



When Recognition Matters



EXAM PREPARATION GUIDE

PECB Certified ISO 22000 Lead Implementer

The objective of the “Certified ISO 22000 Lead Implementer” examination is to ensure that the candidate has the knowledge and the skills to support an organization in implementing and managing a Food Safety Management System (FSMS) based on ISO 22000:2005.

The target population for this examination is:

- Project managers or consultants wanting to prepare and to support an organization in the implementation of a Food Safety Management System (FSMS)
- ISO 22000 auditors who wish to fully understand the Food Safety Management System implementation process
- Persons responsible for the food safety conformity in an organization
- Members of a food safety team
- Expert advisors in food safety
- Technical experts wanting to prepare for a food safety function or for an FSMS project management function

The exam content covers the following domains:

- Domain 1: Fundamental Principles and Concepts of Food Safety
- Domain 2: Food Safety Best Practices
- Domain 3: Planning a FSMS Based on ISO 22000
- Domain 4: Implementing a FSMS Based on ISO 22000
- Domain 5: Performance Evaluation, Monitoring and Measurement of an FSMS Based on ISO 22000
- Domain 6: Continual Improvement of an FSMS Based on ISO 22000
- Domain 7: Preparing for an FSMS Certification Audit

The content of the exam is divided as follows:

Domain 1: Fundamental Principles and Concepts in Food Safety Management System

Main objective: To ensure that the ISO 22000 Lead Implementer candidate can understand, interpret and illustrate the main Food Safety Management concepts related to a Food Safety Management System (FSMS).

Competencies	Knowledge statements
<ol style="list-style-type: none"> 1. Understand and explain the operations of the ISO organization and the development of Food Safety Management standards. 2. Ability to identify, analyze and evaluate the Food Safety Management compliance requirements for an organization. 3. Ability to explain and illustrate the main concepts in Food Safety Management System. 	<ol style="list-style-type: none"> 1. Knowledge of the application of the eight ISO management principles to Food Safety Management System. 2. Knowledge of the main standards in Food Safety Management. 3. Knowledge of the different sources of Food Safety Management System requirement for an organization: laws, regulations, international and industry standards, contracts, market practices, internal policies. 4. Knowledge of the main Food Safety Management concepts and terminology as described in ISO 22000. 5. Knowledge of the concept of risk and its application in Food Safety Management. 6. Knowledge of the difference between preventive, detective and corrective controls and their characteristics.

Domain 2: Food Safety Management Best Practice Based on ISO 22000

Main objective: To ensure that the ISO 22000 Lead Implementer candidate can understand, interpret and provide guidance on how to implement and manage Food Safety Management requirements based on best practices of ISO 22000.

Competencies	Knowledge statements
1. Ability to identify, understand, classify and explain the clauses with requirements from ISO 22000.	1. Knowledge of operational planning and control.
2. Ability to detail and illustrate the requirements and best practices by concrete examples.	2. Knowledge of business impact analysis and risk assessment.
3. Ability to compare possible solutions to a Food Safety Management issue of an organization and identify/analyze the strength and weakness of each solution.	3. Knowledge of Food Safety Management strategy.
4. Ability to select and demonstrate the best Food Safety Management solution in order to address Food Safety Management objectives stated by the organization.	4. Knowledge of establishing and implementing Food Safety Management procedures.
5. Ability to create and justify an action plan to implement a Food Safety Management by listing the activities related.	5. Knowledge to establish a food safety management system (FSMS) based on the requirements from ISO 22000.
6. Ability to analyze, evaluate and validate action plans to implement a specific requirement.	6. Knowledge to establish documentation of food safety management system (FSMS) including: food safety policy, procedures and other required documents by the ISO 22000.
	7. Knowledge of Food Safety Management Best Practices.
	8. Knowledge on compiling FSMS action plan including its activities.
	9. Knowledge on implementing and managing action plan to support FSMS implementation in an organization.

Domain 3: Planning an FSMS Based on ISO 22000

Main objective: To ensure that the ISO 22000 Lead Implementer candidate can plan the implementation of an FSMS in preparation for an ISO 22000 certification.

