2023 CCE Written Exam Review Webinar Series

August 9, 2023, through October 11, 2023

Session #9 Product Development & Facilities Management

October 4, 2023

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Disclaimer: The material and opinions presented in this course are those of Chris Riha and not of the MITRE Corporation

About the host/moderator

Ishtar Al-Tahir

Ishtar Al-Tahir is a Clinical Engineer working towards her Professional Engineering Certification (PEng.) at the Children's Hospital of Eastern Ontario (CHEO). She joined CHEO in the fall of 2022, however her Clinical Engineering career began at Service New Brunswick in early 2021. She has a Masters in Science in Electrical Engineering (MSc.EE) from the University of New Brunswick, where she defended her biomedical engineering research thesis at the Institute of Biomedical Engineering on myoelectric controlled prosthesis.

In her spare time, she enjoys reading, cooking, playing ultimate frisbee, and learning as much as possible about Clinical Engineering. She volunteers her time with the ACCE, the Clinical Engineering Society of Ontario, and is the publicity co-chair of the CMBEC46 conference. Her passions also lie with promoting engineering and STEM fields to women and youth. She always looks forward to meeting new people, especially if they show her pictures of their dog.

Logistics

❖**All attendees have their microphones muted during the presentation.**

❖**Questions to the panelists 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 panelists/host.**

❖**Please remember to complete the webinar evaluation after attending. A link will be provided at the end.**

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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).

Learning Objectives: Product Development-Facilities Management

- Regulatory Compliance Activities,
- New Product Testing & Evaluation
- Documentation Development/Management
- Device Modifications
- Medical Device Design
- Product Research and Development
- Facility Emergency Preparedness Activities
- Emergency Electrical Power
- Building Plan Review
- Medical Gas System Testing
- Building Design
- Facility/Utility Remediation Planning

Product Development-Applicable Standards

Product Development	Standard
Safe Integration of Medical Devices (references Open ICE)	AAMI/ANSI 2700
Medical devices-Applications of Risk Management to Medical Devices	ANSI/AAMI/ISO 14971
Medical Device Software Life Cycle Processes	AAMI SW68:2001
Software Lifecycle	ANSI/AAMI/IEC 62304
Classification of Defects in Healthcare	ANSI/AAMI SW91
Technical/Communication	**Standard**
Cabled Ethernet	IEEE 11073-30400
Wi-Fi	IEEE 11073-00101
Infrared	IEEE 11073-30300
Domain Information Model (DIM)	IEEE 11073-10201
Web Services	IEEE 11073-20702
Architecture and Protocol Binding (BICEP)	IEEE 11073-20701
Medical Electrical Equipment Package	IEC 60601-1 & 60601-1-2
Cybersecurity	UL 2900-1 &2900-2
Syntactic	**Standard**
Clinical Terminology	SNOMED CT
Observations	LOINC
API	FHIR
Hierarchical Health Information Message Structure	HL7 2.X
XML HL7	HL7 3
Units of measure	UCUM
Semantic	**Standard**
Nomenclature	IEEE 11073-10101

Regulatory Compliance: FDA Classifications

Class I- Lowest regulatory controls requiring 'general controls' which include 'good manufacturing processes'.
Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments
Class II- Middle tier regulatory requirements, which include all requirements for Class I plus post market surveillance.
Examples of Class II devices include acupuncture needles, powered wheelchairs, infusion pumps, air purifiers, N95 respirators
Class III- Most stringent requirement requiring a premarket approval known as a 510k. Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury.[1]
Examples of Class III devices that currently require a premarket notification include implantable pacemakers, pulse generators, HIV diagnostic tests, automated external defibrillators, and implants

Regulatory Compliance: FDA Medical Device Data Systems

MDDS Details:

1. A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:
    1. The electronic transfer of medical device data;
    2. The electronic storage of medical device data;
    3. The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
    4. The electronic display of medical device data.
2. An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

