High Reliability Performance in Amgen Engineering

by

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Abstract

Amgen is in the midst of a transformative initiative to become operationally more efficient. For Amgen Engineering, this initiative has prompted a reevaluation of the entire organization and brought to light the need to standardize, define processes, and promote a culture wherein reliable outcomes are both possible and expected. One way to accomplish this is by evaluating and then implementing the concepts of High Reliability Organization (HRO).

This thesis focuses on using concepts such as HRO to evaluate the Engineering organization at Amgen and then provide tools, frameworks, and recommendations for driving increased reliability and greater process maturity across Amgen's entire asset lifecycle (Plan, Build/Lease, Operate/Maintain, Reinvest/Dispose).

Three main deliverables resulted from this project's reliability efforts. The first deliverable is a set of recommendations and strategies to help the Engineering organization operate as an HRO. The second deliverable is an enhanced process maturity model that implements reliability concepts to drive the maturity of Engineering's business processes. The model better defines criteria for each level of maturity and will be used as a guidance tool for organizational advancement in the coming years. The last deliverable focuses on the maintain portion of the asset lifecycle, and is a Maintenance Excellence Roadmap that defines what maintenance excellence looks like and provides a strategy to best utilize the systems and tools that Amgen has in place, and will need in the future, to get there.

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1 Introduction

1.1 Project Context

Amgen is the largest biotechnology company in the world, and currently a company in transition. Like its peers, Amgen is operating in an industry that is becoming more mature and competitive. This means a transformative shift is needed in Amgen's operational strategy, with greater emphasis placed on lean operations, spending control, and focused growth strategies.

Large biotechnology organizations typically have research & development, operations, and corporate/commercial development functions. Historically, competitive advantage has been sourced through research & development and its new product innovation. Changes in the competitive environment, though, have forced companies to reevaluate traditional business models and place greater emphasis on operational efficiency and effectiveness. As blockbuster drugs become less prevalent, companies are diversifying resources and focusing efforts on more complex and challenging projects in research & development to maintain competitive advantages in the industry. Uncertainty in the industry pipeline has also led companies to identify measures to increase operational efficiency and effectiveness through a number of targeted strategies that include leaning out operations, standardizing processes, and searching for increased reliability in daily work streams and asset lifecycle management decisions.

At Amgen, efforts are underway to identify areas for standardization and improved efficiency. These efforts have resulted in new strategies to enact sweeping changes across the company. Research & Development (R&D) has focused on more targeted approaches for therapeutic drug development. In Operations, focus has been placed on identifying and implementing strategies to become more efficient and effective at manufacturing and delivering product to the end user.

This project will focus its efforts specifically within Operations in the Engineering organization – which manages the company's asset lifecycle – to identify measures for improvement across the organization's footprint. It will establish a targeted end-state of greater efficiency, effectiveness, and reliability, and then develop tools and strategies to help the Engineering organization achieve this desired state of operation (The asset lifecycle is made up of four distinct phases that include plan, build, operate/maintain, and reinvest/dispose. Each phase will be described in greater detail below).

1.2 Hypothesis

A high reliability organization (HRO) is an organization that operates daily within a complex and risky work environment and has managed to avoid accidents and disruptions at a best-in-class rate while producing consistently reliable outcomes[1]. By creating strategies to bring standardization to business processes, drive process maturity, and implement high reliability organization concepts, the Engineering organization can reach a state where reliable outcomes are not only possible, but expected. This will allow the organization to create competitive advantages for Amgen by becoming an HRO while achieving best-in-class operations in asset lifecycle management.

1.3 Project Overview

To help foster the implementation of strategies that enable the organization to standardize processes, drive process maturity, and act as an HRO, a gap analysis between current state and desired state Engineering operations was performed. We started by undertaking an extensive HRO study to identify organizational and operational characteristics that would ultimately shape the vision for our desired future state. To assess the current state, we immersed ourselves in Engineering's people, processes, and systems. We imbedded ourselves in work streams –such as cross-functional staff meetings and performance board reviews – throughout the organization, and identified key stakeholders for internal interviews. Targeted interview questions were developed based on each of the principles and criteria of high reliability organizations. The responses from interviewees allowed us to gain a better understanding of the areas in which the organization were doing well and those areas that could be improved both in terms of process and resulting outcome. Following the gap analysis, a list of detailed recommendations was developed with executable strategies for enabling HRO principles.

[1] (Weick & Sutcliffe, 2001)

Based on past strategy implementation experiences, we also knew that a cultural shift of this magnitude would need to happen at many levels and across many platforms in order to ensure sustainability and adoption. As a result, we looked for other areas to target that would provide the greatest potential impact and change possibilities. We viewed the processes by which the organization operates as a key platform for driving change and HRO adoption; at all levels, the processes interconnect the organization's people and systems daily, and dictate how and when strategies are executed. To further imbed HRO concepts within the organization, we developed an enhanced process maturity model with defined levels for process maturity. The process maturity model was used to assess all defined business processes within Engineering, and will now drive improvement efforts for each process through its defined targets for maturity.

The HRO study not only served the purpose of assessing the organization, but it also allowed the project the opportunity to identify those work streams that are high achievers both from an efficiency and effectiveness standpoint. From this, learning opportunities came about to benchmark and drive improvement efforts more broadly within the organization.

One such group identified as a high achiever, relative to its peers within Engineering, was the Maintenance Excellence group. The group had implemented many tools and systems that accelerated their learning capabilities and feedback mechanisms for continuous improvement. We wanted to learn from their efforts and better understand their challenges faced in driving change. We also wanted to identify opportunities to help Amgen's maintenance organization reach its desired state of best-in-class operations. To do so, we developed a maintenance excellence roadmap that defines what a state of maintenance excellence looks like at Amgen; it further maps out processes and tools already in place, and identifies those tools that will be needed in the future based on feedback from maintenance staff and benchmarking against maintenance best practices. To test the current state of the maintenance group, we analyzed the implementation of a new cooling tower technology at a manufacturing facility and its impact on maintenance.

Please reference Figure 1. below for a visual representation of the project overview as described above, where work stream A represents the HRO recommendations, work stream B the process maturity model, and work stream C the maintenance excellence effort.

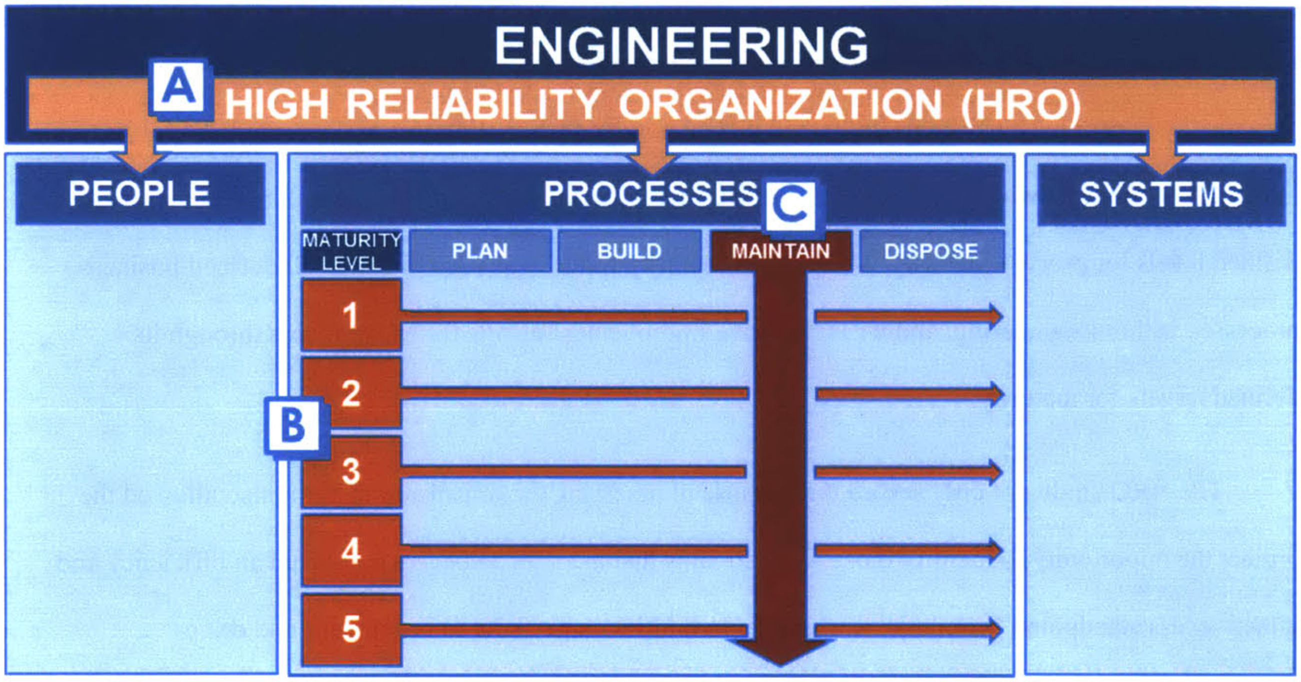

Figure 1. Visual Representation of Project Deliverables

1.4 Thesis Overview

Chapter 1 provides a brief project overview and summary of the sections in the thesis.

Chapter 2 looks broadly to provide a background of the biotechnology industry and Amgen, while also giving detail on the Engineering groups impacted as part of this project at Amgen. The section further looks to provide an overview of the concepts employed through the study of High Reliability Organization (HRO). With the context set, the section closes with a description of the project motivation for change.

Chapter 3 looks at Work Stream A- HRO Recommendations. It describes the process for baselining the organization utilizing the McKinsey 7-S framework, and then compares this current state to the characteristics of an HRO. Data from interviews and other organizational interactions was used to develop recommendations to close any identified gaps and help the organization operate in a more reliable manner.

Chapter 4 looks at Work Stream B- Process Maturity Model. The chapter describes the effort undertaken to define and mature business processes in the Engineering organization utilizing HRO concepts as the basis to drive change. Building on the HRO work from Chapter 3, an enhanced process maturity model was developed with defined criteria for levels of maturity and HRO concepts imbedded throughout. The model provides a platform for business process owners to advance processes using a systematic method to achieve quicker, more reliable outcomes.

Chapter 5 looks at Work Stream C- Maintenance Excellence. It details the work done with the Maintenance Excellence group to help advance Amgen's maintenance organization to best-in-class status. Research of modern industry best practices and a case study of the maintenance effects on a new technology implementation at Amgen's Thousand Oaks site help to shape the development of a Maintenance Excellence Roadmap.

2 Background

2.1 Biotechnology

In its simplest form, biotechnology is defined as any technology that makes use of living organisms or biologic systems to develop products[2]. While this definition can apply broadly across many industries, in healthcare, it focuses specifically on the production of therapeutics to combat complications resulting from a number of areas including autoimmune disorders and cancer. While still relatively young, biotechnology has grown into a multi-billion dollar a year industry with hundreds of products currently on the market.

Modern biotechnology finds its origin in the advent of recombinant DNA in the 1970s[3]. Traditionally, pharmaceutical drugs had almost exclusively been developed from organic, "small molecules". Recombinant DNA provided a new platform to develop therapeutic drugs by allowing for pieces of genetic material from different sources to be combined into "large molecule" proteins. This technological development resulted in the 1982 FDA approval and subsequent release of the first recombinant protein, Humulin®, Genentech's human insulin product to treat diabetes[4]. Following Humulin's® release to market, an entirely new class of biotechnology-driven drug was born called biopharmaceuticals. This marked a dramatic expansion in modern pharmaceuticals as drugs were now not just derived from chemical substances but also living organisms.

[2] (Amgen Brochure- An Introduction to Biotechnology, 2009)
[3] (Amgen Brochure- An Introduction to Biotechnology, 2009)
[4] (Amgen Brochure- An Introduction to Biotechnology, 2009)

2.2 Amgen

Amgen is the largest independent biotechnology company in the world with approximately 17,000 staff and $15 billion annual revenue as of 2010[5].

	Amgen	Biogen Idec	Genzyme
Year Founded	1980	1985	1981
Employees	~ 17,000	~ 5,000	~ 10,000
2010 Revenue ($B)	15.05	4.72	4.05
2010 Net Income ($B)	4.63	1.01	0.422

Table 1. Comparison of Amgen and Competitors as of 2010

The company's core mission is to serve patients worldwide by bringing to market therapeutics and treatments that restore health and save lives. Its corporate headquarters are located in Thousand Oaks, CA on the same site that the company was founded some 30 years prior.

Amgen was founded in 1980 with a goal to make innovative therapeutics using newly discovered advances in the field of biotechnology. After years of research, the company released the blockbuster drugs EPOGEN® and NEUPOGEN® following FDA Approval in 1989 and 1991 respectively[6]. EPOGEN® helps to increase red blood cell counts for anemic patients and is commonly used in conjunction with treatments such as chemotherapy for cancer, while NEUPOGEN® helps to increase production of neutrophils (an important blood cell in the immune system) in the body and is likewise used in conjunction with chemotherapy treatments and others that put the human body in a compromised state. Almost immediately, these drugs proved successful for the company with market penetration and revenue growth achieving levels rarely seen before in the pharmaceutical industry. This paved the way for massive expansion in the areas of research & development and manufacturing for Amgen through the 1990's and 2000's.

[5] (Amgen Fact Sheet- About Amgen, 2011)
[6] (Binder, 2008)

The company has become a market leader in bio-manufacturing through its continued focus on implementing innovative technologies in commercial manufacturing. It is constantly evaluating new technologies that can help improve product yield and quality. An example of Amgen's work to advance manufacturing is its exploration of disposable equipment technology in the biomanufacturing process[7]. Many people across the biotechnology sector feel that disposable technology has potential benefits that include lower operating costs, reduced cleaning cycle times, and reduced viral contamination odds.

Amgen has also undertaken an expansion effort internationally looking to grow into new markets. Recent international expansion of manufacturing such as the acquisition of Brazilian-based pharmaceutical company Bergamo and the acquisition of the Dun Laoghaire, Ireland facility from Pfizer, both in 2011, have signaled the start of this trend[8] [9]. Currently, there are ten therapeutics manufactured and distributed by Amgen at locations across the world including: Thousand Oaks, California, Boulder and Longmont, Colorado, Juncos, Puerto Rico, West Greenwich, Rhode Island, Louisville, Kentucky, Breda, The Netherlands, and Dun Laoghaire, Ireland[10]. Continued international expansion may lead to new challenges for Amgen and present many opportunities to make impactful advancement across the organization.

2.3 Engineering Organization

Amgen's Engineering organization sits under the umbrella of the Operations function, and is responsible for management of the company's asset lifecycle. The asset lifecycle is made up of four distinct phases that include plan, build, operate/maintain, and reinvest/dispose. During the plan phase, the organization looks to gain a better understanding of what assets are needed, where they are needed, and how they would help aid the company in achieving their operational goals. Once complete, the company

[7] (Steel vs Bag Study- Amgen Inc., 2005)
[8] (Amgen Bergamo Acquisition- Amgen Inc., 2011)
[9] (Amgen Fact Sheet- Amgen Manufacturing, 2011)
[10] (Amgen Fact Sheet- Amgen Manufacturing, 2011)

begins to design the process or facility to match these needs. In the build phase, Engineering works to ensure that the assets being brought on-line, whether as a greenfield addition or as a modification to an existing asset, are done so according to the scope, schedule, and budget as set forth in project approvals. During the operate/maintain phase, the organization focuses its efforts and resources on maintaining the assets so that they continue to operate as they were intended, and in the most cost effective manner possible. Finally, at the end of the asset lifecycle, the organization goes through the process of deciding whether to reinvest, repurpose, or dispose of the asset.

To make the correct decisions at each one of these steps in the asset lifecycle, the Engineering organization is broken into seven key functional groups that are responsible for overseeing the decisions made at various stages along the lifecycle. The functional groups include Global Asset Planning (GAP), Engineering Technical Authority (ETA), Global Capital Projects Management (GCPM), Project Controls and Services (PCS), Compliance and Risk (CR), Global Facilities Operations (GFO), and Engineering Excellence (EE).

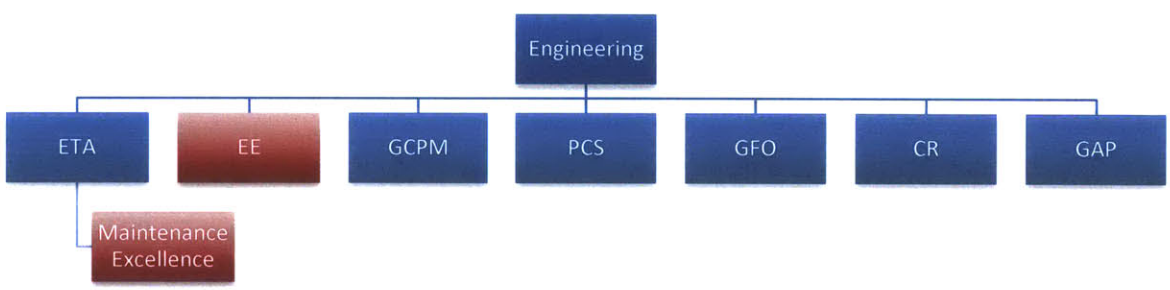

Figure 2. Engineering Organizational Chart

Each one of these groups plays a key role in helping the Engineering organization make the best possible decisions for Amgen's assets moving forward by taking broader company-wide goals and working to ensure that they are best facilitated through the management of the asset lifecycle. The majority of the work in this project is executed through the Engineering Excellence and Maintenance Excellence (a part of the ETA) groups, whose work and mission will be explained in greater detail below.

