Fail Safe Use of Complex Medical Devices

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Director, System Clinical Programs

Teresa Ryan, RN, BSN, CPHRM
Manager, Risk Mgmt, MH Southeast Hospital

M. Michael Shabot, MD, FACS, FCCM, FACMI
Executive Vice President, System Chief Clinical Officer
AAMI Foundation

Mission

The AAMI Foundation drives reductions in preventable patient harm and improvements in outcomes associated with the use of health technology.

- National Coalition for Alarm Management Safety
- National Coalition for Infusion Therapy Safety
- National Coalition to Promote Continuous Monitoring of Patients on Opioids
- National Coalition to Promote the Safe Use of Complex Healthcare Technology
A Special Thanks
Thank You to Our Industry Partners!

DIAMOND

BD

icumedical

Johnson & Johnson

Masimo

Medtronic

Further, Together
LinkedIn Questions

Join our group

Please post questions on the AAMI Foundation’s LinkedIn page.
OR
Type a question into the question box on the webinar dashboard.
Speaker Introduction

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Fail Safe Use of Complex Medical Devices
How is healthcare different from many other industries?
How is healthcare different from many other industries?

High Reliability in Healthcare

MEMORIAL HERMANN
U.S. Coal Mining Deaths

Coal Mining Deaths in the US, 1900 to 2013

Carpe Diem Blog

Source: Mine Safety and Health Administration
Hospital Patient Harm

**Question:** How many avoidable deaths occur in U.S. hospitals each year?

- 25,000
- 50,000
- 100,000
- 200,000

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- 50,000
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Equivalent to a fully-loaded Boeing 737 crashing **every 7 hours**

Question: How many avoidable deaths occur in U.S. hospitals each year?

Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. Martin Makary and Michael Daniel assess its contribution to mortality and call for better reporting.

Martin A Makary professor, Michael Daniel research fellow
Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21287, USA
Question: How many avoidable deaths occur in U.S. hospitals each year?

- 25,000
- 50,000
- 100,000
- 200,000

Equivalent to a fully-loaded Boeing 737 crashing every 7 hours.


Memorial Hermann’s Goal

0 (Zero)

Medical error—the third leading cause of death in the US.

Medical errors—r included cases of patient deaths. Martin Makary and Michael Daniel assess its contribution to mortality and call for better reporting.

Martin A Makary professor, Michael Daniel research fellow. Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21237, USA.

737 crash every 5.5 hours.
How Can Memorial Hermann Get to Zero?

New Doctors?

New Nursing Staff?

All New Execs?
How Can Memorial Hermann Get to Zero?

Robust Process Improvement

The Path to Quality Outcomes
Robust Process Improvement: Path to Quality Outcomes

Lean

Six Sigma

Change Management
Robust Process Improvement: Changing Standard Work

Standard Work = What we do every day

What we do every day = CULTURE!
Robust Process Improvement:
High Reliability Standard Work

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<td>Chlorhexidine</td>
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<tr>
<td>MD gown, gloves, hat &amp; mask</td>
<td>100.00%</td>
<td>97.37%</td>
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<td>100.00%</td>
<td>97.14%</td>
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<tr>
<td>Crape patient head to toe</td>
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<td>100.00%</td>
<td>100.00%</td>
<td>100.00%</td>
<td>96.43%</td>
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<td>Sterile field maintained during procedure</td>
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<tr>
<td>Assistant Hand Hygiene</td>
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<td>97.50%</td>
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<td>Assistant gown, gloves, hat &amp; mask</td>
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<td>100.00%</td>
<td>96.88%</td>
<td>97.50%</td>
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<td>Insertion Bundle Compliance</td>
<td>95.65%</td>
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<td>% Femoral Lines</td>
<td>8.70%</td>
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<td>2.50%</td>
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<td>0.00%</td>
<td>0.00%</td>
<td>2.86%</td>
<td>2.78%</td>
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<td>% Femoral Lines justified by careful site selection</td>
<td>100.00%</td>
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<td>Ultrasound Guidance</td>
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<tr>
<td>% Ultrasound Guided CVC insertions</td>
<td>100.00%</td>
<td>100.00%</td>
<td>92.31%</td>
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</tbody>
</table>

