For use of FSSC 22000 logo please see additional information in annex 7.



# 12 Register

The certifier keeps public registers on organisations certified in accordance with these regulations on its website (www.kiwa.com/fi). The registers list currently valid certificates.



Non-conformties found at audits	Actions
Minor non-conformity	Corrective actions to be sent to the certifier as agreed
Major non-conformity	Actions decided on separetely









Inspecta Sertificinti Oy

The colors for the mark are:

**Black** 

CMYK: C:100% M:52% Y:0% K:13%

RGB: R:0 G:106 B:222

Gray

C:75% M:68% Y:67% K:90%

RGB: R:1 G:1 B:1

The proportions of the mark are as shown. We recommend using a minimum width of 2.0 cm. There is no maximum size. There shall be space enough around the mark in order to separate it from other eventual marks near it.



**Business ID** 

1065745-2

ISO 9001 Quality management system

## 2 Special features of the assessment and certification procedure

Management review is assessed at the certification audit stage 1, as well as the procedure for internal audits and their situation.

Also the process description, the responsibilities and authorities thereto connected, interaction between different processes as well as targets and measurements are audited in this connection.

## 3 Certification mark and technical definitions



The colors for the mark are:

**Black** 

CMYK: C:100% M:52% Y:0% K:13%

RGB: R:0 G:106 B:222

Gray

C:75% M:68% Y:67% K:90%

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fi.certification@kiwa.com

ISO 14001 Environmental management system

## 2 Special features of the assessment and certification procedure

The maturity level of the management system is stated at the certification audit stage 1 by also assessing the significance and diversity of the environmental aspects, legal requirements and communication. All this, added with the sensitivity of the surrounding environment as well as the perspectives of interest parties, also effect the eventual extent of the certification audit.

Concerning audits of environmental management systems, the organizations are also reported the eventual deficiencies found in the fulfilment of the requirements of environmental legislation.

#### 3 EMAS verification

The verification procedure in accordance with EU's EMAS regulation (EY) N:o 1221/2009. The verification procedure may well be integrated in the assessment and certification process of an environmental management system.

#### 4 Certification mark and technical definitions



Inspecta Sertifiointi Oy

The colors for the mark are:

Black

CMYK: C:100% M:52% Y:0% K:13%

RGB: R:0 G:106 B:222

Gray

C:75% M:68% Y:67% K:90%

RGB: R:1 G:1 B:1



OHSAS 18001 Occupational health and safety management systems. Requirements

ISO 45001 Occupational health and safety management systems – Requirements with

guidance for use

## 2 Special features of the assessment and certification procedure

In the application, the information provided to Inspecta Sertificinti Oy by the authorized representative of the applicant organization on its processes and activities shall also include the identification of the key hazards and OH&S risks associated with processes, the main hazardous materials used in the processes, and any relevant legal obligations coming from the applicable OH&S legislation.

The application shall contain details of personnel working on, as well as working away from the organization's premises.

# **Conducting Audits**

The audit team shall interview the following personnel:

- i) the management with legal responsibility for Occupational Health and Safety,
- ii) employees' representative(s) with responsibility for Occupational Health and Safety,
- iii) personnel responsible for monitoring employees' health
- iv) managers and permanent and temporary employees.

Other personnel that should be considered for interview are:

- i) managers and employees performing activities related to the prevention of Occupational Health and Safety risks, and
- ii) contractors' management and employees.

The organization representative shall be requested to invite the management legally responsible for occupational health and safety, personnel responsible for monitoring employees' health and the employees' representative(s) with responsibility for occupational health and safety to attend the closing meeting.

#### 3 Duty to declare factors affecting certification

An organization shall inform Inspecta Sertificienti Oy should there be a serious accident, or serious breach of regulation necessitating the involvement of the competent regulatory authority.

The organization shall inform Inspecta Sertificinti Oy of the situation within three (3) working days. Inspecta Sertificinti Oy will then evaluate the case and its effects on certification and take appropriate action. The organization shall also report on the case to Inspecta Sertificinti Oy as agreed. Inspecta Sertificinti Oy is also entitled to carry out special audits, should it deem such necessary.



#### 4 Certification mark and technical definitions



Inspecta Sertifiointi Oy



Inspecta Sertifiointi Oy

The colors for the mark are:

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CMYK: C:100% M:52% Y:0% K:13%

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C:75% M:68% Y:67% K:90%

RGB: R:1 G:1 B:1



ISO/IEC 27001 Information security management system

## 2 Special features of the assessment and certification procedure

Stage1 of certification assessment includes the following assessments:

- results of internal assessments
- results of possible other independent reviews or assessments on information security
- management review
- assessment and treatment process of information security risks
- applicability statement including the management methods of information security risks or references to them.

