

1.0 PURPOSE and SCOPE:

It covers all the certifications to be made by Unicert company, 1st and 2nd stage audit, surveillance audit, follow-up audit and certificate renewal audit and special audits..

2.0 DEFINITIONS

Certification body: United Certification Inc. is the third party organization that audits and certifies the suppliers' management system according to the published management system standards and any additional documents required in the system. It is the title of the certification body. It will be referred to as **Unicert**.

Supplier: The party responsible for the delivery of the product, process and service and who can provide Management System applications.

Quality management system: The management system necessary to direct and control an organization in terms of quality.

Food Safety Management System: A management system for the management and control of hazards and food safety risks appropriate to an organization's place in the food chain.

Certificate: A document showing the conformity of the supplier Management system according to the specified Management System standard and any additional documents required in the system.

Certification system: Systems with process and management rules created by Unicert in a structure that will meet the requirements of this standard for certification and monitoring for its continuity are as follows:

- ISO 9001:2015 Quality management systems — Requirements
- ISO 22000:2018 Food safety management systems — Requirements for any organization in the food chain
- ISO 14001:2015 Environmental management systems — Requirements with guidance for use
- ISO 45001:2018 Occupational health and safety management systems — Requirements with guidance for use
- ISO/IEC 27001:2022 Information security, cyber security and privacy protection — Information security management systems — Requirements
- ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

Certified organization / body: All or part of the organization's management system has been certified.

Applicant: It means the applicant who has applied to obtain a system certificate for the whole or a part of the system and does not have the certificate yet.

Complaint and appeal committee: It is the committee where all complaints and appeals are evaluated. The audit and documentation is completely independent from the decision maker. It is created within the framework of the relevant procedure.

General Manager: Performs the general management of Unicert.

Certification Manager: Reports to the General Manager. It establishes and enforces a system in accordance with the accreditation requirements, ensures its continuity and continuously improves its effectiveness. It audits the compliance of the audit process with the accreditation requirements, reviews the audit reports and gives approval on whether to issue a certificate, and carries out activities such as scope expansion.

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Impartiality Protection Committee: It provides support to the certification manager regarding the adequacy and independence of certification, and also works on ensuring impartiality. The Impartiality Protection Committee Working Procedure is applied for the establishment and operation of the Impartiality Committee in order to meet its activities such as certification such as ISO 9001:2015, ISO 22000:2005, ISO 14001, ISO 45001, ISO 27001, ISO 13485.

Unicert Logo: It is the logo that companies approved by Unicert and certified by Unicert can use to declare it.

Nonconformity: Failure to meet a requirement.

Major Nonconformity: Nonconformity that affects the management system's ability to achieve its intended results (ISO/IEC 17021-1:2015).

Note 1 to entry: Non-compliance may be classified as major if:

- there is significant doubt about effective process control or the conformity of products and services to specified specifications;
- Multiple minor nonconformities indicating that there may be a systematic deficiency with a condition or subject, thereby creating a major nonconformity.

Minor Nonconformity: Nonconformity that does not affect the ability of the management system to achieve its intended results (ISO/IEC 17021-1:2015).

Technical Expert: Person who provides specific knowledge and expertise to the audit team.

Certification Program: Conformity assessment system related to management systems where the same specified conditions, rules and procedures are applied.

Audit Time: The time needed to plan and perform a full and effective audit of the client's management system.

Management System Audit Time: The portion of audit time spent on audit activities from the opening meeting to the closing meeting.

3.0 REFERENCE DOCUMENTS

- EN ISO/IEC 17021-1:2015
- EN ISO/IEC 17021-3:2018
- ISO/TS 22003
- IAF MD 1:2018
- IAF MD 2:2017
- **IAF MD 5:2019**
- **IAF MD 11:2013**
- **IAF MD 9:2012**
- **IAF MD 22:2018**

4.0 IMPLEMENTATION

Unicert evaluates the client organization's legal and regulatory compliance. In cases of non-compliance with relevant legislation and regulations, it is responsible for determining that appropriate measures are taken, including reporting incidents requiring reporting to the Regulatory Authority.

4.1 Receiving the Application

Filling the relevant System Certification Application Form completely by the company (in cases where it is not suitable in practice, the application form is filled by the Unicert employee who conducts the interview and approved by the company), the information about the scope of the application is clear, and the scope is clarified by contacting the applicant company if necessary.

Information on the following subjects must be given at the application stage, and these are evaluated by communicating with the applicant company representative.

- The requested certification scope,
- Number of employees in the company (with the number of subcontractors and seasonal employees)
- Number of shifts in the firm,
- Number of geographical locations and address(es),
- Standard(s) for the application
- Excluded standard items,
- Outsourced processes / subcontracted processes,
- Status of key processes,
- Mandatory legal conditions, regulations, standards related to the product,
- Availability of system or product documentation,
- Information on obtaining consultancy services in the establishment of the applied management system,
- Number of HACCP studies (for ISO 22000)

Contacts the applicant with the missing information above with the Planning Officer and clarifies the missing issues.

After the application is received, the following issues are determined by the Planning Officer

- IAF , EA and NACE Code related to the application
- Whether Unicert has accreditation in the applied standard and scope,
- Risk/complexity level for ISO 9001:2015,
- Having sufficient audit team
- Stage 1 and Stage 2 audit man/day,

When necessary, customer visits can be made as part of the evaluation process before the bidding phase, for reasons such as clarification of unresolved issues, the need for more detailed information in the evaluation of the application, etc.

The results of the visits and the review are presented to the Customer Visit Form Certification Manager.

4.1.1. Review of the ISO 22000:2018 application:

The personnel who carry out the application form review process should be provided as a full-time or subcontracted food engineer, food technician or legally equivalent specialist who meets the criteria specified below. If the personnel reviewing the application is not qualified for the category of the applicant company, he/she takes the opinions of the lead auditor-auditor-expert with the relevant qualification from the Lead Auditor/Auditor/Candidate Auditor/Technical Expert List. In case of absence/appointment of competent personnel, the review process is carried out by the Certification Manager.

- Must have completed at least university education
- Ability to apply application review requirements in ISO/TS 22003 and ISO/IEC 17021
 - (ISO/IEC 17021-1 A.4.1) Information on specific management system standards/documents with mandatory provisions: Information on what the management system standard or documents with mandatory provisions require for certification.
 - (ISO/IEC 17021-1 A.4.2) Knowledge of Unicert's processes: Sufficient knowledge of the certification body's processes for the appointment of sufficient certification team members and the correct determination of audit duration.
 - (ISO/IEC 17021-1A.4.3) Knowledge of the client's business sector: Sufficient knowledge of the client's business sector common terminology, practice and process for the appointment of sufficient certification team members and the correct determination of audit duration.
 - (ISO/IEC 17021-1 A.4.4) Knowledge of the client's product, process and organization: Sufficient information about the client's product and process types for the appointment of sufficient certification team members and the correct determination of audit duration.

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- Must be trained in HACCP principles, hazard assessment and hazard analysis, food safety management system principles including prerequisite programs, relevant food safety management system standards and legal requirements.
- The auditor must have completed the audit processes training specified in the ISO 19011 guide.
- Categorization of applicants by food chain categories and sectors
- Evaluation of applicants' products, processes and practices
- Placement of ISO 22000:2018 auditors according to qualifications and requirements
- Determination of audit date and duration
- Unicert policy and procedures regarding contract review
- Any particular seasonal factors to the establishment and its food category and products;
- Special cultural and social habits related to the geographical divisions or categories to be evaluated
- Special factors required to control the food product, process or service
- Must show that they can apply their knowledge and skills in their subjects.

The conditions for the application to be multi-branch (multi-site assessment) are specified in the inspection period determination instruction.

4.1.2. Review of the ISO 9001:2015 application:

Personnel carrying out the application form review process must be a full-time or subcontracted graduate with at least 4 years of university degree in accordance with the criteria set out below. If the personnel reviewing the application is not qualified for the category of the applicant company, he/she takes the opinions of the lead auditor-auditor-expert with the relevant qualification from the Lead Auditor/Auditor/Candidate Auditor/Technical Expert List. In case of absence/appointment of competent personnel, the review process is carried out by the Personnel Certification Manager.

- To have received training on the Management System Standard.
- To be able to use Office Programs effectively.
- To have been trained in ISO 17021.
- IAF MD Documents (MD 1, 2, 5, 10, 11)
- EA Documents (EA 7/05, EA 3/11)
- To be trained in ISO 9001, ISO 19011 Standards.
- Must have received Internal Auditor Training.

4.1.3. Review of the ISO 14001 application:

Personnel carrying out the application form review process must be a full-time or subcontracted graduate with at least 4 years of university degree in accordance with the criteria set out below. If the personnel reviewing the application is not qualified for the category of the applicant company, he/she takes the opinions of the lead auditor-auditor-expert with the relevant qualification from the Lead Auditor/Auditor/Candidate Auditor/Technical Expert List. In case of absence/appointment of competent personnel, the review process is carried out by the Personnel Certification Manager.

- To have received training on the Management System Standard.
- To be able to use Office Programs effectively.
- To have knowledge of EA and IAF rules.
- To be trained in ISO 17021 Standards.
- IAF MD Documents (MD 1, 2, 5, 10, 11)
- EA Documents (EA 7/05, EA 3/11)
- To be trained in ISO 14001 Standard.
- To have received NACE REV02 training.
- Must have received Internal Auditor Training.

4.1.4. Review of the ISO 45001 application:

Personnel carrying out the application form review process must be a full-time or subcontracted graduate with at least 4 years of university degree in accordance with the criteria set out below. If the personnel reviewing the application is not qualified for the category of the applicant company, he/she takes the opinions of the lead auditor-auditor-expert with the relevant qualification from the Lead Auditor/Auditor/Candidate Auditor/Technical Expert List. In case of absence/appointment of competent personnel, the review process is carried out by the Personnel Certification Manager.

- To have received training on the Management System Standard.
- To be able to use Office Programs effectively.
- To have knowledge of EA and IAF rules.
- To be trained in ISO 17021 Standards.
- IAF MD Documents (MD 1, 2, 5, 10, 11)
- EA Documents (EA 7/05, EA 3/11)
- To be trained in ISO 45001 Standard.
- To have received NACE REV02 training.
- Must have received Internal Auditor Training.

4.1.5. Review of the ISO 13485 application:

Personnel carrying out the application form review process must be a full-time or subcontracted graduate with at least 4 years of university degree in accordance with the criteria set out below. If the personnel reviewing the application is not qualified for the category of the applicant company, he/she takes the opinions of the lead auditor-auditor-expert with the relevant qualification from the Lead Auditor/Auditor/Candidate Auditor/Technical Expert List. In case of absence/appointment of competent personnel, the review process is carried out by the Personnel Certification Manager.

- To have received training on the Management System Standard.
- To be able to use Office Programs effectively.
- To have knowledge of EA and IAF rules.
- To be trained in ISO 17021 Standards.
- IAF MD Documents (MD 1, 2, 5, 10, 11)
- EA Documents (EA 7/05, EA 3/11)
- To be trained in ISO 45001 Standard.
- To have received NACE REV02 training.
- Must have received Internal Auditor Training.

4.1.6. Review of the ISO 27001 application:

The personnel who carry out the application form review process should be provided as a full-time or subcontracted food engineer, food technician or legally equivalent specialist who meets the criteria specified below. If the personnel reviewing the application is not qualified for the category of the applicant company, he/she takes the opinions of the lead auditor-auditor-expert with the relevant qualification from the Lead Auditor/Auditor/Candidate Auditor/Technical Expert List. In case of absence/appointment of competent personnel, the review process is carried out by the Certification Manager.

- Must have completed at least university education
- Ability to apply application review requirements in ISO 27001 and ISO/IEC 17021
- (ISO/IEC 17021-1 A.4.1) Information on specific management system standards/documents with mandatory provisions: Information on what the management system standard or documents with mandatory provisions require for certification.

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- (ISO/IEC 17021-1 A.4.2) Knowledge of Unicert's processes: Sufficient knowledge of the certification body's processes for the appointment of sufficient certification team members and the correct determination of the audit period.
- (ISO/IEC 17021-1A.4.3) Knowledge of the client's business sector: Sufficient knowledge of the client's business sector common terminology, practice and process for the appointment of sufficient certification team members and the correct determination of audit duration.
- (ISO/IEC 17021-1 A.4.4) Knowledge of the client's product, process and organization: Sufficient information about the client's product and process types for the appointment of adequate certification team members and the correct determination of audit duration.
- The auditor must have completed the audit processes training specified in the ISO 19011 guide.
- Evaluation of applicants' products, processes and practices
- Placement of ISO 27001 auditors according to qualifications and requirements
- Determination of audit date and duration
- Unicert policy and procedures regarding contract review
- Must show that they can apply their knowledge and skills in their subjects.

The conditions for the application to be multi-branch (multi-site inspection) are specified in the assessment period determination instruction.

4.1.7. Evaluation and Finalization of Incoming Applications

The Planning Officer has to process any incoming certification application.

- The Unicert Planning Officer reviews the application to ensure the following, using the "FR-002 Application Review Form".
- Knowledge of the applicant organization and its management system is sufficient to carry out an audit programme,
- Known different understandings between the certification body and the applicant body have been resolved,
- The certification body has the competence and capability to carry out certification activities,
- Consideration of the scope of the certification studies, the facility/premises where the activities of the applicant organization are carried out, the time required to complete the audit and other issues (language, security conditions, threats to impartiality, etc.) affecting the certification activities.
- After review of the application, Unicert accepts or rejects the application. If Unicert rejects the application as a result of the review, the reasons for the rejection of the application are clearly explained to the customer in writing or by e-mail or telephone.
- Based on this review, Unicert determines the competencies to be included in the audit team for the certification decision.

