ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

2023 CCE Written Exam Review Webinar Series

August 9, 2023, through October 11, 2023

Session #10: Risk Management / Safety

October 11, 2023

Alan Lipschultz, PE, CSP, CPPS, CCE, FACCE, AAMIF
Alan@hctc.pro

About the host/moderator

Jeff Hooper

Jeff Hooper, PhD is the Senior Manager of Medical Device Security at Children's National Hospital in Washington DC. He is an adjunct professor and lectures at the Catholic University of America in the biomedical engineering division.

In addition, he is on the Advisory Board for the school of biomedical engineering at The University of the District of Columbia. Jeff has over 35 years of experience in healthcare technology management.

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.

Alan Lipschultz, PE, CCE, CSP, AAMIF, FACCE

About the Faculty

- Alan Lipschultz is President of HealthCare Technology Consulting based in Maryland, primarily consulting as an expert witness in legal cases. He is a registered Professional Engineer (PE), Certified in Clinical Engineering (CCE), Certified Safety Professional (CSP), Certified Professional in Patient Safety (CPPS), Fellow in the American College of Clinical Engineering (FACCE), and an AAMI Fellow.

- From 1989 to 2011, Alan was the director of Clinical Engineering @ Christiana Care Heath System in Delaware. He received his Master's Degree in Health Care Technology from Washington University, St. Louis in 1973

Learning Objectives

Risk Management / Safety

Patient Safety, Product Safety / Hazard Alerts / Recalls, Incident / Untoward Event Investigation, Engineering Assessment of Medical Device Failures, Risk Management, Root Cause Analysis, Medical Device Incident Reporting (SMDA), Infection Control, Failure Mode and Effect Analysis, Workplace Safety Practices (OSHA), Fire Protection/Safety (Life Safety Code), Radiation Safety, Hazardous Materials, Industrial Hygiene, Other Risk Management / Safety Responsibilities, Expert Witness, Forensic Investigations

Risk Management Terms

Definitions – From ANSI/AAMI/ISO 14971-2007(R)2010 Application of risk management to medical devices

----

- **Harm -** physical injury or damage to the health of people, or damage to property or the environment
- **Hazard -** potential source of harm
- **Residual risk -** risk remaining after risk control measures have been taken
- **Risk -** combination of the probability of occurrence of harm and the severity of that harm
- **Risk management -** systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk
- **Severity -** measure of the possible consequences of a hazard
- **Use error -** act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user

“Use Error” versus “User Error”

- Also called slips, lapses, or mistakes
- “Use Error” doesn’t assign blame.
  - Human Factors
  - Distractions
  - Inadequate design, labeling and/or training
- Definition of “Use Error” = *“an act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user.”*
- AAMI Technical Information Report (TIR50) “Post-market Surveillance of Use Error Management”

“No Problem Found” (NPF) workorders

- CE often gets devices sent to them & CE unable to replicate the problem
- I wrote a BI&T article about NPF WO being an opportunity for CE
- NPF is frequently associated with “Use Error”, but don’t assume that is true
- Was problem reported by “the person who had problem” or another person?
- If discussing the NPF finding, tell clinical staff member who had problem, you are “*unable to reproduce*” the reported problem; this may lead to more detail about the “real” problem.
- Disposables, cables, or other connected devices may be the “real” problem
- Anything changed in environment?
- Intermittent problem (IP)? Watch for reoccurrence. Document as much detail as you can; CE needs to try and connect the dots the next time(s).
- Involve Clinical Educators or Clinical Managers, especially if an IP or possible Use Error

FDA – MAUDE

Manufacturer and User Facility Device Experience

- (MAUDE) – FDA database acronym
- Safe Medical Device Act (SMDA)
- Medical Device Reports (MDR) feed into MAUDE
- Med device manufacturer (or device importers) – mandatory MDR reporting of all device complaints to FDA
- Device user facilities – mandatory MDR to manufacturer and/or FDA
- MAUDE also includes reports from importers, distributors; and voluntary reporters such as health care professionals, patients and consumers.

Device User Facility Reports

LAW: Code of Federal Regulations (21 CFR Part 803) MEDICAL DEVICE REPORTING

Device User Facilities: a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician's office, as defined in this section. School nurse offices and employee health units are not device user facilities.

Device User facilities must report a suspected medical device-related death to both the FDA and the manufacturer.

User facilities must report a medical device-related "*Serious injury*" to the manufacturer, or to the FDA if the medical device manufacturer is unknown.

User facilities must file an annual summary report

Definition – Serious Injury FDA link cited on prior page, section (w)

Serious injury means an injury or illness that:

(1) Is life-threatening,

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

If you are a device user facility, you are considered to have "become aware" when medical personnel, as defined in this section, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event.

Summary of Mandatory Reporting Requirements for User Facilities

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Device-related Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	Form FDA 3500A	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	Form FDA 3419	FDA	January 1 for the preceding year

From: FDA's "Medical Device Reporting for User Facilities" guidance document

Search MAUDE database (hyperlink)

Spellings must be EXACT! This considered "Advanced Search"

Search Database

Help Download Files

Product Problem

Product Class

Event Type

Manufacturer

Model Number

Report Number

Brand Name: HEARTSTART

Product Code

Date Report Received by FDA *(mm/dd/yyyy)*: 02/01/2022 to 02/28/2022

Go to Simple Search | 10 Records per Report Page | Clear Form | Search

MAUDE database – Advanced Search

1 2 3 4 5 6 7 8 9 10 >

306 records meeting your search criteria returned- **Brand Name:** *HEARTSTART* **Report Date From:** *02/01/2022* **Report Date To:** *02/28/2022*

New Search

Export to Excel | Help

Manufacturer	Brand Name	Date Report Received
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/27/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/27/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/27/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART XL+ DEFIBRILLATOR/MONITOR	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART XL+ DEFIBRILLATOR/MONITOR	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX -EMS DEFIBRILLATOR	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART XL+ DEFIBRILLATOR/MONITOR	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX -EMS DEFIBRILLATOR	02/25/2022

Each of these records is a hyperlink to the full MDR

MAUDE search for “HEARTSTART” in “Brand Name” field – 306 records

NOTE: <u>MAX 500 records</u>. If search was for “MRX” or “Heart”, no records would have shown!

