

American Society for Quality (ASQ)
CERTIFIED FOOD SAFETY AND QUALITY AUDITOR (CFSQA)
BODY OF KNOWLEDGE

The topics in this Body of Knowledge include additional detail in the form of subtext explanations and the cognitive level at which the questions will be written. This information will provide useful guidance for both the Exam Development Committee and the candidate preparing to take the exam. The subtext is not intended to limit the subject matter or be all-inclusive of what might be covered in an exam. It is meant to clarify the type of content to be included in the exam. The descriptor in parentheses at the end of each entry refers to the maximum cognitive level at which the topic will be tested. A complete description of cognitive levels is provided at the end of this document.

I. Food Safety and HACCP System (27 Questions)

A. HACCP Terminology

Define, describe, and apply basic terms and elements related to a HACCP system including 1) deviation, 2) hazard condition, 3) validation, 4) verification, 5) National Advisory Committee on Microbiological Criteria for Foods (NACMCF), and 6) Codex Alimentarius. (Apply)

B. Food Safety Terminology

Describe and apply the connection between basic terms related to a food safety system including 1) food safety, 2) food safety culture, 3) food quality, 4) food quality plan, and 5) animal food and animal feed. (Apply)

C. Prerequisite Programs

1. Foundations for a Food Safety and HACCP System

Define and describe the foundations for a Food Safety and HACCP system which control the operational conditions within a food establishment such as: (Analyze)

- a. Good Manufacturing Practices (GMPs), including personal hygiene programs
- b. Good Agricultural Practices (GAPs)
- c. Good Laboratory Practices (GLPs), including testing continuity plan
- d. Sanitation Standard Operating Procedures (SSOPs)
- e. Chemical and hazardous materials control
- f. Employee training
- g. Calibration of equipment
- h. Integrated Pest Management (IPM)
- i. Foreign material control (e.g., wood, metal, glass, brittle plastic, and ceramic control)
- j. Maintenance programs (e.g., preventive, routine, emergency, and temporary)
- k. Waste management
- l. Supplier and material qualification (e.g., raw materials, finished goods, and primary packaging)
- m. Distribution and transportation

2. Product traceability and recall

Define and distinguish between material identification and status in relation to product traceability and recall such as label control, mock recalls, and traceability exercises. (Analyze)

3. Crisis management

Understand and apply crisis management plans including business continuity and outbreak management. (Apply)

4. Food defense and facility design

Apply facility design, security methods and operational conditions necessary to mitigate bioterrorism threats and intentional adulteration. (Apply)

5. Environmental control and monitoring

Apply various programs to support proper environmental conditions such as 1) controls for temperature, 2) humidity, 3) dust, 4) pathogens, 5) water, 6) air and ice safety, and 7) facility design elements. (Analyze)

6. Food fraud

Understand the impact caused by the intentional or unintentional use of ingredients (e.g., substitution, mislabeling, misbranding, dilution, and counterfeiting) that may compromise economic integrity, safety of the final product, or quality of the final product. (Understand)

D. Preventive Controls

1. Process controls

Analyze appropriate procedures, practices, and processes for safe manufacturing, processing, packing, or holding of food to significantly minimize or prevent hazards, including but not limited to sanitation, process, CCP practices, and prerequisite programs. (Analyze)

2. Supply chain control

Apply supplier preventive process control measures and methods (e.g. sanitary transport, appropriate in-house storage, and appropriate labeling) used for hazard analysis and control, supplier performance and for documenting process control. (Apply)

3. Allergen control

Analyze specifications used for control within an allergen management process (e.g., storage, labeling, packaging, and shipping). Explain how specifications are used for preventing or mitigating cross-contact and cross-contamination. (Analyze)

II. Food Safety and HACCP Management (9 Questions)

A. Preliminary Tasks

Use the following preliminary tasks to develop a Food Safety and HACCP system. (Apply)

1. Assemble and train the Food Safety and HACCP team, including qualified individuals.
2. Describe the product and its distribution.
3. Describe the intended use of the product and its end-user (e.g., consumer, patient, vulnerable group).
4. Develop a product or process flow diagram.
5. Verify the product or process flow diagram.

