

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 130 Introduction to ISO 9000

**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:**

In-depth knowledge of quality system standards required for ISO 9000 Quality Management Systems. Participants will be provided the information, skills, and tools necessary to develop, implement, and monitor an ISO 9000 quality program. Students will participate in developing an ISO 9000 quality system manual that will address several quality system requirements. In addition, students will be introduced to the Harmonized European Standards required to CE Mark products for International sale in Europe. These European Standards include EN 46001 and the Medical Device Directive required for selling medical device products internationally. CSU

**SPECIFIC COURSE OBJECTIVES:**

Successful students will be able to:

1. Explain basic terms, definitions, processes of ISO 9000.
2. Evaluate ISO 9000 background, its documentation system, legalities, and accreditation process.
3. Describe the implementation process and minimal cost.
4. Explain certification process and registrars.
5. Prepare a quality system manual.
6. Prepare supporting procedures.
7. Discuss what the auditor will look for during the audit.

8. Compare requirements of audit systems such as CE Marking.

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

- I. ISO 9000 Background
  - A. What is ISO 9000?
  - B. Evolution of the ISO 9000 standards
  - C. Technical committee 176
  - D. European community
  - E. Legal system
  - F. Accreditation
  - G. ISO 9000 preparation and implementation
  - H. Certification process
  - I. Requirements
  - J. Quality system auditing
  - K. Documentation requirements
  - L. Records to be maintained
  - M. Assessment statistics
  - N. Pitfalls during certification
  - O. Benefits gained
  
- II. Quality Manual
  - A. General information
  - B. Documentation hierarchy
  - C. Purpose of the quality manual
  - D. Structure of the manual
  - E. Applications
  - F. Description of responsibility and authority
  - G. Elements of the quality manual
  
- III. Practice Writing A Quality Manual
  - A. Management responsibility
  - B. Quality system
  - C. Contract review
  - D. Design control
  - E. Document and data control
  - F. Purchasing
  - G. Control of customer-supplied products
  - H. Product identification and traceability
  - I. Process controls
  - J. Inspection and testing
  - K. Control of inspection, measuring, and test equipment
  - L. Inspection and test status
  - M. Control of nonconforming products
  - N. Corrective and prevention action
  - O. Holding, storage, packaging, preservation, and delivery
  - P. Control of quality system records
  - Q. Quality system auditing
  - R. Quality system training
  - S. Servicing
  - T. Statistical techniques

**REQUIRED READING:**

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

Wortman, Bill. ISO Primer. West Terre Haute, IN: Quality Council of Indiana, 1995.

**SUGGESTED READING:**

Any additional auditing books published by the ASQ Quality Press.

**REQUIRED WRITING:**

Prepare a quality manual and supporting procedures.

**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

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

Yes  No

If yes, check all that apply. (See guidelines for preparation for definitions.)

- telecourse
- mediated instruction
- computer assisted instruction

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

A = 100 - 90	Participation = 170 points
B = 89 - 80	Quizzes = 170 points
C = 79 - 70	Quality Manual = 120 points
D = 69 - 60	Mid-term exam = 100 points
F = below 60	Final exam = 100 points
	Total = 660 points

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

Yes  No  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:

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