MAUDE database – Advanced Search

1 2 3 4 5 6 7 8 9 10 >

306 records meeting your search criteria returned- **Brand Name:** *HEARTSTART* **Report Date From:** *02/01/2022* **Report Dat To:**

New Search

Export to Excel | Help

Manufacturer	Brand Name	Date Report Received
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/27/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/27/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/27/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART XL+ DEFIBRILLATOR/MONITOR	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART XL+ DEFIBRILLATOR/MONITOR	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX -EMS DEFIBRILLATOR	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX MONITOR/DEFIB	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART XL+ DEFIBRILLATOR/MONITOR	02/25/2022
PHILIPS NORTH AMERICA LLC	HEARTSTART MRX -EMS DEFIBRILLATOR	02/25/2022

Link to "EXPORT" all records to Excel (actually "csv" file)

NOTE: In Excel, every column header is a field name.
After editing the file, don't forget to save it in .XLS format

MAUDE database – “Simple Search”

Search Database

Help Download Files

Product Problem

Product Class

Event Type

Manufacturer

Model Number

Report Number

Brand Name

Product Code

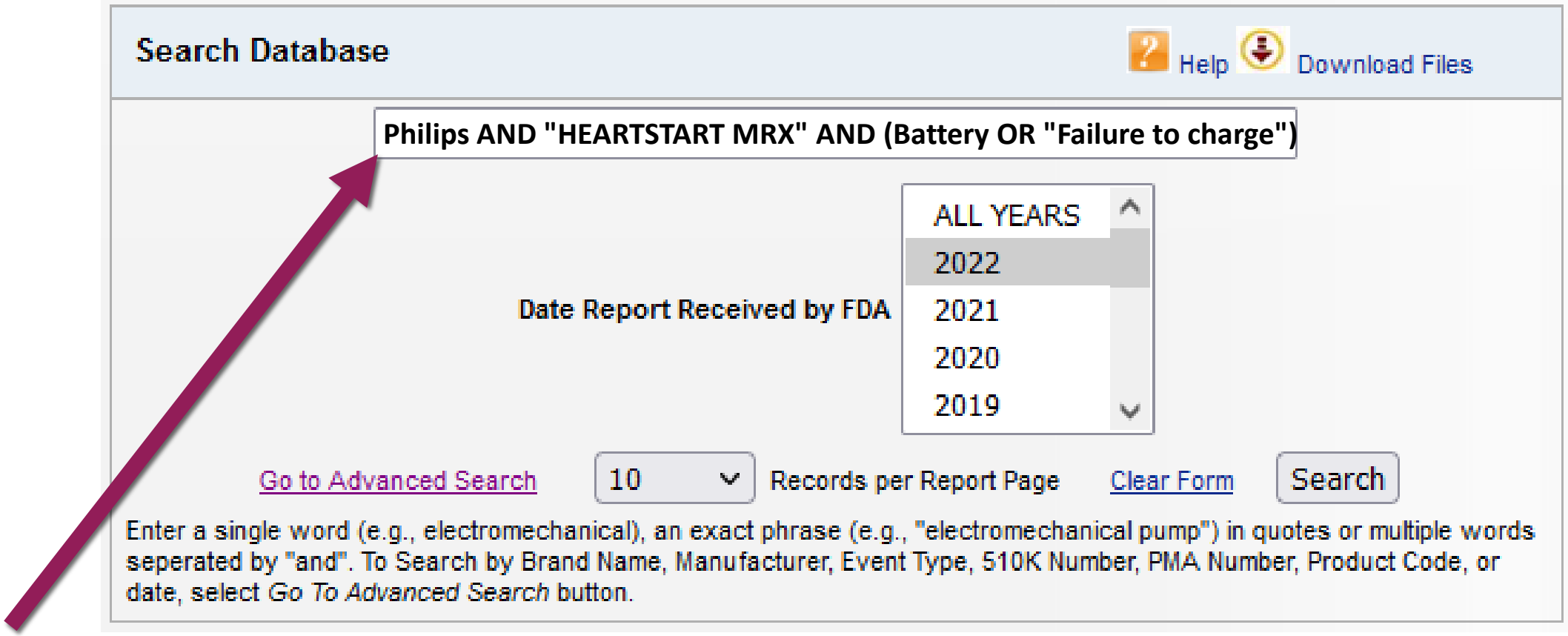
Date Report Received by FDA *(mm/dd/yyyy)* 02/01/2022 to 02/28/2022

Go to Simple Search 10 Records per Report Page Clear Form Search

Product Code Database hyperlink

Hyperlink: “Go to Simple Search”