https://www.fda.gov/medical-devices/medical-device-data-systems/identifying-mdds

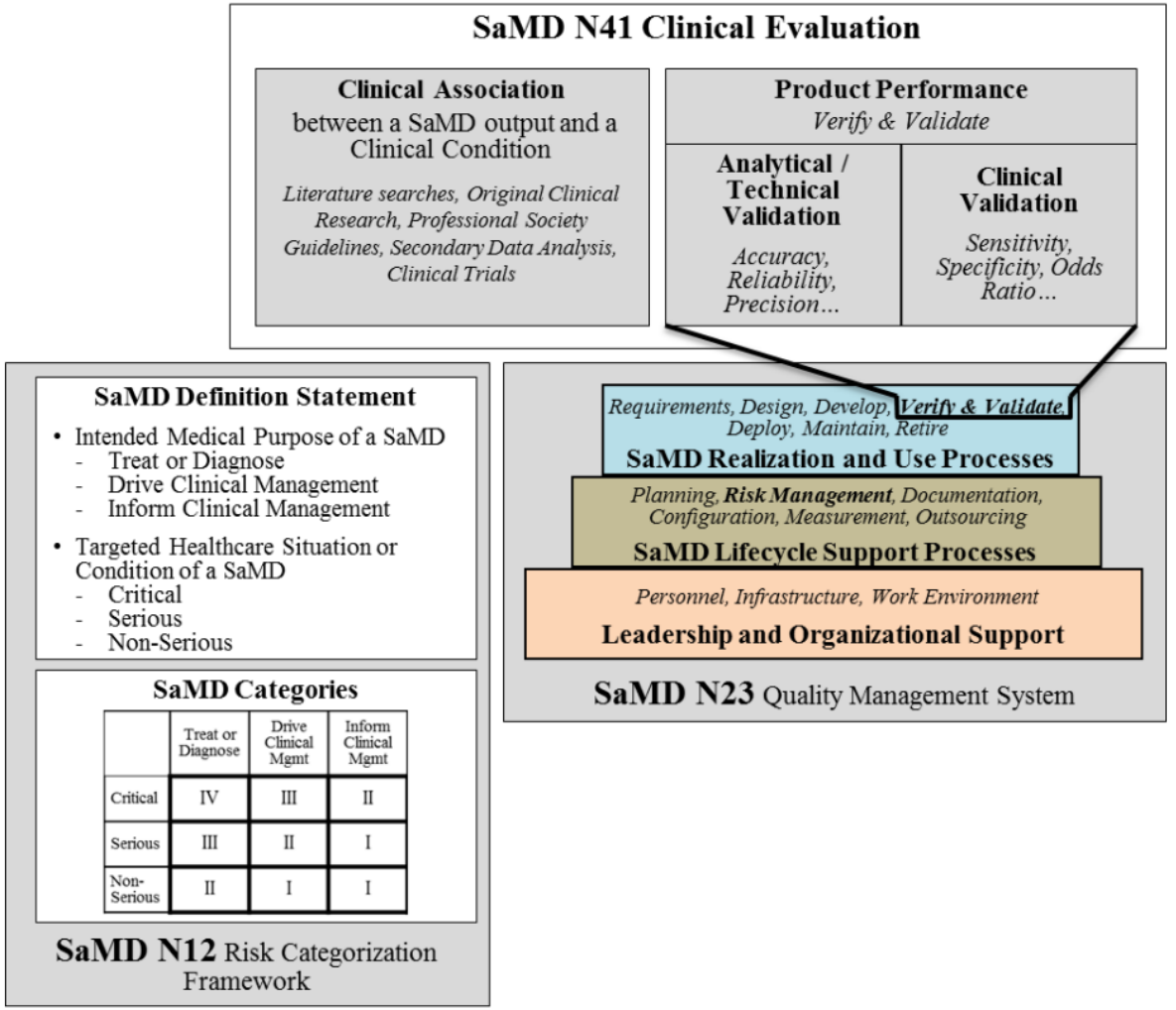
Regulatory Compliance: FDA De Novo Classification

‘The De Novo request provides a marketing pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. De Novo classification is a risk-based classification process.’*

*Excerpt from FDA website, https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request

Regulatory Compliance: FDA Software as a Medical Device (SAMD)

Risk Based Approach for managing software designed and intended for use in the treatment and diagnosis of diseases in healthcare.



Graphic from: Software as a Medical Device (SAMD): Clinical Evaluation - Guidance for Industry and Food and Drug Administration, https://www.fda.gov/media/100714/download

Regulatory Compliance: FDA New Product Testing and Evaluation

- Pre Market Notification 510(k) required for Class III
- Pre Market Testing requires submission of clinical data

  Investigational Device Exemption-Allows for the collection of clinical data for 510(k)
- Quality System Regulation (GMP)

  ISO 13485:2016 Medical devices

  Cybersecurity
- Documentation
  - Intended use
  - Operational
  - Technical

Regulatory Compliance: FDA Emergency Use Authorization

‘The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation’s public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.’*

*Excerpt from FDA website, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#infoMedDev

Regulatory Compliance: Review Question

Identify the item that is expected in a User's Manual.

a. Schematics
b. Required maintenance information
c. Alarm setting procedures
d. Pricing information

Regulatory Compliance: Review Question

Select the item that does NOT need to be reviewed for claims relative to the FDA clearance.

a. Product Development Plan
b. Service Manual
c. E-mail announcement to potential buyers
d. Instructions for Use

Facilities Management: Emergency Preparedness Considerations

- Emergency Power
- Medical Device Equipment Utilization
- Supply Chain challenges for consumables
- Medical Gases
- Staffing
- Continuity of clinical data flow

Facilities Management: Building Design Considerations

- Space
  - Structural
- Utilities
  - Electrical
  - HVAC
  - Telecom
- Integrated Systems
  - Network/WiFi
- Infection control
  - Airflow/Filtration

Facilities Management: Review Questions

Emergency Preparedness drills are required

a. Quarterly
b. Biannually
c. Semi-annually
d. Annually

Facilities Management: Review Questions

Which regulatory organization provides codes and standards on fire, electrical and life safety to the public in the US, related to the building process design?

a. NFPA
b. ASHE
c. JCAHO
d. OSHA

Facilities Management: Review Questions

According to the Compressed Gas Association, oxygen tanks in the US are to be painted

a. Green
b. Blue
c. Grey
d. Black

Facilities Management: Review Questions

In surgical areas, zone valves should be located:

a. At the end of the hall closest to the nurse's station.
b. Inside the operating room as close as practical to the anesthesia machine.
c. As near as possible to the fire alarm for the area.
d. Just outside the door of the operating room suite.