B. System Scope

Define the scope of a Food Safety and HACCP system in terms of product-safety management. Describe how that scope affects the relationship between HACCP and other systems, such as quality management, risk management, the Global Food Safety Initiative (GFSI). Describe the impact that non-safety regulatory requirements and customer specifications can have on the scope of a Food Safety HACCP system. (Evaluate)

C. Management Responsibility

Understand the importance of management's commitment to Food Safety and HACCP prerequisite programs, preventive controls, establishment of a food safety culture, and current and emerging domestic and global standards. (Apply)

III. HACCP Principles (22 Questions)

A. Principle 1 – Hazard Analysis

Conduct a hazard analysis by 1) identifying hazards and 2) evaluating them in terms of severity and likelihood of occurrence utilizing tools such as a risk matrix; then 3) establish control measures for any hazards that are likely to occur. (Analyze)

B. Principle 2 – Critical Control Points (CCPs)

Define and distinguish between 1) control points and 2) critical control points (CCPs) in various operations; then 3) develop and use CCP decision trees. (Analyze)

C. Principle 3 – Critical Limits

Describe and distinguish between various types of limits, including 1) operational and process control limits and 2) specification limits. Identify and use appropriate scientific sources related to chemical, microbiological and physical limits, etc., as the basis for establishing critical limits. (Apply)

D. Principle 4 – Monitoring

Establish monitoring procedures that include details about: 1) whether to use continuous or scheduled (intermittent) monitoring, 2) how frequently data should be gathered and by whom, and 3) what sampling and testing methods to use in support of these procedures. (Apply)

E. Principle 5 – Corrective Action

Use the following steps to establish corrective action procedures. (Analyze)

- 1) Identify the cause of the deviation.
- 2) Determine disposition of affected product.
- 3) Identify and document corrective action.
- 4) Implement corrective action and determine its effectiveness.
- 5) Reevaluate the HACCP plan after changes have been made.

F. Principle 6 – Verification

Use the following steps to establish verification procedures for ongoing assessment. (Analyze)

- 1) Verify prerequisites and CCPs.
- 2) Review documents and records.
- 3) Review calibration processes and system operation.
- 4) Test and analyze product samples.
- 5) Validate the HACCP system.

G. Principle 7 – Recordkeeping and Documentation

Establish procedures for maintaining these elements. (Apply)

- 1) Documents and records used to develop the initial HACCP plan
- 2) CCP monitoring records
- 3) Records of corrective actions taken in response to deviations, including root cause analysis results, verification activities, etc.
- 4) A formal document control system

IV. Implementation and Maintenance of Food Safety and HACCP System (21 Questions)

A. Implementation and Assessment

Use the following steps to implement the system. (Apply)

- 1) Conduct a pilot or initiate the system.
- 2) Conduct operational qualifications (critical control points, process control plans, etc.).
- 3) Assess training programs.
- 4) Evaluate the project's effectiveness in relation to its stated objectives.
- 5) Review the system requirements (regulatory, internal, etc.) to determine whether changes need to be made.

B. Validation and Reassessment

Use the following steps to assess an ongoing system. (Evaluate)

- 1) Validate the stated system objectives in relation to the results of the pilot, system initiation, or product/process change as needed.
- 2) Reassess the system periodically to verify that the requirements are met through reviewing data sources such as complaints, recalls, deviations, and corrective actions.

