

American Society for Quality (ASQ)

CERTIFIED HACCP AUDITOR (CHA)

BODY OF KNOWLEDGE

The topics in this Body of Knowledge include the cognitive level at which the questions will be written and is designed to provide guidance for both the Exam Development Committee and the candidate preparing to take 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 the various cognitive levels is provided at the end of this document.

I. HACCP SYSTEM (25 QUESTIONS)

A. HACCP Terminology

Define, describe, and apply basic terms related to a HACCP system: 1) deviation, 2) hazard condition, 3) preventive maintenance, and describe and apply elements of 4) NACMCF (National Advisory Committee on Microbiological Criteria for Foods) and 5) *Codex Alimentarius* in various situations. (Apply)

B. Prerequisite Programs

1. Foundations for a HACCP system

Define and describe various prerequisite programs, including good manufacturing practices (GMPs), good agricultural practices (GAPs), good laboratory practices (GLPs), sanitation standard operating procedures (SSOPs), personal hygiene programs, chemical and hazardous materials control, etc., and provide employee training in these areas. (Analyze)

2. Product traceability and recall

Define and distinguish between material identification and status in relation to product traceability and recall. (Apply)

3. Security and Facility design

Identify and use various facility design and security methods to ensure control over operational conditions in buildings and other process areas where products are produced and stored. (Apply)

4. Environmental control

Use various programs, including controls for allergens, temperature, humidity, dust, etc., to support proper environmental conditions. (Analyze)

C. Preliminary Tasks

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

1. Assemble and train the HACCP team.

2. Describe the product and its distribution.

3. Describe the intended use of the product and its end-user: consumer, patient, vulnerable group, etc.

4. Develop a product or process flow diagram.

5. Verify the flow diagram.

D. System Scope

Define the scope of a 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, medical devices, the Global Food Safety Initiative (GFSI). Distinguish between voluntary and regulatory HACCP programs, and describe the impact that non-safety

regulatory requirements and customer specifications can have on the scope of a HACCP system. (Understand)

E. Management Responsibility

Describe the importance of management's commitment to HACCP and prerequisite programs and use various methods to keep management apprised of current and emerging domestic and global standards, hazards, technologies, and related regulations. (Apply)

II. HACCP PRINCIPLES (30 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; then 3) establish control measures for any hazards that are likely to occur. (Analyze)

B. Principle 2 – 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 3) chemical, microbiological, 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.
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

III. IMPLEMENTATION AND MAINTENANCE OF HACCP SYSTEM (20 QUESTIONS)

A. Implementation and Assessment

Use the following steps to implement a HACCP project or 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 related to the HACCP .
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 HACCP project or system. (Evaluate)

1. Reevaluate the stated system objectives in relation to the results of the pilot, system initiation, or product/process change.
2. Review the system requirements to verify that the project continues to meet those requirements.

C. Verification and Maintenance

Review various HACCP system records, including 1) monitoring, 2) corrective action, 3) calibration, and 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)

IV. AUDITING FUNDAMENTALS (22 QUESTIONS)

A. Basic Terms and Concepts

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

[NOTE: all other basic quality and audit terms are covered in specific subtopics of BOK area V.B. Audit Performance.]

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 (SMEs). (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)

V. AUDITING PROCESS AND AUDITOR COMPETENCIES (28 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 interviewing people, observing work activities, taking physical measurements, examining paper and electronic documents, 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 use coaching, guidance, and other facilitation techniques to support effective teams. (Apply)

VI. 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. 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.]

E. Qualitative / Quantitative Analysis and Attributes / Variables Data

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

SIX LEVELS OF COGNITION

BASED ON BLOOM'S TAXONOMY (REVISED)

In addition to *content* specifics, the subtext detail also indicates the intended *complexity level* of the test questions for that topic. These levels are based on the "Revised Levels of Cognition" (from Bloom's Taxonomy, 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.