REDUCING ALARM FATIGUE FOR OPTIMAL PERFORMANCE: ANALYSIS OF A MULTI-UNIT HEALTH SYSTEM PROCESS IMPROVEMENT

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Reducing Alarm Fatigue for Optimal Performance: Analysis of a Multi-unit Health System Process Improvement

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Abstract

Technology in healthcare greatly enhances service delivery, safety, and efficacy yet when systems are not optimized any benefits of the technology are lost. This dissertation examines remote temperature monitoring systems and the inefficiencies of the alarms generated. Using six sigma methodology for performance improvement in healthcare, this dissertation focuses process improvement, specifically, reducing alarm/alert fatigue in healthcare generated by temperature monitoring systems. Extant research fails to examine non-patient alarms as distractions endured by healthcare professionals. Temperature and humidity control of the environment is critically important in clinical environments for infection control, pharmaceutical and food storage, and equipment function, among other reasons. Manual monitoring is resource-laden and error-prone, and automated environmental monitoring offers significant time-savings and reallocation of resources to other job tasks. However, without a robust infrastructure and implementation rules problems may arise. The case analysis of a multi-unit health system redesign of automated environmental monitoring highlights the complexity and inherent failures related to alarm management. Further, this case study examines alarm redeployment following11,000 environmental excursion alerts occurred each month with only 22% of those alerts being addressed. Using qualitative data from stakeholders, three research hypotheses were developed and examined relative to an end user:

1. The presence of user policies or procedures for use impacted the number of alarms generated;
2. Regular review of monitoring requirements and consistent system interaction impacted the number of alarms generated; and

3. Alert parameters determined by expert definition or empirically based system use impacted the number of alerts with corrections documented.

Baseline data is compared to post-improvement data to validate hypotheses and determine efficacy of real-time improvements. Continued improvement throughout the course of the project is measurable and sustainable. The author also proposes enhancements and improvements can be realized using six sigma methodology for technology installations that become out-moded to provide optimal performance.

Dedication

This scholarly work is dedicated to Joe – You know why!

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Chapter I

Introduction

Alarm fatigue has been discussed as a risk to patient safety for many years. Position statements from The Joint Commission, ECRI Institute, and many professional nursing organizations elaborate on the burden of alarms, including distraction, noise, prioritization, and multi-tasking combined with alarm setting management, accuracy, and dependability create an information avalanche [1]. This notification burden was named by ECRI as a top ten (six) global healthcare challenge in 2020 [2]. This burden is real and affects the entire patient care team. For an intensive care nurse caring for two patients in a twelve-hour shift there could be between 400-1000 alarms [3-9]. For wired hospitals, those tied to notifications from the electronic health record, emails, secure chat applications, pagers, the global notification burden is most pronounced [10]. More importantly, it has been noted that upwards of 99% of the alarms are false due to settings, patient movement, dislocation of sensors, or other persistent technology failures [9-11]. This factor can cause the patient care team to disable an alarm or modify the settings and this can contribute to patient safety events [10].

Patient care requires healthcare professionals to perform highly complex tasks with concentration and attention to detail in an environment that is prone to distraction and interruption [12]. Interruptions are likely contributors to medical errors and ultimately, have a negative impact on patient safety [1 2 13]. Adoption of technology aids in healthcare, like pagers, cell phones, biometric monitors, and environmental monitors, may improve patient care; however, these improvements come at a price. These aids contribute to distraction by increasing noise and task reprioritization. The Joint

Commission estimates that on a single patient care unit, technology aids alert staff thousands of times each day with 85-99% of the alerts not requiring intervention [1]. Several systems operational problems contribute to this phenomenon when using technology aids, including improper settings, situational awareness, or consideration of the technology aid application [8 14-16]. These alerts contribute to information saturation and creates "alarm fatigue" for healthcare professionals. Alarm fatigue is the state of sensory overload due to an overwhelming number of alerts in the environment [1-3 12 16]. Moreover, global notification burden is defined as the volume of technological notifications a patient care team member receives in the course direct patient care, on or off-shift depending on the system. This could be electronic health record messages, pager notifications about lab work, or other diagnostic testing, audible alarms in the patient vicinity, calls to/from consultants, patient families, or other notifications [2 17] Consequently, alarm fatigue and notification burden directly contribute to burnout of healthcare professionals [18 19]. Current research in burnout indicates that technological “failures”, where systems do not function as expected, significantly contribute to healthcare staff dissatisfaction and propensity for professional burnout [20]. In this state, the healthcare professional may dismiss the alert without intervention, turn down the volume, or change the setting on the alert to signal infrequently [1 8 17].

In the last twenty years, two foundation publications promulgated alarm fatigue and the impact on patient safety in healthcare [1 13]. These publications have served as research primers on alarm fatigue and guided much of the available, though limited, research. Researchers have published studies focused primarily on biometric alarms directly monitoring patient conditions like telemetry monitors; vital sign monitors,

including pulse-oximetry, blood pressure, temperature; intravenous fluid pump monitor; and falls monitors [14 16 21-23]. Regulatory white papers followed the original literature to embed safety expectations into standards and guidelines [2 24]. Additionally, there are published studies in nursing or biomedical engineering literature which have not crossed into other healthcare disciplines. There is a dearth of case studies of other hospital alarm systems, especially non-patient, non-physiological alarms. The healthcare environment has few test cases that demonstrate task saturation and how to effectively manage alarm fatigue. There is a significant gap in research associated with non-patient monitoring systems that impact the healthcare professional. These systems are not linked to direct patient care so there may be a tendency to dismiss their contribution to alarm fatigue. More likely, however, end-user responsibility for system function may be undefined or ambiguous due to assigned roles and job tasks for patient care staff [3 8 15 17 25]. This concept was reported as a common theme in patient safety events analyzed by Addis, Cadet and Graham [26].

Surprisingly, studies related to alarm fatigue in healthcare are limited in the literature. Few studies provide comparability or scalability for benchmarking across patient populations or hospital units. Most research focuses on intensive care units or specific patient populations, like telemetry patients [9 27-30]. Other studies focus on biometric patient monitoring systems, intravenous fluid pumps monitoring, or other technology aids used for direct patient care [1 8 11 14 16 31]. There were very few relevant studies evaluating the contribution of alarms from non-patient care technology aids to alarm fatigue [32-35]. Research contributions of non-patient care alarms were limited to laboratory or pharmacy practices where automation was an improvement from

previous manual temperature collection methods, and were not scalable across other healthcare settings [32-36].

Statement of the Problem

This study explores interruption and distraction of healthcare professionals by a non-patient care technology aid. Specifically, automated environmental monitoring of healthcare settings, for infection control, storage, research, to maintain, or improve operational integrity of health care supplies like food, pharmaceuticals, specimens, and surgical instruments. This case study presents the redesign of automated environmental monitoring using an integrated visibility software and analytics platform deployed across a hospital system with varied monitoring needs in variety of healthcare settings. Over 2,156 unique environments (referred to as assets) were monitored. Control of the platform infrastructure, including upgrades, patches, system stability, user access, and security settings was maintained by a centralized information services department (IS). Customization of the system was decentralized for convenience of the end user, including asset parameter setting, alarm schemes, and alarm notification hierarchy. End-users could also access data analytics for troubleshooting, real-time asset management, and record keeping meeting regulatory requirements.

For the purposes of this study, environmental monitoring included ambient, refrigerated and frozen environments using a Wi-Fi enabled visibility application that collected real-time status of the intended environment using a wireless tag installed for each asset, noted as location, instrument, or equipment [37]. Tags were installed in assets deployed across the hospital system and analytics of the tag data were included in this study. Status checks were sent to the software application at pre-defined intervals, for

this study the interval was configured at five minutes. When the condition exceeded end-user defined parameters (temperature or humidity ranges), an alarm was sent to the end-user and/or designee. For equipment and rooms located on patient care units, those alerts were sent to unit staff, including registered nurses, patient care technicians, or certified nurse assistants.

The initial implementation of the system occurred in 2011 in the laboratory and pharmacy departments of the hospital system. Over the course of time, more tags were deployed for a range of functional uses, i.e., decentralized storage of sterile supplies, maintaining temperature controls in operating suites, medication storage outside of pharmacy, and monitoring temperature of quality control supplies for point-of-care laboratory testing. As deployment advanced beyond the original users to include 180 users and more than 2,100 assets outside the lab and pharmacy, vague instructions for use [11], a lack of deployment specifications [9], and limited expert resources [38] set an untenable course. Decentralized alarm contributed to uncontrolled alarm fatigue and by 2017, the system was unstable, with unscheduled downtimes and regular rebooting required to maintain functionality. Further review of the system identified thousands of unanswered alarms as the main culprit. Each month 11,000 alarms were sent from the automated environmental monitoring system indicating an excursion outside of set parameters, typically temperature. For those alarms, only 22% had documentation of corrections required to return the status within parameter settings. Alarm management was the key to achieving system stability and reducing alarm fatigue.

Hypotheses

To reduce the number of excursion alarms, analysis of current failure points was critical for the system redesign. Three hypotheses to reduce nuisance alarms and improve end-user corrections were derived from stakeholder feedback using two process design tools: Cause and Effect Matrix and Failure Modes and Effects Analysis (FMEA) tools. A Cause and Effects Matrix helped to prioritize the inputs (Cause) for the process in relation to the needed output (Effect) for the end-user. Additionally, the FMEA was used to evaluate the future-state process to forecast and prioritize any potential design failures prior to implementation to fail-safe the new process. After review of the results provided by the tools, three potential variables presented the most improvement opportunities: reintroducing the system functionality to the end-user, incorporating system function and evaluation as part of routine work, and setting alarm parameters based on policy, or guideline. Three separate hypotheses were constructed

> H1: The presence of user policies or procedures, indicating familiarity and regular use of the system, had an impact on the number of alarms generated for an end-user.
>
> H2: Regular review of monitoring requirements and consistent system interaction had an impact on the number of alarms generated for an end-user.
>
> H3: Alert parameters determined by expert definition or empirically based system use had an impact on the number of alerts with corrections documented.

Each hypothesis was tested to determine statistical significance with the expectation that a p value <0.05 was an indication to reject the null hypothesis.

Need for the Study Including Theoretical and Practical Need

This study expands applicable research of alarm fatigue beyond those systems designed for patient care monitoring to other systems that may contribute to the alarm response burden placed on healthcare professionals. The ECRI Institute listed alarm, alert and notification overload as the sixth health technology hazard for 2020 [2]. As the literature is scant related to similar systems, these non-patient care alarms have not been fully investigated for impact to the healthcare team and may be overlooked when first evaluating alarm fatigue. Alarms from these ancillary systems are necessary, but often prioritized as less critical to immediate patient care. This creates an inadvertent delay in addressing the alarm, which could lead to downstream patient safety events [3 17 38]. Inventory loss of procedural supplies, pharmaceuticals, and food, in addition to lapses in infection prevention and quality control are examples of patient safety impact when non-patient care alarms are not managed appropriately [33-36]. The misconceived idea with the non-patient care alarms is that they work out of the box, meaning that alarm optimization is not necessary, and the system has the knowledge base built in. This plug-and-play concept could not be further from actuality. In fact, unlike the biometric alarms that have strict parameters based on physiologic requirements, the non-patient care alarms are used in many different applications, from pharmacy to the operating suite to an animal research lab. The wide applicability of non-patient care alarms prevents the standardization of alarm management and optimization. To think of it another way, these alarms fill gaps that replace the temperature log sheet on a clipboard in a sleek, hands-off

way that appeals to the patient care team. To use the alarms for all those manual applications, a strict process structure for implementation is needed and regular maintenance is required for success.

Chapter II

Literature Review

Alarm Management

The literature was searched using PubMed, MEDLINE (EBSCOHost), and MEDLINE (OVID) using the Rutgers Library System and GoogleScholar. Table 1 shows the relevant key words searched within the various databases.

Table 1: Literature Search Strings for PubMed and Medline (EBSCOHost/OVID)

General Searches	Special Searches Medical Engineering, Pharmacy, and Laboratory
Alarm	Temperature Monitoring
Alarm Fatigue	Environmental Monitoring in healthcare
Alarm Management in Healthcare	Environmental Integrity
Alert fatigue	Automated Alarm Management in Healthcare
Temperature Monitoring in Healthcare	

Additional Google searches for relevant regulatory, accreditation, and expert sources were also performed using similar search terms. The resulting articles were scanned for relevance based on the following criteria:

1. Published within the last 5-7 years; but due to paucity of literature, this was increased to the last 10 years;
2. Focus on alarm fatigue, notification burden, or alarm reduction;
3. Case studies evaluating alarm systems for noise, interruption, distraction, patient safety, employee burnout, employee overload, and/or employee satisfaction regardless of the applied healthcare setting;

4. System evaluation of alarm management in any health care setting; and
5. Non-physiologic alarm systems.

There were fewer than 70 articles meeting the criteria in Table 1. Of the relevant literature no studies were found that discussed management of non-physiologic alarm systems directed at reducing the notification burden of the patient care team. With the lack of supporting literature to frame the context of this research, or explanation of improvement methodology undertaken in these publications, there were no direct analyses or comparisons from which to model new research. This identified gap in notification burden in healthcare research is relevant and this case study in alarm management to reduce the notification burden is timely.

Six Sigma in Healthcare

In the absence of formal study design in the literature to address process improvement, research was conducted to establish methodology that could be applied to complex healthcare problems. Healthcare quality literature from the 1990s established total quality management (TQM) principles as the framework for process improvements in healthcare [39]. The premise of TQM was that hospitals would apply business principles for productivity and cost containment to healthcare. In healthcare a key concept utilized was quality circles. A quality circle was a group of employees, charged with a troubled process, coming to together to discuss ways to improve the process [39]. One important flaw with TQM was that the employee group was often tasked with finding solutions for problems outside their sphere of influence which led to organization indecision and propagation of more flawed processes. As TQM was unable to deliver the quality outcomes many in healthcare needed to align quality measure with performance

measures required by governmental and third party payors, the industry struggled to find performance or process improvement methodology that would address the complexity of healthcare, but allow for expert stakeholders to participate, and in some cases, drive the improvement efforts. Six Sigma methodology provided that opportunity.

Six Sigma (SS) has been successfully used in healthcare to deliver quality improvements, such as reducing costs, improving patient outcomes, and managing resources. From the development of the SS concepts by Motorola in the 1980s, and adoption of SS concepts by other industries, like manufacturing, finance, and service industries in the 1990s, SS proved quality could be measurable with data-driven results. Early industry adopters of SS enthusiastically shared the principles with employees through massive training campaigns, that included team-building, shared accountability, and milestone celebrations [39]. The process was easy to use and effective, removing the preconceived idea that process improvement was arduous. This wave of quality improvement strategy was slower to take hold in healthcare. Originally, SS methods were difficult concepts to incorporate in healthcare quality for two reasons:

1. Healthcare involved human patients. Care was complex with human-to-human interaction required. Testing solutions for optimal outcome could not be conducted in a simulated environment and meant that patient safety was at risk each time a change was initiated.
2. Manufacturing and other industries' improvement examples had not been extrapolated to healthcare. Defect rate or line efficiencies that were being improved in early examples were too simple for direct comparison to patient care [39].

Table 2: Healthcare Compared to Manufacturing

Manufacturing	Healthcare
Large variability in quality of product	Large variability in time taken to carry out 'jobs'
Unavailable parts/materials	Staff waiting on information
Excessive material/parts handling	Duplication/excessive information transfers
Errors *and* waste	Errors *and* waste
Frequent re-work, scrapped product	Relapse, recurrence, demise

Note: Table recreated from Table 14.1 [40]

The quality paradigm shifted in November 1999, with the publication of the Institute of Medicine, To Err is Human: Building a Safer Health System. Embedded in the discussion points for improving the health delivery system in the US was the concept that healthcare could be counted using outcome measures and systems could be improved using data converted into meaningful information and insight. Those comparisons of healthcare to manufacturing and service industries could be articulated. SS tools were relevant and adoption of the SS model for improvement was underway [13].

Six Sigma in healthcare literature peaked in the early 2000s and has been widely accepted as a methodology for improvement in healthcare systems and has a broad range of applicability [39 41 42]. Based on the applicability in complex systems improvements, adaptability using appropriate tools for each step in the process, and sustainability as part of the control plan, SS methodology provided the structure and framework for the process improvement undertaken in this analysis.

The Six Sigma in Healthcare literature was searched using PubMed, MEDLINE (EBSCOHost), and MEDLINE (OVID) using the Rutgers Library System. Key words searched were "Six Sigma in Healthcare" and a subsequent focused search for "Six

Sigma Alarm" and "Six Sigma Alarm Fatigue" was also conducted. There were numerous publications returned for the former search; but there was no literature returned for the latter search. The resulting literature for SS were scanned for relevancy based on the following criteria:

1. Published in the last 10-12 years;
2. Definition of Six Sigma;
3. Evidence of SS applicability to healthcare, quality, systems improvements;
4. Explanation of SS methodology, including phases and/or tools;
5. Case studies using SS structural elements, including charter, SIPOC, and DMAIC phases – due to lack of specific work directly related to alarm management and/or notification burden.

The lack of relevant literature returned for SS applications used to improve alarm fatigue further demonstrates a need for continued research focused on notification burden and alarm management in non-physiologic alarm systems used in healthcare.

Chapter III

Research Methods

Six Sigma Methodology

Through Six Sigma (SS), this study aims to improve alarm management in an environmental monitoring system with the goal of reducing aberrant alarms and increasing corrective action response when outliers are detected. Any SS project is managed using the DMAIC process and each letter represents a phase of improvement that guides the work.

Table 3: DMAIC Process in Six Sigma [42]

Phase	Description
Define	The problem within the process
Measure	Count the defects
Analyze	Causes and failures
Improve	Remove the causes
Control	Make sure the defects do not recur

Using these phases, the project is easily tracked, and the scope can be managed to ensure timely completion. The SS toolbox contains many tools for process improvement, not all tools are useful for all projects. Tools used in each phase of DMAIC are described in the following subsections of this chapter. This chapter concludes with the case study of alarm fatigue in a large health system and the SS tools used.

Define Phase

A project charter defines the problem, assigns resources, sets expectations, and establishes the project timetable in a SS project. The voice of the customer (VOC) is an important element to determine success after the DMAIC is finished. The first step is the Define Phase which includes several critical components. Tools most often used in the Define Phase are: Project Charter and SIPOC.

Project Charter Tool

The charter (see Appendix A) has required fields used to define the process to be improved and how success is measured. This is the roadmap of the project and should be referred to throughout the project course to confirm the initial problem are being addressed, timelines are being met, and the stakeholders are informed of the progress. Revisions can be made to the charter if the stakeholders approve, and deliverables are agreed upon prior to changes. The expectation is that the charter is a living document that captures the whole improvement process.

SIPOC

SIPOC is a SS tool (see Figure 1) used to evaluate the process steps in the workflow and as an acronym, SIPOC. To create a SIPOC the first step is the determine the 4-5 high level process steps from start to finish. This is often referred to as the 30,000-foot view. Once the process steps are determined, then parameters for success are defined: inputs and outputs and then suppliers (inputs) and customers (outputs) are added. The final addition to the SIPOC are the Critical-to-Quality standards (CTQ). For each process step

the CTQ establishes the significant elements that when left out or not considered become a barrier to end-user satisfaction or create a system failure.