Facilities Management: Review Questions

The pressure for the oxygen delivered at the bedside outlet should be:

a. 95-100 psi
b. 75-80 psi
c. 50-55 psi
d. 35-40 psi

Facilities Management: Review Questions

The number of air changes to be used in isolation rooms, intended for patients with airborne diseases, should be higher than that used in common areas. The use of higher renewal rates aims to dilute the contaminant (microorganisms) with fresh air. The air change per hour (ACH) in these environments should be:

a. 6 ACH
b. 10 ACH
c. 12 ACH
d. 15 ACH

Facilities Management: Review Questions

What is the minimum number of oxygen outlets required per patient in a critical care environment?

a. 1
b. 2
c. 3
d. 4

Facilities Management: Review Questions

Legionellosis is an acute human infection caused by Legionella pneumophila, a fastidious gram-negative bacillus. Two types of infection occur. The first is the long-incubation, non-pneumonic form called Legionaries' disease. It occurs sporadically or in epidemic clusters and may be a fatal illness. The second is the short-incubation, non-pneumonic form termed Pontiac fever. Legionella can grow in many parts of building as, for example:

a. Hot and cold-water storage tanks, water heaters, water hammer arrestors, expansion tanks, water filters and electronic and manual faucets

b. Medical equipment (such as CPAP machines, hydrotherapy equipment, bronchoscopes)

c. HVAC humidification systems, cooling towers, filters, and air ducts

d. All of above

Facilities Management: Review Questions

The structure where patient services are located such as medical gases, electrical outlets, communication ports, monitors and other is called

a. Headboard
b. Side rails
c. Ceiling
d. Headwall

Reference Material

FDA/Compliance

https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

https://www.iso.org/iso-13485-medical-devices.html

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices

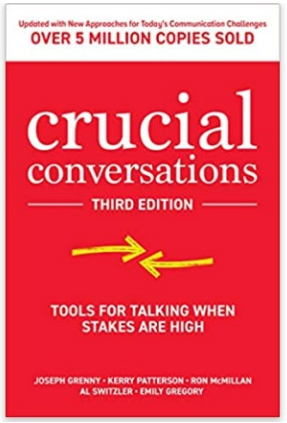
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#infoMedDev

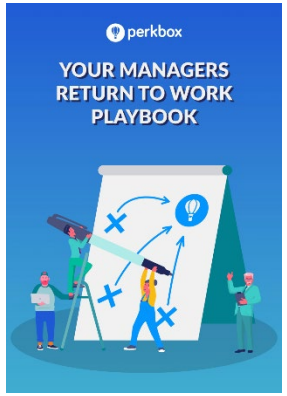
Facilities Management

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/General-Resources-for-Emergency-Preparedness.pdf

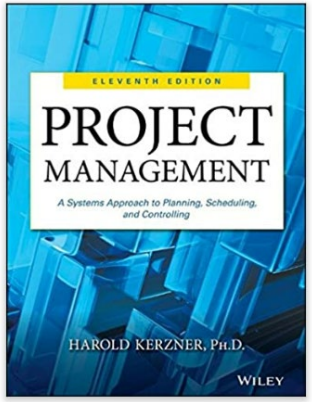
Reference Material

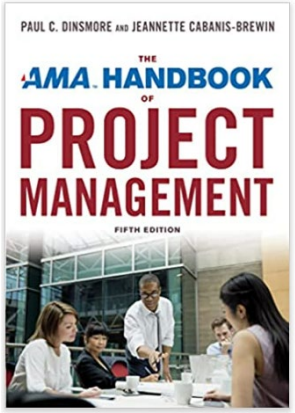
Personnel Management:





Project Management:

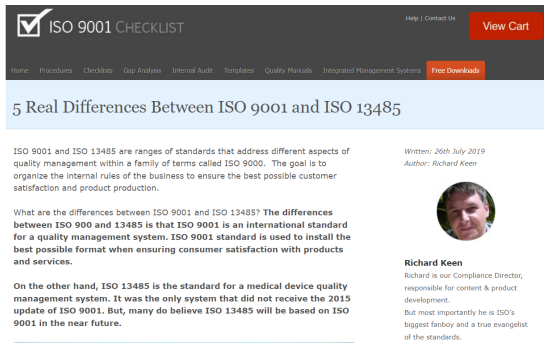




Quality Management:

ISO 9000 Series

ISO 13485



Questions & Discussions

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or scan the QR code: