

**PALOMAR COLLEGE**  
**COURSE OUTLINE OF RECORD FOR**  
**DEGREE CREDIT COURSE**

X Transfer Course X A.A. Degree applicable course  
(check all that apply)

**COURSE NUMBER AND TITLE:** QAT 135      Quality System Auditing

**UNIT VALUE:** 3

**MINIMUM NUMBER OF SEMESTER HOURS:** 48

**BASIC SKILLS REQUIREMENTS:** Appropriate language and computational skills.

**ENTRANCE REQUIREMENTS**

**PREREQUISITE:** None.

**COREQUISITE:** None.

**RECOMMENDED PREPARATION:** None.

**SCOPE OF COURSE:**

Introduction to the principles and practices of effective quality auditing. Necessary information, tools, and techniques will be provided to guide students with the development of skills and confidence to effectively conduct internal and external quality audits. Audit phases include planning, preparing, performing, reporting, and audit follow-up. Quality system audits are a vital tool for upper management which facilitates continuous improvement. A matrix of several quality system standards including ISO 9001 will be utilized extensively. CSU

**SPECIFIC COURSE OBJECTIVES:**

Successful students will be able to:

1. Explain the audit process to support work functions.
2. Apply oral and written communication tools required for successful auditing.
3. Explain required information to support the audit process.
4. Plan a successful internal or external audit.
5. Perform a successful internal or external audit.
6. Report on audit results and issue an audit report.
7. Demonstrate communication tools to upper management through the audit process.
8. Provide compliance to ISO 9001 Section 4.17 and the FDA QSR 820.22.
9. Explain basic statistical techniques to track and trend audit results.

## **CONTENT IN TERMS OF SPECIFIC BODY OF KNOWLEDGE:**

- I. Ethics, Professional Conduct, and Liability Issues
  - A. ASQ code of ethics
    - 1. Conflict of interest
    - 2. Confidentiality
  - B. Professional conduct and responsibility
    - 1. Auditor conduct
    - 2. Auditor responsibilities
    - 3. Discovery of illegal or unsafe conditions or activities
  - C. Liability issues
    - 1. Personal and corporate
    - 2. Audit record disclosure
  
- II. Audit Preparation
  - A. Audit definition and plan
    - 1. Identification of authority
      - a. Internal
      - b. External
    - 2. Determination of audit purpose
    - 3. Determination of audit type and scope
    - 4. Determination of resources required
    - 5. Team selection and identification of roles
    - 6. Requirements to audit against (standards, contracts, specifications, policies, and quality award criteria).
  - B. Audit Design
    - 1. Strategy
      - a. Tracing
      - b. Discovery
  - C. Documentation review and preparation
    - 1. Audit related document review
    - 2. Auditee's performance history review
    - 3. Preparation of audit checklists, guidelines, and log sheets
  - D. Communication and distribution of the audit plan
  
- III. Audit Performance
  - A. Audit management
    - 1. Audit team management
    - 2. Communication of audit status to auditee
    - 3. Audit plan changes
      - a. schedule
      - b. priorities
  - B. Opening Meeting
    - 1. Presentation and review of the audit plan
    - 2. Confirmation of audit logistics
    - 3. Discussion of auditee concerns
  - C. Data Collection
    - 1. Document/Record Examination
    - 2. Interviews
    - 3. Physical examination
    - 4. Conversation of work activities

- D. Audit working papers
  - 1. Documentation of the audit trail
    - a. checklists
    - b. supporting evidence
  - 2. Record of observations
- E. Audit Analysis
  - 1. Corroboration and objectivity of evidence
  - 2. Data patterns and trends
    - a. repeat observations
    - b. systematic problems
  - 3. Classification of observations
  - 4. Classification of non-compliance
  - 5. Conclusion
- F. Exit meeting
  - 1. Presentation of audit results
  - 2. Discussion of follow-up actions
  - 3. Expectation of the auditee, auditor, client

#### IV. Audit Reporting

- A. Review and finalize audit results
- B. Written report format and content
  - 1. Audit details
    - a. purpose
    - b. team members
  - 2. Compliance
  - 3. System effectiveness
  - 4. Conclusions to be reported
  - 5. Request for corrective action
- C. Issue written report
  - 1. Obtain approvals
  - 2. Distribution of report
- D. Audit record retention

