ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

2022-2023 Educational Webinar Series

CE and Risk Management Associated with Medical Device Incident Investigations in the VA Healthcare System

December 08, 2022

Speakers:

Henry Stankiewicz, Jr., CCE
Clinical Engineer
Sigma Healthcare Consulting

Shelly Leacock, MS, CCE
Biomedical Engineer
VA Center for Engineering & Occupational Safety and Health

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About the Moderator

Nader Hammoud, BE, MBA, CHTM

Biomedical Engineering Manager
John Muir Health

Nader Hammoud is currently the Biomedical Engineering Manager, at John Muir Health

- Biomedical Engineer with 3 degrees in Biomedical Engineering and an MBA
- International Experience
- Active member of the HTM community
- Member of the Technology Management Council at AAMI
- ACCE Education Committee Co-Chair
- California HTM of the year for 2018
- Recognized by ECRI and FDA for efforts in the domain

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 host/moderator.
- Please remember to complete the webinar evaluation after attending. A link will be provided at the end.

About the speaker

Henry (Hank) Stankiewicz

HENRY (HANK) STANKIEWICZ is a Clinical Engineer with Sigma Healthcare Consulting for the past 10 years.

- Worked 35 years as a Biomedical Engineer and senior management roles in the VA
- Led HTM programs as Chief BME at the medical center, regional, and enterprise levels
- Pioneered a regional consolidated HTM Program within VA

AWARDS

- ACCE Lifetime Achievement Award (2021)
- VA Chief BME of the Year (2x)
- ACCE Leadership Award (2011)

HTM COMMUNITY ENGAGEMENT

- Former member ACCE Certification and Awards Committees
- Former VP of the Healthcare Technology Foundation
- Member of ACCE, IEEE, Etta Kappa Nu, and NESCE

About the speaker

Shelly Crisler Leacock, MS, CCE, PMP

VA | U.S. Department of Veterans Affairs

SHELLY LEACOCK is a Clinical Engineer with the Department of Veterans Affairs (VA) for over 18 years

- Provides direction and support regarding equipment management, alerts, recalls, incident response, continuing education, medical device safety, and more.

AWARDS

- AAMI Young Professional Award (2014)
- AAMI & Becton Dickinson's Patient Safety Award (2019)

HTM COMMUNITY ENGAGEMENT

- ACCE Board
- AAMI Healthcare Technology Leadership Council
- AAMI Equipment Management (EQ) Standards Committee
- NFPA 99 Medical Equipment Standards Committee
- Medical Device Servicing Community
- ECRI Health Devices Advisory Board

Session Description

- How the VA investigates the medical device incidents that occur in its 171 hospitals and numerous clinics, the VA Incident Investigation Guidebook
- How the VA communicates the information across the enterprise and manages the risk associated with these incidents; Brief description of the Alert and Recall Management
- Review the data trends from almost 10 years of formal incident investigations
  - Devices involved in incidents
  - Root and secondary causes
- Discuss future directions and activities

Agenda

1. Presentation Learning Objectives
2. VA HTM and Sigma Health Consulting
3. Hospital Roles
4. Incident Investigations
5. Alerts and Recall Management

Agenda

1 **Presentation Learning Objectives**

2 VA HTM and Sigma Health Consulting

3 Hospital Roles

4 Incident Investigations

5 Alerts and Recall Management

1 Presentation Learning Objectives

1. Understand the role of VA Office of HTM and Local Hospital Biomed in patient safety - medical equipment incident investigations and Alert/Recall Remediation
2. Understand the roles of Hospital Biomedical Engineers, Risk Management, and Patient Safety Officers in the VA
3. Understand how HTM works on incident investigations and alerts/recalls

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1 Presentation Learning Objectives

2 **VA HTM and Sigma Health Consulting**

3 Hospital Roles

4 Incident Investigations

5 Alerts and Recall Management

2 VA HTM and Hospital Biomedical Engineering

1 CENTRAL OFFICE

18 VETERAN INTEGRATED SERVICE NETWORKS

171 MEDICAL CENTERS

1,800
Biomedical Engineering professionals

$10 billion
of healthcare technology

900,000
medical devices and clinical systems

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2 Sigma Health Consulting

Sigma Health Consulting is a woman, veteran-owned small business (WOSB, VOSB) and leading consulting services firm. Our team of clinical/biomedical engineers, technicians, and management consultants specialize in providing support and services to healthcare technology management (HTM)/biomedical engineering organizations.

