

2023 CCE Written Exam Review Webinar Series

August 9, 2023, through October 11, 2023

Session #6: General Management

September 13, 2023

Chris Riha, MS, CCE, CSEP PMP, ITILv3 Foundation, CISSP, PSM, HCISSP, CPHIMS, Security+
cdriha@crihaconsulting.com

About the host/moderator



Daisha J. King

Daisha King joined the VA Healthcare Technology Management Program Office at the start of the year as the Director of the newly formed Medical Technology Division.

Prior to joining the HTM Program Office, she was a Biomedical Engineer in the Pacific Northwest Region for the VISN 20 Office. Originally from Minnesota, she now resides outside of Jackson Hole, Wyoming.

Logistics

- ❖ All attendees have their microphones muted during the presentation.
- ❖ Questions to the faculty must be submitted via the “Q&A” feature in Zoom at any time. They will be addressed at the Q&A portion.
- ❖ If there is any urgent issue, please use the “chat” feature to communicate with the host/moderator.
- ❖ Please remember to complete the webinar evaluation after attending. A link will be provided at the end.

About the faculty

Chris Riha, MS, CSEP, PMP, CISSP, CCE

Chris Riha has been a Certified Clinical Engineer since 1998. Chris is currently employed at Dexcom as their Sr Cybersecurity Analyst on the Hospital Team, as well as guest lecturer at Virginia Tech University in the Biomedical Engineering Department.

Prior to his work at Dexcom Chris worked as the Lead Health System Engineer at MITRE, and as an independent consultant for 4 years, providing Clinical Engineering, Cybersecurity and Project/Program Management expertise to a wide variety of clients.

Mr. Riha also had a 14 year tenure Carilion Clinic. He was responsible for managing up to 70 FTE's in a dynamic and mission critical environment, reporting to the 'C' suite and clinical leaders of the organization. His responsibilities at Carilion included management of the Clinical Engineering Department, as well as application support for all clinical, and business applications, for a \$1.2B healthcare delivery organization.

In addition to his CCE certification, Chris has also earned : CSEP (Certified Systems Engineering Professional), CISSP (Certified Information Security Specialist Professional), Security+, ITILv3 Foundation, CCE (Certified Clinical Engineer), as well as PSM (Professional Scrum Master), Health Care Information Security and Privacy Professional (HCISSP) and PMP (Project Management Professional).



Disclaimer: The material and opinions presented in this course are those of Chris Riha

Learning Objectives

General Management

- Budget Development/Execution, Personnel, Management / Supervision, Staffing, Staff Skills / Competency Assessment, Policy/Procedure Management / Development, Performance Improvement / CQI, Business/Operation Plan Development/ Management, Committee Management, Other General Management Activities, Revenue Producing Activities

General Management: Budget Development/Execution

- Healthcare Delivery Organization Funding Streams
 - Government
 - Private Insurance (aka 3rd party)
 - Private Pay
- Clinical Engineering Funding Streams
 - For Profit
 - Cost Center in a Healthcare Delivery Organization
 - Fixed Cost vs Reimbursement for Services

General Management: Budget Development/Execution

- Operational
 - Labor expenses
 - Service/Maintenance Expenses
 - Training expense
 - Travel costs
 - Profit/Loss Statements
- Capital
 - Equipment Life Cycle Planning
 - New equipment/technology
 - Total Cost of Ownership

General Management: Personnel Management

- Administrative Processes
- Mentoring
 - Coaching
- Conflict Resolution
- Competency Assessment
- Skills Assessment
 - Training Requirements/Planning

General Management: Continual Quality Improvement (CQI)

