BSI Certification Requirements

BSI Standard Terms and Conditions
Addendum

ISO 22000:2018

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Contents

Revision History

Rev No	Revision Date	Author	Approved by	Page No	Sec. No	Brief Description of Change
1	December 2020	Ana Cicolin	Todd Redwood	New document		

1   Introduction

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). ISO 22000 establishes the food safety management system (FSMS) requirements for any organization in the food chain. The adoption of a FSMS is a strategic decision for an organization that can help to improve its overall performance in food safety.

The potential benefits to an organization of implementing a FSMS include the ability to consistently provide safe foods and products and services that meet customer and applicable statutory and regulatory requirements; addressing risks associated with its objectives and the ability to demonstrate conformity to specified FSMS requirements.

2   Accreditation Status and BSI Scope of Accreditation

BSI holds a valid global ISO/IEC 17021-1:2015 accreditation. The accreditation for ISO 22000 is scoped in accordance with ANAB (for all categories except J) and JASANZ (only for category J) accreditation rule and ISO/TS 22003:2013.

3   The Recognition Process

The following section outlines the steps that apply during the BSI recognition process for ISO 22000. BSI reserves the right to provide its clients and those that request quotations with marketing and technical information relating to standards, training and compliance services.

3.1   Initial Enquiry

BSI will respond to either verbal or written expressions of interest from sites interested in one or more of our programs. If your site is located near one of BSI's offices, an advisory visit may be arranged to discuss your recognition requirements and how BSI can help your site achieve them. BSI will also, on request and receipt of a Request for Proposal, prepare a proposal suited to your site's needs.

3.2   Application for Certification and Assessment

Receipt of your site's Application form (or authorized acceptance of a valid BSI proposal), along with the accompanying payment of the non-refundable application fee (or invoicing instructions) together with this document forms the contract between your site and BSI.

Your requirements will be entered into our database and an auditor will be appointed to look after your certification or assessment requirements. The auditor will be your primary point of contact with BSI and is responsible for ensuring that our certification/assessment services are delivered to your site in the most effective manner possible.

3.2.1   Application Form Client Contact

1)   BSI will require completion of an official application form, signed by an authorized representative of the applicant site.

2)   It is the responsibility of the applicant site to ensure that adequate and accurate information is shared with BSI about the details of the applicant site.

3.3   Certification Contract

As soon as practicable after receipt of your signed application/proposal, a BSI auditor (or nominated representative) will contact your site. Your auditor will seek to establish a working relationship between your site and BSI, and to confirm your recognition requirements in terms of the certification or assessment services, standards or codes of practice, locations, and activities and/or products to be included in the scope of certification.

The auditor will seek to gain an appreciation of the structure of your site and the activities being conducted. In particular the auditor will:

- Seek an appreciation of the nature and scope of your site's activities, structure and location(s), including any activities for which certification is being excluded; and

- Determine the status of system documentation and implementation including organizational policies, objectives and targets.

If your site is working with a consultant it is often useful for that person to be party to the communication process.

3.4   Conduct a Self-Assessment / Pre-assessment Audit (not mandatory)

A self-assessment or pre-assessment audit can assist in identifying gaps in your site's ISO 22000 System so that corrective action can occur before engaging BSI for a full certification audit. It can be conducted using internal resources, an ISO 22000 consultant, or an ISO 22000 auditor. Once your site has signed a contract with BSI, BSI can provide an assessment checklist free of charge to utilize in a self-assessment / pre-assessment audit.

3.5   Identifying the Scope of Certification

ISO 22000 certification is site and product specific. When activities are carried out in different premises but are overseen by the same senior, operational, and technical management, and are covered by one ISO 22000 System, the scope can be expanded to include those off-site activities.

The scope of certification forms part of the certificate of registration. It describes the food sector categories (refer to table below) and the products processed and handled on that site. The certificate of registration outlines the location of the site and nature and extent of the ISO 22000 certification.

The audit scope will be agreed between your site and BSI before the certification audit begins. The scope of the audit shall cover the required level of certification, the food sector categories, and the products listed under the scope of certification for a site.

Category			Subcategory	Coverage (Examples of included activities)
A	Farming of animals Note: Activities such as hunting, or trapping are not included	**AI**	Farming of animals for meat/ milk/ eggs/honey	Raising animals (other than fish and seafood) used for meat production, egg production, milk production or honey production. Growing, keeping, trapping and hunting (slaughtering at point of hunting). Associated farm packing[(a)] and storage