Sigma services to VHA Office of HTM:

Patient Safety | Incident Investigation and Recall Management

Cybersecurity

Technology Standards Development

Equipment Lifecycle Management

Program Strategy and Communications Management

Data Analytics and Reporting

Meeting and Conference Planning and Facilitation

Program Assessment

Agenda

1 Presentation Learning Objectives

2 VA HTM and Sigma Health Consulting

3 **Hospital Roles**

4 Incident Investigations

5 Alerts and Recall Management

3 VA HTM Levels

1 CENTRAL OFFICE

HTM PROGRAM OFFICE | National level

Provides national guidance and direction on incidents and compliance

Centralizes management of alerts and recalls

18 VETERAN INTEGRATED SERVICE NETWORKS

VISN HTM/BIOMEDICAL ENGINEERING OFFICE | Regional level

Coordinates application of national guidance and supports hospital compliance

171 MEDICAL CENTERS

LOCAL HOSPITAL BIOMEDICAL ENGINEERING | Local level

Identifies and responds to incidents and alerts/recalls

Responsible for mitigation and compliance

3 Hospital Risk Management

Risk management is an integrated function that utilizes several disciplines to reduce the potential for organizational losses. Most hospital risk management activities are **proactive** or **preemptive techniques** designed to mitigate or prevent losses

Because the health care industry is driven by quality measurements and the need for legal compliance, risk management demonstrates it's worth through **reducing risk and incidents thus providing a safer environment and ultimately cost savings**

ROLES		
HOSPITAL RISK MANAGER	PATIENT SAFETY MANAGER	BIOMEDICAL ENGINEERS

3 Hospital Risk Manager

- A **hospital risk manager** is a professional who continually assesses and minimizes various risks to staff, patients and the public in health care organizations. These hospital administrators play a vital role in reducing potential safety, finance and patient problems
- Hospital risk managers are trained to handle different ongoing or unexpected PR, personnel, operations or financial problems. They are part of the upper medical administration staff, but their specific duties depend on the position itself and the health care organization
- Risk Managers may work in clinical research, or they may help hospitals prepare for emergencies. Also, they may work directly with insurance and finance companies to streamline claims management.
- Almost all hospital Risk Managers **will assist with incident management** involving minor, daily problems and major, unexpected events and in **Alert and Recall** remediation

HOSPITAL RISK MANAGER

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3 Patient Safety Managers and NCPS

- **Patient Safety Managers** at all VA Medical Centers and Patient Safety Officers at 18 VISNs participate in the patient safety programs established by the National Center for Patient Safety (NCPS) at the local medical centers
- **NCPS** promotes best practices for safe patient care and optimal patient care utilization throughout the organization. Accordingly, NCPS guides the VHA and external stakeholders on policies and strategies to do the following:
  - Measure and mitigate harm to the Veteran and those who support their care;
  - Track utilization and address deficient patient practice;
  - Model characteristics of a High Reliability Organization including promotion of clinical team training and a just and safe culture; and
  - Evaluation of healthcare solutions, technology, and innovations from a patient safety and value-based perspective.

3 Biomedical Engineers

- **Biomedical Engineers** work with Risk Managers, Patient Safety Managers, clinical staff, and others to assess, control, and investigate incidents involving patients and medical equipment

- When incidents occur, Biomedical Engineers perform an investigation to find the root and contributing causes of incidents, working with local, regional, national teams, including VA Central Office HTM

- Biomedical Engineers are responsible for acknowledging relevant alerts and recalls within their medical centers, executing mitigation actions, and tracking progress and completion

BIOMEDICAL ENGINEERS

Agenda

1 Presentation Learning Objectives

2 VA HTM and Sigma Health Consulting

3 Hospital Roles

4 **Incident Investigations**

5 Alerts and Recall Management

4 Medical Equipment Incidents

WHAT IS A MEDICAL EQUIPMENT INCIDENT?

An event that could have resulted in harm or did result in unnecessary harm to a patient and involved **medical equipment**

LIFE SUPPORT	THERAPEUTIC	DIAGNOSTIC	MONITORING	ANALYTICAL
sustain and support a patient's physical life functions	help patients recover after medical treatments	helps clinicians detect and diagnose diseases	allow medical staff to measure a patient's medical state	Medical devices that analyze patients' biochemistry
examples				
				
VENTILATORS	INFUSION PUMPS	CT SCANNERS	ECG SYSTEMS	HEMATOLOGY ANALYZERS

4 Incident Investigation Process

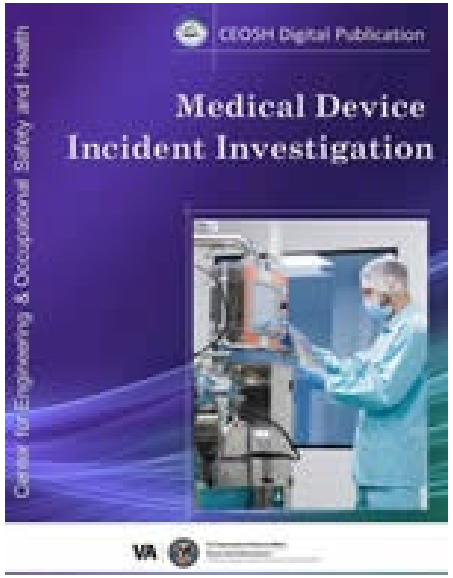
VA HTM Central Office
remotely supports investigations of medical equipment – patient incidents

HTM Central Office works with:
Local and VISN Biomedical Engineers
Local Patient Safety Managers (PSM)
Local Risk Managers
Local OEM Field Service Providers
National OEM Representatives
VA National Center for Patient Safety

1. VA Medical Center Biomedical Engineering performs initial investigation to find the root and contributing causes
2. VA Medical Center reports a medical equipment incident or requests “outside” investigation/ analysis assistance
3. VA VISN and Central Office HTM joins the investigation, following the procedures and steps in the **VA HTM Incident Investigation Guidebook**
4. Investigation team determines if the issue has national implications so others can be notified, and potential risks can be mitigated

4 Incident Investigation Guidebook

VA MEDICAL DEVICE INCIDENT INVESTIGATION GUIDEBOOK



ACCE and **AAMI** Award winning Guidebook!

A collaboration of the VA Office of HTM, Center for Engineering and Occupational Safety and Health (CEOSH), National Center for Patient Safety (NCPS), and **VA Hospital Biomedical Engineers**, published Aug. 30, 2018

Guides VHA staff through timely and thorough investigations of medical device incidents

Includes tools and enclosures to effectively support field-based teams in implementing strategies that can improve patient safety within their own facilities

2nd Edition **COMING SOON!**

4 Incident Investigation Guidebook

KEY FEATURES OF THE

MEDICAL DEVICE INCIDENT INVESTIGATION GUIDEBOOK

GUIDEBOOK CHAPTERS:

1. Overview
2. Background
3. Policies and Procedures
4. **Critical Steps for Conducting a Medical Device Incident Investigation**
5. Reporting Medical Device Incidents
6. **When to Involve Others**
7. Lessons Learned
8. Incident Response Preparedness

TOOLS AND RESOURCES:

- Sample Go-Bag Assembly List
- Sample Medical Device Incident Investigation: Response, Sequestering, Analysis, and Reporting Policy
- Response Guide: Medical Device Incident Investigation Checklist
- Sample Letter for Returning Devices to Manufacturers

4 Incident Investigations | Culture of No Blame

VA HIGH RELIABILITY ORGANIZATION

JUST CULTURE OF NO BLAME

FOSTER A JUST CULTURE

A culture of "**blame and shame**" encourages employees to hide mistakes.

Fostering a Just Culture facilitates the thoughtful detection of vulnerabilities that contribute to harm.