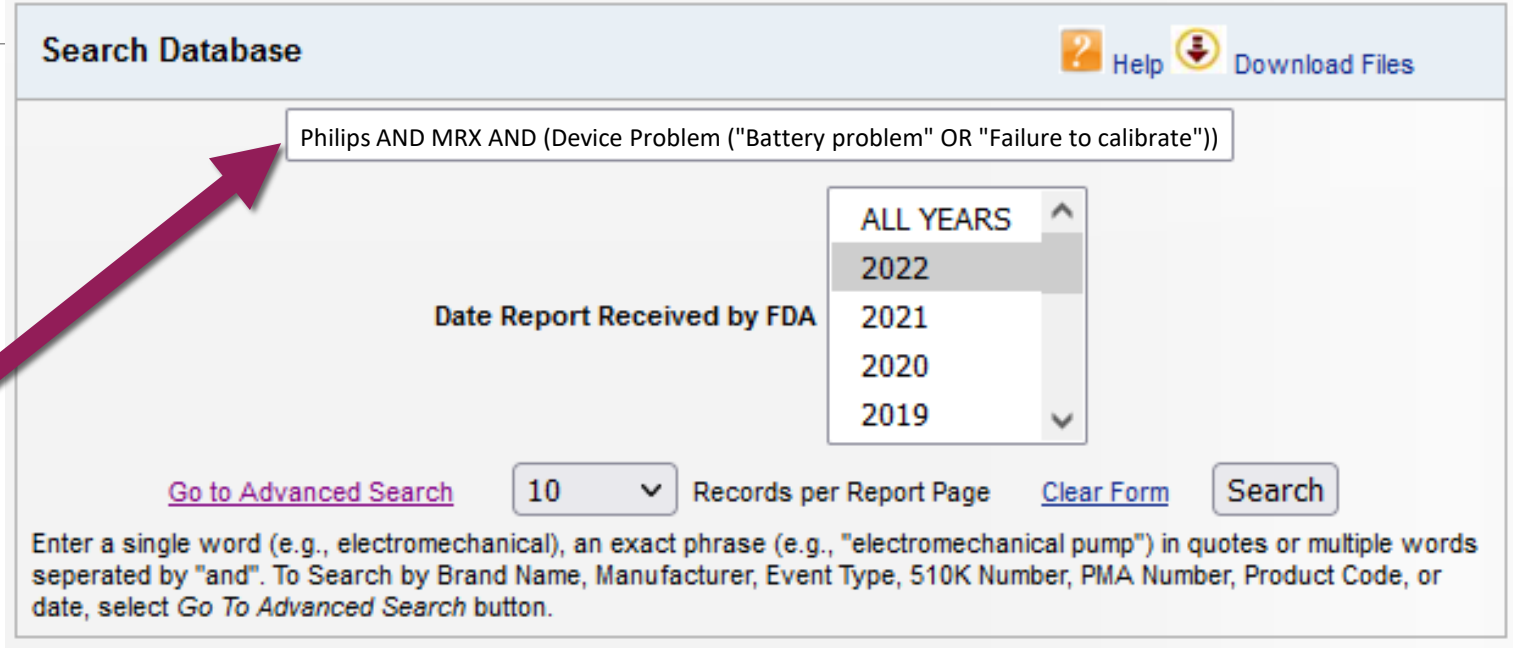
MAUDE database – Simple BOOLEAN Search



Philips AND "HEARTSTART MRX" AND (Battery OR "Failure to charge")

Quotation marks indicate an exact phrase. Lower or upper case okay here.

MAUDE database – Simple Search #2



- Philips AND MRX AND (Device Problem ("Battery problem" OR "Failure to calibrate")) Note: “Device Problem” is a field name.
- There are many more search options ! Still 500 records MAX.

FDA MEDSUN reporting system

The Medical Product Safety Network (MedSun) is a partnership between volunteer Clinical Sites and FDA's CDRH to serve as a powerful two-way channel of communication. Once a problem is identified, FDA MedSun researchers work with each facility's representatives to clarify and understand the problem. Reports and lessons learned are shared with the clinical community and the public, without facility and patient identification, so that clinicians nationwide may take necessary preventive actions.

Medsun search interface is similar to MAUDE

CE & Risk Management - Intersection

CE & Risk Management should have a contract as to roles & expectations

- Device Recalls
- Device Tracking/Reporting (SMDA)
- Incident Investigations
- Medical Technology risks (MRI, laser, anesthesia, radiation, infection control, etc.)
- Alternate parts (have you qualified vendors?)
- Network security, and devices on the network
- Disposal of used equipment

Your own HCO's event reporting system

- Usually Risk Management is in charge
- Clinical staff should get clear message that more reports are "good"
- It should be very easy for clinicians to file an event report.
- Clinicians entering a report should answer a Y/N for "medical device potentially involved"?
- CE should receive an automatic notification for the subset where answer is "Y"

Incident / Untoward Event Investigation

What % of events in your organization do you know about?

Despite the existence of incident reporting systems, hospital staff did not report most events that harmed Medicare beneficiaries. (based on a 2012 HHS Medicare study)

- Of the events experienced by a national sample of beneficiaries discharged in October 2008, hospital incident reporting systems captured only an estimated 14 percent of events (86% not reported).
- Staff did not perceive them as reportable
- Why? No perceptible error occurred (62% of all events); or they commonly reported, but not this case (25%)

Patient Safety

- ACCE Certification Study Guide p152 *(pdf 157)* – info not in this presentation
- Patient Safety should be written into CE group's Mission Statement
- CE Staff members should be focused on patient safety
- Does CE staff know response to device related events?
- Has CE staff been trained on how to communication with care providers regarding problems (e.g. possible Use Error?)
- Know the Patient Safety Officer (PSO) in your organization (build bridges)
- Certified Professional in Patient Safety (CPPS) *I have this certification*.

Definition:
Adverse Patient Event & Device Related Event

Definitions – from BI&T article "Adverse Patient Events Involving Medical Devices"

- **Adverse Patient Event (APE):** An unanticipated event that causes harm to a patient arising from any aspect of healthcare management.
- **Device Related Event (DRE):** An APE that involves a medical device(s).

Definition – Near Miss Event

From same article

Near-Miss Event (NME): Events that are sufficiently clear precursors of adverse events to point the way to identification of specific individual and systems failures. NME are much more common than Adverse Patient Events and thus represent a much greater opportunity for organizations to improve safety, by preventing future events.

- **Close Call** (TJC's similar term): Used to describe any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome.

AHRQ reference: **Adverse Events, Near Misses, and Errors**

3 Categories of DRE or NME

For each, how will they be coded in CMMS?