|					
		AII	Farming of fish and seafood	Raising fish and seafood used for meat production.	
				Growing, trapping and fishing (slaughtering at point of capture).	
				Associated farm packing[a] and storage	
B	Farming of plants	**BI**	Farming of plants (other than grains and pulses)	Growing or harvesting of plants (other than grains and pulses): horticultural products (fruits, vegetables, spices, mushrooms, etc.) and hydrophytes for food.	
				Associated farm packing[a] and storage	
		BII	Farming of grains and pulses	Growing or harvesting of grains and pulses for food.	
				Associated farm packing[a] and storage	
C	Food manufacturing	**CI**	Processing of perishable animal products	Production of animal products including fish and seafood, meat, eggs, dairy and fish products	
		CII	Processing of perishable plant products	Production of plant products including fruits and fresh juices, vegetables, grains, nuts, and pulses.	
		CIII	Processing of perishable animal and plant products(mixed products)	Production of mixed animal and plant products including pizza, lasagne, sandwich, dumpling, ready-to-eat meals	
		CIV	Processing of ambient stable products	Production of food products from any source that are stored and sold at ambient temperature, including canned foods, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, food-grade salt.	
D	Animal feed production	**DI**	Production of feed	Production of feed from a single or mixed food source, intended for food-producing animals	
		DII	Production of pet food	Production of feed from a single or mixed food source, intended for non-food producing animals	
E	Catering			Preparation, storage and, where appropriate, delivery of food for consumption, at the place of preparation or at a satellite unit. Examples include restaurants, hotels, cafeterias, canteens, coffee shops, food trucks event catering.	
F	Distribution	**FI**	Retail / Wholesale	Provision of finished food products to a customer (retail outlets, shops, wholesalers)	
		FII	Food Broking / Trading	Buying and selling food products on its own account or as an agent for others.	
				Associated packaging[b]	

G	Provision of transport and storage services	GI	Provision of transport and storage services for perishable food and feed	Storage facilities and distribution vehicles for the storage and transport of perishable food and feed. Associated packaging[b]
		GII	Provision of transport and storage services for ambient stable food and feed	Storage facilities and distribution vehicles for the storage and transport of ambient stable food and feed. Associated packaging[b]
H	Services			Provision of services related to the safe production of food, including water supply, pest control, cleaning services, waste disposal.
I	Production of food packaging and packaging material			Production of food packaging material
J	Equipment manufacturing			Production and development of food processing equipment and vending machines
K	Production of (Bio) chemicals			Production of food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes and processing aids Pesticides, drugs, fertilizers, cleaning agents

[a] "Farm packing" means packaging without product modification and processing.
[b] "Associated packaging" means packaging without product modification and processing and without altering the primary packaging.

3.6   Certification Cycle

A three-year certification cycle shall be applied to ISO 22000 and shall be respected at all times. The first three-year certification cycle begins with the certification decision (original registration date). Subsequent cycles begin with the recertification decision.
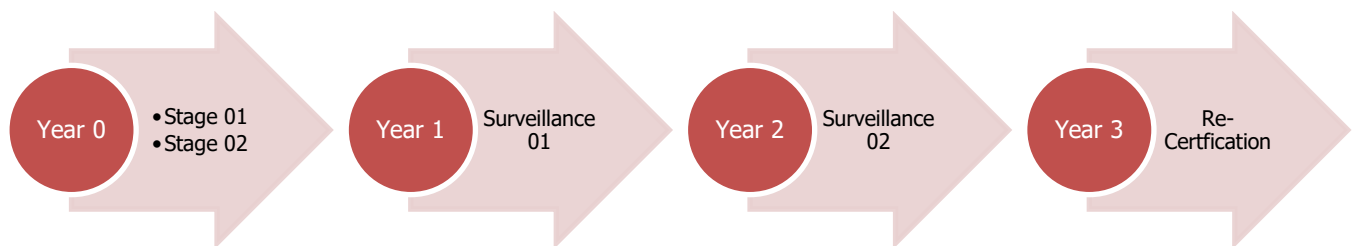
3.6.1   Planning Audits

The basis of timings applied to the certification and audit cycles for ISO 22000 scheme is that each certificate shall become attached permanently to a month for the CAVs (surveillances) and RAs (Re-certifications) audits. This month is defined as a Reoccurring Audit Month (RAM) in which it is expected that these audits shall occur on a regular basis.

The RAM is determined by counting 8 months from the initial certification decision date. Therefore, the RAM is 4 months in advance of the anniversary of the certification decision date and all audits following the initial certification decision date shall occur every 12 months, in the same month, in a regular pattern. Audits should occur in or prior to the RAM month

Regardless of the audit cycle, the certification cycle remains based on the expiration date. Audits should occur within or prior to the RAM month.

3.7   Audit Criteria

The audit criteria represents set of requirements used as a reference against which objective evidence is compared. ISO 22000 certification audit criteria shall include the requirements as below:

- ISO 22000:2018 requirements;
- The defined processes and documentation of the management system developed by the organization;
- Related statutory/regulatory requirements; and
- Related customer requirements.

