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**ISO 22000** 

If you should require any further information then please do not hesitate to contact us. We will be please to help you.

Please contact us via mail to <a href="mailto:info.tncert@tuev-nord.de">info.tncert@tuev-nord.de</a> or by telephone 0800 245 74 57 (Free-phone from within Germany) or +49 511 9986-1222 from abroad.

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#### **ISO 22000**

The rules and descriptions of service and performance regarding certification according to the ISO 22000 apply alongside our offer. They are valid alongside the general Conditions of Certification. The auditors are selected by the Head of the Certification Body of TÜV NORD CERT GmbH in accordance with their approvals for the particular sector and their qualification.

In the case of a product recall, the client shall inform the certification body immediately and will describe the details regarding the incident. For its part, the certification body will take suitable steps in order to assess the situation and its impact on the certification and will take appropriate action

The following mailbox shall be used for the information of the CB: <a href="mailto:tncert-food-recall@tuev-nord.de">tncert-food-recall@tuev-nord.de</a>

# 1. CERTIFICATION PROCEDURE

#### 1.1. General

Annual audits shall take place to ensure certificate validity or that recertification is granted before the expiry date of the certificate. Surveillance audits shall be conducted within the calendar year. The 3-year certification cycle shall be respected.

The customer shall communicate any local holidays or shutdowns in a timely manner to facilitate audit scheduling

The audit shall be conducted over a continuous number of days.

The audit shall be carried out in a mutually agreed language. An interpreter may be added to the team. A site is required to be operational when conducting ISO 22000 audits. When there is no production, the audit must be rescheduled

## 1.2. Audit Preparation

Following signing of the contract, the auditor prepares for the audit based on the questionnaire filled in by the customer and the calculation sheet, and discusses and agrees the further procedure with the organization to be audited.

During preparation for the surveillance or recertification audit, the organizations to be audited have the duty to report fundamental changes in their organisational structure or changes in procedure to the certification body.

The organization shall ensure that the relevant products and/ or services and related processes for the scope of certification are in place and can be assessed during the audit.

# 1.3. Audit Stage 1

The Stage 1 audit is conducted in order to

- audit the management system documentation of the customer,
- assess the site and site-specific conditions of the customer and hold discussions with the personnel of the organization in order to determine the degree of preparedness for the Stage 2 audit,



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- assess the status of the customer and his understanding of the requirements of ISO 22000 particular with regard to identification of key performance or significant aspects, processes, objectives and operation of the management system,
- collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g. food safety legal aspects of the client's operation, associated risks, etc.),
- review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit,
- evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.

If nonconformities were identified in the stage 1 audit, these must be corrected by the customer before the stage 2 audit.

If at the end it cannot be established positively that the customer is ready for the Stage 2 Audit, the audit is broken off after the Stage 1 Audit.

The lead auditor is responsible for the coordination of the activities of the stage 1 audit and if necessary for coordination and cooperation of the auditors concerned amongst themselves.

# 1.4. Audit Stage 2 - Certification Audit

The customer receives an audit plan at the beginning of the stage 2 audit. The plan is agreed with the customer in advance.

The audit begins with a start-up meeting, in which the participants are introduced to each other. The procedure to be followed in the audit is explained. Within the framework of the audit at the organization's premises, the auditors review and assess the effectiveness of the management system which has been installed. The basis for this is standard ISO 22000 respectively.

The task of the auditors is to compare the practical application of the management system with the documented processes and to assess them in relation to fulfilment of the requirements of the standard. This is achieved by means of questioning of the employees, examining the relevant documents, records, orders and guidelines and also by visiting relevant areas of the organization

A final meeting takes place at the end of the on-site audit. At least those employees take part in the audit who have management functions within the organization and whose areas were included in the audit. The lead auditor reports on the individual elements and explains the positive and negative results. If nonconformities are established, the lead auditor can only recommend the organization for issue of the certificate after acceptance or verification of the corrective actions by the audit team. Attention must be drawn to this fact in the final meeting.



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The audit is documented in the audit report (the documentation must be separate for stage 1 and stage 2 audits) and is completed by means of further records (e.g. audit questionnaire and hand-written records)

#### 1.5. Award of Certificate

The certificate is issued when the certification procedure has been reviewed and released by the head of the certification body or his deputy or nominated representative. The person who reviews and releases the procedure may not have participated in the audit.

The certificate can only be issued when the nonconformities have been accepted or verified by the audit team.

The certificates are valid for 3 years.

# 2. SURVEILLANCE AUDIT

The company data are updated before the surveillance audit, in order to take any changes which have a significant influence on the area of activity or the operational methods of the client into consideration.

Surveillance audits must be conducted once per year during the period of validity of the certificate. Surveillance audits shall be performed prior the due date / planning-relevant date.

The planning-relevant date for the annual surveillance audit, which follows the initial certification audit, may not be later than 12 months after the last day of the stage 2 audit. The planning-relevant date controls all the surveillance audits.

# 3. UNANNOUNCED AUDITS

If the client wishes, the audits can also be conducted unannounced. This can, for example, be done within the framework of combined audits with other standards. In this case, the requirements of the other standards regarding the manner and timing of the audit must be observed.

The execution of the unannounced audit must be contractually agreed upon.

#### 4. RECERTIFICATION AUDIT

The audit for re-certification must be conducted before the expiration date of the certificate. For the evaluation of corrective actions and any subsequent audits, as well as for the decision on re-certification as part of the approval process, a grace period of up to 6 months is available.

The re-certification audit includes a review of the company's management system documentation and an on-site audit, taking into account the results of the previous monitoring program(s) over the duration of the certification. All standard requirements are audited.

Activities related to re-certification audits may require a Stage 1 audit if there are significant changes in the management system or related to the company's activities (e.g., changes in legislation).



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Changes to the food safety system must be communicated to the certification body by the client with the relevant documents in advance.

The audit methodology in the re-certification audit is consistent with that of a Stage 1 audit.

#### 5. SPECIAL AUDITS

# **Extension of scope audit**

An extension of scope can be conducted within the framework of a surveillance audit, a recertification audit or at a time which is set independently.

#### **Short Notice Audits**

If the certification body gains knowledge of incidents which have an impact on the safety or legality of the product, the certification body is entitled to perform announced or unannounced audits at any time, and, following assessment of the situation and its effects, to withdraw the certificate(s).

# 6. TRANSFER OF CERTIFICATION FROM OTHER CERTIFICATION BODIES

Generally, only certificates from accredited certification bodies, where the accreditor is a signatory of the Multilateral Agreements (MLA) of the EA (European Co-operation for Accreditation), can be transferred. Companies with certificates issued by non-accredited certification bodies should be treated as new clients.

The issuing certification body will be informed about the planned transfer. As soon as there are no known reasons from the issuing certification body and the client that would preclude the transfer of the valid certificate according to IAF MD 2:2017, the transfer can be carried out.

A "Pre-Transfer Review" must be conducted by a competent person from the receiving certification body, which typically involves reviewing key documents and a visit to the client.

Certificates that are suspended or at risk of suspension must not be transferred. Open deviations should, where practicable, be resolved with the previous certification body before the transfer. Otherwise, they must be addressed during the audit.

The existing monitoring program will be maintained.

#### 7. MULTIPLE FUNCTIONS ACROSS MORE THAN ONE SITE

For organizations with multiple sites, the sampling method ("Multisite Certification") can be applied. For ISO 22000, a sampling method is only possible for companies with more than 20 sites and for categories A, B, E, F, and G.

In this case, the client assures that the following conditions are met at all sites within the scope of the certificate. Changes or non-compliance with one or more conditions must be reported to the certification body immediately.

Conditions for Multisite Certification:



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An organization with multiple sites does not need to be a single legal entity, however, all sites must have a legal or contractual connection with the organization's headquarters and be subject to a common management system that is established and implemented by the headquarters, and is subject to regular monitoring and internal audits by the headquarters. This means that the headquarters has the right to demand corrective actions from the sites if necessary.

- The processes must be essentially similar at all sites and carried out with similar methods and procedures.
- The organization's management system must be centrally managed under a centrally controlled plan and subject to central management review. All associated sites (including the central administrative function) must be subject to the organization's internal audit program and audited in accordance with this program.
- It must be demonstrated that the organization's headquarters has established a management system in accordance with the relevant management system standard to which the audit is subject, and that the entire organization meets the requirements of the standard.

