Development of Site Quality Assurance and Compliance Near Miss Program

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Abstract

The focus of this project is to create a Quality Assurance & Compliance (QAC) Near Miss program in a medical device company with the objective to reduce the number of 2023 near misses by 25%. A ranking system and tracking tool were created to log, track, and assess each near miss. In addition, the near miss program works in conjunction with the site's inspection readiness program. At the culmination of the project the objective of reducing the 2023 Near Miss list by 25% was met by addressing/solving three of the eleven near misses. Both the ranking system and near miss tracking are within the same Excel tool, which will allow the site to continue to log, track, and assess near miss going into 2024.

Background

Abbott is a global medical device and health care company dedicated to providing products and services to improve the quality of life of patients. The Abbott Manufacturing site in Atlanta, GA is responsible for the design/development and manufacturing of the CardioMEMs Heart Failure System [1] for remote monitoring of the pulmonary artery (PA) pressure. Refer to Figure 1 for an example of how the CardioMEMs Heart Failure System works.
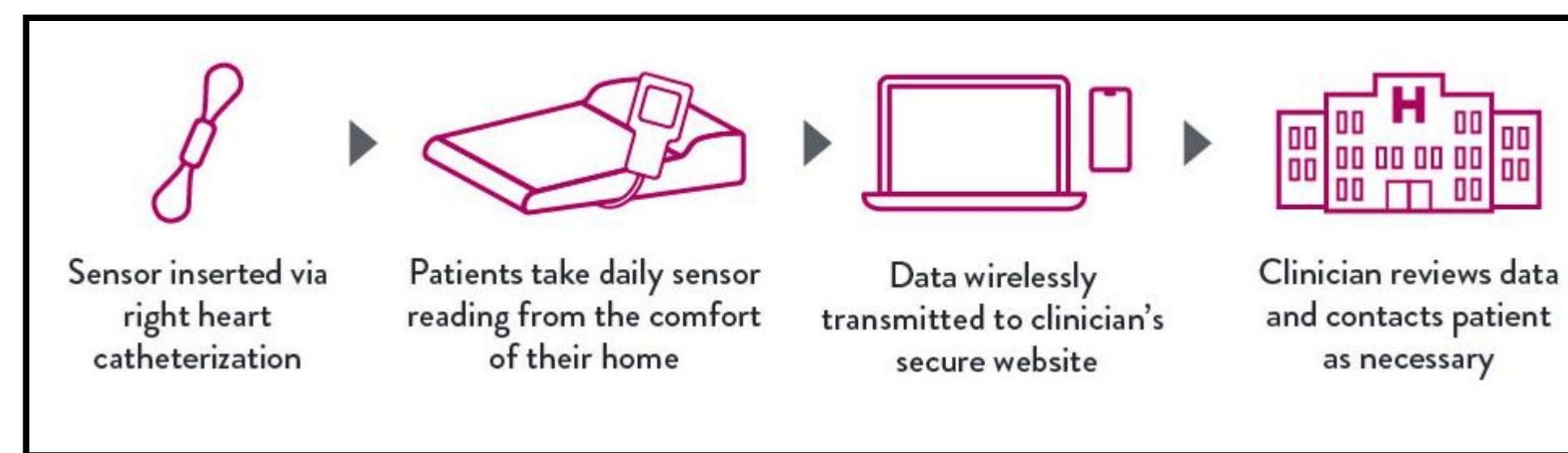

Figure 1: Example of How CardioMEMs HF System Works [1]

At the Abbott Manufacturing Site in Atlanta there is a need within the Quality Assurance and Compliance (QAC) department to develop a business program on how to manage what is known internally as quality system "near miss" mostly identified within internal and external site quality system audits.

Within the Atlanta QAC department, a near miss is locally defined as situations where the quality records, products, and/or processes are barely conforming, but if the near miss is not addressed, could potentially lead to a future audit observation/quality system nonconformance.

Near miss is not a new concept. It's a term used within the Environment, Health, and Safety (EHS) industry. It is defined as "any situation in which an ongoing sequence of events was prevented from developing further and hence preventing the occurrence of potentially serious (safety related) consequences" [2]. Extrapolating the concepts used in EHS, where the key to manage near misses is "to get them reported, described, analyzed and interpreted into suggestions for actions" [2].

