



# Exam Preparation Guide

ISO 22000 Lead Auditor

## GENERAL

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The objective of the “PECB Certified ISO 22000 Lead Auditor” exam is to ensure that the candidate has the necessary competence to: perform a food safety management system (FSMS) audit in compliance with ISO 22000 requirements; manage an audit team by applying widely recognized audit principles, procedures, and techniques; and, lastly, plan and carry out internal and external audits as per the guidelines of ISO 19011 and in compliance with the ISO/IEC 17021-1 certification processes.

### **The ISO 22000 Lead Auditor exam is intended for:**

- Auditors seeking to perform and lead food safety management system (FSMS) audits
- Managers or consultants seeking to master the FSMS audit process
- Individuals responsible to maintain conformity with the FSMS requirements in an organization
- Technical experts seeking to prepare for an FSMS audit
- Expert advisors in food safety management

### **The exam covers the following competency domains:**

- **Domain 1:** Fundamental principles and concepts of a food safety management system
- **Domain 2:** Food safety management system (FSMS) requirements
- **Domain 3:** Fundamental audit concepts and principles
- **Domain 4:** Preparing an ISO 22000 audit
- **Domain 5:** Conducting an ISO 22000 audit
- **Domain 6:** Closing an ISO 22000 audit
- **Domain 7:** Managing an ISO 22000 audit program

The content of the exam is divided as follows:

## Domain 1: Fundamental principles and concepts of a food safety management system

**Main objective:** Ensure that the candidate understands and is able to interpret ISO 22000 principles and concepts

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to distinguish between the various standards that are part of the ISO 22000 family of standards</li> <li>2. Ability to define the scope of ISO 22000</li> <li>3. Ability to list other food safety-related standards</li> <li>4. Ability to explain the advantages of a food safety management system</li> <li>5. Ability to explain the certification process for an implemented management system</li> <li>6. Ability to distinguish between accreditation bodies and certification bodies</li> <li>7. Ability to define what food safety is</li> <li>8. Ability to define other core terms related to the food safety management system</li> <li>9. Ability to identify the principles of food safety management system</li> <li>10. Ability to explain the process approach and its role in ISO 22000</li> <li>11. Ability to understand the risk-based thinking and its relationship to ISO 22000</li> <li>12. Ability to distinguish between a prerequisite programme (PRP), critical control point (CCP), and operational prerequisite programme (OPRP)</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the standards that are part of ISO 22000 family of standards</li> <li>2. Knowledge of the scope and applicability of ISO 22000</li> <li>3. Knowledge of the other food safety-related standards</li> <li>4. Knowledge of the advantages that organizations can obtain through the implementation of a food safety management system</li> <li>5. Knowledge of the certification process steps</li> <li>6. Knowledge of the differences of an accreditation body from a certification body</li> <li>7. Knowledge of the definition of food safety, as set out by the Codex Alimentarius Commission</li> <li>8. Knowledge of the core terms related to the food safety management system</li> <li>9. Knowledge of the principles of a food safety management system, as combined by ISO 22000</li> <li>10. Knowledge of the importance of process approach and its adoption in an FSMS</li> <li>11. Knowledge of the concept of risk-based thinking and its application in ISO 22000</li> <li>12. Knowledge of the definitions and differences between a PRP, CCP, and OPRP</li> </ol>

## Domain 2: Food safety management system (FSMS) requirements

**Main objective:** Ensure that the candidate understands, is able to interpret, and identify the requirements for a food safety management system based on ISO 22000

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to understand what comprises a management system</li> <li>2. Ability to identify the common elements of ISO management systems that can be integrated</li> <li>3. Ability to understand the ISO 22000 requirements and the structure of the standard</li> <li>4. Ability to describe the standard's requirements with regard to the context of the organization, interested parties, and FSMS scope (clause 4)</li> <li>5. Ability to identify the standard's requirements with regard to the leadership and commitment of the top management and their role and responsibilities in the FSMS (clause 5)</li> <li>6. Ability to understand the requirements with regard to the risks and opportunities, objectives of the FSMS, and planning of changes (clause 6)</li> <li>7. Ability to ensure that sufficient resources are available for the implementation, operation, maintenance, and continual improvement of the FSMS (clause 7)</li> <li>8. Ability to understand the requirements for prerequisite programmes, traceability system, emergency preparedness and response, hazard control, and control of product and process nonconformities (clause 8)</li> <li>9. Ability to identify the requirements and approaches for performance evaluation (clause 9)</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the elements that comprise a management system</li> <li>2. Knowledge of the integrated management systems</li> <li>3. Knowledge of the requirements and structure of ISO 22000</li> <li>4. Knowledge of the common external and internal issues that affect the context of an organization, interested parties, and requirements for the scope of the FSMS</li> <li>5. Knowledge of the requirements for leadership and commitment</li> <li>6. Knowledge of the requirements with regard to identification of risks and opportunities, setting of objectives, and planning of changes</li> <li>7. Knowledge of the required resources, competences, awareness, communication, and documented information for an effective FSMS</li> <li>8. Knowledge of the requirements for operational planning and control</li> <li>9. Knowledge of the approaches, techniques, and programs used for the monitoring, measurement, analysis, evaluation, internal audits, and management reviews</li> <li>10. Knowledge of the requirements for nonconformity and corrective actions, continual improvement, and update of the FSMS</li> </ol>