2.3.1 Engineering Excellence Group

Engineering Excellence (EE) is the group within Engineering that is responsible for driving continuous improvement and operational excellence strategies throughout the organization. EE is a small, nimble group. The team has diverse backgrounds ranging from lean/six sigma to workforce planning to portfolio management. The group interacts heavily with members of the rest of the organization, and works to identify areas for improvement to help the other groups within Engineering operate more efficiently and effectively. When improvement opportunities in the organization are identified, EE works with the other departments to design and roll out new initiatives to close gaps and drive improvement. EE is also constantly aware of the initiatives funneled down from Corporate and from Operations, and helps to ensure that these are rolled out in the smoothest and most effective manner possible for Engineering. Once strategies and goals have been identified, the group's goal is to ensure that they get implemented and achieved across the organization in a sustainable manner.

2.3.2 Maintenance Excellence Group

The Maintenance Excellence group, like Engineering Excellence, works to drive and implement new strategies for continuous improvement, but focused in the area of maintenance. The Maintenance Excellence group is a part of the Engineering Technical Authority (ETA), and looks to implement systems and tools that help operators and maintenance managers make the best decisions possible regarding equipment and other assets. The group implements systems and tools globally at every site across the maintenance network, and works to ensure that efforts are coordinated and information is readily accessible in order to facilitate the right actions being taken at the right times.

2.4 High Reliability Organizations (HROs)

A high reliability organization (HRO) is an organization that operates daily within a complex and risky work environment and has managed to avoid accidents and disruptions at a best-in-class rate while producing consistently reliable outcomes [11]. HROs have been a topic of study for years, with the majority of the research focused on certain industries that include the US naval aircraft carrier program, the FAA's air traffic control program, and nuclear power plants. While there was quite a bit of research that resulted from these studies, the work struggled to gain traction because the studies had largely been focused in glorified industries where many of the day-to-day challenges faced weren't directly translatable to other applications. Much of the research was theoretical in nature, and came up short in explicitly linking behaviors to resulting outcomes.

The study and benchmarking of high reliability organization concepts gained popularity again in the 1990's when Karl Weick and Kathleen Sutcliffe, both University of Michigan professors, began publishing their research on the topic, which ultimately culminated in the publishing of their book "Managing the Unexpected: Assuring High Performance in an Age of Complexity". Through their work, they found that all HROs share a common state of "mindfulness", which keeps them aware of their changing surroundings and unexpected events. There are three forms of unexpected events that can occur for any organization: (1) The first form happens when an event that was expected to occur fails to occur; (2) the second form of the unexpected happens when an event that was not expected to occur does occur, and (3) the third form of the unexpected happens when an event that was simply unthought-of of occurs[12]. Being mindful allows HROs to have a detailed understanding of these unexpected events and subsequent emerging threats. It promotes an awareness that encourages the development of capabilities to track even the smallest of failures and ultimately learn from them for future application. This allows HROs to maintain a competitive advantage relative to peers by being able to anticipate these changes and adapt at a moment's notice.

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[11] (Weick & Sutcliffe, 2001)
[12] (Weick & Sutcliffe, 2001)

HROs can be characterized by a culture that is uniform across the organization. At all levels, the organization is characterized by four cultural attributes: a reporting culture, a just culture, a flexible culture, and a learning culture[13]. In a reporting culture, it is an accepted practice for employees to come forward and report mistakes or near misses in an effort to promote safety. In a just culture, the organization recognizes that employees make mistakes, but it has zero tolerance for reckless behavior. In a flexible culture, the employees are nimble and able to adapt within their evolving work environment. Finally, in a learning culture, the organization seeks to constantly learn from both new experiences and old, and never become complacent as a result of successes. Developed in parallel, each of these cultural attributes forms the basis for the actions and beliefs of high reliability organizations.

[13] (Weick & Sutcliffe, 2001)

HROs share five common principles that are rooted in their culture, three of which can be categorized as anticipatory in nature and two as reactive[14]:

	HRO Principles	HRO Criteria
Anticipation	Preoccupation with Failure	Encourage reporting of errors
		Learn from near failure experiences rather than celebrating your luck
		Articulate mistakes to be avoided
	Reluctance to Simplify	Avoid bucketing and decision making for broad categories
		Put a premium on multi-functional skill sets and frames of reference
		Revise assessments as evidence changes
	Sensitivity to Operations	Encourage contact with the frontlines
		Raise doubts publicly to raise information
		Promote situational awareness (what is being done vs. what was intended)
Reaction	Commitment to Resilience	Have capabilities in place to detect, contain, and bounce back to original state or better in times of error
		Enlarge competencies and response repertoires to accelerate feedback
		Treat past experiences (both successes and failures) with ambivalence
	Deference to Expertise	Create flexible decision structures where decision making can migrate to the right skill-set
		Encourage expertise (group) vs. experts (singular)

Table 2. HRO Principles and Criteria

Each principle contributes to the core notion that HROs are aware of their surroundings, adaptable to changing environments, and are able to minimize and contain the effects of errors while also learning from them.

[14] (Weick & Sutcliffe, 2001)

2.5 Project Motivation

The Engineering organization's understanding of network interdependencies, processes, and resulting outcomes is not at the level that would typically be observed of a high reliability organization. Why is this the case? When we think of an HRO, we can look to an organization like the US naval aircraft carrier program. This is an organization noted for its broad-based network understanding, detailed process execution, and reproducible results. It has gotten to this point by understanding its strengths and weaknesses, and by leveraging this knowledge to breed consistent incremental improvement. Expectations for continual improvement are disseminated down through the lowest levels of the organization, and have come to embody the culture. The Engineering organization, on the other hand, does many things well but with key gaps that slow it from becoming better.

Not every aspect of how an aircraft carrier operates can be directly translated and then adopted into the Amgen Engineering organization, but many can and these are the ones that will be transformative. Figuring out those organizational touch points will be the focus of this project with the ultimate goal of helping Amgen Engineering become a high reliability organization.

3 Work Stream A- HRO Recommendations

3.1 Approach

A current state analysis of the Engineering organization is performed in order to identify areas to target for improvement and implement HRO concepts. The data collection is done through a number of methods that allow for observation of the work processes of the organization. These methods include working and interacting with other employees while on cross-functional teams, and also interviewing members of each of Engineering's seven functional groups.

To perform the interviews, a list of targeted interview questions are developed based on the HRO principles and criteria listed above. In total, 26 interview questions are utilized during each interview:

Interview Question:
1. Is there a process in place to track deviations/errors?
2. In your organization, is it safe to report errors and admit mistakes?
3. How are errors discussed in your group?
4. Is staff trained to report errors? If yes, in what ways?
5. What are your group's goals & objectives for identifying and reducing risk?
6. Does your group track near misses?
7. Do you feel comfortable reporting near misses?
8. How does your group act upon near misses?
9. Is risk management imbedded within your work processes? If yes, how so?
10. How does your group communicate risks and concerns?
11. Do people in your group feel comfortable communicating risks/concerns?
12. Does the org. structure allow for decisions to be made at the appropriate level (by the right people)?
13. Are processes documented and utilized to carry out all critical work streams?
14. Does the decision making process typically involve multiple people with multiple viewpoints?
15. Does cross functional skill development occur, and is it encouraged?
16. Are group strategies regularly assessed, and revised where necessary?
17. Are there processes and procedures in place to revisit these strategies?
18. Does management look for input from workers down to the lowest levels?
19. Does management see value in this input from the frontlines?
20. Does management listen for concerns from workers and elevate where applicable?
21. Do you feel like your group is cognizant of the work going on around you that you directly or indirectly affect?
22. Are processes in place to resolve errors and all affected work streams?
23. How does the group react when errors are discovered?
24. Do skill sets overlap between members of the group?
25. Do you feel like your group provides solutions to problems quickly or could this be improved?
26. Does your group look to aspects of both past failures and successes to drive future strategies?

Table 3. Targeted Interview Question List

To ensure that the questions are broad-reaching in scope and touch upon all facets of the organization, an evaluative framework called the McKinsey 7-S model is employed. Each interview question –developed to elicit a response measuring the existence of HRO principles in the organization – is mapped against the framework's 7-Ss to drive recommendations.

7s Framework	HRO Principles				
	Preoccupation with Failure	Reluctance to Simplify	Sensitivity to Operations	Commitment to Resilience	Deference to Expertise
Structure		Question 12	Question 18, 20	Question 24	Question 12, 24
Systems	Question 1, 6, 9	Question 12, 13, 17	Question 1, 22	Question 22	
Staff		Question 14	Question 18		Question 24
Style	Question 3, 8, 10		Question 10, 21		Question 14
Strategy		Question 16		Question 26	
Skills	Question 4	Question 15		Question 23, 25	
Shared Values	Question 2, 7, 11		Question 11, 19		Question 19

Figure 3. HRO Interview Question Matrix

3.1.1 McKinsey 7-S Framework

The McKinsey 7-S framework was developed in the 1980's by two organizational design thought leaders, Thomas J. Peters and Robert H. Waterman Jr., while working at McKinsey as consultants. The framework is designed to provide a platform for evaluating the current state of the organization and analyzing the potential affects that a new strategy or change implementation will have. The model looks at the interdependencies of each of the 7-Ss (structure, systems, style, staff, skills, strategy, and shared values) thought to make up an organization, and provides a platform to evaluate the impact of a change to the organization[15]. The model looks to both the tangible "Hard Ss" and intangible "Soft Ss" elements of an organization and links them through a unifying framework. The "Hard Ss" include the organization's staff, structure, and systems. The "Soft Ss" include the organization's style, strategy, skills, and shared

[15] (Peters & Waterman, 2004)

values[16]. The model proposes that alignment of each of the seven elements is a must to move forward with strategies for organizational advancement.

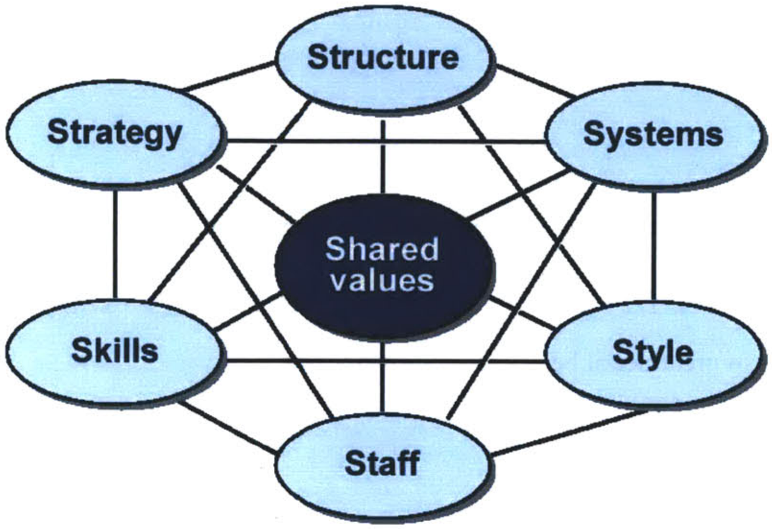

Figure 4. McKinsey 7-S Framework[17]

The framework views the shared values of an organization as the central pillar around which all other elements revolve. The shared values, in addition to each of the other six elements, are defined in greater detail below:

1. **Structure**- how the organization's units/components are organized and relate to one another
2. **Staff**- number and types of people working in the organization
3. **Systems**- procedures and processes that characterize how work is to be done
4. **Strategy**- plan for achieving the organization's desired goal with all available resources
5. **Style**- cultural aspects and how workers behave in working towards the organization's goals
6. **Skills**- core competencies or capabilities of the organization and/or the people within it
7. **Shared Values**- the pillar around which all organizational aspects both connect and revolve. These are the organization's core values and central beliefs

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[16] (Peters, 2011)
[17] (Vector Study: McKinsey 7-S, 2008)

In regards to this project, the framework provides a means to evaluate Amgen Engineering's current state, establish a baseline, and drive improvement actions towards a new state of greater reliability in its people, processes, systems, and their resulting outcomes. By mapping the interview questions and HRO concepts against the framework, a detailed analysis of the gaps in the current state of the organization emerges.

3.2 Data

Using the process outline above, observations from interviews and other interactions within the organization help to paint a picture of the current state of the organization. Each of the 7-Ss for Engineering is described in great detail below.

3.2.1 Structure

From the McKinsey 7-S model, structure is defined as how the organization's units/components are organized and relate to one another. Good structure is any that helps the organization best facilitate work to reach its defined goals and targets. This typically calls for clearly designated –and full coverage of– responsibility, understanding of network interdependencies between groups, and clear channels of communication that promote knowledge sharing. Failing to have the right structure in place for any organization can lead to delays and breakdown in execution of strategies and projects.

Amgen Engineering has seven functional groups that make up the organization:

1. **Global Asset Planning (GAP)** – GAP is responsible for all real estate transactions and space planning and allocation. The group plays a large role in Amgen's mergers & acquisition strategies to evaluate how to best incorporate and utilize real estate that is involved in transactions.

2. **Engineering Technical Authority (ETA)** – The ETA is largely made up by employees with an engineering background. The group is responsible for engineering standards and specifications, maintenance requirements and strategies via the Maintenance Excellence group, and asset troubleshooting. It also has oversight of the technical authorities at each manufacturing site.

3. **Global Capital Projects Management (GCPM)** – GCPM oversees the implementation of the capital projects undertaken by Amgen and largely made up by project managers and project directors who oversee these projects.

4. **Project Controls and Services (PCS)** – PCS is responsible for tasks including estimating, scheduling, cost controls, forecasting, invoice review, and risk modeling for capital projects.

5. **Global Facilities Operations (GFO)** – GFO oversees all site facilities operations including administrative, research & development, and lab spaces. The group works closely with corporate Environmental, Health, and Safety (EHS) to ensure that standards are being met during the operation and maintenance of assets.

6. **Compliance and Risk (CR)**- CR is responsible for ensuring that Engineering is compliant with the requirements of all internal and external regulatory stakeholders.

7. **Engineering Excellence (EE)** – EE is responsible for driving continuous improvement projects within Engineering. EE works closely with each of the five other functional groups to help them drive towards a state of the most efficient and effective outcomes possible.

The organization is structured in such a manner that the groups have clear responsibilities in the management and execution of strategies in the asset lifecycle. This allows for the majority of the decisions to be made by the right people and groups at the right times. While some groups have many touch points at various stages of the asset lifecycle, others are focused on executing work in one specific phase. This clear understanding of where responsibilities start and stop allows for efficient information exchanges on processes between connected groups.

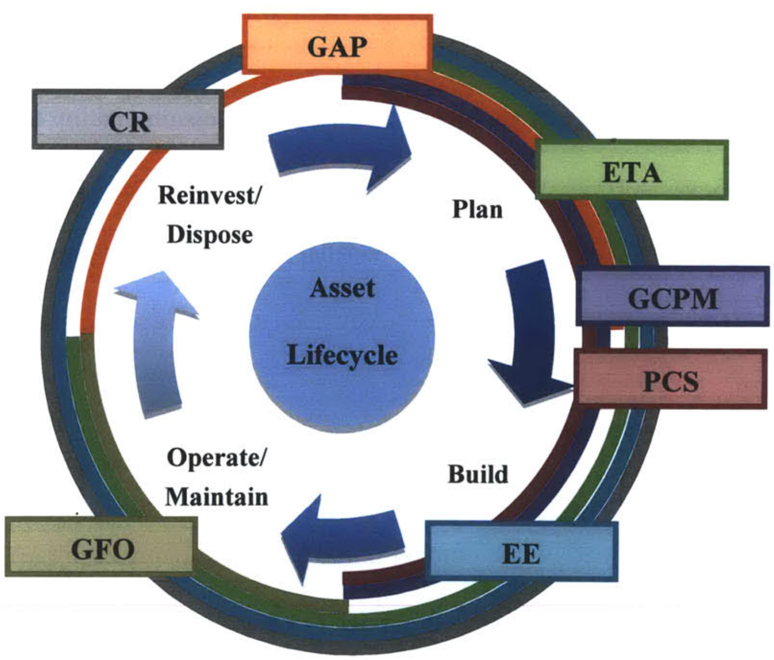

Figure 5. Amgen Asset Lifecycle Management

Engineering's distinct structure, though, has the potential to allow single points of failure in terms of knowledge within the groups. Opportunities exist to better define the roles and responsibilities for the organization where instances exist of not having a full understanding of upstream and downstream needs and/or where there is little skill-set overlap for many of the key knowledge banks.

On several occasions, interviewees cited single points of failure as a risk to the organization. Several of the positions within groups have become employee-dependent due to the maturity levels of process documentation and communication. There are opportunities to identify these single points of failure and then develop cross-functional training to close the knowledge gaps, so that the organization is no longer at risk of losing key knowledge bases should these employee-dependent positions be vacated. One specific example that was cited in interviews was of an employee involved in real-estate planning who left their position in the organization. They had largely worked autonomously and not documented many of the work processes utilized, so the organization was left exposed to knowledge loss. Once all current examples similar to this one are exposed, the organization can better protect one of its most important assets in its knowledge base.

While the organizational structure of Engineering allows for decision making to migrate to the right people at the right times, the correct migration sometimes doesn't happen. This is likely due to a number of reasons including the priorities for one group conflicting with those of another, employee reluctance to trust that the decision making will happen elsewhere, and risk aversion that pushes decisions too high in the organization.

3.2.2 Staff

An organization's staff is defined by the number and types of people working in it. To understand if the right staff is in place, a simple place to start is by understanding the organization's purpose, work streams, and desired output. Mapping the workers against these three buckets shows if the organization is staffed correctly to achieve the desired outcomes. A good organization will have the right people in the right places and in the right numbers, with sufficient employee cross-training to cover high risk work streams. Poor staffing results in too few staff for the required work streams with substantial gaps in knowledge coverage resulting, or too much staff that over burdens the systems and slows down progress and innovation.

Because much of the work done by the Engineering organization is done in support of customer projects in other organizations, the staff has a great deal of experienced management who oversees the project execution and roll out. As a whole, the staff has a great deal of industry experience and is able to draw upon this experience to execute new projects. In most instances, they have spent the majority of their time at Amgen working in Engineering for the same groups. This promotes a deep understanding of the project execution across the various groups and work streams, and allows for cross-functional work to be done in an efficient manner by those employees who have large networks to draw upon.

The current structure of the organization, though, has created somewhat of disconnect of information exchange between upper-level management and the organization's frontline staff. Most of the management wants and accepts input from workers, but some don't necessarily seek it out. Most of the staff is comfortable providing input and raising concerns to their immediate supervisors; however, they don't always feel comfortable doing this with more senior level management. As a result, some ideas and concerns may go unheard at times. This could be due to the fact there are not enough safe forums for the lower-level workers to elevate inputs and concerns to management.

3.2.3 Systems

The McKinsey 7-S model defines systems as the procedures and processes that characterize how work is to be done. When implemented correctly and in the right forms, the systems help to streamline the work of the staff and make their production more efficient and effective. Systems also help to standardize work. When no systems are in place, the staff in an organization is able to define their own process and procedures for executing work, which leads to unpredictable results.

The systems in place for some groups within the Engineering organizations to execute work are in their relative infancy. Feedback from employees in certain groups showed that the systems that are in place and used most prevalently are the ones linked to the most critical work streams (typically those associated with cost and safety). In the remaining work streams for these groups, employees perform work by their own processes they've developed to be more efficient. When this occurs, it can preclude knowledge sharing and cross-functional learning from occurring on several work streams that are the same for multiple positions. For instance, an employee in GCPM could be doing workforce planning calculations using an entirely different process than someone in the ETA. While both may achieve similar results, best practices are not developed to arrive at an optimal process that can be standardized across all groups.

Many of the metrics and tracking tools needed for the organization are just now being defined. Formal goal development and deployment processes exist to identify system improvements and implement them organization-wide. Much of this definition work is being done by the Engineering Excellence group who is working to develop tools to help the organization become more proactive in addressing potential problem areas rather than reacting to them after they have occurred. Because the work done by Engineering is evolving to include new areas and functions, the implementation of predictive tools and identification of potential sources of error can be difficult. Most metrics currently in place have resulted from past issues or errors, so the group is working to identify future problem areas and implement metrics to track their leading indicators of failure.

The group is also working to develop workforce planning models to help the organization allocate resources across the various projects. This will help groups better understand the variety and number of projects that they will be able to take on, given their current employee count and utilization rate.

Greater organization-wide focus is now being placed on developing the systems and tools necessary to help the staff execute their roles in the most efficient and effective manner possible. The implementation and advancement of the systems has largely been group-specific, with some placing more emphasis on deployment than others. The majority of metrics that currently exist are those that track compliance and safety-based issues. This means that certain groups like GCPM and GFO, which inherently have more exposure to safety incidents through their work, have advanced metrics relative to their peers.

Risk management is another area where work has been group-specific. Risk management tools have largely evolved from quantifiable scenarios (e.g. impacts and costs associated with a piece of equipment or a process failing vs. the odds and frequency of it failing). Greater emphasis on developing risk-based tools will provide for more informed decisions given the risk profile for future projects.

3.2.4 Strategy

Strategy is defined by the McKinsey 7-S model as a plan for achieving the organization's desired goal with all available resources. Good strategies can propel an organization into successful times for years to come, while bad strategies can cause irreparable damage. Thus it is important for an organization to understand the changing environment in which it works and be able to successfully adapt and develop strategies to best position itself for the future.

Many of the larger strategies and goals for the Engineering organization are rolled out in support of larger initiatives by Amgen Operations. Operations typically releases its goals for the upcoming year to the various organizations that it encompasses. Each organization will then meet to develop its own strategies that help to best support the broader Operations-wide goals. For Engineering, this occurs through the Engineering Leadership Team (ELT) which is composed of the Vice President of Engineering and his team of Executive Directors. They meet periodically to both develop, and then monitor the progress of the goals and strategies for the organization. An issue for both Engineering and Operations, though, has been the engagement of lower-level employees in the goal definement process. The goals are sometimes rolled out into the functional groups, though, without buy-in from the employees who will be deploying the work in practice. This can lead to strategies being disconnected across groups because the goals have not been communicated clearly enough at all levels of the organization.

Feedback from employees showed that in the past when decisions were made, the organization had been inclined to proceed with less risky decisions, even if it meant devoting more resources and time. In the biotech industry, safety and the well-being of the patient is always held in the highest regard. But, there must be some way to better quantify risk. This risk aversion plays a role in the organization's goal setting. While the organization looks to past experiences (both failures and successes) to drive future strategies, it can do a better job to quantify risks associated with the strategies. There needs to be more emphasis placed on developing risk-based approaches for decision making.

3.2.5 Style

From the McKinsey 7-S model, the style of an organization is made up of the cultural aspects and how workers behave in working towards the organization's goals. A good culture motivates workers to show up to work every day and produce to the best of their ability. While it can be difficult to achieve, when a great culture surfaces it can be a competitive advantage for an organization.

The staff in the Engineering organization is very collaborative and meeting-centric. Many of the decisions and strategies are made by groups in meetings. This can be effective because it allows for different thought processes and points of view to be discussed by key stakeholders. Each thought is taken into careful consideration when making a decision that affects multiple stakeholders. Errors are also discussed and communicated regularly during meetings across the organization. This has been engrained within the corporate culture across Amgen and contributes greatly to knowledge sharing. The smaller errors are typically communicated via meetings, while larger errors and organizational concerns are issued through newsletters and bulletins throughout the organization.

Still, 42% of employee interviews indicate that this collaborative nature can also be a hindrance to arriving at decisions in a timely manner because the voices of the smallest stakeholders can influence the larger group by derailing consensus. Often times, this can simply be due to those stakeholders not having a full understanding of the implications to other groups with their ideas or proposals. Most employees are cognizant of the work that is going on around them, but not always how the work they are doing is affecting the work of others. Feedback from interviews indicated this is likely due to the fact that the understanding of the network interdependencies is isolated at the top with senior management and not communicated down to the employees engaging in the work. Those staff members that have an understanding of their work's network interdependencies have developed a strong communication network from which they can draw upon to understand influences.

3.2.6 Skills

Skills are defined as the core competencies or capabilities of the organization and/or the people within it. Skills, like many of the other 7-S's, can be greatly enhanced by understanding what the organization needs and then developing skills to best meet those needs. An organization that doesn't have the skill in place to achieve desired results will inevitably fail, or at the very least be stuck in an endless cycle of churning, as it will always be playing catch up to the changing environment in which it operates.

The Engineering organization's core competency lies in the management of Amgen's asset lifecycle. It works daily to manage the present state operations of the assets in all phases of the asset lifecycle while developing strategies for managing those assets in the future. As can be expected, this is a difficult challenge given the scope and complexity of Amgen's operations. It takes a coordinated effort that involves communication and adaptability, both of which the organization does quite well. It also takes a staff trained with multi-functional skill sets. Amgen encourages cross-functional skill development, but there can be improvements in helping to facilitate it. Because staff is limited in the time they have available to develop additional skill sets outside of those in their immediate roles, it often doesn't happen unless opportunities for learning have been identified by others. By better defining the roles and responsibilities for each position, a more accurate assessment of necessary development measures can be done to drive continuous improvement within the organization.

Employees understand their limitations and the boundaries within which they work, and are able to mobilize quickly once errors are discovered. The organization is quick and responsive to fix errors and implement measures to prevent reoccurrence in the future. Identifying errors and other leading indicators of failure can be improved though. Once processes become more mature and metrics gain robustness, the organization and its employees will have the infrastructure in place to identify and circumvent failures at their infancy or before they occur.

3.2.7 Shared Values

The McKinsey 7-S model defines shared values as the pillar around which all organizational aspects both connect and revolve. Simply put, these are the organization's core values and central beliefs. Shared values are difficult to quantify, but have an irreplaceable value in an organization. They are what defines an organization, the people within it, and the mission and principles acted out each day at work. When shared values are disrupted, a ripple down effect occurs to every other aspect of the organization because shared values are imbedded everywhere.

Amgen's mission in developing therapeutics is to serve patients in the best way possible through its work. Across the campus, via testimonials of current patients and other forms of end-user attachment, this mission statement is constantly reiterated to engrain the direct link between the work the employees do and the positive effects that their work has on thousands of patients' lives each day. This link is easy to convey in groups like Research & Development and Manufacturing because they are working with the product. They physically see the product being developed and shipped each day to the user. For the Engineering organization, its work is more difficult to directly relate to the end product because the work it does is largely service-based for internal customers.

The employees in Engineering, however, are a motivated group striving to drive continuous improvement in the organization. They realize that in the changing face of the biotechnology industry they must continue to anticipate changes and evolve as a result. The organization is undertaking many initiatives now to help the organization best position itself to be a leader in the industry for years to come. It understands that the deep-rooted culture and shared values of the employees dictate how its employees execute work, and as a result, is in the process of identifying its strengths and weaknesses in order to help itself become a competitive advantage for Amgen. Work like implementing HRO concepts and driving process maturity are integral steps to helping the organization reach this state.

3.3 Discussion

Application of the McKinsey 7-S framework to analyze the Engineering organization brings to light improvement areas that can be addressed. Following the scientific analysis method described above, observations and feedback from employee interviews were collated into common themes. A 5-Why analysis diagnoses the root cause of the trouble areas, and from that a set of actionable recommendations has been developed to better facilitate HRO principles. The resulting recommendations for each of the organization's 7-S's are summarized below.

Structure

The organization's structure was found to be highly functional and effective in supporting the larger goals of Amgen. Improvement areas identified for the organizational structure largely revolve around information flow and communication not being facilitated through the channels that were in place. Decision making and management communication are cited as the two key areas than can be improved moving forward to help the organization become less siloed and have more information sharing.

For the correct communication migration to occur, the organization can further develop the mapping of stakeholders, the decision making process, and how they inter relate for specific decisions. By building in the capabilities for decision making to occur at the correct staff levels, it will innately free up more time for the management to interact with their staff and processes, thus enabling them to seek out feedback when necessary. Other ideas to help facilitate communication between management and staff are the implementation of skip level meetings and regular performance board reviews. See Table 4. below for a summary of the improvement areas and resulting recommendations.

What was Said	Why?	Recommendation
1. The organizational structure of Engineering allows decision making to migrate to the right people at the right times, but the correct migration often doesn't happen	a. Priorities for one group can conflict with those of another b. Employees are reluctant to trust that the decision making will happen elsewhere c. Risk aversion pushes decisions too high in the organization	• Map decision making process for the organization o Build in the discipline to push decisions lower to encourage ownership • Eliminate unnecessary approvers for a decision
2. Management wants and accepts input from frontlines, but doesn't necessarily seek it out	a. Not enough structured opportunities for this information exchange to occur b. Management is busy with other commitments	• Create more communication forums including: o Skip level meetings for all levels of management o Regular performance board reviews with all staff • Follow-up on outcomes of forums

Table 4. Structure Analysis and Recommendations

Staff

The staff in the organization are extremely collaborative in the decision making process, which promotes a sense of impact for all parties involved. There are, however, drawbacks to this style of decision making as it can slow down the process of making decisions and distort stakeholder rank. Tying back to the recommendation presented in the structure section regarding stakeholder mapping, this effort will help streamline the decision making process, enable the right stakeholders to be heard, and eliminate unnecessary approvers for decisions that could otherwise block progress.

Feedback also shows a common theme of staff internalizing job knowledge and resulting concerns and improvement ideas. This condition could slow the organization's continuous improvement efforts if not identified and corrected. Because staff roles and responsibilities sometimes evolve to overlap, knowing where to go for information can be difficult. Creating a knowledge sharing platform and identifying formal subject matter experts for staff to turn to will help alleviate some of these issues and reduce single points of failure within the organization. See Table 5. below for a summary of the improvement areas and resulting recommendations.

What was Said	Why?	Recommendation
1. Amgen Engineering staff are collaborative and very meeting-centric. This allows everyone's' voice to be heard, but the right voices may not be heard at the right time.	a. There are often too many inputs in decision making b. The loudest voice may belong to the smallest stakeholder	• Map out stakeholders responsible for a decision in order to eliminate unnecessary approvers
2. Staff is not always comfortable raising concerns to management	a. Staff is comfortable raising concerns with immediate supervisors but not comfortable taking issues higher b. Not enough safe forums to communicate concerns	• Create more communication time with upper management including skip level meetings • Develop method to voice serious concerns anonymously • Promote "safe" communication culture to staff
3. There are many single points of failure in terms of staff roles and knowledge	a. Staff roles and responsibilities are not clearly defined b. A lack of engrained knowledge sharing	• Define and communicate staff roles and responsibilities to identify single points of failure • Identify formal subject matter experts

Table 5. Staff Analysis and Recommendations

Systems

The systems in place in the Engineering organization are undergoing improvement. Engineering recognizes the importance that tools, analytics, and metrics can play in advancing its work practices and are devoting a great deal of resources to develop and implement them.

The metrics that currently do exist are largely driven by past instances. Greater emphasis can be placed on imbedding risk management practices and documenting processes throughout the organization. A big step in helping drive metrics implementation is the shift in the organization to become more proactive in identifying problem areas and implementing solutions before they occur. By developing a formalized business process that gathers all important metrics and evaluates the results regularly, a process for improvement can be developed to assess the changing work environment and implementing metrics revisions where necessary.

Another area that directly ties to the metrics is risk management. Engineering will see great benefits by focusing on strategies to implement risk management throughout all functions and groups, regardless of the work that they do. Some groups are inherently more advanced in their risk management analytics than others due to the nature of their work. Still, great value will be seen by investing in resources to advance risk-based metrics in groups where risk isn't directly at the forefront of their work. Formalized risk management practices should be developed for these groups with strict guidelines that instruct the staff when certain risks are worth taking. See Table 6. below for a summary of these improvement areas along with others, and the resulting recommendations.

What was Said	Why?	Recommendation
1. Metrics implementation and error tracking is largely driven by past incidents	**a. The Engineering group is more reactive in nature rather than proactive** **b. Metrics have been developed by individual functions without an overarching business process**	**• Focus on benchmarking efforts for metrics** **• Create a formalized business process to include data gathering and metrics, wherein metrics are assessed and revised regularly**
2. Near misses/failures are typically only tracked for compliance and safety-related incidents	**a. Engineering has prioritized compliance and safety due to their high importance.**	**• Near misses/failure tracking needs to extend to other leading metrics including product supply, business interruption, and cost impacts**
3. Risk management is strong in some groups and weak in others	**a. Some groups inherently focus on risks due to the nature of their roles, while others do not have risk directly at the forefront of their work**	**• Engrain risk/benefit analyses in all Engineering work streams** **• Become better at evaluating risks and providing guidelines on how to determine those risks that are worth taking**
4. Most critical work streams have documented processes for execution, but tend to focus on cost and product delivery	**a. Cost and product delivery have been identified as the key elements in defining critical work streams for Amgen**	**• Document and mature other work processes which directly impact the ability to serve patients** **o Continue process maturity effort in Engineering**

Table 6. Systems Analysis and Recommendations

Style

While the styles that define the Engineering organization are communication and collaboration, there isn't an all-encompassing platform to document and communicate learning opportunities, such as mistakes to be avoided, outside of immediate groups. A major focus going forward for Engineering needs to be the development of a knowledge sharing database as a resource for staff to draw upon. It has to be engrained in the culture of the employees to both contribute to and rely upon, as a knowledge management system is only as successful as the information that is contributed to it.

Another big step in helping the organization become highly reliable is in its ability to understand its surroundings, networks, and the interdependencies it has with each. Network understanding mostly lies with senior management and those employees at Amgen who have long tenure and a well-developed personal network. This understanding can be extended to the lowest levels of the organization so that all staff is cognizant of the evolving business climate and able to understand how and why decisions are made. By developing formal customer feedback loops for each group in Engineering and their customers outside of the organization, the staff will be able to gain a better understanding of how their work streams impact other groups, which should ultimately spur process improvement. See Table 7. below for a summary of the improvement areas and resulting recommendations.