Therefore, the focus of this project is to set-up the near miss program from a quality perspective with the intent to log/track quality system near misses, ranking system to prioritize the near misses, and assess and defined an action to correct/address the near misses.

Problem Statement

The main situation is that the near miss is identified and there isn't a process in place to record, assess, and address the "near miss" once the audit ends. The expectation of the site Quality Management team is to set-up a business program to log/track a near miss and assess and address those near misses that could potentially lead to quality system nonconformance if improvements are not made. In addition, the program is intended to work in conjunction with the site's Inspection Readiness program known locally as MARCH.

The objective of this project is to reduce by 25% the number of 2023 near misses left unsolved or unaddressed based on the priority ranking by establishing a proposed correction prior to the end date of the project.

Methodology

To solve the situation and meet the project objective the phases outlined in Figure 2 were developed for this project to create the framework of the QAC Near Miss Program.

Data Collection
Create the 2023 "near miss" listing by contacting quality managers and quality engineers that supported during the 2023 internal and external inspections and review of the internal/external audit reports from 2023.
Output: A total of 11 "Near Misses" identified and logged.

Development of Ranking System
Develop a ranking system using Excel to help prioritize what the organization would focus on first by ranking the near misses as High, Medium, and Low.
Output: Ranking system was developed in Excel with 7 categories or questions with fixed answers where each answer has a numeric value. Upon answering each category, the values are added for a total priority ranking value. Table 2 shows the ranges for the total priority values to identify each near miss as High, Medium, or Low.

Application of Ranking System
Assess each "near miss" identified, using the Ranking System
Output: 100% of the items were identified as High, Medium, Low. Refer to Figure 2 for the results of using the ranking system.

Address Near Misses
Starting with the highest priority items, the team will evaluate how to address the near miss. If a planned correction is needed, once the correction is defined, then a task will be created in the MARCH program to track the planned correction to completion by ensuring resources are assigned.
Note: To meet the project objective of 25% reduction, a minimum of three near misses must be addressed by the project end date
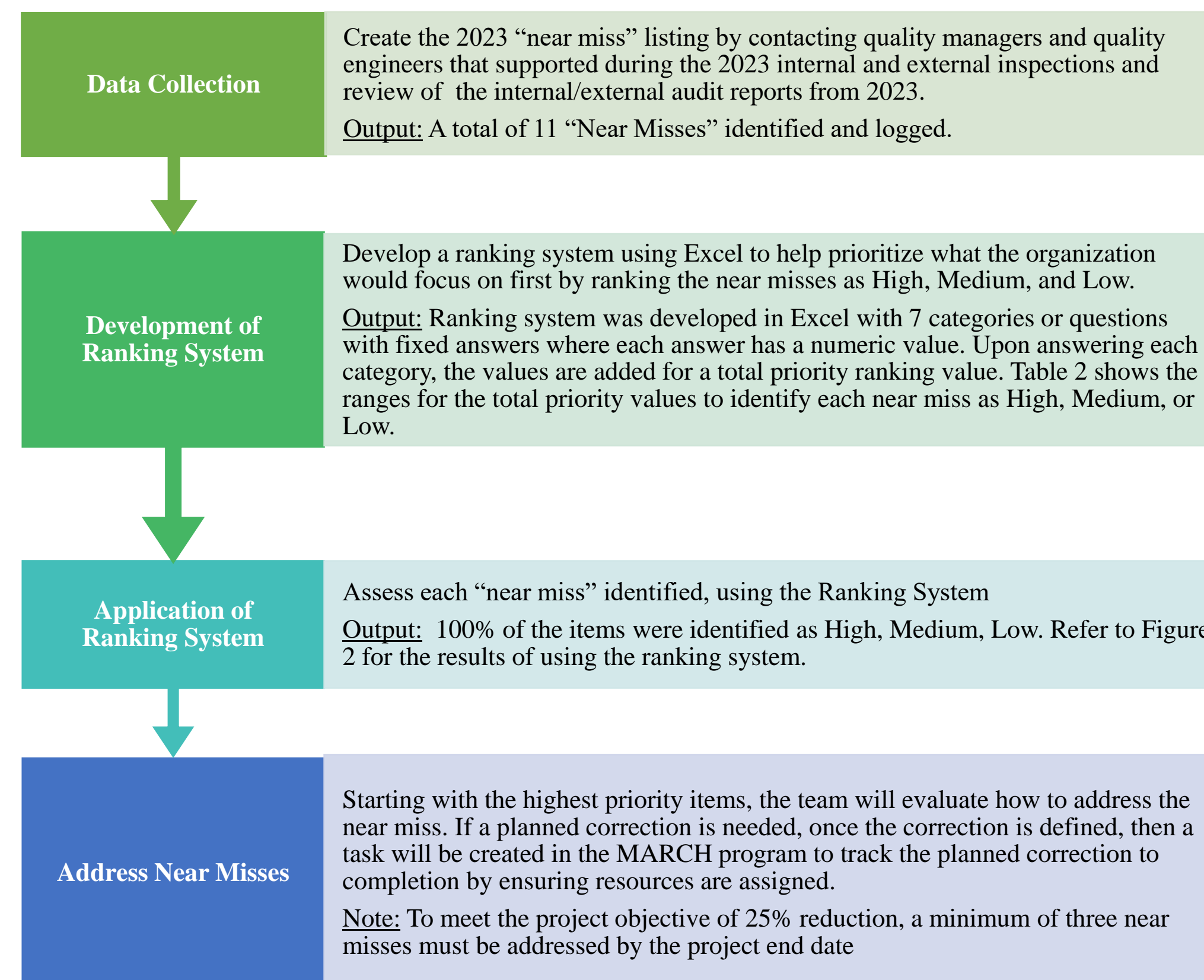
Figure 2: Outline of Project Methodology

Table 1 shows the project timeline, milestones, and status of each milestone. During the Data Collection phase, there was a delay to allow for more time to create the 2023 listing. This extension did not delay the overall project completion date.

Table 1: Project Timeline and Millstones

Phase	Due Date	Phase Milestones	Status
Data Collection	08-Dec-2023 22-Dec-2023	Create the 2023 "near miss" listing	Completed
Ranking System	22-Dec-2023	Develop a ranking system to prioritize and assess a "near miss"	Completed
Use Ranking System	15-Jan-2024	Assess each "near miss" identified, where 100% have been given a priority ranking	Completed
Address "Near Miss"	31-Jan-2024	Starting with the "high priority" start to solve/address each "Near Miss" Note: Objective to reduce the "Near Miss" listing by 25%	Completed

Table 2 Ranking System Priority Values

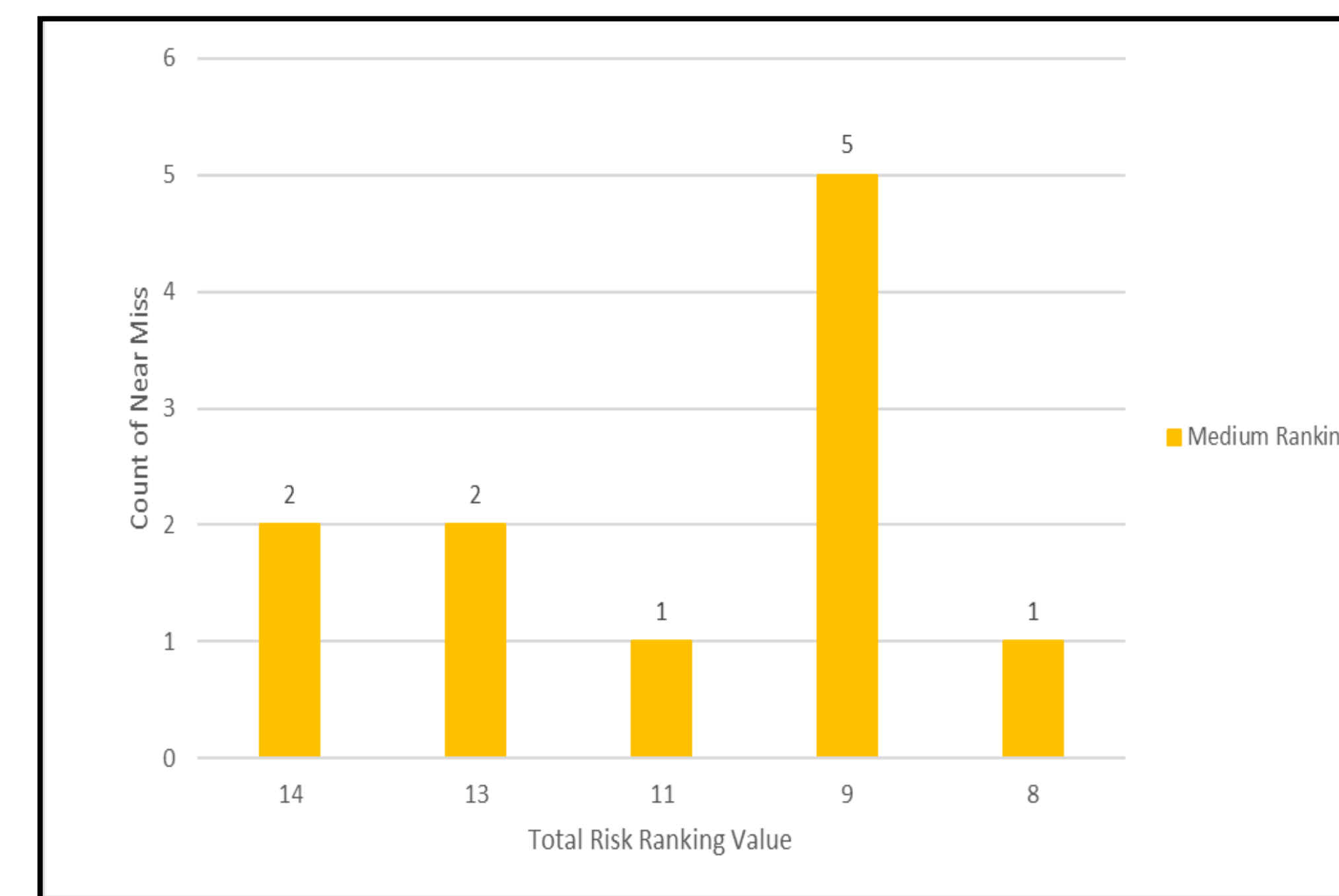| Priority	Value Range
High	17 to 15
Medium	14 to 7
Low	6 to 0

Figure 3: Graphs of Tanking System Results

Results

Two of the four near misses with High priority were resolved by collecting the information presented within the audits into a storyboard format.. Now, the information is readily available for future audits, thus the near misses were marked as addressed/solved.

For another of the four identified with High priority, the proposed plan was created with the cross-functional team. However, as of January 31, 2024, it has not been marked as addressed/solved until the correction plan is created in MARCH with resources assigned to complete the activity. Thus, the near miss has been marked as work-in-progress (WIP). This is to prevent near misses being marked prematurely as addressed/solved to avoid having the program working as a silo.

The last of the four near misses with High priority requires more time to determine the proposed action. Therefore, another near miss was chosen to be addressed to meet with the project objective. Upon review with the cross-functional team, the Near Miss did not require an action plan to be tracked in MARCH as the procedure is being updated as part of the periodic review process.