The planning officer cannot discriminate against religion, language, race, company in any way. Rejections of applications made on these issues must be recorded together with their logical reasons. Applications related to institutions, organizations or individuals that have previously been worked with and do not comply with the commercial ethical rules, applications that do not meet the evaluation criteria can be rejected, but their reasons should be recorded.

The number of days of certification and surveillance audits is determined according to the Instruction for Determining the Audit Period.

The relevant IAF and ILAC documents are used to determine the IAF, EA, NACE and Sector codes and categories.

4.2. Bid Preparation

In line with the information given in the application form, the proposal is prepared by the Certification Manager or management representative or, if these persons are not present at the company, by any employee, based on the instruction of the certification manager, and presented to the relevant applicant

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in the Certification Offer and Contract Form. While preparing the proposal, the conditions specified in the System Certification Application Form are taken into account.

Certification Proposal/Contract Form is created in line with the information in the application. The contract covers stage 1 audit, stage 2 audit, and first and second surveillance audits and certifications. In the re-certification process, the contract is prepared again.

In the bids given, the Fee Determination and Payment Instructions are followed.

The man/day duration affecting the inspection fee is determined according to the Assessment Period Determination Instruction.

- AA-Xx.yy.2xx
- Xx : The last two digits of the bid year (For example, 22 for 2022)
- Yy : The month for which the bid is made (For example, 07 for the month of July)
- Zzz: Number of bids given in the month (For example, if the first bid in July is 201)
- AA : Shows the standard code.

“QMS” for ISO 9001, “FSMS” for ISO 22000, “EMS” for ISO 14001, ISO 45001 “OHSMS”, ISMS for ISO 27001, MDQMS for 13485.

The example is as follows.

The number of the second proposal submitted on 28 July 2022 and the ISO 22000 document given at the end of the work will be FSM-21.07.202.

4.2.1. Bid Review

Bids prepared in accordance with the information in the application form, the Instruction for Determining the Inspection Period and the Instruction for Determining the Fee and Payment are reviewed before being sent to the company. The review process is carried out by the general manager, Certification Manager.

4.3. Making a Contract

After the contract is made, the documents defined below are requested from the customer.

Certification Rules

- Number of HACCP studies (for ISO 22000)
- Management system documentation, (manual, all required documentation, organizational chart, documents showing process interactions, etc.)
- Chamber of Commerce activity certificate, (if any)
- Tax plate,
- Trade registry gazette, (if any)
- Signature circular of the authorized person of the organization who signed the offer,
- Documents showing that sector-specific legal regulations are fulfilled (such as documents, permits, licenses, etc.)
- Catalogues, brochures, CDs, etc., if any. Introductory support documents such as, (if not received at the application stage) (If any)

For the contract to be valid;

- Filling the System Certification Application Form correctly and completely in a way that will show the actual situation of the organization.
- The applicant organization must show that the system they have established has at least 2 months of applications, and that it has held an internal audit and management review meeting.

The following documents must be submitted in full.

- Firm's management system documentation (quality manual, procedures and final revisions of relevant documents, if any)

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- Original signed version of the offer/contract and certification rules

The contract is made by giving a new number in order to offer a new offer to customers whose document renewal date has come and positive response has been received for the renewal of the contract. (Old number is not used).

The existing contract may be revised in case any scope expansion or reduction need arises during the contract period and a change in audit periods arises. In such cases, the change details are obtained from the company in writing, kept in its file, the number of the contract prepared accordingly is expressed by writing -01 next to the normal number, and the contract is signed mutually and kept in the customer's file. When any audit is to be made, the revised contract is taken as a basis.

For the planning of inspections; Documents and documents specified in the contract of the customer requesting System Certification and forwarded to Unicert are examined by the Planning Officer. If the result of the examination is positive and shows that the system has been implemented for at least two months, the audit is planned. The deficiencies found during the application examination are notified to the company and these deficiencies are requested to be completed (for example, official documents, system documents, etc.). If the customer does not make the necessary corrections and completes the application documents within 30 days, the customer's application is cancelled.

If the certification audit is not accepted by the customer and is postponed within 6 months from the date the customer applies for System Certification, the customer's application is cancelled. However, this period does not apply in case of natural disasters. Cancellation of the application can also be made at the request of the customer. Files of customers whose applications are canceled are returned.

4.4. Identification of Lead Auditor and Audit Committee

Appropriate auditor(s) selected from the Lead Auditor/Auditor/Candidate Auditor/Technical Expert List consisting of auditors/technical experts approved in accordance with the Personnel Selection and Evaluation Procedure are determined by the Planning Officer.

The following are taken into account when deciding on the size and composition of the audit team;

- a) Audit objectives, scope, criteria and estimated audit duration,
- b) The audit is combined, integrated or joint, (The team leader of the combined or integrated audit is expected to have in-depth knowledge of at least one of the standards and be aware of other standards used for particular audits.)
- c) the overall competence of the audit team necessary to achieve the audit objectives,
- d) Certification requirements (including applicable legal, regulatory or contractual terms),
- e) Language and culture.

Candidate Auditors

Provided that one of the auditors is designated as the Observer Auditor, he/she can participate in the audit. The Observing Auditor should be competent to fulfill the responsibilities. The Observing Auditor also has final responsibility for the candidate auditor's activities and findings.

Observers

Observers who are planned to participate in the audit are notified to the client with the Client Audit Committee Confirmation form before the audit takes place. The audit team ensures that the observer is not allowed to interfere or interfere with the audit process or affect the audit outcome.

Observers; member of the client organization, consultants, testifying accreditation body staff, regulators or other verified staff.

Technical Experts

The role of the technical expert during an audit is communicated to the client in the Client Audit Board Confirmation form prior to the audit taking place. The technical expert cannot act as an auditor in the audit team. Technical experts are accompanied by a Lead Auditor/Auditor.

NOTE Technical experts may advise the audit team for preparation, planning or audit..

Guides

Unless otherwise agreed by the Lead Auditor and the client, each auditor must be accompanied by a guide. The mentor(s) are assigned to the audit team for the audit to take place. The audit team ensures that the guidelines are not allowed to adversely affect or interfere with the audit process or affect the audit outcome..

The duties of guides may include:

- a) Creating links and scheduling for interviews,
- b) Arranging visits to certain parts of the facility or establishment,
- c) Ensuring that the rules regarding site safety and security procedures are known and followed by the members of the audit team,
- d) Witnessing the audit on behalf of the client,
- e) Provide disclosure or information as requested by the auditor.

Note: If appropriate, the student can act as a guide.

4.5. Document Review, Determination of Onsite Inspection Period and Stage 1 Audit**Stage 1 Audit:**

It is applied for the audits of ISO 9001:2015, ISO 22000:2018, ISO 14001, ISO 45001, ISO 27001 and ISO 13485 systems. It is the first stage of formal control. At this stage, no certification vs recommendation decision is made, it is only preliminary to assess whether the management system applications are ready for the stage 2 audit.

It is examined whether the Firm's Handbook and procedures meet the relevant standard requirements. Audit Period Determination Instruction is taken as basis in determining the document review, Stage 1 and on-site Audit period. In the preparation of the document review report, guidance notes are recorded, which can be verified in the on-site inspection with Stage 1. Stage 1 audit results, ISO 9001:2015 Audit package (stage 1 part-Phase 1 question list and report), ISO 22000:2018 Audit package (stage 1 part-stage 1 question list and report), ISO 14001 Audit package (stage 1 section-Phase 1 question list and report), ISO 45001 Audit package (stage 1 section-Phase 1 question list and report), ISO 13485 Audit package (stage 1 section-Phase 1 question list and report), and ISO 27001:2015 Audit package (stage 1 part-Stage 1 question list and report) and Stage 2 audit is planned and performed according to the results of the Stage 1 audit. If nonconformities are detected as a result of the Stage 1 audit, it is necessary to determine sufficient time to close the nonconformities before the planning of Stage 2 and to monitor the results.

- The main objectives of a stage 1 audit are:
 - Audit of customer's system documentation
 - Evaluating the locations and location-specific conditions of the organization and conducting interviews with the organization personnel for stage 2 audit preparations,
 - Reviewing the organization's status and understanding of the standard requirements (especially reviewing the operation, performance and key aspects, processes of the implemented management system)
 - Gathering necessary information about the scope of the management system, processes, location of the organization, legal regulations,
 - Reviewing the resources required for the stage 2 audit and reaching agreement with the client organization regarding the details of the stage 2 audit,
 - Focusing on planning the stage 2 audit, following the acquisition of sufficient knowledge of the client organization's management system,

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- Performed to assess whether the client is effectively planning and performing internal audits and management reviews, and to determine the adequacy of the implementation level of the management system, and to assess whether the client is ready for a stage 2 audit.

4.5.1. For ISO 9001:2015 Quality Management System (QMS) audits;

For management systems audits, the scope of the company to be audited is evaluated according to the determined critical codes, and if it has a critical code, it is decided to conduct stage 1 audits on site. Stage 1 auditing is done in the office, except for critical codes.

IAF CODE	DESCRIPTION	ISO 9001
1	Agriculture, fishing	OFFICE
2	Mining and quarrying	SITE
3	Food products, beverages and tobacco	SITE
4	Textiles and textile products	OFFICE
5	Leather and leather products	SITE
6	Wood and wood products	OFFICE
7	Pulp, paper and paper products	OFFICE
8	Publishing companies	OFFICE
9	Printing companies	SITE
10	Manufacture of coke and refined petroleum products	OFFICE
11	Nuclear fuel	SITE
12	Chemicals, chemical products and fibers	SITE
13	Pharmaceuticals	SITE
14	Rubber and plastic products	SITE
15	Non-metallic mineral products	SITE
16	Concrete, cement, lime, plaster etc	OFFICE
17	Basic metals and fabricated metal products	OFFICE
18	Machinery and equipment	OFFICE
19	Electrical and optical equipment	OFFICE
20	Shipbuilding	SITE
21	Aerospace	SITE
22	Other transport equipment	SITE
23	Manufacturing not elsewhere classified	OFFICE
24	Recycling	SITE
25	Electricity supply	OFFICE
26	Gas supply	SITE
27	Water supply	OFFICE
28	Construction	SITE
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	OFFICE
30	Hotels and restaurants	OFFICE
31	Transport, storage and communication	OFFICE
32	Financial intermediation; real estate; renting	OFFICE
33	Information technology	SITE
34	Engineering services	OFFICE
35	Other services	OFFICE
36	Public administration	OFFICE
37	Education	SITE
38	Health and social work	SITE
39	Other social services	OFFICE

Determination of the audit period is defined in the mandatory document "MD5:2015 Determination of the Audit Period of quality, environmental, and occupational health & safety management systems ". Correctly determining the initial audit period (Stage 1 + Stage2) is an important part of the application review.

4.5.2. For ISO 14001 EMS audits;

For management systems audits, the scope of the company to be audited is evaluated according to the determined critical codes, and if it has a critical code, it is decided to conduct stage 1 audits on site. Stage 1 auditing is done in the office, except for critical codes.

IAF CODE	DESCRIPTION	ISO 14001
1	Agriculture, fishing	OFFICE
2	Mining and quarrying	SITE
3	Food products, beverages and tobacco	SITE
4	Textiles and textile products	OFFICE

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5	Leather and leather products	SITE
6	Wood and wood products	OFFICE
7	Pulp, paper and paper products	OFFICE
8	Publishing companies	OFFICE
9	Printing companies	SITE
10	Manufacture of coke and refined petroleum products	OFFICE
11	Nuclear fuel	SITE
12	Chemicals, chemical products and fibers	SITE
13	Pharmaceuticals	SITE
14	Rubber and plastic products	SITE
15	Non-metallic mineral products	SITE
16	Concrete, cement, lime, plaster etc	OFFICE
17	Basic metals and fabricated metal products	OFFICE
18	Machinery and equipment	OFFICE
19	Electrical and optical equipment	OFFICE
20	Shipbuilding	SITE
21	Aerospace	SITE
22	Other transport equipment	SITE
23	Manufacturing not elsewhere classified	OFFICE
24	Recycling	SITE
25	Electricity supply	OFFICE
26	Gas supply	SITE
27	Water supply	OFFICE
28	Construction	SITE
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	OFFICE
30	Hotels and restaurants	OFFICE
31	Transport, storage and communication	OFFICE
32	Financial intermediation; real estate; renting	OFFICE
33	Information technology	SITE
34	Engineering services	OFFICE
35	Other services	OFFICE
36	Public administration	OFFICE
37	Education	SITE
38	Health and social work	SITE
39	Other social services	OFFICE

Determination of the audit period is defined in the mandatory document "MD5:2015 Determination of the Audit Period of quality, environmental, and occupational health & safety management systems ". Correctly determining the initial audit period (Stage 1 + Stage2) is an important part of the application review.

4.5.3. For ISO 45001 Occupational Health and Safety Management Systems Audits;

For management systems audits, the scope of the company to be audited is evaluated according to the determined critical codes, and if it has a critical code, it is decided to conduct stage 1 audits on site. Stage 1 auditing is done in the office, except for critical codes.