1. Device clearly involved
   - Defibrillator/AED fails to operate in crisis
   - Overhead patient lift falls apart, while tranferring
   - Ventilator “quits” while on a patient
2. Not clear if Device directly or indirectly involved
   - Patient is hooked to monitor/dialysis machine/ventilator; patient is harmed or dies unexpectedly
   - Electrosurgical Unit in use; patient is “burned” during surgery
3. Maintenance (or lack of) may have had a role

Patient Safety – ADE and NME

- Any one of us, or our family/friends could be (will be) a patient.
- Every Adverse Device Event (ADE) and Near Miss Event (NME) represents an opportunity to improve patient safety by preventing a future event.
- For every ADE, but particularly when there is a serious adverse event, we owe it to everyone involved to get the maximum amount of learning.
- Share that learning with others within your organization and beyond
- Learn from others, before their ADE gets repeated on your patients.

After an ADE ….

Think Before Investigating/Testing

- Natural instinct is to figure out what went wrong
- Risk Management – ADE vs NME vs Serious Injury or Death
- Investigation/testing may alter the evidence
- Delay may be more appropriate
  - May allow better understanding, beyond initial report
  - Maybe appropriate to have others participate
    - Manufacturer (or representative)
    - Neutral party (e.g. consultant, ECRI)
  - CE may have a conflict of interest (e.g. recent repair)
  - Often minimal disadvantage to a delay

ADE - Investigation Basics

- Preserving Evidence
  - Good quality photography or video (ideally at scene of event)
  - Disposables including packaging
  - Control Settings (don’t change unless necessary for patient safety)
  - Electronic records – all logs that can be downloaded
  - Moving/processing/cleaning may change evidence
  - Sequestration until device has been tested
- After testing, return device to service?
  - Maybe an Intermittent Problem?
  - Decision tree for CE staff

ADE - Investigation Basics

Excellent Resource from Agency for Healthcare Research and Quality (AHRQ), entitled System-Focused Event Investigation and Analysis Guide

Always consider the system! Serious ADEs are never simple. There is often a "system" issue, even if event "cause" seems simple.

Advantages of Manufacturer Participation in Inspection/Testing

- You have a SMDA responsibility to report ADE to the manufacturer anyhow
- Manufacturer is responsible for reporting ADE to FDA and issuing a recall/alert if necessary
- Manufacturer should take ADE seriously and should know the product best. They may know of similar events
- When no injury or litigation likely (NME), maybe okay to return device to manufacturer (after internal testing).

After an ADE -
Device to be sent to Manufacturer?
Probably not if Serious Adverse Event

- What if you don't "own" the ADE device?
- Phone company first. Make sure you have right address.
- Get Return Material Authorization (RMA) number or some internal tracking identifier.
  - Event device may be simply "fixed" with no special testing when it gets to company
  - Manufacturer may suggest some testing before shipping. Ask manufacturer what accessories should be sent.
  - If possible, download logs prior to shipping
- Send a cover letter with shipment
- Use a carrier with tracking number
- Clarify - Will manufacturer call you after testing? Fix? Dispose of?

Staff Interviews – Qualitative Data

- Have agreement with Risk Management to define when appropriate for CE to interview clinical staff, without consulting Risk Management
- For NME, or minor injury, probably CE should not hesitate to interview
- For serious adverse event, normally CE should not interview
- If CE had a direct role in event, CE staff may be subject of interview

Staff Interviews – Qualitative Data

If Serious Adverse Event, talk to Risk Management first

- Prepare list of questions relevant to event.
- Don't lead interviewee. Let staff tell their story first without interrupting. Ask open ended questions (e.g. What happened next?)
- If possible, ask staff to demonstrate or show what they did leading up to and after event
- Ask about environmental factors, what was different this time, who else may have witnessed event, unusual noises/smells
- Don't be biased by first or last interviewee
- Document interviews soon after interview

Multiple Causes for a ADE - Points to consider

Most ADE have multiple causes. These tools require an interdisciplinary team to be effective.

- Failure Modes & Effects Analysis (FMEA)
- Root Cause Analysis (RCA)
- Fishbone diagrams
- Flow diagrams

What if you suspect that event may have been caused (primarily or secondarily) by:

- Service (or lack of service) by CE team or outside service vendor? What if CE is out sourced?
- Sabotage?
- Faulty part after service group “substituted” instead of a non-OEM part?
- Operator error or inadequate training?
- Design flaw?
- Human factors? Design flaw?
- Interaction with product from another vendor (e.g. disposables or data interface)?

Discuss these scenarios within your own organization

Evidence Preservation & Storage for Serious Adverse Event - Work with Risk Management

- Done in anticipation of possible litigation
- Secure locked location, controlled environment with very limited access
- Equipment must be labeled – Despoilation of evidence
- Chain of Custody record
- Not practical in some cases (e.g. major imaging rooms).
- Rapid testing witnessed by manufacturer? outside expert?

ADE Documentation – By CE

Discuss this topic with Risk Management **in advance**

- ASAP - Download Device logs (if possible).
- Open up WO in CMMS. Flag as ADE and/or NME. WO type?
- Should CE test? Go invasive? Approval level within CE?
- Criteria before testing?
- General discussion with Risk Management about documentation.
- Best to have a form to guide staff, since an ADE is relatively rare
- Notes of what observed/measured, **not conclusions**
- In general, the more detailed the documentation, the better

ADE Documentation – By CE (page 2)

- The person doing testing may be required to testify years later about what was done
- Attach actual data when possible
- Manager review to make sure documentation is adequate
- Emails associated with ADE
- Meeting records where ADE is discussed.
- Where is documentation stored? In CMMS?
- Repair device? What approval level needed in CE?
- Return device to service?