#### 3 Certification mark and technical definitions



Inspecta Sertificinti Oy

The colors for the mark are:

Black

CMYK: C:100% M:52% Y:0% K:13%

RGB: R:0 G:106 B:222

<u>Gray</u>

C:75% M:68% Y:67% K:90%

RGB: R:1 G:1 B:1



ISO 22000 Food safety management systems.

Requirements for organisations in the food chain

FSSC 22000 Food Safety Management Systems;

FSSC 22000 is based on

- Standard ISO 22000
- Following, category specific technical specifications:
  - ISO/TS 22002-1: Prerequisite programmes on food safety -Part 1: Food manufacturing (C and K)
  - ISO/TS 22002-4: Prerequisite programmes on food safety -Part 4: Food packaging manufacturing (I)
  - ISO/TS 22002-5: Prerequisite programmes on food safety -Part 5: Transport and storage (G)
- Additional FSSC 22000 scheme requirements <u>www.fssc22000.com/documents/standards/downloads</u>

## 2 Special features of the assessment and certification procedure

Concerning systems conforming to standard **FSSC 22000**, the organization is recommended to carry out a self-assessment prior to the certification procedure.

The scope of the system, contents of HACCP/hazard analysis, prerequisite programs (PRP), organizational structure and food safety policy are assessed during the initial audit stage 1.

The following information on an organization, whose FSSC system is certified by Inspecta Sertificinti Oy and then informed of to FSSC Foundation, is found on the FSSC website:

- Name and address of the certified organization
- Scope of certification
- Date of certificate issue
- Date of expiration
- In the case of a temporary withdrawal or a suspension of the certificate, the date of such action.

Customer data and audit results are reported to Portal maintained by the FSSC organization. A (certified) organization is the owner of an audit report, whilst the CB is responsible for the report data. A (certified) organization is the certificate holder, whilst the CB is the data owner of the certificate data.

In addition to initial certification, surveillance and recertification audits, additional assessments can be carried out by the FSSC organisation.

Inspecta Certification collects FSSC's annual fee from FSSC certified sites.



# 3 Non-conformity grading for FSSC 22000

# **Critical non-conformity (CNC)**

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 CNC is issued during an audit, the certificate shall be immediately suspended for a maximum period of six (6) months. The organization must provide Inspecta Sertificiniti Oy with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP) within 14 days after the audit. A follow-up audit shall be conducted within the six (6) month timeframe to verify the closure of the CNC.

# Major non-conformity (MNC)

A major nonconformity shall be issued when the finding affects the capability of the management system to achieve the intended results. When a MNC is issued during an audit, the client must provide objective evidence of an investigation into causative factors, exposed risks and the proposed CAP within 14 days of the audit. Corrective action shall be implemented by the organization within 14 days after the approved plan. Effectiveness of implementation is determined through recording auditor name and date of review on the CAP. Inspecta Sertificiniti Oy will conduct a desk review or follow-up audit to verify the implementation of the CA to close the MNC.

## Minor non-conformity (NC)

A minor nonconformity shall be issued when the finding does not affect the capability of the management system to achieve the intended results. When a NC is issued during an audit, the client must provide objective evidence of an investigation into causative factors, exposed risks and the proposed CAP within 28 days of the audit. Minor non-conformities easily to be fixed and agreed with the auditor must be supported by evidence of their closure within 28 days. If minor non-conformity (NC) is not closed at the next on-site audit, it might become major non-conformity (MNC).

Implementation of the corrective actions is reviewed, at the latest, at the next on-site audit.

#### 4 Unannounced audits for FSSC 22000

One of the two surveillance audits will be replaced by an unannounded audit. Black out days can be taken into consideration meaning time periods when the audited organization is not operating for legitimate business reasons or the scope of certification include seasonal production and possible secondary sites. Black out days is to be agreed beforehand.

#### 5 Duty to declare factors affecting certification

An organization shall inform Inspecta Sertificienti Oy about any major changes in it's operations and should there be knowledge of any legal actions pertaining to the safety or conformance with laws and regulations of its products. This duty also applies to any recalls or withdrawal of products. The organization shall inform Inspecta Sertificienti Oy of the situation within three (3) working days. Inspecta Sertificienti Oy will then evaluate the case and its effects on certification and take appropriate action. Inspecta Sertificienti Oy is also entitled to carrying out supplementary audits, should it deem such necessary.



# 6 Certification marks, logos and technical definitions

The colors for the mark are:

**Black** 

CMYK: C:100% M:52% Y:0% K:13%

RGB: R:0 G:106 B:222

<u>Gray</u>

C:75% M:68% Y:67% K:90%

RGB: R:1 G:1 B:1





Inspecta Sertificinti Oy

Inspecta Sertifiointi Oy

The proportions of the mark are as shown. We recommend using a minimum width of 2,0 cm. There is no maximum size. There shall be space enough around the mark in order to separate it from other eventual marks near it. When necessary we can deliver a negative (white on black) version of the certification mark.