IAF CODE	DESCRIPTION	ISO 45001
1	Agriculture, fishing	OFFICE
2	Mining and quarrying	SITE
3	Food products, beverages and tobacco	SITE
4	Textiles and textile products	OFFICE
5	Leather and leather products	SITE
6	Wood and wood products	OFFICE
7	Pulp, paper and paper products	OFFICE
8	Publishing companies	OFFICE
9	Printing companies	SITE
10	Manufacture of coke and refined petroleum products	OFFICE
11	Nuclear fuel	SITE
12	Chemicals, chemical products and fibers	SITE
13	Pharmaceuticals	SITE
14	Rubber and plastic products	SITE
15	Non-metallic mineral products	SITE
16	Concrete, cement, lime, plaster etc	OFFICE
17	Basic metals and fabricated metal products	OFFICE
18	Machinery and equipment	OFFICE
19	Electrical and optical equipment	OFFICE
20	Shipbuilding	SITE
21	Aerospace	SITE

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22	Other transport equipment	SITE
23	Manufacturing not elsewhere classified	OFFICE
24	Recycling	SITE
25	Electricity supply	OFFICE
26	Gas supply	SITE
27	Water supply	OFFICE
28	Construction	SITE
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	OFFICE
30	Hotels and restaurants	OFFICE
31	Transport, storage and communication	OFFICE
32	Financial intermediation; real estate; renting	OFFICE
33	Information technology	SITE
34	Engineering services	OFFICE
35	Other services	OFFICE
36	Public administration	OFFICE
37	Education	SITE
38	Health and social work	SITE
39	Other social services	OFFICE

Determination of the audit period is defined in the mandatory document "MD5:2015 Determination of the Audit Period of quality, environmental, and occupational health & safety management systems ". Correctly determining the initial audit period (Stage 1 + Stage2) is an important part of the application review.

4.5.4. For ISO 13485 MDQMS audits;

For management systems audits, the scope of the company to be audited is evaluated according to the determined critical codes, and if it has a critical code, it is decided to conduct stage 1 audits on site. Stage 1 auditing is done in the office, except for critical codes.

IAF CODE	DESCRIPTION	ISO 13485
1	Agriculture, fishing	OFFICE
2	Mining and quarrying	SITE
3	Food products, beverages and tobacco	SITE
4	Textiles and textile products	OFFICE
5	Leather and leather products	SITE
6	Wood and wood products	OFFICE
7	Pulp, paper and paper products	OFFICE
8	Publishing companies	OFFICE
9	Printing companies	SITE
10	Manufacture of coke and refined petroleum products	OFFICE
11	Nuclear fuel	SITE
12	Chemicals, chemical products and fibers	SITE
13	Pharmaceuticals	SITE
14	Rubber and plastic products	SITE
15	Non-metallic mineral products	SITE
16	Concrete, cement, lime, plaster etc	OFFICE
17	Basic metals and fabricated metal products	OFFICE
18	Machinery and equipment	OFFICE
19	Electrical and optical equipment	OFFICE
20	Shipbuilding	SITE
21	Aerospace	SITE
22	Other transport equipment	SITE
23	Manufacturing not elsewhere classified	OFFICE
24	Recycling	SITE
25	Electricity supply	OFFICE
26	Gas supply	SITE
27	Water supply	OFFICE
28	Construction	SITE
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	OFFICE
30	Hotels and restaurants	OFFICE
31	Transport, storage and communication	OFFICE
32	Financial intermediation; real estate; renting	OFFICE
33	Information technology	SITE
34	Engineering services	OFFICE
35	Other services	OFFICE
36	Public administration	OFFICE
37	Education	SITE

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38	Health and social work	SITE
39	Other social services	OFFICE

Determination of the audit period is defined in the mandatory document "MD5:2015 Determination of the Audit Period of quality, environmental, and occupational health & safety management systems ". Correctly determining the initial audit period (Stage 1 + Stage2) is an important part of the application review.

4.5.5. For ISO 27001 ISMS audits;

For management systems audits, the scope of the company to be audited is evaluated according to the determined critical codes, and if it has a critical code, it is decided to conduct stage 1 audits on site. Stage 1 auditing is done in the office, except for critical codes.

EA KODU	DESCRIPTION	ISO 27001
1	Agriculture, fishing	OFFICE
2	Mining and quarrying	SITE
3	Food products, beverages and tobacco	SITE
4	Textiles and textile products	OFFICE
5	Leather and leather products	SITE
6	Wood and wood products	OFFICE
7	Pulp, paper and paper products	OFFICE
8	Publishing companies	OFFICE
9	Printing companies	SITE
10	Manufacture of coke and refined petroleum products	OFFICE
11	Nuclear fuel	SITE
12	Chemicals, chemical products and fibers	SITE
13	Pharmaceuticals	SITE
14	Rubber and plastic products	SITE
15	Non-metallic mineral products	SITE
16	Concrete, cement, lime, plaster etc	OFFICE
17	Basic metals and fabricated metal products	OFFICE
18	Machinery and equipment	OFFICE
19	Electrical and optical equipment	OFFICE
20	Shipbuilding	SITE
21	Aerospace	SITE
22	Other transport equipment	SITE
23	Manufacturing not elsewhere classified	OFFICE
24	Recycling	SITE
25	Electricity supply	OFFICE
26	Gas supply	SITE
27	Water supply	OFFICE
28	Construction	SITE
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	OFFICE
30	Hotels and restaurants	OFFICE
31	Transport, storage and communication	OFFICE
32	Financial intermediation; real estate; renting	OFFICE
33	Information technology	SITE
34	Engineering services	OFFICE
35	Other services	OFFICE
36	Public administration	OFFICE
37	Education	SITE
38	Health and social work	SITE
39	Other social services	OFFICE

Determination of the audit period is defined in the mandatory document "MD5:2015 Determination of the Audit Period of quality, environmental, and occupational health & safety management systems ". Correctly determining the initial audit period (Stage 1 + Stage2) is an important part of the application review.

4.5.6. For ISO 22000:2018 FSMS audits;

In the ISO 22000:2018 audit, document review is carried out at the customer's site together with the Stage 1 audit. The category/subcategory information given in the TS/ISO 22003 standard is given below.

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CATEGORY CODE	CATEGORY	SUB-CATEGORY		SECTORS		Category Risk Class
C	FOOD MANUFACTURING	CI	Processing of perishable animal products	CI.1	Red and Poultry Meat and Meat Products	High
				CI.2	Fish and seafood	High
				CI.3	Milk and milk products	High
				CI.4	Egg	High
		CII	Perishable Processed Herbal Products	CII.1	Processing of fresh fruits and vegetables (juice, chopping of fruits and vegetables, etc.)	mid
				CII.2	Production of vegetable products including cereals, nuts and legumes	mid
		CIII	Perishable processed vegetable and animal mixture products	CIII.1	Production of pizza, lasagna, sandwiches, dough, ready meals etc. containing mixed vegetable and animal products	High
		CIV	Long Life processed products	CIV.1	Manufacture of vegetable and animal oils and fats (includes the manufacture of crude or refined oils and fats from vegetable or animal products)	mid
				CIV.2	Manufacture of milled grain products, starches and starchy products (This group includes the manufacture of flour or pellets from cereals and vegetables, the manufacture of flour mixtures or dough from these products, such as the production of rice). In addition, the wet grinding of corn and vegetables, the manufacture of starch and starchy products are also included in this group. Manufacture of milled cereals and vegetable products, such as the manufacture of starch and starchy products)	mid
				CIV.3	Manufacture of bakery and bakery products (This group includes the production of bakery products, pasta, noodle and similar products.)	Mid
				CIV.4	The manufacture of spices, sauces, vinegar and other seasonings and the processing of salt to obtain food salt.	Mid
				CIV.5	Processing of sugar, fruit and vegetables and products kept at room temperature (for example, jam, chips, pickles, hermetically packaged soups, etc.), Cocoa, Coffee, Tea, chocolate, confectionery, chewing gum etc. manufacturing and processing, dried nuts etc.	Mid
				CIV.6	Homogenized food preparations (baby food substitutes for breast milk)	Mid
				CIV.7	Preserves	Mid
				CIV.8	Manufacture of beverages (This division includes the manufacture of beverages such as soft drinks and mineral waters (production of natural mineral water and other bottled waters), the manufacture of alcoholic beverages, mainly wine and beer by the fermentation method, and the manufacture of distilled spirits.	Mid
D	Animal Feed Production	DI	Feed production	DI.1	Manufacture of ready-made feed for farm animals (This group includes the production of feed for animals raised for food intended for human consumption. For example, bovine, ovine, poultry and fish feeds)	Mid
		DII	Pet Food Production	DII.1	Manufacture of ready-made feed for pets (This group includes the production of feed for non-food animals. For example, cat, dog, bird, ornamental fish)	Mid
E	Catering	E	Food	E.1	This class includes the following	High

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			Production and Presentation		activities; - restaurants, - cafeterias, - fast food restaurants, - take away type eating places, - food factories - Hotel kitchens etc.	
H	Services	HI	Services	HL1	Water supply (This section covers the collection, treatment and distribution of water in line with domestic and industrial needs. In addition to the collection of water from various sources, its distribution by various methods is also included in this section.)	High
				HL2	Waste Management (This section covers the collection, treatment and disposal of waste materials, local transportation of wastes and the operation of recycling facilities (plants that sort the wastes according to their types and separate the recyclables).	High
				HL3	Cleaning service (This group includes general interior cleaning of all kinds of buildings, exterior cleaning activities of buildings, specialist cleaning activities for buildings or other specialist cleaning activities, cleaning of industrial machinery, cleaning of the interior of road and sea tankers, disinfection and insecticide activities for buildings and industrial machines. , rodent, etc. destruction activities, cleaning of bottles, cleaning of work uniforms in laundries (washing, drying, etc.).	High
I	Production of Food Packaging and packaging materials	I	Food packaging production	I.1	Production of Food Packaging and packaging materials	Mid
J	Equipment Manufacturing (Hardware Manufacturing)	J	Equipment Manufacturing (Hardware Manufacturing)	J1	Development and manufacture of food processing equipment or vending machines	Mid

4.5.7. Assignment of Auditor for Stage 1 Audit

When planning stage 1 audits, the Management Representative determines the competencies and competencies of the audit team and appoints lead auditor(s) to perform stage 1 and stage 2 audits. Audit team competence is determined by considering the risk of the subject to be audited, the complexity of the audit, legal and regulatory requirements, and geographic locations. At this stage, the appointment of an expert to the audit team can be considered, and other team members are determined.

Personnel Selection and Evaluation Procedure is applied based on ISO 19011 and ISO 22003 in the appointment of auditors. Audit team members are determined by the planning officer from the auditor expert list in accordance with IAF, EA and NACE codes and/or the relevant field.

If the relevant client has completed a cycle of at least 3 years, the audit team to be formed when assigning the auditor must be different from the audit team formed in previous audits. This difference is made by the addition of new members to the audit team, or by the addition of new members to replace one or more of the audit team members. This is important in that relationships that develop over time do not pose a risk to conflicts of interest.

4.5.8. Stage 1 Audit Period and Planning

Stage 1 audit is a part of all audit processes up to certification and is considered together. ISO 9001:2015, ISO 22000:2018 ISO 14001, ISO 45001, ISO 27001 and ISO 13845 management system audits are planned in two stages.

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The audit period related to the Management System certification is determined in total for the Stage 1 and Stage 2 audits in accordance with the Audit Time Determination Instruction, Multi-site Audit Instruction.

For ISO 9001:2015 QMS, the Stage 1 audit period is limited so that the audit is not included in the scope of consultancy in the Stage 1 audit. Stage 1 audits for ISO 9001:2015 QMS; It is planned not to exceed 30% of the total audit time.

For ISO 14001 EMS, the Stage 1 audit period is limited so that the audit is not included in the scope of consultancy in the Stage 1 audit. Stage 1 audits for ISO 14001 EMS; It is planned not to exceed 30% of the total audit time.

For ISO 27001 ISMS, the Stage 1 audit period is limited so that the audit is not included in the scope of consultancy in the Stage 1 audit. Stage 1 audits for ISO 27001 ISMS; It is planned not to exceed 30% of the total audit time.

For ISO 45001 OHSMS, the Stage 1 audit period is limited so that the audit is not included in the scope of consultancy in the Stage 1 audit. Stage 1 audits for ISO 45001 OHSMS; It is planned not to exceed 30% of the total audit time..

For ISO 13485 MDQMS, the Stage 1 audit period is limited so that the audit is not included in the scope of consultancy in the Stage 1 audit. Stage 1 audits for ISO 13485 MDQMS; It is planned not to exceed 30% of the total audit time.

The audit period for ISO 22000:2018 certification is determined in total for Stage 1 and Stage 2 audits, in accordance with the Audit Period Determination Instruction. Stage 1 audits of the audit for ISO 22000:2018; It is planned not to exceed 30% of the total audit time..

Stage 1 audit is planned by the previously appointed audit team in the light of the determined time, and the Audit Plan is sent to the relevant company and confirmed. All audit team members are included in the relevant form. This notice shall be in such a way as to give sufficient time to rebuild the team if the customer has any objections. It should be communicated to the company at least 2 days before the determined audit date.

The client is contacted regarding the day of the stage 1 audit. The audit standard and audit scope are confirmed.

For ISO 9001:2015 QMS, an audit plan is prepared in office Stage 1 audits, but approval is not obtained from the customer.

4.5.9. Conducting ISO 9001 QMS Stage 1 Audits

Document review results of the management system of the organization applying for ISO 9001:2015 QMS and Stage 1 audit results are recorded. Whether the stage 1 audit will be carried out in the office is determined according to the critical code table determined according to the relevant codes of the IAF. If recommended by the lead auditor; Stage 1 audit report is prepared in the site.