Hazard Alerts / Recalls Study Guide p158

- Who is in charge of Hazard Alerts and Recalls in your organization?
- Most Hazard Alerts and Recalls are not for Medical Devices
- Each recall & alert received is an opportunity to prevent future ADE
- Inadequate response + ADE = liability
- Important to have a good system for an adequate response to received recall/alert with documentation
- Internal recall or alert – CE initiates with approval and help from clinician management

The Joint Commission Good resource

Patient Safety Portals

Numerous resources arranged by topic are available for patients and practitioners. Resources developed by The Joint Commission, *Joint Commission Resources*® (*JCR*®), in addition to external resources, are provided to assist health care organizations in improving the safety and quality of care provided.

- Zero Harm
- Emergency Management
- Health care Workforce Safety and Well-Being
- Infection Prevention and Control
- Report a Patient Safety Concern or Complaint
- Suicide Prevention
- Workplace Violence Prevention

https://www.jointcommission.org/resources/patient-safety-topics/

The Joint Commission (TJC) Sentinel Event Definition

"A sentinel event is a patient safety event that results in death, permanent harm, or severe temporary harm. Sentinel events are debilitating to both patients and health care providers involved in the event."

TJC – 2023 National Patient Safety Goals (NPSGs)

Not a complete list

- **Identify patients correctly**
- **Improve staff communication**
- **Use medicines safely**
- **Use alarms safely -** Make improvements to ensure that alarms on medical equipment are heard and responded to on time. NPSG.06.01.01
- **Prevent infection**
- **Identify patient safety risks -** Reduce the risk for suicide.
- **Prevent mistakes in surgery -**
  - Make sure that the correct surgery is done on the correct patient and at the correct place on the patient's body.
  - Mark the correct place on the patient's body where the surgery is to be done.
  - Pause before the surgery to make sure that a mistake is not being made.

NPSG.06.01.01 - Improve the safety of clinical alarm systems – Elements of Performance 1 & 2

1. Leaders establish alarm system safety as a hospital priority.
2. Identify the most important alarm signals to manage based on the following:
   - Input from the medical staff and clinical departments
   - Risk to patients if the alarm signal is not attended to or if it malfunctions
   - Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue
   - Potential for patient harm based on internal incident history
   - Published best practices and guidelines

NPSG.06.01.01 - Improve the safety of clinical alarm systems – Elements of Performance #3

3. Establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following:
   - Clinically appropriate settings for alarm signals
   - When alarm signals can be disabled
   - When alarm parameters can be changed
   - Who in the organization has the authority to set alarm parameters
   - Who in the organization has the authority to change alarm parameters
   - Who in the organization has the authority to set alarm parameters to “off”
   - Monitoring and responding to alarm signals
   - Checking individual alarm signals for accurate settings, proper operation, and detectability

ECRI - Top 10 Patient Safety Concerns 2023 (hyperlink)

1. The pediatric mental health crisis
2. Physical and verbal violence against healthcare staff
3. Clinician needs in times of uncertainty surrounding maternal-fetal medicine
4. Impact on clinicians expected to work outside their scope of practice and competencies
5. Delayed identification and treatment of sepsis
6. Consequences of poor care coordination for patients with complex medical conditions
7. Risks of not looking beyond the “five rights” to achieve medication safety
8. Medication errors resulting from inaccurate patient medication lists
9. Accidental administration of neuromuscular blocking agents
10. Preventable harm due to omitted care or treatment

Root Cause Analysis (RCA) - Study Guide p161 (pdf 165)

- *"Root cause analysis (RCA) is a structured method used to analyze serious adverse events. Initially developed to analyze industrial accidents."* (AHRQ)
- Risk Management, or Quality Assurance, and/or Patient safety usually makes the determination if a RCA is to be conducted (very resource intensive to do an RCA properly).
- CE should ask to be included if the serious adverse events involved one or more medical devices. **Discuss this w appropriate group in advance.**
- CE may elect to use the techniques within CE, or in conjunction with another department, for other quality problems

AHRQ web site on RCA

VA National Center for Patient Safety - web site on RCA

Root Cause Analysis (RCA)

The RCA process is:

- Reactive – after an event
- Inter-disciplinary, involving experts from the frontline services
- Involve those who are the most familiar with the situation
- Continually digging deeper by asking WHY?, WHY?, WHY? at each level of cause and effect
- A process that identifies changes that need to be made to systems
- A process meant to be as impartial as possible

Root Cause Analysis

To be thorough an RCA must include:

- Determination of human and other factors
- Determination of related processes and systems
- Analysis of underlying cause and effect systems through a series of ***why*** questions
- Identification of risks and their potential contributions
- Determination of potential improvement in processes or systems

Healthcare Failure Mode and Effect Analysis (HFMEA)

Hyperlink

Developed by the VA National Center for Patient Safety (NCPS) – A variation on FMEA

HFMEA streamlines the hazard analysis steps found in the traditional Failure Mode and Effect Analysis process by combining the detectability and criticality steps into an algorithm presented as a "Decision Tree."

It also replaces calculation of the risk priority number (RPN) with a hazard score that is read directly from the Hazard Matrix Table. This table was developed by NCPS specifically for this purpose.

The HFMEA tool is uniquely suited to proactive risk assessment of healthcare processes.