MISSION STATEMENT FOR JUST CULTURE

"To engage all VHA leadership in the creation and sustainment of a **safety culture**; one in which employees **actively report** safety concerns, even their own errors, **without fear** of a default to reprisals or punitive action, so the organization can **learn about its failures** and **improve** its care delivery system; to clearly define the boundaries used to determine **individual and organizational accountability**."

4 Incident Investigation Challenges

For the HTM Central Office, remote investigations were always a challenge, COVID-19 magnified those challenges

Not able to see and touch the equipment

Not able to see the workflow associated with the use of the equipment

BEFORE COVID-19 **Local managers made remote incident investigation possible and successful**	DURING COVID-19 **Shift to remote schedules for local managers impeded incident investigations**
Local managers were familiar with incident investigation procedures, the proper equipment function, the workflow, and clinical staff	Many managers were not available for “boots on the ground” support and lacked firsthand knowledge of the issue and the ability to work on the incident
Local managers knew and trusted me, were open and honest, and understood the goal was to solve the issue; not place blame	On-site staff were unfamiliar with incident investigations, the Office of HTM/Sigma’s role, the equipment involved, and the workflow associated with equipment use
OEMs, who do the detailed forensic work on the equipment, were available to respond to requests for assistance	OEMs, were often slow to respond to requests for assistance and often not available to go into the medical centers
Equipment was readily available for testing	Equipment was often put in isolation due to covid concerns

4 Solutions to Incident Investigation Challenges

VA SOLUTIONS NEW CHALLENGES

STRENGTHENED RELATIONSHIPS

- Spent more time **working with the "Acting Leaders"** on the steps and the importance of the local investigation and establishing trust and stressing **"no blame"**
- Leveraged the VA contacts to **engage OEMs**
- Involved the **Veteran Integrated Service Network (VISN) Biomedical Engineers**
- Created **Patient Safety Leads** positions within each of the 18 VISNs to assist in investigations

OFFERED ADDITIONAL TRAINING

- Shared the **skills of doing remote work** for several years with the remote local managers to keep them involved and engaged
- Provided **monthly training calls** for the VISN Patient Safety Leads
- Implemented Patient Safety Courses: Basic 101 and Advanced 201 on Patient Safety Concepts for Biomed and PSMs that include curriculum from **"world class" speakers** on conducting successful incident investigations

4 Recent Incident Trends

Completed **342** incidents since **2013**

and assigned each to a **primary failure cause category**

Primary Failure Cause	Fiscal Year 2020 10/1/2019-9/30/2020		Fiscal Year 2021 10/1/2020-9/30/2021	
Device Use Issues	24	47%	20	56%
Device Failures	19	37%	16	44%
Software Issues	6	12%	0	0%
IT Issues	2	4%	0	0%
Total	**51**	**100%**	**36**	**100%**

Note the significant drop in incidents from **51 in Fiscal Year 2020** to only **36** incidents in **Fiscal Year 2021**

Last **Fiscal Year, 2022**, shows a similar decrease in reported incidents – only **15** incidents through the Fiscal Year mid point

It is unknown if there are less incidents or less reporting of incidents

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5 **Alerts and Recall Management**

5 Medical Equipment Recalls

- A medical equipment recall is a method for **correcting or removing** medical devices from use that are in violation of laws administered by FDA or otherwise deemed defective or potentially harmful to patients.
- **Correction** means repair, modification, adjustment, relabeling, destruction or inspection of a medical device without its physical removal.
- Medical Equipment Recalls may be conducted on manufacturer's own initiative, by FDA request, or by FDA order under statutory authority. Medical Equipment Recalls may also be conducted internally by VHA.
- It is **VHA policy** that each VA medical facility establishes and maintains a safe, reliable and risk-managed medical equipment safety program to ensure the well-being of patients and staff.