3.7.1   Legal and Regulatory Audit Requirements

Legislative and regulatory compliance is a requirement of ISO 22000. The maintenance and evaluation of legal compliance is the responsibility of the client. BSI's role is to establish confidence that the ISO 22000 system functions adequately in this regard and to confirm that the ISO 22000 system is capable of achieving continued compliance.

BSI will verify that the client has included legal and regulatory compliance in their ISO 22000 system and can show that action has been taken in cases of non-compliance with relevant legislation. BSI will not issue certification to a site where an infringement of food safety related legislation or regulation is discovered. Where an action plan to achieve compliance has been agreed with the appropriate regulator an exception may be requested.

BSI will notify the client if an infringement is discovered. Action will depend upon the nature of the infringement, corrective action proposals and the stance taken by the appropriate enforcement authority but would normally constitute a major non-conformity followed up with a re-audit visit.

Similarly, action will be taken where a post certification infringement is discovered. The conditions of contract require the client to notify BSI of post certification breaches. De-registration is an option for persistent failure to comply.

Where licenses/consents/permits have not been issued by appropriate authorities, including incomplete document submissions, and steps are being taken to achieve compliance in agreement with the regulator a non-conformity should be raised.

3.8   Initial Certification Audit – Two Stage Audit process

BSI shall perform the stage 1 and stage 2 audits for initial certification according to the requirements of ISO/IEC 17021-1 and ISO/ TS 22003:2013. The interval between stage 1 and stage 2 audits shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.

3.8.1 Stage 01

The objectives of stage 1 are to provide a focus for planning the stage 2 audit by gaining an understanding of the organization's FSMS and the organization's state of preparedness for stage 2 by reviewing the extent to which:

a) the organization has identified prerequisitie programs (PRPs) that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements);

b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);

c) relevant food safety legislation is implemented;

d) the FSMS is designed to achieve the organization's food safety policy;

e) the FSMS implementation programme justifies proceeding to the audit (stage 2);

f) the validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard;

g) the FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties; and

h) if there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance.

Stage 01 also aims to:

- Review the allocation of resources for stage 2 and agree the details of stage 2 with the client;
- Evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2;
- Review the client´s management system documented information;
- Evaluate client´s site specific conditions to undertake discussions with client´s personnel to determine the preparedness for stage 2;
- Obtain necessary information regarding the scope of the FSMS, including client´s site, process and equipment used, levels of controls established and applicable statutory and regulatory requirements.

Where an organization has implemented an externally developed combination of control measures, the stage 1 shall review the documentation included in the FSMS to determine if the combination of control measures is: suitable for the organization, was developed in compliance with the requirements of ISO 22000 and is kept up to date. The availability of relevant authorizations shall be checked when collecting the information regarding the compliance to regulatory aspects.

The results of the stage 1 may lead to postponement or cancellation of the stage 2.

3.8.2 Stage 02

The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's FSMS. The stage 2 shall include the auditing of:

- all ISO 22000 requirements;

- performance monitoring, measuring, reporting and reviewing against key performance objectives and targets;

- the client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;

- operational control of the client's processes;

- internal auditing and management review;

- management responsibility for the client's policies.

3.9   Surveillance audits

Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.

Note: It can be necessary to adjust the frequency of surveillance audits to accommodate factors such as seasons or management systems certification of a limited duration (e.g. temporary construction site).

A surveillance audit shall be planned in order to maintain confidence that the client's certified management system continues to fulfil requirements between recertification audits.

BSI shall develop its surveillance activities so that representative areas and functions covered by the scope of the management system are monitored on a regular basis and take into account changes to its certified client and its management system.

Surveillance audits are not necessarily full system audits and shall be planned together with the other surveillance activities so that BSI can maintain confidence that the client's certified management system continues to fulfil requirements between recertification audits. Between the two surveillance audits BSI shall ensure that the entire management system is audited as well as all ISO 22000 requirements covered. In addition to that each surveillance shall include as mandatory:

- internal audits and management review;

- a review of actions taken on nonconformities identified during the previous audit;

- complaints handling;

- effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);

- progress of planned activities aimed at continual improvement;

- continuing operational control;

- review of any changes;

- use of marks and/or any other reference to certification.

3.10   Re-certification

ISO 22000 re-certification shall be a full audit against all ISO 22000 requirements.

The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification.

A recertification audit shall be planned and conducted to evaluate the continued fulfilment against ISO 22000 requirements. This shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date.

The recertification activity shall include the review of previous surveillance audit reports and consider the performance of the management system over the most recent certification cycle. Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the management system, the organization, or the context in which the management system is operating (e.g. changes to legislation).

The recertification audit shall addresses the following:

- the effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;

- demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;

- the effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system.

For any major nonconformity, the related correction and corrective actions shall be implemented and verified prior to the expiration of certification.

When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the recertification decision.

If BSI has not completed the recertification audit or is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification shall not be recommended and the validity of the certification shall not be extended. The client shall be informed and the consequences shall be explained.