Figure 1: SIPOC Process

S	I	P	O	C	CTQ
Suppliers	**Inputs**	**Process Step**	**Outputs**	**Customers**	**Critical to Quality**
Who supplies the inputs	Required to make the process successful	Steps necessary to complete the task	Results that the process delivers	End-user receiving the output	Actionable specification for success of the process step

Measure Phase

The Measure Phase sets to explain the process as it exists (baseline) to move forward to improving the process. In this phase it is tempting for the stakeholders to jump to solutions, but focus should be on collecting information about the process, as what appears to be the problem or barrier, may not be the root cause. A significant amount of stakeholder time is spent in this phase to understand the process and how suppliers impact, or at least influence, outcomes that lead to customer dissatisfaction and, ultimately, system failure. In this phase, commonly used SS tools are process mapping, fishbone diagram, cause and effect matrix, failure modes and effects analysis, and Pareto chart. Baseline data from current state is displayed in a control chart. As improvements are initiated, stacked control charts display different project periods on the same graph for easy comparison.

Process Mapping

To improve a system, all steps of the process must be identified and flowcharted. This process map of the existing conditions is known as the Current State Map. Analysis of the current state map offers an opportunity to identify bottlenecks, waste, redundancy, and ambiguity in the process. Redundancy with the inability to arrive at the next step in the flowchart is often referred to as a re-work loop. Furthermore, ambiguity in any step(s) of the flowchart is known as a cloud in the process. Cloud is the term used because the flow or output of a step may be dependent on the required input, or variation between suppliers or customers. A cloud may be difficult to see through to the next step of the process and prevents stakeholders from understanding the expectations or requirements at each step of the process.

Fishbone Diagram

The fishbone diagram allows stakeholders to identify failures in different categories displayed in an array resembling a fish skeleton [39 41]. Each SS project is different, and the fishbone diagram allows for some inter-project variability in selecting the categories contributing to failure (bones) and with the number of contributions each stakeholder can make. The latter allows for team size variation.

Once the fishbone diagram is complete the next step is to have the stakeholders multi-vote on the ultimate cause for failure by placing a vote by the one cause that contributes the most to system failure, from their own perspective. The votes are counted and the causes with the most votes are carried over to the cause and effect matrix.

Cause and Effect Matrix

To build an improved system evaluation of the current state must be thorough. The Cause and Effect Matrix (C&E) is a SS tool to identify which causes for failure from the multi-voted fishbone diagram are most impactful on the CTQs. The tool is completed with the failures listed in rows on the left side and each CTQ across the top of the matrix. A consistent rating scale is assigned, with high rating for high correlation between the cause and the CTQ. Rating in each box is totaled at the end of each row. The cause with the highest score is considered most impactful to success, and each row is prioritized in rank order.

Failure Modes and Effects Analysis

Failure Modes and Effects Analysis (FMEA) can be used in SS to evaluate process steps in the future state to error-proof the new state prior to implementation. FMEA can be used as a stand-alone SS tool in projects, or as in this project, used after the C&E to confirm all the potential critical Xs have been identified. An FMEA is used to determine potential failures at each process step to establish the effect of that potential failure on the output of the process. The process steps are listed along the left side of the grid and the process step is drilled to identify things that could go wrong, the cause of the potential failure, how prevalent the failure would be, and if there are any controls in place to prevent the failure.

Once the failure modes are identified, the severity of each is rated on a 1-10 scale with higher numbers associated with increased severity (SEV Rating). Then, for each failure mode, the cause(s) is identified and ranked on a 1-10 scale based on the frequency of occurrence, with lower numbers assigned to less frequent causes of failure and higher

numbers assigned to more frequently occurring failures (OCC Rating). Then, for each cause, determine if there are controls in place to prevent the failure or to detect the failure before preventing harm. Each cause is assigned a rating based on the efficacy of the control on a scale of 1-10, with lower numbers assigned to causes with ineffective controls (or no controls) and higher numbers if the controls are effective (DET Rating). Finally, each failure mode is calculated by multiplying the ratings for SEV, OCC, and DET. The calculated value is the Risk Priority Number (RPN) and the failure modes are ranked by RPN.

Pareto Chart

The third step in the Measure Phase uses a Pareto chart to visualize data collected through the process review with the stakeholders. The data are categorized and represented in a bar graph with the results frequency plotted from left to right along the x-axis. The ratings are displayed cumulatively is plotted from left to right on a secondary axis that indicates the total percent frequency the causes account for failure. For SS the 80/20 rule is applied when assigning criticality to the Xs. Identifying 80% of the failures and assessing process significance prevents analysis-paralysis and inaction toward improvement. When the evidence of failure is overwhelming it is difficult to pick a place to start improving. The Pareto chart helps by displaying the data in an organized structure and prioritization based on the VOC. Improvements can be designed to eliminate biggest process barriers and realize end-user satisfaction quicker.

Analyze Phase

Analysis of the of the Measure Phase outputs clarify key factors needed for a good process. Potential critical Xs are tested for significance in the contribution to improvement. Testing the hypotheses with available relevant data provides an opportunity to Data collection, synthesis, and statistical analysis tools are used to objectively assigned significance to the variable being tested. Tools used in Analyze Phase are Descriptive Statistics, Two-sample t test, and box plots.

Statistics

When displaying hypothesis analysis, descriptive statistics explains the test and control groups with N size, mean, confidence interval and standard deviation used in comparison of the groups.

A common SS tool for relevance is a 2-sample t-Test. The 2-sample t-Test compares the mean of each group with a 95% Confidence Interval for Difference (alpha level of 0.05). Results of the test with a p value <= 0.05 are considered significant and the null hypothesis should be rejected. For a project that would indicate that the cause of failure was significant to the project outcome and particular focus should be given to improve.

Improve Phase

All hypotheses where the null hypothesis was rejected create the framework for corrective action planning and process improvement is expected. Rapid cycle changes (RCC) are engineered to conform to existing data collection tools and are deemed effective when results demonstrate all measurements are within the control limits and the

mean moves closer to the goal. The results are monitored with staged control charts where each stage marks an implemented RCC. Any RCC that does not improve the process should be evaluated and removed if the process data is no longer within the control limits.

Control Phase

To sustain the improvements after the project has closed a control plan is key. Specific instructions for maintenance, auditing and evaluation are formalized and all stakeholders are educated about the new state and procedures to ensure sustainability. A periodic review of the control plan prevents backsliding and promotes process integrity. A master control plan tool is often used in SS to memorialize the process improvements and provide a current state standard.

Analysis of a Multi-Unit Health System Process Improvement

To improve notification burden from a remote environmental monitoring application with 2,156 monitored environments, a large health system, with multiple campuses and outpatient locations, utilized SS methodology for system restructuring, re-deployment, and reimplementation. The environmental monitoring system was originally installed in 2011, with approximately 200 assets that included temperature in equipment located in several departments, including pharmacy, laboratory, and food service. These departments had controlled locations and were staffed 24/7, so a trained employee was always present to answer alarms. Initially, the system was used for monitoring room temperature, refrigerator or freezer temperatures and was optimized for use in each department following evidence-based guidelines or regulations. Over the course of

several years, the system was decentralized from the original deployment to include patient care nursing units, vaccine storage, patient nourishment, medication storage, operating rooms, and clean and sterile supply storage. By January 2018, there were over 4,200 sensors deployed, of which 2.156 were placed for environmental monitoring (See Table 4). Four hospital campuses had 1,855 sensors deployed and actively recording. Deployment across multiple services and departments, included cardiac catherization laboratories, peri-operative suites, endoscopy procedure rooms, dialysis, sterile processing departments, pharmacy, laboratory, food and nutrition equipment, specialty clinics, and physical and occupational therapy locations. Additionally, over 150 outpatient locations, multiple residential treatment facilities and over 70 animal research laboratories were analyzed as part of this study. With the additional deployment, system structure was failing with over 11,000 alarms firing each month. The greatest notification burden falling to the patient care team in those aforementioned areas. Additionally, many alarms were unanswered causing information systems (IS) server failure. The system was unsustainable. Of importance, the health system had experienced a refrigerator monitoring failure in a remote pharmacy location, where $600,000 of chemotherapy pharmaceuticals were lost due to a temperature excursion in a single refrigerator. This event and the system instability were the impetus for improvement.

Table 4: Environmental Monitoring Sensors Deployed Across Health System

Affiliate	Department/Area	Patient Care	Ancillary	Total
Hospital Affiliate A	Facilities		50	
	Food and Nutrition			
	Main Kitchen	17		
	Remote Location on Campus	130		
	Information Services		7	
	Laboratory	230		
	Off Campus Clinics	23		
	Patient Care Equipment	89		
	Peri-operative Areas	69		
	Pharmacy	83		
	Off-Campus Medication Locations	83		
	On- Campus Medication Locations	223		
	Point of Care Lab Supplies	47		
	Procedural Rooms	19		
	Sterile Processing Areas	14		
	Affiliate Subtotal	**1027**	**57**	**1084**
Hospital Affiliate B	Facilities		43	
	Food and Nutrition			
	Main Kitchen	21		
	Remote Location on Campus	39		
	Laboratory	76		
	Off-Site Clinic Locations	57		
	Pharmacy	25		
	On Campus Medication Locations	52		
	Off Campus Medication Locations	82		
	Patient Care Equipment	71		
	Peri-operative Area	10		
	Physical Therapy Equipment	8		
	Procedural Rooms	25		
	Sterile Processing Areas	2		
	Affiliate Subtotal	**468**	**43**	**511**

Hospital Affiliate C	Food and Nutrition			
	Main Kitchen	12		
	Remote Location on Campus	17		
	Laboratory	40		
	Off-Site Clinic Locations	4		
	Patient Care Equipment	33		
	Peri-operative Area	6		
	Pharmacy	44		
	On Campus Medication Locations	20		
	Off Campus Medication Locations	2		
	Physical Therapy Equipment	3		
	Procedural Rooms	1		
	Affiliate Subtotal	**182**		**182**
Hospital Affiliate D	Employee Health	2		
	Food and Nutrition			
	Main Kitchen	20		
	Remote Location on Campus	36		
	Pharmacy	3		
	On Campus Medication Locations	16		
	Off Campus Medication Locations	1		
	Affiliate Subtotal	**78**		**78**
Mental Health Affiliate E	Food and Nutrition Locations	46		
	Medication Locations	27		
	Affiliate Subtotal	**73**		**73**
Offsite Clinics and Outpatient Service Locations	Food and Nutrition	10		
	Pharmacy			
	Medication Locations	92		
	Vaccine Storage Locations	11		
	Laboratory Locations	19		
	Peri-operative Area	2		
	Physical Therapy Equipment	30		
	Sterile Processing Area	3		
	Affiliate Subtotal	**157**		**157**
Research	Animal	71		
	Affiliate Subtotal	**71**		**71**
	Health System Total	**2056**	**100**	**2156**

For the case study, a project charter was completed (see Appendix A). The Problem Statement explained that environmental monitoring automation had been available across all affiliates since 2011. At the time of project initiation, there were approximately 11,000 excursion alerts each month with 22% of those alerts addressed with corrective action documentation and successful follow-up (see Figures 2 and 3).

Figure 2: Baseline Control Chart of Alerts by Day

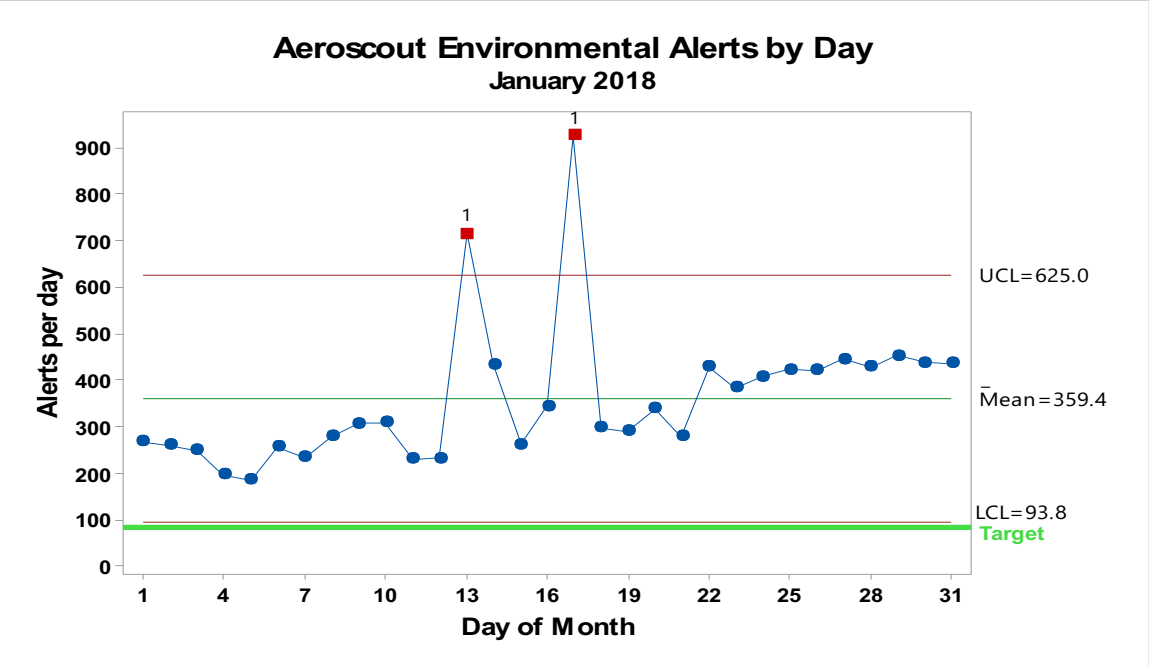
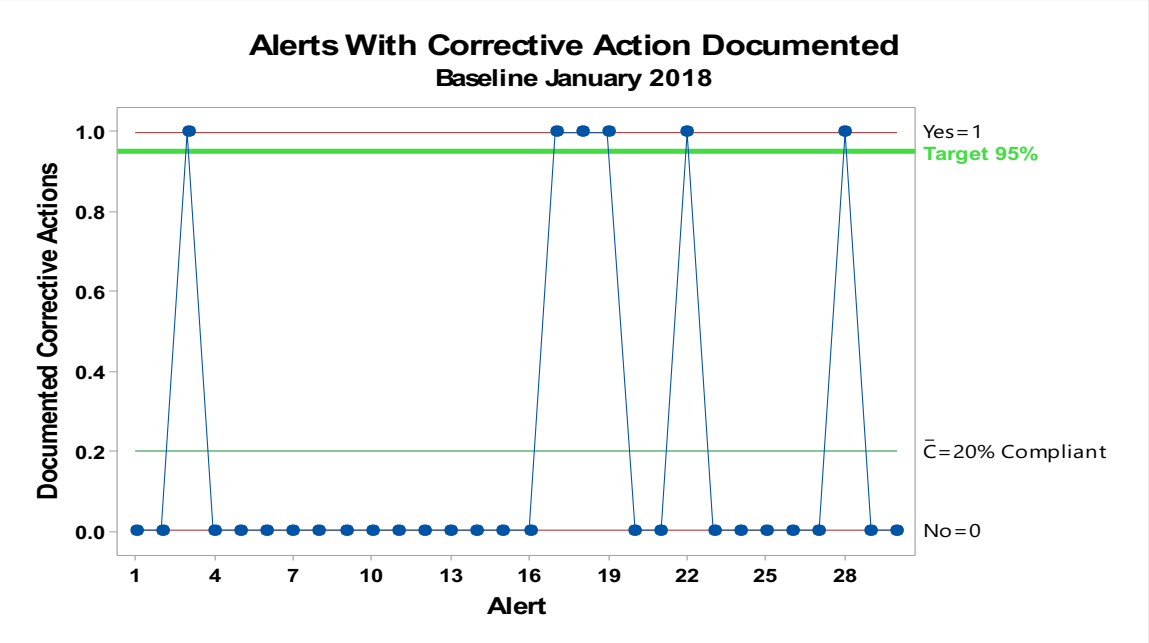


Figure 2 displays the average number of alarms each day over a 31-day period plotted on the x-axis. The mean number of alarms per day was 359. The upper and lower control limits mark 1.5 standard deviations away from the mean and data outside of the control limits indicates a process out of statistical control. On two days the number of alarms were more than 1.5 standard deviations away from the mean, indicating just such

a process. The green reference line was added to acknowledge the improvement target of 83 alarms per day.

Figure 3 displays a random sample of 30 alerts from the 11,000 alerts in the 31-day period. In this graph, those alarms with corrective actions entered were assigned the attribute "Yes" and those alarms without a corrective action were assigned the Attribute "No". Twenty percent of the alarms had corrective actions documented. The green reference line was added to acknowledge the improvement target of 95% of alarms with corrective action documented.

Figure 3: Baseline Chart of Alerts with Corrective Action



A team of 24 end-users were identified as stakeholders and assigned to the SS project team to establish the Voice of the Customer (VOC). For the future state, the optimal process would decrease the number of alerts to eliminate system alarm fatigue while ensuring the processed alarms were appropriate and necessary for deliberate action.

The starting point was identifying a need for environmental monitoring and the end point was successful monitoring of the environment. The project goal was to optimize the system with standardized workflow and reduced variation across departments and affiliates. Goal setting for success was drastic, and due to the instability of the information system supporting the application, needed to avoid expenses for new servers, software upgrades, and staff resources to diagnose and fix system problems. Success would be demonstrated by reducing alarms by 75% to fewer than 2,750 each month and of those remaining alarms, 95%, or approximately 2,600 alarms, would have appropriate follow-up documentation. Those goals would correct the server instability (frequent crashes) and alarm fatigue for the end-users.

In this project, a SIPOC was created define the parameters of the project scope and to ensure that the high-level process steps were identified and the voice of the customer was embedded in the Critical to Quality (CTQ) box for each step. The CTQ was created by the stakeholders. Throughout the Define Phase of the project the stakeholders participated to ensure the current state process was captured and any improvements would be representative of the needs of the end-user. Figure 4 shows the SIPOC for this project.

Figure 4: Project SIPOC

Supplier	Inputs	Process	Outputs	Customers	Critical to Quality
Department, Regulator, Accreditor	Policies, regulations, guidelines, laws	Identify need for environmental monitoring	Purchase order for tag	Department leader	Department knows and complies with monitoring requirements for their application 100% of the time
IS	Heat Ticket entered for tag, specifications for monitoring	Acquire tag	Tag, Instructions for use and monitoring, contact information for troubleshooting and additional resources	Departmental and Service line Leaders/designees, Nursing, Facilities, designated front-line user	Tags are acquired and activated using a standard work process 100% of the time. Responsible parties will be trained to use the system, when assigned a system role, 100% of the time.
IS, Medical Engineering, Facilities	Specialized laptop for tag activation, specifications for environmental conditions to be monitored, contacts for alert monitoring, location and name	Set up tag	Tag set up to monitor appropriate conditions determined by department, Alert scheme, Standard reports	Departmental and Service line Leaders/designees, Nursing, Facilities	Assets are assigned to the correct responsible parties 100% of the time. The alert is received by the correct responsible party 100% of the time.
Department leaders, Facilities	Instructions for best locations for tag placement	Place tag	Tag reading documented in system	Department leaders	Assets are categorized for reporting to responsible parties 100% of the time.
IS, Stanley HC, Departmental leaders	Alerts, reports, user role definition	Monitor environment	Fewer aberrant alerts, lower alert fatigue, proficient and efficient use of the system	IS, Finance, Risk/Loss Prevention, Departmental and Service line Leaders/designees, Nursing, Facilities	Standard reports will be delivered to the responsible parties 100% of the time. Reports will be utilized by the responsible party to correct any outliers 100% of the time. Corrective actions are completed and documented 100% of the time.

Once the SIPOC was created and the high-level process steps were identified, a process map was created that incorporated all detailed steps for the current state of the alarm management process. In contrast with the 4 high-level process steps in the SIPOC, the process flowchart was quite complex, with overlapping steps, known as re-work loops, and ambiguity embedded at certain points in the workflow, known as clouds. Understanding where the bottlenecks, failures, and clouds provided the opportunity to consider immediate changes to the process that would demonstrate “quick wins” and renew stakeholder interest in solving the problems and creating a successful model for re-deployment.

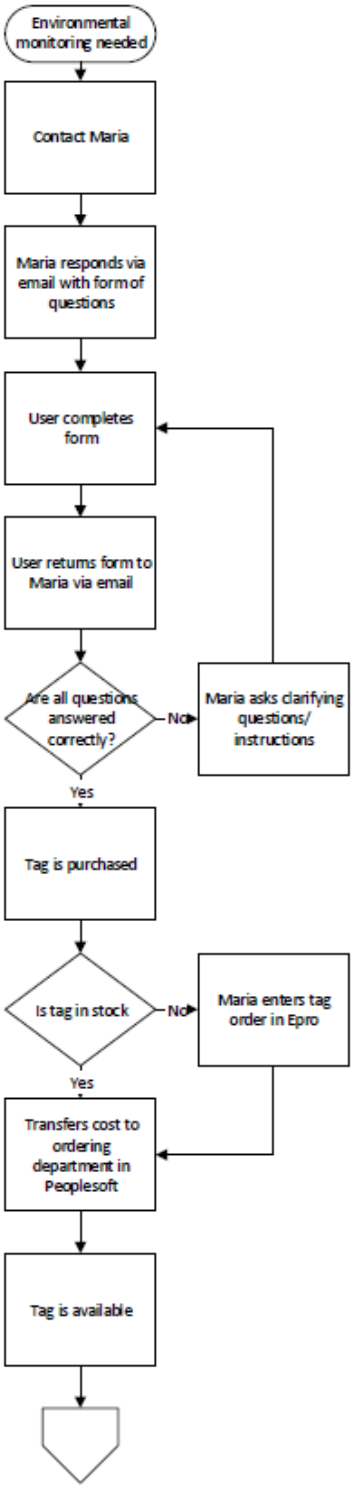
Mapping every action and decision point in the process was important to later phases in the SS process. As Figure 5 shows, there were 36 steps with three re-work

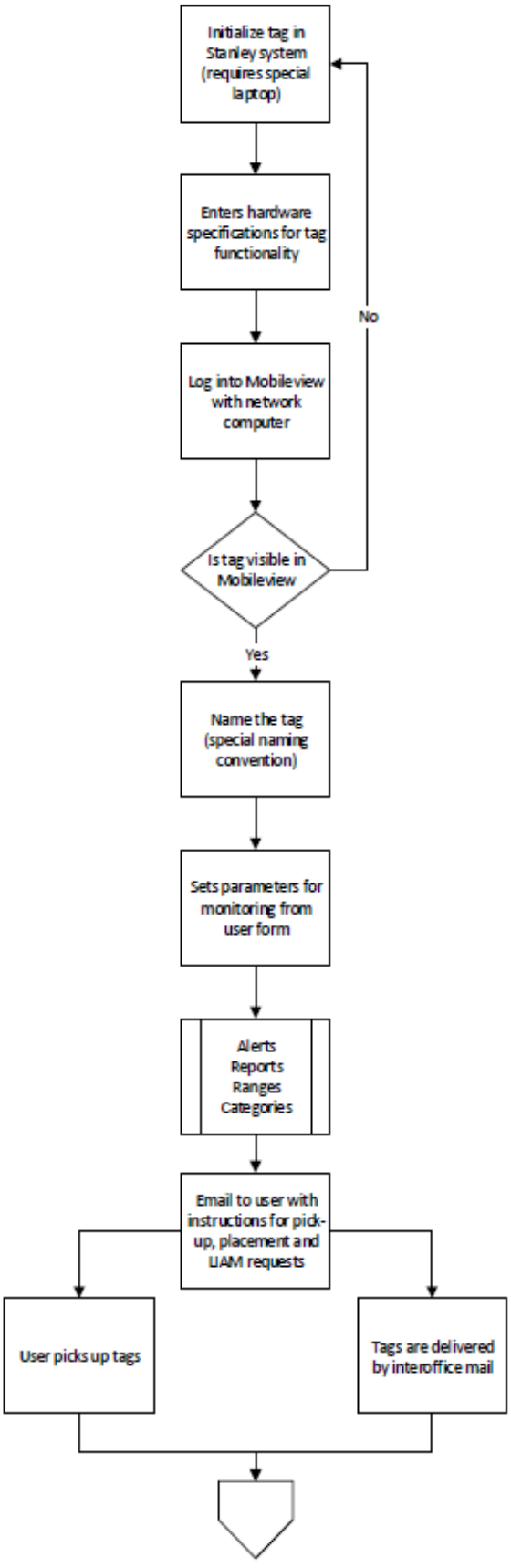
loops and 4 steps with significant variability (clouds). Six steps required email communication which contributed to significant delays when the receiver was unavailable/performing other job tasks (see Figure 5).

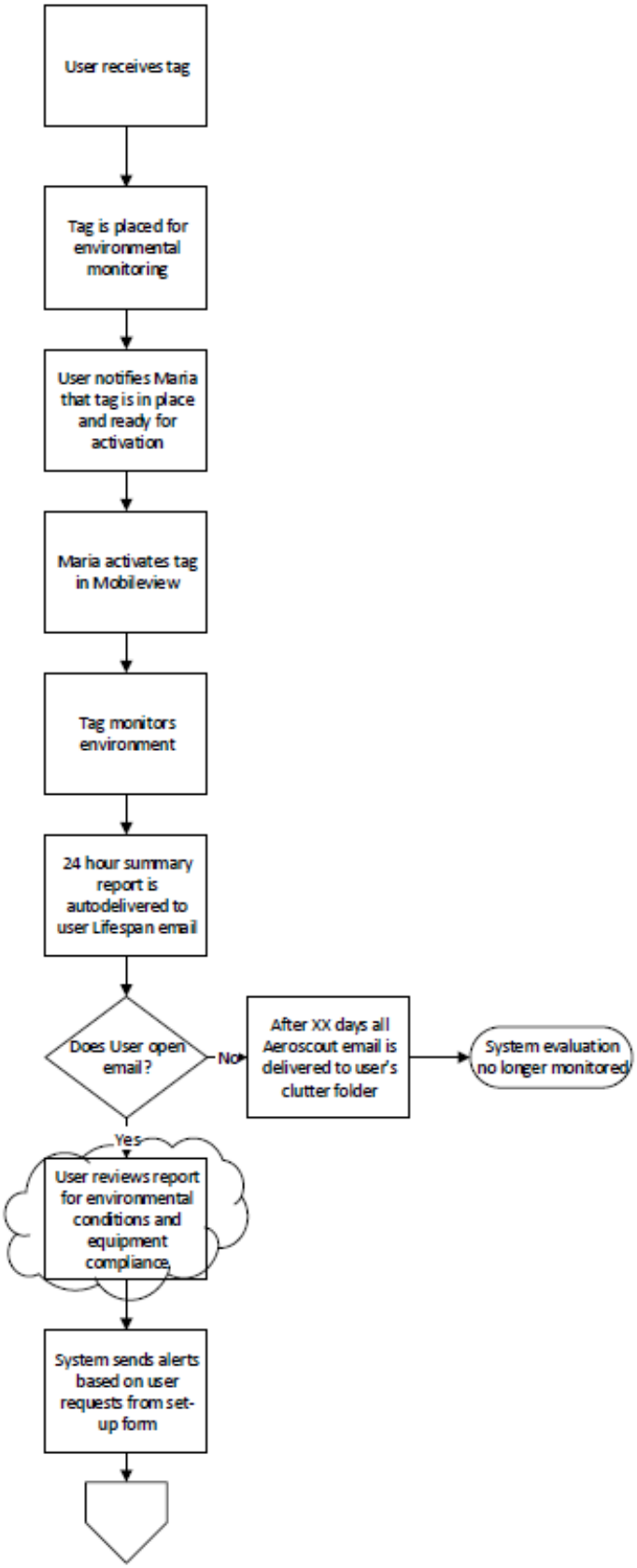
As the critical element in the Define phase, this process map illustrated the complexity of the process, especially to the stakeholders who were unaware of the process steps where they were not involved. As the end-user, stakeholders did not understand the lead time needed for steps in the process or the lag time that was created when emails went unanswered. Process steps that were dependent on a single source (one employee) did not consider employee absence, other job tasks, or competing organizational priorities. Visualizing the process map provided an opportunity for stakeholders to evaluate the dysfunction of the process, establish key drivers for dissatisfaction, and learn appreciation for all involved. This stakeholder buy-in was crucial for the success during the improvement process.

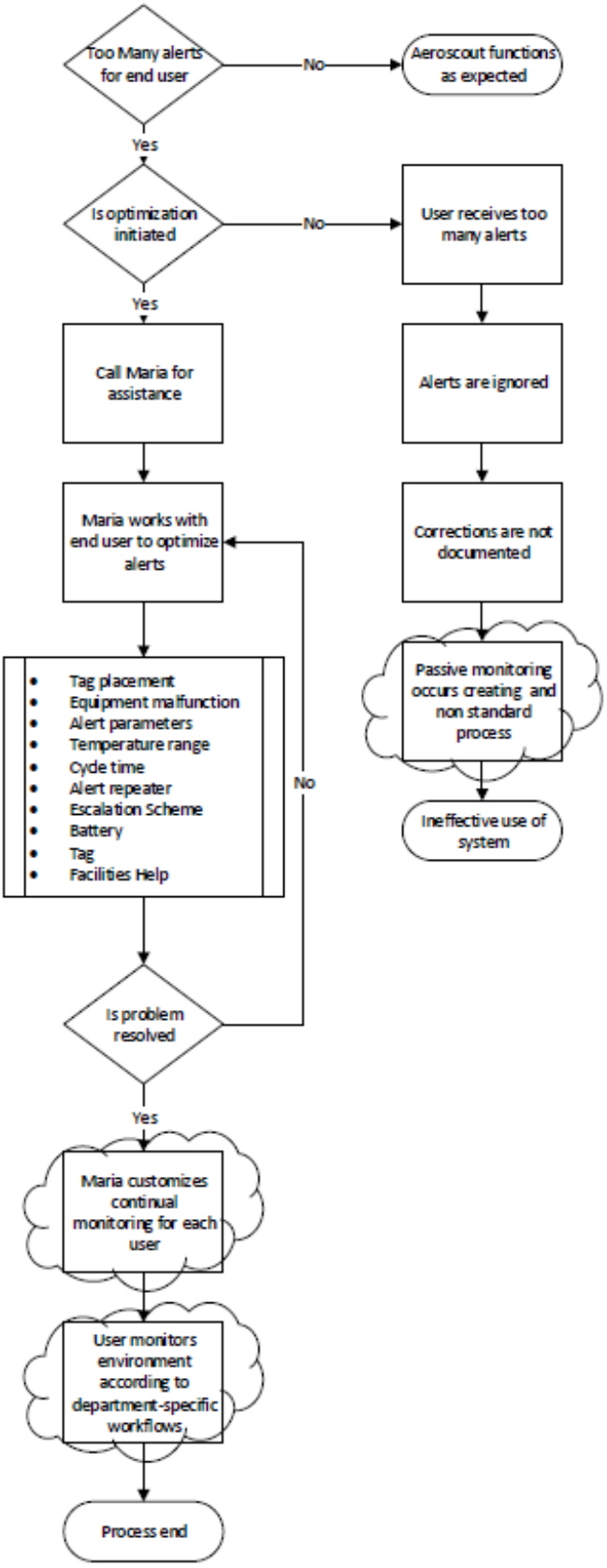
The current state process map was created reactively when the environmental monitoring system was implemented, as the original design plan was incomplete and did not address all possible uses the system had grown to include. Failures during implementation, causing re-work or ambiguity, led to process steps that were layered to prevent failure, as explained by Reason's Swiss Cheese Model [43]. Layering of process steps to prevent failures does not address the underlying problem in the process but patches the process gap to account for a single failure. Eventually, the entire process could be a series of patches without identifying root causes and establishing a process solution that proactively manages the given process before failure ensues [43]. That was the current sate process in place at the outset of this redesign.

Figure 5: Current State Workflow




Initialize tag in Stanley system (requires special laptop)
Enters hardware specifications for tag functionality
Log into Mobileview with network computer
Is tag visible in Mobileview
No
Yes
Name the tag (special naming convention)
Sets parameters for monitoring from user form
Alerts
Reports
Ranges
Categories
Email to user with instructions for pick-up, placement and LIAM requests
User picks up tags
Tags are delivered by interoffice mail


User receives tag
Tag is placed for environmental monitoring
User notifies Maria that tag is in place and ready for activation
Maria activates tag in Mobileview
Tag monitors environment
24 hour summary report is autodelivered to user Lifespan email
Does User open email?
No
After XX days all Aeroscout email is delivered to user's clutter folder
System evaluation no longer monitored
Yes
User reviews report for environmental conditions and equipment compliance
System sends alerts based on user requests from set-up form


Too Many alerts for end user
No
Aeroscout functions as expected
Yes
Is optimization initiated
No
User receives too many alerts
Yes
Call Maria for assistance
Alerts are ignored
Maria works with end user to optimize alerts
Corrections are not documented
Tag placement
Equipment malfunction
Alert parameters
Temperature range
Cyde time
Alert repeater
Escalation Scheme
Battery
Tag
Facilities Help
No
Passive monitoring occurs creating and non standard process
Ineffective use of system
Is problem resolved
Yes
Maria customizes continual monitoring for each user
User monitors environment according to department-specific workflows
Process end

Analysis of the process map (Table 5) indicated that fourteen, or 39%, of the 36 process steps were non-value added to the process of alarm management. A non-value-added step is one that does not impact the output, nor is it critical to quality in maintaining expectations from the VOC.

Table 5: Analysis of Process Map

Steps	Count
Total Number of Steps in the Process	36
Number of Non-Value-Added Steps • Constitute 39% of the Process • 6 of the NVA Steps Pertain to Email Communication	14
Number of Re-work Loops in the Process	3
Number of "Clouds" in the Process	4

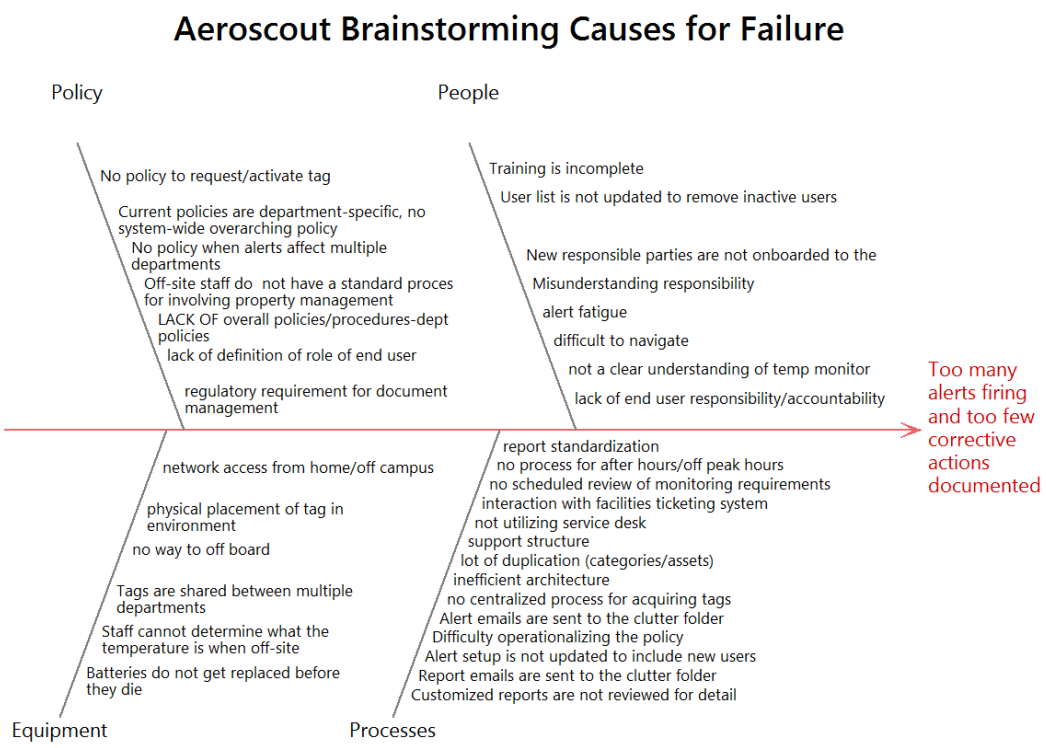
In order to determine the improvements needed to streamline the process and improve efficiency the stakeholders participated in a brainstorming session to identify the actual and potential causes of failures that contributed to alert fatigue and instability of the system. During this meeting, stakeholders were first asked to identify the main reason for system failure. Two overarching contributors were identified by the stakeholders:

1. Too many alerts were firing causing alert fatigue and server overload. End-users were complacent about answering the alerts due to the sheer number of alerts each day and this directly contributed #2.
2. The unreconciled alerts backlogged on the server, required server rebooting every 3rd day to clear the cache and reset the system.

From these system failures, the stakeholders brainstormed causes for these failures and identified. The causes for the failures were plotted on a fishbone diagram, also known as an Ishikawa diagram [41 42].

Each stakeholder was given one opportunity to identify a cause impacting the system and contributing to the overall failure of the system to meet his/her needs. After each stakeholder had identified one cause a second round of contributions was offered. Figure 6 shows the fishbone diagram for this project and identifies a total of 34 causes spread across the four categories: Policy, People, Equipment, Processes.

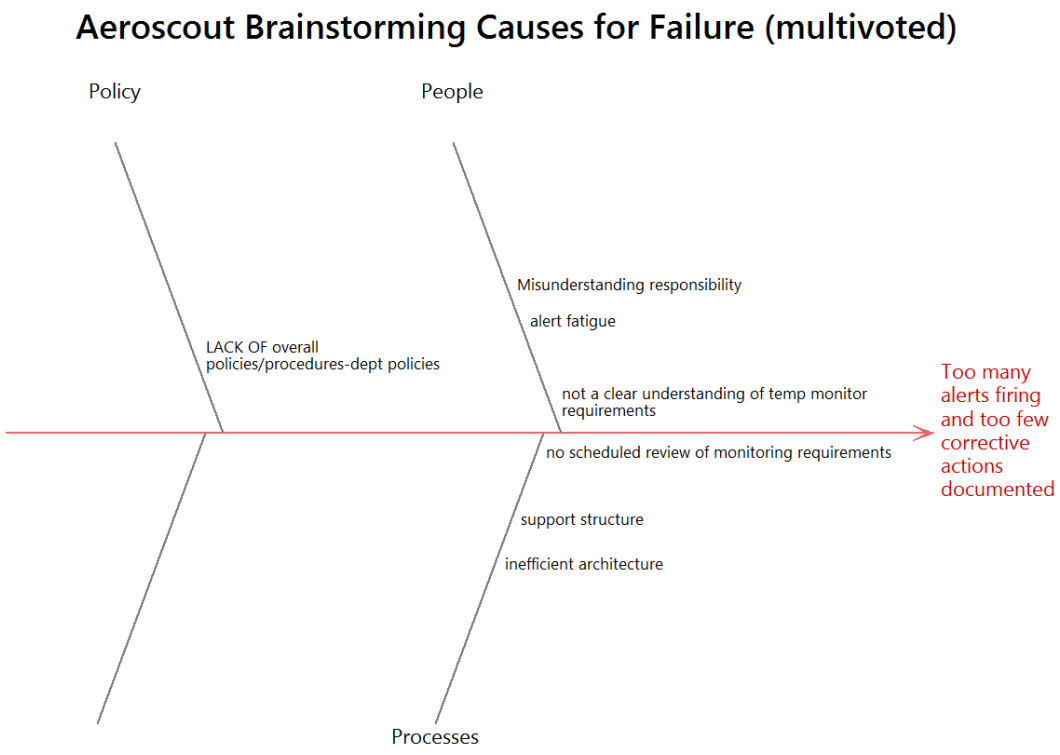
Figure 6: Fishbone Diagram with All Causes for Failure



In the next step, the stakeholders were given one vote to identify the most likely contributor to system failure. From 34 causes, multi-voting (shown in Figure 7) left

seven causes that most likely contributed to the system failure. Those failures were noted in Policies, People, and Processes categories.