The purpose of the stage 1 audit is to:

- a) Reviewing the information documented in the client's management system,
- b) Assessing client site and site-specific conditions and negotiating with client's personnel in determining readiness for a Phase 2 audit;
- c) Understanding the standard requirements for reviewing the client's status and in particular identifying key performance or key issues, processes, objectives and operation of the management system;
- d) Obtaining necessary information regarding the scope of the management system, including:
 - Customer's site/area,
 - processes and equipment used,

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- Established control levels (especially for customers with multiple sites),
- applicable situational and regulatory conditions,
- e) Reviewing the allocation of resources for the Stage 2 audit and agreeing with the client on the details of the Stage 2 audit;
- f) Focus on planning the Phase 2 audit, providing adequate understanding of the client's management system and field operations in the context of the management system standard or other relevant documents;
- g) Evaluating whether internal audits and a management review are planned and carried out, and assessing the level of implementation of the implemented management system and the client's readiness for a Phase 2 audit.

Customer organization; In the site audit report

- Evaluation results of site-specific conditions,
- The status of the organization,
- Evaluation of organization scope and exclusions,
- Evaluation of key points such as processes and objectives of the management system,
- Not meeting the legal requirements related to the product, creating an opportunity to identify important/critical nonconformities such as infrastructure,
- Compliance with ISO 9001:2015 QMS documentation requirements (document review is part of Stage 1 audit),
- Meeting with key and other relevant personnel and getting opinions and suggestions,
- Implementation status of corrective actions, internal audits and Management Review (MR),
- Qualification review for stage 2 audit,
- Availability of resources (such as logistics, transportation, accommodation, guide)
- The stage 2 audit plan includes the necessary notes for the audit date.

In the office audit report

- The status of the organization,
- Evaluation of organization scope and exclusions,
- Compliance with ISO 9001:2015 QMS documentation requirements (document review is an MR part of Stage 1 audit),
- Implementation status of corrective actions, internal audits and
- Qualification review for stage 2 audit,
- Stage 2 audit plan includes necessary notes for audit date..

4.5.10. Conducting ISO 14001 Stage 1 Audits

Stage 1 audits for ISO 14001:2015; It is planned not to exceed 30% of the total audit time. Document review results and Stage 1 audit results of the management system of the organization applying for ISO 14001:2015 are recorded. Whether or not the Stage 1 inspection will be carried out in the field is determined according to the critical code table determined according to the codes in the relevant guide of the IAF. If recommended by the lead auditor; Stage 1 audit report is prepared on site.

The purpose of the stage 1 audit is to:

- a) Reviewing the information documented in the client's management system,
- b) Assessing client site and site-specific conditions and negotiating with client's personnel in determining readiness for a Phase 2 audit;
- c) Understanding the standard requirements for reviewing the client's status and in particular identifying key performance or key issues, processes, objectives and operation of the management system;
- d) Obtaining necessary information regarding the scope of the management system, including:
 - Customer's site(s),
 - processes and equipment used,
 - Established control levels (especially for customers with multiple sites),
 - applicable situational and regulatory conditions,
- e) Reviewing the allocation of resources for the Stage 2 audit and agreeing with the client on the details of the Stage 2 audit,

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- f) Focus on planning the Stage 2 audit, providing adequate understanding of the client's management system and site operations in the context of the management system standard or other relevant documents;
- g) Evaluating whether internal audits and management reviews are planned and carried out, and assessing the level of implementation of the implemented management system and the client's readiness for a Stage 2 audit.

Customer organization; in the site audit report

- Evaluation results of site-specific conditions,
- The status of the organization,
- Evaluation of organization scope and exclusions,
- Evaluation of key points such as processes and objectives of the management system,
- Not meeting the legal requirements related to the product, creating an opportunity to identify important/critical nonconformities such as infrastructure,
- Compliance with ISO 14001 documentation requirements (document review is part of Stage 1 audit),
- Meeting with key and other relevant personnel and getting opinions and suggestions,
- Implementation status of corrective actions, internal audits and MR,
- Qualification review for stage 2 audit,
- Availability of resources (such as logistics, transportation, accommodation, guide)
- Stage 2 audit plan includes necessary notes for audit date.

In the office audit report

- The status of the organization,
- Evaluation of organization scope and exclusions,
- Compliance with ISO 14001 documentation requirements (document review is part of Phase 1 audit.)
- Implementation status of corrective actions, internal audits and MR,
- Qualification review for stage 2 audit,
- Stage 2 audit plan includes necessary notes for audit date.

4.5.11. Conducting ISO 27001 Stage 1 Audits

Stage 1 audits for ISO 27001; It is planned not to exceed 30% of the total audit time. Document review results and Stage 1 audit results of the management system of the organization applying for ISO 27001 are recorded. Whether the Stage 1 audit will be carried out in the field is determined according to the critical code table determined according to the codes in the relevant IAF guide. If recommended by the lead auditor; Stage 1 audit report is prepared on site.

The purpose of the stage 1 audit is to:

- a) Reviewing the information documented in the client's management system,
- b) Assessing client site and site-specific conditions and negotiating with client's personnel in determining readiness for a Stage 2 audit;
- c) Understanding the standard requirements for reviewing the client's status and in particular identifying key performance or key issues, processes, objectives and operation of the management system;
- d) Obtaining necessary information regarding the scope of the management system, including:
 - Customer's site/area,
 - processes and equipment used,
 - Established control levels (especially for customers with multiple sites),
 - applicable situational and regulatory conditions,
- e) Reviewing the allocation of resources for the Stage 2 audit and agreeing with the client on the details of the Stage 2 audit;
- f) Focus on planning the Stage 2 audit, providing adequate understanding of the client's management system and field operations in the context of the management system standard or other relevant documents,

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g) Evaluating whether internal audits and a management review are planned and carried out, and assessing the level of implementation of the implemented management system and the client's readiness for a Stage 2 audit.

Customer organization; in the site audit report

- Evaluation results of site-specific conditions,
- The status of the organization,
- Evaluation of organization scope and exclusions,
- Evaluation of key points such as processes and objectives of the management system,
- Not meeting the legal requirements related to the product, creating an opportunity to identify important/critical nonconformities such as infrastructure,
- Compliance with ISO 27001 documentation requirements (document review is part of Stage 1 audit.),
- Meeting with key and other relevant personnel and getting opinions and suggestions,
- Implementation status of corrective actions, internal audits and MR,
- Qualification review for stage 2 audit,
- Availability of resources (such as logistics, transportation, accommodation, guide)
- The stage 2 audit plan includes the necessary notes for the audit date.

Office audit report

- The status of the organization,
- Evaluation of organization scope and exclusions,
- Compliance with ISO 27001 documentation requirements (document review is part of Stage 1 audit),
- Implementation status of corrective actions, internal audits and MR,
- Qualification review for stage 2 audit,

The stage 2 audit plan includes the necessary notes for the audit date.

4.5.12. Conducting ISO 45001 Stage 1 Audits

Stage 1 audits for ISO 45001; It is planned not to exceed 30% of the total audit time. Document review results and Stage 1 audit results of the management system of the organization applying for ISO 45001 are recorded. Whether the Stage 1 inspection will be carried out in the field is determined according to the critical code table determined according to the codes in the relevant IAF guide. If recommended by the lead auditor; Stage 1 audit report is prepared on site.

The purpose of the stage 1 audit is to:

- a) Reviewing the information documented in the client's management system,
- b) Assessing client site and site-specific conditions and negotiating with client's personnel in determining readiness for a Stage 2 audit;
- c) Understand the standard requirements for reviewing the client's status and in particular identifying key performance or key issues, processes, objectives and operation of the management system,
- d) Obtaining necessary information regarding the scope of the management system, including:
 - Customer's site(s),
 - processes and equipment used,
 - Established control levels (especially for customers with multiple sites),
 - Applicable situational and regulatory requirements,
- e) Reviewing the allocation of resources for the Stage 2 audit and agreeing with the client on the details of the Stage 2 audit;
- f) Focus on planning the Stage 2 audit, providing adequate understanding of the client's management system and field operations in the context of the management system standard or other relevant documents;

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g) Evaluating whether internal audits and a management review are planned and carried out, and assessing the level of implementation of the implemented management system and the client's readiness for a Stage 2 audit.

Customer organization; in the site audit report

- Evaluation results of site-specific conditions,
- The status of the organization,
- Evaluation of organization scope and exclusions,
- Evaluation of key points such as processes and objectives of the management system,
- Not meeting the legal requirements related to the product, creating an opportunity to identify important/critical nonconformities such as infrastructure,
- Compliance with ISO 45001 documentation requirements (document review is part of Stage 1 audit),
- Meeting with key and other relevant personnel and getting opinions and suggestions,
- Implementation status of corrective actions, internal audits and MR,
- Qualification review for stage 2 audit,
- Availability of resources (such as logistics, transportation, accommodation, guide)
- Stage 2 audit plan includes necessary notes for audit date.

In the office audit report

- The status of the organization,
- Evaluation of organization scope and exclusions,
- Compliance with ISO 45001 documentation requirements (document review is part of Stage 1 audit),
- Implementation status of corrective actions, internal audits and MR,
- Qualification review for stage 2 audit

The stage 2 audit plan includes the necessary notes for the audit date.

4.5.13. Conducting ISO 13485 Stage 1 Audits

Stage 1 audits for ISO 13485; It is planned not to exceed 30% of the total audit time. Document review results and Stage 1 audit results of the management system of the organization applying for ISO 13485 are recorded. Whether the Stage 1 audit will be carried out on site is determined according to the critical code table determined according to the codes in the relevant IAF guide. If recommended by the lead auditor; Stage 1 audit report is prepared on site.

The purpose of the stage 1 audit is to:

- a) Reviewing the information documented in the client's management system,
- b) Assessing client site and site-specific conditions and negotiating with client's personnel in determining readiness for a Phase 2 audit;
- c) Understanding the standard requirements for reviewing the client's status and in particular identifying key performance or key issues, processes, objectives and operation of the management system;
- d) Obtaining necessary information regarding the scope of the management system, including:
 - Customer's site(s),
 - processes and equipment used,
 - Established control levels (especially for customers with multiple sites),
 - applicable situational and regulatory conditions,
- e) Reviewing the allocation of resources for the Stage 2 audit and agreeing with the client on the details of the Stage 2 audit,
- f) Focus on planning the Stage 2 audit, providing adequate understanding of the client's management system and site operations in the context of the management system standard or other relevant documents;
- g) Evaluate whether internal audits and management reviews are planned and carried out, and assess the level of implementation of the management system implemented and the client's readiness for a Stage 2 audit.

Customer organization; in the site audit report

- assessment results of site-specific conditions,
- The status of the organization,
- Evaluation of organization scope and exclusions,
- Evaluation of key points such as processes and objectives of the management system,
- Not meeting the legal requirements related to the product, creating an opportunity to identify important/critical nonconformities such as infrastructure,
- Compliance with ISO 13485 documentation requirements (document review is part of Stage 1 audit),
- Meeting with key and other relevant personnel and getting opinions and suggestions,
- Implementation status of corrective actions, internal audits and MR,
- Qualification review for stage 2 audit,
- Availability of resources (such as logistics, transportation, accommodation, guide)
- Stage 2 audit plan includes necessary notes for audit date.

In the office audit report

- The status of the organization,
- Evaluation of organization scope and exclusions,
- Compliance with ISO 13485 documentation requirements (document review is part of Stage 1 audit),
- Implementation status of corrective actions, internal audits and MR,
- Qualification review for stage 2 audit,

The stage 2 audit plan includes the necessary notes for the audit date.

4.5.14. ISO 22000:2018 Stage 1 Audit

The purpose of a Stage 1 audit in ISO 22000:2018 is to plan a stage 2 audit by establishing an understanding of the organization's food safety hazards identification, analysis, HACCP plan and prerequisite programmes, policy and objectives, and in particular the preparation of the organization's situation to the audit, within the scope of reviewing: providing an overview.

In Stage 1 audits, the following should be checked in general.

- Evaluation of the applicant company's site and site conditions in preparation for the Stage 2 audit,
- Reviewing the status of the company and evaluating whether it meets the requirements of ISO 22000:2018 standards, especially important factors, processes, targets and operations,
- Necessary information regarding the scope of ISO 22000:2018 FSMS should be collected and the following should be checked;
 - information on managing hazard analyzes (first step),
 - methodology of hazard analysis and determination of acceptable steps,
 - Prerequisite Plan and/or HACCP plans,
 - Basic information of the company's field or fields and processes there,
 - Evaluation and adequacy of relevant legislation and rules
 - Associated risks,
 - Environmental and quality factors within the scope of the firm's application.
- Discussing the details of the Stage 2 audit,
- Adequate understanding of the field operation of the possible significant impacts and ISO 22000:2018 of the company and planning the stage 2 audit accordingly,
- Checking the firm's readiness for a stage 2 audit by checking and evaluating that the management review and internal audits have been carried out,
- Checking that the Company's Prerequisite Program is documented according to the work performed and legal and mandatory requirements,
- Checking whether the company's Food Safety Management System has adequate processes to identify food safety hazards,
- Checking the compatibility of the company's Food Safety Management System with the food safety rules,
- Information about the Food Safety Management System policy and its applications,
- Control of validity, verification and improvement rules in accordance with the requirements of the Food Safety Management System standard,

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- Checking the company's additional documents in preparation for the Stage 2 audit,

According to the stage 1 audits, if it is confirmed that the company fulfills the above general requirements, it can be passed to the stage 2 audit.

How the Stage 1 audit will be conducted and which issues will be addressed are specified in the Audit Procedure.

After a Stage 1 audit, a Stage 2 audit may result in postponement or cancellation. This is reported to the auditee.

For ISO 9001:2015 KYS, ISO 22000:2018GGYS, ISO 14001, ISO 45001, ISO 27001 and ISO 13485, if there are deviations that change the number of audit man/day, this situation is brought to the attention of the customer in order to increase the number of auditor days and audit fee and recorded in the Stage 1 report.