The organization must demonstrate its ability to collect and analyze data from all sites including the central administrative function and its leadership, and initiate necessary organizational changes:

- Management review,
- Complaints,
- Evaluation of corrective actions,
- Planning internal audits and evaluating the results,
- Legal requirements.

The conclusion of an agreement between the client and the certification body that is legally enforceable at all branches/production sites.

#### 8. MANAGEMENT OF NON-CONFORMITIES

Non-conformities and potential improvements are documented in the audit report. The client must create action plans with root cause analysis for the non-conformities.

Root cause analysis, corrective actions with an action plan, and possibly objective evidence for non-conformities NC A and NC B must be submitted by the client within 6 weeks after the last day of the audit.

# **Non-conformities NC B:**

The verification of the effectiveness of the corrections and corrective actions is based on an action plan with root cause analysis submitted by the client. Within 3 months after the last day of the audit, the action plan with root cause analysis submitted by the client must be evaluated by the auditor. An evaluation of the measures taken for non-conformities will occur in the subsequent audit.

If the available audit evidence indicates that the audit objectives cannot be achieved, or there is an immediate and significant risk (e.g., safety), further measures will be determined. These measures may



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include reconfirmation or modification of the audit plan, changes to the objectives or scope of the audit, or even termination of the audit.

#### **Non-conformities NC A:**

The verification of the effectiveness of the corrections and corrective actions is based on an action plan with root cause analysis and objective evidence submitted by the client, either through document review or, if necessary, through a follow-up audit.

The verification must be completed within 3 months after the last day of the audit. An evaluation of the measures taken for non-conformities will occur in the subsequent audit.

If the non-conformities are not closed within the specified period, the certificate will be suspended or the de-certification process will be initiated in coordination with the TIC Manager.

If the verification of the implementation of corrections and corrective actions for any significant nonconformity is not completed within 3 months after the last day of Stage 2, a repeat Stage 2 must be conducted before recommending certification.

If a minor non-conformity (NCB) cannot be positively verified in the follow-up audit, the auditor must escalate this non-conformity in the follow-up audit and document it as a significant non-conformity (NCA). New corrections and corrective actions must be submitted by the client. The new significant non-conformity (NCA) must be closed and verified within the specified deadline.

# **Critical Non-conformity:**

A critical non-conformity is raised if it is determined during the audit that a situation affecting product safety and legality exists without appropriate measures being taken by the company, or if the legality and/or integrity of the certification is at risk.

The following measures are taken:

The certificate is suspended for up to 6 months.

The client is required to create a root cause analysis and a corrective action plan. This must be sent to the certification body within 14 calendar days after the audit.

An additional follow-up audit is conducted within a period of 6 weeks to 6 months after the audit to verify the closure of the implemented corrective actions. This involves a full audit (audit effort of at least 1 day on-site).

After passing the follow-up audit, the certificate is reinstated and the current certification cycle continues. The follow-up audit is documented and uploaded.

If the critical non-conformity is not demonstrably closed within the deadline, the certificate will be withdrawn.

If a critical non-conformity is identified during a certification audit, the audit is failed and the full certification audit must be repeated.

# **Handling Non-Conformities in Multisite Certifications**

Identified non-conformities must be examined to determine if they apply to more than one site. If so, the auditor must be provided with evidence of corrective actions being implemented at all relevant sites.



# 9. CERTIFICATE SUSPENSION, WITHDRAWAL OR SCOPE REDUCTION

# Suspension:

The certificate will be suspended in the following cases:

- A critical non-conformity is identified.
- It is proven that the client is unwilling or unable to send objective evidence or close the nonconformities within the specified timeframes.
- Evidence exists that the company is unwilling or unable to maintain conformity with the system requirements.

#### Withdrawal:

A certificate will be withdrawn if:

- The suspension of the certificate cannot be lifted within 6 months.
- The company discontinues its ISO 22000 certification.
- A situation arises that jeopardizes the integrity of the certificate or the audit process.

# **Scope Restriction:**

If a company has a certificate whose scope does not accurately reflect the management system, for example, due to changes at the sites, the scope will be adjusted by the certification body. It is not possible to exclude activities, processes, products, or services from the scope if they influence the food safety of the end products covered within the scope.