<p>10. Ability to understand the requirements for continual improvement of the FSMS (clause 10)</p>	
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## Domain 3: Fundamental audit concepts and principles

**Main objective:** Ensure that the candidate understands, is able to interpret, and apply the main concepts and principles related to an FSMS audit

<b>Competencies</b>	<b>Knowledge statements</b>
<ol style="list-style-type: none"> <li>1. Ability to understand, explain, and illustrate the application of the audit principles in an FSMS audit</li> <li>2. “Ability to differentiate first, second, and third party audits”.</li> <li>3. Ability to identify and judge situations that would discredit the professionalism of the auditor and violate the PECB Code of Ethics</li> <li>4. Ability to identify and judge ethical issues considering the obligations related to the audit client, auditee, law enforcement, and regulatory authorities</li> <li>5. Ability to determine and evaluate the level of materiality and apply the risk-based approach during the different stages of an FSMS audit</li> <li>6. Ability to judge the appropriate level of reasonable assurance needed for an FSMS audit</li> <li>7. Ability to understand the legal implications related to any irregularities committed by the auditee.</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the main audit concepts and principles as described in ISO 19011</li> <li>2. Knowledge of the differences between first, second, and third party audits</li> <li>3. Knowledge of the principles of auditing: integrity, fair presentation, due professional care, confidentiality, independence, evidence-based approach, and risk-based approach</li> <li>4. Knowledge of an auditor’s professional responsibility and the PECB Code of Ethics</li> <li>5. Knowledge of the risk-based approach to an audit and the different types of risks related to audit activities such as inherent risk, control risk, and detection risk</li> <li>6. Knowledge of the concept of materiality and its application to an audit</li> <li>7. Knowledge of the concept of reasonable assurance and its application to an audit</li> <li>8. Knowledge of the laws and regulations applicable to the auditee and the country it operates in, etc.</li> </ol>

## Domain 4: Preparing an ISO 22000 audit

**Main objective:** Ensure that the candidate is able to prepare a food safety management system audit

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to understand and illustrate the steps and activities to prepare an FSMS audit considering the specific context of the audit</li> <li>2. Ability to explain and compare evidence types and their characteristics</li> <li>3. Ability to determine and justify the type and amount of evidence required in an FSMS audit</li> <li>4. Ability to understand and explain the roles and responsibilities of the audit team leader, audit team members, and technical experts</li> <li>5. Ability to determine and evaluate the level of materiality during the different stages of an FSMS audit</li> <li>6. Ability to determine the audit feasibility</li> <li>7. Ability to determine, evaluate, and confirm the audit objectives, the audit criteria, and the audit scope for an FSMS audit</li> <li>8. Ability to explain, illustrate, and define the characteristics of the terms of the audit engagement and apply the best practices to establish the initial contact with an auditee</li> <li>9. Ability to develop audit working papers and elaborate appropriate audit test plans in an FSMS audit</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the main responsibilities of the audit team leader and audit team members</li> <li>2. Knowledge of the roles and responsibilities of technical experts</li> <li>3. Knowledge of the audit objectives, audit scope, and audit criteria</li> <li>4. Knowledge of the difference between an FSMS scope and the audit scope</li> <li>5. Knowledge of the factors to take into account during the audit feasibility</li> <li>6. Knowledge of the cultural aspects to consider in an audit</li> <li>7. Knowledge of the characteristics of terms of the audit engagement and the best practices to establish the initial contact with an auditee</li> <li>8. Knowledge of the audit plan preparation procedure</li> <li>9. Knowledge of the preparation and development of audit working papers</li> <li>10. Knowledge of the different types of audit evidence: physical, mathematical, confirmative, technical, analytical, documentary, and verbal</li> <li>11. Knowledge of the best practices for the creation of audit test plans</li> </ol>