What was Said	Why?	Recommendation
1. Errors are discussed and communicated regularly within groups, but often not through formal documented channels	**a. Amgen has a collaborative work environment** **b. Current error communication happens via tribal knowledge** **c. Formal documenting and knowledge sharing processes are rarely utilized**	**• Develop knowledge sharing databases and documented lessons learned programs that are engrained in Amgen culture for utilization**
2. Engineering is generally aware of what is going on around it, but not necessarily how its work affects those activities	**a. Understanding of network interdependencies is isolated** **b. Strong personal networks are currently necessary to be aware impact on surroundings**	**• Identify network interdependencies for work streams and communicate clearly to each member of the network** **• Create formal customer feedback loops for each group to gain a better understanding of how their work stream impacts customers**

Table 7. Style Analysis and Recommendations

Strategy

Amgen's strategies have been developed within a culture that is risk averse. The biotech industry and the stringent requirements to meet FDA standards have helped contribute to this, but so has Amgen's history of financial success. Simply put, Amgen has been able to afford to be conservative. Now that the company is maturing and focusing on reducing costs, new methods for calculating and accepting risks need to be developed. The Engineering organization, whose decision making often gets pushed too high in the organization, can benefit by implementing and following a structured risk evaluation process. The key is to develop a new culture wherein risk taking is an accepted practice when done within the guidelines of the corporate structure. The ideal state for Engineering should be instances where an organization that looks at taking an appropriate risk by following the structured risk evaluation process is looked upon more favorably than not having taken the risk at all. See Table 8. below for a summary of the improvement areas and the resulting recommendations.

What was Said	Why?	Recommendation
1. Amgen strategies have been developed within a culture that is risk averse	a. Risk aversion pushes decisions too high in the organization	• Identify areas where calculated risks can be taken • Follow a structured risk evaluation process o Promote a culture wherein taking an appropriate risk following the structured process is looked upon better than not taking the risk at all
2. Strategies, goals, and visions are developed at the senior management level, with not enough input from the lower levels	a. Operations goals cascade to Engineering b. Understanding of network goals are limited at the senior management level	• Create a process to have senior management consult with frontlines to actively develop goal and strategy proposals o Once goals and strategies are completed and agreed upon by senior management, consult with frontlines again to ensure alignment and ownership prior to deployment

Table 8. Strategy Analysis and Recommendations

Skills

Amgen encourages cross-functional skill development, but there can be improvements in helping to facilitate it. Because staff is limited in the time they have available to develop additional skill sets outside of those in their immediate roles, it often doesn't happen unless mandated. Outside of on-the-job training within roles, formal training programs through Amgen are typically the only means by which training gets accomplished. Engineering can become more proactive in identifying its knowledge-based vulnerabilities and weaknesses, and then develop training programs to help close those gaps to better promote multifunctional skill sets. To encourage knowledge proliferation outside of formal programs, a broad-based pool of subject matter experts (in addition to those subjects covered by the ETA) should be identified, and then act as sources of reference for staff for any issues or questions that arise in their specific areas.

Reporting of errors and other leading indicators of failure is another area identified for improvement. Instituting metrics and analytics that better identify and track errors is an important first step for the organization, but their also must be an actionable culture that supplements the metrics for the program to truly sustain. Developing a formal training program –that can be tailored to specific groups– to train staff on identifying, reporting, and learning from errors will help cultivate this culture. The key is the learning aspect, as this is the truest test of an organization's ability to comprehend the work it is doing and how it affects and/or contributes to broader goals. See Table 9. below for a summary of the improvement areas and the resulting recommendations.

What was Said	Why?	Recommendation
1. There is no formal process for training staff to report errors outside of safety-related issues	a. Safety has top priority at Amgen b. Errors are not easily identified outside of safety and compliance-related issues	• Develop a formal training program to train staff on identifying, reporting, and learning from errors (e.g. SRCA) and expand to include areas in addition to safety
2. Cross-functional training is encouraged but not actively facilitated	a. Staff is limited in time available to develop additional skill sets outside of those in their immediate roles b. Roles and responsibilities have not been fully defined across the organization to identify gaps or single points of failure in knowledge	• Identify and map out work processes within groups to better understand single points of failure and then implement training programs to close gaps in knowledge • Create an online knowledge database with subject matter experts who are responsible for documenting and communicating specific areas of expertise
3. Groups mobilize quickly once errors are found, but there can be improvement in predicting errors	a. Processes are not mature enough to be able to anticipate where errors are likely to happen	• Develop detailed process workflows through process maturity effort • Identify and implement leading indicators of failure

Table 9. Skills Analysis and Recommendations

Shared Values

Amgen has a core mission to always serve its patients in the best way possible by helping to improve the way in which they are able to live their lives. This resonates loudly throughout the organization and is evident in the work done daily in most functions. The Engineering Organization, due to the nature of the work it does, is one group wherein this mission statement can be lost at times. Because Engineering largely performs work in support of other organizational efforts at Amgen, its staff is removed from the product/patient interaction.

The mission can be better engrained by simply being communicated more regularly and by drawing links from the end product to the work done by staff. For employees that lack the cross-functional interaction to other organizations, an easy way to relate the mission statement to their work is by bringing in members of other organizations, such as R&D and manufacturing, to staff meetings to talk about the work they do and show how Engineering helps to support their efforts through the work it does.

Another area marked for improvement is in the identifying and reporting of errors. The Engineering organization does a very good job at error reporting for the more visible types of errors that occur in safety and compliance. Yet, because it does not have mature work processes in every element of its scope, the group hasn't yet devised a way to track and document inefficiencies that occur with daily work streams away from measurable work environments (i.e. manufacturing, maintenance, etc.) as desk jobs account for the majority of the roles in the Engineering organization.. By continuing with the process maturity efforts and focusing on developing intermediate tracking metrics for error reporting, the organization will be able to better capture problem areas and implement solutions through the continuous improvement cycle. See Table 10. below for a summary of the improvement areas and the resulting recommendations.

What was Said	Why?	Recommendation
1. Amgen's mission to serve patients is at times lost in the work done by Engineering	**a. Work is far removed at times from the downstream process of delivering products to patients** **b. How Engineering helps Amgen serve patients is not communicated regularly enough**	**• Bring in members of sales/marketing, manufacturing, R&D, etc. to communicate Engineering's contributions to Amgen's mission**
2. Error reporting is typically limited to more visible types of errors (e.g. safety and compliance)	**a. Less visible mistakes or errors can be fixed through rework** **b. Engineering creates a safe environment to report these types of errors**	**• Advance process maturity efforts to further incorporate error tracking and documentation in daily work streams** **• Work on creating a shared value in learning from all types of errors**

Table 10. Shared Values Analysis and Recommendations

3.4 Conclusion and Recommendations

Amgen's Engineering organization recognizes that continuous improvement is necessary for it to increase competitive advantage for Amgen. By benchmarking against high reliability organizations and implementing strategies based on their concepts, Engineering can itself achieve a state of more reliable outcomes. Because Engineering is at the intersection of so many organizational interfaces due to its management of the asset lifecycle, there is room for great impact not just in Engineering but also elsewhere in Operations by advancing these efforts.

A few quick advancement opportunities for Engineering's HRO efforts include:

1. Utilizing designated facilitators to provide training and follow up evaluations in regards to HRO adoption and implementation. Employees in Engineering have already been designated with continuing the HRO implementation efforts. As part of those efforts, there needs to be designated subject matter experts who train business process owners and other staff members on the HRO principles, and then support them through any advancement efforts.

2. Tracking HRO implementation and maturity levels for each process in a group on its performance board with targeted action plans for improvement. We found that while some groups utilize their performance boards to communicate and monitor progress, many still do not. By making regular performance board reviews the norm rather than the exception, HRO implementation and process improvement efforts can be tracked in a more collaborative environment.

3. Using the Operational Excellence (OE) core teams and steering committee as a way to discuss and implement HRO-based strategies and progress. Every business process is categorized into a group and has a business process owner. Representatives of all groups meet regularly to discuss OE initiatives, so monitoring the progress of the HRO implementation will bring structure and accountability to the process.

We don't believe that change will simply happen by just creating a list of recommendations, so to further advance our mission of driving towards greater reliability we have identified Engineering's business processes as a platform for change. Chapter 4 below describes the strategies employed to help advance the business processes (and in turn the behaviors of staff) utilizing HRO principles.

4 Work Stream B- Process Maturity Model

4.1 Approach

In an effort to identify further improvement areas for Engineering, the organization looks to its business processes as an important target to investigate further. Because the processes have many touch points across the organization and dictate how employees interact with the available systems and tools, their improvement can lead to overall improvement of the organization's work streams.

This project looks to identify and implement a method to drive improvement efforts by incorporating HRO principles into each business process. The desired state, after all, for any process should be to have highly reliable, reproducible outcomes. Rather than look to tailor each process improvement effort individually, a resource is sought that can baseline the processes and drive improvement efforts broadly. Enter the idea for a process maturity model.

Operations has for several years used its Quality Management System (QMS) Process Maturity Model to assess and then improve upon several important operations-based processes. While effective, the maturity model focuses to drive improvement efforts in the area of compliance (with the FDA in mind) on the critical processes that had been initially targeted. Engineering's business processes have more comprehensive needs going forward. While compliance is viewed as a central focus of the improvement efforts, there are other areas to target in order to reach a desired state of having reliable, reproducible outcomes for each business process. With this in mind, the project has identified four critical areas that must mature in order for the organization to achieve its desired state. These areas include: (1) compliance, (2) efficiency & effectiveness, (3) reliability, and (4) safety & risk mitigation.

Figure 6. Engineering Desired State

The QMS Process Maturity Model assesses processes with a compliance-driven focus, but only briefly touches upon the three remaining areas. To most effectively advance Engineering's business processes, a more comprehensive process maturity model is needed going forward.

Figure 7. QMS Process Maturity Model Coverage

Rather than develop an entirely new maturity model, the project looks to see if Engineering can build off of the Operations-wide QMS Process Maturity Model and improve upon it to meet Engineering's needs. This decision was arrived at for two main reasons: (1) it would encourage complete adoption and avoid confusion amongst users of the QMS Process Maturity Model, and (2) it would allow the organization to more quickly implement the enhanced process maturity model and assess its business processes. The ideal resulting outcome is an Engineering supplement which supplies new criteria and specifications to the existing model and acts to imbed HRO principles within each business process through the assessments.

To develop the enhanced process maturity for Engineering, the project develops strategies to close the gaps seen in the other three areas (efficiency & effectiveness, reliability, and safety & risk mitigation) of the desired state. The project's hypothesis was that studying HRO concepts and then imbedding them within the process maturity model would close the gaps seen in the areas of reliability and safety & risk mitigation. A gap analysis of each criteria in the existing process maturity model vs. HRO principles shows where the model effectively develops reliability capabilities and where it is deficient. To close the gaps in the area of efficiency & effectiveness, the project looks to undertake a benchmarking effort to learn from the strategies and tools employed in the maintenance organization through its maintenance excellence work. A visual representation for this strategy is shown in Figure 8. below.

Figure 8. Strategy to Develop Enhanced Process Maturity Model

4.2 Data

4.2.1 HRO vs. QMS Maturity Model criteria

The QMS Process Maturity Model is broken into three categories and 10 sub-categories. Each category and sub-category has criteria that define what a process should look like for the various maturity levels.

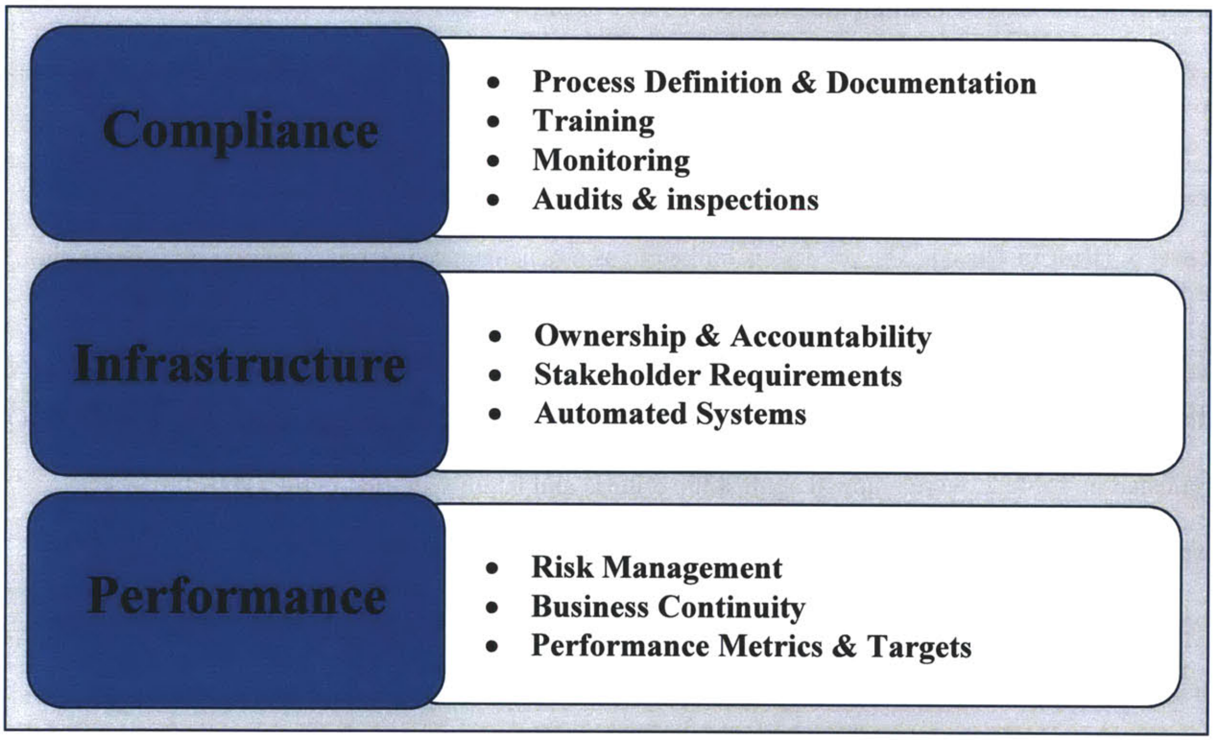

Figure 9. QMS Process Maturity Model Categories

There are five distinct levels of maturity across the process improvement platform. At each level there is a stepwise improvement for the process relative to the previous based on the criteria that must be met. As the process matures, it evolves to become more mature through better metrics, documentation, training, etc. The levels are defined as follows:

Level 1 (Initial)- There is no defined, documented process for the work stream .

Level 2 (Developing)- The process is ad-hoc and performed differently across multiple uses. Some documentation exists detailing the process.

Level 3 (Stable)- The process is fully defined, implemented, effective and repeatable across multiple uses and applications.

Level 4 (Continually Improving)- The process is continually reviewed to identify and implement improvement measures that result in better performance and results.

Level 5. (Best in Class)- The process is looked to as a benchmarked standard among its peers in the industry.

A gap analysis of the existing criteria vs. HRO principles shows where the existing model was effectively assessing the reliability of a process and where it had room for improvement. Each of the HRO criteria listed in Table 2. were mapped against the criteria and intent specified in the QMS Process Maturity Model. The criteria in the maturity model were tested to see if they either fully or partially supported the HRO content. The analysis showed that the model was very strong in assessing processes for their built in ability to have documentation and adapt as the environment around it changes. Gaps in coverage of HRO principles in the model were found to exist in encouraging the reporting of errors, learning from near system failures, and decision making strategies. See Appendix B for this analysis.

4.2.2 Benchmarking

A key aspect of this project was to learn from Engineering's top performing groups and apply working practices and principles to the broader organization. One such organization that the project focused on was the Maintenance Excellence group. The group had deployed a tool to assess the maintenance practices of the broader maintenance organization, and seen favorable results in the advancement of best practices across the manufacturing sites. Maintenance was seeing better results in their metrics that measured the efficiency and effectiveness of their operations. The project wanted to learn from the equipment maintenance assessment tool (EMAT) and better understand why it had been effective in advancing maintenance efforts and also see what, if any, principles could be extracted and applied to the process maturity model. Any good assessment or questionnaire is designed at its core to extract the right information and bring to light areas for praise and areas for concern. In effort to better understand how the equipment maintenance assessment tool did this in application, a rigorous analysis was performed.

The EMAT is composed of several sections which are designed to assess maintenance practices. There are a total of four sections that include: Work Planning & Control, Productivity & Effectiveness Process, Equipment Reliability, and Parts Inventory Management. While it was readily apparent that many of the criteria specified in the EMAT were specific to maintenance, the project knew that many of the concepts could still be applied more broadly to the process maturity model to make it more robust.

To do this, the EMAT criteria were analyzed and bucketed into groupings of characteristics that they would support or elicit. A total of 10 characteristics, that encompassed all of the criteria, were observed including:

1. **Safety/Risk Mitigation**
2. **Efficiency & Effectiveness/Automation**
3. **Compliance**
4. **Reliability**
5. **Documentation**
6. **Communication/Knowledge Sharing**
7. **Organization/Structure/Alignment**
8. **Accountability**
9. **Revisit/Review/Assess as things change**
10. **Planning**

The detailed analysis for this effort can be found in Appendix A., but in brief summary the EMAT was found to be extremely strong in promoting Efficiency & Effectiveness/Automation, Documentation, and Organization/Structure/Alignment through its criteria.

4.2.3 Engineering Processes

The Compliance and Risk (CR) group within Engineering spearheaded an effort to identify all key business processes in the organization. They began the effort by surveying all Engineering tasks through a combination of talking to employees and capturing the work being done. Once into a database, the group cataloged all related tasks into right-sized processes. Not every task was Engineering-specific though, so the group developed a structured approach to identify Engineering-owned processes by mapping tasks against the asset lifecycle and then developing VSM's. Once complete, a total of 12 processes across several categories were identified and documented with 57 sub-processes. The twelve processes were as follows:

Engineering Processes	# sub Processes Identified
Facility Operations	4
Facility & Equipment Maintenance	8
Facility Services	3
Lab Equipment Maintenance	1
Engineering Quality Systems	5
Facility Capital Re-investment	3
Engineering Project Delivery	10
Lease Lifecycle Mgmt	7
Strategic Portfolio/ Master Planning	6
Engineering Strategic Governance	2
Occupancy Planning (Individual Staff Level)	3
Integrated Facilities Management	5

Figure 10. Defined Engineering Processes

4.3 Discussion

Knowing now where Engineering was effectively driving change, the project began developing new criteria that could be applicable to the engineering supplement in the process maturity model. A total of 52 criteria were developed to target a number of areas including continuous improvement, metrics & monitoring, and customer alignment. These 52 criteria were then compared against the criteria in the maturity model to determine what was already covered and what needed to be supplemented. A review team composed of stakeholders was formed to provide input on this effort. The team worked to confirm if the newly developed criteria were applicable, and if so, where they would be placed in the maturity model and in what function. Once agreed upon by all parties involved, this effort paved the way for the creation of the enhanced process maturity model with engineering supplement.

4.3.1 Development of the Engineering Supplement

With HRO gaps identified and criteria developed based on the benchmarking efforts with the Maintenance Excellence group's EMAT, the process for developing the enhanced process maturity model with engineering supplement began. The maturity model is made up of criteria that must be met to achieve a certain level of maturity, and then also specifying intent which helps the assessors and business process owners better understand if the process being assess meets the criteria. To best encourage adoption and sustainment of the engineering supplement, every effort was made to supplement existing criteria with Engineering-specific intent based on the HRO and benchmarking work. In areas where this wasn't possible, new criteria were incorporated into the model. These new criteria resulted in the development of an entirely new sub-category of the model entitled "Efficiency & Effectiveness" targeted at measuring performance of the process. The new sub-category tests the process to see whether or not work is produced with the appropriate level of effort and as it was intended to be done. Key new criteria include documented process execution steps with corresponding stakeholders in a workflow map or VSM, decision making authority, and metrics to track continuous improvement implementations vs. their targeted schedule.

4.3.2 Pilot

Through an effort to gain real-time feedback, the newly enhanced process maturity model with engineering supplement was used to assess each of the defined business processes for the Engineering organization. This allowed the organization to gain a better understanding of the maturity levels for its processes and create a plan for moving forward with its maturity efforts. A member of the Compliance & Risk team conducted the process assessments along with the business process owners for each of the sub-processes that had been identified for assessment. A maturity assessment score for each sub-process was generated based on where the process matched up with the criteria for each level.

A detailed breakdown for the maturity assessment score of each process is provided in Figure 11. below.

DISGUISED DATA

Engineering Processes	AVG Maturity of sub Processes
Facility Operations	4.0
Facility & Equipment Maintenance	2.5
Facility Services	3.0
Lab Equipment Maintenance	2.0
Engineering Quality Systems	1.5
Facility Capital Re-Investment	3.0
Engineering Project Delivery	1.5
Lease Lifecycle Mgmt	2.0
Strategic Portfolio/ Master Planning	2.5
Engineering Strategic Governance	2.0
Occupancy Planning (Individual Staff Level)	2.0
Integrated Facilities Management	2.5

Figure 11. Average Process Maturity Score for Engineering Processes

Furthermore, a regression analysis of the results of the assessment for each category of the process maturity model is provided in Figure 12. The results here show that for each of the three categories of compliance, infrastructure, and performance, the processes are approximately at the same level of maturity.

DISGUISED DATA

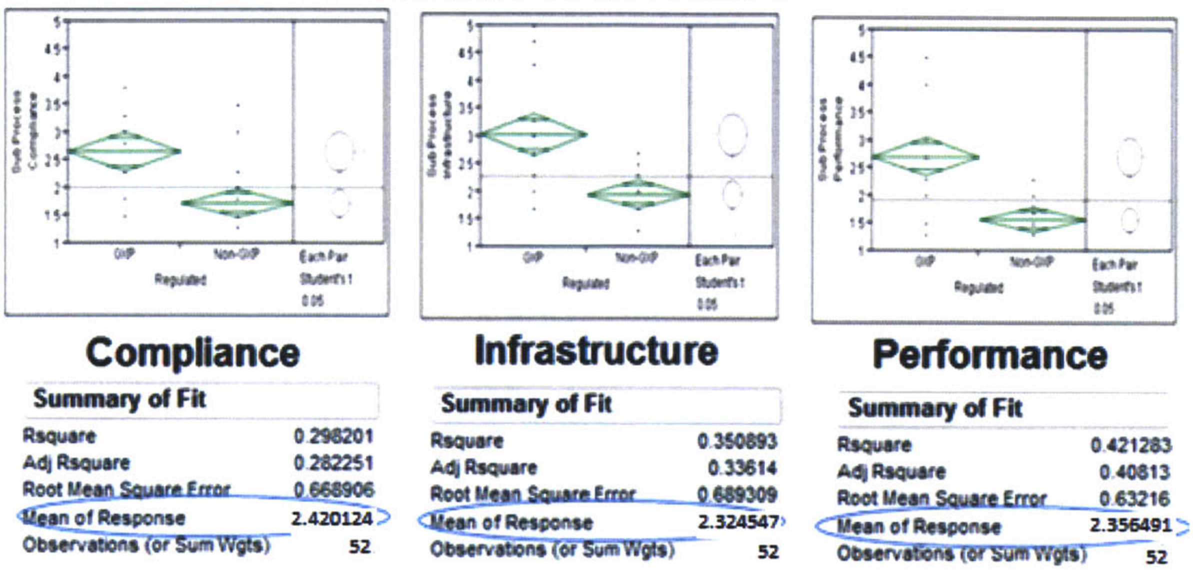

Figure 12. Regression Analysis for Categories of Process Maturity Model

The pilot not only was beneficial by establishing a baseline for the processes in the Engineering organization, but it also provides real-time feedback for where the engineering supplement is effective and where it needed to still be improved. The bulk of the additional criteria was added in the new sub-category of the model entitled “Efficiency & Effectiveness” and was targeted at ensuring the performance and the outcomes of the process were as they were intended to be. The feedback from the pilot, though, showed that the model was still not fully assessing how similarly a process was being performed across the network at different sites, how well the process and its business process owner understood its network interdependencies upstream and downstream with interconnected processes, and how well improvement efforts were shared and implemented across the network at different sites. As a result of the feedback, a new sub-category of Performance entitled “Network Effectiveness” was developed that better assesses these important aspects.

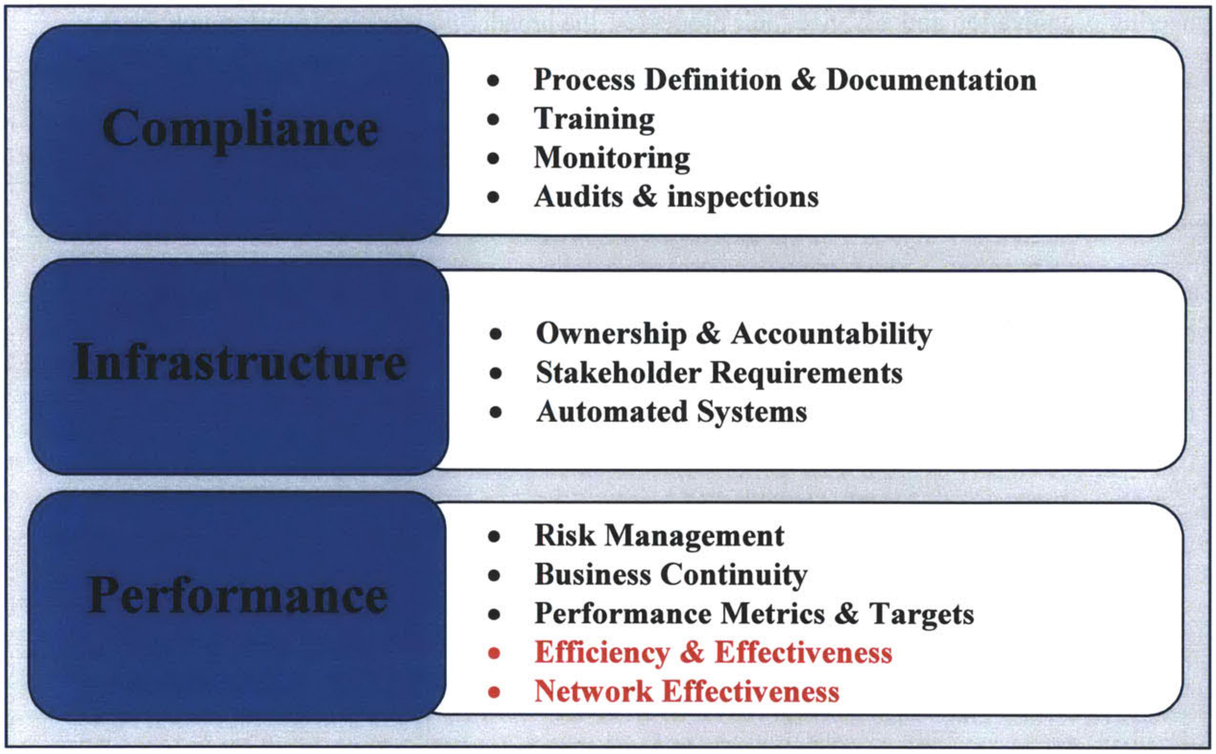

Figure 13. Enhanced Process Maturity Model Categories

4.4 Conclusion and Recommendations

With the baseline assessment of the processes in the Engineering organization now complete and the process maturity model finalized, the organization will begin its process improvement effort using the enhanced model as the guide for the improvements. Each business process owner will look to the model to define targets and implementation efforts. To reach the next level of maturity, each process will need to meet the stated criteria in the maturity model. Moving forward, the processes will be ranked in order of criticality to determine where to focus efforts earlier in the improvement cycle. By first advancing all processes to Level 3, the organization will be able to have a more focused approach and better sustainment of the process improvement efforts.

Another goal of the project's efforts with the process maturity model work is to socialize the work to other groups within Operations. We believe that defining processes and advancing their maturity can be a central platform to imbed HRO concepts throughout an organization. Since Engineering has so many touchpoints throughout Operations and the rest of Amgen, if other groups are able to mirror the efforts of the Engineering organization and advance their processes, the broader network will work much more cohesively towards common goals and with greater network awareness. This in turn will result in more efficient and effective operations for all parties involved. The Supply Chain group in Operations is one example of a group that is learning from this project's efforts and adapting the process maturity model to fit their needs and drive towards more reliable work results and outcomes.

5 Work Stream C- Maintenance Excellence

5.1 Approach

Focusing specifically in the maintain portion of the asset lifecycle, the projects seeks to continue to implement strategies that align with the concept of high reliability organization. Here, the goal is to help the maintenance organization achieve its desired goal of world class maintenance practices. A gap was identified in the cohesiveness of the many efforts currently undertaken by the maintenance organization. In an effort to better understand how the various efforts fit together and drive towards a common goal of maintenance excellence, the project develops a maintenance excellence roadmap.

Maintenance excellence is the desired state of operation for any maintenance organization. To achieve a state of maintenance excellence, an organization and its maintenance program must have full comprehension of an asset's needs and utilization within the day-to-day operations. At Amgen, maintenance excellence refers to a state of best-in-class maintenance whereby the organization effectively utilizes tools and processes as enablers to ensure reliability, efficiency, effectiveness, safety, and compliance in its maintenance program. Amgen maintenance views reliability, efficiency, effectiveness, safety, and compliance as the pillars for a strong maintenance network, with enablers acting as the foundation of support for each of the five pillars.

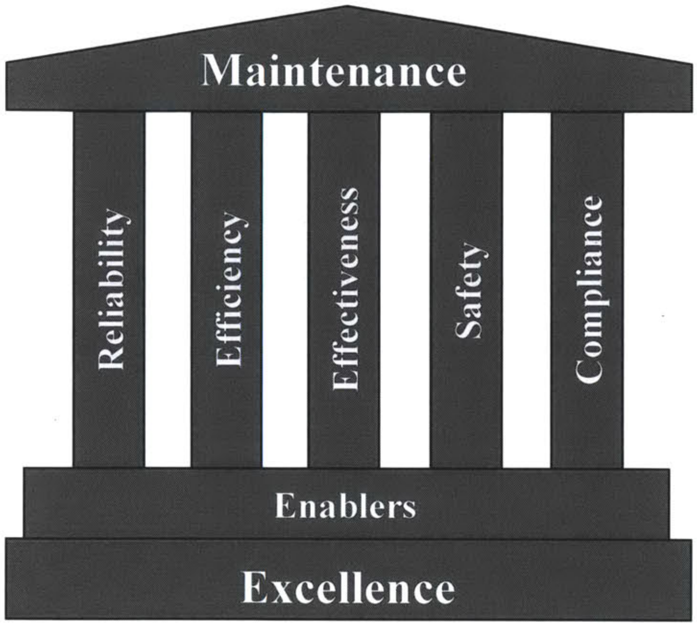

Figure 14. Amgen Maintenance Excellence

With this definition in mind, the Maintenance Excellence Roadmap defines what a state of maintenance excellence looks like at Amgen, and provides detail for each of the elements that make up the core pillars. The goal of the Maintenance Excellence Roadmap is to drive awareness within Amgen to the strategies put in place by the maintenance organization, and to ultimately provide a framework to identify missing elements from the current maintenance management program that are needed to help the organization achieve a state of maintenance excellence.

To map current efforts to Amgen's maintenance excellence framework, the project looks to define each of the five pillars in terms of maintenance and then establish expected best maintenance practices to fit within each of the pillars. This is done by looking at external benchmarking, maintenance publications, and studying the progression of maintenance maturity at Amgen to understand why certain decisions were made and with what intended results. Next, the project will evaluate all tools, processes, and efforts that exist –or are underway– in the maintenance organization and map them against each of the pillars.

In an effort to learn how a maintenance organization reacts to changes in operations, a case study of the implementation of a new technology in the utilities and offsites at Amgen is being performed. The technology implementation selected for the case study is the implementation of a new cooling tower cell that services cooling water to surrounding buildings on Amgen's Thousand Oaks site. The maintenance staff for the facility must take great precautions to be prepared for the technology change over to avoid business impacts. In the case study, an overview of cooling towers and their application will be provided. The case will then progress to take an in-depth look at how the maintenance organization prepares for the change-over in technology.

From this mapping process and the data garnered from the case study, a better understanding of what is further needed will evolve and drive new efforts.

5.2 Data

The data collection portion of the maintenance excellence roadmap began by defining each of the five pillars and their foundation. The definitions are as follows:

1. **Reliability**- The probability that an asset or process will perform its intended function without failure over its intended operating or use time[18].
2. **Efficiency**- Efficiency is the relationship between the result achieved and the resources used[19].
3. **Effectiveness**- Effectiveness is a measure of the extent to which planned activities are realized and planned results achieved[20].
4. **Safety**- Safety is a condition of being free of an environment that causes hurt, injury, or loss. Safety standards in both manufacturing and operations continue to rise sharply[21].
5. **Compliance**- Compliance is the foundation established by an organization to ensure that personnel are aware of, and take steps to comply with relevant laws and regulations[22].
6. **Enablers**- Enablers are the supportive systems, procedures, activities and resources that enable an organization to operate its maintenance program efficiently and effectively.

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[18] (British Standards Institute, 2008)
[19] (British Standards Institute, 2008)
[20] (British Standards Institute, 2008)
[21] (British Standards Institute, 2008)
[22] (British Standards Institute, 2008)

With the definitions in place, the project next mapped any tools, processes, and systems to the pillars. These included both those that were already in place or being put in place at Amgen, and those that are not but have been identified as future implementation ideas. This effort was facilitated by conducting interviews with members of the maintenance organization and the Maintenance Excellence team, along with consulting industry publications for benchmarking ideas. A number of elements were identified through this process, and a summary table of these elements is provided in Table 12. below:

Reliability
Predictive Maintenance Equipment Performance Monitoring and Betterment Failure Trending Root Cause Analysis (RCA) Failure Modes, Effects, and Criticality Analysis (FMECA) Lean Maintenance Needs Assessment (LMNA) Maintenance Program Performance Monitoring Operator Asset Care (OAC)
Efficiency
Work Planning and Scheduling Cost Management
Effectiveness
Mean Time between Failures (MTBF) Mean Time to Repair (MTTR) Mean Time between Maintenance (MTBM) Nonconformance (NC) Tracking Amis Maintenance Assessment Tool
Safety
Maintenance Risk Assessment Lockout/Tagout (LOTO) Critical Control Devices
Compliance
Audits
Enablers
Maximo BOBJ (Business Objects) CiM Planning & Scheduling

Table 11. Maintenance Excellence Summary Table of Elements

5.2.1 Cooling Tower Case Study

The cooling tower case study takes an in-depth look at a new technology implementation. This provides a platform to evaluate the behaviors of the maintenance organization and utilize the resulting analysis as an input into the maintenance excellence roadmap.

A cooling tower is a device that takes waste heat from a process and rejects it to the atmosphere. Industrial cooling towers have application in many industries including chemical manufacturing, oil refining, power generation, and in this case campus facilities cooling. Cooling towers serve an extremely important function in operating a facility or site, so their operation and maintenance is imperative. While they can be rather expansive in size, cooling towers represent a relatively cheap and easy method of heat removal.

Figure 15. Counterflow Cooling Tower[23]

In an industrial setting, cooling towers are connected to the users on a site via a closed loop system. The process is one that operates continuously by removing waste heat from the buildings and dispelling it to the atmosphere. The tower sends cooling fluid (typically water) to the plant chillers and

[23] (SPX, n.d.)

then receives the reject heat back in the form of hot water. Evaporative cooling via air intake at the cooling tower rejects the heat to the atmosphere, and a supply of cool make-up water is fed to the cooling tower to replace the water lost to evaporation. Please see Figure 16. below for a diagram of the cooling process.

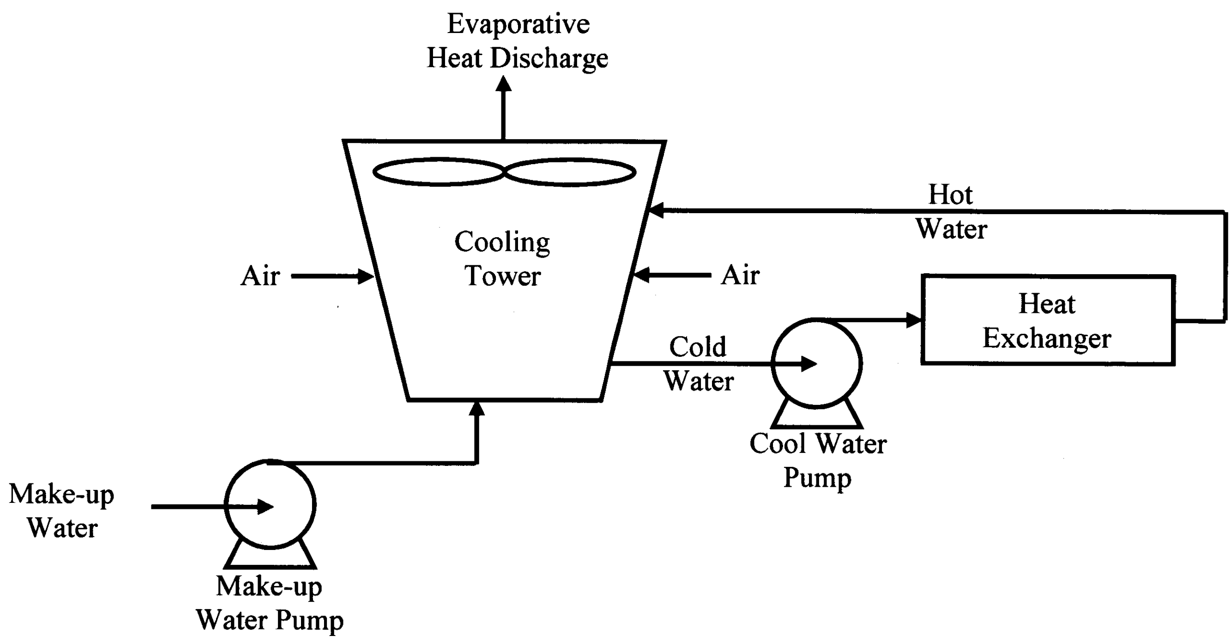

Figure 16. Cooling Tower Process

There are two types of industrial cooling towers, the natural draft tower and the mechanical draft tower. Natural draft towers are typically relegated to very large flow rates and as such are usually seen in power production facilities. This study will focus on the mechanical draft tower since it is the type being installed at Amgen Thousand Oaks. The mechanical draft cooling tower uses fan blades to induce air flow into the cooling tower. Air enters through the cooling tower cells in the "fill" and is pulled up through hot water that has entered the cooling tower. A transfer of heat occurs in the cooling tower cell and warm moist air exits into the atmosphere. The fill helps to disperse the water over more surface area in order to provide maximum air-to-water contact which in turn leads to greater heat transfer from the closed-loop system to the atmosphere. In addition to the fill, there are several other important components of the cooling tower design that must be discussed:

Fan- the fan acts to pull air through the hot water –in order to induce maximum heat transfer– to the top of the cooling tower cell where it exits to the atmosphere. These typically run on a variable frequency drive (VFD) which allows the speed of the fan to be adjusted based on atmospheric conditions and to match the desired flow rate through the cooling water loop.

Cold Water Basin- the cold water basin stores cold water that is used in the circulation of cooling water to the heat exchanger. Return water from the heat exchangers collects back to the basin if not lost to the atmosphere, as does the make-up water supply which is fed to the basin to from an external source. The basin is typically located directly under the cooling tower and is made of concrete.

Drift Eliminators- Drift eliminators act to remove moisture from the warm air that is exiting through the top of the cooling tower cell as a result of wind or evaporation. The drift eliminators reduce operating costs in the form of the make-up water that must be supplied to replace the moisture that has been lost to the atmosphere.

Spray nozzles- The spray nozzles act to disperse the hot return water over the fill in order to maximize surface-to-surface contact and heat removal.

Of the mechanical draft cooling towers, the two methods of heat exchange are the crossflow design and the counterflow design. In the crossflow design, the hot water return flows over the top of the cooling tower cell while the air enters through the sides of the cooling tower cell fill and is induced to the top by the fan. The air in this configuration flows perpendicular to the flow of the water coming over the top of the cooling tower cell. In the counterflow design, the hot water again flows over the top of the cooling tower cell, but here the air enters at the bottom of the cell and is induced to the top by the fan. The air in this configuration flows parallel against the flow of the water coming over the top of the cooling tower cell. Figure 17. below provides a visual representation of how the crossflow and counterflow cooling tower designs differ.

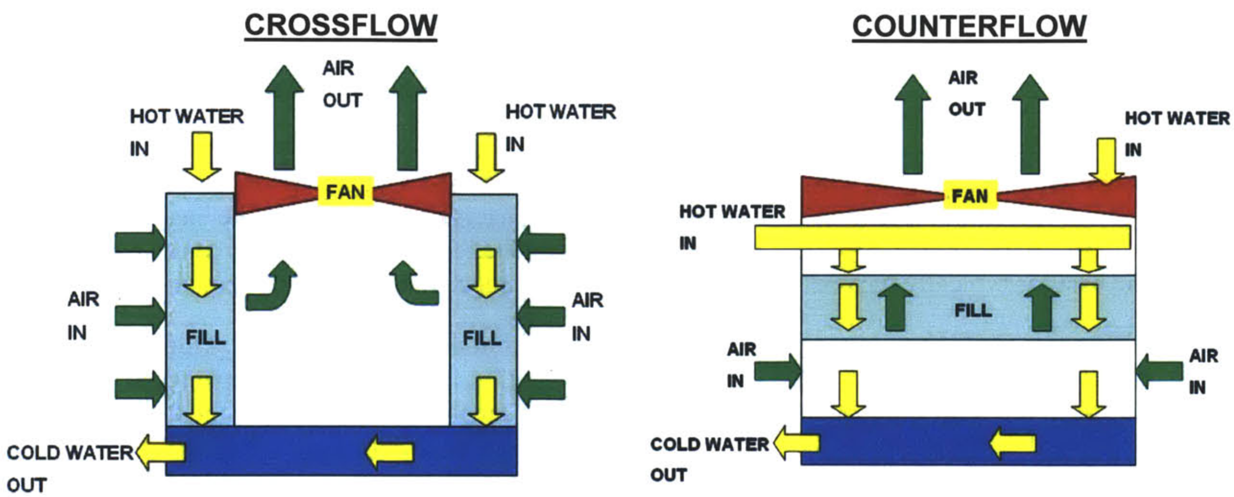

Figure 17. Crossflow and Counterflow Cooling Towers[24]

Cooling tower performance is largely dependent upon the environment in which it operates. Variables such as temperature and relative humidity determine the day-to-day performance of the cooling tower, and dictate the operating and maintenance schedules for the equipment that the cooling water system interacts with. These important variables are reflected in the ambient wet-bulb temperature at the location of the cooling tower, which is by far the biggest determinant in the sizing and design of cooling towers for a given cooling water circulation rate. The ambient wet-bulb temperature is the lowest temperature that can be obtained by evaporating water into air[25]. This is an important measure because it essentially dictates how much additional water vapor from the cooling tower that the ambient air can hold at current conditions. The drier the ambient air is, the greater the evaporation that can take place from a wetted surface or body which in turn leads to a lower possible wet-bulb temperature. Because moisture cools air when introduced, the wet-bulb temperature will always be lower than the dry-bulb temperature (the temperature measured by a thermometer) except in instances where the ambient air has 100% relative humidity. In this case the two temperature measurements would be the same.

[24] (Mechguru, n.d.)
[25] (Oklahoma Mesonet, n.d.)

When designing a cooling tower application, the highest reported wet-bulb temperature will be used for the region in which it is to be located. The wet-bulb temperature dictates the expected temperature of the cooled circulating water in the system. The difference between the ambient wet-bulb temperature and the outlet cold water temperature is called the "approach" and is typically specified for anywhere between 5-10° F. Cooling tower manufacturers are usually reluctant to guarantee the performance on a tower that has an approach below 5° F. The difference between the outlet cold water temperature and the inlet hot water temperature is called the "range" of the cooling tower. While this value is entirely dependent upon the heat load from the plant chillers and the amount of cooling water in circulation, the range of the cooling tower operation is typically designed for between 10-20° F. Reference Figure 18. below for a visual representation of the approach and range relative to the ambient wet-bulb temperature.

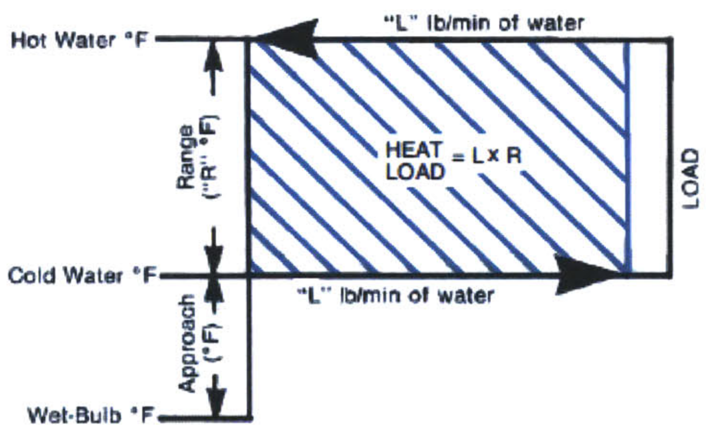

Figure 18. Cooling Tower Design Performance[26]

The heat load to be absorbed and then released to the atmosphere as waste heat is simply a sum of all design heat exchanger loads in the system. This sum would be the maximum amount of reject heat that is desired to be removed from the system at any moment in time, so the cooling water system is designed based on this value. Typically, companies needing to implement a cooling tower will work with the cooling tower supplier to decide the range and corresponding size for a cooling tower operation. Because

[26] (SPX, n.d.)

the cooling water rate and cooling tower range are inversely proportional, the company must weigh the economics vs. the operability of the design. When specifying a range for a cooling tower, the amount of circulating water (in gpm) needed to remove the heat from the manufacturing process can be calculated as follows:

$$\dot{C} = \frac{\dot{Q}}{R} \times {}^{3}/_{25}$$

Where,

$\dot{C}$ = cooling water circulation rate (gpm)
$\dot{Q}$ = heat load (Btu/min)
R = range (°F)
${}^{3}/_{25}$ = gal/lb of water

Figure 19. Cooling Water Circulation Rate Formula[27]

The cooling water circulation rate varies with the heat load being presented to the system. When the heat load drops the circulation rate can be throttled back, and when the heat load increases the circulation rate can be increased.

While the cooling water basin provides a buffer in terms of water storage, it is important to have a make-up water supply ready and available at all times. Water is lost from the cooling water system in three ways: evaporation, drift, and blowdown. Evaporation losses are the losses in water as a result of the hot moist air leaving the cooling tower. Evaporation losses represent a significant portion of the overall water losses. Evaporation losses can be calculated as follows:

[27] (SPX, n.d.)

$$\dot{E} = \frac{\dot{C} \times R \times c_p}{H_v}$$

Where,

$\dot{E}$ = cooling water evaporation rate (gpm)
$\dot{C}$ = cooling water circulation rate (gpm)
R = range (°F)
c_p = specific heat of water = 1 Btu/lb°F
H_v = latent heat of vaporization of water = 970 Btu/lb

Figure 20. Cooling Water Evaporation Rate Formula

Drift losses are those losses typically attributable to wind, and are relatively small in comparison to the evaporation and blowdown losses. Drift losses are typically estimated as a percentage of the cooling water circulation rate. For cooling towers with a drift eliminator installed, the drift losses can be estimated to represent a total of 0.01% of the overall cooling water circulation rate. Cooling towers without drift eliminators installed will typically see drift losses on the order of 10 times larger than those that have them installed.

Water naturally has dissolved impurities like salts and metals that have been picked up from contact with soil and earth. These are referred to as total dissolved solids (TDS). When the circulating cooling water undergoes evaporation at the cooling tower, impurities remain behind in the cooling system rather than leaving with the water vapor into the atmosphere. With each pass of the circulating water, these dissolved solids become increasingly concentrated in the system. This can lead to deposits or scaling on the cooling tower and piping that negatively affect the integrity of the structure. To prevent the deposits from occurring, water is continually bled of from the cooling water circulation and replaced with the unconcentrated make-up water (chemical treating is also used). The total number of cycles that the cooling water makes before being bled off is referred to as the cycles of concentration. The cycles of concentration is simply the ratio of chlorides in the circulating cooling water to chlorides in the make-up water, and can vary greatly based on the quality of the make-up water and the chemical treatment program in place.

Blowdown losses are water losses that result from the increasing concentration of total dissolved solids (TDS) in the circulating cooling water and their subsequent removal. The blowdown required for a cooling water system can be estimated as follows if the desired cooling tower operation cycles of concentration is known:

$$\dot{B} = \frac{\dot{E}}{Cycles - 1} - \dot{D}$$

Where,

$\dot{B}$ = cooling water blowdown rate (gpm)
$\dot{E}$ = cooling water evaporation rate (gpm)
$\dot{D}$ = cooling water drift rate (gpm)
$Cycles$ = cycles of concentration

Figure 21. Cooling Water Blowdown Rate Formula

5.2.1.1 Amgen Application

Amgen Thousand Oaks needs increased cooling water capacity to match increased demand of chilled water at sites around the campus. This increased demand has pushed the current cooling system to its design limits, and limited its ability to supply full cooling to some buildings on high ambient temperature days. During these periods, low cooling water supply flow rates along with high cooling water return temperatures have been reported. As a result of these issues, the cooling tower cells at the site are being replaced in order to increase the maximum cooling water load that can be supplied to the surrounding facilities. The new cooling tower cells will extend the useful life of the cooling water system by another 25 years and have built in design margin to allow for continued growth and expansion in the future where necessary. The goal of the replacement project is to supply cooling water to the operation at 85 °F and receive it back at 95°F (a 10 °F range) during the most extreme atmospheric conditions. The design that has been selected is a counterflow mechanical draft cooling tower cell. Of the eight existing cells currently at the facility, four will be removed and replaced by the new cooling tower cell units. The cells have a design capacity of over 10,000 gpm and require increased cooling water storage capacity over the existing cold water basin. In order to reduce the impact on surrounding operations, the replacement of the cooling tower cells is scheduled to occur during the winter months. This will presumably be when the temperatures in the area are at their lowest, which will allow for increased efficiency of the remaining cooling tower cells in operation and lower cooling water circulation rate requirements.

The changeover in technology will nonetheless affect the operation of the plant being supplied cooling water currently by the cooling tower. Site Operations staff must work to prepare their plant chillers for the shutdown and acquire make-up cooling water capacity from other sources where needed. Maintenance staff will be involved at the earliest stages in the changeover process to help streamline the technology implementation and identify potential problem areas. Both during the planning stages and then again during the start-up and commissioning of the cells, the maintenance team will work to ensure that peripheral equipment requiring cooling water will not be negatively affected structurally. A study of the work done by the maintenance staff during the cooling tower technology implementation will show the extent of challenges faced and the ideas that must be considered in helping to ensure HRO outcomes are achieved.

5.3 Discussion

The ability and level of preparedness of the maintenance organization for an operational transition such as the cooling tower implementation is directly reflective of the maturity of its processes, tools, and working practices. The maintenance organization should play a key role both during the initial plan/design phase and again during the operate/maintain phase of the cooling tower asset.