The lead auditor should record the Stage 1 results in the Stage 1 audit report. An audit plan is prepared to meet all of the client's processes and activities, and a copy of the plan and the Stage 1 audit report is left to the client. One day can be discussed for the stage 2 audit and a discussion is made about how the audit will be carried out.

Aşama 1 denetiminden sonra aşama 1 denetim raporu hazırlanır. Müşteri eğer Aşama 1 denetiminden geçmesi halinde Aşama 2 denetimi gerçekleştirilir. Aşama 1 denetim sonucu, Aşama 2 denetiminin iptaline veya ertelenmesine neden olabilir. Aşama 2 denetimleri müşteri tesislerinde gerçekleştirilir. Aşama 1 ve Aşama 2 denetimleri arasındaki maksimum zaman 90 gündür.

At the end of the stage-1 audit, the customer must notify Unicert of any changes that may occur during the period until the stage-2 audit time, before approving the stage-2 audit plan to be sent by Unicert.

4.5.15. Reporting the Stage 1 Audit

In reporting, ISO 9001:2015 Stage 1 Audit Report and Question List (this question list and report are in the audit package), ISO 22000:2018 Stage 1 Audit Report and Question List (this question list and report are in the audit package), ISO 14001 Stage 1 Audit Report and Question List (this question list and report are in the audit package), ISO 45001 Stage 1 Audit Report and Question List (this question list and report are in the audit package), ISO 27001:2015 Stage 1 Audit Report and Question List (this question list and the report is in the audit package), ISO 13485 Stage 1 Audit Report and Question List (this question list and report are in the audit package) are used. Findings related to the items of the standard are recorded. Nonconformities are recorded in the Nonconformance report. If there is an observation, it is recorded in the report content. Classes of nonconformities must be specified. The firm should plan corrective action to prevent the root cause and recurrence of nonconformities. Objective evidence that corrective actions have been taken and have taken place should be communicated to the lead auditor or Unicert head office. The report is reviewed by the competent auditor and the situation is recorded. If appropriate, Stage 2 audit (Planning) is initiated by ensuring coordination with the lead auditor planning department. If the corrective action cannot be accepted, the deficiencies are explained to the company and the corrective action is requested to be completed again.

If there is a significant deviation from the information in the application and the contract, the customer is contacted and the proposal / contract is submitted again in order to increase / decrease the number of auditor days and to re-determine the cost.

Documented results of meeting the objectives of Phase 1 and preparation for Phase 2 (which may be classified as non-conformances during the Phase 2 audit) should be communicated to the client. Stage 1 outputs do not need to meet all the requirements of an audit report (see 17021-1:2015 Clause 9.4.8). In determining the interval between Stage 1 and Stage 2 audits, the time required by the client to resolve issues identified during the Stage 1 audit is taken into account. This period of time is determined by Unicert, not to exceed a maximum of 90 days. Unicert may also need to revise its

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arrangements for Stage 2. If there are significant changes that affect the management system, Unicert considers duplication of all or Stage 1. The client is informed at the Tier 1 audit that the results of Tier 1 may lead to delay or cancellation of Stage 2.

On-site audit / Stage 2 audit is performed no later than 90 days from the date of ISO 13485 ISO 9001:2015 QMS, ISO 22000, ISO 14001, ISO 45001, ISO 27001 Stage 1 audits. If this time is exceeded, stage 1 is repeated or cancelled.

The minimum time between the Stage 1 audit and the Stage 2 audit is the time the client specifies in the Nonconformance Report in the Stage 1 audit.

There is a possibility that any part of the QMS/FSMS that is determined to be fully executed, effective and compliant with the requirements and the customer during the stage 1 audit will not need to be re-audited during the stage 2 audit. However, Unicert auditors state in their audit reports that the previously audited QMS/FSMS parts continue to comply with the certification rules. In this case, the stage 2 audit report includes these findings and declares that compliance was determined during the stage 1 audit.

Stage 1 audit report is checked by certification decision makers. And the situations that may cause a change in the stage 2 plan are reported to the planning officer.

4.6. Situations That May Require More Audit Time

For ISO 9001:2015 QMS

- Complex layout, activities / processes being in more than one place,
- Implementation of design and development activities,
- Documentation structure,
- Complexity of product characteristics and processes,
- Multi-site operation
- Training and experience of key personnel and other relevant personnel,
- Using an interpreter in the audit,
- Having processes with high order rules.
- The workplace is too large for the number of employees
- Having many regulations and legal requirements (food, medicine, aviation, nuclear energy, etc.)
- Need to visit temporary sites to verify firm scope
- The firm has outsourced operations/processes
- In the previous audit of the company, the number of audit man/day was determined to be insufficient.

For ISO 14001

- Complex layout, activities / processes being in more than one place,
- Implementation of design and development activities,
- Documentation structure,
- Complexity of product characteristics and processes,
- Multi-site operation
- Training and experience of key personnel and other relevant personnel,
- Using an interpreter in the audit,
- Having processes with high order rules.
- The workplace is too large for the number of employees
- Having many regulations and legal requirements (food, medicine, aviation, nuclear energy, etc.)
- Need to visit temporary sites to verify firm scope
- The firm has outsourced operations/processes
- In the previous audit of the company, the number of audit man/day was determined to be insufficient.

For ISO 27001

- Complex layout, activities / processes being in more than one place,
- Implementation of design and development activities,
- Documentation structure,
- Complexity of product characteristics and processes,
- Multi-site operation
- Training and experience of key personnel and other relevant personnel,
- Using an interpreter in the audit,
- Having processes with high order rules.
- The workplace is too large for the number of employees
- Having many regulations and legal requirements (food, medicine, aviation, nuclear energy, etc.)
- Need to visit temporary sites to verify firm scope
- The firm has outsourced operations/processes
- In the previous audit of the company, the number of audit man/day was determined to be insufficient.

For ISO 45001

- Complex layout, activities / processes being in more than one place,
- Implementation of design and development activities,
- Documentation structure,
- Complexity of product characteristics and processes,
- Multi-site operation
- Training and experience of key personnel and other relevant personnel,
- Using an interpreter in the audit,
- Having processes with high order rules.
- The workplace is too large for the number of employees
- Having many regulations and legal requirements (food, medicine, aviation, nuclear energy, etc.)
- Need to visit temporary sites to verify firm scope
- The firm has outsourced operations/processes
- In the previous audit of the company, the number of audit man/day was determined to be insufficient.

For ISO 13485

- Complex layout, activities / processes being in more than one place,
- Implementation of design and development activities,
- Documentation structure,
- Complexity of product characteristics and processes,
- Multi-site operation
- Training and experience of key personnel and other relevant personnel,
- Using an interpreter in the audit,
- Having processes with high order rules.
- The workplace is too large for the number of employees
- Having many regulations and legal requirements (food, medicine, aviation, nuclear energy, etc.)
- Need to visit temporary sites to verify firm scope
- The firm has outsourced operations/processes
- In the previous audit of the company, the number of audit man/day was determined to be insufficient.

For ISO 22000:2018

- Complicated settlements, multiple buildings, facilities, separate sections, etc.,
- Using an interpreter in the audit,
- Very special activities
- Additional meeting requirements (Review meeting, Coordination meeting, audit team briefing)
- Number of product types

- Number of product lines
- Product development
- Number of critical control points
- Number of operational prerequisite programs
- Building area
- Infrastructure
- In-house laboratory experiments

In the follow-up audits conducted for nonconformities detected in multi-enterprise organizations, if ongoing non-conformities are detected in the central office or at least one of the enterprises, in the relevant management system and/or application, the certification is not made or the existing certificate is cancelled. Multi-site sampling is planned according to MD.1. Multi-site application is made with the System Certification Application form in applications.

4.7. Situations That May Require Reducing Audit Time

For ISO 9001:2015

- Design clause out of scope/not applicable
- Exclusion of standard items/not applicable
- Absence of outsourced processes,
- The document structure is understandable and easily auditable,
- Being a non-risky product / process,
- The maturity level of the management system,
- Competence levels of employees,
- Having an existing certificate from another organization,
- Having other system certificate,
- The workplace has a small area compared to the number of employees
- Prior knowledge of the company's management system (eg, having been previously documented by Unicert in another standard)
- High level of automation
- Presence of personnel working outside the field (eg sales personnel, drivers, service personnel, etc.) and their activities and audit compliance can be achieved by examining the records.

Audit time cannot be reduced by more than 30% as determined time for ISO 9001:2015 QMS certification audits.

For ISO 22000:2018

Calculation is made according to the Audit Period Determination Instruction. Situations that will require reduction of Audit time in the Food Safety Management System are described below.

- The workplace has a small area compared to the number of employees
- Maturity level of the management system
- Prior knowledge of the company's management system (eg, having been previously documented by Unicert in another standard)
- The company's preparation for certification (Ex: It has been subject to any 3rd party audit or has been previously certified)
- High level of automation
- Simple process(s)
- Majority of employees doing the same job
- Size of the organization
- Product volume and variety
- Medium or low risk category

4.8. Stage 2 Audit Planning

The lead auditor and audit committee are appointed by the Certification Manager. The Audit Team Assignment Form, which includes the scope and information of the firm, is sent to the members of the audit team by e-mail and approval is obtained from the auditor(s). The original form of the form must be kept in the customer file.

Transportation, accommodation, etc. organizations are carried out by the Planning officer and/or the lead auditor. The lead auditor prepares the Audit Plan. The resumes of the audit committee and the audit plan are sent to the company by e-mail at least 2 days before the audit date to get the firm's confirmation.

According to the determined scope; Audit Plan is created by the lead auditor and should show which items of the standard in which process / department / activity he will audit. It should plan to audit for a maximum of 8 hours a day for each auditor. The audit plan should be created starting from the management and following the logical flow according to the policy, purpose, objectives and work flow of the company.

The number of audit days cannot be reduced by extending the daily audit hour. The daily audit time is only 8 hours. If necessary, the daily working hours can be increased by a maximum of 20%. This condition is not to shorten the audit period for full days. Audit time allocated should not be reduced by scheduling longer working hours per day during the initial planning stages.

It is the lead auditor's responsibilities to liaise with the audit team, to inform about previous developments, to talk about the audit and to answer questions from the auditors. Regarding the problems that cannot be resolved by the lead auditor, the Certification Manager is consulted.

Planning and report writing activities are planned in such a way that they do not reduce the duration of the site audit to less than 10% of the total time given in the Audit Period Determination Instruction for Quality Management System certifications, and these activities do not reduce the duration of the site audit to less than 70% of the total audit period.

ISO 9001, ISO 22000, ISO 14001, ISO 45001, ISO 27001 and ISO 13485 Stage 2 audit plan is made by the lead auditor in line with the findings obtained in Stage 1.

Both Stage 1 and Stage 2 audits are added to the total audit time. The time spent on audits should be compatible with the organization's processes, critical control points, and size. Audit periods are determined in accordance with the Instruction for Determining the Audit Duration.

After closing the nonconformities identified in the Stage 1 audit, if any, the Certification Manager or Lead Auditor contacts the client to set a date for the Stage 2 audit to be performed and, if necessary, resends the revised audit plan including the audit team and their roles. At this stage, it is reviewed whether there are any conditions or issues requested with the customer that have not been discussed before. Stage 2 planning can also be done at the end of the Stage 1 audit if there are no nonconformities.

4.9. Performing Stage 2 Audit

The audit is carried out within the framework of the Audit Procedure and according to the relevant standard, and ISO 9001 Stage 2 Audit Report and Question List, ISO 22000 Stage 2 Audit Report and Question List, ISO 14001 Stage 2 Audit Report and Question List, ISO 45001 Stage 2 Audit Report and Question List, ISO 27001 Stage 2 Audit Report and Question List are reported using ISO 13485 Stage 2 Audit Report and Question List. The report is delivered to the office within 7 days at the latest (by hand, e-mail, cargo, etc.)

The lead auditor is responsible for the management and reporting of the audit. According to the determined scope; implemented within the framework of the audit plan created.

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At the beginning of the audit, the opening meeting is held and recorded in the Stage 2 Audit Report and the Attendance Minute in the Question list. Agenda Items are stated in the Audit Procedure and the audit report question list for each standard.

A sufficient number of examples to show the suitability of the subjects specified in the scope are examined and reported.

Process-based audit is carried out. It is audited whether the organization is capable of meeting, maintaining and continuously improving customer requirements.

The audit is carried out according to the plan made previously. Questionnaires may be used by the audit team to appropriately cover all areas of the audit, but these should include references to the client's written system.

The objective/purpose of the audit is to confirm that it complies with all the articles of the standard, to determine whether the developed system is designed to provide legal compliance and to determine that legal compliance is actually achieved, to determine compliance with the Organization's own policies and procedures. The audit team is required to hold a closing meeting with client management to present its findings. In this meeting, non-conformities and problems related to legal compliance of the customer are discussed. The customer is expected to find a solution to these.

In all management system audits, the legal compliance of the organization within the scope of the relevant management system is audited. The necessary licenses and permits are investigated. Objective evidence of this conformity is stated in the report. Certification recommendation cannot be made for an organization that cannot demonstrate this conformity. If legal compliance cannot be demonstrated, a Nonconformity Report is written. Evidence regarding the corrective actions regarding the nonconformities as a result of the audit should be added to the report by the audit team.

At the end of the audit, a closing meeting is held and recorded in the Stage 2 Audit Report and the Attendance Minute in the Question list.

Necessary corrections should be made for minor nonconformities, but corrective actions that require time can be closed with a Corrective Action Plan, provided that their effectiveness is measured in the next audit. Major non-conformances are closed after all relevant corrective and corrective actions have been completed. Nonconformities that do not require a follow-up audit can be closed by the lead auditor who performed the audit, another lead auditor or Certification Manager assigned within the relevant scope. ISO 22000 nonconformities can be closed by a designated ISO 22000:2018 lead auditor.