5 Medical Equipment Recall Process

OBTAIN NOTIFICATION

VHA: Centrally receive safety reports/notices involving medical equipment from multiple sources

ANALYZE

VHA: Determine and issue remediation actions to ensure successful prevention or mitigation of safety issues

DISSEMINATE & TAKE ACTION

VHA: Communicate actions to all affected VA facilities

VAMCs: Verify inventory and implement assigned actions

REPORT & CONFIRM

VHA: Review recall data, distribute completion reports, and share lessons learned

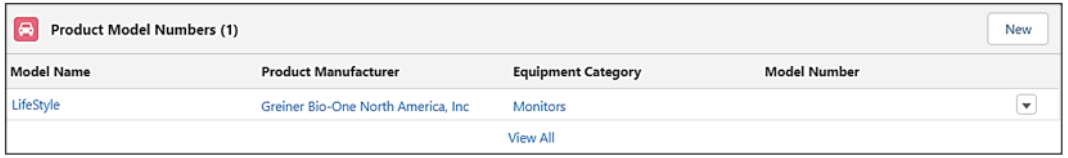
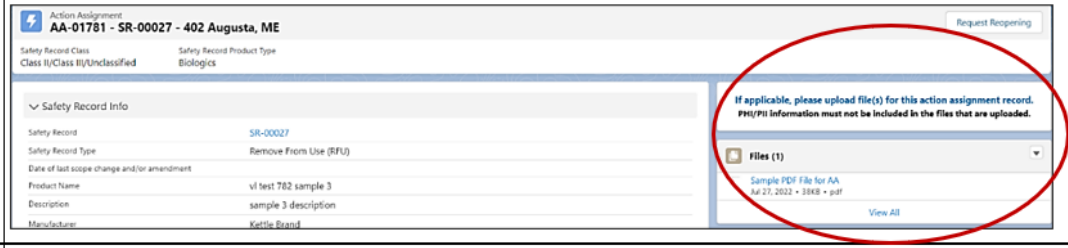
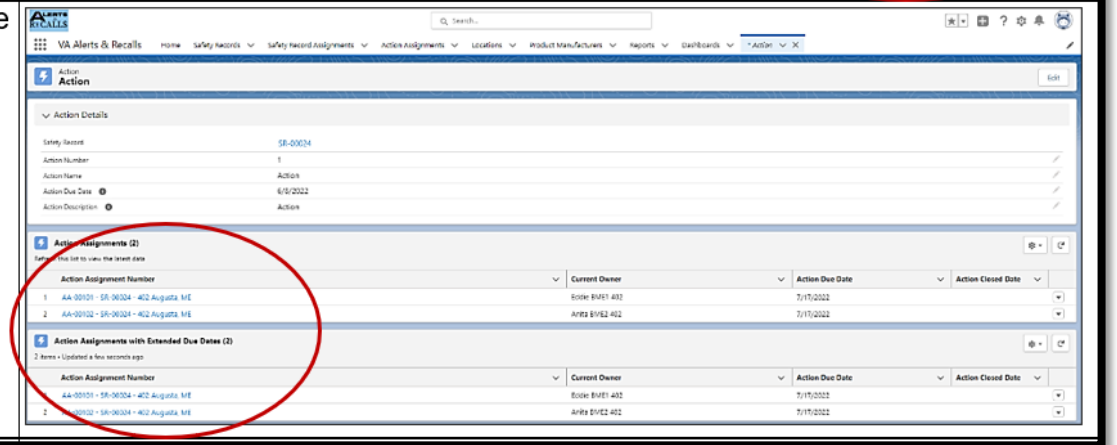
VAMCs: Confirm completion of all actions