Figure 7: Multi-voted causes for Failure



The seven remaining causes from the multi-voting were added to the C&E for evaluation. The highest rating was assigned to lack overall policies/procedures with a score of 325. Figure 8 shows the C&E matrix for this project.

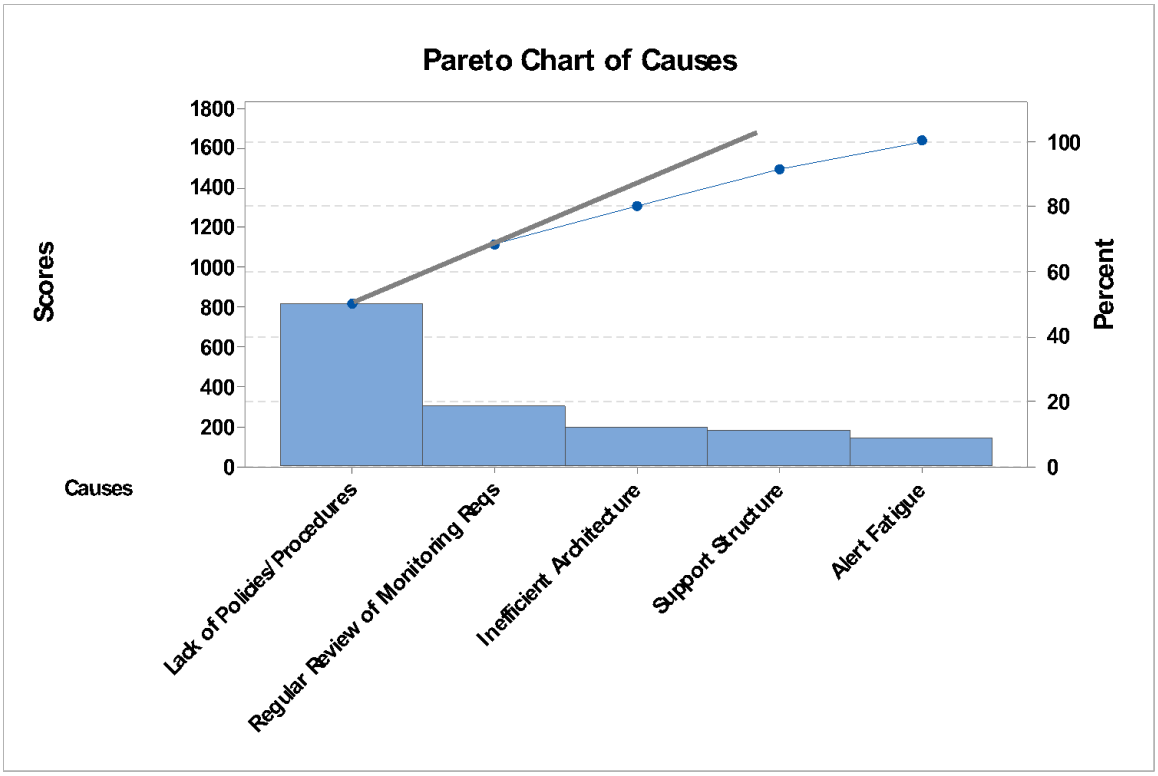
Figure 8: Cause and Effect Matrix

9 – strong relationship 3 – moderate relationship 1 – weak relationship	CTQ #1	CTQ #2	CTQ #3	CTQ #4	CTQ #5	CTQ # 6	CTQ # 7	CTQ #8	CTQ #9	Weight	Rank
	9	1	9	3	9	1	1	3	9		
Cause #1 Misunderstanding responsibility	9	1	9	1	1	1	1	3	9	267	**3**
Cause #2 alert fatigue	1	1	1	1	3	3	1	3	9	143	**7**
Cause #3 not a clear understanding of temp monitor requirements	9	1	3	1	1	9	1	3	9	221	**4**
Cause #4 Lack overall policies/procedures-dept policies	9	9	9	3	3	1	9	9	9	325	**1**
Cause #5 inefficient architecture	1	1	3	9	9	9	9	1	3	193	**5**
Cause #6 support structure	1	9	3	9	9	9	9	1	1	183	**6**
Cause #7 no scheduled review of monitoring requirements	9	1	1	9	9	1	9	3	9	299	**2**

The results from the C&E were plotted in a Pareto chart with the first two causes accounting for approximately 70% of the process failures. to aid with identifying the potential critical Xs. In SS, a critical X is an input to the process being studied that has significant influence over the success of the output of the process. From the critical Xs, hypotheses are derived for testing. Any critical X testing where statistical significance is demonstrated ($p<=0.5$) the null hypothesis should be rejected in favor of the alternate hypothesis. From the Pareto chart for the C&E (Figure 9), two potential critical Xs were identified as having significant influence over the success of alarm management:

1. Lack of policies/procedures
2. Regular review of monitoring requirements.

Figure 9: Pareto Chart of Causes from C&E



Failure Modes and Effects Analysis

In this project the stakeholders identified twelve failure modes across the five high level process steps (Figure 10). The two highest RPNs from the FMEA were:

1. Ignoring alarms due to alarm fatigue
2. Wrong alarm assignment

Figure 10: Original FMEA

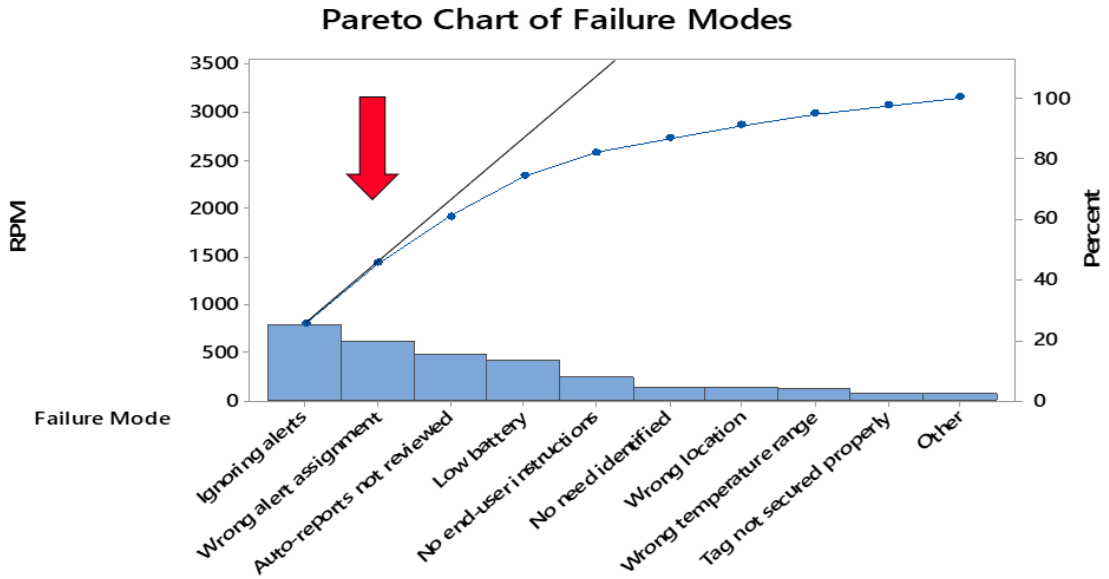
Process Step	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Process Controls	DET	RPN
Identify Need for environmental monitoring	No need identified	Equipment, supplies not monitored	7	Unaware of regulatory, research requirement	2	None	10	140
Acquire tag	Tag not available	Delay in monitoring	5	Low inventory	3	Single IS person assigned	1	15
				Delay in shipment				
	Wrong tag	No monitoring	4	Ordering	3	Vendor spec sheets and instructions for use	5	60
				Unaware of requirements				
Set up tag	No end user instructions	Too much data to manage	6	No system policy for use	7	Single IS person assigned	6	252
				No formal user education				
	Wrong temperature range	Alert fires	3	Unaware of requirements	4	None	10	120
				Assigned to wrong category				
	Wrong alert assignment	Unnecessary alert fires	9	Assigned to wrong alert schema	7	None	10	630

Process Step	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Process Controls	DET	RPN
Place Tag	Wrong location	Unnecessary alert fires	7	Unaware of system requirements	4	Remote/email assistance	5	140
				No instructions for placement				
	Tag not secured properly	Lost tag	5	No instructions for placement	2	Remote/email assistance	8	80
	Tag not activated	No monitoring	3	Malfunctioning activator	1	Remote/email assistance	3	9
Monitor Environment	Low battery	Lose tag/monitoring	7	Not checking status reports	6	None	10	420
				No battery report set up for user	4	Single IS person assigned	6	168
	Auto-reports not reviewed	No monitoring	6	Sent to Clutter email	8	None	10	480
	Ignoring alerts	System instability	10	Alert Fatigue	8	None	10	800
				Lack of training	5	None	10	500

To determine which failure modes that had the most influence over the process, the FMEA ratings were placed in a second Pareto chart for analysis (see Figure 11). From the Pareto chart for the FMEA, two potential critical Xs were identified as having significant influence over the success of alarm management:

1. Ignoring alerts
2. Auto-reports not reviewed

Figure 11: Pareto Chart from FMEA



Hypotheses

From the C&E and FMEA the four 4 potential critical Xs were developed into hypotheses for testing:

1. Lack of policies/procedures
2. Regular review of monitoring requirements
3. Ignoring alerts

4. Auto-reports not reviewed

Critical Xs 2 and 4 were redundant and consolidated into one hypothesis (#2). The three hypotheses tested were:

H1: The presence of user policies or procedures, indicating familiarity and regular use of the system, would have an impact on the number of alarms generated for an end-user.

H1 Null (0): The presence of user policies or procedures, indicating familiarity and regular use of the system, had no impact on the number of alarms generated for an end-user.

H1 Alternate (1a): The presence of user policies or procedures, indicating familiarity and regular use of the system, had an impact on the number of alarms generated for an end-user.

H2: Regular review of monitoring requirements and consistent system interaction had an impact on the number of alarms generated for an end-user.

H2 Null (0): The regular review of monitoring requirements and consistent system interaction had no impact on the number of alarms generated for an end-user.

H2 Alternate (2a): the regular review of monitoring requirements and consistent system interaction had an impact on the number of alarms generated for an end-user.

H3: Alert parameters determined by expert definition or empirically based system use had an impact on the number of alerts with corrections documented which ultimately, would reduce server burden and unnecessary rebooting and downtime.

H3 Null (0): Alert parameters determined by expert definition or empirically based system use had no impact on the number of alerts with corrections documented.

H3 Alternate (3a): Alert parameters by expert definition or empirically based system use had an impact on the number of alerts with corrections documented.

Each hypothesis was tested to determine statistical significance with the expectation that a p value <0.05 was an indication to reject the null hypothesis. The results of the data analysis would be used to focus improvements that would be impactful and sustainable. A tenet in SS the data drives the project; and in this case study resources would be allocated based on a plan where the data support the biggest opportunity for success. The hypotheses introduced in this case study were formed from an exhaustive process driven by the VOC and SS tools focused on objectively identifying root causes for system processes that contributed to the failures of the environmental monitoring system.

The case study review of the Analyze, Improve, and Control Phases is discussed in Chapter IV: Data and Analysis.

Chapter IV

Data and Analysis

In a Six Sigma process, the first two phases (Define and Measure) set the stage for the Analyze, Improvement, and Control Phases. This chapter examines the three latter phases of SS. Ongoing data was collected on alarms and the response and resolution of each of those alarms. Baseline data collected in January 2018, indicated that an average of 379 alarms per day were sent to end-users signifying temperature excursions outside of established ranges and of those alarms, approximately 20% were assessed and corrected. A Data Collection Summary was created (discussed in depth below) to provide an executive overview of hypotheses tested, statistical testing, and project relevance in an executive summary format. Displaying the data design this way helps a stakeholder relay the importance of the potential process improvements with all levels of the organization in a concise manner without the granular details.

Hypothesis 1: Policy Impact on Alarms

From the Cause and Effect matrix (C&E) the stakeholders identified that one of the root causes of the failure of the environmental monitoring system was that the end-users did not have policies or procedures to guide the end-user on how to use the system, optimize settings in the system to reduce alarms, or identify problems and perform basic troubleshooting. Existence of a published policy was used as a surrogate marker for active and appropriate alarm management. In order to test this hypothesis, all environmental-related alarms for a six-week period were reviewed, with demographic information, including equipment name (if refrigerator or freezer) or room number (if

ambient), department responsible for the equipment/room number, equipment location, and date and time of the alarm. The data was sorted by department responsible and were cross walked to published policies or procedures from any department. The source of the published documents was the health system Intranet policy repository. The department specific alarms were divided into two groups based on availability of published policies or procedures: Group One contained all departments without a published policy or procedure for the environmental monitoring system, and Group Two contained all departments with at least one policy or procedure published on the health system Intranet. Further research regarding any policies available in a department, but not published on the health system Intranet was collected for a final division before analysis.

Data collected to test hypothesis 1 (H1) included 15,318 alarms generated from April 14, 2018 through May 31, 2018. Alarms were sorted into two groups:

- Group 1: 8,251 alarms from departments without alarm management policies or procedures published on the health system intranet or available in hard copy;
- Group 2: 7,067 alarms from departments with specific alarm management policies or procedures published on the health system intranet or available in hard copy.

Group 1 contained alarm data from twelve departments with an average number of alarms at 688. Group 2 contained alarm data from thirteen departments with an average number of alarms at 544. Results from the 2-sample t-test (see Table 6) demonstrated that having policies or procedures had no significant impact on the number of alarms a department received as demonstrated by a high p-value of 0.645. For H1, the null

hypothesis was accepted. While policies and procedures were important to the stakeholders, presence of policies or procedures did not impact the number of alarms generated for the end-user. The box plot displayed in Figure 12 represents the two groups, with the Group1, with no policies, displayed with wider variation of alarms and Group 2 with less variation. The means of the two groups were similar at 688 alarms per day in Group 1 and 544 in Group 2. There was no statistical significance between the two groups. However, it was noted that a robust system structure and reference materials were needed to sustain the results through the Control Phase and beyond; so the information services (IS) stakeholders opted to draft a policy to outline and encourage proper system use by end-users as a supplement to the project efforts and to promote stable sever and processor management. Having a published policy was not a surrogate for appropriate alarm management; but the importance of structure and design in the process map (See Figure 5) illustrated a need for the future state to have a policy that helped end-users successfully use the system. A final system-wide policy was included in the control plan at the project's conclusion.

Table 6: Statistics for Hypothesis 1 (MiniTab)

Two-Sample T-Test and CI: Total, Policy
Method

μ_1: mean of Total when Policy = 0

μ_2: mean of Total when Policy = 1

Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics: Total

Policy	N	Mean	StDev	SE Mean
0	12	688	822	237
1	13	544	709	197

Estimation for Difference

Difference	95% CI for Difference
144	(-497, 785)

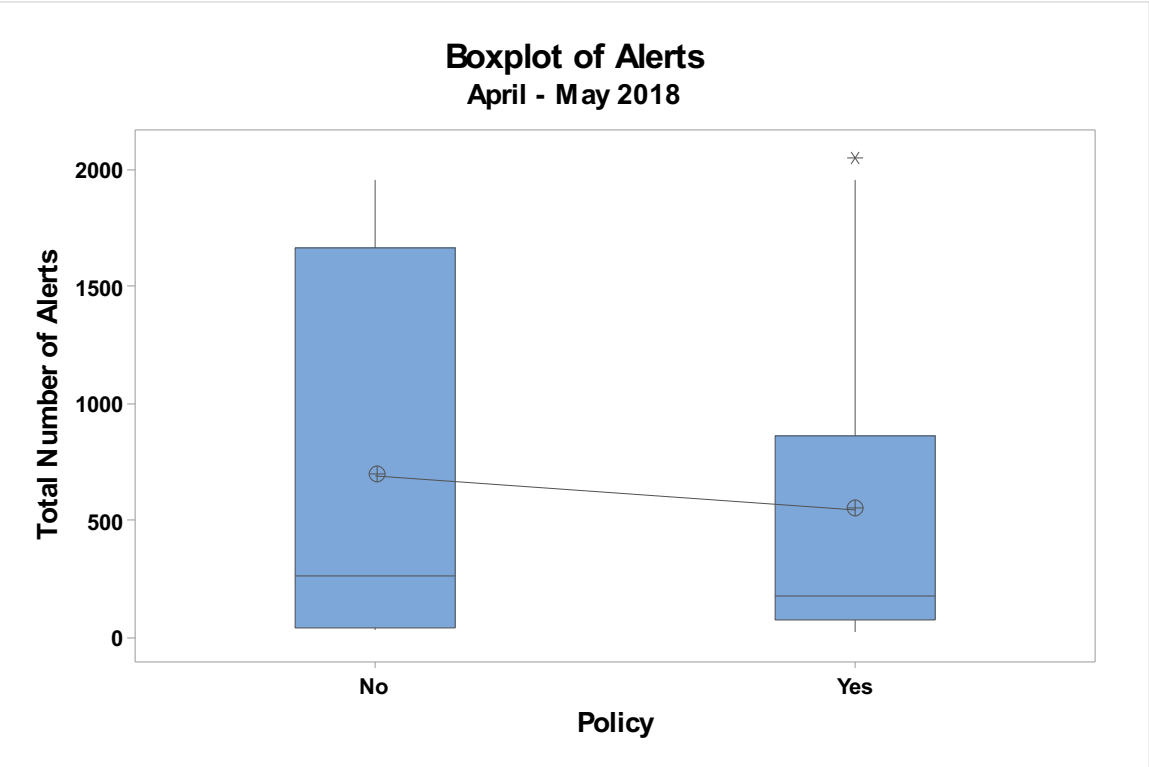
Test

Null hypothesis H_0: $\mu_1 - \mu_2 = 0$

Alternative hypothesis H_1: $\mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
0.47	21	0.645

Figure 12: Box plot of for Hypothesis 1



Hypothesis 2: Active Users Impact Alarms

The second critical X identified from the C&E was that departments without consistent and current use of the system would have more significant alarm fatigue than the departments actively managing the system. Active management included updating or removing users, updating parameters, entering corrective actions, and documenting follow-up because of an alarm. The failure to actively use the system was identified as a potential root cause to the system failure. In addition, the inactivity was considered the biggest factor in server instability. Alarms without any mitigation or correction remained active on the server and over the course of a few days the number of unmanaged alerts created a backlog on the server that could only be remedied by rebooting the server. This caused delays and slow response times when navigating in the system, often displaying

error messages, or kicking the end-user out of the system. In order to test this hypothesis, all environmental-related alarms for a six-week period were reviewed, including demographic information, including equipment name (if refrigerator or freezer) or room number (if ambient), department responsible for the equipment/room number, equipment location, and date and time of the alarm. The data was sorted by department responsible. For further categorization, a list of all end-users was reviewed for activity. Activity was defined as an end-user logging in to the system for maintenance of monitoring parameters, end-user information and access updates, entering corrective actions, creating ad-hoc reports, or troubleshooting. The system audit log was used to discern the end-user activity. Activity was attributed to alarms in each department and added as an attribute to the alarm data.: Group One contained all departments without active use of the system, and Group Two contained all departments with at least one activity episode in the six-week study period.

Data collected to test hypothesis 2 (H2) included 15,318 alarms generated from April 14, 2018 through May 31, 2018. Alarms were sorted into two groups:

Group 1: 16 departments without an end-user logging into the system within the study period for system review.