As of January 31, 2024, a total of three near misses out of the eleven identified have been addressed, meeting with the project objective. Refer to Figure 4 for a graph showing the status of the eleven near misses as of January 31, 2024.
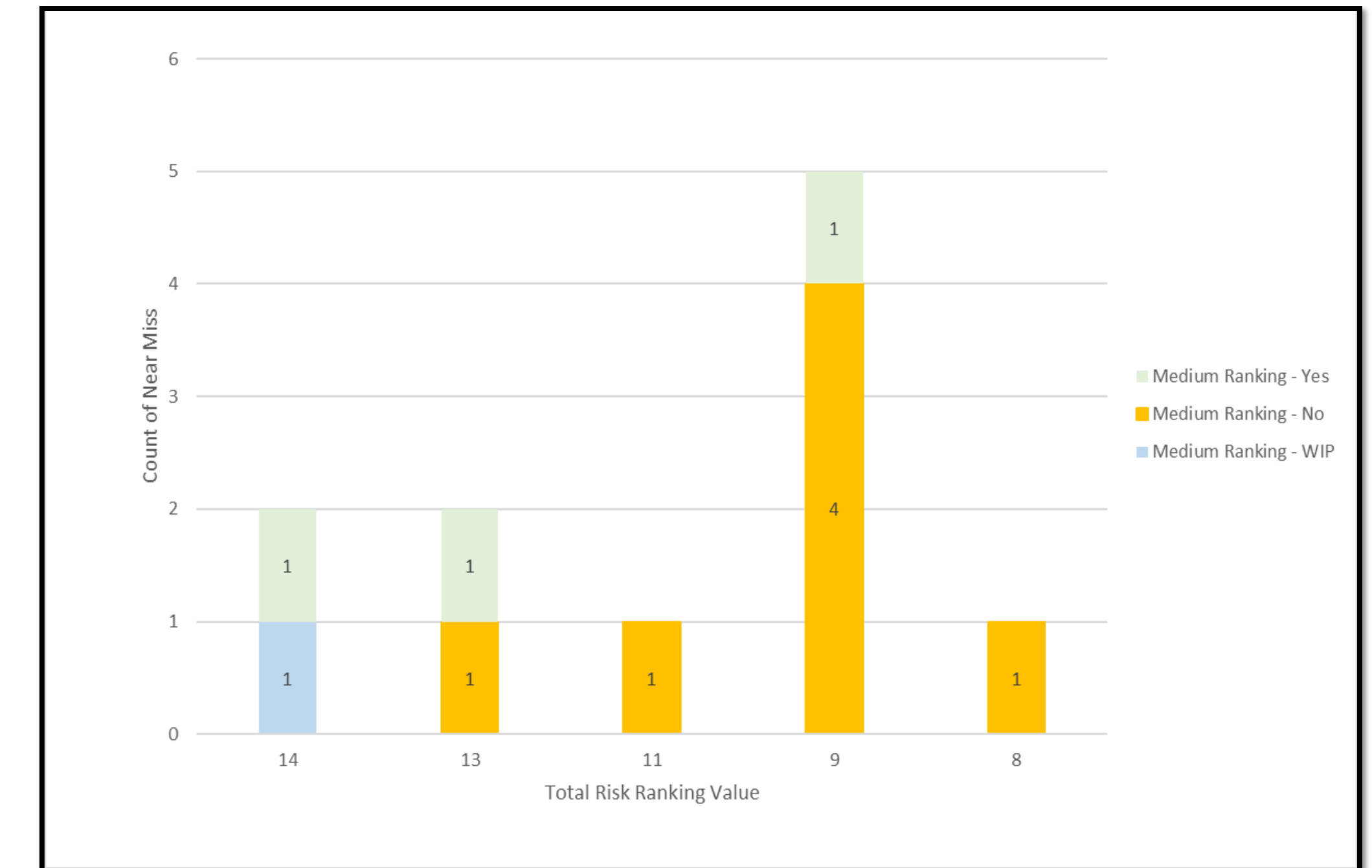

Figure 4: Graphs of Ranking System Results showing the Status of each Near Miss

Conclusions

The project objective of reducing the 2023 near miss list by 25% was met by addressing/solving three of the eleven near misses by the project end data.

Future Work

After the project end date, the pending 2023 Near Misses to be addressed have been marked as WIP and are targeted to be addressed/solved by the end of the first quarter of 2024. Both the ranking system and near miss tracking are within the same Excel tool, which will allow the site to continue to log, track, and assess near miss going into 2024. Thus, the site Quality Management expectation of having a sustainable QAC Near Miss program set-up to support within inspection readiness activities was also achieved through the course of this project.

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References

[1] MAT-1900882 v11, "How CardioMEMS HF System Remote PA Pressure Monitoring Works", © 2024 Abbott. All Rights Reserved.. Website: https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/pulmonary-pressure-monitors/cardiomems/about/how-it-works.html

[2] Van der Schaf T.W., Lucas, D.A., Hale, A.R.,. "Near Miss Reporting as a Safety Tool", First Published 1991, Oxford, Butterworth-Heinemann Ltd 1991.