## Domain 5: Conducting an ISO 22000 audit

**Main objective:** Ensure that the candidate can efficiently conduct an FSMS audit

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to conduct the stage 1 audit, taking into account the documented information evaluation criteria</li> <li>2. Ability to organize and conduct an opening meeting</li> <li>3. Ability to conduct the stage 2 audit by appropriately following the procedures that this stage entails</li> <li>4. Ability to apply the best practices of communication to collect the appropriate audit evidence</li> <li>5. Ability to consider the roles and responsibilities of all the interested parties involved</li> <li>6. Ability to explain, illustrate, and apply evidence collection procedures and tools</li> <li>7. Ability to explain, illustrate, and apply the main audit sampling methods</li> <li>8. Ability to gather appropriate evidence from the available information during an audit and evaluate it objectively</li> <li>9. Ability to explain, illustrate, and apply the audit evidence approach in an FSMS audit</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the objectives and the content of the opening meeting in an audit</li> <li>2. Knowledge of the difference between stage 1 audit and stage 2 audit</li> <li>3. Knowledge of stage 1 audit requirements, steps, and activities</li> <li>4. Knowledge of the documented information evaluation criteria and ISO 22000 requirements</li> <li>5. Knowledge of stage 2 audit requirements, steps, and activities</li> <li>6. Knowledge of the best communication practices during an audit</li> <li>7. Knowledge of the roles and responsibilities of guides and observers during an audit</li> <li>8. Knowledge of the different conflict resolution techniques</li> <li>9. Knowledge of the evidence collection procedures and tools such as interview, documented information review, observation, analysis, sampling and technical verification</li> <li>10. Knowledge of the evidence analysis techniques: corroboration and evaluation</li> <li>11. Knowledge of the main concepts, principles, and evidence collection procedures used in an audit</li> <li>12. Knowledge of the advantages and disadvantages of using audit checklists</li> </ol>

## Domain 6: Closing an ISO 22000 audit

**Main objective:** Ensure that the candidate is able to conclude an FSMS audit and conduct audit follow-up activities

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to explain and apply the evidence evaluation process: drafting audit findings and preparing audit conclusions</li> <li>2. Ability to understand, explain, and illustrate the concept of the benefit of the doubt</li> <li>3. Ability to report appropriate audit observations in accordance with audit rules and principles</li> <li>4. Ability to conduct quality reviews to audit documentation</li> <li>5. Ability to draft and present audit conclusions</li> <li>6. Ability to complete audit working documents</li> <li>7. Ability to organize and conduct a closing meeting</li> <li>8. Ability to write an ISO 22000 audit report and justify the recommendation for certification</li> <li>9. Ability to conduct the activities following an initial audit, including the evaluation of action plans, audit follow-ups, and surveillance activities</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the evidence evaluation process: to draft audit findings and to prepare audit conclusions</li> <li>2. Knowledge of the characteristics and differences between the concepts of conformity, minor nonconformity, major nonconformity, anomaly, and observation</li> <li>3. Knowledge of the guidelines and best practices to draft nonconformity reports</li> <li>4. Knowledge of the guidelines and best practices to draft and report audit observations</li> <li>5. Knowledge of the benefit of the doubt principle and its application in the management system audits</li> <li>6. Knowledge of the guidelines and best practices to complete audit working documents and perform a quality review</li> <li>7. Knowledge of the guidelines and best practices to present audit findings and conclusions to the management of an audited organization</li> <li>8. Knowledge of the possible recommendations that an auditor can issue during the certification audit</li> <li>9. Knowledge of the guidelines and best practices to evaluate action plans</li> <li>10. Knowledge of audit follow-ups, surveillance audits, and recertification audit requirements, steps, and activities</li> <li>11. Knowledge of the conditions for the modification, extension, suspension, or withdrawal of an organization's certification</li> </ol>

## Domain 7: Managing an ISO 22000 audit program

**Main objective:** Ensure that the candidate understands how to establish and manage an FSMS audit program

Competencies	Knowledge statements
<ol style="list-style-type: none"> <li>1. Ability to understand and explain the establishment of an audit program and the application of the PDCA cycle into an audit program</li> <li>2. Ability to understand and explain the importance of protecting the integrity, availability, and confidentiality of audit records and the auditors' responsibilities in this regard</li> <li>3. Ability to understand the documented information management process</li> <li>4. Ability to understand the process of evaluating the efficiency of the audit program by monitoring the performance of each auditor and audit team member</li> <li>5. Ability to demonstrate the application of the personal attributes and behaviors associated with professional auditors</li> </ol>	<ol style="list-style-type: none"> <li>1. Knowledge of the application of the PDCA cycle in the management of an audit program</li> <li>2. Knowledge of the requirements, guidelines, and best practices regarding audit resources, procedures, and policies</li> <li>3. Knowledge of the requirements, guidelines, and best practices regarding the management of audit records</li> <li>4. Knowledge of the management of combined audits</li> <li>5. Knowledge of the personal attributes and behaviors of a professional auditor</li> </ol>

Based on the above-mentioned domains and their relevance, 12 questions are included in the exam, as summarized in the table below:

		Level of understanding (Cognitive/Taxonomy) required						
		Points per question	Questions that measure comprehension, application, and analysis	Questions that measure synthesis and evaluation	Number of questions per competency domain	% of the exam devoted to each competency domain	Number of points per competency domain	% of points per competency domain
Competency domains	Fundamental principles and concepts of a food safety management system	5	X		1	8.33	5	6.67
	Food safety management system (FSMS) requirements	5		X	2	16.67	10	13.34
		5	X					
	Fundamental audit concepts and principles	5	X		2	16.67	10	13.34
		5	X					
	Preparing for an ISO 22000 audit	5	X		1	8.33	5	6.67
	Conducting an ISO 22000 audit	10	X		3	25	25	33.35
		5		X				
		10		X				
	Closing an ISO 22000 audit	5		X	1	8.33	5	6.67
	Managing an ISO 22000 audit program	5		X	2	16.67	15	20
		10		X				
Total points		75						
Number of questions per level of understanding			6	6				
% of the exam devoted to each level of understanding (cognitive/taxonomy)			50.00	50.00				

The exam passing score is **70%**.

After successfully passing the exam, candidates will be able to apply for the “PECB Certified ISO 22000 Lead Auditor” credential depending on their level of experience.

## TAKING THE EXAM

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### General Information on the Exam

Candidates are required to arrive/be present at least 30 minutes before the exam starts. Candidates who arrive late will not be given additional time to compensate for the late arrival and may even be denied to enter the exam.

Candidates are required to bring a valid identity card, such as a national ID card, driver's license, or passport and show it to the invigilator.

The duration of the exam is three hours. Non-native speakers will receive an additional 30 minutes.

### PECB Exam Format and Type

PECB exams are available in two formats:

1. **Paper-based format:** Exams are provided on paper to candidates. The use of electronic devices, such as laptops, tablets, smartphones, etc., is not allowed. The exam session is supervised by a PECB Approved Invigilator.
2. **Online format:** Exams are provided electronically via the PECB Exams application to candidates. The use of electronic devices, such as tablets and cell phones, is not allowed. The exam session is supervised remotely by a PECB Invigilator via the PECB Exams application and external/integrated camera.

For more detailed information, please refer to the PECB Online Exam Guide

<https://pecb.com/help/wp-content/uploads/2018/06/Preparing-for-your-PECB-Online-Exam-Guide.pdf>

**The exam comprises essay type questions.** This type of questions is a tool used to determine and evaluate whether a candidate can clearly answer questions with regard to the content of the training course. Additionally, problem-solving techniques and arguments that are supported with reasoning and evidence, will also be evaluated.

The exam will be “open book” and is not intended to measure memorizing or recalling information. Open book exam aims to evaluate candidates’ comprehension, analytical skills and applied knowledge. Therefore, candidates are required to provide logical and convincing answers and explanations in order to demonstrate that they have understood the content and the main concepts of the training course. At the end of this document, samples of exam questions and possible answers to them have been provided.

Since the exam is “open book,” candidates are authorized to use the following reference materials:

- A copy of the **ISO 22000 standard**
- Training course materials
- A copy of the ISO 19011 standard
- Any personal notes made by the candidate during the training course
- A hard copy dictionary

Any attempts to copy, collude, or otherwise cheat during the exam session will automatically lead to failure of the exam.

PECB exams are available in English and other languages. For the availability of the exam in a particular language, please contact [examination@pecb.com](mailto:examination@pecb.com).

## RECEIVING THE EXAM RESULTS

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Exam results will be communicated via email within a period of three to eight weeks from the exam date for essay type exams, two to four weeks for multiple-choice paper-based exams, and instantly for online multiple-choice exams. There will be no exact grade included in the communication of the results to the candidate, only pass or fail.