Healthcare Failure Mode and Effect Analysis (HFMEA)

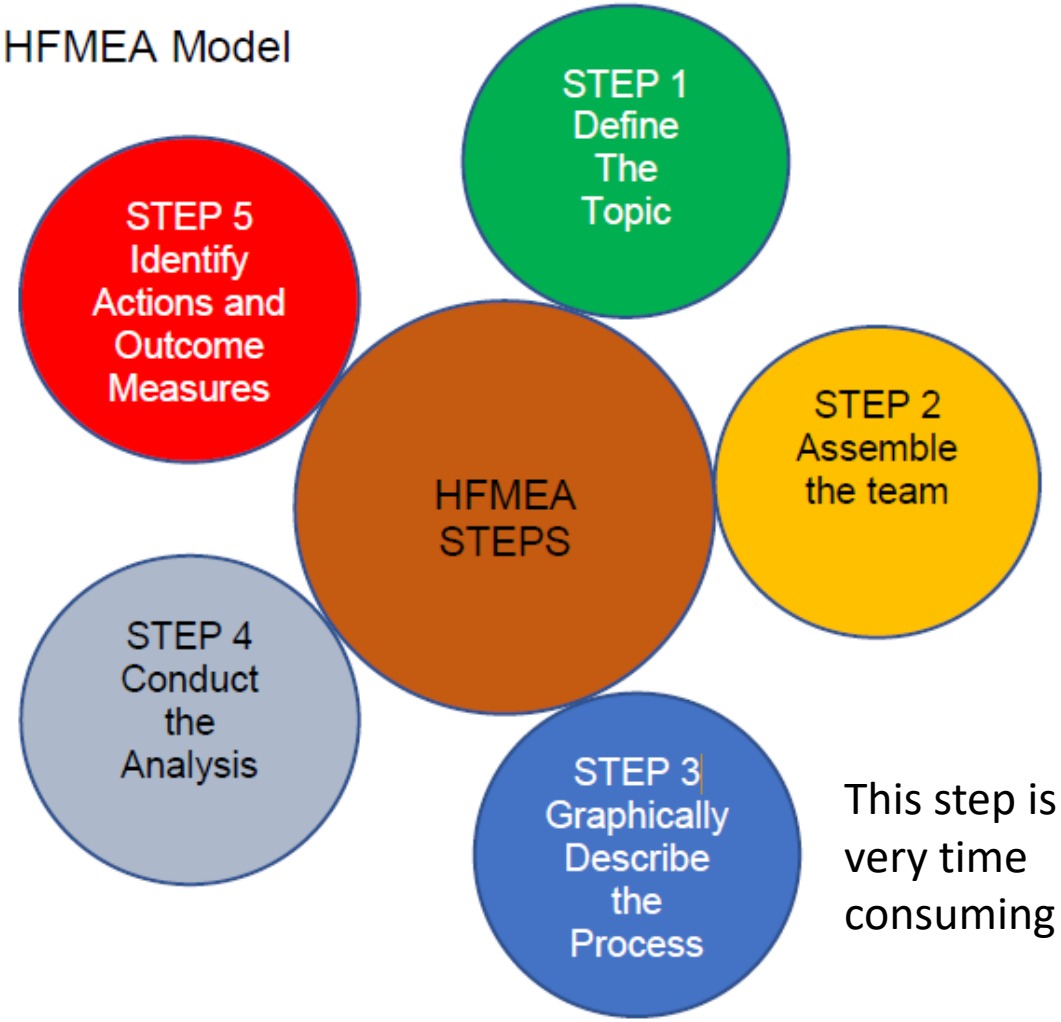
DEFINITIONS:

Hazard Analysis - A hazard analysis is the process of collecting and evaluating information on hazards associated with the selected process. The purpose of hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled.

Hazard Score- A score used to help prioritize failure modes and failure mode causes. The hazard score is determined by assigning severity and probability ratings to a hazard and looking up the result on the HFMEA Hazard Matrix. The hazard score replaces the risk priority number (RPN) used in traditional FMEA.

Healthcare Failure Mode and Effect Analysis (HFMEA)

Diagram 1. HFMEA Model



Next going to focus on STEP 4

This step is often very time consuming

Healthcare Failure Mode and Effect Analysis (HFMEA)

STEP 4: Conduct a Hazard Analysis

Once a process flow diagram has been completed start to consider what might go wrong and conduct a hazard analysis. The purpose of the hazard analysis is to develop a list of hazards or vulnerabilities that are of such significance that they are reasonably likely to cause injury or illness if they are not effectively controlled. There will be multiple subprocesses involved. The hazard analysis process helps the team determine potential failure modes and failure mode causes significant enough to develop actions and outcome measures. The HFMEA Worksheet will assist the team in keeping track of the subprocess steps (See Appendix B). The hazard analysis sequence of events is as follows:

HFMEA – STEP 4: Conduct a Hazard Analysis

HFMEA Step 4 - Hazard Analysis								
Failure Mode: First Evaluate failure mode before determining potential causes	**Potential Causes**	Scoring			Decision Tree Analysis			
		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?
	→							

