




RULES FSMS

Food Safety Management Systems

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GENERAL

These Rules define the additional procedures and/or substitute, applied by QS for the certification of Food Safety Management Systems, in comparison to what is already defined in the General Rules for the certification of Management Systems.

QS issues the certification in accordance with requirements of standard ISO 17021-1:2015 and the standard ISO/TS 22003:2013 to Organizations whose Management System has been recognized in accordance with the requirements of standard ISO 22000:2005/2018.

REFERENCE STANDARD / REQUIREMENTS FOR CERTIFICATION

To obtain QS certification, a FSMS must initially and over time satisfy the requirements of ISO 22000 and the additional ones, if required, by the Accreditation Body and/or by private Organization which manages the Standard.

In particular, to obtain the certification of the management system, the Company have to:

Have prepared the Documentation which is:

- defining the goal/scope/field of application of the Food Safety Management System
- describing the main processes and their interactions, and contains or implies its documented procedures.

The description of the processes and their applications is to be extended to all those developed by the organisation (also the outsourced processes) required to manufacture/provide a particular product/service which is decisive as regards the capacity of the product/service to satisfy the applicable requirements.

This description can be created in different ways:

- descriptions
- Flow charts or logograms
- tables or matrices
- other
- taking into consideration the requirements of the standard and giving a description, not necessarily detailed, of the resources and procedures used to ensure compliance with these requirements,
- containing a suitable description of the company organisation.

Every information received from the client is reserved.

CERTIFICATION APPLICATION

The certification process begins by filling and sending by the applicant organisation of the documents relating to the request for quotation signed by its legal representative.

In addition to what defined in the QS General Rules point 10.1, organizations wishing to obtain certification of their food safety management system must provide to QS the relevant data of their organization and their activities and the location of the site(s), sending the application form "Application form ISO 22000" completed in all its parts on the basis of which is formulated by QS a quotation.

It is responsibility of the applicant organization:

- the compilation of documents in its entirety being as indispensable condition for the correct formulation of the QS quotation;
- the truthfulness of the information communicated by filling and sending of the documents in question;
- to examine the QS regulations.

Any additions or clarifications may be required prior to issuance of the offer.

The customer must provide the following information to QS:

- company name;
- complete addresses of sites;
- PEC address/certified e-mail
- the scope of certification required;
- number of employees and shifts;
- number of sites;
- system start up date and any admitted exclusions and reasons;
- consultant's name (if present);
- copies of any certificates in their possession
- number of active HACCP covering del scope of certification
- specify periods, schedules, shifts of relevant product lines/operations covering the scope of certification
- any outsourcing activity/temporary site included in the certification
- any relation with other Society of big dimension
- list of sites where the services are performed (e.g. catering, cooking centres, etc)

ANALYSIS OF CERTIFICATION APPLICATION, ISSUING OF OFFER AND PLANNING OF THE AUDIT

In addition to what defined in the QS Quality Services Ltd General Rules point 10.2 performs an analysis of the request and evaluates its ability to complete the task. Following the positive outcome, QS investigates the information received and send analysis results to the Administrator for permission to issue the offer.

Audit times are calculated in accordance with ISO/TS 22003 latest version into force Annex B, whereas the total headcount of employees of the company and the activity of the same in such a way as to verify the food safety system completely and effectively. Furthermore, it is necessary to be considered in determining the audit time of the assessment: relevant standard requirements FSMS, the legislative and technological context of company, any outsourcing activities included in the scope, results of previous audits. The audit shall be carried out in premises, in any other sites to be certified, and the outsourcing work activities included in the scope.

The Body shall plan audit activities so that the audit team has the opportunity to verify the representative products lines, sectors, categories and services that are included in the certification scope. Cannot be excluded parts of the process, sectors, products or services from the scope of certification when those process have direct influence on the safety of the final product/service being part of the scope in question.

NB: The offer and the audit planning are compiled according to data provided by the customer. If, during the execution of the certification process, will occur variations on the evaluated initial situation considered such to affect the first economic assessment, QS reserves the right to proceed to the revision of the offer and the audit plan.

INITIAL CERTIFICATION

In substitution to what is established at the point 10.1 of QS Quality Services Ltd of the General Rules, organisations wishing to get QS certification for their Food Safety Management System must provide to the essential data of their organization and its activities and the location of the site (s), by submitting the appropriate form "informative questionnaire" completed in all its parts on the basis of which is then formulated an economics quotation by QS.

In particular, the informative questionnaire requires information about:

- the scope requested for the certification;
- general information of the organization;
- the number of permanent and temporary sites involved in certification, together with the name, the address/es of sites and the relative activities carried out there
- HACCP plan related to the scope of certification;
- the possible involvement with bigger companies, if is the case;
- other certification obtained, if is the case;
- the involvement of any consulting services related to management system.

In substitution of the paragraph 10.4 of QS Quality Services Ltd General Rules, together with the certification request, or after that, the organisation must transmit to QS the following documentation:

- a documentation related to the Food Safety Management Systems (e.g. last valid revision HACCP plan);
- a comparative table between the requirement of the applicable standard and the procedures/paragraph/documents of the Documentation of the Food Safety Management Systems
- list of the internal procedures related to the Food Safety;
- copy of the Chamber of Commerce certificate or equivalent document, as evidence of the existence of the company and its effective activity;
- list of all the main regulations/law applicable to the product/service provided.

QS may require, at its discretion, to evaluate, as well as other documents besides those mentioned above, considered important for the assessment of the Management System for Food Security.

The above mentioned documentation is evaluated by QS to be in compliance with the referred standard and to the requirements of this Rule.

The cost of certification activity is proportional to the number of man-days (m/d) necessary to the evaluation of the Food Safety Management Systems of the Organization and to the level of complexity/criticality of it in reference to the document ISO/TS 22003:2013(E).

In substitution of the paragraph 10.6 of QS Quality Services Ltd General Rules, the initial audit is made by two stage:

- Audit stage 1
- Audit stage 2

Both performed on the site.

During the initial audit the company must demonstrate that the Management System is fully-effective since at least 3 months and that is applying the same system and the relative procedures.

At completion of initial audit, with favourable outcome, and subject to validation by QS, is issued for the Management System for Food Safety, a three-year validity certificate of conformity to the reference standard.

In the certificate there are the name and the address of the company, the address or addresses of the operative sites included in the certification, the scope of certification, the food category/ies involved in the certification, the first issue date, the current issue and the expire date.

The validity of the certificate depends on the result of the successive annual surveillance audits and on the recertification of the Management System audit after three years..

The periodicity and the extension of the subsequent audits for the maintenance of the certification are established by QS case by case with the elaboration of a three year audit plan, which is sent to the organisation.

EXECUTION OF THE AUDIT

GENERAL

In addition to what established at point 10.8 of QS Quality Services Ltd, is meant as a major non-conformity a situation which can compromise the safety of food products, the non-observance of legal requirements of production and destination Countries and any situation that could lead to a serious danger to the health of consumers.

Moreover, if there aren't authorization or registration of the site, as requested by the current legislation, the certification process is suspended.

THE INITIAL CERTIFICATION AUDIT

The initial certification audit consists of two stages (STAGE 1 e STAGE 2)

STAGE 1

In substitution of what is mentioned at paragraph 10.6 of QS Quality Services Ltd General Rules, Audit Stage 1 carried out at the organization, aims to:

- Verify that the documentation of the Food Safety Management System, including procedures, meet all the requirements of the standard;
- assess whether the internal audits and the management review have been planned and executed at all sites of the organization involved to the certification;
- Review the status and understanding of the client regarding the requirements of the standard, with particular reference to the identification of key performance or significant aspects, processes, objectives and operation significant for the Food Safety Management System;
- collect the necessary information concerning the scope of the management system, processes and /and localization / the customer, including related legal and regulated, and compliance with them;
- verify that the Organization has all necessary authorizations/licences relating to food safety and its activities and that they are valid and consistent with the applicable law;
- perform an inspection of the Manufacturing site (s) of the Organization to evaluate any critical situation not already considered by Management System for food safety of the Organization;
- Review the allocation of resources for STAGE 2 audit and agree with the customer details of the audit STAGE 2;
- Focus on the audit planning STAGE 2, gaining a sufficient understanding of the management system and activities and the customer site, with the possible significant aspects;
- the FSMS is operative since at least three months and that procedures are efficaciously implemented.

The outcome of the audit STAGE 1 is issued to the organization by leaving a copy of the audit report of STAGE 1 on which are among other reported any findings that may be encountered including those classified as nonconformities (major or minor) during the audit STAGE 2.

The actions taken by the Organisation for the resolution of these findings are verified during the audit STAGE 2.

In the presence of very critical NC, the technicians who performed the audit stage 1 decide if they must be resolved before proceeding with the Stage 2 audit at the organization; in case of audit stage 1 and stage 2 consecutive audit Stage 2 will be rescheduled and postponed to a date (not exceeding 6 months from the date of the audit stage 1)

STAGE 2

STAGE 2 audit at the organization must be performed within a maximum period of 6 months following completion of STAGE 1 of the audit.

The stage 2 audit at the organization is carried out to verify the correct and effective implementation of the Management System.

QS sends to the organization, before the audit stage 2 at the site / s, an audit plan in which is given in detail, the description of assets and provisions for the conduct of the audit

If the activities to inspect are carried out on multiple operating sites, the audit is carried out according to criteria previously established and communicated to the Organization by QS.

The stage 2 audit is performed by qualified QS technicians based on the audit report stage 1 and on the documents of the Food Safety Management System prepared by the Organization in the updated edition.

Essentially the audit stage 2 consists of:

- an initial meeting with the Technician of the Organization to agree on the scope and methods of the audit and to confirm the audit plan;
- a review of the implementation of effective adaptation measures with regard to remarks made during the audit phase 1;
- an inspection of the Production site /s Organization to verify the compliance of the for Food Safety Management System reference documents and its full implementation;
- a final meeting to explain the outcome of the inspection.