Following expiration of certification, BSI can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

3.11 Audit Duration

The ISO 22000 audit duration is determined by using the following factors:

- Product Category[a];

- Number of HACCP plans/studies[b];

- Presence of a relevant management system in place[c]

- Number of Employees [d]

  (a) Product Category: For the audit duration calculation the country salesperson must choose the appropriate category and subcategory for the scope of certification that has been requested. Note: If the scope of one specific client organization covers more than one category, the audit-time calculation

shall be taken from the highest recommended basic audit time (meaning the category with the larger audit duration shall be applied).

(b) A HACCP study corresponds to a hazard analysis for a family of products /services with familiar hazards and similar production technology and, where relevant, similar storage technology.

(c) Relevant management system for ISO 22000 includes ISO 9001 and GFSI recognized schemes. The certificate of the relevant management system can only be accepted if:

- it covers the intended ISO 22000 certification scope (processes and products);

- is an accredited certificate;

- the certificate is current (has not expired);

- the certificate has been issued by BSI. Certificates from another CB cannot be accepted.

(d) Number of Employees: The number of employees involved in any aspect of food safety shall be expressed as the number of Full Time **Equivalent** (FTE) Employee. When an organization deploys workers in shifts and the products and/or processes are similar, the FTE number will be calculated based **on employees on the main shift.**

FTE shall include: Production/ manufacturing/ supporting activities/ wholesale/ transport/ quality assurance/ research and development/ office based, full time, part time and seasonal workers.

3.11.1 Basic Guides for Audit Duration

BSI shall calculate the audit duration based on the information gathered from the organization's application and following the requirements of ISO/IEC 17021-1, ISO/TS 22003 and ISO 22000 as follows:

- The duration of an audit day is normally eight (8) hours (unless otherwise stated in local legislation).The effective on-site audit duration **does not include a lunch break** (unless otherwise stated in local legislation)

- The audit duration calculation for ISO 22000 shall be documented in the contract review form, including justifications for reduction or addition of time based on the minimum audit duration;

- The on-site audit time does not include planning, reporting or travel activities, only actual on-site auditing time. The on-site audit time shall only apply to auditors that are fully qualified, approved as ISO 22000 auditors (provisional or lead auditors). Trainee auditors do not contribute to audit duration;

3.11.2 ISO 22000 Audit Duration Calculation

The total on-site audit time (for a single site) is defined as T_s. In additional to that, BSI shall include appropriate time for the audit report.

Calculate the T_S : The minimum audit time for a single site, T_S, expressed in man-days, is calculated as follows: $T_S = (T_D + T_H + T_{MS} + T_{FTE})$, where the values of the variables represented in the table below are:

- T_S = the minimum audit time for a single site;

- T_D = is the basic on-site audit time, in days;

- T_H = is the number of audit days for additional HACCP studies

- T_{MS} = is the number of audit days for absence of relevant management system

- T_{FTE} = is the number of audit days per number of employees

Category	Basic, on-site audit time, in audit days T_D	Number of audit days for each additional HACCP study T_H	Number of audit days for absence of certified relevant management system T_{MS}	Number of audit days per number of employees (FTE on the man shift) T_{FTE}	For each additional site visit (belonging to a multisite)
A	0.75	0.25			
B	0.75	0.25			
C	1.50	0.50			
D	1.50	0.50		1 to 19 = 0	
E	1.00	0.50		20 to 49 = 0.5	
F	1.00	0.50	0.25	50 to 79 = 1.0 80 to 199 = 1.5 200 to 499 = 2.0 500 to 899 = 2.5 900 to 1299 =3.0 1300 to 1699 = 3.5 1700 to 2999 = 4.0 3000 to 5000 = 4.5 >5000 = 5.0	50% of minimum on-site audit time
G	1.00	0.25			
H	1.00	0.25			
I	1.00	0.25			
J	1.00	0.25			
K	1.50	0.50			

In summary the ISO22000 calculation shall look as follow:

Audit Type	Calculation
IA	**IA (Initial Audit)** = T_s + Report Time ○ Stage 01: 1/3 of (T_s) ○ Stage 02: 2/3 of (T_s) + Report Time ○ Stage 01 + Stage 02 = IA
CAV	**CAV 01 (Surveillance 01)** = (1/3 x T_s) + Report Time **CAV 02 (Surveillance 02)** = (1/3 x T_s) + Report Time
RA	**RA (Re-certification)** = (2/3 x T_s) + Report Time

Note: Report Time is not mandatory

The minimum surveillance audit time shall be one-third of the initial certification audit time, with a minimum of 1 audit day (0,5 audit day for categories A and B).

The minimum recertification audit time shall be two-thirds of the initial certification audit time, with a minimum of 1 audit day (0,5 audit day for categories A and B).