Competencies	Knowledge statements
1. Ability to manage an FSMS implementation project following project management best practices.	1. Knowledge of the main project management concepts, terminology, process and best practice as described in ISO 10006.
2. Ability to gather, analyze and interpret the necessary information to plan the FSMS implementation.	2. Knowledge of the principal approaches and methodology frameworks to implement an FSMS.
3. Ability to observe, analyze and interpret the external and internal environment of an organization.	3. Knowledge of the main concepts and terminology related to organizations.
4. Ability to perform a gap analysis and clarify the Food Safety Management objectives of an organization.	4. Knowledge of an organization's external and internal environment.
5. Ability to state and justify an FSMS scope adapted to the objectives of a specific organization.	5. Knowledge of the main interested parties related to an organization and their characteristics.
6. Ability to select and justify the selected approach and methodology adapted to the needs of the organization.	6. Knowledge of techniques to gather information on an organization and to perform a gap analysis of a management system.
7. Ability to perform the different steps of the risk assessment and risk treatment phases.	7. Knowledge of the characteristics of an FSMS scope in terms of organizational, technological and physical boundaries.
	8. Knowledge of the different approaches and main methodology characteristics to perform a risk assessment.
	9. Knowledge of the main activities of the risk identification, estimation, evaluation related to the processes included in the FSMS of an organization.

Domain 4: Implementing an FSMS Based on ISO 22000

Main objective: To ensure that the ISO 22000 Lead Implementer candidate can implement the processes of an FSMS required for an ISO 22000 certification.

Competencies	Knowledge statements
1. Ability to understand, analyze needs and provide guidance on the attribution of roles and responsibilities in the context of the implementation and management of an FSMS.	1. Knowledge of the roles and responsibilities of the key actors during the implementation of an FSMS and in its operation after the end of the implementation project.
2. Ability to define the document and record management processes needed to support the implementation and the operations of an FSMS.	2. Knowledge of the main organizational structures applicable for an organization to manage Food Safety Management.
3. Ability to define and design processes and document them.	3. Knowledge of the best practices on document and record management processes and the document management life cycle.
4. Ability to define and write an FSMS policy and Food Safety Management policies & procedures.	4. Knowledge of the characteristics and the differences between the different documents related to FSMS: policy, procedure, guideline, standard, baseline, worksheet, etc.
5. Ability to implement the required processes and of an FSMS.	5. Knowledge of model-building controls and processes techniques and best practices.
6. Ability to define and implement appropriate Food Safety Management training, awareness and communication plans.	6. Knowledge of controls and processes deployment techniques and best practices.
7. Ability to define and implement an incident management process based on Food Safety Management best practices.	7. Knowledge of techniques and best practices to write Food Safety Management policies, procedures and others types of documents include in an FSMS.
8. Ability to transfer an FSMS project to operations and manage the change management process.	8. Knowledge of the characteristics and the best practices to implement Food Safety Management training, awareness and communication plans.
	9. Knowledge of the characteristics and main processes of an information management incident management process based on best practices.
	10. Knowledge of change management techniques best practices.

Domain 5: Performance Evaluation, Monitoring and Measurement of an FSMS Based on ISO 22000

Main objective: To ensure that the ISO 22000 Lead Implementer candidate can evaluate, monitor and measure the performance of an FSMS in the context of an ISO 22000 certification.

Competencies	Knowledge statements
1. Ability to monitor and evaluate the effectiveness of an FSMS in operation.	1. Knowledge of the techniques and best practices to monitor the effectiveness of an FSMS.
2. Ability to verify the extent to which identified requirements have been met.	2. Knowledge of the main concepts and components related to a Food Safety Management Measurement Programme: measures, attributes, indicators, dashboard, etc.
3. Ability to define and implemented an internal audit program for ISO 22000.	3. Knowledge of the characteristics and the differences between an operational, tactical and strategic Food Safety Management indicators and dashboard.
4. Ability to perform regular and methodical reviews regarding the suitability, adequacy, effectiveness and efficiency of an FSMS with policies and objectives of an organization.	4. Knowledge of the techniques and methods to define and document adequate and reliable indicators.
5. Ability to define and implement a management review process and counsel management on it.	5. Knowledge of the main concepts and components related to the implementation and operation of an FSMS internal audit program.
	6. Knowledge of the differences between the concepts of major nonconformity, minor nonconformity, anomaly and observation.
	7. Knowledge of the guidelines and best practices to write nonconformity report.
	8. Knowledge of the best practices on how to perform management reviews.

Domain 6: Continual Improvement of an FSMS Based on ISO 22000

Main objective: To ensure that the ISO 22000 Lead Implementer candidate can provide guidance on the Continual improvement of an FSMS in the context of ISO 22000.

