

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 (22 QUESTIONS)

A. Scope (Comprehension)

1. Product safety management system
2. Relationship of HACCP to other systems such as quality management, risk management, non-safety regulatory requirements, customer specifications

B. Management Responsibility (Application)

1. Commitment to HACCP
2. Commitment to prerequisite programs
3. Knowledge of current and emerging regulations, hazards, and technology

C. HACCP Terminology (Application)

1. Deviation
2. Hazard condition
3. Preventive maintenance
4. National Advisory Committee on Microbiological Criteria for Foods (NACMCF)
5. Codex Alimentarius

D. Prerequisite Programs (Application)

1. Foundation for HACCP system
2. Control of operational conditions
3. Control of environmental conditions
4. Application of good practices (e.g., QMS, GMPs, SSOPs, GAPs, GLPs)

E. Preliminary Tasks (Application)

1. Assemble the HACCP team
2. Describe the product and its distribution
3. Describe the intended use and end-user, consumer, patient
4. Develop a process flow diagram
5. Verify the process flow diagram

II. HACCP PRINCIPLES (21 QUESTIONS)

- A. Principle 1—Conduct a Hazard Analysis (Application)**
 - 1. Identify hazards
 - 2. Evaluate hazards in terms of severity and likelihood of occurrence
 - 3. Identify control measures for hazards identified as “reasonably likely to occur”
- B. Principle 2—Determine Critical Control Points (CCPs) (Application)**
 - 1. Identify control points
 - 2. Identify critical control points
 - 3. Create CCP decision trees
- C. Principle 3—Establish Critical Limits (Application)**
 - 1. Critical limits
 - 2. Specification limits
 - 3. Operating limits
 - 4. Process control limits
 - 5. Sources of information for establishing limits
- D. Principle 4—Establish Monitoring Procedures (Application)**
 - 1. Continuous monitoring
 - 2. Sampling and testing
 - 3. Procedural elements (such as methods, frequency, and responsibility)
- E. Principle 5—Establish Corrective Actions (Application)**
 - 1. Identify cause of deviation
 - 2. Determine product disposition
 - 3. Record corrective actions
 - 4. Implement preventive action
 - 5. Reevaluate HACCP plan
- F. Principle 6—Establish Verification Procedures (Application)**
 - 1. Documentation and record review
 - 2. Calibration
 - 3. Testing and analysis
 - 4. Validation
- G. Principle 7—Establish Record-keeping and Documentation Procedures (Application)**
 - 1. Support documentation used to develop the HACCP plan
 - 2. Records of CCP monitoring

3. Records of corrective action
4. Records of verification activities
5. Document control

III. IMPLEMENTATION AND MAINTENANCE OF HACCP SYSTEM (14 QUESTIONS)

- A. Implementation and Assessment (Application)**
 1. Pilot a HACCP project or initiate the system
 2. Conduct operational qualifications
- B. Validation and Reassessment (Application)**
 1. Evaluate system objectives (product safety, etc.) after pilot or initiation
 2. Review system requirements (e.g., regulatory, internal) after pilot or initiation
- C. Verification and Maintenance (Application)**
 1. Review monitoring records
 2. Review corrective action records
 3. Review calibration records
 4. Review record-keeping procedures
 5. Observe system procedures directly

IV. AUDITING FUNDAMENTALS (17 QUESTIONS)

- A. Basic Terms and Concepts (Application)**
 1. Process safety
 2. Quality assurance
 3. Quality control
 4. Evidence
 5. Finding
 6. Observation
 7. Noncompliance
 8. Nonconformance
- B. Purpose of Audits (Analysis)**
 1. Organizational effectiveness
 2. System efficiency
 3. Process effectiveness
 4. Performance measuring and monitoring
 5. Risk management

6. Conformance to requirements

- C. Types of Audits (Analysis)

1. Product
2. Process
3. System
4. Compliance
5. 1st-, 2nd-, and 3rd-party
6. Internal
7. External
8. Desk

- D. Audit Criteria (Analysis)

1. Standards
2. Contracts
3. Specifications
4. Policies
5. Regulations

- E. Roles and Responsibilities of Audit Participants (Application)

1. Audit team members
2. Lead auditor
3. Client
4. Auditee

- F. Ethical, Legal, and Professional Issues (Application)

1. Audit credibility
2. Auditor independence and objectivity
3. Liability issues, including improper auditor actions, carelessness, negligence, and client and auditee liability
4. Professional conduct and responsibilities, including due diligence and due care, confidentiality, conflict of interest, discovery of illegal activities or unsafe conditions, etc.