Root causes of nonconformities are recorded in the Nonconformity Report by the audited organization after the audit. A copy of the nonconformance reports is available to Unicert auditors.

4.10. Reviewing the Report and Editing the Document (Deciding on Certification)

Certification decision; It is given within the methods specified in the Unicert certification procedure. While making the certification decision, in addition to the above principles, IAF accreditation guidelines, Accreditation Standards and the relevant guidelines, rules and instructions of the accreditation institution whose accreditation is used are taken into consideration and no certification can be made against them.

While making the certification decision, the relevant audit team and the lead auditor's advice on the subject and the scope specified in the audit report are taken into consideration. The existence of sufficient objective evidence regarding the determined scope is sought. If there is no problem in this regard, the certification decision is made. If there is any problem, one of the following decisions is made;

- a) Rejection of the relevant scope article,
- b) Performing an additional audit on the relevant scope,
- c) Conducting the next interim audit earlier,

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- d) Warning the Auditor / Lead Auditor about taking sufficient samples in the next interim audit.
- e) In matters such as Food Safety, the scope is decided by taking into account all the activities of the applicant, whether they are within the scope or outside of the scope, and whether risk analyzes have been made or not.

The recommended scope includes a non-accredited scope. According to the recommendation, one of the following decisions is made.

- Rejection of the relevant scope article,
- Making a change in scope and making an application to the accreditation body for scope expansion in the relevant scope.

In all management system audits, the legal compliance of the organization within the scope of the relevant management system is audited. The necessary licenses and permits are investigated. Certification recommendation cannot be made for an organization that cannot demonstrate this conformity. If legal compliance cannot be demonstrated, a non-compliance report is written.

As a result of the audit, the evidence regarding the corrective actions related to the nonconformities is added to the report by the audit team. In order for the certification decision to be made, all major and minor nonconformities must be closed.

Corrective actions that require time to close minor nonconformities can be closed with a Corrective Action Plan, provided that their effectiveness is measured in the next audit. Major nonconformities are closed only after all relevant corrective and corrective actions have been completed. Nonconformities that do not require a follow-up audit can be closed by the lead auditor who performed the audit, another lead auditor or Certification Manager (if holding the IAF 9001-Category 22000 code).

Before deciding on certification, suspension or cancellation of the certificate and the continuation of the certificate, the following are carried out with the Certification Decision Form in order to ensure the accuracy, independence and impartiality of the decision.

- All forms, records and official documents that should be in the company file are checked.
- The report is evaluated by the certification manager.
- The adequacy of the audit team and auditor assignments is reviewed by the certification manager.
- Whether all the tasks to be performed during the audit have been fulfilled and whether all the records have been completed completely are reviewed by the certification manager..

With the review;

- The audit is properly planned, the audit plan is appropriate
- The audit team is able to meet the firm scope and audit standard applied to the firm
- Audit duration and scope are adequate for certification of the firm.
- The audit report has sufficient findings to support the certification-related recommendation made by the lead auditor.
- The report and the information provided by the audit team are sufficient to certify in the relevant standard and scope.
- The proposed scope of certification is acceptable and all activities within this scope have been audited.
- Applicable legal requirements have been audited.
- The scope of the company's certification must include the scope of accreditation.
- The generated report complies with reporting standards.
- Identified nonconformities and their grading are appropriate and sufficient data is given in the report about them.

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The review records should meaningfully demonstrate that the audit report was made in accordance with the audit rules and audit criteria. Recorded nonconformities need to be addressed in the following aspects.

- The reason for the written nonconformities is in line with the audit criteria and the scope of the certification.
- All must be correctly rated.
- Their definitions are meaningful.

Certification decision is not taken before major nonconformity is closed, and certification decision is not taken without corrective action plan in minor nonconformity.

According to the relevant document, the certification manager can take a certification decision to the extent that it is sufficient in ISO 9001:2015 critical codes and other codes according to the risk groups determined according to the IAF.

In case the Certification Manager does not have the qualification in the IAF CODE of the company for ISO 9001:2015, the Certification Manager approves the certification decision and/or decision by getting the opinion of a lead auditor and/or technical expert with the required qualification from the Lead Auditor/Auditor/Technical expert list. This opinion is achieved by sending the audit documents by mail/mail and examining the sent documents and deciding on the Certification decision form. This decision is definitely delivered to the Unicert office and the decision is kept in the company file. When the certification manager goes to the audit, the substitute decision maker is assigned to the certification decision instead.

In ISO 22000 systems, the Certification Manager can make the certification decision alone in the sub-category(s) to which he is assigned, as long as he has the necessary training that meets the ISO 22003 requirements. Otherwise, an auditor or technical expert meeting the requirements of ISO 22003 is selected from the list of Lead Auditor-Auditor-Technical expert (if he does not have experience in the relevant product, process and applications/in the sub-category to which he is not assigned) and can make a decision together with this person. It is essential that the person(s) concerned do not take part in the audit team of the firm to be decided. When the certification manager goes to the audit, a substitute decision maker with ISO 22003 requirements is assigned to the certification decision.

In ISO 14001 systems, the Certification Manager can make the certification decision alone in the sub-category(s) to which he is assigned, as long as he has the necessary training that meets the requirements of ISO 17021-1. Otherwise, an auditor or technical expert who meets the requirements of ISO 17021-1 (if he has no experience in the relevant product, process and applications / in the subcategory to which he is not assigned) is selected from the list of Lead Auditor-Auditor-Technical experts and can decide together with this person. It is essential that the person(s) concerned do not take part in the audit team of the firm to be decided. When the certification manager goes to the audit, a substitute decision maker with ISO 17021-1 requirements is assigned to the certification decision.

In ISO 45001 systems, the Certification Manager can make the certification decision alone in the sub-category(s) to which he is assigned, as long as he has the necessary training that meets the requirements of ISO 17021-1. Otherwise, an auditor or technical expert who meets the requirements of ISO 17021-1 (if he has no experience in the relevant product, process and applications / in the subcategory to which he is not assigned) is selected from the list of Lead Auditor-Auditor-Technical experts and can decide together with this person. It is essential that the person(s) concerned do not take part in the audit team of the firm to be decided. When the certification manager goes to the audit, a substitute decision maker with ISO 17021-1 requirements is assigned to the certification decision.

In ISO 13485 systems, the Certification Manager can make the certification decision alone in the sub-category (s) to which s/he is assigned, as long as she has the necessary training that meets the requirements of ISO 17021-1. Otherwise, an auditor or technical expert who meets the requirements of ISO 17021-1 (if he has no experience in the relevant product, process and applications / in the subcategory to which he is not assigned) is selected from the list of Lead Auditor-Auditor-Technical experts and can decide together with this person. It is essential that the person(s) concerned do not take

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part in the audit team of the firm to be decided. When the certification manager goes to the audit, a substitute decision maker with ISO 17021-1 requirements is assigned to the certification decision.

In ISO 27001 systems, the Certification Manager can make the certification decision alone in the sub-category (s) to which she is assigned, as long as she has the necessary training that meets the ISO 27006 requirements. Otherwise, an auditor or technical expert who meets the requirements of ISO 27006 is selected from the list of Lead Auditor-Auditor-Technical expert (if he does not have experience in the relevant product, process and applications / in the sub-category to which he is not assigned) and can decide together with this person. It is essential that the person(s) concerned do not take part in the audit team of the firm to be decided. When the certification manager goes to the audit, a substitute decision maker with ISO 27006 requirements is assigned to the certification decision.

If the substitute decision maker does not have the qualifications in the IAF Code and/or Category code within the scope of the company, the lead auditor, auditor or technical expert who has the relevant conditions can be selected from the list of Lead Auditor-Auditor-Technical experts and decide together with this person.

Certification Decision Form is prepared for the certification decision. The certification manager does not take part in the audits he decides on. In addition, the person(s) who will make the certification decision sign the Audit Team Assignment Form and make it clear that they have no ties to the company to be audited.

No	DECISIONS	DESCRIPTION	Decision Maker
1	Issuance of the certificate	No nonconformities were detected in the initial certification audit or Major nonconformities were closed, if minor, corrective action plans exist. Closing the previously found non-conformities if follow-up audit has been made. <i>It could be surveillance. There is no number limit.</i>	Certification Manager, in cases where it is not sufficient, with technical expert support.
2	Maintaining the certificate	Failure to detect non-conformities in surveillance audits or closing non-conformities, if any. Closing previously found nonconformities, if follow-up audit has been carried out. <i>It could be surveillance. There is no number limit.</i>	Certification Manager, in cases where it is not sufficient, with technical expert support.
3	Renewal of the certificate	Failure to detect nonconformities in the document renewal audit or the nonconformities, if any, have been closed. Closing previously found nonconformities, if follow-up audit has been carried out. <i>It could be surveillance. No number limit</i>	Certification Manager, in cases where it is not sufficient, with technical expert support.
4	Failure to issue certificate	Failure to close the nonconformities detected in the first certification audit within 3 months on a document basis or with a follow-up audit.	Certification Manager, in cases where it is not sufficient, with technical expert support.
5	Performing a follow-up audit	Identification of nonconformities that can be verified on site during audits (such as certification, surveillance, follow-up, certificate renewal). <i>It could be surveillance. No number limit</i>	Certification Manager, in cases where it is not sufficient, with technical expert support.

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6	Requesting full audit again	Improper application of accreditation and Unicert procedures that could seriously affect the audit process. The audit is not sufficient to measure the competence of the client. For example, the audit team is not competent, the audit period does not comply with the IAF, the audit is carried out in the wrong scope.	Certification Manager
7	Requesting on-site audit of a certain part again	Improper application of accreditation and Unicert procedures, affecting only a certain part of the audit process. The audit is not sufficient to measure the competence of the client. For example, not auditing the covered activity at another address. Such as not auditing an activity in the audit plan and scope.	Certification Manager
8	Requesting corrective action from the supplier	Minor non-conformities by the client with the Unicert certification procedure, contract and accreditation requirements. Due to minor customer complaints.	Certification Manager
9	temporary suspension of the certification	Non-conformities detected in the audits of certified customers is not closed within 1 month (with or without follow-up audit). Failure of the customer to comply with the Unicert certification procedure (using the logo and document for different purposes, non-compliance with payment terms, etc.) Postponement of the planned audit date by more than 2 months. The firm loses its legal compliance or fails to demonstrate it.	Certification Manager
10	withdrawal of certification	Failure of follow-up audits for nonconformities found in surveillance and certificate renewal audits. Failure of the customer to fulfill the conditions to remove the suspension within the suspension period. Failure of the customer to comply with the Unicert certification procedure and accreditation requirements seriously, or failure to implement the corrective actions initiated by Unicert in this regard or due to customer complaints.	Certification Manager
		Failure of the supplier/customer to fulfill (not pay) the Unicert certification agreement terms	General manager

The company whose certificate is issued is recorded in the "Audit Program Form". This form specifies the details of the audits conducted during a company's 3-year certification cycle.

4.11. Surveillance Audit

Surveillance audit is carried out at least once a year, based on the duration recommended by the lead auditor as a result of the previous audit, and customer complaints.

In management systems certification, the expiry dates of the organization's permits and licenses are taken into account, as well as the advice of the lead auditor. According to the importance of the subject, the surveillance audit can be taken earlier.

In the surveillance audit, the implementation efficiency of the nonconformities found and closed in the previous audit is monitored. A plan is made so that all standard items are audited at least once until the document renewal audit.

Surveillance Audit Program;

- Internal audits and management reviews,
- Reviewing the actions taken for nonconformities identified in previous audits,

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- Monitoring of complaints,
- The effectiveness of the client's management system regarding the achievement of objectives,
- The development of planned activities aiming at continuous improvement,
- Operational controls,
- Reviewing the changes,
- It is carried out in a way to cover the use of logo or other references to documentation (advertising materials, packaging, web page, advertisements, etc.).

The following ISO 9001:2015 items are audited at every audit;

- 4.4** Quality Management System and Processes
- 8.4** Control of outsourced processes, products and services
- 7.5** Documented information
- 5** Leadership
- 7** Support
- 8.1** Operational Planning and Control
- 8.5.1** Production and service delivery
- 9** Performance evaluation

The following ISO 22000:2018 items are audited in every audit;

- 4.4** Food Safety Management System and Processes
- 7.5** Document control
- 5** Leadership
- 7** Resources
- 8** Study
- 9** Performance evaluation

The following ISO 14001 items are audited in every audit;

- 4.4** Requirements for environmental management systems
- 8.4** Control of outsourced processes, products and services
- 7.5** Documented information
- 5** Leadership
- 7** Support
- 8.1** Operational Planning and Control
- 8.5.1** Production and service delivery
- 9** Performance evaluation

The following ISO 45001 items are audited in every audit;

- 4.4** Requirements for OHS management systems
- 8.4** Control of outsourced processes, products and services
- 7.5** Documented information
- 5** Leadership
- 7** Support
- 8.1** Operational Planning and Control
- 8.5.1** Production and service delivery
- 9** Performance evaluation

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The following ISO 27001 items are audited in every audit;

- 4.4** Requirements for ISMS management systems
- 8.4** Control of outsourced processes, products and services
- 7.5** Documented information
- 5** Leadership
- 7** Support
- 8.1** Operational Planning and Control
- 8.5.1** Production and service delivery
- 9** Performance evaluation

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The following ISO 13485 items are audited in every audit

- 4.4** Requirements for MDQMS management systems
- 8.4** Control of outsourced processes, products and services
- 7.5** Documented information
- 5** Leadership
- 7** Support
- 8.1** Operational Planning and Control
- 8.5.1** Production and service delivery
- 9** Performance evaluation

At least 2 surveillance audits are carried out during the document usage period (3 years). Surveillance audits should be carried out at least once every calendar year. The first surveillance audit to be carried out after the initial certification should not exceed 12 months from the date of certification. 2. Surveillance audit should be completed within the calendar year (eg: first certification decision date: 25.09.2020 1. audit date 24.09.2021, 2. audit date should be carried out until 21.10.2022).