C. Verification and Maintenance

Review various food safety and HACCP system records, including 1) monitoring, 2) corrective action, 3) calibration, 4) training, and review 5) recordkeeping procedures and 6) operational procedures when the system is active to confirm that they are being implemented properly. (Apply)

V. Auditing Fundamentals (23 Questions)

A. Basic Terms and Concepts

Define and distinguish between quality assurance and quality control. (Apply)

B. Purpose of Audits

Explain how audits can be used to assess a wide variety of activities, including 1) organizational effectiveness, 2) system and process effectiveness, 3) performance measurement, 4) risk management, and 5) conformance to requirements. (Analyze)

C. Types of Audits

Define and distinguish between various audit types, including 1) product, 2) process, 3) system, 4) 1st, 2nd, and 3rd party, 5) compliance, etc. (Analyze)

D. Audit Criteria

Define and distinguish between various audit criteria, such as 1) standards, 2) contracts, 3) specifications, 4) policies, and 5) regulations. (Analyze)

E. Audit Participants

Define and describe the roles and responsibilities of various audit participants, including 1) audit team members, 2) lead auditor, 3) client, 4) auditee, and 5) technical or subject matter experts. (Apply)

F. Ethical, Legal, and Professional Issues

1. Audit credibility

Identify and apply ethical factors that influence audit credibility such as auditor independence, objectivity, and qualifications. (Apply)

2. Liability issues

Identify potential legal and financial ramifications of improper auditor actions (e.g., carelessness and negligence) and the effects such actions can have on liability issues for all parties. (Apply)

3. Professional conduct and responsibilities

Define and apply the concepts of due diligence and due care with respect to confidentiality, conflict of interest, the discovery of illegal activities or unsafe conditions, etc. (Apply)

VI. Auditing Process and Auditor Competencies (23 Questions)

A. Audit Preparation and Planning

1. Elements of audit planning
Identify and implement audit planning steps, including verifying audit authority, determining the purpose, scope, type of audit, requirements to audit against, and resources necessary, such as size and number of audit teams. (Evaluate)
2. Pre-audit documents
Identify and analyze pre-audit documents such as audit criteria or reference materials, prior audit results, etc. (Evaluate)
3. Auditing strategies
Identify and use various tactical methods for conducting an audit, including forward- and backward-tracing, discovery, etc. (Apply)

B. Audit Performance

1. Opening meeting
Describe the elements of an opening meeting, including explaining to the auditee the purpose, scope, and elements of the audit to be conducted. (Apply)
2. Data collection and analysis
Select and apply various data collection methods, such as obtaining access to documents, interviewing people, observing work activities, taking physical measurements, examining paper and electronic documents, and confirming flow diagrams, and analyze the results. (Evaluate)
3. Working papers
Identify types of working papers, such as checklists, auditor notes, attendance rosters, etc., and determine their importance in providing evidence for an audit trail. (Evaluate)
4. Objective evidence
Identify and differentiate various characteristics of objective evidence, such as observed, measured, verified, and documented. (Analyze)
5. Observations
Evaluate the significance of observations in terms of positive, negative, chronic, isolated, and systemic. (Evaluate)
6. Nonconformances
Classify nonconformances in terms of significance, severity, frequency, and level of risk. (Evaluate)
7. Audit process management
Define and apply elements of managing an audit as it is being performed, including coordinating team and team member activities, reallocating resources, adjusting audit plans when necessary, and communicating with the auditee as needed. (Analyze)
8. Exit meeting
Describe the elements of an exit meeting, including presenting audit observations and findings to the auditee and discussing post-audit activities, who will be responsible for performing them, and their deadlines. (Apply)

C. Audit Reporting

1. Basic steps

Implement the common steps in generating an audit report, including reviewing and finalizing results, organizing and summarizing details, obtaining necessary approvals for report distribution, etc. (Evaluate)

2. Effective audit reports

Evaluate various components that make audit reports effective: e.g., executive summary, prioritized data, graphical data presentation, and the impact of conclusions. (Evaluate)

D. Audit Follow-up and Closure

1. Corrective and preventive action (CAPA)

Identify and apply CAPA elements, including problem identification, assigning responsibility, root cause analysis, recurrence prevention, etc. (Apply)

2. Review and verification of corrective action plans

Use various methods to verify and evaluate corrective actions plans, including examining revised procedures and processes or re-auditing to confirm the adequacy of corrective actions taken. (Apply)

3. Follow-up on ineffective corrective actions

Identify and develop strategies to use when corrective actions are not implemented or are not effective, including communicating to the next level of management, re-issuing the corrective action, re-auditing, etc. (Evaluate)

4. Audit closure

Identify various elements of audit closure and any criteria that have not been met and would prevent an audit from being closed. (Evaluate)

5. Records retention

Identify and apply record retention requirements, such as type of documents to be retained, length of time to keep them, and storage considerations. (Apply)

E. Auditor Competencies

1. Characteristics

Identify characteristics that make auditors effective, such as interpersonal skills, problem-solving skills, close attention to detail, the ability to work independently and in a group or on a team. (Apply)

2. Conflict resolution

Identify typical conflict situations (disagreements, auditee delaying tactics, interruptions, etc.) and determine appropriate techniques (negotiation, cool-down periods, etc.) for resolving them. (Apply)

3. Written communication techniques

Develop and review technical reports for critical factors, including whether the document meets the needs of the intended audience, how the report will be used, what type of photographs, illustrations, or graphics will be effective, etc. (Apply)

4. Interviewing techniques

Define and use appropriate interviewing techniques, including active listening, open-ended or closed question types, determining the significance of pauses and their length, prompting a response, clarifying by paraphrasing, etc., in various situations, such as when supervisors are present, during group interviews, a group of workers, when using a translator, etc. (Apply)

5. Team dynamics and facilitation skills

Define and use various techniques to support team-building efforts and to help maintain group focus, both as a participant and as a team leader. Describe the classic stages of team development (forming, storming, norming, performing and adjourning, and use coaching, guidance, and other facilitation techniques to support effective teams. (Apply)

F. International Regulations and Inspections

Identify regulatory and international food sector requirements such as Food Safety Modernization Act (FSMA), FDA 21 CFR 117 and FDA 21 CFR 507, Foreign Supplier Verification Program (FSVP), FDA 9 CFR 416 and FDA 9 CFR 417, and Dietary Supplement cGMP Requirements. (Remember)

G. Auditing Schemes

Distinguish between various auditing schemes and auditee requirements including SQF Food Safety Code, FSSC 22000 Standard, BRC Global Standards, Primus, Global G.A.P., GRMS Global Red Meat Standard, IFS International Food Standard, Canada G.A.P., and Global Aquaculture Alliance. (Remember)

VII. Quality Tools and Techniques (10 Questions)

A. Basic Quality Tools

Identify, interpret, and apply the seven basic quality tools: 1) Pareto charts, 2) cause and effect diagrams, 3) flowcharts, 4) control charts, 5) check sheets, 6) scatter diagrams, and 7) histograms. (Apply)

B. Descriptive Statistics

Identify, interpret, and use 1) measures of central tendency (mean, median, mode) and 2) dispersion (standard deviation, variance, and frequency distribution). (Apply)

C. Sampling Methods

Identify, interpret, and use sampling methods such as 1) acceptance, 2) random, 3) stratified, and 4) define terms such as consumer and producer risk, confidence level, etc. (Analyze)

D. Statistical Process Control

Interpret the data presented in statistical process control results. (Understand)
[NOTE: this topic will be tested at the *understand* level; no calculations will be required.]

E. Process Capability

Identify and distinguish the basic elements of C_p and C_{pk} . (Remember)
[NOTE: this topic will be tested at the *definition* level; no calculations will be required.]

F. Qualitative / Quantitative Analysis and Attributes / Variables Data

Describe and distinguish between 1) qualitative and quantitative analyses and 2) attributes and variables data. (Apply)

Levels of Cognition
Based on Bloom's Taxonomy – Revised (2001)

In addition to **content** specifics, the subtext for each topic in this BOK also indicates the intended **complexity level** of the test questions for that topic. These levels are based on “Levels of Cognition” (from Bloom's Taxonomy – Revised, 2001) and are presented below in rank order, from least complex to most complex.

Remember

Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.

Understand

Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Apply

Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.

Analyze

Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

Evaluate

Make judgments about the value of proposed ideas, solutions, etc., by comparing the proposal to specific criteria or standards.

Create

Put parts or elements together in such a way as to reveal a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.