Central Line Sterile Insertion Bundle

Ultrasound Guidance for Central Line Punctures

OR Surgical Safety Checklist

High Reliability Hand Hygiene
Central Line Associated Bloodstream Infections
Ventilator Associated Pneumonias
Surgical Site Infections
Retained Foreign Body
Iatrogenic Pneumothorax
Accidental Punctures and Lacerations
Pressure Ulcers Stages III & IV
Hospital Associated Injuries
Deep Vein Thrombosis and/or Pulmonary Embolism
Deaths Among Surgical Inpatients with Serious Treatable Complications
Birth Traumas
Serious Safety Events
Central Line Associated Bloodstream Infections
Ventilator Associated Pneumonias
Surgical Site Infections
Retained Foreign Bodies
Iatrogenic Pneumothorax
Accidental Punctures and Lacerations
Pressure Ulcers Stages III & IV
Hospital Associated Injuries
Deep Vein Thrombosis and/or Pulmonary Embolism
Deaths Among Surgical Inpatients with Serious Treatable Complications
Birth Traumas
Serious Safety Events
High Reliability
Certified Zero Award

1. Zero Events

2. 12 Consecutive Months

3. Certified Zero Category
High Reliability Certified Zero Award

To: TIRR Memorial Hermann
Zero Central Line Associated Bloodstream Infections
Hospital-wide for 24 months
June 2014 to May 2016

Benjamin K. Chu, M.D.
President & Chief Executive Officer

M. Michael Shabot, M.D.
System Chief Clinical Officer

Will Williams
Chair, Health System Board
MH Northwest: Zero Retained Foreign Bodies

Northwest Adult FB
Foreign Body Left During Procedure
Rate/1000 Discharges for Secondary Diagnosis

MD/Nursing OR Count Policy
Mandatory RFID Scanning

Zero Retained Foreign Bodies x 60 Months

2012 2013 2014
Reporting Months

Generated: 1/16/2014 9:05:32 AM
Source file date: 1/14/2014

produced by System Quality and Patient Safety
Hospital Acquired Conditions
“Never Events”

Acute Hemolytic Transfusion Reactions

Transfusion Events Jan 2007 - Dec 2016

2,617,000 Adjusted Admissions
14,234,000 Adjusted Pt Days
1,240,000 Transfusions
Hospital Acquired Conditions
“Never Events”

Acute Hemolytic Transfusion Reactions

Transfusion Events Jan 2007 - Dec 2016

PSI 16 Transfusion Reaction - Per 1000

2,617,000 Adjusted Admissions
14,244,000 Adjusted Pt Days
1,240,000 Transfusions

Zero
ICU Central Line Associated Bloodstream Infections (18)
ICU Catheter Associated Urinary Tract Infections (16)
Hospital-Wide Central Line Associated Bloodstream Infections (7)
Hospital-Wide Catheter Associated Urinary Tract Infections (5)
Ventilator Associated Pneumonias (23)
Surgical Site Infections
  Retained Foreign Bodies (46)
  Iatrogenic Pneumothorax (24)
Accidental Punctures and Lacerations (3)
Pressure Ulcers Stages III & IV (37)
Hospital Associated Injuries (7)
Deep Vein Thrombosis and/or Pulmonary Embolism (2)
Deaths Among Surgical Inpatients with Serious Treatable Complications (1)
  Birth Traumas (16)
Obstetric Trauma in Natural Deliveries with Instrumentation (4)
  Serious Safety Events 1&2 (21)
  Serious Safety Events 1 & 2 for 1000 Days (2)
  All Serious Safety Events (1)
  Early Elective Deliveries (9)
Manifestations of Poor Glycemic Control (21)
Complex Device Case Scenario