There may be a need to adjust the frequency of the certification audit to accommodate factors such as seasons or limited time management system certification (eg: temporary construction site).

The Management Representative will contact the company at the latest 30 days in advance (e-mail, telephone, postal, etc.) and receive written proof of whether there has been any change in the information in the company that will affect the audit (number of employees, scope, audit address, etc.) and notifies relevant persons..

Postponement requests from customers for surveillance audits are evaluated by the Management Representative, and a maximum of 6 months can be postponed for special cases (for example, seasonal products/services, natural disasters, economic crisis, etc.). In case of postponement, the date of the surveillance audit does not bind to the next audit date.

The client is obliged to carry out the implementation of the Reference System Standard regarding the Management Review and Internal Audit items at least once a year, and must submit the records of these practices to the Audit Team during the surveillance audits. If major non-conformities are detected as a result of the surveillance audit, the certificate may be suspended, and then the suspension may be lifted by performing a follow-up audit at the request of the customer.

When the Unicert audit team determines during the audit that it has consistently or seriously failed to maintain some of the scope specified by the client, it gives an opinion to the Certification decision makers to narrow the scope.

4.12. Custom Audit

4.12.1. Scope Expansion/Reduction (Scope change)

The customer may request an expansion or reduction in the scope of the document he has. In Scope Change Audits, an assessment is made regarding the scope of the change. As a result of the Scope Change Audit; If it is decided to expand or reduce the scope in line with the decision made, the old document is requested back from the customer and a new document is prepared. If the scope change affects the number of man days, a new contract is made.

A written application is received by the certification manager. The application is evaluated by taking the opinions of the certification manager and the lead auditor who went to the audit before.

As a result of the evaluation;

- 1.** If the previous audit covers the change request, only if the scope is defined differently, the application is accepted without the need for a re-audit, and it is submitted to the person who will take the certification decision, together with the reasons for the scope change.

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2. Absolutely unacceptable status of scope change. If the company is not sufficient to make changes in terms of infrastructure and procedures, the change cannot be accepted without even the need for a re-audit. This situation is announced to the company in writing along with the reasons..
3. Re-audit and decision to change. If the change is within the scope of accreditation; A written request is received from the company (details are requested when necessary) and examined. If additional documents are needed at this stage, they are requested. At least one of the appointed auditors or experts must be assigned in the relevant IAF / EA / NACE Category-Sub-Category. Which items of the auditing standard should be audited for scope changes are determined by the lead auditor as “auditor x days”. It is a prerequisite for the internal audit and management review regarding the change in audit. In the audit, all the articles of the relevant standard are re-audited within the scope of the amendment. (Here, there is no need to audit the sub-clauses of the standard that are not related to the change made). In requests for changes that are not within the scope of accreditation, this is communicated to the organization. If the organization accepts, the audit is carried out in accordance with the above-mentioned rules and the certification is submitted for decision to be taken.

The certified organization is warned to communicate any process or scope changes regardless of the organization's request.

In case of a request for a scope change in ISO 22000:2018 certification, it is checked whether it requires legal, prerequisite and operational prerequisite conditions. It is checked whether the scope of change is within the previously determined risk assessment and HACCP studies. If not, risk assessment and HACCP studies are requested. This assessment assesses whether it requires a Stage 1 audit. Considering the Instruction for Determining the Audit Period, the number of audit man-days is calculated for which items the change covers.

Scope change can be made during surveillance audits. May require additional time and expertise when done in conjunction with surveillance audits. Scope expansion requests received during the audit are not taken into account..

The audit performed does not affect the interim audit date..

4.12.2. Audit of suspended certificate for withdrawal

Organizations whose certificate has been suspended must notify Unicert in writing that the grounds for suspension have been eliminated.

The scope and duration of the audit carried out within the scope of the suspension is determined by the management representative depending on the reason for the suspension of the certificate.

At the end of the audit, the suspension of the certificate of the organization whose conformity has been verified is removed. If the reasons for suspension are not eliminated, the document is withdrawn.

The suspension of the certificate is notified to the organization in writing or by e-mail.

4.12.3. Short Term Audit

Stage 1, stage 2 is the audit performed outside of surveillance, document renewal and follow-up audit. It is the type of audit that may be needed in case of unfair / fraud use of the document or logo by the customer, in case of practices contrary to Unicert Certification and/or in case of complaints about the customer, and should be carried out in a short time without wasting time.

Unicert reserves the right to briefly review the above-mentioned uses. It is also recorded with the contract made with the customer. The Certification Manager decides to conduct a short-term audit.

The scope and criteria of the audit are determined after being reviewed by the appointed lead auditor. This can be a full, partial or just a process/section depending on the circumstances.

The audit team is determined by the planning. Unicert Personnel Selection and Evaluation Procedure is applied in short-term audits, as in other audits. Since the audit must take place in a short time, the

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audit committee should be formed in such a way that the firm does not object to the committee. At least one of the audit team (especially in the audit of departments such as design, process, quality control) must be appointed according to the appropriate IAF, EA and NACE code.

If there is no suitable lead auditor / auditor / technical expert, the audit is not carried out until the auditor / technical expert is found.

The audit date determined, including the processes and sections to be audited, is notified to the company at the latest 2 days in advance of the Audit Plan.

If a completely specific subject / process is to be audited in a short-term audit, it is ensured that it is audited by the lead auditor by an auditor / expert with sufficient qualifications for that job. This procedure is also applied in Unicert's regular audits.

Auditor X number of days is determined according to the number of employees in the departments to be audited, within the framework of Unicert procedure and IAF rules.

Unicert's normal procedures and reporting formats are applied in performing and reporting the audit.

The prepared report is submitted to the Certification Manager for decision.

The Certification Manager decides within the framework of the Certification Procedure and other relevant international guidelines / standards.

The audit performed does not affect the interim audit date.

4.13. Address change

It is the audit performed when there is a change in the facility address of the document owned by the customer. The customer has to submit the documentation changes required by the address change to Unicert. In case the address change affects the field of activity, a full audit is carried out and a new document is issued by canceling the old document when necessary.

If the change of address affects the number of man x days, the contract is made again.

On-site inspection is mandatory. If the company moved only the head office in the address change, the audit is carried out only at the head office. If the place where the address change is made is any site, then the head office and the site must be audited. The audit of the central office can be done in the form of document review with the decision of the Certification Manager, and the site audit of the site where the address change is made. The head office should be audited in any case.

For the production sector included in the Food Safety Management System, if the change of address affects the HACCP plans, risk analyzes, prerequisite programs; The certification manager decides whether a stage 1 audit is required with the opinion of the lead auditor who performed the previous audit. If a Stage 1 audit is required, it is performed, if not, the process is concluded with a Stage 2 audit only.

Address change in Food Safety management system documents necessarily requires re-audit. The only exception to this is if the last address that was changed in previous audits was audited.

The audit does not affect the interim audit date.

4.14. Name change

The organization is requested to apply with a petition and documents showing the change in its annex (such as a trade newspaper, etc.). With the certification decision, other documents such as new documents and contracts are prepared in the name of the new title. The old document is taken and the new one is given. In case of a title change, an audit can be carried out when necessary, according to

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the decision of the Certification Manager. In particular, when changes occur in the organization and process structure, the audit can be carried out according to the decision of the Certification manager.

The audit does not affect the interim audit date.

4.15. Recertification audit

It is an audit performed three years after the first certification date.

At least 2/3 of the certification audit should be timed. The company application is taken again, the contract is made. The Certification Manager evaluates whether there are significant changes in the company system or within the context of the text in which the management system is operated (eg legislation, scope, address, legal conditions, number of employees, and/or HACCP Plans, etc.).

Recertification audits are not separated into Stage 1 and Stage 2. It is carried out in one step. If the firm decides that there are significant changes compared to the previous audit, according to the information obtained before the re-certification audit, it may decide to conduct this audit as stage 1 and stage 2.

The purpose of the recertification audit is to,

Confirmation of the continuing suitability and effectiveness of the management system as a whole and its compatibility and applicability for the scope of certification. The recertification audit is planned and performed to assess that all the requirements of the relevant management system standard and other mandatory document are consistently met.

Whether there are any changes, including the ones stated above, from the customer to be recertified is determined by the Management Representative with the Certification Proposal Agreement Form.

Based on the information received from the customer about the changes, the Certification Manager notifies the reason why the re-certification audit should be carried out in 2 stages with the Offer-Contract Form. If the audit will be in 2 stages, the reason for this is recorded in the Application Review and Evaluation Form during the application review. In addition, the reason for the 2-stage is also stated in the Audit Program.

The following issues are addressed in document renewal field audits:

- The effectiveness of the management system in its entirety, in the light of internal and external changes,
- The continued relevance and applicability of the management system effectiveness to the scope of certification,
- Demonstrated commitment to maintaining the effectiveness and improvement of the management system to increase overall performance,
- Whether the operation of the management system contributes to the achievement of the organization's policy and objectives.

If non-conformities is detected during certificate renewal audits, the organization is recommended to complete its corrective actions before the current certificate expires and a planning is made accordingly. If the organization does not close its non-conformities before the current certificate expires, the audit is renewed to meet the initial certification audit.

The certificate renewal decision is taken according to the results of the certificate renewal audit, the results of the system review during the certification period, and the complaints from the users, if any, before the validity period of the current certificate expires. Unicert receives and evaluates all the information required for the audit in the recertification audit with the System Certification Application Form.

Unicert warns the customer that the date of the corrective action(s) to be determined by the customer in case of nonconformities arising in the recertification audits should not exceed the certificate period, otherwise the audit should be renewed to cover the initial certification. This warning is for the certification period not to expire. This warning is stated in the closing meeting items at the closing meeting.

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At the end of the certification period, Unicert may withdraw the certification for 6 months, provided that significant recertification activities are completed, otherwise it will perform at least a Stage 2 audit. The valid date on the document may be the recertification date or later and the validity period is based on the previous certification cycle. **(ISO 17021-1 madde 9.6.3.2.5)**

When the Unicert audit team determines during the audit that it has consistently or seriously failed to maintain some of the scope specified by the client, it gives an opinion to the Certification decision makers to narrow the scope.

4.16. Suspension and Cancellation of Document

Document Suspension Conditions;

No	Status	Conclusion
1	Major or minor non-conformities identified in the audit are not closed within 3 months (with or without follow-up audit)*	At the end of 3 months, the document is suspended. The suspension period is 6 months. If non-conformities are closed within the 6-month suspension period, a follow-up audit is performed. If the result is appropriate, the document is continued. If it is not suitable or if a follow-up inspection cannot be made within the 6-month suspension period, the certificate will be cancelled. Additional time may be given to the above-mentioned periods with the decision of the Certification Manager (it can be extended for a maximum of 1 month).
2	Non- conformities with the terms of the contract (non-compliance with terms such as logo use, payments, etc.) a) Corrective action is requested from the company within the framework of the procedure for evaluating complaints and objections. b) Suspending the direct document and requesting corrective action from the company.	a) The duration of the corrective action is maximum 3 months. If this period is exceeded or corrective action is not taken, the certificate is suspended. The suspension period is 6 months. If the result is still negative, it is decided to cancel the certificate (all decisions are made by the Certification Manager.) b) The duration of the corrective action is maximum 3 months. If this period is exceeded or corrective action is not taken, it is decided to cancel the certificate (all decisions are made by the Certification Manager).
3	The company's request for cancellation or suspension due to any reason (strike, natural disasters, production / service stoppage, etc.). Workload, tenders, changes in location, personnel, address, scope changes cannot be accepted as reasons for the postponement of the audit.	With the decision of the Certification Manager, the suspension period is maximum 6 months, if the audit is not carried out, it is canceled, if the audit is done, the normal certification procedure is applied.
4	Postponement of the planned audit for more than 2 months..	The document is suspended. The suspension period is a maximum of 6 months. If there is no audit at the end of 6 months, the certificate is canceled.
5	The firm loses its legal compliance or fails to demonstrate it.	It is decided to suspend the certificate immediately and cancel it after the 6-month suspension period, based on the continuation of the situation.
6	Failure to comply with legal sanctions other than the relevant standard regarding the product/service within the scope of certification,	It is decided to suspend the document and to cancel it if it is not corrected at the end of the suspension period.
7	The company's 1st Surveillance Audit must have been carried out within 1 year, not exceeding the Stage 2 audit date of the certification audit.	If the company requests to postpone the audit without giving a justified reason, the certificate is suspended. If the audit does not take place at the end of the suspension period, it is decided to cancel the certificate.
8	The audit is planned by sampling according to the number of temporary sites owned by companies operating in business areas with temporary sites. If the company does not have a site at the	If the firm declares that it cannot get a job until the first surveillance and cannot show the site, the certificate is suspended during the first interim audit.

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	time of the audit, the audit is not carried out.	
9	Failure of companies to comply with the rules in the certification agreement	The certificate is suspended.

* Nonconformity closure period in initial certification audits is 3 months.