# **FSSC Logo use**

The organization commits itself to obeying the rules set for the use of the FSSC logo. The FSSC 22000 logo must be reproduced in the specified colors and in a size that makes all features of the logo clearly distinguishable.



## Color specifications:

Color	PMS	СМҮК	RGB	#
Green	348 U	82/25/76/7	33/132/85	218455
Grey	60% black	0/0/0/60	135/136/138	87888a

Use of the logo in black and white is permitted when all other text and images are in black and white. When used by the licensed certification body or by the certified organization, the size of the FSSC 22000 logo must not differ from the size of the certification bodies' mark and they must always appear together.

For further details please see FSSC Additional requirements (Part 2, 2.5.5): <u>FSSC-22000-Scheme-Version-5.1</u> pdf.pdf



ISO 3834-2, ISO 3834-3 or ISO 3834 Quality management system of welding

#### 2 Special features of the assessment and certification procedure

Documentation for compliance with the ISO 3834 series of standards is reviewed on the basis of the system description when developing the assessment plan.

ISO 3834 certification requires the company to have adequate qualification requirements for welding personnel, to apply good manufacturing practices and to perform the necessary inspection procedures for its production. The evaluation of these is included in the production activities for assessment of conformity with the ISO 3834 standard.

#### 3 Certification mark and technical definitions







Inspecta Sertifiointi Oy

Inspecta Sertificinti Oy

Inspecta Sertificinti Oy

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RGB: R:1 G:1 B:1



ISO 17100 Translation services - Requirements for translation services.

#### 2 Special features of the assessment and certification procedure

The ISO 17100 standard does not have the structure (HLS) of the management system standards. The use of post-edited machine translations is not included in the scope of this standard. This standard also does not apply to interpreting services.

Certification assessment Stage 1 (ABC 200 Section 3.4)

The standard does not require management reviews or internal audits.

#### 3 Certification mark and technical definitions



Inspecta Sertifiointi Oy

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RGB: R:1 G:1 B:1



ISO/IEC 20000-1 Management system for service management

## 2 Special features of the assessment and certification procedure

In Stage 1 of the certification assessment, it is ensured that the organisation applying for a certificate has in place the management and development responsibilities and authorisations of the services, service components and processes of the service management system to be certified in a manner required by the standard.

## 3 Certification mark and technical definitions



The colors for the mark are:

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Gray

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RGB: R:1 G:1 B:1





AQAP system ANNEX 11

#### 1 Standards on which the certification is based

AQAP-2110 AQAP system

## 2 Special features of the assessment and certification procedure

AQAP certification requires a valid ISO 9001 certification.

#### 3 Certification mark and technical definitions



The colors for the mark are:

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CMYK: C:100% M:52% Y:0% K:13%

RGB: R:0 G:106 B:222

<u>Gray</u>

C:75% M:68% Y:67% K:90%

RGB: R:1 G:1 B:1





ISO 13485 Quality management system in the field of medical devices

## 2 Special features of the assessment and certification procedure

In stage 1 of the certification audit, the risk assessment, the process descriptions and diagrams, and the procedures (i.a. incident reports, recalls, traceability, advisory notices, regulatory requirements and legal requirements) are assessed on a sample basis in connection to ISO 13485.

ISO 13485 is based on ISO9001:2008 and also:

Management review is assessed at the certification audit stage 1, as well as the procedure for internal audits and their status.

Also the process description, process related responsibilities and authorities, interaction of processes as well as objectives and indicators are assessed in this connection.

There is a reference in ISO 13485 standard to ISO 14971 standard (ISO 14971:2019 Medical devices. Application of risk management to medical devices).

This certifies the quality system, but also requires the part of a notified body if a higher class medical device is released onto the market. This is sufficient for Class 1 devices.

#### 3 Certification mark and technical definitions



The colors for the mark are:

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Inspecta Sertificinti Oy



ISO 22301 Business continuity management system

## 2 Special features of the assessment and certification procedure

In Stage 1 of the certification assessment, the operational description of the business impact analysis and the procedures for initiating continuity management activities are assessed.

In addition, the descriptions of the prepared continuity plans and the exercise plans related to the plans are evaluated.

#### 3 Certification mark and technical definitions



The colors for the mark are:

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CMYK: C:100% M:52% Y:0% K:13%

RGB: R:0 G:106 B:222

Gray

C:75% M:68% Y:67% K:90%

RGB: R:1 G:1 B:1

The proportions of the mark are as shown. We recommend using a minimum width of 2,0 cm. There is no maximum size. There shall be space enough around the mark in order to separate it from other eventual marks near it.

**Business ID** 

1065745-2