To establish the scope of the implementation during the design phase, the maintenance staff will become involved with operations to determine the ideal operating parameters for the cooling tower cells given the criticality of the process and economic limitations. For something like a cooling tower, there will typically be several cooling tower cells that are identical in nature. If the facilities it is servicing are deemed highly critical, the decision may be made to purchase extra cooling water capacity in the form of additional cells. This allows for the cooling water system to have cells sitting idle should there be a need to take a cell offline for maintenance or should a breakdown in equipment occur.

If equipment spares exist, the maintenance team will work to establish sparing philosophy and maintenance programs to ensure longevity in the cooling tower operating life. Sparing philosophy refers to how the different cooling tower cells and other associated equipment such as circulating water pumps will be utilized over the course of the operation to equalize wear, bridge unexpected shutdowns, and plan for maintenance servicing. In Amgen's case, if it has eight cooling tower cells available, only six or seven may be operational at any one time. This allows for the remaining one or two cells to sit idle in preparation for other cells to go offline. The maintenance team will work with the operating staff to normalize the usage of the cooling tower cells by distributing their online operating time equally.

Another important step that the maintenance team is involved with is the startup and commissioning of the equipment. This is the period of time after installation where all parties, including the equipment supplier, work to ensure that each piece of equipment is installed and working correctly, operator training occurs, and operations and maintenance manuals are implemented. In developing a maintenance program, the maintenance team will consult with technical experts at the equipment supplier and rely on past experiences with similar equipment or assets to ensure the best program is developed. For each unit or piece of equipment, a maintenance checklist will be developed that details when and how specific maintenance tasks are to be performed. For a unit like the cooling water system, the different pieces of equipment may be identified as follows:

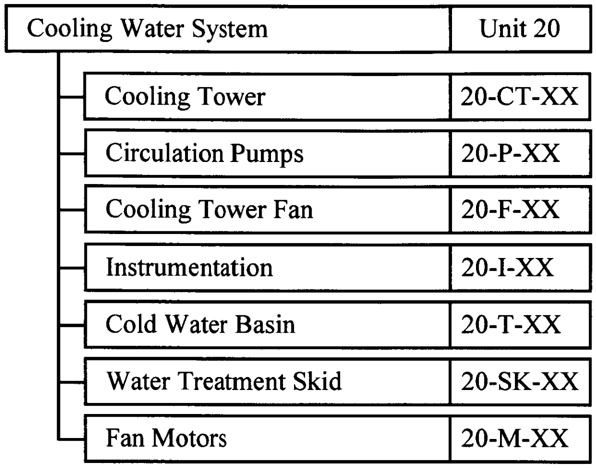

Figure 22. Example Cooling Water System Equipment List

For each piece of equipment specified in the unit, a maintenance checklist will be developed detailing the tasks to be completed for proper maintenance and upkeep. When the new cooling tower cells are installed, this checklist will be used by the maintenance team to facilitate scheduled maintenance walkthroughs. An example checklist for something like the centrifugal pumps may look like the following:

Equipment	Maintenance Requirement	Maintenance Type
20-P-XX Circulation Pumps	1. Check pump housing and clean fan motors of surrounding debris 2. Inspect for leaks of pumping fluid in and around housing 3. Inspect pump seals for lubrication leaks 4. Check vibration trends to ensure pump motor is in alignment	Scheduled Maintenance

Table 12. Example Equipment Maintenance Checklist

By establishing the run parameters of each cell, the maintenance team is able to incorporate detailed maintenance plans and schedules for the equipment months in advance without threatening the ability to run the process as it was intended. This proactive approach will reduce the number of instances where unexpected shutdowns will occur and will cultivate greater efficiencies in cost control as a result of reduced spending on unexpected maintenance. Utilizing the basic six step process to maintenance planning and scheduling (identify, plan, schedule, perform, follow-up on, and evaluate results of work) a detailed work flow will be created that connects all interdependent processes and personnel. The team will utilize the CiM planning and scheduling tool within Maximo to collate work schedules for the various assets and personnel in order to optimize labor availability and utilization in the execution of maintenance programs and thus minimizing resource allocation conflicts.

With the case study performed and the elements identified for maintenance excellence, the roadmap was developed. An overview of the information that went in to the roadmap is provided below.

5.3.1 Maintenance Excellence Roadmap

5.3.1.1 Reliability

Reliability is the probability that an asset or process will perform its intended function without failure over its intended operating or use time[28]. It is central to maintaining safe and productive operations. The goal of any maintenance program is to ensure that the assets under management continue to perform as their users intended them to do. Thus, maintenance program elements such as predictive maintenance, equipment performance monitoring and betterment, maintenance program performance monitoring, and operator asset care are central to ensuring reliable outcomes and performance.

5.3.1.1.1 Predictive Maintenance

A comprehensive predictive maintenance program helps the maintenance organization to keep assets performing as intended by identifying potential sources of failure. The predictive maintenance program consists of the asset to be monitored, the software and hardware used to do the monitoring, and the process and data used to identify potential points of failure and drive corrective actions[29]. Examples of predictive maintenance techniques include vibration analysis, ultrasound analysis, infrared analysis, and oil analysis.

The program should have its data collection methods integrated directly into the CMMS (from this point forward referred to as Maximo) in order to communicate comprehensive reports. The reports should detail potential failure corrections with targeted completion dates.

5.3.1.1.2 Equipment Performance Monitoring and Betterment

Implementing effective equipment performance monitoring is important to ensure reliability in operations. It allows the maintenance organization to continuously improve upon maintenance strategies while avoiding future/repetitive failures. Furthermore, equipment performance monitoring helps to

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[28] (British Standards Institute, 2008)
[29] (Wireman, 2004)

eliminate non-value added maintenance activities. Examples of techniques include failure trending, root cause analyses, failure modes, effects and criticality analyses, and lean maintenance needs assessments.

Failure Trending

Failure trending allows the maintenance organization to create a continuous collection, examination, review, and classification cycle of failures to determine trends that can lead to an RCA, FMECA, or LMNA analysis. Reports for failure trending data should be generated on a monthly basis through Maiximo and should drive continuous improvement recommendations.

Root Cause Analysis (RCA)

Root cause analyses are performed as the result of a failure trend that has been identified or a catastrophic failure that has occurred. An RCA should help identify root causes of reported failures, and facilitate effective corrective and preventive actions that will prevent failure reoccurrence. Methodologies of analysis could include five why's, fault tree analysis, fishbone, and pareto analysis. RCAs performed should be recorded in Maximo for future reference.

Failure Modes, Effects and Criticality Analysis (FMECA)

The failure modes, effects, and criticality analysis helps the maintenance organization to identify what must be done in order to ensure that assets and systems continue to operate as their users intended them to. FMECAs are performed as the result of a failure trend that has been identified. FMECAs should follow a standard process for analysis, reporting, and recommendations. Once completed, the FMECA should be documented and recorded for future reference.

A criticality assessment is performed to determine the effect that a loss of function of a system/subsystem would have on personnel safety, the environment, product quality, and production. This approach provides a risk based evaluative tool to the maintenance organization to better understand risk that is acceptable and risk that is not. To effectively perform a criticality assessment, all relevant risk factors to the organization must be decided upon.

Lean Maintenance Needs Assessment (LMNA)

The lean maintenance needs assessment is used to implement maintenance requirements developed by the engineering technical authority (ETA), eliminate non-value added maintenance activities, and ensure that the sub-systems under review are in compliance with standards and protocols. LMNAs should follow a standard process for analysis, reporting, and recommendations, and should be documented upon completion.

5.3.1.1.3 Maintenance Program Performance Monitoring

The objective of performance monitoring of the maintenance program is to review the actual performance of key performance indicators to identify potential roadblocks in achieving established goals. Evaluating the KPIs allows the organization to determine if they reflect actual performance in terms of quality, safety, and business compliance. Examples of maintenance program performance monitoring include metric control programs, maintenance costs, PdM metrics, and equipment performance metrics.

5.3.1.1.4 Operator Asset Care (OAC)

An Operator Asset Care program provides a platform for asset monitoring and inspection by those personnel directly involved in the asset's operation. A typical OAC program involves daily unit walkthroughs and inspection by operations personnel, and then identification and reporting of potential risks where found. With regular attention and application of OAC, many issues can be avoided and continuous improvement ideas implemented, resulting in a sometimes drastic reduction in maintenance costs and equipment downtime.

5.3.1.2 Efficiency

Efficiency is the relationship between the result achieved and the resources used[30]. Efficiency in maintenance operations is enhanced greatly through focused work planning and scheduling, and detailed

[30] (British Standards Institute, 2008)

cost management programs. Each contributes to drive efficiency by focusing efforts on proactive work and continuous improvement rather than firefighting activities.

5.3.1.2.1 Work Planning and Scheduling

Work planning and scheduling is a process used to allocate resources in order to optimize productivity and minimize work that wastes resources. Effective work planning and scheduling leads to a more efficient maintenance workforce and generates tangible results in the areas of cost control, continuous improvement, and productivity monitoring.

Maximo should largely drive planning and scheduling, with its stored data dictating future work. Maximo acts as central repository for important inputs to planning and scheduling and should help facilitate accurate time and cost estimates, effective planning of tasks, and work order turnarounds. An integrated planning and scheduling platform between maintenance and manufacturing should be a targeted goal.

There are six basic steps to the planning and scheduling cycle:

1. **Identify Work**: Identify all anticipated maintenance work and store within the CMMS.
2. **Plan Work**: Determine the resources (people, materials, etc.) and time necessary to execute and complete the job. Create a time based prioritization of jobs, with emphasis on moving away from emergency work and more towards a best-practice mode of planned and scheduled work.
3. **Schedule Work**: Create a single schedule weekly for all activities (including production and maintenance) between the maintenance and operations groups with greater visibility given to planned maintenance work.
4. **Perform Work**: Perform the work as it is specified in the weekly report details.
5. **Follow-up on Work**: Allocate work to resources and then follow-up on for schedule compliance through work completion.
6. **Evaluate Results of Work**: Evaluate the results through a formal evaluation process that looks at the effectiveness of the maintenance process and recommends solutions for improvement in future maintenance work execution.

5.3.1.2.2 Cost Management

Cost management in the maintenance organization is a tool used to demonstrate cost competitiveness and portray maintenance as a value adding function. Cost management should be executed through Maximo with all parts, labor, and material costs reported on an actual cost basis.

Cost reports must be produced at the level of the responsible work team, with the teams required to show the cost-effectiveness of the maintenance strategies being executed and a target for the cost of each work type. To recover maintenance costs through work orders, it is imperative that the hourly costing rate accurately reflect all potential maintenance spend including equipment, direct and indirect labor, and overhead.

Cost histories for assets should be maintained in Maximo. Cost histories should regularly be reviewed by members of both the maintenance and operations organizations to identify high cost activities and implement improvement initiatives where applicable.

5.3.1.3 Effectiveness

Effectiveness is a measure of the extent to which planned activities are realized and planned results achieved[31]. While efficient operations are important, the success of any process hinges on its ability to produce predictable and reliable outcomes through its outputs. Effectiveness, like efficiency, is a direct output of the work procedures and metrics put in place. Greater robustness and tighter process controls will inevitably lead to more effective operations.

There are several metrics and/or signals that should be considered when determining how well a maintenance program and/or asset are working together to generate consistent, desired outputs:

5.3.1.3.1 Mean Time between Failures (MTBF):

The mean time between failures metric provides a predictive measure of how often the asset in question will be out of service. When using MTBF, it is important to define at what point an asset or

[31] (British Standards Institute, 2008)

operation reaches its failure mode. When utilized correctly, MTBF can be used to better understand how often an asset is out of service and drive planning procedures to circumvent issues that may arise as a result of the asset downtime.

MTBF = Operating time (hours) / Number of Failures

5.3.1.3.2 Mean Time to Repair (MTTR):

The mean time to repair metric is a measurement of the time it takes to repair or replace an asset to its intended working state. It is important to define the repair time as the time between the moment the asset ceases to operate and the time at which it is back to its intended working state.

MTTR = total repair or replace time (hours) / number of repair or replacement events

5.3.1.3.3 Mean Time between Maintenance (MTBM):

The mean time between maintenance metric provides a measure of duration of operating time between maintenance events or actions for an asset. The maintenance event should only be inclusive of those that interrupt the working state of the asset and can include those actions that are preventative and those that are corrective. The MTBM metric is an important tool in helping to understand the effectiveness of an asset, and can be used to guide asset maintenance strategies for the future.

MTBM = Operating time (hours) / Number of maintenance actions

5.3.1.3.4 Nonconformances (NCs)

Nonconformances are deviations from the standards or expected outcomes for operation, performance, production, etc. for a specific asset. The typical nonconformance investigation should include problem identification, root cause analysis, corrective and preventive action identification, and effectiveness measurements for those actions that are implemented. This nonconformance process helps to make the future operation of the asset more robust, and allows operators to better anticipate and prevent future problems.

5.3.1.3.5 AMIS Maintenance Assessment Tool

The maintenance assessment tool provides the maintenance organization with an assessment of its current state operating practices. The tool assesses maintenance practices in the areas of work planning & control, productivity & effectiveness process, equipment reliability, and parts inventory management. Once the assessment of these areas is complete, an overall maintenance maturity score is generated. The assessment maturity score is a primary effectiveness metric in guiding the maintenance organization towards its desired state of Maintenance Excellence.

5.3.1.4 Safety

Safety is a condition of being free of an environment that causes hurt, injury, or loss. Safety standards in both manufacturing and operations continue to rise sharply[32]. Thus, the ability of the maintenance program to ensure reliable equipment operation is imperative. Safety should be managed as the first priority of the maintenance program. Emphasis should be placed on revisiting and evaluating maintenance practices regularly for safety.

There are several key strategies employed to promote safety through maintenance best practices. These include measures such as maintenance risk assessments, lockout/tagout, and the use of critical control devices.

5.3.1.4.1 Maintenance Risk Assessment

A Maintenance Risk Assessment is performed to determine if changes to a maintenance practice pose a significant risk to safety, the environment, or ongoing production operations. The risk assessment addresses three key questions:

1. What would happen should the risk in question actually occur?

2. What is the likelihood of the risk occurring?

[32] (British Standards Institute, 2008)

3. Is the risk in question tolerable under the current operating environment?

5.3.1.4.2 Lockout/Tagout (LOTO)

Lockout/tagout is a set of procedures designed to protect maintenance workers from the unexpected startup of machinery and equipment while performing service work. LOTO is the physical placement of a locking device and tag on an energy-isolating device. The lock helps to ensure that the energy-isolating device cannot be started up, while the tag serves to communicate and warn others in the area of the lockout/tagout condition. Amgen has zero tolerance for accidents, so LOTO, if implemented correctly, can greatly reduce the risk of injury during maintenance work.

Lockout/tagout should be performed by utilizing Hazardous Energy Control Procedures (HECP) which provide step-by-step instructions for: (1) identifying potentially hazardous sources of energy, (2) isolating those sources, (3) releasing any stored energy, and then (4) checking to ensure that the source is in a zero-energy state prior to the initiation of maintenance work.

5.3.1.4.3 Critical Control Devices

Critical control devices are safety risk mitigation measures implemented on high risk equipment and systems. Control devices act as a last line of defense when an asset is operating outside its established limitations. Thus, it is imperative that the control device work as intended when situations for its use arise.

The maintenance organization must take care to ensure that the devices are properly maintained. Each critical control device should be properly logged in Maximo in order to track maintenance work. At Amgen, critical control devices are grouped into the areas of fire, safety, hazardous material, environmental, and ventilation.

Moving from a maintenance organization that is reactive in nature to one that is proactive greatly enhances safety in the workplace. In reactive situations, there is often less planning involved in executing work tasks. This leads to risks being taken that wouldn't normally happen with maintenance work that is planned and scheduled prior to execution. Proactive maintenance programs involve substantial planning, but when implemented lead to safer, more efficient working conditions.

5.3.1.5 Compliance

Compliance is the foundation established by an organization to ensure that personnel are aware of, and take steps to comply with relevant laws and regulations[33]. Compliance makes certain that the organization is operating within the boundaries established by relevant laws and regulations. This can happen through a number of measures, but is most often done through the audits of maintenance processes, results, and performance metrics.

5.3.1.5.1 Audits

The audit process serves to ensure that working practices in the maintenance program abide by the processes and standards put in place to meet or exceed requirements of applicable laws and regulations. The audit measures whether or not the maintenance program being evaluated was applied correctly and if the conclusions drawn from the maintenance work were the right ones.

The audit should have involvement from parties with intimate knowledge of the asset or maintenance program being evaluated. While senior management does not necessarily need to perform the audit, it is in their best interest to maintain active involvement since they assume overall responsibility in the event of an asset failure. Senior management should ensure that the auditors have a thorough understanding of maintenance best practices.

An audit should be performed as soon as possible following the application of the maintenance program. This allows those involved in the process to accurately recall why specific decisions were made, which yields quick directed feedback in the event of procedural deviations or mistakes. It also better enables the people executing maintenance programs to understand the work that they are doing, the

[33] (British Standards Institute, 2008)

potential ramifications of their decisions on other processes, and any shortcomings that may negatively affect the viability of the asset.