The calculation from table above is refereed only to on-site time. Report time time is not included and is up toe BSI and client agreed about report time. **On site time cannot be used for report time purpose in any circumstances**. The amount of time to be added regarding report time is up to country decision and is not mandatory to be added. It is recommended 0.5 man-day for report time to be added when client and BSI decide that is appropriated.

3.11.2.1 Multisite

Where multisite applies, a reduction of 50% can be applied for each additional site.

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

The sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites as illustrated on the table below:

	Total number of sites								
	Number of sites to be audited between 1 and 20	21	22	23	24	25	26	27	28
Number of sites above 20	0	1	2	3	4	5	6	7	8
Additional number of sites to audit	0	1	1	1	1	1	2	2	2
Number of sites to be audited	20	21	21	21	21	21	22	22	22

For detail about how manage multisite certification refer to the PP001 (ISO 22000 Global scheme manual).

3.11.3 Rounding

If after the duration calculation the result is a decimal number, this shall be rounded downwards or upwards to the nearest half day under mathematical rounding rules (the automated calculators are already set for this rounding rule).

3.11.4 Additional Time

3.11.4.1 Use of translator:

Additional on-site audit time shall be added in case a translator is required to support the audit team. For translation the minimum time recommended to be added is 0.25 on site auditor day. The maximum time needed will depend about the percentage of duration that the translator will attend the audit.

3.11.4.2 Combined audit

Where the ISO 22000 audit is undertaken in combination with other food safety audits (2nd party schemes and/or GFSI audit and/or GMP & HACCP certification) **as a combined audit (under the same scope of certification, audit on the same day(s) by the same audit team)**, the need to increase duration shall be assessed by the BSI contract reviewer. The base for assessment is that if the additional scheme has additional requirements (beyond those included on the ISO 22000) so the contract reviewer

shall decide the additional time to be added to the ISO 2200 audit duration (normally from 01 – 04 additional hours) to ensure the minimum ISO 22000 audit duration is respected to audit the related ISO 22000 requirements. If the requirements of ISO 22000 and the additional schemes are the same or equivalent, no additional audit time shall be added.

Where the ISO 22000 audit is undertaken in combination with other food safety audits (2nd party schemes and/or GFSI audit and/or GMP & HACCP certification) **as a combined audit (<u>under different scope of certification</u>, audit on the same day(s) by the same audit team)**, the duration shall be increased (normally from 01 – 04 additional hours) in addition to the ISO 22000 duration. The minimum ISO 22000 audit duration shall always be respected. Total audit duration is then longer than for ISO 22000 alone. This is considered as an increase in audit duration and the reason for this shall be justified.

3.11.4.3 Extension of Scope

If the scope extension audit is combined with one audit belonging to the regular cycle, the total audit duration shall be calculated by including the parameters of the extended scope. If a stand-alone extension of scope audit is required, the duration may vary depending of the intended scope extension.

Both situations above refer to an extension of scope in a site already ISO 22000 certified. If the site is not ISO 22000 certified yet, it shall be treated as a new certification process based on the initial audit duration calculation.

3.11.4.4 ISO 22000 Special Audit

If a separate special audit is required, the duration may vary depending on what will be audited. If the special audit is combined with one audit belonging to the regular cycle, the audit duration shall be increased on the top of ISO 22000 assessment.

3.11.5 Reduction in Time

When properly documented and justified, a reduction can be made in a less complex organization measured by number of employees, size of the organization and/or product volume or within categories having an initial minimum audit time of less than 1,5 audit days.

3.11.5.1 Integrated audit

Audit of integrated management system means an audit of an organization's management system against two or more sets of audit criteria/standards conducted at the same time.

Integrated management system (IMS) means a single management system managing multiple aspects of organizational performance to meet the requirements of more than one management standard, at a given level of integration.

Audit of an IMS could result in increased time, but where it results in reduction, it shall not exceed 20% from the starting point T. The IAF MD 11 shall apply.

3.11.6 ISO 22000 Follow Up Audits

In the case where a follow up audit is required, duration will depend on the objective of the follow up audit and so shall be analysis case by case.

3.12   Audit Report

At the conclusion of the audit, the audit team will prepare a written report on the audit findings and the audit team leader will present these findings to your site's senior management at the exit meeting.

Non-conformities will be discussed with your team during the auditor's visit and outlined at the exit meeting. Non-Conformities are categorized as Major and Minor.

These Non-Conformities and their categorization at the exit meeting are preliminary and are subject to a technical review by BSI.

The audit findings include a summary of the overall compliance of your system with the requirements of the relevant standard(s) or codes of practice.

If you are unclear regarding the meaning of anything in your report, please contact your BSI auditor or local office.

The ownership of the certificate and audit report content is held by BSI. At the request of food safety authorities, information related to the certification and auditing process shall be shared

3.13   Non-conformities

It is your site's responsibility to respond to the non-conformities detailed in your audit report by the designated time frame. Failure to do so may result in suspension or cancellation of your certification.

Close out of non-conformities is via your BSI ISO 22000 auditor. The auditor will review the information provided and will either approve and close out the non-conformance or request further information from your site until such time as the sufficient information has been received. Certain non-conformances require a revisit to the site to confirm satisfactory closure.

3.13.1 Nonconformities Levels

All non-conformities raised in an ISO 22000 audits shall be addressed by the organization.

The non-conformities against ISO 22000 requirements shall be graded in 2 levels being minor and major.

- Minor non-conformity (NC): a minor NC is issued when the finding does not affect the capability of the management system to achieve intended results

- Major non-conformity (NC): a major NC is issued when the finding affect the capability of the management system to achieve intended results and/or when a direct food safety impact without appropriate action by the organization is observed during the audit and/or when a legality and/or certification integrity are at stake.

The audit team may identify opportunities for improvement.

3.13.2 Non-Conformity Management

Minor: The organization shall provide to BSI, the CAP (corrective action plan) including correction, root cause analysis and corrective action within 28 calendar days from the last day of the audit. BSI should review and approve it when acceptable, no later than 30 days from the last day of the audit.

Correction and corrective action shall be implemented by the organization within the timeframe proposed on the CAP by the organization and agreed by BSI. Evidence of implementation and its effectiveness shall be reviewed, at the latest, at the next scheduled audit.

Note: Failure to address a minor nonconformity from the previous audit could lead to a major nonconformity being raised at the next scheduled audit

Major: The organization shall provide to BSI the CAP (corrective action plan) including correction, root cause analysis and corrective action, within 14 calendar days from the last day of the audit. BSI shall review the corrective action plan and conduct a follow up audit (desk review or on site, up to auditor´s decision based on risk) within 28 calendar days from the last day of the audit to close the major NC. Where completion of corrective actions might take more time, the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action plan is implemented.

Note: Major NCs must be closed prior to the issue/re-issue of a certificate.

3.14 Granting Certification

Certification of an ISO 22000 System shall be awarded to an organization with no outstanding non-conformities. Whilst the certificate is issued to the applicant site, it remains the property of BSI under the conditions outlined in the contract.

3.15 Multi-site certification

BSI can certify a multi-site organization under one management system, providing that the following conditions apply:

- all sites are operating under one centrally controlled and administered FSMS as defined in ISO 22000:2018, Clause 4, or equivalent for other FSMS;
  - o The organization shall identify its central function;
  - o The central function is part of the organization and shall not be subcontracted to an external organization;
  - o The central function shall have organizational authority to define, establish and maintain the single management system;
  - o The central function shall be responsible for ensuring that data is collected and analyzed from all sites and shall be able to demonstrate its authority and ability to initiate organizational change as required in regard, but not limited, to: (i) system documentation and system changes; (ii) management review; (iii) complaints; (iv) evaluation of corrective actions; (v) internal audit planning and evaluation of the results; and (vi) statutory and regulatory requirements pertaining to the applicable standard(s).
- an internal audit has been conducted on each site within one year prior to certification;
- audit findings of the individual sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

Note: A multi-site organization need not be a unique legal entity, but all sites shall have a legal or contractual link with the central function of the organization and be subject to a single management system, which is laid down, established and subject to continuous surveillance and internal audits by the central function.

For all cases of multi-site certification, the central function shall be audited at least annually and prior to the site audits.

When sampling is not allowed, all sites (connected to the central function) must be audit every year.

4   ICT (Information and Communication Technology) use in ISO 22000 Audits

The standard method for conducting ISO 22000 audits is either through full on-site audits as described on this global scheme manual or as ICT audit approach (remote + on site). Both of which are accredited.

The ISO 22000 full remote option is an **accredited, voluntary option <u>that can only be utilized where access to the premises of the certified organization is not possible as a direct result of a serious event</u>**, supported by a risk and feasibility assessment.

4.1   Definition

- **Full Remote Audit:** A full remote audit is defined as an audit that takes place entirely at a location other than that of the certified organization through the use of ICT.

- **ICT audit approach (Remote + On Site):** ISO 22000 audit as a split process utilizing ICT. The ICT audit approach audit consists of 2 main steps being the remote audit and the on-site audit.

- **ICT:** is the use of technology for gathering, storing, retrieving, processing, analyzing and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others.

4.2   ICT audit approach

The ICT Audit Approach is voluntary and shall to be mutually agreed between the BSI and the certified organization prior to the audit. The ICT audit approach consists of 2 main steps:

- <u>Remote audit component</u> consisting of a document review and interview key personnel using ICT.

- <u>On-site audit component</u> focusing on the implementation and verification of the FSMS, the physical inspection of the production process and any requirements not covered during the remote audit.