Candidates who successfully complete the exam will be able to apply for one of the credentials in the respective certification scheme.

In case of exam failure, the results will be accompanied with a list of domains in which the candidate has failed to fully answer the question(s). This can help the candidate better prepare for a retake exam.

Candidates that disagree with the results may request for a reevaluation by writing to [results@pecb.com](mailto:results@pecb.com) within 30 working days from the exam date. Reevaluation requests received after 30 days will not be processed. If candidates do not agree with the results of the reevaluation, they have 30 working days from the date when they received the reevaluated exam results to file a complaint through the [PECB Ticketing System](#). Complaints received after 30 days will not be processed.

## EXAM RETAKE POLICY

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There is no limit on the number of times that a candidate may retake an exam. However, there are certain limitations in terms of the allowed time frames between exam retakes.

- If a candidate does not pass the exam on the 1<sup>st</sup> attempt, the candidate must wait 15 days (from the initial date of the exam) for the next attempt (1<sup>st</sup> retake). The retake fee applies.

**Note:** *Candidates who have completed the full training course but failed the written exam are eligible to retake the exam once for free within a 12-month period from the initial date of the exam.*

- If a candidate does not pass the exam on the 2<sup>nd</sup> attempt, the candidate must wait three months (from the initial date of the exam) for the next attempt (2<sup>nd</sup> retake). The retake fee applies.
- If a candidate does not pass the exam on the 3<sup>rd</sup> attempt, the candidate must wait six months (from the initial date of the exam) for the next attempt (3<sup>rd</sup> retake). The retake fee applies.
- After the fourth 4<sup>th</sup> attempt, the waiting period for further retake exams is 12 months from the date of the last attempt. The retake fee applies.

For candidates that fail the exam in the 2<sup>nd</sup> retake, PECB recommends to attend a training course in order to be better prepared for the exam.

To arrange exam retakes (date, time, place, costs), candidates need to contact the PECB Reseller/Distributor who has initially organized the training session.

## CLOSING A CASE

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If a candidate does not apply for the certificate within three years, their case will be closed. Candidates whose case has been closed due to the expiration of the certification period have the right to request to reopen their case. However, PECB will no longer be responsible for any changes in the conditions, standards, policies, candidate handbook, or exam preparation guide that were applicable before the case was closed. A candidate requesting their case to reopen must do so in writing and pay the required fee.

## EXAM SECURITY

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A significant component of a successful and respected professional certification credential is maintaining the security and confidentiality of the exam. PECB relies upon the ethical behavior of certificate holders and applicants to maintain the security and confidentiality of PECB exams. Any disclosure of information about the content of PECB exams indicates violation of PECB's Code of Ethics. PECB will take action against individuals who violate PECB Policies and the Code of Ethics. These actions include permanently barring individuals from pursuing PECB credentials and revoking the awarded credentials. PECB will also pursue legal action against individuals or organizations who infringe upon its copyrights, proprietary rights, and intellectual property.

## SAMPLE EXAM QUESTIONS

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**Question 1:** You have received a corrective action plan for review. As such, evaluate the effectiveness of the proposed corrective actions and explain whether you agree with them or not. If you do not agree with them, propose a more adequate corrective action.

Nonconformity 1: The employees were not aware of the procedure that requires them to monitor and verify the PRPs.

Corrective action plan: Inform (Timeframe: immediately) and train (Timeframe: within six months) the employees about the monitoring and verification procedure and require that they follow such procedures.

**Possible answer:**

*I agree with the proposed corrective action since it addressed the problem by providing training the employees and requiring that once they become familiar with the procedure, they strictly follow it.*

*As an auditor, a sampling will be performed during the surveillance audit to find out if the procedure is being followed.*

**Question 2:** Prepare an audit test plan by selecting at least three appropriate audit procedures to validate conformity to ISO 22000, clause 7.5.1. Mark “N/A” for the procedures that do not apply.

**Possible answer:**

Audit test plan	
<b>Observation</b>	N/A
<b>Interview</b>	<i>Interview the person or team responsible for the FSMS, in order to determine whether the documented information required by the standard, documented information required by the organization, and documented information required by laws are identified and included in the FSMS.</i>
<b>Documented information review</b>	<i>On a random basis, request a combination of documented information required by the standard, organization, and laws, in order to determine whether the organization has properly identified and included them in the FSMS.</i>
<b>Technical verification</b>	<i>Validate the electronic structure for classifying and storing documented information, verify their protection mechanisms, and their availability.</i>