ICU Ventilator
Just Culture Performance Management Decision Guide

Start

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Did the individual intend to do harm?</td>
<td>Is there evidence of ill health or substance abuse?</td>
<td>Departure from well understood policies, procedures or performance expectations?</td>
<td>Would individuals with comparable skills &amp; experience act the same under similar circumstances?</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>Actions to Consider</td>
<td>Yes</td>
<td>Actions to Consider</td>
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<tr>
<td><strong>Actions to Consider</strong></td>
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<tr>
<td>• Disciplinary action</td>
<td>• Health referral</td>
<td>• Disciplinary action</td>
<td>• Consolation</td>
</tr>
<tr>
<td>• Report to professional group or regulatory body</td>
<td>• Adjustment of duties</td>
<td>• Job-fit reevaluation</td>
<td>• Coaching, mentoring</td>
</tr>
<tr>
<td>• Law enforcement referral</td>
<td>• If substance abuse: drug testing &amp; disciplin. action</td>
<td></td>
<td>• Increased supervision</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Adjustment of duties</td>
</tr>
</tbody>
</table>

Possible System Error

• Consolation
• Coaching
• Fix process problems

Adapted from James Reason’s *Managing the Risks of Organizational Accidents*
The Process Challenge

Process that assures that new **critical life safety and monitoring devices** are not placed into service on nursing units until nurses and other care givers who use these devices on patients have received **formal in-service training** and this training is **documented in writing** for each.

Process includes a requirement of **100% compliance** with individual caregiver education prior to rolling out the equipment onto the unit.
“Fail Safe” Project Team

**Charge** - Streamline a “Fail Safe” Process - ultimate goal of zero harm

**Six Sigma – Process Work Flow Design**
- Time efficient
- Cost Effective

**Executive Sponsor**

**Interdisciplinary Project Team**
- Quality and Safety
- Risk Management
- Education Management and Specialists – Nursing and Other
- Clinicians
- Supply Chain
Fail Safe Project & Team Charter

**Executive Sponsor:** Dr. Shabot

<table>
<thead>
<tr>
<th>Problem Statement</th>
<th>Project Scope</th>
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</table>
| Patients may be harmed if staff does not receive training on all new equipment and devices, especially critical life support or monitoring devices such as ventilators and physiological monitors. Clinicians and caregivers must be sufficiently trained on these devices in a timely manner, and must be able to demonstrate competency prior to using equipment / devices. | In scope:  
New Equipment with risk assessment of high risk (critical).  
Memorial Hermann Patient units and procedural areas  
Clinicians and caregivers that touch patients  
Out of scope:  
New Equipment with risk assessment of low / medium risk.  
Pharmacy Department & Physicians and Physician Assits. |

Currently, there is no standardized process to ensure adequate and timely training for clinicians and caregivers using critical equipment so that they do not suffer the consequences of informal training. (October 2013)

<table>
<thead>
<tr>
<th>Project Goal</th>
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<tbody>
<tr>
<td>Develop a process to ensure that staff education has been completed, documented and signed off on a per nurse and other appropriate caregiver basis before newly acquired critical equipment, especially, monitoring or life support equipment, is placed into service in a clinical area. All new equipment will require initial training before being put into use. Each equipment will be labeled a risk assessment category and have different levels of responsibility for training and competency assessment.</td>
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</table>

<table>
<thead>
<tr>
<th>Customers</th>
<th>Project Alignment with Strategic Plan</th>
</tr>
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</table>
| **Primary:** Patients  
**Key Stakeholders:** Clinicians and Caregivers  
MHHS & Facility Leaders  
Risk Management | **Quality & Safety**  
**Customer Satisfaction** |

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<tr>
<th>Business Case:</th>
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<tbody>
<tr>
<td>Employees must perform at efficient and effective levels; thus, it is critical to be trained and knowledgeable about new critical equipment in their areas, to avoid risks of regulatory non-compliance and inconsistencies in patient care.</td>
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</table>
(October 2013)
**In Scope:**
- **Devices** with Risk Assessment of Critical - High Risk
- **Units:** Patient Care Units and Procedural Areas
- **Clinicians:** RNs, RTs, and other clinicians that touch patients with the identified devices