- Deming Cycle

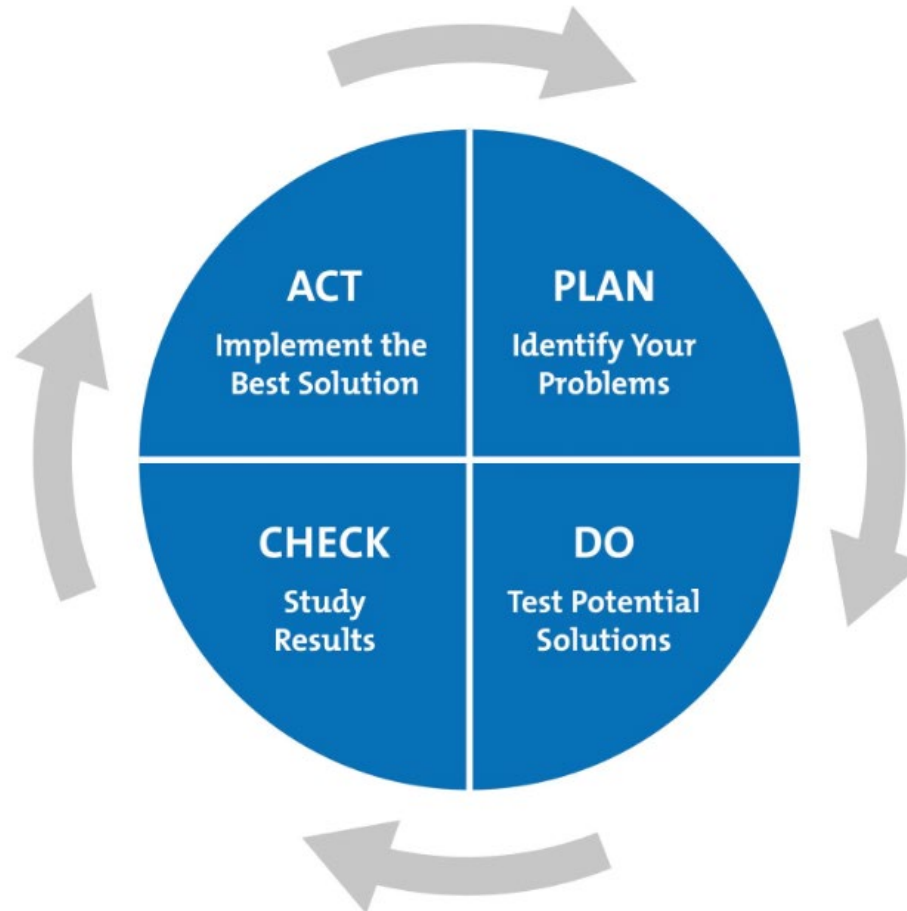


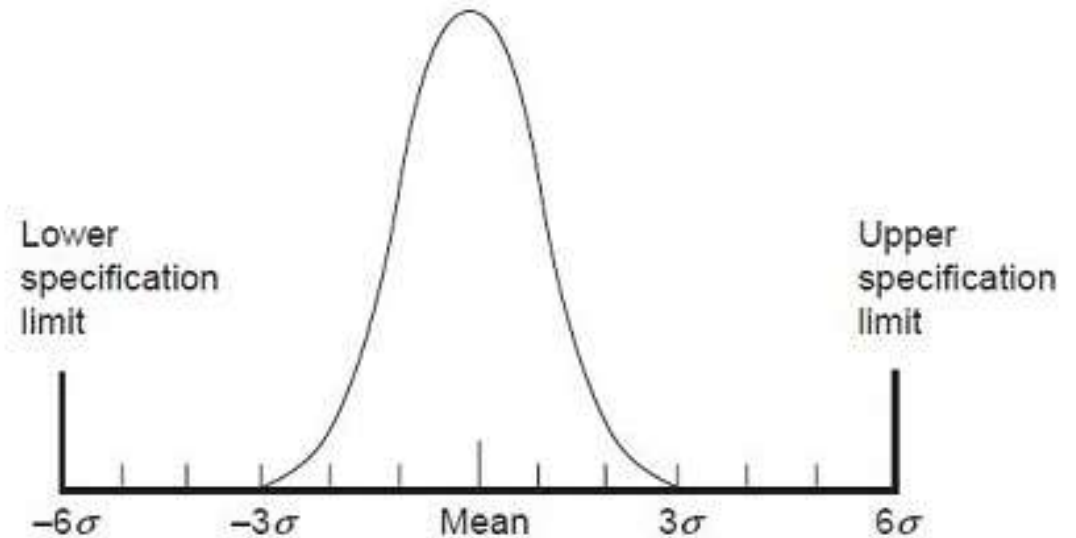
Image from Mind Tools

General Management: Continual Quality Improvement (CQI)

- ISO 9000 Series-Series of quality management standards for organizations.
- ISO 13485 -Quality Management standard for medical device manufacturers.

General Management: Continual Quality Improvement (CQI)

- Lean Six Sigma
 - Six Sigma
 - DMAIC
 - Control Charts
 - Process Mapping
 - Lean Six Sigma
 - FMEA
 - Hot Wash



Graphic and definitions from American Society of Quality Engineering,

General Management: Discussion Question

Continuous improvement of your department is a must in order to continue to adapt to the ever-changing landscape of healthcare. Which of the following processes listed below can help with this as a manager:

- A. Lean Six Sigma
- B. Communications with the front office
- C. Attending conferences
- D. Constant staffing changes to bring in new staff members better equipped with the current healthcare processes

General Management: Discussion Question

As a new manager of a clinical engineering department, you realize that one of your technicians has been falsifying PM records for some time. How do you as a clinical engineer handle the situation to hold this individual accountable for his actions?

General Management: Discussion Question

As a healthcare technology manager, the best way to approach the hiring process to help the growth of your department is:

General Management: Management Structures in Healthcare

- Functional structure
- Divisional structure (also known as multidivisional structure)
- Flatarchy structure (also known as horizontal, or flat, structure)
- Matrix structure

General Management: Clinical Engineering Staffing

- Common Metrics
 - Number of Beds per FTE
 - Number of Equipment Pieces per FTE
 - Total Acquisition Cost per FTE
 - FTE Calculator

'The FTE Calculator is the most accurate way to determine department FTEs. $FTE = (\text{number of pieces of medical equipment}) \times (\text{time needed for maintenance, service, repair of per device}) / (\text{hours available per FTE})$.' *

* Excerpt ACCE Clinical Engineering Certification Study Guide v9.0

General Management: Clinical Engineering Staffing

Example of Actual CE Department Metrics

	25th percentile	Sample HDO
BME Expense as % of Original Purchase Price	4.20%	2.60%
Total Expense per Bed Served	\$5,844.21	\$6,313
Total expense per CMI adjusted discharge	\$51.41	\$61.49
Hours Worked per 100 Devices Maintained	185.3	198
Labor Expense per 100 Devices Maintained	\$7,426.91	\$7,420.43

General Management: Clinical Engineering Staffing/Competency Assessment and Training

- Required annual training for all clinical personnel
- OEM vs 3rd Party Training
- Cross training of staff

General Management: Clinical Engineering Revenue Producing Activities

Considerations:

Corporate structure of organization

Liability

Impact of staffing

Travel time and expense

Business Plan Development P/L analysis

General Management: Clinical Engineering Committee Management

- Defined Charter or Scope
- Thoughtful and purpose selection of members and their respective roles
- Well managed meetings
- Well documented meetings
 - Agendas sent prior to meetings
 - Minutes or notes from meetings taken, distributed and archived

General Management: Clinical Engineering Committee Management Discussion Question

You are the clinical engineering manager at a large tertiary care hospital with an academic affiliate. You are charged with heading up a committee to evaluate and develop a plan for a Radiation Oncology Center of Excellence. In an effort to assemble the appropriate team, you form an integrated product team composed of: (please select the “best” fit)

- a. Executive Management Team Representative, Engineering, Clinical Engineering, Radiology Supervisor
- b. Executive Management Team Representative, Strategic Planner/ Capital Asset Manager, Radiation Oncologist, Medical Physicist, Clinical Engineering, Information Technology, Purchasing, Engineering, Dosimetrist
- c. Strategic Planner, Radiation Oncologist, Information Technology, Clinical Engineering
- d. None- No integrated product team is needed.

General Management: Clinical Engineering Committee Management Discussion Question

You are the clinical engineering manager at a large tertiary care hospital with an academic affiliate. You are charged with chairing the equipment committee. You notice that Medicine Service (the largest clinical service in the hospital) often misses out on capital purchases due to lack of attendance to meetings. You have reached out to the Medicine Service representative, their supervisor and executive leadership about the issue and the attendance of the service has not improved. What is the best course of action to take?

- a. Continue to contact the representative and ask them to attend.
- b. Remove the Medicine Service representative from the group- they are making it more difficult to reach a quorum.
- c. During the committee's annual review, make note of attendance and create an action/ suggestion to change the group's membership or for the service to appoint multiple representatives.
- d. Take no action.

General Management: Clinical Engineering Business/Operational Plan Development/Management

Core Components of Business Plan Development

- Medical Equipment Management Plan
- Accurate Inventory including software network connectivity
- Medical Equipment maintenance history
- Staff training and competencies (both internal and end user)
- Medical Equipment Life Cycle Analysis
- Cybersecurity
- Contract management

General Management: Clinical Engineering Business/Operational Plan Development/Management

Discussion Question

You are the clinical engineering manager in a large tertiary care teaching hospital. You currently are not responsible for the repair and maintenance of any imaging equipment. You are asked to evaluate whether or not to start up an in-house imaging services program in the next 90 days. Which of the following describes the best action plan for this task?

- a. Discuss with other Clinical Engineering managers who have done this in the past, interview radiology maintenance person, estimate costs
- b. Develop a business plan
- c. Hire one of the imaging equipment manufacturers to assess the equipment and based on their assessment write a business plan.
- d. Inventory equipment, collect cost information (contracts, fee-for-service etc), determine availability of personnel and estimate labor and parts costs, perform a cost analysis (preliminary information that could later be turned into a business plan)

General Management: Clinical Engineering Policy/Procedure Management/Development

Definitions:

Policies: Guidelines or laws that drive the Processes and Procedures.

Processes: High-level view or map of the tasks to be performed.

Procedures: Detailed steps required to perform an activity within a process.

Reference Material

Personnel Management:

<https://www.perkbox.com/uk/platform/recognition/people-management-skills-to-thrive-as-a-manager>

Crucial Conversations, by Joseph Grenny, Kerry Patterson, Ron McMillan, Al Switzler, Emily Gregory

Quality Management:

ISO 9000 Series: <https://www.iso-9001-checklist.co.uk/ISO-9000-vs-ISO-9001-whats-the-difference.htm>

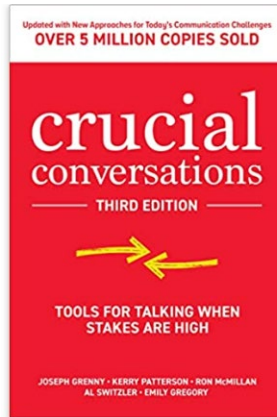
ISO 13485: <https://www.iso-9001-checklist.co.uk/ISO-9000-vs-ISO-9001-whats-the-difference.htm>

Meeting Management:

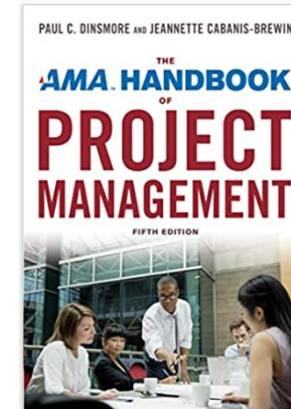
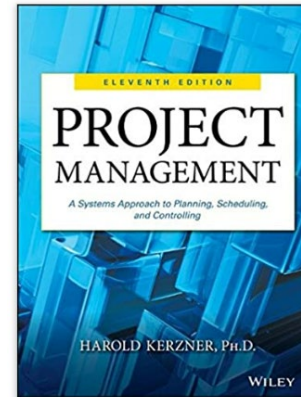
<https://www.ala.org/yalsa/aboutyalsa/yalsahandbook/effectivecommittees>

Reference Material

Personnel Management:



Project Management:



Quality Management:

ISO 9000 Series


ISO 9001 CHECKLIST Help | Contact Us View Cart

Home | Products | Checklists | Gap Analysis | Internal Audit | Templates | Quality Manuals | Integrated Management Systems Free Download

ISO 9000 Vs ISO 9001 - What's The Difference

When it comes to owning and operating a business, ISO 9001 certification is usually something that is very sought after. With this stamp of approval, so to speak, it is confirmed that your company upholds and maintains a certain quality standard. However, not many people are as well-versed in ISO 9000.

Written: 27th July 2019
Author: Richard Keen



Richard Keen
Richard is our Compliance Director, responsible for content & product development.
But most importantly he is ISO's biggest fanboy and a true evangelist of the standards.
[Learn more about Richard](#)

What is the difference between ISO 9000 and 9001? The difference between ISO 9000 and ISO 9001 is very simple. While ISO 9000 is technically an entire family of standards, inclusive of ISO 9001, there is an additional standard called ISO 9000 that defines all of the terminology used within the category.

ISO 9001, on the other hand, is an individual standard with a specific set of regulations that are laid out within a series of clauses. Detailed processes including gap analysis and internal audits must be conducted while using ISO 9001 in order to maintain the quality management system.

ISO 9001 certification has become a staple in all kinds of businesses all around the world, regardless of the personnel size or the industry in question. This is due to the fact that business owners, employees, management, and customers all benefit from the well-oiled machine that is a certified business.

ISO 13485

ISO 9001 CHECKLIST Help | Contact Us View Cart

Home | Products | Checklists | Gap Analysis | Internal Audit | Templates | Quality Manuals | Integrated Management Systems Free Download

5 Real Differences Between ISO 9001 and ISO 13485

ISO 9001 and ISO 13485 are ranges of standards that address different aspects of quality management within a family of terms called ISO 9000. The goal is to organize the internal rules of the business to ensure the best possible customer satisfaction and product production.

Written: 26th July 2019
Author: Richard Keen



Richard Keen
Richard is our Compliance Director, responsible for content & product development.
But most importantly he is ISO's biggest fanboy and a true evangelist of the standards.

What are the differences between ISO 9001 and ISO 13485? The differences between ISO 900 and 13485 is that ISO 9001 is an international standard for a quality management system. ISO 9001 standard is used to install the best possible format when ensuring consumer satisfaction with products and services.

On the other hand, ISO 13485 is the standard for a medical device quality management system. It was the only system that did not receive the 2015 update of ISO 9001. But, many do believe ISO 13485 will be based on ISO 9001 in the near future.



Questions
&
Discussions

Thank
you



Please complete the evaluation form for session6 at:

<https://www.surveymonkey.com/r/2023-session6>