The customer stops the use of the document and logo as of the notification of the decision to suspend the document. The customer returns the documents and attachments to Unicert within 15 (fifteen) days at the latest. If the customer does not return it, the customer is first warned in writing, and if the warning is not taken into account, legal action is initiated. If the customer declares that she has lost her certificate, attachment or contract, she is requested to notify the Certification Department of the published loss notice with a petition. During the suspension period, the customer cannot benefit from the rights of the document. During this period, all rights of Unicert are reserved.

Unicert has the right to publish the decisions regarding the suspension of the document with reasons on its website, in its publications and in daily newspapers. When it is proven that the reason for suspension of the certificate has been resolved as a result of the audit, the certificate is suspended.

The suspension period of the document is 3 months at the most. However, this period can be extended by a maximum of 3 months for special cases (seasonal products, natural disasters, economic crisis, etc.) with the decision of the Certification Manager.

In the cancellation of the document, the old document is requested again. The prohibition of using the logo while the document is suspended is notified in writing to the customers.

Cancellation Conditions of the Document;

In the event that any of the following situations are detected regarding the companies that have received a certificate from Unicert, the current or suspended certificate is canceled by the decision of the Certification Committee. The company whose certificate has been revoked is immediately notified of the situation regarding this issue, and the use of the certificate is prevented. The Management Representative is responsible for following these situations..

- The customer does not allow an audit to be carried out until the end of the suspension period, or there is a major nonconformity in the audit conducted at the end of the suspension period.
- Using the Customer Management System Document in areas different from the product or service specified in its scope.
- Customer's bankruptcy or termination of activity under the certificate
- The customer's incomplete and misleading information during the audit
- Misleading and unfair use of the document
- Non-payment of Unicert certification fee
- In the audits carried out within the validity period of the certificate, it is determined that the customer's system has lost its compliance with the relevant standard.
- The customer is not present at the facility address specified in the document.
- If the customer violates the provisions of this instruction
- The customer's destruction of documents and attachments
- As a result of the customer's request
- Change of customer's legal personality
- Non-payment of wages,

Belgenin iptal edilmesinde eski belge tekrar istenilir. Belge askıdayken logo kullanımının yasaklanması ise müşterilere yazılı bir şekilde bildirilir.

After the decision is made to cancel the certificate, the Certification manager notifies the company in writing in an explanatory manner, together with the reason, that the certificate has been cancelled. This notification is made by e-mail, fax, courier.

4.17. Follow-up Audit

It is the audit that is carried out if the customer is not entitled to receive a certificate as a result of the Certification Audit or the certificate of the certified customer is suspended due to the reasons specified in the Suspension article, and the detected nonconformities require a follow-up audit.

Two types of follow-up audits may be required:

1. Performing only document control without the need for on-site re-audit.
2. On-site audit. It is an audit for on-site verification of nonconformities. Only relevant nonconformity items are considered. However, if necessary, the lead auditor may also audit other standard items that may be affected by nonconformity. A follow-up audit should be carried out within a maximum of three months. In the case of Follow-up Audit after the Certification Audit, if the determined corrective action period exceeds 3 months, the follow-up audit is planned and performed as a full audit. In addition, if the customer does not give confirmation for a follow-up audit within 6 months following the decision date, his application will be cancelled. In the case of a follow-up audit after the Surveillance Audit, if the customer has not applied for a follow-up audit within 6 months after the certificate is suspended, the document contract is canceled and the certificate is withdrawn.

4.18. Changes to the Certification Rules

If there is a change in the certification rules, if this change affects the contract terms, this change is communicated to the customer in writing by the Certification manager, and a new contract is made with the customer, one week before deciding on the final form and effective date of the change. If there is a change in the certification rules, if this change affects the contract terms, this change is communicated to the customer in writing by the Certification manager, and a new contract is made with the customer, one week before deciding on the final form and effective date of the change.

4.19. Certification Printing

In case the certification or re-certification decision is taken for the customer by the Certification Manager, the document is prepared in accordance with the information in the Certification Decision Form as much as the number of copies agreed by the Certification Manager. The information that should be on the document is explained in the Document Printing Instructions.

Relevant logos are sent to the certified companies and made available to the customer. Customers must comply with the Logo Usage Instructions when using the Logos.

1 copy of the created document is duplicated with a photocopy and archived in the file opened for the organization.

The certificate validity date is determined as 3 years from the date of the certification decision.

If group certification is done, one of the alternatives is applied as explained in the Document Printing Instruction for the printing of documents.

The printed documents are checked by the Certification Manager and/or the Management representative in terms of format, date and other information. If there is no problem, the document is signed by the general manager.

Any party can check it at <https://unicert.us/> when they want to query documents.

The document has been given to the scope of the management system certification application and cannot be used outside of this scope. Customers who continue to use certificates by failing to comply with these criteria, even though they are determined to the contrary and warned in writing by Unicert, are processed in accordance with the Cancellation of Certificate article.

The document is the property of the customer named in the document and cannot be transferred to another institution or legal entity in any way. The responsibility arising from the unfair use of documents by third parties belongs to the customer.

4.20.Independence and Impartiality of Certification

Depending on the Documentation Procedure, the reports are evaluated under the principles of independence and impartiality and the decision (positive or negative) is given.

Certification decision is not taken before major nonconformity is closed, and certification decision is not taken without corrective action plan in minor nonconformity.

If there is a disagreement on any issue or the company does not accept the non-conformities, the certification manager deals with the issue first. The certification manager discusses the issue with both the audit team leader and the client, and a decision is made by the committee according to the Complaints and Appeals Evaluation Procedure.

Certification Decision Form is prepared for the certification decision.

4.21. Adequacy of Certification

Unicert will only use auditors or experts whose competence has been accepted by the relevant accreditation body in the subjects for which it is accredited. Although this condition is not required in non-accredited matters, auditors or experts who do not deviate from the approach given in Unicert procedures and instructions in accordance with the general approach and comply with IAF rules can be used.

The international validity of the certifications is important for Unicert and it works with the appropriate accreditation bodies in this regard.

If it cannot find sufficient and competent auditors or experts in the subject and sector related to Management Systems, it does not make certification.

4.22. Continuity of Certification

Unicert takes all measures to ensure the continuity of its certification. If there is a concern about continuity after the certification audit, the management representative or the lead auditor may require that the interim audit date be brought forward.

Professional liability insurance has been taken out for risks that may arise from certification activities.

While third parties are protected by insurance regarding the risks arising from Unicert's activities, Unicert uses its own budget in case of risks of second parties (for example, repetition of audit etc.).

Unicert attaches importance to customer continuity and permanence, and monitors this issue at policy and target level as a responsibility of the Certification manager.

While the right to use the certificate belongs to the relevant organization, the ownership right of the certificate remains with Unicert. Certificates are valid for a period of 3 years if surveillance audits are carried out from the moment of registration.

If the organization does not want the certificate to be renewed, this request must be notified in writing to Unicert at least 4 months before the expiry date of the certificate.

4.23. Responsibilities of a Certified Organization

1. It should always be ensured that the certificate rules are followed.
2. It is the responsibility of the organization to implement the system in a way that ensures continuity and continuous improvement. The validity of the certificate depends on the implementation of this application, this will be confirmed by surveillance audits by Unicert.
3. The use of the logo should be made in accordance with the terms and conditions specified in the "Logo Usage Instructions" (for example, upon registration after successful audit, the certified organization is entitled to use the relevant Unicert logo. The logo should only be used by certified organizations and always with the name and address(es) stated on the certificate. When the logo is desired to be used in correspondence, advertisement and promotion areas, it should be used in a way that includes the absolute certificate number and the appropriate management standard. The logo can only be used by specifying the organization that registered the certificate and related to the area where the registration is made. When the continuity of the certificate is stopped for any reason, the use of the logo should be stopped immediately.).

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1. Where necessary, copies of all or any part of the documents included in the system in accordance with ISO 9001:2015, ISO 22000:2018, ISO 14001, ISO 45001, ISO 27001 and ISO 13485, and in the Unicert work of the Certification Manager; It should be allowed to be available so that it can be used as a reference.
2. The arrangements made in the system by the applicant / certified organization must be notified to Unicert. If the edit made is important (for example, removing a procedure completely from the system), notification will be made immediately in writing. Minor changes should be reported to Unicert at the next audit or review visit.
3. Organization In the audits made by Unicert; Cooperate in order to obtain sufficient objective evidence to demonstrate the compliance of the auditing standard. The absence of this situation is considered a reason for suspension or cancellation of certification.
4. The person representing the management on the certificate and more than one proxy should be appointed. In the absence of the representative (or when it needs to be changed), the proxies will be responsible for all relations required by the certificate and in case of any change in other information regarding the conditions of the certificate, which is the customer notified to Unicert. They will make a signed statement at each visit, if requested by the Unicert representative, including their complaints. Unicert recommends recording customer complaints and corrective/preventive actions taken for the resolution of each complaint in the system in all certified organizations.
5. When the certificate expires (regardless of the reason), the use of the logo, including the advertising materials and references on which the logo is present, should be stopped immediately.
6. Unicert should be informed as soon as possible of any adverse situation related to the document, especially for events with high potential such as crimes and lawsuits.
7. Unicert has the right to claim its costs during the provision of the service.
8. Fees to be Paid by the Organization:
Additional charges: Travel, accommodation, re-certification or approval, etc.
Audit fee: Payable in all circumstances (even if maintenance of the certificate is not desired).

4.24. Appeals and Evaluation

A customer requesting certification or having already been certified may appeal against any decision taken by Unicert. The customer can make this appeal within 15 days following the receipt of the said decision notification.

Details regarding the evaluation of the complaint are specified in the Procedure for Evaluation of Complaints and Appeals.

4.25. Unicert's Responsibilities

1. Unicert assumes responsibility for all decisions taken regarding the preparation of the contract, the formation of the audit committee, the outsourcing of audits, the performance of the audits, the issuance of the certificate, the maintenance of the certificate, the extension of the scope, the narrowing of the scope, the change of address, the audits made in special cases, the suspension of the certificate and the cancellation of the certificate.
2. It ensures that the suppliers are registered in the Unicert audit visits program, informed about the visit and its time (these visits are made at least once a year or twice when deemed necessary), and a representative is sent to ensure that the necessity of certificate registration in the organization is adequately understood and is being worked on.
3. It ensures that the body to be certified is informed about the applicable guidance and all changes in the standards, and that reasonable time is provided to allow the relevant processes and procedures to be changed as desired in line with the opinions of the certification management.
4. It ensures that all information about suppliers is kept confidential, except for those that are publicly available.
5. Informs all customer complaints about the products within the scope of the supplier's document.
6. If the certified organization cannot temporarily ensure the continuity of these desired rules, Unicert may immediately request the suspension of the use of the "Unicert" logo and other rights until it is satisfied that the relevant continuity has been reinstated or until the still unsolved appeal is concluded.
7. If the certified organization fails to ensure the continuity of these rules, the Certification Manager may decide to withdraw the certificate, to narrow its scope, not to issue a certificate or not to renew it, when deemed necessary according to the specified conditions. These decisions and the reasons for taking decisions are notified in writing by the Certification Manager.

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8. The Certification Manager is obliged to withdraw the certificate, not to issue or renew the certificate in cases where the organization becomes subject to bankruptcy laws, any arrangement or agreement with its creditors, liquidation by force or his own will, the buyer of the business exits and his capacity to be a bona fide entrepreneur is lost. Such decisions and their reasons will be communicated to the organization in writing..

9. In the event that the organization or the applicant objects to any decision made by the board of directors depending on the certification rules, this request must be made in writing within 15 days from the date of official notification to the organization of the decision giving rise to the appeal. The complaints and appeal committee will inform the appellant at least 7 days in advance of the date and place of the meeting to be held within 30 days. The appellant will be informed of how and from whom the committee will be formed and how they can object. In such appeals, Unicert General Manager may make changes in the composition of the committee, if deemed necessary. The Certification Manager, who makes an appeal in the committee formed with the participation of the appellant, has the right not to express an opinion in front of everyone if they wish. The meeting ends after the chairman of the committee announces the final and irreversible decision taken with the participation of the majority.

10. It will be notified to the organization in writing by the management representative, In cases where changes are made that may affect the use of the logo and other services, the rule changes do not affect your right to use the logo and other provided services, except for the cases that must be completed not less than 6 months from the date of notification of the change, in order for the organization to make the relevant significant change.

11. Unicert services are available to all potential customers. Our services are ready for use without any discrimination, without unnecessary financial burdens and conditions. A list of organizations registered with us is publicly available at our head office.

12. If it is necessary to contact Unicert when required by these rules, it is necessary to contact Unicert in writing and signed by the organization by regular mail, prepaid registered or returned registered mail (due to the possibility of a change in the given address(es)) to the previously notified address(es) It is necessary to do. Any information received by us through the mail (unless proven otherwise) is deemed to have been posted 48 hours ago. In order to receive correspondence more effectively, it should be ensured that the address information is provided completely and correctly in accordance with these rules.

5. Related documents

- Personnel Selection and Evaluation Procedure
- Procedure for Evaluation of Complaints and Appeals
- Audit Procedure
- Fee determination and payment instruction
- Instruction for determining the audit period
- Multi-Site audit instruction
- Document Printing Instruction
- Certification Proposal Agreement
- Audit team assignment form
- ISO 9001:2015 Stage 1 and Stage 2 Audit Report and Question List
- ISO 22000:2018Phase 1 and Stage 2 Audit Report and Question List
- Audit Program
- Document Confirmation Form
- ISO 14001:2015 Stage 1 and Stage 2 Audit Report and Question List
- ISO 27001:2018Phase 1 and Stage 2 Audit Report and Question List
- ISO 45001:2015 Stage 1 and Stage 2 Audit Report and Question List
- ISO 13485:2018Phase 1 and Stage 2 Audit Report and Question List