4.3   Full remote

The ISO 22000 full remote option is an **accredited, voluntary option <u>that can only be utilized where access to the premises of the certified organization is not possible as a direct result of a serious event</u>**, supported by a risk and feasibility assessment. Mutual agreement between BSI and the certified organization is required prior to conducting the full remote audit.

A full remote audit is defined as an audit that takes place entirely at a location other than that of the certified organization through the use of ICT.

Note: <u>Full remote audit IS NOT A DESK REVIEW. Full remote is an audit with client interaction by using ICT and not constitute at any point as a desk review to be performed only through documents review.</u> Remote audit activities follow the same principles of the on-site audit activities.

4.3.1 Transfer of certification

BSI will follow the requirements of IAF MD 2 for all transfer certification.

4.3.2 Special Audits

Additional special audits shall be performed in addition to – but never as a replacement of the annual surveillance/ recertification audits.

4.3.2.1 Extension of Scope

BSI shall, in response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit or with a re-certification or separated from the audit cycle being conducted as special audit.

4.3.3 ISO 22000 Follow Up Audits

For follow up audit duration will depend on the number of non-conformities that shall be closed.

4.4 Auditor Rotation

ISO 22000 has a restriction in place that one auditor may conduct no more than six (6) consecutive audits at the same company. After six (6) audits, another auditor must be assigned to visit your premises. Following this change, the original auditor may return for up to another six (6) consecutive audits after a minimum period of one year.

5 Certificate Suspension, Withdrawal or Scope Reduction

Suspension: BSI shall immediately suspend certification when there is evidence that the client is either unable or unwilling to establish and maintain conformity with ISO 22000 requirements. Besides that, BSI shall also suspend the certificate in cases when:

- the client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system;
- the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies;
- the certified client has voluntarily requested a suspension.

Under suspension, the client's management system certification is temporarily invalid. BSI shall restore the suspended certification if the issue that has resulted in the suspension has been resolved no later than six months after suspension. Failure to resolve the issues that have resulted in the suspension in a time established by BSI shall result in withdrawal or reduction of the scope of certification.

Withdrawal: BSI shall withdraw a certificate when:

- the status of suspension cannot be lifted within six (6) months;
- the organization ceases its ISO 22000 certification activities;
- any other situation where the integrity of the certificate or audit process is severely compromised.

5.1   Actions Upon Suspension, Withdrawal and Scope Reduction

In case of suspension or withdrawal, the organizations' management system certification is invalid.

In case of scope reduction, the organizations' management system certification is invalid beyond the revised certification scope statement.

6   Use of Marks (ANAB and BSI)

To acess BSI Marks of Trust (assurance marks) and ANAB logo (or JASANZ logo) please contact food@bsigroup.com

To access the insructions for use to promote your BSI certification access Guidelines for use related to ANAB, JASANZ and BSI Marks.

7   Confidentiality

BSI will keep confidential information confidential for a period of 6 years after it has received it and will not use or disclose it except for the purpose of exercising or performing its rights and obligations under the contract, or to the extent required by law, or by any governmental or other regulatory authority, or accreditation authority, or by a court or other authority of competent jurisdiction and/or by the Foundation.

In these cases, BSI will not be required to notify you of such disclosure and will not be required to oppose any demand made by such entities.

The ownership of the certificate and the audit report content of your site is held by BSI. At the request of food safety authorities, information related to the certification and auditing process shall be shared.

8   Additional Obligations

Following certification, there are a number of managerial responsibilities which your site will need to fulfil to maintain BSI's certification. These include:

- Continued compliance with the relevant systems standard(s) or code(s) of practice;

- Compliance with BSI's Standard Commercial Terms and Conditions and obligations as specified in this document as well as other guidance documentation that may be specifically provided from time-to-time;

- Conduct of regular internal reviews of your system, with appropriate documentation of such reviews and of any subsequent corrective actions;

- Notification to BSI of any significant changes in the structure (key responsibilities and management system), ownership and operations of your site to enable the impact of such changes on the certified ownership system to be evaluated; and

- Notification to BSI of any litigation or serious events or matters that relate to the scope of your certification within twenty-four (24) hours of the event.

8.1   Complaints

Your site is required to keep a record of all known complaints. These records must be made available to the audit team and BSI when requested.

Your site is required to demonstrate that you have taken appropriate action to address these complaints through investigation and correct any deficiencies found. These actions must be documented.

8.2   Certification Agreement

Your site is required to meet the requirements of the Certification Agreement. This requires that your site and products remain compliant with the scheme requirements and the conditions of certification at all times.

Your site is required to implement appropriate changes as communicated by BSI in a time appropriate manner.

8.3   Assessment Scheduling

Your site is required to make all necessary arrangements to allow the evaluation and surveillance activities to take place. This includes but is not limited to; Equipment, Product, Locations, Personnel and Sub-contractors.