**Out of Scope:**
- **Units:** OR Surgical Services
- **Clinicians:** Physicians

(2014)
**In Scope Addition:**
- **Devices** with Risk Assessments of Complex-Medium Risk and Simple-Low Risk

(2016)
**In Scope Addition**
- **Units:** Operating Rooms, PACUs, Endoscopy, Cath Lab, Ambulatory Services
System Fail Safe Steering Committee

Interdisciplinary Membership

- Executive Sponsor
- CMO representation
- CNO Representation
- Quality
- Risk Management
- Infection Prevention
- Outpatient Services
- Operating Rooms
- Education – Nursing and other
- Clinical Specialty Representation /Hospital Representation (e.g. ER, NICU, ICU, Pedi
- Supply Chain
- Environmental Services
Fail Safe Steering Committee

Scope and Responsibilities

- Oversee the High Level Process for education plan associated with New Medical Devices approved to come into Memorial Hermann Hospital System.
- Assign the Risk Assessment Category for each Medical Device (Critical, Complex, or Simple).
- Oversee each Medical Device Education Plan, Roll Out Status, and Completion.
- Communicate Initiative Purpose and Process Throughout the System.
- Oversee the ongoing evaluation of the Fail Safe Initiative, including Cost Benefit Analysis when appropriate.
Intake Request and Criteria for Fail Safe Analysis

Is it a Medical Device? (http://www.fda.gov/aboutfda/transparency/basics/ucm211822.htm)

Is there a potential for injury or harm?

What is the complexity and/or the Change?
- Current device (new location for use)
- New Device
- Upgrade:
  - Change in current practice
  - Change in display or functionality
  - Change in technology
- Substitute (temporary with changes)
- Replacement

- Name of Individual Requestor and Date
- Name and description of Medical Device
- Vendor Company Name
- Vendor Representative Name/Contact Information
- Supply Chain Contact/Project Manager
- Scope of Change: System or Facility
- Type of roll out: Single or Staggered - phases
- Recommended Target Clinical Area
- Recommended Target Employee Group
- Contract for Purchase finalized with internal purchase number availability
- Projected Date for roll out
Medical Device ________________Vendor ________________

Discussion Topics for the Vendor Presentation

1. Medical Device Review: Purpose, Function, Technology, Type of Change, Cost
2. FDA Risk Classification
3. System implementation vs Facility Based approval for roll out
4. Evaluation Information: Number of devices evaluated, Hospital/Hospitals participating, outcome evaluation of evaluation
5. Maude reports or any negative outcome impacting safety reported
6. Training: Target population-end users
7. Training Material and Support: Training material availability including online support, competency check off tool availability, length of training required, vendor support quantified
8. Cleaning process recommendation
Critical, Complex, or Simple?

Risk Analysis
What do we need from the Risk Assessment process:

- An understanding of the potential risks inherent to medical device malfunction before using a new medical device ~ or ~ operating a device with enhanced or undated technology
- User friendly and comprehensive tool for measuring the above

The Risk Assessment tool criteria:

- Potential severity of harm to patients ***
- Probability of occurrence and frequency of harm to patients***

Resulting assessment or score:

- Determines educational rigor to be applied prior to device roll out

***without education and practice accountability
Medical Device-Technology Assessment Tool

Fail Safe Medical Device-Technology Risk Assessment Tool

- Probability of Occurrence of Harm to Patients
  - Frequent
  - Probable
  - Occasional
  - Remote
  - Improbable

- Severity of Harm to Patients
  - Negligible
  - Marginal
  - Critical
  - Catastrophic

- Simple Low Risk
- Complex Medium Risk
- Critical High Risk

Date:
Medical Device/Technology:
Name of Reviewer:

