FAILURE MODES & EFFECTS ANALYSIS AS A QUALITY IMPROVEMENT PROCESS

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FMEA Project - Background
The Health Centers’ Respiratory Compressed Air (RCA) system which consists of three parallel compressors completely shut down when the main 100A fuse feeding the RCA system blew. Investigations revealed that the BeaconMedaes Triflex RCA system, compressor #1 had short-circuited and failed to trip the dedicated circuit breaker for compressor #1 and had instead blown the 100A supply fuse to the entire RCA Beacon Triflex system, shutting down both back up compressors. An analysis of the incident showed that the cause of failure was due to a mismatch between circuit breaker and fuse technologies with these devices having different tolerances to short circuit current.

FMEA Taskforce
The taskforce included the following stakeholders:
- Director of Clinical Engineering
- Assoc. VP Facilities Management and Operations
- Director of Mechanical Engineering
- Electrical Engineering
- Plumbing Department Supervisor
- BeaconMedaes Sales and Service
- Quantum Engineering
- Director of Respiratory Therapy
- Director of Patient Safety
FMEA Project Overview
A Failure Modes and Effects Analysis (FMEA) was undertaken to evaluate all steps and potential failure points for the entire RCA delivery process including electrical feeds, performance of the Beacon TriFlex system, alarm systems and emergency back up response procedures. Each of the failure points was scored for Severity, Frequency and Detectability using the Sheff & Marder FMEA Process, and the ten highest priority risk of failures were addressed in an Action Plan. Several action steps were completed immediately, and the remaining steps were completed during subsequent weeks, including electrical feed changes by UCHC, an upgrade to the RCA by BeaconMedaes, changes to RCA monitoring protocols, and review of available back up systems and RCA loss response protocols.

FMEA Process Guide
“The Step-by-Step Guide to Failure Modes and Effects Analysis” by Sheff & Marder was applied to the schematic (flow chart) of the power supply to the air compressors and for the Respiratory Compressed Air delivery to the hospital which resulted in a completed FMEA Failure Mode Prioritization Chart. This chart included a score from 1-10 for each step on the schematic for the following categories: Severity, Frequency and Detectability. The scores were multiplied, with the highest resulting Risk Prioritization Numbers (RPN’s) serving to focus attention on the highest risk of failure steps on the flow chart.

Medical Air Compressor System Schematic (Flow Diagram)

SEVERITY SCORE
1  No significant impact on clinical outcome
2  Mild impact
3  Moderate impact
4  Significant impact
5  Entire process will fail

FREQUENCY SCORE
1  May occur once in 100 years
2  May occur once every 10 years
3  May occur once every 5 years
4  May occur once each year
5  May occur once a month
6  May occur once a day
7  May occur one or more times per day
Detectability Score

1. Very easy to detect; highly visible; multiple steps
2. Fairly easy to detect; several steps
3. Moderately detectable; fair visibility; 2 or more steps in process
4. Moderately difficult to detect; low visibility; only one step prior to failure
5. Extremely difficult to detect; invisible
Action Plans – Top 10 Scores

- Install holder for replacement 100A fuses for emergency situations
- Install three separate fused feeds to Beacon Air Compressors
- Beacon to annunciate compressor power failure at Environmental Control Center (ECC)
- Beacon to annunciate control logic failure at ECC
- Beacon to annunciate lag alarm in ECC to ensure quick response
- On rounds, Plumbers to verify that all three compressors are cycling
- Verify pressure monitoring systems for early detection of problems
- Correct medical air intake piping – protect from pigeons; remove extraneous filter
- Verify secondary Quincy compressor system will remain on Normal Power vs. Emergency Power in case emergency switchgear fails
- Review backup and response strategies for Medical Air Compressor system failure
- Train clinical personnel on contingency plans for loss of Medical Air
- Verify that the wiring and power distribution system to the Medical Air compressors are adequate.

<table>
<thead>
<tr>
<th>ACTION</th>
<th>PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Step</td>
<td>Failure Modes</td>
</tr>
<tr>
<td>Beacon Circuit Breaker #1,2,3</td>
<td>Failure to trip</td>
</tr>
<tr>
<td>Beacon Starter/Controller</td>
<td>Control logic failure</td>
</tr>
<tr>
<td>Beacon Compressor #1,2,3</td>
<td>Failure to start</td>
</tr>
</tbody>
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<tr>
<td>Process Step</td>
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</tr>
<tr>
<td>Air intake</td>
<td>Contaminated</td>
</tr>
<tr>
<td>Med Gas Pressure Alarm</td>
<td>Inoperative</td>
</tr>
<tr>
<td>Response Protocol - Back up cylinders, regulators, hoses</td>
<td>Elec Engr - UCHC verified that thermal survey is completed annually.</td>
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<tr>
<td>Response Protocol - Staff Knowledge</td>
<td>Training new UCHC personnel on RCA backup systems, locations, and plans. Review new use of air compressors on adult ventilators and ensure Resp Therapy staff are aware of back up systems for RCA.</td>
</tr>
<tr>
<td>UCHC testing</td>
<td>Verify testing and distribution system to RCA is properly sized.</td>
</tr>
<tr>
<td>UCHC testing</td>
<td>Wire disconnects or spares.</td>
</tr>
</tbody>
</table>
Summary

1. Install three separate fused feeds to Beacon Air Compressors
2. Beacon to annunciate compressor power failure/lab alarm/control logic failure at Environmental Control Center (ECC)
3. Correct medical air intake piping – protect from pigeons; remove extraneous filter
4. Review backup and response strategies for Medical Air Compressor system failure

Example: FMEA-MRI Safe NICU Ventilator Project

Clinical Engineering coordinated a Failure Modes and Effects Analysis of a new Biomed Devices MRI-Safe infant ventilator. A team analyzed the flow of installing the special ventilator in the MRI procedure room; connecting and monitoring the infant during scanning; following MRI-safe procedures; and analyzing the contingency plans for emergency situations.

Summary

As a result of the Failure Modes and Effects Analysis…
1. Modify regulators to have 2” pressure gauges for better visibility;
2. Replace clear med gas tubing with color-coded tubing (green for O2 and yellow for Air);
3. Non-ferrous code kit;
4. Physicians to research impact of tissue heating (SAR) and gradient noise levels on neonates.
Questions?
Discussion