8.4   Misleading Statements

Your site is not permitted to use its certification in a manner that could bring BSI into disrepute. This includes making misleading or unauthorized statements. If you are unsure if a statement could be misleading you are advised to contact BSI prior to making the statement. Statements include but are not limited to advertising (including your website) and internal communication. The use of the logo on product and product packaging is not permitted.

If your site is required to provide copies of certification documents these must be reproduced in its entirety. Failure to do so may be misleading to the recipient as to the scope of certification.

8.5   Communication Obligations

Your organization has the obligation to communicate with your local BSI office within 3 working days related to the following:

a) any significant changes that affect the compliance with the ISO 22000 requirements and obtain advice of BSI in cases where there is doubt over the significance of a change;

b) changes to organization name, contact address and site details;

c) changes to organization (e.g. legal, commercial, organizational status or ownership) and management (e.g. key managerial, decision-making or technical staff);

d) changes to the management system, scope of operations and product categories covered by the certified management system;

e) an extraordinary event affecting a certified site or BSI may temporarily prevent BSI from carrying out planned audits on-site. When such a situation occurs, BSI in consultation with the certified site will need to determine a reasonable planned course of action;

f) any other change that renders the information on the certificate inaccurate.

8.6   Management of extraordinary serious event

In case your organization is affected by public food safety incidents (such as e.g. public recalls, calamities, food safety outbreaks, etc.) BSI shall be notified within 03 working days through food.recall@bsigroup.com

There is no obligation to communicate product withdrawals to BSI. The definitions of product withdrawal and product recall are listed below for reference:

- Product Recall: The removal by a supplier of a product from the supply chain that has been deemed to be unsafe and has been sold to the end consumer and is available for sale (GFSI v7.2:2018).

- Product Withdrawal: The removal of a product by a supplier from the supply chain that has been deemed to be unsafe and which has not been placed in the market for purchase by the end consumer (GFSI v7.2:2018).

In case your organization is affected by serious events that impact the FSMS, legality and/or the integrity of the certification which includes legal proceedings, prosecutions, situations which pose major threats to food safety, quality or certification integrity as a result of natural or man-made disasters (e.g. war, strike, terrorism, crime, flood, earthquake, malicious computer/cyber hacking, etc.), BSI shall be contacted within 03 working days through critical.food@bsigroup.com.

BSI will manage extraordinary serious event as per IAF ID3:2011.

8.7   Observers

- From time to time BSI requires an observer to be in attendance at an audit. This may be related to training of new staff and witness assessment of existing staff. It is a requirement of certification that your site allows these activities to occur.

- BSI will, at all times, ensure that the use of observers is kept to a minimum and your site will be advised prior to the assessment activity.

- The observer does not take an active part in an assessment.

- By accepting the ISO 22000 BSI quote your organization accept cooperate with such process

8.8   Witnessing Assessment by BSI

From time to time the accreditation body requires a performance of a witnessing process. By accepting the ISO22000 BSI quote your organization accepts to cooperate with such processes that can be conducted on site or remotely in which the normal confidentially requirements apply.

8.9   Technical Experts (TEs) used by BSI

BSI may need to use a TE during an ISO 22000 audit. By accepting an ISO 22000 proposal presented by BSI, your organization accepts to cooperate with such process that can be conducted on site or remotely in which the normal confidentially requirements apply.

9   Complaints and Appeals

Appeals against certification decisions and/or complaints against service delivery levels may be raised with your auditor. If you remain dissatisfied, contact BSI in writing using the contact details below.

BSI will also investigate legitimate documented complaints, relevant to operation of the system, from clients/customers of certified sites.

If your site's application for certification has been refused; or your certified site's certification has been suspended, withdrawn, or reduced in scope, you may appeal against the decision. All complaints will be investigated and the originator of a complaint will be advised of the outcomes, as appropriate.

Where necessary a Review Committee will be established and operated as set out below:

- The appellant shall, within 28 days of the disputed advice from BSI, lodge a written notice of appeal with an affidavit as to the grounds of appeal;

- The BSI Global Operations & Compliance Management Group shall be advised within 14 days of receiving the appellant's notice;

- The Global Operations & Compliance Management Group shall then establish a Review Committee;

- The Review Committee shall consist a minimum of three persons considered as experts in the area of technology or business relevant to the appeal. The Review Committee shall be constituted as follows:

    o One-person expert in the relevant area of technology or business

    o Two persons selected by the appellant from a list of four persons

- The appellant shall represent himself and no legal representation will be allowed unless approved by the Review Committee; and

- The Review Committee will carry out investigations as are required, including assessment of information supplied by the appellant and, within a reasonable time, decide by majority vote whether or not to reverse the original decision.

- The Global T&C Director for food shall give notification of the decision to the appellant within 14 days of the Review Committee decision

To raise a complaint or appeal against the service delivery by BSI or audit outcome please notify:

- Todd Redwood

    Global Techncial & Compliance Director - Food

    Email: todd.redwood@bsigroup.com