Severity of Harm to Patients without Education and Process Accountability

<table>
<thead>
<tr>
<th>Severity</th>
<th>Criteria</th>
<th>Rank</th>
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<tbody>
<tr>
<td>Catastrophic</td>
<td>Death or life threatening</td>
<td>4</td>
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<tr>
<td>Critical</td>
<td>Major injury / adverse health outcome</td>
<td>3</td>
</tr>
<tr>
<td>Marginal</td>
<td>Moderate injury / adverse health outcome</td>
<td>2</td>
</tr>
<tr>
<td>Negligible</td>
<td>Possible minor injury / adverse health outcome</td>
<td>1</td>
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Occurrence of Harm to Patients

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<tr>
<th>Occurrence</th>
<th>Criteria</th>
<th>Rank</th>
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<tbody>
<tr>
<td>Frequent</td>
<td>Expected to occur frequently, almost on every occasion</td>
<td>5</td>
</tr>
<tr>
<td>Probable</td>
<td>Expected to occur in most circumstances, will occur several times</td>
<td>4</td>
</tr>
<tr>
<td>Occasional</td>
<td>Likely to occur sometimes</td>
<td>3</td>
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<tr>
<td>Remote</td>
<td>Unlikely, but possible</td>
<td>2</td>
</tr>
<tr>
<td>Improbable</td>
<td>So unlikely, it can be assumed occurrence may not be experienced</td>
<td>1</td>
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</table>

FDA Class Definitions

- Class I: low risk and are therefore subject to the least regulatory controls
- Class II: higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device’s safety and effectiveness
- Class III: the highest risk devices are are therefore subject to the highest level of regulatory control, and must typically be approved by FDA before marketed

100% education required prior to roll out? Yes No

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Innovative Solutions, Quality Leadership
Fail Safe Education

Fail Safe Assessment & Education Process

Fail Safe Committee
- Review Device & Assigns Risk Score

Fail Safe Education Representatives
- Develop Education Plan

Education/ Specialty Council
- Review Education Plan

Facility Educators
- Educate staff & document in PIL

Hand Off Communication Tool

Training Program Guide
## Hand Off Communication Tool and Guide

<table>
<thead>
<tr>
<th>Medical Device:</th>
<th>Fail Safe Meeting Date:</th>
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<tbody>
<tr>
<td>Owner:</td>
<td>Date of Request:</td>
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- Description of the Medical Device
- Reason for analysis by Fail Safe Steering Committee
- Type of Change
- FDA Rating
- MAUDE Report/s
- Vendor/Contact Information
- Supply Chain Product Manager
- Device Evaluation: Dates/Location /Specialties
- Approvals: Councils/Other
- **Risk Assessment Rating/Competency Accountability Requirement**
  - Scope of Change and Facilities with Roll Out
  - Target Population: Clinical Areas and Employee groups
  - Product Availability and Cost
- Key Dates: Projected Time for Roll Out
# Training Program Guide for (Medical Device)

## Equipment Risk Assessment

<table>
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<tr>
<th>Training Program (Minimum Requirements)</th>
<th>Simple Low Risk</th>
<th>Complex Medium Risk</th>
<th>Critical High Risk</th>
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<td><strong>Content Deliverable</strong></td>
<td>✓</td>
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<td>✓</td>
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<td>PIL module</td>
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<tr>
<td>Vendor module</td>
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<td>written documents</td>
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<tr>
<td>Other (Specify)</td>
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<tr>
<td><strong>Validation of Skill Knowledge</strong></td>
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<td>✓</td>
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<tr>
<td>written / online quiz</td>
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<tr>
<td>oral quiz</td>
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<tr>
<td>Return Demonstration (verbal or action)</td>
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<tr>
<td>Other (Specify)</td>
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<tr>
<td><strong>Hands on Facilitated / Precepted &quot;skills&quot; Return Demonstration</strong></td>
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<tr>
<td>Bedside</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simulation Lab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (Specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Identified and Trained Super Users</strong></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Unit specific individuals (on every shift)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operational Administrators (OAs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (Specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Support and Resources during Facility &quot;Go Live&quot;</strong></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Onsite Vendor Representative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>System Supply Chain Project Manager</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>System Bio Med Project Manager</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Educator</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Director and Managers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Materials Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Bio Med</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