Group 2: 9 departments with an end-user logging into the system within the study period for system review.

Group 1 had 13.3 alarms per day on average. Group 2 had 4.68 alarms per day on average. The results of a 2-sample t-Test (see Table 7) demonstrated that departments actively logging in to the system for parameter management and documentation had significantly fewer alarms to manage than departments not actively logging in for

parameter management. These results were statistically significant with a p-value of 0.047. For H2 the null hypothesis was rejected. The box plot in Figure 13 represents the average number of alarms in the two groups. The means displayed were 13.3 alarms per day for group 1 and 4.68 for Group 2. The most striking measure in Figure 13 is the spread of alarms; Group 1 ranged from zero to 35, yet Group 2 had a marked lower range of alarms per day at zero to fifteen. The difference in the means was statistically significant. Active system use was included in the corrective action plan to decrease

Table 7: Statistics for Hypothesis 2 (MiniTab)

Two-Sample T-Test and CI: Ave apd, active
Method

μ_1: mean of Ave apd when active = 0

μ_2: mean of Ave apd when active = 1

Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics: C8

Active	N	Mean	StDev	SE Mean
0	16	13.3	14.3	3.6
1	9	4.68	5.99	2.0

Estimation for Difference

Difference	95% CI for Difference
8.64	(0.14, 17.15)

Test

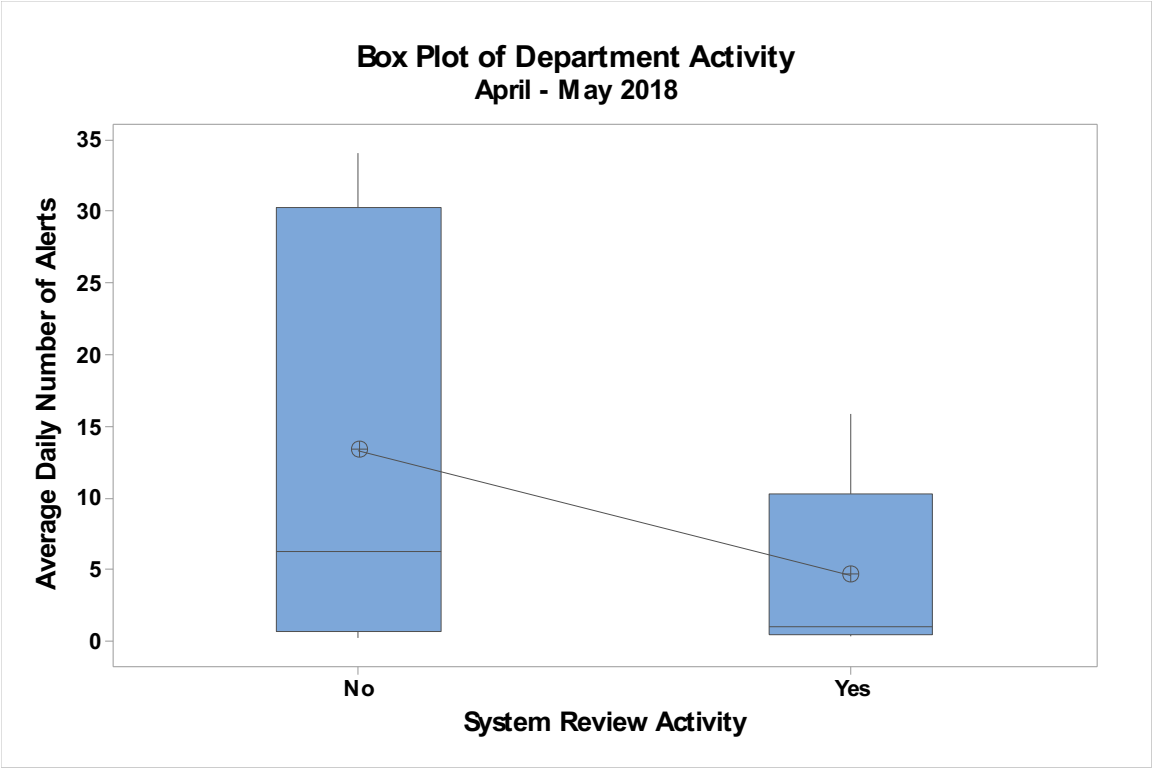
Null hypothesis $H_0: \mu_1 - \mu_2 = 0$

Alternative hypothesis $H_1: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
2.11	21	0.047

alarms. Process improvement in this area would ultimately decrease the number of alarms for the end-user.

Figure 13: Box Plot for Hypothesis 2



Hypothesis 3: Evidence Based Support Impact Alarms

The third critical X was identified from the Failure Modes and Effects Analysis (FMEA), did evidence-based guidance for alarm parameters correlate to reduced alarm which, in turn, promoted system stability? Environmental monitoring parameters were evaluated for consistency and operational appropriateness. From the widespread use of the system, it was apparent that all similar environments did not have the same parameters. For example, a refrigerator in the hospital kitchen did not have the same temperature range as a refrigerator in the hospital blood bank and ambient temperatures

in the operating suite and cardiac catherization lab had different range settings. Research in this area identified that while some departments had defined parameter settings based on regulatory requirements, governing body guidelines, peer-reviewed best practices, or research protocols, some departments did not have similar parameter restrictions or had adjusted beyond the restrictions due to inability to manage the alarms without nuisance alarms burdening the end-users. This analysis generated two unanswered but related questions:

1. Did the imposed restrictions from expert definitions or empirically based best practice cause more alarms?
2. Did the imposed restrictions from expert definitions or empirically based best practice drive end-users to document corrective actions?

To answer these questions additional analysis was needed to determine the validity of expert definition or evidence based support could have on impacting the end-user to enter corrective actions which would, ultimately lead to system stability in order to allocate resources for guided improvement. Based on system configuration, similar environments with similar monitoring functions were categorized together, i.e. all off-site refrigerators were in one category and all ambient environments where medication were stored were in another category. Eighty-five distinct categories were further analyzed for presence of expert definition or empirical precedent for environmental monitoring and management. The data were sorted by category of environmental alarms and whether expert guidance was used to set alarm parameters.

Group 1: 28 departments without expert definition or empirical evidence supporting alarm parameters, defined as federal, state, or local regulations, peer-reviewed guidelines, research protocols, or other peer-published best practice.

Group 2: 57 departments with expert definition or empirical evidence supporting alarm parameters.

Group 1 had 226 alarms per day on average. Group 2 had 24.3 alarms per day on average. The results of a 2-sample t-Test (see Table 8) demonstrated that departments

Table 8: Statistics for Hypothesis 3 question 1 (MiniTab)

Two-Sample T-Test and CI: Count_1, Evid Method

μ_1: mean of Count_1 when Evid = 0

μ_2: mean of Count_1 when Evid = 1

Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics: Count_1

Evid	N	Mean	StDev	SE Mean
0	28	226	370	70
1	57	24.9	48.6	6.4

Estimation for Difference

Difference	95% CI for Difference
200.6	(56.4, 344.9)

Test

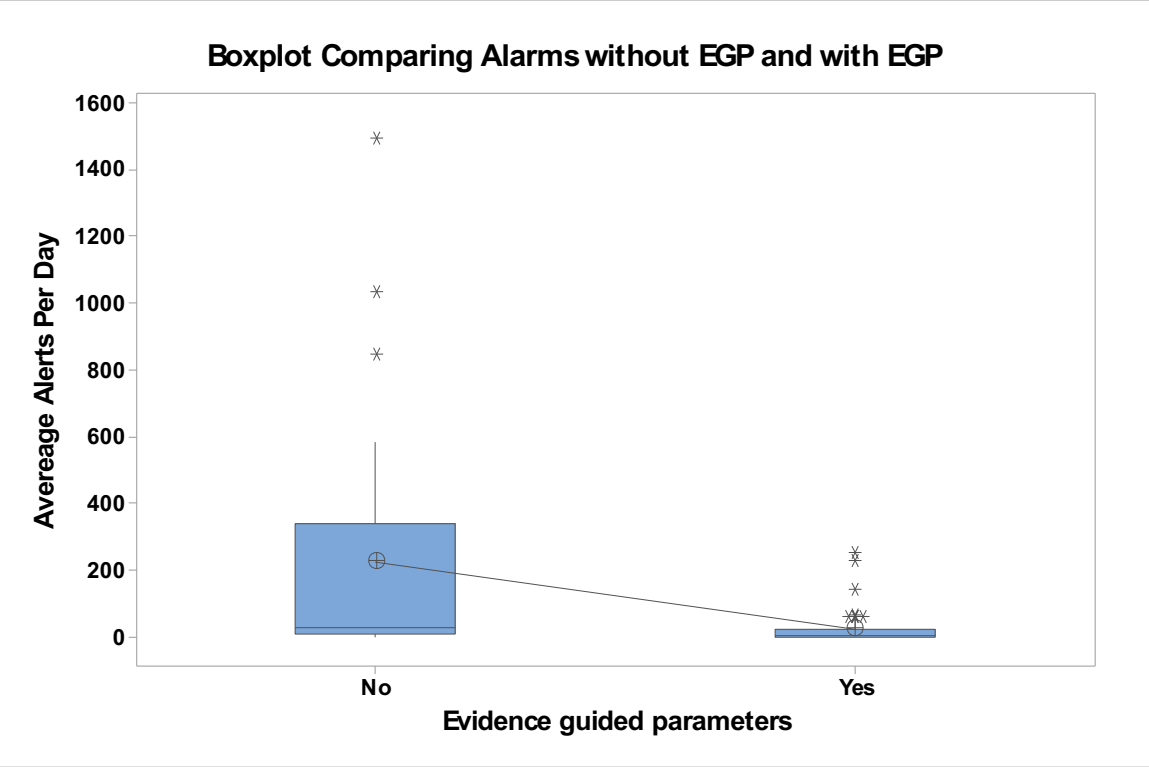
Null hypothesis $H_0: \mu_1 - \mu_2 = 0$

Alternative hypothesis $H_1: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
2.85	27	0.008

using expert definition or empirical evidence to support alarm parameters had significantly fewer alarms to manage than departments without expert definition or empirical evidence. These results are statistically significant with a p-value of 0.008. The box plot in Figure 14 displays the difference of the means graphically, with Group 1 having a wider spread indicating greater variation in number of alarms per day than the members of Group 2.

Figure 14: Box Plot for Hypothesis 3, question 1



Data collected to test hypothesis 3 (H3), question 2 (Q2) included alarms generated from May 1, 2018, 2018 through May 31, 2018. Alarms were sorted into two groups:

Group 1: 40 departments without expert definition or empirical evidence supporting alarm parameters, defined as federal, state or local regulations, peer-reviewed guidelines, research protocols, or other peer-published best practice.

Group 2: 45 departments with expert definition or empirical evidence supporting alarm parameters.

Group 1 had 167 alarms per day on average. Group 2 had 23.6 alarms per day on average. The results of a 2-sample t-Test demonstrate that departments with expert definition or empirical evidence supporting alarm parameters were more likely to correct alarms and document those corrections in the system (See Table 9). By documenting the alarm correction in the system, fewer alarms were held in the cache, freeing up server and process capacity, this reducing downtime, error messages and rebooting. These results are statistically significant with a p-value of 0.008. For H3 the null hypothesis was rejected for both unanswered questions. The box plot in Figure 15 graphically displays the number of alarms per day in each group. The group with expert definition or empirical evidence had significantly more corrective actions entered than the group without expert definition of empirical evidence. Process improvement in this area would ultimately decrease the number of alarms for the end-user, which would reduce unprocessed alarms remaining on the server. This would stabilize the server and prevent unnecessary server rebooting and downtimes.

Table 9: Statistics for Hypothesis 3 question 2 (MiniTab)

Two-Sample T-Test and CI: Count, CA Method

μ_1: mean of Count when CA = 0

μ_2: mean of Count when CA = 1

Difference: $\mu_1 - \mu_2$

Equal variances are not assumed for this analysis.

Descriptive Statistics: Count

CA	N	Mean	StDev	SE Mean
0	40	167	321	51
1	45	23.6	57.6	8.6

Estimation for Difference

Difference	95% CI for Difference
143.3	(39.5, 247.2)

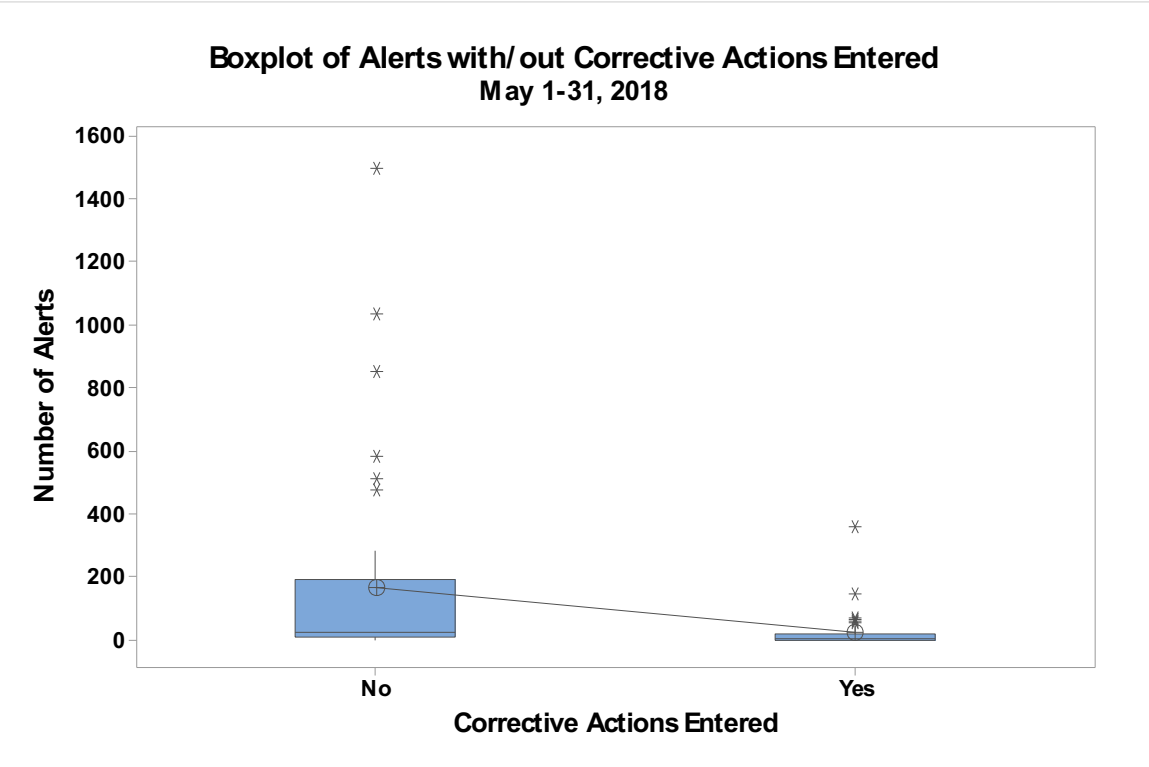
Test

Null hypothesis $H_0: \mu_1 - \mu_2 = 0$

Alternative hypothesis $H_1: \mu_1 - \mu_2 \neq 0$

T-Value	DF	P-Value
2.79	41	0.008

Figure 15: Box plot for Hypothesis 3 question 2



A Data Collection Summary Tool was created (see Figure 16) to provide a clear overview of the data collected and analyzed in the project. This SS tool consolidated all the hypotheses testing to a single table for quick reference explaining each hypothesis, statistical test results and whether the potential Critical X for each hypothesis was critical to the process. In Figure 16 the statistical test performed for each hypothesis was a 2-sample t-test and for X2 and X3, the null hypotheses were rejected in favor of the alternate hypotheses indicated by the low p value for each test. In conclusion, the active system use, and corrective action documentation were significant determinants to be included in the Future State process.

Figure 16: Data Collection Summary

Potential X's	H_o- null hypothesis	H_a- alternative hypothesis	Tool	Conclusions	Critical X?
X1 – Lack of policies/ procedures	The presence of dept. policies **HAS NO IMPACT** on number of alerts	The presence of dept. policies **HAS AN IMPACT** on number of alerts	Alert data divided into 1.Departments with published policies 2. Departments without published policies 2-sample t test	Comparing Aeroscout alert dismissal results between departments with published policies and without. There was no significant difference in system use when the presence of a policy was used as a marker for engagement **Accept the null** p-value = 0.645	No
X2 – Regular review of monitoring	Active system review/maintenance **HAS NO IMPACT** on number of alerts	Active system review/maintenance **HAS IMPACT** on number of alerts	Alert data divided into 1. Departments interacting with system 2. Departments not interacting with system 2-sample t test	Comparing Aeroscout departments with active use (defined as alert dismissal results, user updates and other documentation) and inactive use (alerts sent without follow-up from department). There was significant difference in the number of alerts in active use departments compared to inactive use departments **Reject the null** p-value = 0.047	Yes
X3 - Alert notification	Alert notification scheme HAS NO IMPACT on corrective action documentation and alert dismissal in Aeroscout	Alert notification scheme HAS AN IMPACT on corrective action documentation and alert dismissal in Aeroscout	Alert data divided into 1.Departments entering corrective action or auto-dismissing alerts 2. Departments not entering corrective actions or auto-dismissing alerts 2-sample t test	With revisions to Aeroscout system and user set-up, an accurate alert scheme significantly increases corrective action documentation **Reject the null** p-value = 0.008	Yes

Process Improvements

From the data collection summary, two critical Xs were confirmed as significant for improving the environmental monitoring process and rapid cycle changes were undertaken to make process improvements. The significance of the changes was monitored using control charts with each rapid cycle change period collected and denoted as a stage.

Another SS tool is Rapid Cycle Changes (RCC), throughout the course of an improvements project it is important to identified small process changes that can be implemented quickly and can be measured with the data collection tools in place. Incorporating RCCs during all phases of the DMAIC, demonstrates stepwise improvements that are not overwhelming or difficult. RCCs also allow quick testing of possible long-term solutions to determine if an RCC will have a positive impact on the

final process. An effective data collection summary will show improvements in real-time and keeps the stakeholder engaged. The RCCs deployed in this project were

1. RCC #1 – Evaluating the system for active end-users
2. RCC #2 – Creating auto-dismissal of an alert when the temperature came back into range
3. RCC #3 – Researching and reviewing evidence guidance for environmental monitoring for each department and reset any parameters that were not guided by best practice.
4. RCC #4 – Resetting alarm parameters for environmental monitoring for all departments with like functions, i.e., all food and nutrition areas were consolidated to one set of evidence guided parameters.

Rapid Cycle Change 1

For this project, Step 2 of the SIPOC identified one opportunity for immediate change which was to review and update the list of end-users assigned for alarms and the alarm parameters that generated their alarms. This process was rapid cycle change #1 (RCC#1). The list of active end-users was 820 employees who had logged into to the system at some point during their employment. End-users were removed from the system if they met the following criteria:

1. No longer employed in the healthcare system;
2. No longer employed in the same job and did not have alarm monitoring as part of their current job function;
3. An employee who had not logged in to the system in the last 90 days.

There were 640 end-users that met the criteria for removal, leaving 180 active end-users. Once the end-user was removed from the system, all active alarms that were associated to that end-user were decommissioned. RCC#1 reduced the notification burden from an average of 359 alarms per day to an average of 187 alarms per day, which was a 48% reduction of alarms (see Figure 17). On one during the RCC #1 period the goal of 83 alarms per day was surpassed as illustrated in Figure 17 by the datapoint on Day 43 falling below the green target line. The RCC #1 period is a process in control (no red datapoints beyond the upper control limit) and tighter control limits than the baseline period.

Data collected to measure the compliance with corrective action documentation remained at 20% no change from baseline, indicating the process change implemented in RCC #1 had no effect on the end-user compliance with entering corrective actions for alarms (see Figure 18).