Competencies	Knowledge statements
1. Ability to understand the principle and concepts related to continual improvement.	1. Knowledge of the main concepts related to continual improvement.
2. Ability to counsel an organization on how to continually improve the effectiveness and the efficiency of an FSMS.	2. Knowledge of the characteristics and the difference between the concept of effectiveness and the efficiency.
3. Ability to implement FSMS continual improvement processes in an organization.	3. Knowledge of the concept and techniques to perform a benchmarking.
4. Ability to determine the appropriate business improvement tools to support continual improvement processes of a specific organization.	4. Knowledge of the main processes, tools and techniques used by professionals to identify the root-causes of nonconformities.
5. Ability to identify, analyze the root-causes of nonconformities and proposed action plans to treat them.	5. Knowledge of the characteristics and the difference between corrective actions and preventive actions.
6. Ability to identify, analyze the root-cause of potential nonconformities and proposed action plans to treat them.	6. Knowledge of the main processes, tools and techniques used by professionals to develop and proposed the best corrective and preventive action plans.

Domain 7: Preparation for an FSMS Certification Audit

Main objective: To ensure that the ISO 22000 Lead Implementer candidate can prepare and assist an organization for the certification of an FSMS against the ISO 22000 standard.

Competencies	Knowledge statements
1. Ability to understand the main steps processes and activities related to an ISO 22000 certification audit.	1. Knowledge of the Knowledge of evidence based approach in an audit.
2. Ability to understand, explain and illustrate the audit evidence approach in the context of an ISO 22000 audit.	2. Knowledge of the different types of evidences: physical, mathematical, confirmative, technical, analytical, documentary and verbal.
3. Ability to counsel an organization to identify and select a certification body that meets their needs.	3. Knowledge of the difference of the stage 1 audit and the stage 2 audit.
4. Ability to review the readiness of an organization for an ISO 22000 certification audit.	4. Knowledge of stage 1 audit requirements, steps and activities.
5. Ability to coach and prepare the personnel of an organization for an ISO 22000 certification audit.	5. Knowledge of the documentation review criteria.
6. Ability to argue and challenge the audit findings and conclusions with external auditors.	6. Knowledge of stage 2 audit requirements, steps and activities.
	7. Knowledge of follow-up audit requirements, steps and activities.
	8. Knowledge of surveillance audits and recertification audit requirements, steps and activities.
	9. Knowledge of the requirements, guidelines and best practices to develop action plans following an ISO 22000 certification audit.

Based on these seven domains and their relevance, 12 questions are included in the exam, as summarized in the following table:

		Points per Question	Level of Understanding (Cognitive/Taxonomy) Required		Number of Questions per competency domain	% of test devoted to each competency domain	Number of Points per competency domain	% of Points competency domain
			Questions that measure Comprehension, Application and Analysis	Questions that measure Synthesis and Evaluation				
Competency Domains	Fundamental principles and concepts in Food Safety Management	5	x		2	16.67	10	13.33
		5	x					
	Food Safety Management Best Practices based on ISO 22000	10	x		3	25.00	25	33.33
		10	x					
		5	x					
	Planning an FSMS based on ISO 22000	5		x	1	8.33	5	6.67
	Implementing an FSMS based on ISO 22000	5		x	3	25.00	15	20.00
		5		x				
		5		x				
	Performance evaluation, monitoring and measurement of an FSMS based on ISO 22000	10		x	1	8.33	10	13.33
	Continual improvement of an FSMS based on ISO 22000	5	x		1	8.33	5	6.67
	Preparation for an FSMS certification audit	5		x	1	8.33	5	6.67
Total points		75						
Number of Questions per level of understanding			6	6				
% of Test Devoted to each level of understanding (cognitive/taxonomy)			50.00	50.00				

The passing score is established at **70%**.

After successfully passing the exam, candidates will be able to apply for the credentials of Certified ISO 22000 Lead Implementer, depending on their level of experience.

TAKE A CERTIFICATION EXAM

Candidates will be required to arrive at least thirty (30) minutes before the beginning of the certification exam. Candidates arriving late will not be given additional time to compensate for the late arrival and may be denied entry to the exam room (if they arrive more than 5 minutes after the beginning of the exam scheduled time).

All candidates will need to present a valid identity card with a picture such as a driver's license or a government ID to the invigilator.

The exam duration is three (3) hours.

The questions are essay type questions. This type of format was chosen because the intent is to determine whether an examinee can write a clear coherent answer/argument and to assess problem solving techniques. Because of this particularity, the exam is set to be "open book" and does not measure the recall of data or information. The examination evaluates, instead, comprehension, application, analysis, synthesis and evaluation, which mean that even if the answer is in the course material, candidates will have to justify and give explanations, to show they really understood the concepts. At the end of this document, you will find sample exam questions and their possible answers.

As the exams are "open book"; candidates are authorized to use the following reference materials:

- A copy of the ISO 22000:2005 standard,
- Course notes from the Participant Handout,
- Any personal notes made by the student during the course and
- A hard copy dictionary.

The use of electronic devices, such as laptops, cell phones, etc., is not allowed.

All attempt to copy, collude or otherwise cheat during the exam will automatically lead to the exam's failure.

PECB exams are available in English. For availability of the exam in a language other than English, please contact examination@pecb.com.

RECEIVE YOUR EXAM RESULTS

Results will be communicated by email in a period of 6 to 8 weeks, after taking the exam. The results will not include the exact grade of the candidate, only a mention of pass or fail.

Candidates who successfully complete the examination will be able to apply for a certified scheme.

In the case of a failure, the results will be accompanied with the list of domains in which the candidate had a low grade, to provide guidance for exams' retake preparation.

Candidates who disagree with the exam results may file a complaint. For more information, please refer to www.pecb.com

EXAM RETAKE POLICY

There is no limit on the number of times a candidate may retake an exam. However, there are some limitations in terms of allowed time-frame in between exam retakes, such as:

- If a candidate does not pass the exam on the first attempt, he/she must wait 15 days for the next attempt (1st retake). Retake fee applies.

Note: *Students, who have completed the full training 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 second attempt, he/she must wait 3 months (from the initial date of the exam) for the next attempt (2nd retake). Retake fee applies.
- If a candidate does not pass the exam on the third attempt, he/she must wait 6 months (from the initial date of the exam) for the next attempt (3rd retake). Retake fee applies.

After the fourth attempt, a waiting period of 12 months from the last session date is required, in order for candidate to sit again for the same exam. Regular fee applies.

For the candidates that fail the exam in the 2nd retake, PECB recommends to attend an official training in order to be better prepared for the exam.

To arrange exam retakes (date, time, place, costs), the candidate needs to contact the PECB partner who has initially organized the session.

CLOSING FILES

Closing a file is equivalent to rejecting a candidate's application. As a result, when candidates request that their file be reopened, PECB will no longer be bound by the conditions, standards, policies, candidate handbook or exam preparation guide that were in effect before their file was closed.

Candidates who want to request that their file be reopened must do so in writing, and pay the required fees.

EXAMINATION SECURITY

A significant component of a successful and respected professional certification credential is maintaining the security and confidentiality of the examination. PECB relies upon the ethical behaviour of certificate holders and applicants to maintain the security and confidentiality of PECB examinations. When someone who holds PECB credentials reveals information about PECB examination content, they violate the PECB Code of Ethics. PECB will take action against individuals who violate PECB Policies and the Code of Ethics. Actions taken may include permanently barring individuals from pursuing PECB credentials and revoking certifications from those who have been awarded the credential. PECB will also pursue legal action against individuals or organizations who infringe upon its copyrights, proprietary rights, and intellectual property.

SAMPLE EXAM QUESTIONS AND POSSIBLE ANSWERS

1. Interpretation of ISO clauses

For each of the following clauses of the ISO 22000:2005 standard, please provide at least two different evidences that would be acceptable to verify the implementation of the requirement.

- 4.2.2 Control of documents

A documented procedure shall be established to define the controls needed

c) to ensure that changes and the current revision status of documents are identified

Possible answers:

- Validate that they have a formal procedure for control of documents that describes how they perform document revision and identification.
- Review sample of documents to ensure that these are adequately identified, versioned and if any of those documents had changes to verify the identification of changes.

2. Development of metrics

For each of the following clauses of the ISO 22000 standard, please provide two examples of metrics that would be acceptable to measure the conformity to the clause.

- 5.8 Management Review

Possible answers:

- Total of management review meetings completed according to the annual planning
- Average participation rates in management review meetings to date

3. Recommendations

The management of the organization would like to receive recommendations from you to improve the processes in place to comply with the requirements of ISO 22000 on control of documents

Possible answers:

1. Document and implement a procedure for control of documents
2. Maintain a log for documents changes with records of the approvals.
3. Communicating the new process and organize training session.