5.3.1.6 Enablers

Enablers are the supportive systems, procedures, activities and resources that enable an organization to operate its maintenance program efficiently and effectively. In Amgen's maintenance organization, the three key enablers used to promote efficient and effective operations are Maximo, BOBJ, and CiM Planning & Scheduling.

5.3.1.6.1 Maximo

Maximo is the CMMS used by Amgen, and is a software platform that integrates maintenance management practices directly into the company's asset lifecycle. Maximo's value lies in its ability to tie directly into the asset's performance and monitor, calibrate, and track the asset across its lifecycle in order to drive better maintenance decisions.

At Amgen, Maximo plays a central role in work order planning and control. By tracking work orders through the CMMS platform, an in-depth equipment history is able to be built and relied upon for future use. This allows asset management decisions that may directly or indirectly affect that specific piece of equipment to be referenced and facilitate effective and timely maintenance decisions. Other uses for Maximo include spare part and inventory management, certifications, and metrics reporting.

5.3.1.6.2 BOBJ (Business Objects)

BOBJ is a business objects tool utilized by Amgen Maintenance to provide metrics and reporting for key maintenance areas. BOBJ provides comprehensive functionality and business intelligence in the areas of (1) reporting & analysis, (2) dashboards, and (3) data exploration:

1. The reporting and analysis of metrics allows the maintenance organization to determine trends and predict potential outcomes based on those trends.

2. The dashboards provide an interface between the maintenance personnel and visual representations of asset performance. This allows those users to make quick, informed decisions where needed.

3. The data exploration functionality makes information readily available to maintenance workers by leveraging the existing knowledge databases to provide relevant solutions.

5.3.1.6.3 CiM Planning & Scheduling

CiM provides a built-in tool for planning and scheduling through Maximo. The planning and scheduling tool leverages Maximo to collate work schedules into a single database for various assets and personnel, which then allows users to optimize labor availability and utilization in the execution of maintenance programs. A key benefit to the CiM planning and scheduling tool is the ability to generate different work scenarios based on planned maintenance activities. Maintenance managers are able to evaluate multiple planning and scheduling options side-by-side and identify resource allocation conflicts before they happen.

5.4 Conclusion and Recommendations

Amgen's maintenance organization is being transformed through the efforts of the Maintenance Excellence group. The Maintenance Excellence group is advanced in its ways of thinking and has put continuous improvement at the forefront of its work. It has a strategy in place to help Amgen's maintenance organization become a world-class operation, and is tactically implementing new tools and processes to help this strategy become a reality. Utilizing a document such as the maintenance excellence roadmap to communicate this strategy to others, both in the maintenance organization and elsewhere within Amgen, will help visualize the process in a cohesive manner and drive quicker change through encouraging buy-in.

Also, through its work on the maintenance excellence roadmap, this project identified the need for a more integrated tool where the AMIS maintenance assessment tool currently sits. To advance maintenance practices at sites across the Amgen manufacturing network, a series of recommendations are provided below.

5.4.1 Equipment Maintenance Assessment Tool

As mentioned above, the AMIS maintenance assessment tool provides the maintenance organization with an assessment of its current state operating practices. The tool has been deployed across several sites, and has been beneficial in maturing maintenance practices within a cost-focused frame of reference. The assessment has successfully brought to light several improvement areas for maintenance practices and driven several successful change implementations. Also, great benefit is seen in its benchmarking capabilities, as Amgen's maintenance assessment score can be compared versus those of other companies in other industries where the assessment has been performed.

Going forward though, the maintenance organization needs continued improvement to reach its desired state of best-in-class operations. To accomplish this, a comprehensive analysis tool is needed to drive changes. The assessment tool, in its current state, doesn't account for some factors which increase cost and slow down advancement of best practices. A more rigorous, comprehensive program is needed that incorporates the benefits of the AMIS assessment tool while expanding into new areas.

To better assess maintenance practices and monitor implementation strategies in the future, we recommend that programs of yearly maintenance assessments be standardized at each site in the maintenance network. This program would entail utilizing the AMIS assessment tool every 2-3 years to take advantage of its benchmarking capabilities, and then developing an internal assessment tool to be used in the other years that the AMIS assessment is not deployed. A team of maintenance experts at Amgen should be assembled to develop the internal assessment tool. The team should look to integrate modern maintenance practices used across multiple industries, while focusing on incorporating additional criteria

To deploy the internal assessment tool, a team of maintenance practitioners from each site should be involved in each assessment performed across the maintenance network. This will greatly enhance the knowledge sharing and learning capabilities of the effort, and set forth continuous improvement ideas for future assessments. Once completed, the final maintenance assessment score should be used as the leading metric for maintenance effectiveness at Amgen, and as the baseline for each site to improve upon year over year.

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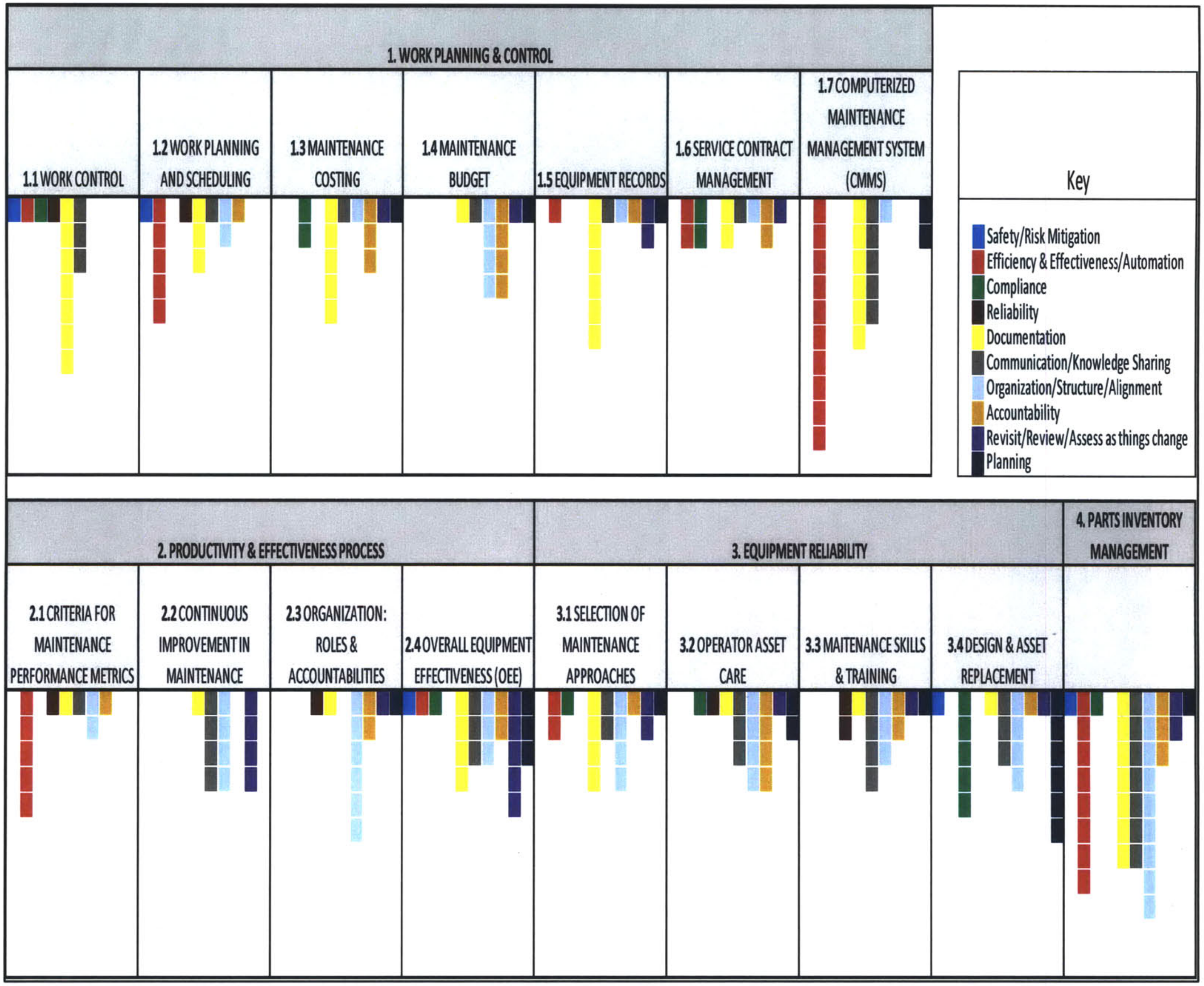
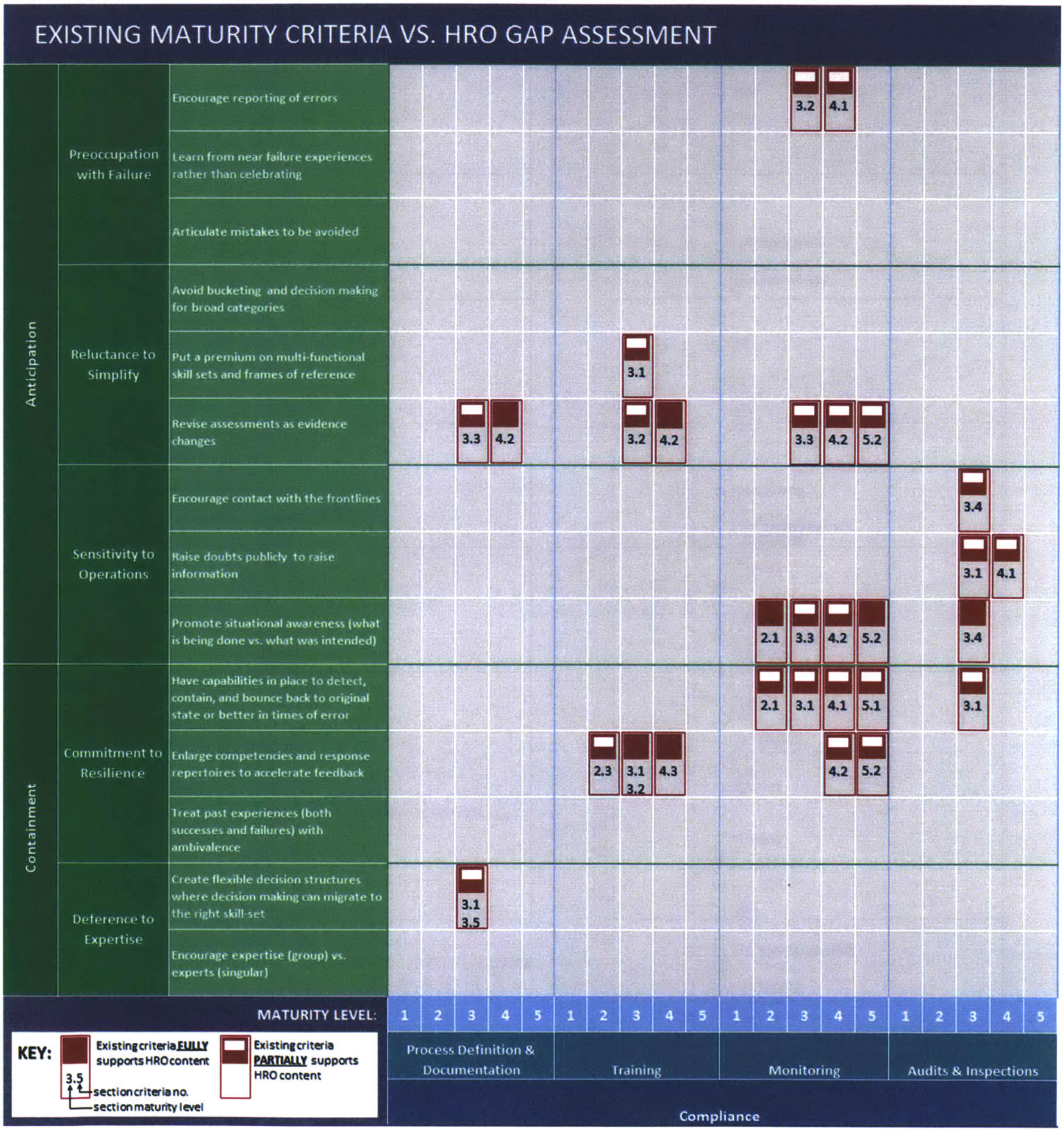
7 Appendix

Appendix A



Appendix B


EXISTING MATURITY CRITERIA VS. HRO GAP ASSESSMENT
Anticipation
Containment
Preoccupation with Failure
Encourage reporting of errors
Learn from near failure experiences rather than celebrating
Articulate mistakes to be avoided
Reluctance to Simplify
Avoid bucketing and decision making for broad categories
Put a premium on multi-functional skill sets and frames of reference
Revise assessments as evidence changes
Sensitivity to Operations
Encourage contact with the frontlines
Raise doubts publicly to raise information
Promote situational awareness (what is being done vs. what was intended)
Commitment to Resilience
Have capabilities in place to detect, contain, and bounce back to original state or better in times of error
Enlarge competencies and response repertoires to accelerate feedback
Treat past experiences (both successes and failures) with ambivalence
Deference to Expertise
Create flexible decision structures where decision making can migrate to the right skill-set
Encourage expertise (group) vs. experts (singular)
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MATURITY LEVEL:
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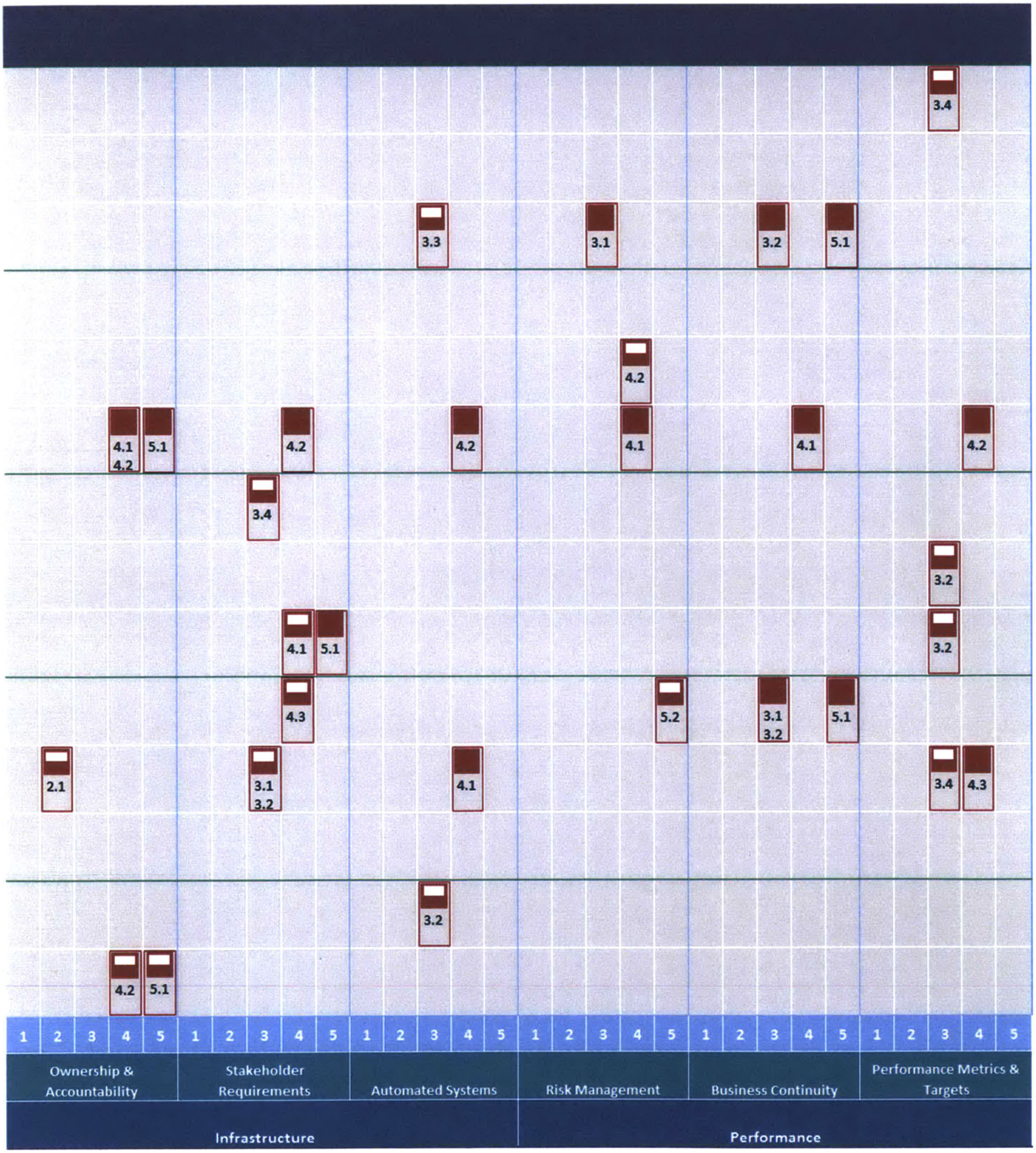
Process Definition & Documentation
Training
Monitoring
Audits & Inspections
Compliance
KEY:
Existing criteria FULLY supports HRO content
3.5
section criteria no.
section maturity level
Existing criteria PARTIALLY supports HRO content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Ownership & Accountability
Stakeholder Requirements
Automated Systems
Risk Management
Business Continuity
Performance Metrics & Targets
Infrastructure
Performance