Figure 17: Two-Stage Control Chart Illustrating Effectiveness of RCC#1

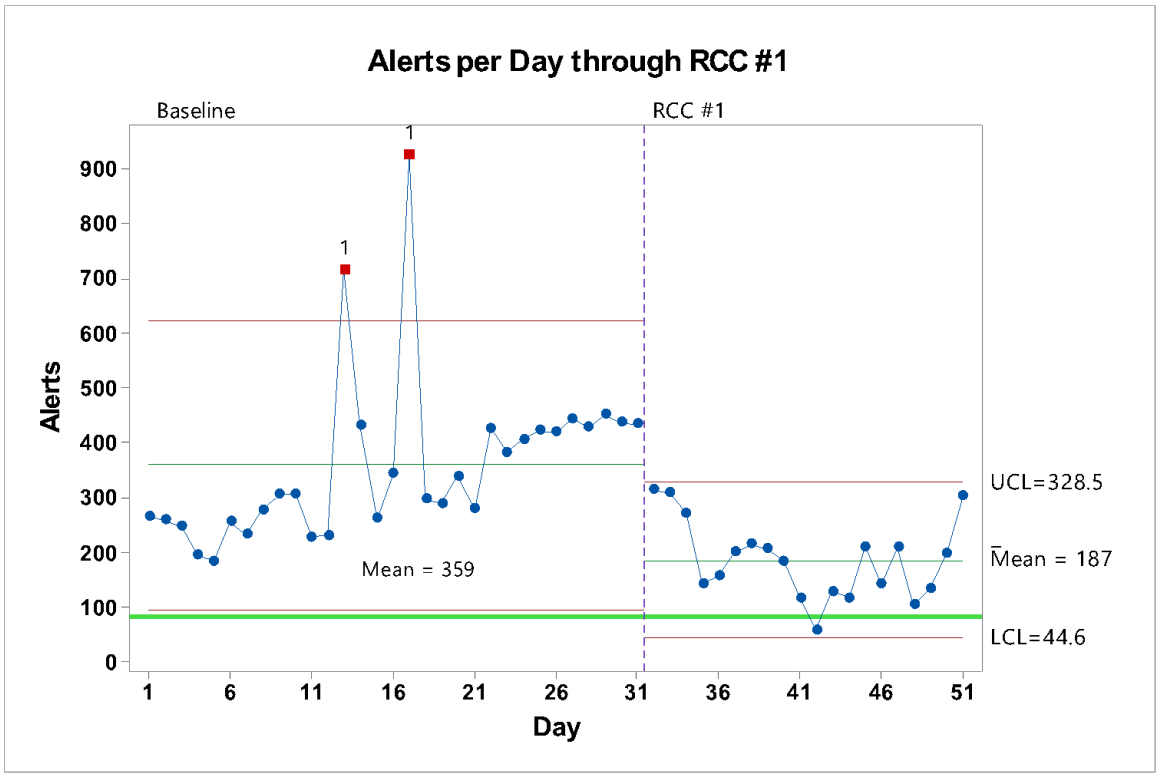
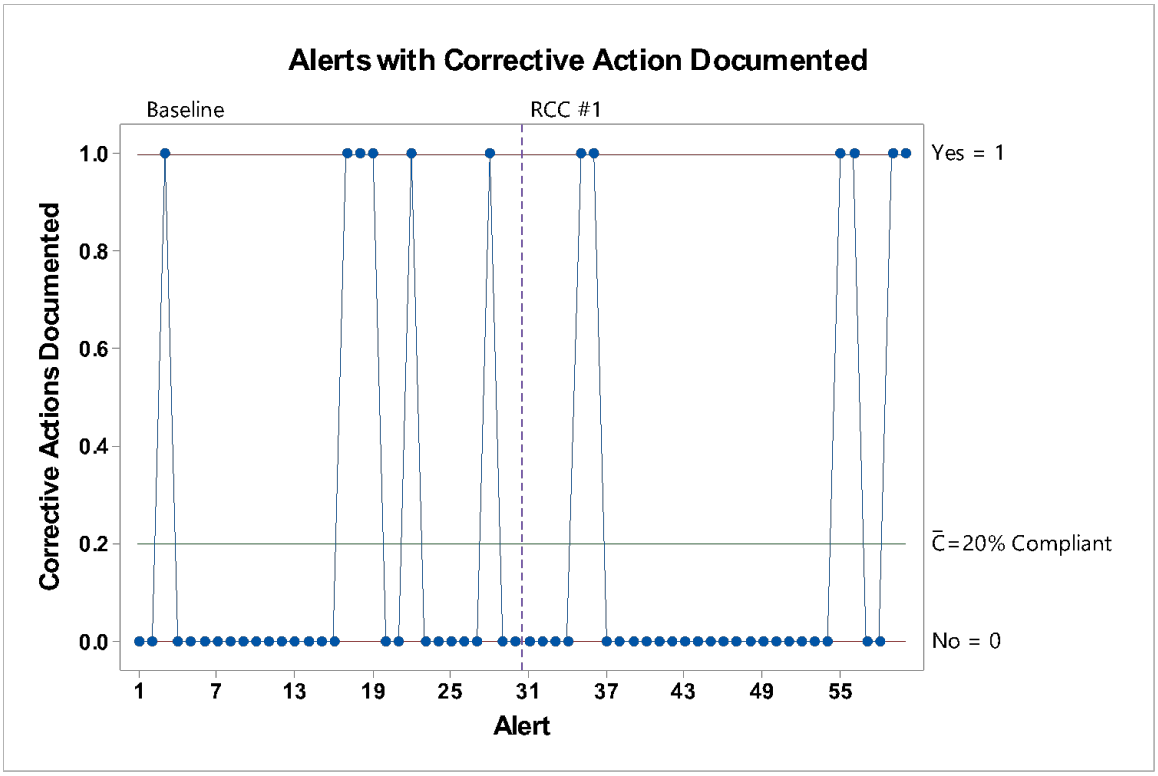


Figure 18: Alerts with Corrective Actions Documented through RCC #1



Rapid Cycle Change 2

For RCC #2, an alarm parameter was assessed that modified the alarm notification burden for the end-user [37]. When an environment was outside of parameter settings, i.e., temperature excursion outside of acceptable range, and then returned to acceptable range within a short period of time, a system setting was changed to allow the system to auto-dismiss the original alarm. This prevented the end-user from having to enter a corrective action, yet the alarm was removed from the active alarm cache preventing a backlog. Over a 20-day period each department was queried to determine if this setting would hinder or help alarm management and all departments accepted the change, with one exception. The outlier was Animal Research, where auto-dismissal was determined to be not appropriate for the sensitive animal environments requiring monitoring. This

system setting change reduced the number of alarms each day to a mean of 167, from the original baseline +RCC #1 of 187 (see Figure 19) which was an 11% reduction in alarms from RCC #1 and an 53% overall reduction of alarms from baseline. On two days during RCC #2 period the goal of 83 alarms per day was achieved as illustrated by the datapoints falling below the green target line. Further review of the dataset for RCC #2 period showed a process in control (no red datapoints beyond the upper process control limit) and tighter control limits indicating less variability in the process for RCC #2. However, fewer corrective actions were entered during the RCC #2 period (see Figure 20). Compliance decreased to 17% compared to baseline and RCC #1, where compliance was 20%.

Figure 19: Staged Control Chart displaying Alerts per Day Through RCC #2

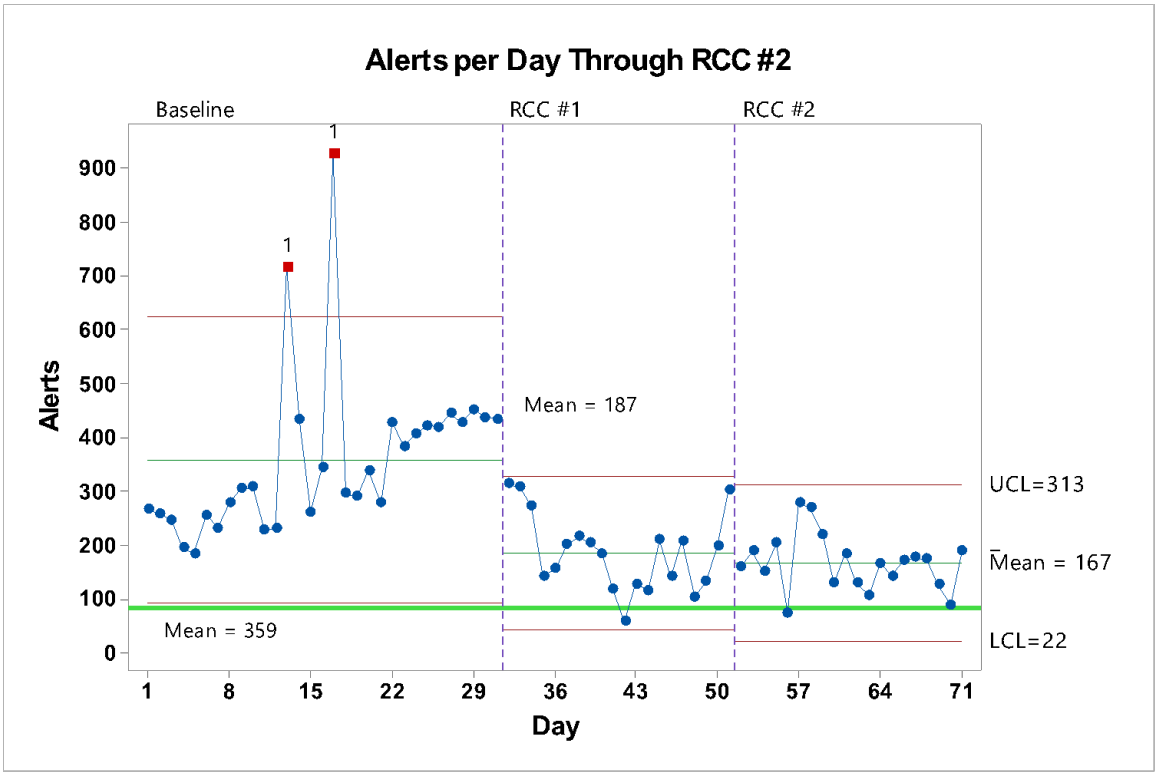
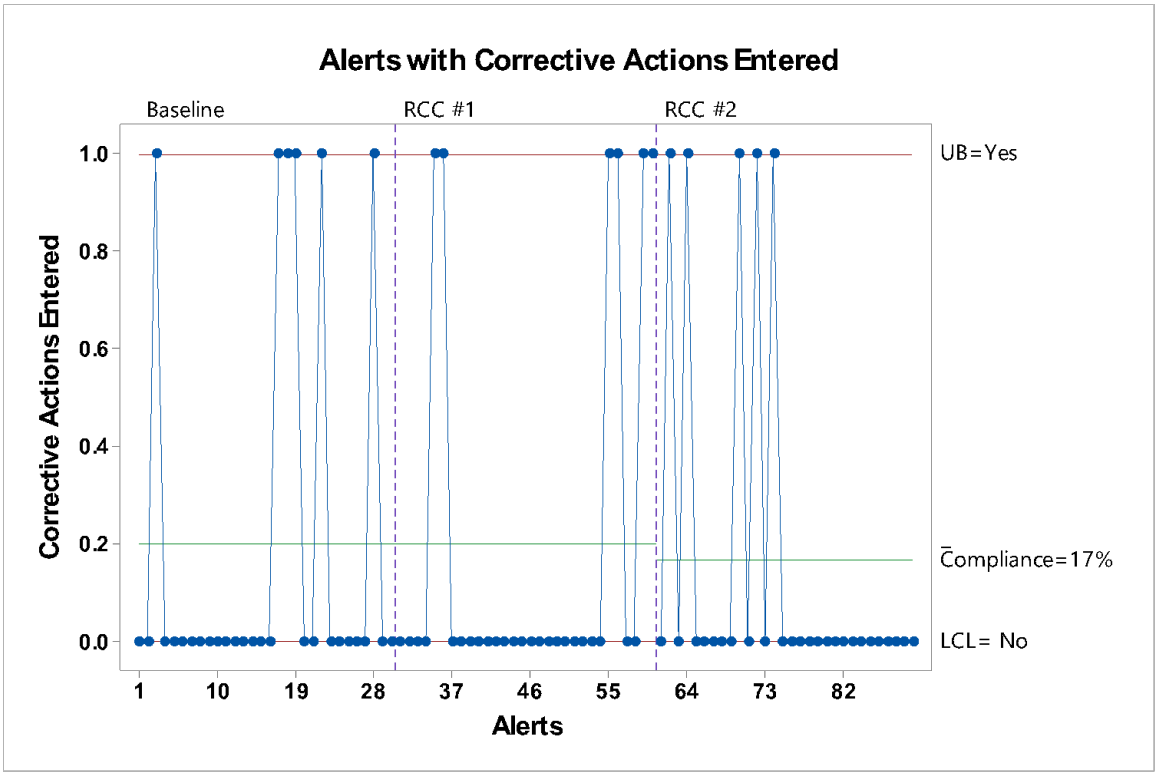


Figure 20: Alerts with Corrective Actions Documented Through RCC #2

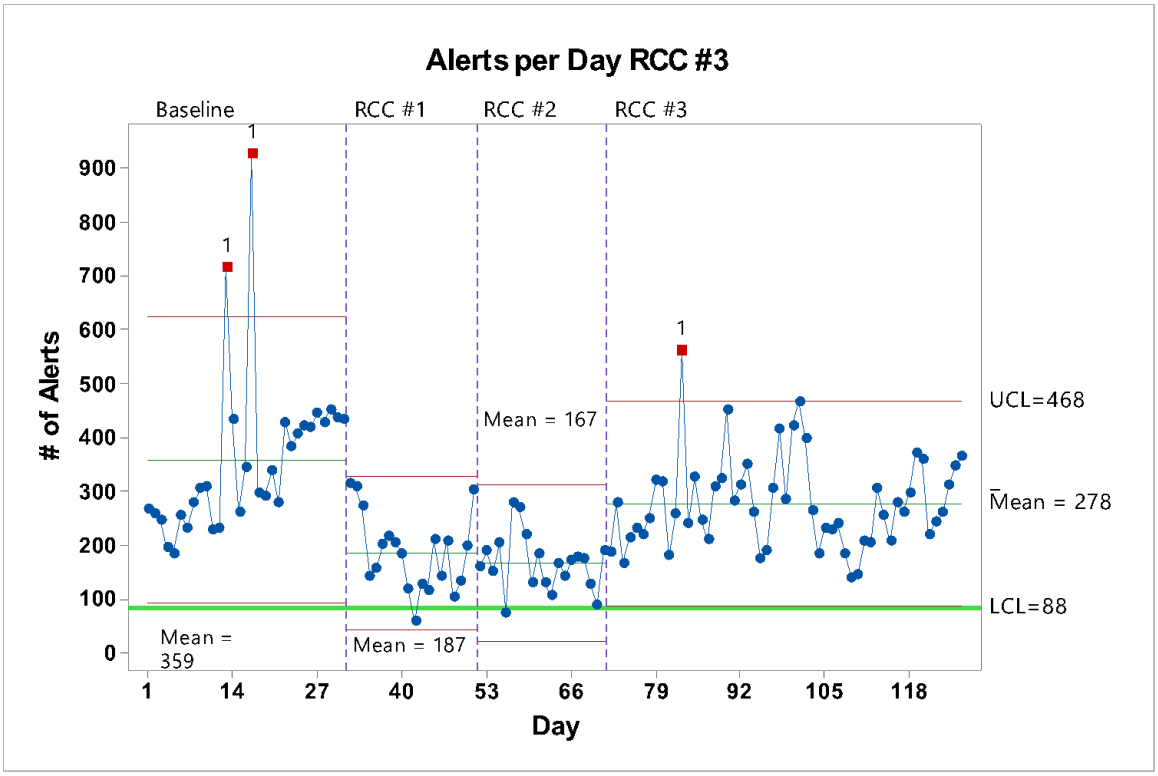


Rapid Cycle Change 3

To standardize alarm management and increase use of the system to assist improvement efforts based on H3, each department stakeholder was interviewed to review existing parameters for environmental monitoring. The interview included current environments monitored, settings for each environment, and alarm frequency, and mode for alarm communication. After current state review, each department was asked to update the system settings with evidence based best practice, expert definitions, regulatory requirements, or other guidelines for environmental monitoring. If the end-user did not have supporting documentation, then consideration was given to similar services with similar requirements. The biggest variable in monitoring was the frequency of alarms. In the current state, each department had structured alarms, escalating alarms

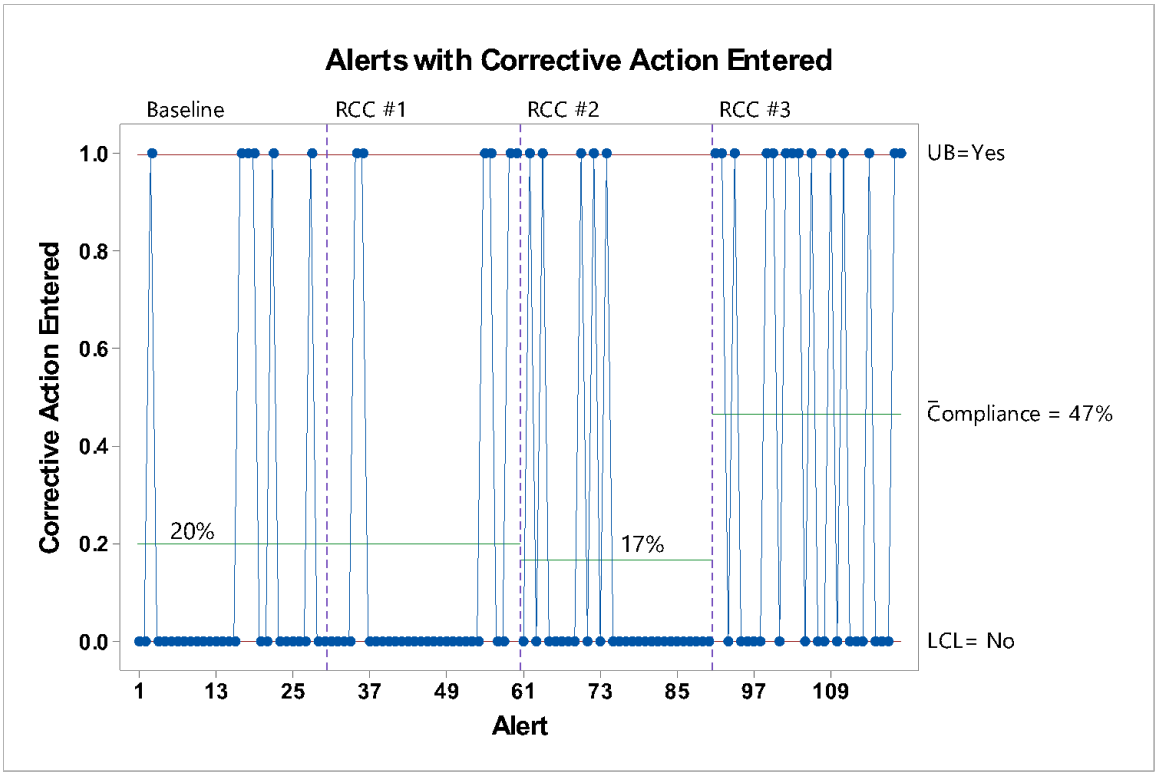
and repeating alarms at different intervals based on perceived severity of loss if supplies in an environment were rendered unusable due to environmental integrity. Repeater alarms – those alarms that were set to repeat at specific intervals if the alarm was not originally answered – were inactivated in RCC #3. Additionally, escalation alarms – those alarms generated to a second end-user when an environment remained out of acceptable range for a specified period of time– were reduced. With variation between department settings for escalation alarms generated at a frequency between five minutes and eight hours, process improvement focused on standardizing to one interval for escalation alarms. As illustrated in RCC #3, this standardization required time, daily system analysis, and end-user acceptance. The iterative steps of Plan, Do, Check, Act (PDCA) was integral to this RCC. This was the longest RCC period in the project and spanned 55 days. During RCC #3 period, the mean number of alarms per day increased to 278, an increase from RCC #2 of 66%, but still a decrease from baseline of 23% (see Figure 21). One datapoint was outside of the upper control limit, rendering this process out of control. This corresponds to the slower data collection related to in-person interviews and review of current state parameters, changes in system settings as supporting documentation allowed, and iterative process of end-user acceptance. End-users were encouraged to set new parameters, evaluate the changes and react to the changes as part of the PDCA cycle. The last 20 days of the RCC #3 improved and the process normalized with all datapoint falling within the control limits as illustrated in Figure 21.