✓ Represents a "Must Have" in Training Design
# Training Program Guide for Ventilator (Example)

## Fail Safe - Training Program Design Guide

Medical Device/Technology: Name

**Ventilator-Critical**

<table>
<thead>
<tr>
<th>Training Program (Minimum Requirements)</th>
<th>Simple Low Risk</th>
<th>Complex Medium Risk</th>
<th>Critical High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>*<em>Content Deliverable—<em>Including Practice Accountability</em></em></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>PIL module</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Vendor module</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written documents</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Other (Specify)</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

**Validation of Skill Knowledge**

| Written / online quiz | ✓ | ✓ | ✓ |
| Oral quiz | | | ✓ |
| Return Demonstration (verbal or action) | | | |
| Other (Specify) | | | |

**Hands on Facilitated / Precepted "skills" Return Demonstration**

| Classroom | ✓ | ✓ | ✓ |
| Bedside | | | |
| Simulation Lab | | | |
| Other (Specify) | | | |

**Identified and Trained Super Users**

| Unit specific individuals (on every shift) | Respiratory T |
| Operational Administrators (OAs) | ✓ |
| Other (Specify) | |

**Support and Resources during Facility "Go Live"**

| Onsite Vendor Representative | ✓ | ✓ | ✓ |
| System Supply Chain Project Manager | | | |
| System Bio Med Project Manager | | | |
| Facility Educator | | | |
| Facility Director and Managers | | | |
| Facility Materials Management | | | |
| Facility Bio Med | | | |

✓ Represents a "Must Have" in Training Design

Revised 4.2016
Fail Safe Compliance with Database Management

Database Management Process

- **FS POC**
  - Enter FS device information

- **FS POC**
  - Enters proposed education plan

- **FS POC**
  - Enters any changes to plan

- **FS Support**
  - Enters LMS completion info

- **FS Director**
  - Send report monthly to stakeholders
  - Education/Specialty Council
  - Fail Safe Steering Committee
  - CNO Council
  - Enterprise Risk Committee

*Process Stakeholders*
- FS POC-Point of Contact
- FS Support - Administrative
- FS Director - Clinical Director

Fail Safe Education Compliance Report
## Fail Safe Database Resource

### Calculate completion percentage & education cost

| # of employees requiring education by cost center | 0 |
| # of employees completed education by cost center | 0 |
| % Completion | 0% |
| Cost of Education * | $ - |

* # of employee X $40/hr X ed time

### Cost Centers

<table>
<thead>
<tr>
<th>Job Codes</th>
<th>Required</th>
<th>Complete</th>
<th>Required</th>
<th>Complete</th>
<th>Required</th>
<th>Complete</th>
<th>Required</th>
<th>Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>RNI PC0901</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RN II PC1001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RN III PC1101</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RN IV PC1207</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

% Complete | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0%

### Objective

- Using LMS reports, input compliance data into database
# Education Compliance Report

## Fail Safe Device Education Dashboard

### FY 2018

<table>
<thead>
<tr>
<th>Device (Example)</th>
<th>Fail Safe Committee</th>
<th>Facility/Specialty Team</th>
<th>Education/Specialty Council</th>
<th>Risk Assessment</th>
<th>Education % Required</th>
<th>Scope of Change</th>
<th>Clinical Area</th>
<th># of Staff Educated</th>
<th>Completion %</th>
<th>Estimated Education Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>EKG leads</td>
<td>8/1/2017</td>
<td>8/15/2017</td>
<td>9/6/2017</td>
<td>Simple 2</td>
<td>100%</td>
<td>System-wide</td>
<td>Respiratory Tx</td>
<td>216</td>
<td>95%</td>
<td>$ 6,566.40</td>
</tr>
<tr>
<td>Midline Catheter</td>
<td>8/1/2017</td>
<td>8/21/2017</td>
<td>9/6/2017</td>
<td>Critical 7</td>
<td>100%</td>
<td>System-wide</td>
<td>Nursing - All</td>
<td>1023</td>
<td>78%</td>
<td>$ 25,534.08</td>
</tr>
<tr>
<td>Chest Compression Device</td>
<td>10/3/2017</td>
<td>11/5/2017</td>
<td>Complex 4</td>
<td>80%</td>
<td>TMC</td>
<td>Nursing - All</td>
<td>1023</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABC Rapid Infuser</td>
<td>10/3/2017</td>
<td>11/5/2017</td>
<td>Critical 7</td>
<td>100%</td>
<td>TMC</td>
<td>ICU</td>
<td>325</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>XYZ Code</td>
<td>10/3/2017</td>
<td>11/5/2017</td>
<td>Critical 7</td>
<td>100%</td>
<td>System-wide</td>
<td>Nursing - All</td>
<td>1023</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Report Objectives