Appendix C. Severity Rating

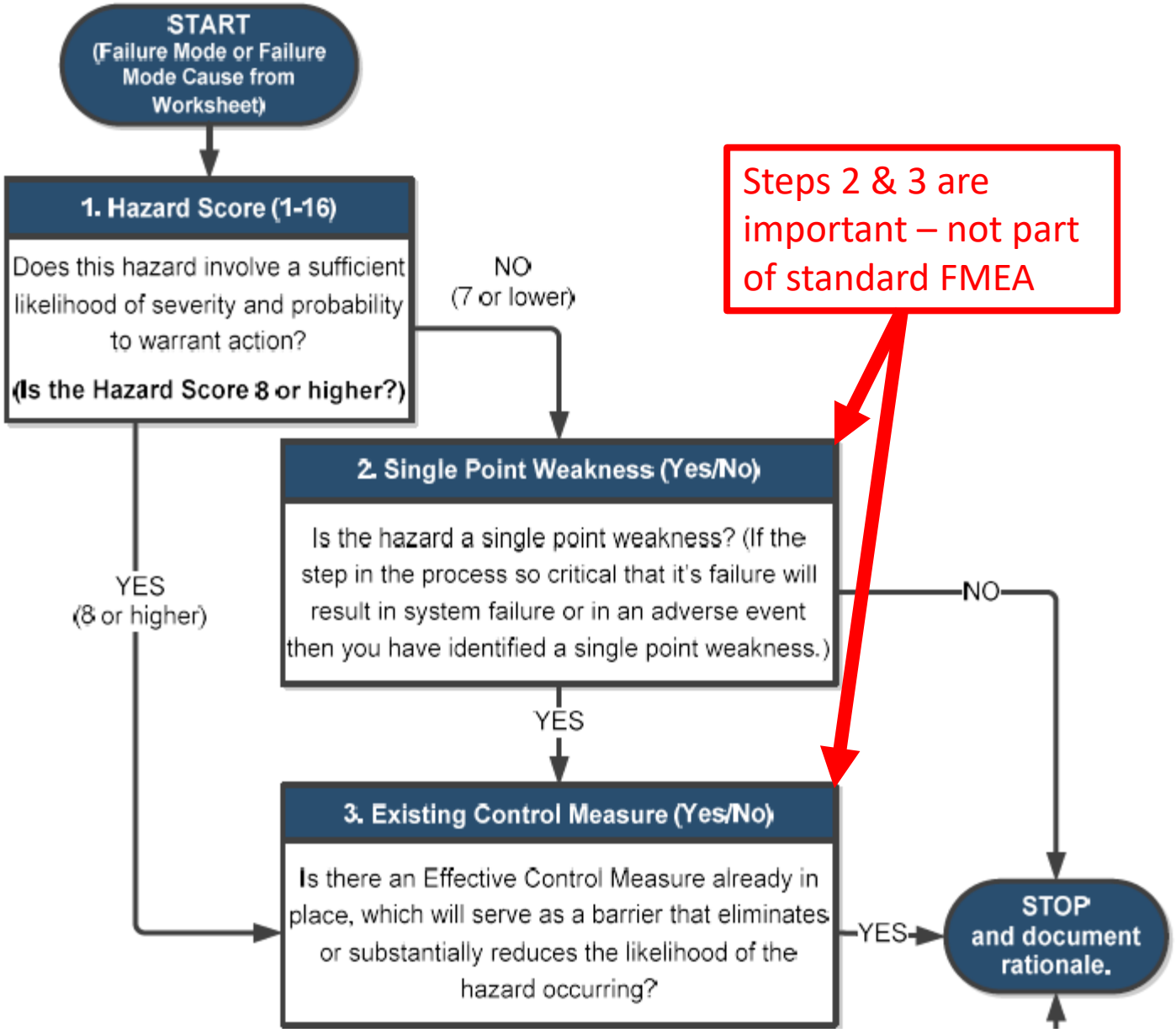
	Patient Outcome	Visitor Outcome	Staff Outcome	Equipment or Facility
Catastrophic Event (4)	[a, b] Death, major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery or procedure on the wrong patient or wrong body part	Death; **or** hospitalization of 3 or more visitors	A death **or** hospitalization of 3 or more staff	Damage equal to or more than $250,000. Any fire that grows larger than an incipient stage
Major Event (3)	[a] Permanent lessening of bodily function, disfigurement, surgical intervention, increased length of stay or level of care for 3 or more patients	Hospitalization of 1-2 visitors	Hospitalization of 1-2 staff, 3 or more staff with lost time or restricted duty injuries/illnesses	[c] Damage equal to or more than $100,000.

ACCE

HFMEA Probability Ratings

HFMEA Probability Ratings
Frequent Event (4) Likely to occur immediately or within a short period (may happen several times in one year)
Occasional Event (3) Probably will occur (may happen several times in 1 to 2 years)
Uncommon Event (2) Possible to occur (may happen sometime in 2 to 5 years)
Remote Event (1) Unlikely to occur (may happen sometime in 5 to 30 years

HFMEA Decision Tree
(partial)



Steps 2 & 3 are important – not part of standard FMEA

No

HFMEA

Actions Listed by Strength Category

These strength categories are also very useful in an FMEA.

Important when considering risk mitigation

Hierarchy of Actions	
Stronger Actions	• Architectural/physical plant changes • New device with usability testing before purchasing • Engineering control or interlock (forcing functions) • Simplify the process and remove unnecessary steps • Standardize on equipment or process or care maps • Tangible involvement and actions by leadership in support of patient safety • High Reliability training (perpetual, including simulation, competency evaluation, staff off patient care, leadership sanctioned)
Intermediate Actions	• Increase in staffing/decrease in workload • Software enhancement/modifications • Eliminate/reduce distractions (sterile medical environment) • Checklist/cognitive aid • Eliminate look sound alike • Read back • Enhanced documentation/communication • Redundancy • Training using simulation
Weaker Actions	• Double checks • Warnings and labels • New procedure/memorandum/policy • Training • Additional study/analysis

Hazard Vulnerability Analysis (HVA) (Hyperlink)

The Joint Commission requires an HVA as part of their Emergency Management requirement **EM.01.01.01 EP 2, EM.03.01.01 EP 1**

- Identify potential emergencies, for locations within the organization/facility and the community. The potential emergencies could affect demand for services and/or the ability to provide services
- Similar to HFMEA, in that both are proactive, and look at overall process
- I've used HVA (as part of a team) for major projects before they go live
  - New fetal monitoring system
  - Flexible monitoring system

(HVA) Kaiser EXCEL Toolkit

Kaiser – developed a publicly available Excel tool

- Separate Tabs for
  - Natural Hazards
  - Technological Hazards
  - Human Hazards
  - Hazardous Materials
- Automatic Scoring (Probability x Severity = Risk)

Failure Mode and Effect Analysis (FMEA)

Study Guide p168

- Used to eliminate or reduce the risk of FUTURE FAILURES
- Use a team
- List all the possible failure modes
- Rate each one for likelihood, severity, detectability
- Identify the highest risk failure modes
- Redesign the system to reduce the risk of those modes failing

FMEA – Typical scoring

Severity (S)

- Catastrophic (4)
  (hazardous, death, permanent injury)
- Major (3)
- Moderate (2)
  (increased length of stay)
- Minor (1)
  (Little effect)

Probability (P)