Figure 21: Staged Control Chart Displaying Alarms per Day Through RCC #3



While the number of alarms increased during RCC #3, the number of alarms with corrective actions entered showed increased compliance of 47% (see Figure 22). This was a 176% increase from the RCC#2 period and a 135% increase over baseline. This improvement was directly attributed to end-user engagement with the system. Comparing current alarm settings with evidence based supporting information and mapping alarms parameters to best practice provided an opportunity for the end-user to gain trust in the alarm management process while optimizing alarms for their departments. This was a win-win situation that offered department leaders establishment of specific alarm management criteria unique to their monitored environments and provide reassurance to end-users that nuisance alarms would immediately decrease.

Figure 22: Alerts with Corrective Actions Documented Through RCC #3



Rapid Cycle Change 4

Slippage from the goal of an average of 83 alarms per day during RCC #3, required a review of all the SS project tools in use and the Project Charter to re-examine expectations, system performance, optimization, and end-user satisfaction. Over the course of the three RCC periods, system performance had improved (RCC2), end-user activity in the system had increased (RCC1,2,3), and anecdotally, end-user satisfaction was improving. As RCC #4 period began, the focus shifted from improving and sustaining to returning to the new baseline in RCC #3 and improving beyond that target to the original goals of 83 alarms per day, with 95% of those alerts having corrective action documentation in the system. As this case study included hospitals in a large health system (see Table 4), there were many opportunities to compare environmental

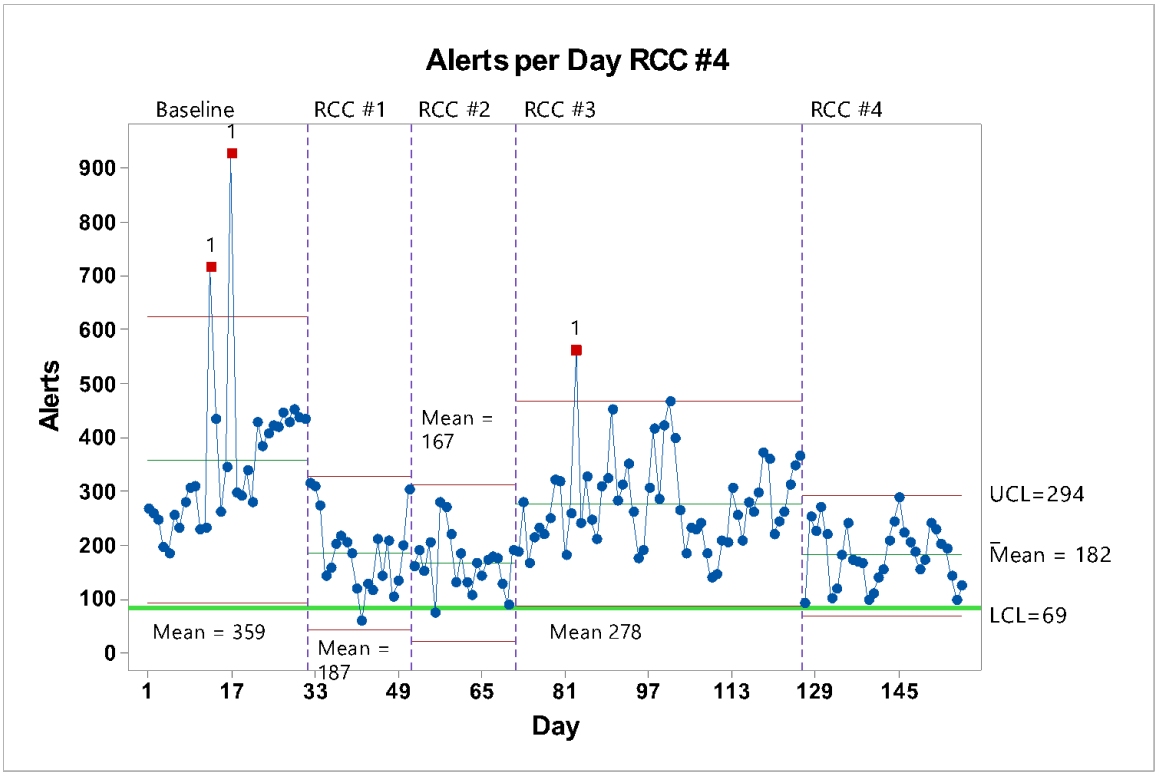
monitoring parameters within disciplines. Alarms from departments with higher than expected alarm volume were reviewed for standard practices. During this review two opportunities were identified to reduce the alarm burden.

1. Alarm frequency was different for departments performing the same job functions at different hospitals, i.e. food and nutrition had eighteen different alarm intervals at four different hospitals.
2. Alarms were sent with redundancy, i.e. an end-user could receive alarm notices by email, text message on a cell phone, through a desktop application, or alphanumeric page simultaneously.

Standardizing was key to the success of RCC #4. For the first point, each like department on each campus was requested to work with colleagues across the system to develop one notification scheme for the service. This included alarm frequency, escalation paths, temperature settings, corrective actions, and overall compliance with the system. For the second point, all alarms going to cell phones were inactivated, the desktop application was removed, and as the health system completed a pager return project to reduce the number of pagers, those alarms were deactivated as well. Email was the notification system of choice, reducing the notification on personal electronic devices.

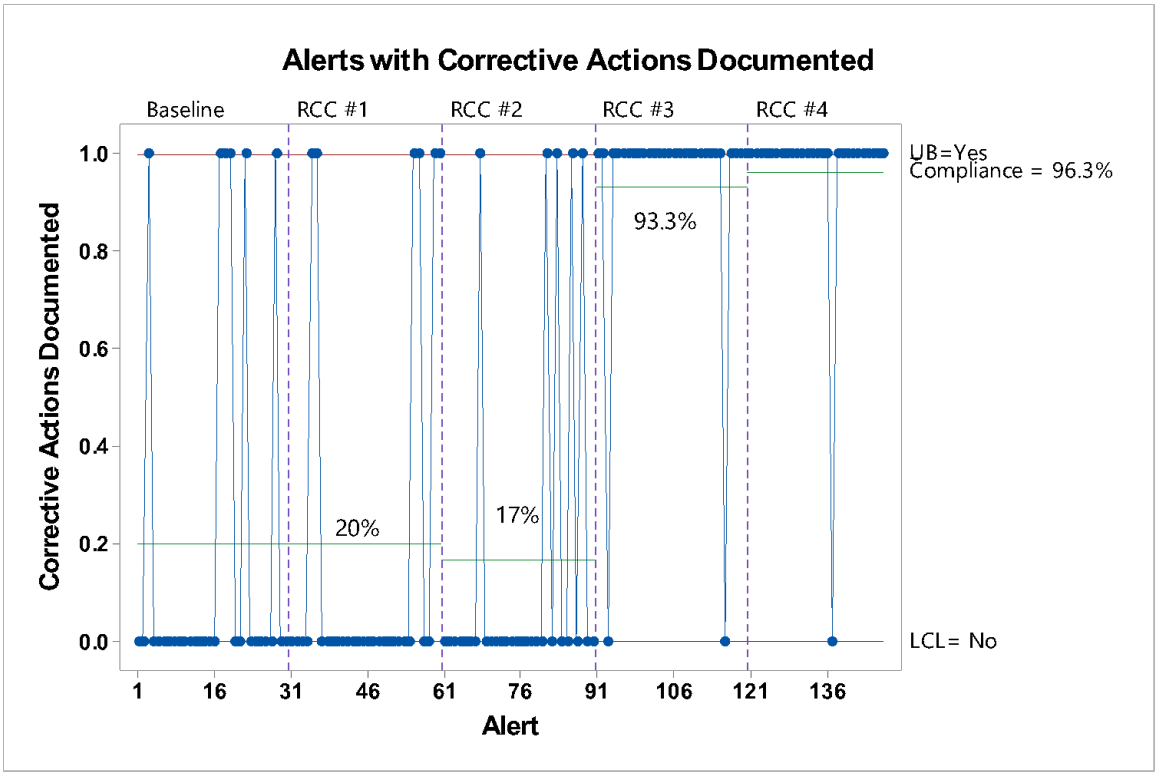
These improvements are illustrated in Figure 23. The average number of alarms per day decreased to 182 from 278 in RCC #3, a 35% decrease. An overall decrease from the baseline period of 49%. Control limits are tighter, and the process is in control. However, the goal of 83 alarms per day was not achieved during this RCC period.

Figure 23: Staged Control Chart Displaying Alarms per Day Through RCC #4



Improvements in corrective action documentation dramatically increases during this RCC period. Compliance increased to 93.3% and sustained through RCC #4 at 96%. Most important to the improvement in RCC #4 was the collaboration with colleagues across the health system to create standard alarm management processes. This improvement is illustrated in Figure 24.

Figure 24: Alarms Displayed with Corrective Actions Documented Through RCC #4



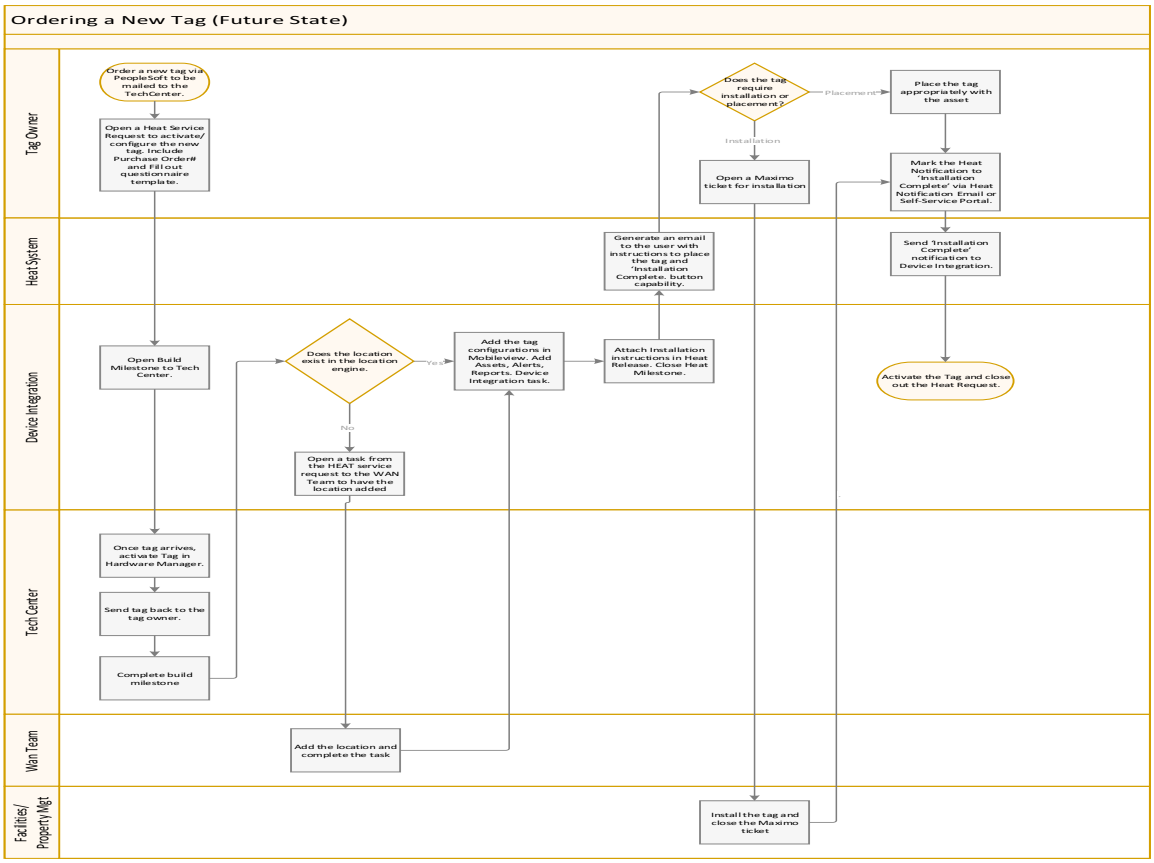
Control Phase

At the conclusion of RCC #4, the project moved into the Control Phase. A full review of the process map from the Measure Phase was conducted and a future state process map was created. The future state process was efficient with an overall reduction of steps and removal of rework loops and clouds (see Figure 25). The simplicity of the future state process map reduced redundancy related to identified failure points from the current state process map and removed role ambiguity while preventing the single source bottlenecks that were. The new process map was created using swim lanes to display responsible parties associated with each step (see Figure 25). There was no more

patching for process gaps or layering of process fixes that was embedded in the current state process map but were not always assigned to a role.

To ensure compliance with the future state process, the health system Intranet became the central location for policies, education, instructions and guides for system use, maintenance, and troubleshooting. This removed several process steps in the current state map related to email communication. Efficiencies were gained by eliminating bottlenecks related to single-source (one employee) process steps with this central repository.

Figure 25: Future State Process Map



Comparing the current state and future state process maps, the future state process map reduced the number of total steps in the process from 36 to 18, a reduction of 50% (see Table 10). Seventeen of the remaining process steps were value-added and all re-work and clouds were removed.

Table 10: Comparison of Current State and Future State Maps

Steps	Current State	Future State
Total Number of Steps in the Process	36	18
Number of Non-Value-Added Steps	14	1
• Constitute X% of the Process	39%	6%
• 6 of the NVA Steps Pertain to Email Communication		
Number of Re-work Loops in the Process	3	0
Number of "Clouds" in the Process	4	0

With the new process map completed, a review of the original Failure Modes and Effects Analysis was conducted to ensure all failure modes identified in the current state process map were addressed and proper mitigations and controls were in place to prevent recurrence. Each failure mode was reviewed and evaluated comparing the old causes (DET), frequency of occurrence of the failure (OCC) and the controls in place within the new process map to prevent or mitigate failures (SEV). The Risk Priority Number was recalculated for each failure (see Figure 26). The RPN decreased in 10 of 14 failure modes for the new process. The most dramatic decrease was in the failure mode "ignore alarms" with the original RPN of 800 reduced to 60, indicating that the future state process decreased the notification burden and re-established trust among stakeholders that the remaining alarms were accurate and required corrective action.

Figure 26: Revised FMEA

Process Step	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Process Controls	DET	RPN	
Identify Need for environmental monitoring	No need identified	Equipment, supplies not monitored	7	Unaware of regulatory, research requirement	2	None	10	140	
Acquire tag	Tag not available	Delay in monitoring	5	Low inventory Delay in shipment	3	HEAT System	1	15	
	Wrong tag	No monitoring	4	Ordering Unaware of requirements	3	Vendor spec sheets and instructions for use	5	60	
Set up tag	No end user instructions	Too much data to manage	6	No system policy for use No formal user education	3	HEAT System	1	18	
	Wrong temperature range	Alert fires	3	Unaware of requirements Assigned to wrong category	1	System Lock-down	1	3	
	Wrong alert assignment	Unnecessary alert fires	9	Assigned to wrong alert schema	3	System Lock-down	3	81	

Process Step	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Process Controls	DET	RPN	
Place Tag	Wrong location	Unnecessary alert fires	7	Unaware of system requirements No instructions for placement	2	HEAT System	2	28	
	Tag not secured properly	Lost tag	5	No instructions for placement	2	HEAT System	2	20	
	Tag not activated	No monitoring	3	Malfunctioning activator	1	Remote/email assistance	1	3	
Monitor Environment	Low battery	Lose tag/monitoring	7	Not checking status reports	2	IS Policy/Workflow	1	14	
				No battery report set up for user	2	HEAT System	1	14	
	Auto-reports not reviewed	No monitoring	6	Sent to Clutter email	8	None	10	480	
	Ignoring alerts	System instability	10	Alert Fatigue	3	None	2	60	
				Lack of training	2	None	2	40	

All improvements were compiled and summarized for inclusion in the new system policy (H1). Education material was presented at leadership forums at each hospital and added to the health system Intranet for reference. Online tutorials were published on the Intranet to explain initiating environmental monitoring, setting parameters, and troubleshooting problems. Additionally, the contact information for the system administrator was published on the same webpage.

Control Plans

At the conclusion of an SS project, a hand-off to the stakeholders is required to ensure smooth transition from the project to standard ongoing work to maintain the improvements needed as established in the project charter. The control plan is the roadmap for process sustainability and the key to preventing entrenchment in the old process. Control plans need to address any factors that may have barriers that prevent success, processes that need improvement but may not have been prioritized for project work or may have excluded from the scope during the Define Phase. As part of the control plan, the stakeholders agree on data to be collected and reviewed for maintenance and a schedule for the review.

To conclude this project, three control plans were delivered to the new system administrator to provide expectations and on-going success with the new process (see Figures 27-29). Explained as problems in the new process, next steps for the system administrator were clear with deliverables, timetable for completion, and responsible parties included.

The first control plan was created to address a software issue when older monitoring tags remained in use (see Figure 27). The battery in the older tag required to

be reset after battery changes. Since batteries in the monitoring tags had a life expectancy of 1.5 years, this control plan was instituted to prevent the loss of institutional knowledge transfer when batteries were replaced far into the future. If possible, at the next battery change, the old monitoring tag would be replaced with a new one that would not be affected in subsequent battery changes. If tag replacement was not possible, then a reminder to the party responsible for battery replacement to reset the counter was included in the control plan.

Figure 27: Control Plan #1

Problem: Re-activation after battery changes	**Goal: Standard process for re-activation using TED at each affiliate**	**Where We Are: Newport has approved purchase of TED, Miriam does not need TED. Waiting on response from Rhode Island Hospital and Property Management for approval for acquiring TED**
How we plan to maintain gains realized: Discontinue tags older than 4 years. Device Integration will facilitate TED purchase and roll-out		
What is being tracked? Battery Level Reports and requests for battery changes through the developed workflow. How often? By Whom? In real-time. By designees in each Facilities Departments When are these results going to be presented to the Champion? As needed, no more frequently than every 6 months. DESCRIBE THE PLAN THAT THE PROCESS OWNER IS LEFT WITH: Using the battery replacement workflow, the facilities departments will replace batteries at the request of the end users.		

The second control plan involved Animal Research. As explained in Chapter 3, Animal Research environments were deemed too sensitive to change the alarm notification scheme and optimization of the system was put on hold for future study. For continued improvement to the future state, additional work to consolidate alarms, reduce the frequencies of nuisance alarms and prevent an alarm backlog in the cache, more work was needed for end-users. It was identified that a potential new alarm management

project would be scoped to address the unique environments in Animal Research. All information captured in this project was included in the hand-off to the system administrator to transfer the institutional knowledge and create a starting point for the future project. The control plan included a six- month touchpoint with the end-users to evaluate opportunities for improvement that could be initiated (see Figure 28).