- Distribute to identified stakeholders
- Obtain feedback
- Revise process as needed
Medical Device Assessments

Fall Safe Committee Count of Medical Device Assessments by Year and Risk Category

- Phase 1 - 47% (39) assessed as Critical
- Phase 2 - 39% (7) OR Medical Devices assessed as critical (since May 2016)
Why we assess the risk....

RM s share lessons learned from adverse events involving medical device use in the acute care setting to include:

✓ Gaps identified in the existing safety culture
✓ ID ways to engage third party partners in adopting and supporting a safety culture
✓ Re-engagement of RM and hospital leadership oversight of equipment management to mitigate future risks to our patients and to the organization

Our goal is, with 100% compliance, the frequency of all medical device safety events will decrease!
Serious Safety Events
2014

MEMORIAL HERMANN

High Reliability Certified Zero Award

To: Memorial Hermann Northwest Hospital

Zero Serious Safety Events 1 & 2 for 12 months

January 2013 to December 2013

Dan Wolteman
President & Chief Executive Officer

M. Michael Shabot, M.D.
System Chief Medical Officer

Will Williams
Chair, Health System Board
2015

Memorial Hermann

High Reliability
Certified Zero Award

To: Memorial Hermann Katy Hospital

Zero Serious Safety Events for 24 months

June 2013 to March 2015

Breakthroughs in Patient Safety

President & Chief Executive Officer

Will Williams
Chair, Health System Board
September 6, 2015
MH Greater Heights Hospital
1000 Days Since Last SSE1-2
John M. Eisenberg Patient Safety and Quality Award

March 8, 2013 | Washington, DC

The Joint Commission

National Quality Forum
MH Sugar Land Hospital
Malcolm Baldrige Award

2016 Award Recipient
High Reliability Organizations

Commercial Aviation

Nuclear Aircraft Carriers

Air Traffic Control
High Reliability Organizations

Memorial Hermann Health System

Nuclear Aircraft Carriers

Air Traffic Control

Commercial Aviation
Thank you!

“You must be the change you want to see in the world”

Mahatma Gandhi (1869-1948)
Future/Ongoing Initiatives
December 15, 2017 12 noon to 1 pm EST

“UCSF’s Experience With Sending Alarms to Phones in the Intensive Care Nursery”

*Please join us to learn the strategy UCSF used to determine how and when and which alarms to send to the nurses phones in the NICU…and all the lessons learned!*

Presenter: Kevin Spolini, MSN, RN
Clinical Informatics Mission Bay Hospitals
UCSF Benioff Children's Hospital
San Francisco, CA
January 15, 2018 12:00 PM to 1 PM EST

“Clinical Alarm Management Strategies – Meaningful Alerts; Reducing Non-actionable Alarms”

*Please join us to learn the technique of creating alarm default settings specific to certain patient profiles to reduce alarm fatigue!*

Presenter: Sharon H. Allan, DNP, RN, ACNS-BC

Central Nursing - Clinical Standards

*The Johns Hopkins Hospital*
Thank You to Our Industry Partners!

DIAMOND

[Logos of BD, icu medical, Johnson & Johnson, Masimo, Medtronic]
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