V. AUDIT PROCESS (36 QUESTIONS)

- A. Audit Preparation and Planning (Evaluation)

1. Elements of audit planning, including verifying audit authority, determining purpose, scope, type of audit, requirements to audit against, and resources necessary such as size and number of audit teams

2. Audit-related documentation, including pre-audit reference materials, prior audit results, etc.
3. Auditing tools, such as checklists, log sheets, sampling plans, procedural guidelines, etc.
4. Auditing strategies (such as forward and backward tracing, discovery, etc.)

B. Audit Performance (Evaluation)

1. Opening meeting to cover the audit's purpose, scope, elements, etc.
2. Data collection and analysis, including interviewing, observing, taking physical measurements, examining paper and electronic documents, etc.
3. Working papers, such as checklists, auditor notes, attendance rosters, etc.
4. Objective evidence, such as observed, measured, verified, documented, etc.
5. Observations, including positive, negative, chronic, isolated, systemic, etc.
6. Nonconformances, including significance, severity, frequency, level of risk, etc.
7. Audit process management, such as coordinating team activities, allocating and adjusting resources, adjusting audit plan, communicating with auditee, etc.
8. Exit meeting to cover audit observations, findings, post-audit activities, etc.

C. Audit Reporting (Evaluation)

1. Basic elements (e.g., review and finalize results, organize and summarize details, obtain necessary approvals, distribute the report)
2. Effective audit reports (e.g., executive summaries, prioritized data, graphic presentation, potential impact of conclusions)
3. Records retention (length of time, storage considerations, etc.)

D. Audit Follow-up and Closure (Evaluation)

1. Corrective and preventive action processes, including problem identification, assigning responsibility, root cause analysis, recurrence prevention, etc.
2. Review of corrective action plan, including strategies for negotiating changes to unacceptable plans
3. Verification of corrective action, including examining revised procedures and processes or re-auditing to confirm adequacy of corrective actions taken
4. Ineffective corrective action response, including communicating to the next level of management, re-issuing the corrective action, re-auditing, etc.
5. Audit closure, including requirements for closure by audit type, etc.

VI. AUDITOR COMPETENCIES (13 QUESTIONS)

A. Auditor Characteristics (Application)

1. Interpersonal skills

2. Problem-solving skills
3. Attention to detail
4. Cultural sensitivity
5. Ability to work independently and on a team

B. Conflict Resolution (Application)

1. Negotiation
2. Cool-down periods

C. Communication Techniques (Application)

1. Writing and reviewing technical reports
2. Using active listening techniques
3. Using empathy
4. Paraphrasing for clarification

D. Interviewing Techniques (Application)

1. Using open-ended and closed question types
2. Interpreting the significance of pauses and their length
3. Knowing when and how to prompt a response in various situations, such as when supervisors are present, when interviewing a group of workers, when using a translator, etc.

E. Team Membership, Leadership, and Facilitation (Application)

1. Team-building efforts
2. Maintaining group focus
3. Leadership roles and techniques
4. Presentation techniques, including using graphs, charts, diagrams, multimedia aids, etc., for written and oral presentations

F. Verification and Validation (Analysis)

1. Reviewing documents and processes to confirm their validity
2. Verifying that documented procedures and processes are being used

VII. QUALITY TOOLS AND TECHNIQUES (12 QUESTIONS)

A. Quality Control Tools (Analysis)

1. Pareto charts
2. Cause and effect diagrams
3. Flowcharts
4. Control charts

5. Check sheets
 6. Scatter diagrams
 7. Histograms
- B. Quality Improvement Tools (Analysis)**
1. Root cause analysis
 2. Plan-Do-Check-Act (PDCA)
 3. Corrective and preventive action (CAPA) methods
- C. Descriptive Statistics (Analysis)**
1. Measures of central tendency (mean, median, and mode)
 2. Measures of dispersion (standard deviation and frequency distribution)
- D. Sampling Methods (Analysis)**
1. Acceptance
 2. Random
 3. Stratified
 4. Related concepts such as consumer and producer risk, confidence level, etc.
- E. Process Capability (Knowledge)**
1. Cp
 2. Cpk
- F. Qualitative and Quantitative Analysis (Analysis)**
1. Attributes data
 2. Variables data
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Six Levels of Cognition based on Bloom's Taxonomy (1956)

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 "Levels of Cognition" (from Bloom's Taxonomy, 1956) and are presented below in rank order, from least complex to most complex.

Knowledge Level

(Also commonly referred to as recognition, recall, or rote knowledge.) Be able to remember or recognize terminology, definitions, facts, ideas, materials, patterns, sequences, methodologies, principles, etc.

Comprehension Level

Be able to read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Application Level

Be able to apply ideas, procedures, methods, formulas, principles, theories, etc., in job-related situations.

Analysis

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

Synthesis

Be able to put parts or elements together in such a way as to show 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.

Evaluation

Be able to make judgments regarding the value of proposed ideas, solutions, methodologies, etc., by using appropriate criteria or standards to estimate accuracy, effectiveness, economic benefits, etc.