Figure 28: Control Plan #2

Problem: Re-activation after battery changes	**Goal: Standard process for re-activation using TED at each affiliate**	**Where We Are: Newport has approved purchase of TED, Miriam does not need TED. Waiting on response from Rhode Island Hospital and Property Management for approval for acquiring TED**
How we plan to maintain gains realized: Discontinue tags older than 4 years. Device Integration will facilitate TED purchase and roll-out		
What is being tracked? Battery Level Reports and requests for battery changes through the developed workflow. How often? By Whom? In real-time. By designees in each Facilities Departments When are these results going to be presented to the Champion? As needed, no more frequently than every 6 months. DESCRIBE THE PLAN THAT THE PROCESS OWNER IS LEFT WITH: Using the battery replacement workflow, the facilities departments will replace batteries at the request of the end users.		

The control plan with the biggest impact on continued success was Control Plan #3 (CP3) (see Figure 29). To prevent recurrence of several failures, regular system refreshing had to occur. Establishing a six-month refresher program where the system administrator would query the end-user for any changes to the alarm management plan, including new users, contact information, new evidence-based supporting documents or system collaboration that could be used to change parameter setting, and any system problems including unscheduled downtimes or other issues where the end-user had to troubleshoot to restore appropriate system functionality.

Figure 29: Control Plan #3

Problem: Evaluation of Alert Fatigue	**Goal: Continue to reduce the overall number of alerts related to Temperature and Humidity excursions**	**Where We Are: We have reduced the number of alerts from over 300/day to 80-140/day**
How we plan to maintain gains realized: Review information from Aeroscout report to determine errant alerts or environmental problems for correction.		
Control Chart that will be tracked by the Process Owner – Number of alerts/day What is being tracked? How many alerts/day How often? By Whom? Semi-annually by Device Integration Minitab Control Chart When are these results going to be presented to the Champion? Semi-annually DESCRIBE THE PLAN THAT THE PROCESS OWNER IS LEFT WITH: Every 6 months a control chart will be reviewed to determine outlier departments and aberrant alerts causing alert fatigue. This report will be reviewed internally by the device integration team and shared with the System Alarm Management Committee for review and potential solutions.		

Final review of Project

After the control plan hand-off, a 3-month review of the future state process was completed. To complete the review, the original data collection methods were employed to evaluate the average number of alarms per day (see Figure 30) and the number of alarms with documented corrective actions (see Figure 31). Analysis of the results as displayed in Figure 29, indicated alarms had decreased from a baseline average of 359 per day to 55 alarms per day which was an 85% reduction. Figure 30 illustrated that of those remaining alarms there was 96.3% compliance with entering corrective actions for the alarms. Resulting from these improvements, since the Control Phase, there had been no unscheduled system downtimes, server or system reboots, or system timeouts. The engineered improvements created a stable system with little hands-on time required by end-users or the system administrator.

Figure 30: Stacked Control Chart Displaying Alarm Reduction Through Control Phase

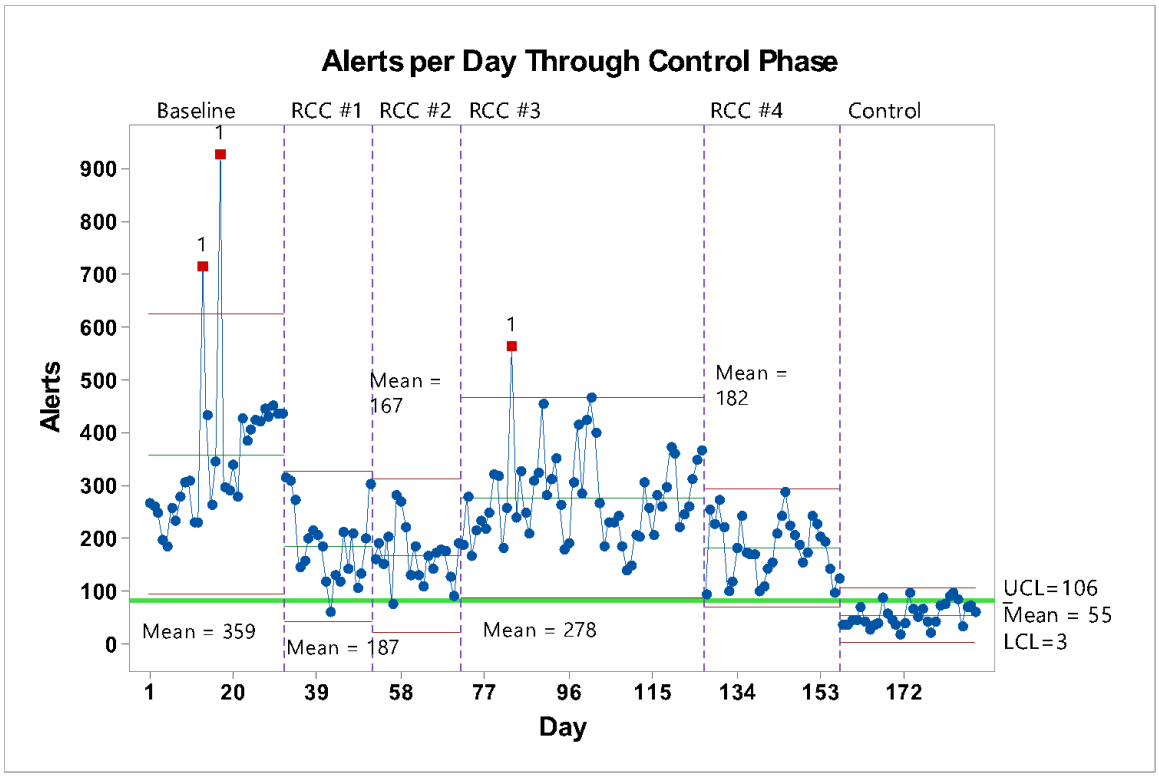
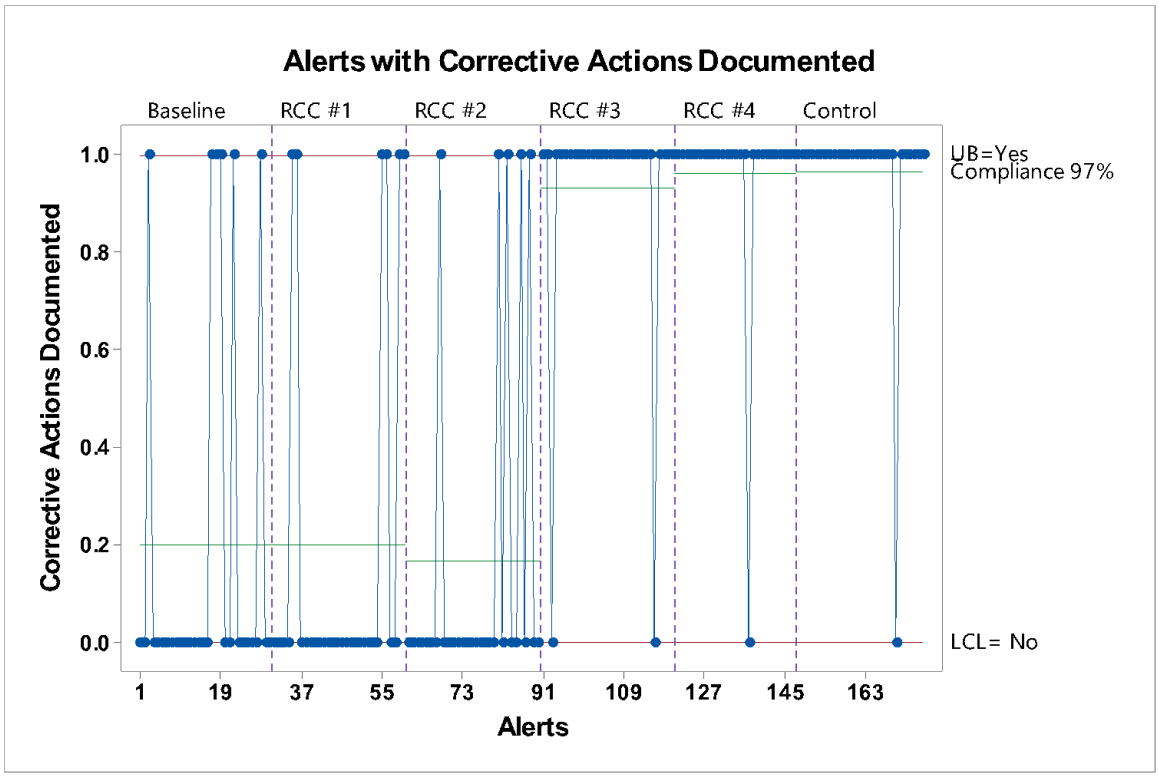


Figure 31: Stacked Control Chart Displaying Corrective Action Improvement



Chapter V

Conclusion

This case study is a defining example of the complexity of processes within healthcare that need a structured improvement plan and dedicated resources for improvement. The original problem statement pointed to alarm burden for patient care team members that interrupted important work related to patient care to manage environmental alarms assigned to the patient care team. As established in the literature, notification burden causes distraction, a sense of overwhelm, and desensitization to alarms, especially when the alarms are for non-physiologic systems like environmental monitoring alarms. For the patient care team, the prioritization of alarm management starts with the bed-side alarms that are used to notify the team to a decline in the patient condition. Only when time allows are alarms from other systems considered for management. Though environmental monitoring in the healthcare setting is important, it lacks urgency from the patient care team's perspective. While failures of the non-physiologic alarm systems can be monetized, the value or magnitude of the loss is a secondary priority to the patient care team when competing job tasks exist. When alarm systems are introduced a full analysis of the process with expectations for alarm management, role responsibilities, and standardization should be included in the outset. When this step is not fully executed or skipped for expediency, failures are expected and lead to process patching as demonstrated in the current state process mapping in this case study.

This study directly contributes to the existing literature about alarm notification burden by templating a roadmap for future work in this area and a clear replicable

process for identifying the root causes. During the literature review process, alarm management literature explored alarm fatigue and its causal factors including noise, work environment, patient assignment, and unit geography. Additional literature discussed reduction methods, but these bodies of work were situational and there was little consideration for other, broader, applications. Studies discussing considerations and improvements for reducing alarm fatigue were present, but the studies evaluated results at baseline and new state without understanding the root cause or an examination of possible solutions for reducing alarm fatigue [5 7 16 34 44 45]. Additionally, studies were not relatable to non-physiologic alarm systems [4 6 18 46]. There was no application of process improvement in the literature that was scalable to other alarm systems regardless of methodology used for improvement.

Reducing alarm burden from 11,000 to 1,650 (average) each month for one alarm system validates the use of SS methodology for this case study. The systematic approach to an ambiguous process provided a clear roadmap for the project and kept the stakeholders involved throughout each phase of DMAIC, maximizing their contributions and capturing the VOC. The latter being paramount to gaining influence for process changes with a result of increased end-user acceptance. Using the VOC, hypotheses were developed that were tested for statistical significance which prioritized work for the future state process. In conclusion, this case was a successful study in reducing alarm fatigue and notification burden using SS methodology for process improvement.

Redesign of the process using the Six Sigma (SS) tools described in Chapters 3 and 4, was objective and considered improvements impacted by the voice of the customer (VOC), creating a future state that contributed to the reduction of alarm notification

burden while stabilizing the information system servers and decreasing processor burden. The simplified future state required fewer resources and allowed for expansion of the system when future needs arose. The cost associated with the system redesign was budget neutral, with no additional staff, supplies, or equipment needed, indicating that system improvements do not have to increase expenses to have good outcomes.

The project hand-off at the end of the Control Phase cannot be overlooked as a key factor in sustaining the improvements. Explicit instructions constructed from expectations set at the beginning of the project period and process improvement delineated in rapid cycle changes were provided to the system administrator to ensure the future state process map would be followed well after the project concluded. Continued data collection and monitoring was instituted to prevent backsliding to the old process. The six-month refresher program would streamline end-user updates which would increase end-user engagement to maintain the system with less effort.

Limitations

The primary limitation of this study was the lack of supporting literature for comparison. As discussed earlier, existing literature on alarm fatigue was limited to physiologic alarm systems or small case study reviews about environmental monitoring in pharmacies or laboratories. There was literature discussing SS application in healthcare, but no applications of SS methodology used to reduce alarm fatigue. Without existing models for research design, an inordinate amount of time was spent on designing the model, where more improvement may have been achievable in less time if models were available and readily adaptable.

Knowledge and application of SS methodology is a limitation for continuing this work and adapting to other research studies. For this level of research design a SS Black Belt – leader trained in Six Sigma who uses the tools to improve customer satisfaction and productivity - would be required to design and execute a research study of this complexity.

Considerations

Without a prevailing research model to use for this study, success of the project and the attainment of the research goal for this study were defined empirically, based on several key metrics:

1. Did the research identify a significant gap in the literature?
2. Did the methodology used to frame the study provide tools for analysis with measurable goals for hypothesis testing?
3. Did the case study project meet the intended goals?

This research study fills a gap in the literature whereby addressing notification burden assigned to the patient care team that may be secondary to patient care job tasks but impacts the patient care team, nevertheless. This case study example of notification burden in an ancillary system, awareness and accountancy of alarms has been showcased and its impact on patient care elevated. If a single environmental alarm system can created a significant notification burden, as illustrated in this case study, then global notification burden [2], must be reduced. To compound the lack of alarm fatigue literature that is applicable for this case study, the lack of consistent process improvement methodology for improving complex healthcare problems in the literature prevents quick action on a plethora of problems seen in healthcare. Without a concept design or scalable

project plan template, improvements in healthcare processes are difficult to complete and, in some cases, impossible to initiate. This project paralysis creates frustration with the patient care team and result in process workarounds – informal solutions when the process does not meet expectations. Six Sigma tools provide a way to capture the process flaws, examine them and re-engineer them for success. This case study and use of SS tools is scalable for team size, project scope, process complexity, deliverables, and expectations. Furthermore, this study combines the need to reduce alarm fatigue and notification burden with SS tools to demonstrate improvements in complex processes in healthcare.

As the study methodology for the case study, SS provided the necessary framework to navigate through the complexity of the problem of alarm fatigue caused by an environmental monitoring system and allowed for flexibility in problem solving with several tools designed for process mapping, identifying failures, data collection, statistical analysis, and sustainability. Two different process maps were used: the flow diagram for the original process map and the swim lane process map for the future state map. Both were helpful in visualizing the different states, redundancy, and re-work. The Cause and Effects Matrix (C&E) and Failure Modes and Effects Analysis (FMEA) were used to identify existing and potential failures with the original process and a new FMEA was created for the future state process to confirm the previous failures were removed or mitigated. Data collection tools were the Data Collection Summary Tool – used to summarize key data elements for review and Control Charts were used to graphically display data throughout the rapid cycle changes. Statistical analysis of the initial dataset was performed using a 2-sample t-test to determine if improvements for specific failures

would be statistically significant for prioritization. Each hypothesis was tested, and p-values were compared to the 95% Confidence Interval p-value of 0.05. If the p-value was <=0.05 the result of the 2-sample t-test was significant and the null hypothesis was rejected (H2 and H3). In the Control Phase, control plans were created for continued management of the project with clear deliverables and timetables.

At the completion of the case study project, the project goals had been met. Alarms had been reduced from11,000 to 1650 (average). With the process improvements in place the number of alarms per day averaged 55 per day which was lower than the original project goal of 83. Alarms with corrective actions entered increased from 20% compliance at baseline to 97% compliance at the end of the Control Phase. The stated goals from the project charter were achieved.

Overall, the research expectations were met, and the case study was a successful application of SS methodology for process improvement as demonstrated through the reduction of alarm fatigue and notification burden and ultimately, information systems stability.

Future Applications

Additional studies are needed to assess notification burden in healthcare. A significant toll on the patient care team, alarm management, while important, is causing distraction and delays in patient care. With the complexity of the immediate patient care environment, it has been commonplace to install a system that is walk-away or plug-and-play that is meant to alleviate the demand of the patient care team. Unfortunately, the addition of these systems without proper structure, implementation, or optimization creates an untenable situation with multiple alarms from multiple systems and no

prioritization scheme for management. The patient care team is forced to make constant adjustments in priorities which lead to confusion, distraction, multi-tasking and ultimately, to alarm fatigue. Future studies focusing on scalable applications, alarm prevention, and/or alarm system optimization would be useful. Additional studies on process improvement methodology used in complex healthcare processes with discussion on how the process is applied to real situations are relevant. Healthcare needs options when embarking on improvements, but not every project has to be founded in principles from randomized control trials or multi-hospital studies. Those take time and, while important to healthcare, many problems need tools that are nimble, adaptable, and easy to use.

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Appendix A: Project Charter

Project Resources	Planned Project Milestone Dates	Actual Project Milestone Dates
Executive Sponsor: **Process Owner:** **Black Belt Candidate:** **Green Belt:**	**Completed Project Charter:**	
	Define: (30-day check in)	
	Measure: (60-day check in)	
	Analyze: (90-day check in)	
	Improve: (120-day check in)	
	Control: (120-day check in)	
DMAIC PROJECT OVERVIEW		
Current State Process Performance Validation/Problem Statement	*Environmental monitoring automation has been available across all affiliates since 2011 via hardware and software. Currently there are approximately 11,000 excursion alerts each month with 22% of those alerts being addressed with corrective action documentation and successful follow-up.*	
Desired Process Performance or the Standard Metric	*The optimal process would decrease the number of alerts to eliminate system alert fatigue while ensuring the processed alerts were appropriate and necessary for deliberate action.*	
Project Scope ***Ensure project is not too large***	***Process start point:*** *Need for environmental monitoring identified* ***Process end point:*** *Environment monitored* ***IN Scope: Temperature, Humidity, Battery*** ***OUT of Scope: Documentation outside of the system, downtime, paper records, tags placed for equipment not designed for temperature, humidity, asset monitoring***	
Opportunity Statement ***SMART format***	*By May 1, 2018, the process for automated temperature, humidity, battery tracking will be optimized to standardize the workflow and reduce variation across departments and affiliates. This will be demonstrated by reducing alerts by 75% (2500 alerts) and of those alerts being generated, 95% (2375 corrective actions) will include the appropriate and complete follow-up documentation.*	
BUSINESS CASE ANALYSIS		
Reasons for doing this project now.	*With 11,000 alerts firing each month, there are concerns about system stability and data management. Additionally, the alert fatigue generated from this system is overwhelming deeming the system ineffective.*	

State the Strategic Alignment of this project.	
The Key Success Factors for this Project/Expected Benefits including cost recovery ***Target savings, target metric reduction***	*Inventory loss is inevitable when the system is not optimized and staff are not trained to utilize the system effectively. Recently, a pharmacy refrigerator stocked with chemotherapy agents failed and the entire inventory was lost. This one event cost the organization ~$600,000. This was an avoidable expense.*
DMAIC PROJECT DETAIL	
Stakeholders	*IS, OpX, Clinical leaders, Operational leaders, Facilities, Medical Engineering, Food and Nutrition Services, Lab, Pharmacy, Rad, Patient Care Services*
Resources/Team Members and Functional Area	Team Members: IS: Facilities Food and Nutrition Lab Rad Pharmacy Peri-operative Areas Procedural Areas Property management Patient Care Services Staff Education Research Vendor representatives Resources List of upgrade enhancements Education curriculum
Deliverables to E-Team ***Driven by project plan and reported by Green/Black Belt***	*- Belt will meet with the project team on weekly basis - to complete DMAIC tools, communicate team assignments needed for each DMAIC phase and discuss project's current progress (rapid cycle changes).* *- Current progress of the project will be presented to the Master Black Belt and the Executive Team, as requested, during check-in sessions, held every 30 days, upon completion of each of the DMAIC phases.*
Constraints ***Possible limitations that will affect project outcomes***	*Affiliate processes* *No system overseer* *Identifying all of the stakeholders for design input and policy development.* *Buy-in from users due to poor historical performance*