In the presence of non-conformity the certification process is suspended; In case of

observations whose numerous, in the opinion of the audit team, would undermine the proper functioning of the management system, the certification process is also suspended.

In such cases, within three months, QS must perform an additional audit in order to verify the effectiveness of treatments and proposed corrective actions; if there is a successful outcome of this audit, the certification process is resumed..

The additional audit may be conducted on site or on the basis of documents according to the type of corrective actions to be verified in the opinion of the audit team.

All expenses relating to any additional audits resulting from deficiencies of the Management System shall be on charge by the Organization.

If this deadline is exceeded, the Management System of the Organization must be submitted to complete review within a period of six months from the end of stage 2 audit

After the six-month period without a successful conclusion of the evaluation, QS can

considered closed the certification, charging time and expenses incurred up to that point. In such cases, the organization that wishes to continue with the QS certification must submit a new request and repeat the certification process.

These time limits may be varied in special cases on a reasoned request of the Organization, according to the opinion of QS.

MULTISITE ORGANIZATIONS – SAMPLING METHOD

A multi-site organization is an organization having an identified central function (hereafter referred to a central office - but not necessarily the headquarters of the organization) at which certain FSMS activities are planned, controlled or managed, and a network of sites at which such activities are fully or partially carried out.

(Examples: organization of operating with franchise, a manufacturing company with one or more production sites and a network of sales office, services organization with multiple sites offering a similar service, organization with multiple branches)

In substitution of what is mentioned at paragraph 11 of General Rules, where an organization operates across multiple sites and all functions relating to the Food Safety for Management System are managed by a central headquarter and a single certification is required the audit may be performed by sampling the sites audited only for the categories allowed by ISO/TS 22003:2013 (A,B,E,F e G) and if the number site exceeds 20 units, provided that:

- The Activity to be certified is the same for all sites and the organization applies the same Food Safety Management System (managed from a central location) for all sites;
- At all sites of the Organization products / services provided are essentially the same kind and are made basically with the same methods and the same procedures and all sites are located in the same country;
- At least the following activities are managed from the headquarters of the Organization:
 - Communication procedures;
 - Management and emergency response;
 - Analysis of the hazards and individuation of associated risks;
 - The traceability system;
 - The assessment of training requirements;
 - The control of document and its amendments;
 - The review of the management system by top management;
 - Evaluation of the effectiveness of corrective and preventive actions (audit findings of the individual sites shall be considered indicative of the entire system and correction shall be implemented accordingly);
 - Planning / execution of internal audit and evaluation of their results;
 - Before the audit of QS the organization must have performed internal audits of each site.

SELECTION CRITERIA

As substitution of the point 11.2 of the General Rules, during the initial certification audit, surveillance and recertification will be carried out sampling in accordance with the ISO/TS 22003:2013.

For organizations with 20 sites or less, all sites shall be audited.

The sampling for more than 20 sites shall be at ratio of 1 site per 5 sites. All sites shall be randomly selected and, after the audit, no sampled sites may be nonconforming

At least annually, an audit shall be performed by the certification body on the required number of sampled sites.

Audit findings of sampled sites shall be considered indicative of the entire system and correction shall be implemented accordingly

MIGRATION TO ISO 22000:2018 FROM ISO 22000:2005

On 18th June 2018 the new standard ISO 22000:2018 has been issued.

On 17th June 2021 the ISO 22000:2005 will be not valid anymore and the new standard ISO 22000:2018 will be effective. For all the information and modality to migrate the certification to the new standard, QS has sent to all customers and also has published on the website www.qualityservices.com.mt the information letter about deadline for the transition and modality.

SUMMARY ON THE VALIDITY OF CERTIFICATIONS

MIGRATION OF CERTIFICATIONS ACCREDITED FROM ISO 22000: 2005 TO ISO 22000: 2018

NEW CERTIFICATIONS AND RENEWALS

Up to 3 years from the publication of the new ISO 22000: 2018, the new certifications and renewals issued for both editions of the ISO 22000: 2005 and ISO 22000: 2018 standards will be valid.

The expiry date of the ISO 22000: 2005 certifications issued during the transitional period of 3 years must however correspond to the end of this period (June 17, 2020) although the effective deadline will be after that date.

Attention: already from 18 June 2020 it will not be possible to issue new certifications or renewals in accordance with ISO 22000: 2005

In order to adapt your MS to the migration of the new standard, we recommend to the organization:

- (if applicable) to resolve any findings / non-conformities for the ISO 22000: 2005 standard issued during the previous audit by QS or other CB, to allow migration to ISO 22000: 2018
- to deepen the content and requirements of the new standard
- to perform an analysis of the standard in question to identify the organizational gaps with respect to the new requirements.
- to develop a migration plan to implement the new requirements or directly apply the changes to the system.
- train all interested parties that have an impact on the efficacy of the MS of Food Safety so that they meet the required competence requirements.
- to agree with QS on a migration plan in accordance with the new standard

According the new IAF communication because of pandemic covid19 crisis, the time to migrate to the new ISO 22000:2018 is postponed of 06 months, thus the customers has time till December 2021