Day 1 → Days 2-14 → Days 15-28 → Days 28-118

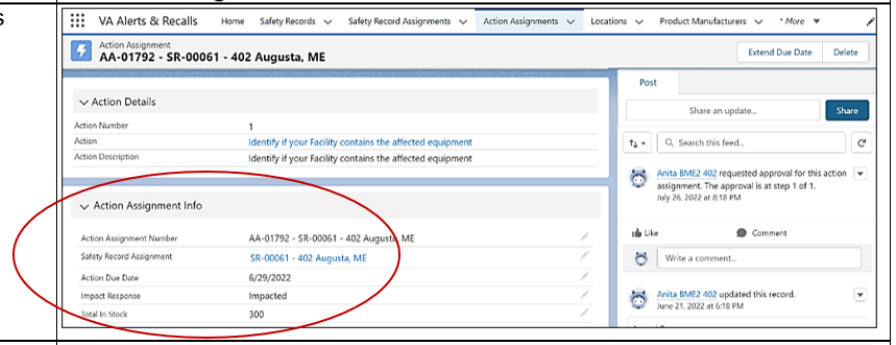
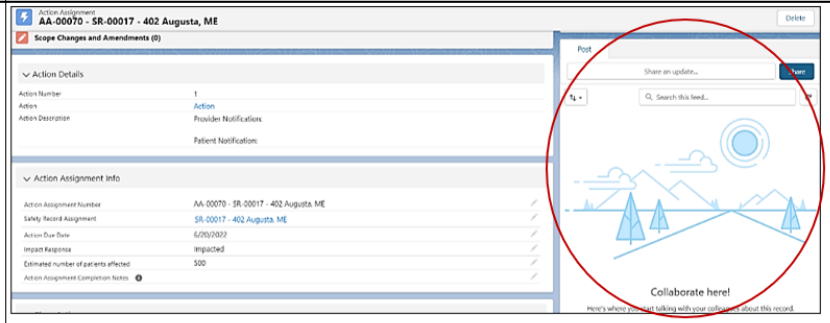
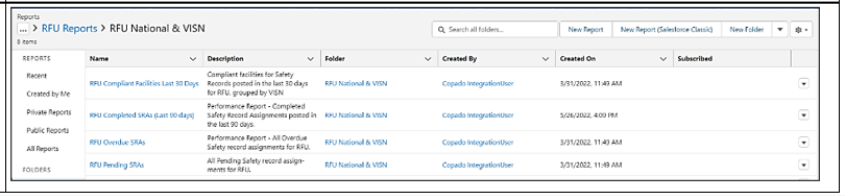
5 Recall Management Challenges and Solutions

CHALLENGES	a new system ARMS 2.0	SOLUTIONS
Cumbersome user-interface		Provides streamlined user interface for both writers and end-user
Inability to extend individual facility due dates		Has capability to alter due dates for individual sites
Limited user-roles		Has capability to select different user-role levels and automate new user requests
No capability for end-users to upload file attachments		Has capability for end-users to upload file attachments
No help desk/live-support		Has Chatter and Teams help-desk

5 ARMS 2.0 | Future State

New Application	Description	Reference Images
Product Model Numbers	Product model numbers, equipment categories and Product Manufacturer information is within the app. Each can be easily accessed, searched for, and selected.	
Files	Files can be attached to any action assignment or Safety Record Assignment. May also be attached after completion.	
Due date extensions	Both blanket and individual due date extensions are available	

5 ARMS 2.0 | Future State

New Application	Description	Reference Images
New fields “Total in Stock” and “Total Affected”	Itemized List has been removed for RMD. The new fields “Total in Stock” and “Total Affected” support the RMD business process than Itemized list.	
Chatter	Chatter is a collaboration tool within the application for communicating with other users on specific records	
Both ad hoc and canned report options are available within the application	Existing users set up with appropriate permissions and new users can be given access easily. The new application also supports vetting of reports.	

5 Recent Alerts and Recalls Trends

Posted **554** alerts and recalls since **2020**

	Fiscal Year **2020** 10/1/2019-9/30/2020	Fiscal Year **2021** 10/1/2020-9/30/2021	Fiscal Year **2022** 10/1/2021-9/30/2022
RMD Alerts/ Recalls Posted	156	190	208

FDA medical device recalls and safety notices are growing in numbers every year. As medical technology advances and becomes more complex, it can be more prone to defects that initiate recall actions. Recalls and safety notices can range from low-risk issues that are not likely to cause any harm to those that can cause serious injury or death.

Conclusions

1. **More Biomedical Engineering and Patient Safety staff**, at more levels of the organization, understand how to conduct a successful incident investigation and how to properly report Alert/Recall remediation. Pre and Post “tests” showed a great improvement in knowledge and understanding

2. The **remote investigation** techniques, skills, and knowledge gained by staff will benefit them in future investigations

3. The **new ARMS system** will enable easier, sortable, and better alert and recall remediation

Questions & Discussions

Enter your questions to the Q&A window

Thank You

Please complete the online evaluation form at https://www.surveymonkey.com/r/ACCE_12-08-22

or scan the QR code