#### V. Corrective Action and Follow-up and Closure

- A. Corrective action follow-up
  - 1. Criteria for acceptable corrective action plans
    - a. Preventive
    - b. Assigned
    - c. Responsibilities
    - d. Timeline
  - 2. Acceptability of proposed corrective action
  - 3. Negotiation of corrective action plans
  - 4. Methods for verifying corrective action
  - 5. Follow-up audit schedule, as required
  - 6. Verification of corrective action completion
  - 7. Effectiveness of corrective action
  - 8. Strategies when corrective action is not implemented or is not effective
- B. Closure
  - 1. Criteria for closure
  - 2. Timeliness

## VI. Audit Program Management

### A. Administration

1. Audit program objectives
2. Identification and justification of resource requirements
3. Management's relationship to the audit function
4. Credibility of the audit function
5. Linkage to business performance
6. Linkage to continuous improvement
7. Evaluation of audit program effectiveness
8. Summary of audit program results for review
9. Long-term audit planning

### B. Process

1. Development and implementation of audit program procedures
2. Development and implementation of audit program schedule
3. Audit record keeping requirements

### C. Audit personnel

1. Qualifications
2. Selection
3. Training
4. Performance Evaluation

## VII. General Knowledge and Skills

### A. Audit basics

1. Quality concepts, terms, and definitions
2. Theories and practices in quality auditing
3. Benefits and consequences of audits
4. Roles and responsibilities of the auditor, auditee, and client
5. Characteristics of system, process, and product audits
6. Characteristics of internal and external audits
7. Characteristics of first, second, and third party audits
8. Characteristics of qualitative and quantitative analysis

### B. Basic skills

1. Time management skills
2. Conflict resolution
3. Effective communication techniques
4. Presentation methods and techniques

### C. Tools and techniques

1. Checklists, guidelines, log sheets
2. Sampling theory, procedures, and applications
3. Flow charts and process mapping
4. Pattern and trend analysis
5. Root cause analysis
6. Cause and effect diagrams
7. Pareto charts
8. Histograms
9. Descriptive statistics
10. Control chart interpretation
11. Process capability (Cp, Cpk) interpretation

**REQUIRED READING:**

Milford, Doreen. A Matrix of Standards for ISO 9001, EN 46001, QSR, Drug GMPs and GLP. San Marcos, CA: Palomar College Mailroom, 1998.

Wortman, Bill. CQA Primer. West Terre Haute, IN: Quality Council of Indiana, 1997.

**SUGGESTED READING:**

Any additional auditing books published by the ASQ Quality Press.

**REQUIRED WRITING:**

Audit plans, audit reports, and corrective action requests each of at least two pages in length.

**OUTSIDE ASSIGNMENTS:**

**Students are expected to spend a minimum of three hours per unit per week in class and on outside assignments, prorated for short-term classes.**

Read required text, study lecture notes, complete written assignments.

**INSTRUCTIONAL METHODOLOGY:****Check all that apply:**

- lecture
- laboratory
- lecture-laboratory combination
- directed study

**DISTANCE LEARNING:**

**This course may be offered as a distance learning course and meets Title 5 regulations 55370, 55372, 55374, 55376, 55378, and 55380.**

Yes  No

**If yes, check all that apply:**

- Television Course (Video one-way, e.g. ITV, video cassette, etc.)
- Online Course (Text one-way, e.g. newspaper, correspondence, electronic file, etc.)
- Two-Way Video Conferencing (Two-way interactive video and audio)
- One-Way Video Conferencing (One-way interactive video and two-way interactive audio)
- Computer Assisted Instruction (A specialized form of mediated instruction relying primarily on student access to information and prepared lessons or teaching materials through a computer terminal, but not under immediate supervision of a qualified instructor.)

**GRADING POLICY AND STANDARDS** (include methods of determining whether the stated objectives have been met by students):

The course grading policy will be determined by individual instructors and may include the following:

- Exams
- Quizzes
- Research projects
- Writing assignments
- Classroom presentations
- Research papers
- Lab assignments
- Journal writing
- Classroom participation & discussion
- Homework

**IS COURSE REPEATABLE FOR REASON(S) OTHER THAN DEFICIENT GRADE?**

Yes \_\_\_\_ No X Number of times course may be taken for credit: 1

If yes, identify specific provision of Title 5 Division 2 section(s), 55761-55763 and 58161 which qualifies course as repeatable:

**CONTACT PERSON:** Director, Vocational Programs, Ext. 2286

**SIGNATURES ON FILE**