- Frequent (4)
  (failure is certain)
- Occasional (3)
  (high number of failures likely)
- Uncommon (2)
  (Occasional failure)
- Remote (1)
  (failure unlikely)

Detectability (D)

- Remote (4)
  (not likely to detect failure)
- Low (3)
  (might detect failure)
- Moderate (2)
  (most likely will detect failure)
- High (1)
  (will detect failure before it can cause harm or interrupt procedure)

RPN = Risk Priority Number scoring
For different Failure Modes (examples)

Failure Mode *(Cause of failure)*	**S**	**P**	**D**	**RPN**
Defibrillator left unplugged.	4	4	3	48
Faulty battery manufacturing process.	4	3	3	36
Power cord disconnection (detachable power cord).	4	3	2	24
Poor (inadequate) periodic testing of battery capacity.	4	3	2	24

S = Severity, P = Probability, D = Detectability, RPN = Risk Priority Number (SxPxD)

Infection Control - Study Guide p 163 (pdf 168)

Excellent Reference: AAMI - Checklists for Preventing Healthcare-Associated Infections (HAIs)

- "*Every reusable medical device has the potential to be related to transmission of pathogenic agents due to contamination*."
- "*checklists are provided to reinforce and facilitate the successful acquisition and adoption of a reusable medical device with an eye on identifying, managing, and mitigating contamination risks; thereby reducing the likelihood of disease transmission and subsequent HAIs*."
- "*Facility culture and compliance requirements help to set adherence expectations for all employees*."
- "*Infection prevention is most effective when all stakeholders actively participate in achieving a common objective*."
- Clinical Engineering plays a part – "***Staff consistently implement infection prevention protocols***"
- CE depends on the Infection Control team in your organization to help set CE standard operating procedures (SOP) regarding infection prevention.
- AAMI BI&T article - "**Infection Control Practices for Biomeds**"
- AAMI BI&T article - "**Medical Equipment and Infection Control: It's All About Cooperation**"

Workplace Safety Practices (OSHA) - Study Guide p 171-3

The ACCE Study Guide – Covers the OSHA (Occupational Safety and Health Administration) quite well.

In addition:
AAMI BI&T Article: "**Safety: Protecting Yourself Should Be Your #1 Priority**"

Fire Protection/Safety (Life Safety Code) - Study Guide p 170 (pdf 175)

This topic is adequately covered in the Study Guide

Radiation Safety - Study Guide p171-2 (PDF 176-7)

This topic is adequately covered in the Study Guide

Hazardous Materials - Study Guide p 173 (pdf 178)

This topic is adequately covered in the Study Guide

Industrial Hygiene - Study Guide p 174 (pdf 179)

This topic is adequately covered in the Study Guide

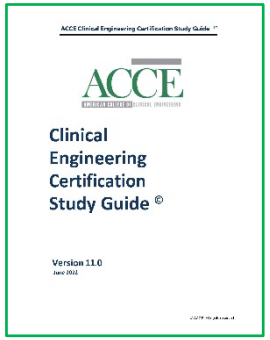
Expert Witness - Study Guide p 175-176 (pdf 180-1)

This topic is adequately covered in the Study Guide

But – For the past 11 years, my consulting has primarily been as an expert witness for both plaintiff and defense attorneys. While the Study Guide has all you need to know for the CCE Exam, I am happy to entertain questions on this topic. Save for Q&A or use my email (Alan@HCTC.pro), if you'd prefer.

References from this presentation

1. ANSI/AAMI/ISO 14971-2007(R)2010 Application of risk management to medical devices (slide 7)
2. AAMI Technical Information Report (TIR50) "Post-market Surveillance of Use Error Management" (slide 8)
3. 'No Problem Found' Service Calls—Keep Digging; Lipschultz; BI&T July/Aug 2014 (slide 9)
4. Manufacturer and User Facility Device Experience (MAUDE) (slide 10)
5. Code of Federal Regulations (21 CFR Part 803) MEDICAL DEVICE REPORTING (slide 11)
6. FDA's "Medical Device Reporting for User Facilities" guidance document (slide 13)
7. Search MAUDE database (slide 14)
8. MAUDE Product Key database (slide 14)
9. MAUDE Database Verity Search HELP (slide 19)
10. FDA - Medical Product Safety Network (MedSun) (slide 20)
11. Certified Professional in Patient Safety (CPPS) (slide 24)
12. Adverse Patient Events Involving Medical Devices; Lipschultz; BI&T March/April 2013 (slide 25)
13. AHRQ - Adverse Events, Near Misses, and Errors (slide 26)
14. Agency for Healthcare Research and Quality (AHRQ) - System-Focused Event Investigation and Analysis Guide (slide 31)
15. The Joint Commission – Patient Safety Portals (slide 42)
16. AHRQ – Patient Safety Network – Primer on Root Cause Analysis (slide 48)
17. VA National Center for Patient Safety – Root Cause Analysis (slide 49)
18. The Joint Commission – Webinar on Hazard Vulnerability Analysis (slide 51)
19. Kaiser – Hazard Vulnerability Analysis – Excel Tool (slide 52)
20. VA National Center for Patient Safety - Healthcare Failure Mode and Effect Analysis (HFMEA) (slide 56)
21. AAMI - Checklists for Preventing Healthcare-Associated Infections (HAIs) (slide 65)
22. AAMI BI&T article - "Infection Control Practices for Biomeds" (slide 65)
23. AAMI BI&T article - "Medical Equipment and Infection Control: It's All About Cooperation" (slide 65)
24. AAMI BI&T Article: "Safety: Protecting Yourself Should Be Your #1 Priority" (slide 66)



ACCE CCE Study Guide, v12.0, 2023

Alan Lipschultz
Alan@HCTC.pro
302-584-1050

Please complete the evaluation form at: https://www.surveymonkey.com/r/CCE-session10

or scan the QR code: