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Enchaining Lifecycle Reliability with Robust Engineering and Prognostic Health Management

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1.1 Introduction

In a competitive market, quality, price, and cost of ownership are critical factors. The product's performance in its operational environment significantly impacts both the customer's quality experience and the cost of ownership. Initially, many products may attract buyers with their appealing features, but long-term success depends on customer-perceived reliability. If reliability falls short, negative sentiment and a damaged reputation can quickly arise and be difficult to rectify. From a producer's perspective, substantial amounts are often spent on warranties, with warranty costs sometimes equaling the product development expenses. Reliability is one of the most important characteristics of an engineering system. Reliability performance is largely established during the product development phase. Therefore, systematic efforts to prevent failures must be implemented throughout the entire development process, with specific strategies tailored to each phase. Poor product reliability typically stems from variation and a lack of knowledge. In this book, we present an approach for managing variation at various stages of product development. And we also introduce a new approach to addressing both lack of knowledge and variation within a unified framework.

Reliability can be measured as robustness over time, serving as a leading key performance indicator (KPI). Product development has a significant impact on revenue streams and reliability. It is most cost effective and less time consuming to make designs insensitive to uncontrollable user environments in terms of variation and uncertainty during the upfront design phase. Variation and uncertainty have become integral to our modern worldview. In the industrial sector, concepts like Six Sigma DMAIC (define, measure, analyze, optimize, control) and Design for Six Sigma (DFSS) have gained prominence. The quality movement initiated by Walter A. Shewhart was founded on understanding variation. Deming suggested that "understanding variation" should be one of the fundamental components of what he termed "profound knowledge," essential for management to significantly enhance organizational capability, as outlined in his 14 points for management. Shewhart introduced the important distinction between "chance causes" and "assignable causes" of variation. "Chance causes" stem from numerous minor, indistinguishable sources of variation, while "assignable causes" lead to noticeable changes in the process. According to Shewhart, only chance causes can be modeled using probability models, enabling probabilistic predictability. Processes exhibiting only chance causes are described as "in statistical control" and "predictable within limits." In manufacturing, the objective is to achieve processes under statistical control. However, in companies lacking systematic improvement programs, few processes achieve statistical control. Nonetheless, the outcomes of these processes are often modeled using probabilistic models, assuming that the underlying statistical processes are under some form of control and, therefore, predictable.

We aim to highlight the importance of understanding variation in creating reliable products. Additionally, we will broaden our perspective to discuss other uncertainties that may affect the reliability assessment of a product. The first type of uncertainty arises from random variation, the second type stems from our lack of knowledge, such as lack of good-quality data, when modeling product characteristics or estimating parameters.

How can we effectively manage variation and uncertainty? Our conventional approach may involve efforts to control variation and mitigate risks stemming from uncertainties. However, the challenge with this “control” mindset is that it can lead to solutions that are neither effective nor efficient, often resulting in extended implementation times and increased costs. Achieving a reliable design for a dynamic system involves ensuring it is robust and can withstand the influence of uncontrollable user environments, known as noise factors. Robustness refers to a state where a product is insensitive to these noise factors. Noise factors frequently contribute significantly to design failures and unsatisfied end users. In situations where there exists a model or prototype of a system or component, it may be possible to reduce the impact of noise factors by carefully selecting the levels of one or more design parameters.

Robustness thinking is essential to improve quality and reliability proactively by factoring the activities of design for reliability (DFR). Robustness development in manufacturing can reduce the variability of those processes with valuable benefits to manufacturing yields, cycle time, and costs. Robustness development in DFR process provides benefits in reduction of early-on physical testing and traditional test-fix-test cycles. Robustness thinking in prognostics and health management (PHM), which is utilized when high risks are associated with the mission-critical requirements affecting functionality, reliability, maintainability, and operability of the product, encourages innovative and cost-effective approach to plan for PHM. Robustness achieved early in development enables shorter cycle times in the later design phases. Robust design bridges the gap between product development, performance measurements in manufacturing and field tracking, and PHM strategy by identifying, selecting, and verifying health indicators in an earlier design phase, thereby improving the effectiveness of PHM.

1.2 Purpose

The purpose of this book is to build a robustness-thinking-based approach for robust design for reliability (RDfR) and prognostic health management as the best practice from early product design to the whole product lifecycle management in a high level of engineering confidence at the lowest cost and in shorter time. Our title for this book links two important engineering approaches: the development of robustness in a product’s design as a leading indicator and is focused on preventing problems, and the integrative data fusion (i.e., design, manufacturing, field operation, and maintenance) for prognostic health management. As we will discuss, robustness is foundational to reliability, and its development should be the early focus of team members responsible for meeting reliability goals and tracking the health of lifecycle performance. Our plan is to provide value-added strategies for robustness development in new products and health management with helpfully characterized three main types of robustness development and reliability growth case study: intrinsic, instrumental, and collective. Applied appropriately, it can help generate information on how multiple forms of engineering knowledge come together to inform decision-making within reliability contexts.

1.3 Essentials of Robustness and Robust Design in Reliability Improvement

An important development in reliability engineering is robust parameter design pioneered by Genichi Taguchi [1]. For any design concept, there is a potentially large space of control factor settings that will nominally place the function at the desired target value. In robust parameter design, the engineer explores the design space seeking changes that will make the system more robust while keeping the performance on target. Taguchi's method employs orthogonal arrays to explore the design space. At the same time, outer arrays or compounded noises are used to explore the range of possible operating conditions. Signal-to-noise ratio (S/N ratio) might be used as measures of the robustness of the system and guide the engineer to preferable levels of the control factors shown in Eq. (1.1).

$$\begin{aligned} \text{S/N ratio} &= \frac{\text{Energy (or power) that is transformed into intended output}}{\text{Energy (or power) that is transformed into unintended output}} \\ \text{S/N ratio} &= 10 \log \frac{\bar{y}^2}{\sigma^2} \end{aligned} \quad (1.1)$$

Compounded noise is a noise management strategy, when system uncertainty is more complicated, like in a highly dynamic system in which the behavior varies over time. Robust design methods have continued to be refined and are still an active area of systems engineering innovation. To improve reliability, improving robustness in system, parameter, and tolerance design is essential.

There are three fundamental ways to improve the reliability of a product, manufacturing, and supply chain during the design stage [2–4]:

- Reduce the sensitivity of the product's function to the variation in the product parameters.
- Reduce the rate of change of the product parameters.
- Include redundancy.

Summary of essentials of robustness and robust design in reliability improvement is:

- Design-in reliability upfront.
- Eliminate failures prior to testing.
- Increase deployed reliability.
- Promote rapid, cost-effective deployment of health and usage monitoring systems.
- Improve diagnostic and prognostic techniques and processes.
- Decrease operational and support costs.

1.4 Effective Reliability Efforts in an Integrated Product Development Environment

System reliability is a key requirement for a system to function successfully under the full range of conditions experienced in industries, including oil and gas, automotive and others. From a probabilistic viewpoint, reliability is defined as the probability a system will meet

its intended function under stated conditions for a specified period of time; therefore, to predict reliability, you must know three things:

- Function.
- Stated conditions.
- The specified useful life or time period.

A typical textbook that addresses reliability will present a set of probabilistic concepts, such as a survival function, failure rates, and mean times between failures. These concepts are related to a model of the causes of failure, such as component reliabilities or material and environmental variability. To quantify, specified operating conditions are defined as an agreed-upon range of allowable conditions or an estimated probability density function for uncertain or variable parameters. This approach is well suited to calculating predicted failure rates when all of the data are available.

To improve reliability prediction capability when useful data are not available or not sufficient, an alternative approach can be to:

- Identify all potential function failure modes, make a risk assessment, and implement countermeasures.
- Make the product insensitive to user environments.
- Identify shortfalls in verification test plans and enhance verification tests to ensure detection of all failure modes.
- Execute efficient verification tests that demonstrate a product is mistake free and robust under real-world use conditions.

System reliability requires fulfilling two critical conditions: mistake avoidance and robustness.

- Mistake, in this case, is defined as the error due to design decision and manufacturing operations. Examples of mistakes in product development include missing components, installing a component backward, or interpreting a software command as being expressed in inches when it is actually in centimeters. Product reliability can be improved by reducing the incidence of such mistakes through a combination of knowledge-based engineering and problem-solving processes, such as Six Sigma's DMAIC.
- Robustness is the ability of a system to function (that is, insensitive to the user's environment to avoid failure) under the full range of conditions that may be experienced in the field.

System design faces two different challenges:

- Developing a system that functions under tightly controlled conditions, such as in a laboratory.
- Making that system function reliably throughout its lifecycle as it experiences a broad set of real-world environmental and operating conditions.

An example of this real-world challenge is effective system reliability engineering. The most cost-effective and least time-consuming way to make a reliable product—one that is insensitive to the user environment, or robust—is to start in the development or design phase by discovering and preventing failure modes soon after they are created and implementing countermeasures before production.

Although most reliability professionals and companies already practice reliability engineering within design, whether formally or informally, implementing a structured reliability program can significantly improve business. Through our approach to lifecycle reliability through robustness development and PHM, we can help you reduce returns and warranty costs, enhance quality assurance, and comply with latest standards.

- Reliability concerns both robustness and mistake prevention.
- Reliability = Robustness + Mistake Prevention.

Proactively integrating Design for Reliability (DfR) through transfer function-based robustness improvement within the DFSS framework is essential for modern reliability engineering. Robust design is the foundational principle of reliability, enabling engineers to manage variability, protect margin, and prevent failures by design, not by post hoc correction. While traditional DfR practices have improved reliability, they are now largely procedural, test-centric, and reactive-an approach that is increasingly inadequate for today's complex, software-intensive, and AI-enabled systems operating under compressed development cycles. To address these challenges, Robust Design for Reliability (RDR) represents the modern evolution of DfR, emphasizing first-principle robustness thinking, upfront design optimization, and proactive failure prevention. This shift establishes reliability as a required product engineering deliverable, owned and designed by product engineering teams. Reliability engineers enable this outcome through methods and validation; however, reliability is created by design.

1.5 Enhancing Reliability Integration into the Product Development Process

One of the more significant challenges for reliability engineering in product development is the complete execution of the planned reliability process in product development. The reliability tools and techniques outlined in the product plan are often skipped or delayed, minimizing the opportunity for outputs to impact the program and product fully.

This contrast of planning and execution does not occur equally with product plan goals such as time to market, developed technical features, and product cost point. Each of those is closely measured in development and has a strong presence when resource is re-negotiated during the program. There is specific consideration that must be made for reliability due to its more complicated nature to measure performance and improve toward the target.

In its traditional formulation, reliability is stated as the probability of failure under specified operating conditions. A typical textbook that addresses reliability will present a set of probabilistic concepts such as a survival function, failure rates, and mean times between failures. These concepts are then related to a model of the causes of failure such as component reliabilities or material and environmental variability. To make the model quantitative, specified operating conditions are stipulated as an agreed-upon range of allowable conditions or an estimated probability density function for uncertain or variable parameters. This approach is well suited to calculating predicted failure rates once all the data are available. This is the general approach of texts that emphasize reliability analysis

(such as Ushakov [5]) as well as texts oriented toward DFR (such as Rao [6]). This is a very sound approach, but here we present an alternative formulation of reliability that has proven very effective in the improvement of reliability early in the development of a new system.

1.6 Physics of Failure (PoF)

A development in reliability engineering closely related to this book is the PoF approach developed at the Computer Aided Life Cycle Engineering (CALCE) Electronic Products and Systems Center at the University of Maryland. The first instance in archival literature of the term “physics of failure” is in Pecht et al. [7], which emphasizes use of a physics-based model for reliability prediction and DFR. This approach has been extended to product development by [8] and to accelerated life testing by Kimseng et al. [9]. This study builds upon the conception of PoF and seeks to extend this conception to the earliest, creative phases of system design.

The PoF approach begins with the first stage of design. A designer defines product requirements, based on customer needs and the supplier’s capabilities. These requirements can include the product’s functional, physical, testability, maintainability, safety, and serviceability characteristics. At the same time, the service environment is identified, first broadly as aerospace, automotive, business office, storage, or the like, and then more specifically as a series of defined temperature, humidity, vibration, shock, and other conditions. The conditions are either measured or specified by the customer. From this information, the designer, usually with the aid of a computer, can model the thermal, mechanical, electrical, and electrochemical stresses acting on the product.

PoF is a scientific discipline that determines the root causes of failure for electrical, electronic, or electromechanical (EEE) items (Figure 1.1). These items can include:

- Piece parts
- Subassemblies
- Modules
- Equipment

Next, stress analysis is combined with knowledge about the stress response of the chosen design materials to identify where failure might occur (failure sites), what form it might take (failure modes), and how it might take place (failure mechanisms). Prior analyses of the root causes of actual field failures are of particular use at this stage. Failure is generally caused by one of the four following types of stresses: mechanical, electrical, thermal, or chemical, and it generally results either from the application of a single overstress or by the accumulation of damage over time from lower-level stresses. Once the potential failure mechanisms have been identified, specific failure mechanism models are employed. The validity of these models can be tested by conducting accelerated aging tests. If no models are available, or if the models are found to be inaccurate, then new models are developed using a series of statistically designed experiments, which identify the most important design and environmental factors governing failure and the mathematical relationship linking those factors to the time to failure.



Figure 1.1 Reliability Physics Analysis.

Wherever possible, variabilities in the factors are specified using distribution functions. The effect of material properties, the geometry at failure sites, any damage to the part, and any manufacturing flaws and defects are addressed at this point as well. Once the models are established, a reliability assessment can be conducted on the product. This consists of calculating the time to failure for each potential failure mechanism, and then using the principle that a chain is only as strong as its weakest link, choosing the dominant failure site and mechanism as those resulting in the least time to failure.

The information from the assessment can be used to determine whether a product will survive for its intended application life, or it can be used to redesign a product for increased robustness against the dominant failure mechanisms and sites.

The PoF approach can be used to qualify design and manufacturing processes to ensure that the nominal design and manufacturing specifications meet or exceed reliability targets. Throughout the development cycle, it is employed to assess stress margins and establish process controls as a means of continuously improving the product's reliability from early prototype testing through final manufacture.

The PoF-based methodology is the preferred methodology for reliability assessment since it utilizes the knowledge of how failures actually occur in a product through degradation methods and can be used to evaluate a product's reliability based on its design and lifecycle. PoF ranks potential failure mechanisms and assists in the DFR, selection of stress test conditions, product qualification and screening, and performing PHM. Currently, PoF as a reliability assessment methodology is widely accepted by industry, professional societies, and the US government organizations, including the IEEE, EIA/JEDEC, and SEMATECH, which have been developing standards to incorporate PoF in the product development and evaluation process.

1.7 Failure-mode Avoidance

Thinking of reliability as failure-mode avoidance can have real advantages, especially in the early stages of system design or in long-term scenarios such as technology development. In early stages of system design, probability theory may be too quantitative for the task at hand. Probability density functions imply a level of precision in modeling the scenario that is often unwarranted, especially during early development. As a project advances through its development stages, the probabilistic view of reliability becomes increasingly useful. Analysis of reliability using probability theory is useful for component selection, system validation, and field-service operations. The value of the failure-mode avoidance conception of reliability is greatest for technology strategy, systems architecting, concept design, and for some robust parameter design activities, all done early during the development of the system.

An important development in reliability engineering is robust parameter design pioneered by Genichi Taguchi [10]. For any design concept, there is a potentially large space of control factor settings that will nominally place the function at the desired target value. In robust parameter design, the engineer explores the design space seeking changes that will make the system more robust while still keeping the performance on target. Taguchi's method employs orthogonal arrays to explore the design space. At the same time, outer arrays or compounded noises are used to explore the range of possible operating conditions. S/N ratios are used as measures of the robustness of the system and guide the engineer to preferable levels of the control factors.

Taguchi's philosophy of robust design is consistent with the approach to reliability engineering discussed here. Taguchi rejected the "goal post" mentality inherent in tolerance limits and specifications. His notion of a quality-loss function replaced consideration of defect rates and process yields with an emphasis on reducing variance followed by adjustment to target. Taguchi encouraged engineers to deliberately expose designs to harsh conditions in experiments. To do this requires a transformation in the culture of an engineering organization. The emphasis must shift from demonstrating adequate performance with high statistical confidence to aggressive improvement followed by adequate confirmation.

Another approach relevant to this study known as "operating window methods" was developed and practiced at Xerox Corporation in the 1970s. The operating window is the set of conditions under which the system operates without failure. In operating window methods, reliability is improved by making the operating window larger. Clausing [11] described the approach in detail in a recent issue of *Technometrics*, but the essence of the approach is simple enough to present here:

- Increase the value of the noise factors so that the failure rate is high.
- Change the value of the control factors to seek a broader operating window at a fixed failure rate.

Despite the use of failure rates as a measure of performance, the operating window method is, upon closer examination, consistent with Taguchi's quality philosophy. Because failure rates were greatly increased by applying aggressive noises, improvements could be made rapidly, even though they sacrificed the ability to accurately predict field reliability.

At the earliest stages of system design when our latitude to make changes is greatest, it is these types of conceptual changes that are most critical to find and implement. Although robust parameter design has been a valued development in systems engineering, large changes in system reliability observed over time cannot be explained by parameter design alone.

We promote and seek to help engineers implement early-stage robustness work, robustness thinking, and robust design methodologies. The next section covers some theoretical developments.

1.8 Design for Six Sigma

DFSS describes the application of Six Sigma tools to product development and process design. The goal is to “design in” Six Sigma performance capability. DFSS is an approach to designing (or redesigning) a product or service. It is equally useful in developing business processes or technical products. DFSS is a defined method—a culture and a way of viewing value creation.

The focus of DFSS begins with critical voice of customer (VOC) analysis and rational business planning. After gaining an understanding of the market and customer needs, design personnel work to understand and characterize critical design parameters and functionality. To achieve a cultural shift—focused on continuous improvement—you must go beyond DMAIC by leveraging a full suite of performance improvement tools. The time to develop new products is a critical success factor in almost any business today. DFSS helps reduce development time by deploying lessons learned throughout the development and manufacturing setup process.

DFSS provides many tangible benefits to organizations. For instance, the DFSS approach results in long-term cost reductions for a product. There are many ways these savings are realized. Instead of debugging products and processes that already exist, DFSS is a reexamination of the function and design parameters.

For a company that has achieved success through Six Sigma activities or equivalent—systematically applying statistical problem-solving methodologies to reduce variation and enhance quality—it is natural to extend these practices into the early stages of product and process development, known as DFSS. In essence, DFSS involves selecting product and process characteristics crucial to customers and manufacturing, identifying noise factors that influence these characteristics, and ensuring the product or process is resilient to variations in these factors. Both innovative approaches and systematic parameter design methodologies are employed.

DFSS starts from scratch with the goal of designing virtually error-free products or processes. This strategy effectively replaces the trial-and-error or built-test-fix processes, and results in product designs that consistently meet customer requirements. There are several different DFSS roadmap models:

- Invention, innovation, develop, optimize, and verify (IIDOV).
- Define, concept, design, optimize, and verify (DCDOV).
- Identify, define, develop, optimize, and verify (IDDOV).
- Define, measure, analyze, design, and verify (DMADV).
- Identify, design, optimize, and verify (IDOV).

Each has a different focus on generic technology development or product commercialization. The roadmap names are not important, but the contents and tasks at each phase defined to enhance product development process are.

A Typical DFSS Approach Includes Four IDOV Phases:

- I—Initiate project. Initiate and prepare projects, establish business case, and project infrastructure.
- D—Design development. Define requirements. Gather and understand customer requirements and develop concepts. Develop, evaluate, synthesize, and select design concepts.
- O—Optimize design. Model, analyze, and develop design to optimize product and process capability.
- V—Verify and validate. Test design outputs against customer requirements under defended operating conditions.

Robustness thinking and robust design are essential components of DFSS, aimed at enhancing product quality and process efficiency. These approaches focus on minimizing variability and ensuring that designs can withstand various conditions and stresses without failure. The ultimate goal is to eliminate inefficiencies and waste in both the design and production processes, thereby saving resources and aligning the end product or service more closely with customer needs, leading to higher satisfaction levels.

1.8.1 The Essence of Robustness Thinking

Robustness thinking is a **first-principle, design-centric approach to reliability engineering** that deliberately anticipates, manages, and absorbs variability and uncertainty before failures can occur. Its objective is not merely to respond to failures after they emerge, but to **prevent failures by intent through proactive design optimization**, rather than discovering them by chance through testing or field experience.

At its core, robustness thinking establishes reliability **upfront**, where design decisions have the greatest leverage and lowest cost of change.

Anticipation and Management of Variability

- Recognizing that **variability is inherent and unavoidable** in real-world systems, arising from manufacturing tolerances, environmental conditions, usage patterns, aging, and operational uncertainty.
- Treating variability and noise as **design inputs**, not exceptions.
- Actively identifying, characterizing, and managing sources of variation early in development to preserve performance margins and failure distance.

Proactive Design Optimization

- Optimizing designs for **stable performance across a wide operating envelope**, rather than maximizing performance under ideal or nominal conditions.
- Allocating and protecting **design margin** to ensure functionality under worst-case and off-nominal scenarios.
- Using transfer functions, sensitivity analysis, and parameter robustness to minimize the impact of noise factors on critical performance characteristics.

Focus on Performance Consistency

- Prioritizing **consistent and predictable system behavior** over peak or point-optimized performance.
- Ensuring that product performance remains within acceptable limits despite uncertainty, degradation, and external disturbances.
- Viewing consistency as a leading indicator of long-term reliability.

Proactive Failure Prevention

- Addressing potential failure mechanisms **during concept and design**, rather than reacting to failures during testing, validation, or field operation.
- Shifting reliability practice from **failure discovery and correction** to **failure avoidance by design**.
- Reducing dependence on extensive testing as a means of uncovering weaknesses late in the lifecycle.

Systems and Lifecycle Perspective

- Treating the product as part of an **integrated system**, encompassing design, manufacturing, supply chain, usage environment, maintenance, and end-of-life considerations.
- Ensuring robustness across the **entire lifecycle**, not just at launch.
- Enabling downstream activities—testing, PHM, digital twins, and AI—to **validate and monitor design intent**, rather than compensate for insufficient robustness.

Key Principle
Robustness thinking enables failures to be prevented deliberately by design, rather than discovered accidentally through testing or field exposure.

1.8.2 Robust Design as a Key Strategy

Robust design, also known as Taguchi methods, is a key strategy within robustness thinking. It aims to create designs that are insensitive to variations in manufacturing, environment, and usage. Key aspects include:

Parameter Design

- Optimizing design parameters to minimize the effect of noise factors on product performance.

Tolerance Design

- Determining the optimal tolerances for parameters to balance performance and cost.

Signal-to-Noise Ratio

- Using this metric to measure how well a design performs in the presence of noise factors.

Driving Proactive Reliability Efforts

Robustness thinking and robust design drive proactive reliability efforts by:

- 1) Early Identification of Potential Issues:
 - By considering variability and noise factors from the start, potential reliability issues are identified and addressed early in the design process.
- 2) Reduction of Sensitivity to Variation:
 - Robust designs are less sensitive to variations in manufacturing, usage, and environment, leading to more reliable products.
- 3) Emphasis on Prevention Rather than Detection:
 - The focus shifts from detecting and fixing failures to preventing them from occurring in the first place.
- 4) Integration of Reliability Considerations Throughout the Design Process:
 - Reliability becomes an integral part of design decisions rather than an afterthought.

1.8.3 Paradigm Shift and Change

The adoption of robustness thinking and robust design represents a significant paradigm shift in reliability engineering:

- 1) **From Reactive to Proactive:**
 - Instead of waiting for failures to occur and then fixing them, the focus is on preventing failures through robust design.
- 2) **From Ideal Conditions to Real-World Variability:**
 - The emphasis shifts from optimizing for ideal conditions to ensuring consistent performance across a range of conditions.
- 3) **From Component-level to System-level Thinking:**
 - Reliability is considered at the system level, including interactions between components and with the environment.
- 4) **From Quality Control to Quality by Design:**
 - Quality and reliability are built into the product from the start, rather than being inspected in at the end.
- 5) **From Cost Center to Value Creator:**
 - Reliability efforts are seen as creating value through improved customer satisfaction and reduced warranty costs, rather than as a necessary expense.

Robustness thinking and robust design are critical disciplines within DFSS that drive proactive reliability efforts and initiate a paradigm shift in product development. By focusing on minimizing variability and ensuring consistent performance under various conditions, these approaches enhance product quality and process efficiency. The ultimate goal is to eliminate inefficiencies and waste, align products more closely with customer needs, and achieve higher satisfaction levels. As organizations adopt these principles, they can expect to see significant improvements in product reliability, customer satisfaction, and overall market success.

1.8.4 DFSS Roadmap: Emphasizing Robustness

The DFSS roadmap is integral to facilitating robust design. The revised DFSS roadmap emphasizes robustness through its stages.

Case Studies and Applications

Real-world applications of robustness thinking and robust design can be seen across various industries. For example:

- **Automotive Industry:** Manufacturers use robust design principles to ensure that vehicles can withstand a wide range of operating conditions and provide reliable performance over their lifespan.
- **Consumer Electronics:** Companies design devices to be resilient against common user errors and environmental factors, ensuring consistent performance and customer satisfaction.
- **Healthcare:** Medical device manufacturers apply robust design techniques to create equipment that performs reliably in critical applications, enhancing patient safety and outcomes.

In every phase of the product development process, we provide nonbinding recommendations regarding the tools that could be used to achieve the necessary deliverables for progressing to the next phase. These recommendations are intended to support rather than restrict the creativity and imagination of the designer. Additionally, checklists are provided to ensure that all required outputs for each phase are captured. From a DFSS perspective, these checklists ensure that no critical aspects are overlooked or omitted.

- 1) **Identify**—Identify market needs. Define customer requirements and project goals. Identify critical to satisfaction (CTS) and related functional targets.

Reliability is often a key CTS on the reliability aspects of a product. The purpose of this stage for the reliability effort is to clearly and quantitatively define the reliability requirements and goals for a product, as well as the end-user product environmental and use conditions.

These can be at the system, assembly, component, or even the failure-mode level. Requirements can be determined in many ways or through a combination of those different ways. Requirements can be based on contracts, benchmarks, competitive analysis, customer expectations, cost, safety, and best practices. Some of the tools worth mentioning that help quantify the VOC include Kano models, affinity diagrams, and pair-wise comparisons. Of particular interest to DFR are the requirements that are critical to reliability (CTR).

The system reliability requirement goal can be allocated to the assembly, component, or even the failure-mode level. After the requirements have been defined, they must be translated into design requirements and into manufacturing requirements.

- 2) **Design**—The purpose of the design phase in RDfR (IDOV) is to develop products that maintain high performance and dependability under a wide range of conditions and throughout their intended lifespan. Understand the system and select design concepts. Map CTS characteristics to lower-level y factors. Relate y factors to

critical to quality (CTQ) or CTR x design factors. Determining use and environmental conditions is an important early step of a DFR program. Know what it is to be designed for and what types of stresses the product should withstand.

The conditions can be determined based on customer surveys, environmental measurement, and sampling. The tendency for the potential failure-mode occurrence is aggravated by noise factors, which are those that engineers have little or no control and negatively influence designed system performance. Fundamental to designing for reliability and robustness using transfer function is the inclusion of noise factors during analysis that challenge the design and uncover potential failure modes.

After uncovering, these failure modes can be avoided by developing appropriate countermeasures—either in the design or manufacturing process. Including noise factors in upfront design analysis has encouraged engineers developing transfer functions to consider appropriate noise factors and realistic levels, as well as strategies to include them in simulations.

It is important to estimate the product's reliability, even with a rough first-cut estimate, early in the design phase. This can be done with estimates based on engineering judgment and expert opinion, PoF analysis, transfer-functions-based simulation models, prior warranty and test data from similar products and components (using life data analysis techniques), or standards-based reliability prediction.

- 3) **Optimize**—Design for robust and reliable performance. That minimizes product or process sensitivity to uncontrollable user environment to have better manufacturability and higher reliability.

In this stage, a robust parameter design helps further factor reliability tasks into the design process by optimizing design function in the presence of noise factors to:

- Identify important variables.
- Estimate their effect on a certain product characteristic.
- Optimize the settings of these variables to improve design robustness.

Noise screen experiments may be necessary to identify high-impact noise factors to single out significant factor results in more realistic reliability tests and more efficient accelerated tests (because resources are not wasted on including insignificant stresses in the test) prior to the robust optimization efforts.

Within the DFR concept, you are mostly interested in the effect of stresses on your test units. Robust design plays an important role in DFR because it assists in identifying the factors that are significant to the product's life, especially when the PoF are not well understood. The robustness of the given concept design can be used to assess the limitation of the given concept design from a reliability improvement perspective.

- 4) **Verify**—Assess the integrated system and subsystem effects on performance. Use reliability and manufacturing verification to assess design performance and the ability to meet customer requirements.

(Continued)

(Continued)

If the design has been “demonstrated,” the product can be released for production. When reaching the manufacturing stage, the DFR efforts should focus primarily on reducing or eliminating problems introduced by the manufacturing process. Manufacturing introduces variations in material, processes, manufacturing sites, human operators, and contamination.

Because manufacturing piece-to-piece variation has been considered as part of noise factors and was optimized in the optimize phase, the product’s performance should be insensitive to manufacturing variation if the noise factors were identified and incorporated in the optimize phase for the robustness study.

However, reliability may be reevaluated considering additional process variables. Design modifications might be necessary to improve robustness. For example, a design should require the minimal possible amount of nonvalue-added manual work and assembly. Whenever possible, it should use common parts and materials to facilitate manufacturing and assembling. It should also avoid tight design tolerances beyond the natural capability of the manufacturing processes.

1.9 Design for Reliability

DFR is a process. Specifically, DFR describes the entire set of tools that support product and process design (typically from early in the concept stage all the way through to product obsolescence) to ensure that customer expectations for reliability are fully met throughout the life of the product with low overall lifecycle costs. In other words, DFR is a systematic, streamlined, concurrent engineering program in which reliability engineering is woven into the total development cycle. The purpose of the DFR process is to provide requirements for DFR activities, which are intended to be an integral part of every product development effort to continuously improve product reliability and robustness. The reliability process integrates with a generic technology and product development process and can be tailored as specified in the technology and product development process. The product development process defines the scope and applicability.

The reliability plan documents the tailoring of the DFR activities. The reliability plan is created by the design team. It is the responsibility of the design team to implement the DFR by completing the activities outlined in this plan. The team must leverage a set of reliability engineering tools along with a proper understanding of when and how to use these tools throughout the design cycle. This process encompasses a variety of tools and practices and describes the overall order of deployment that an organization must follow to design reliability into its products. The reliability is part of the DFSS scorecard. DFR tasks can be well aligned with and embedded in a DFSS roadmap.

To make reliability a key product requirement and understand where reliability efforts stand in terms of the DFR process for designing and manufacturing for reliability, a DFR assessment scorecard can be helpful. The DFR assessment drives reliability goal setting, understanding the quality history, tool selection activities, testing strategies, and reliability demonstration through DFR gates review.

The DFR process can follow the DFSS roadmap—for example, the IDOV framework. With reliability in mind, product program teams can identify the boundary and scope of system requirements and design the product. Meaningful test progression strategies can be developed and emphasized through optimizing the design over the time domain and functional validation of the product.

DFR activities are part of various elements in technology and product development activities during the complete product lifecycle. Goals of the DFR process are as follows:

- Integrate VOC into product requirements to improve reliability and robustness of the product.
- Provide requirements for activities involved in the DFR/DFSS process. Optimize the design over the time domain and functional validation of the product using a test progression strategy.
- Identify methods for defining product reliability requirements and activities involved at each stage of product development.
- Provide the practitioner a means of prioritizing the reliability projects and studies that must be undertaken.
- Continuously improve product reliability and robustness over time.

DFR is an industry-wide practice and a philosophy of considering reliability in an early stage of product design and development, to achieve a highly reliable product with sustainable cost. PoF is recognized as a key approach to implementing DFR in a product design and development process. The author will present a case study to illustrate predicting and identifying product failure early in the design phase with the help of a quantitative PoF-model-based analysis tool.

1.10 Prognostics and Health Management

To fulfill the increasing demand on functionality and quality, modern systems are often built with overwhelming complexities. These systems often feature rich electronics and intricate interactions among subsystems/components. Extremely high requirements of system reliability are essential since a single failure can result in catastrophic consequences. Despite every effort made in the past, disasters keep occurring with profound implications. For example, the infamous sudden acceleration failures of Toyota automobiles which have significantly damaged the company's profit and reputation [8].

In view of the high impact and extreme costs usually associated with system failures, methods that can predict and prevent such catastrophes have long been investigated. Applications of developed methods are not rare in domains such as electronics-rich systems, aerospace industries, automotive industry, or even public health environment [2, 12]. In general, these methodologies can all be grouped under the framework of PHM. Particularly, prognostics is the process of predicting the future reliability of a product by assessing the extent of deviation or degradation of the product from its expected normal operating conditions; health management is the process of real-time measuring, recording, and monitoring the extent of deviation and degradation from normal operation condition [13, 14]. Different from traditional handbook-based reliability prediction methods (e.g., US Department of Defense Mil-Hdbk-217 and Telcordia SR-332 (formerly [15])), which assumed that constant

hazard rate of each component can be tailored by independent “modifiers” to account for various quality, operating, and environmental conditions, PHM methodologies instead monitor the health state in real time and dynamically update the reliability function (hazard rates) based on in situ measurements and tailored evolution models obtained from historical data. Due to the success of existing PHM methodologies, there is growing interest in studying new PHM techniques and applying PHM to underdeveloped domains.

Nevertheless, the increasingly complex modern systems pose new challenges on PHM. One of the most prominent problems is called no fault found (NFF) problem (related terminologies include “cannot duplicate,” “re-test OK,” “trouble not identified,” and “intermittent malfunctions”), particularly in electronic-rich systems. As the name suggests, it refers to the situation that no failure/fault can be detected/replicated during laboratory tests even when the failure has been reported in the field. NFF issues not only make the prognosis and diagnosis extremely difficult, but also can cause skyrocketing maintenance cost. NFF contributes a lot in operational cost in many different application areas. On top of the maintenance costs, potential safety hazards related to NFFs are even more striking. For example, both Toyota and National Highway Traffic Safety Administration (NHTSA) spent quite a long time to investigate the root causes of sudden acceleration failures in some car models, a problem that might be linked to 89 deaths in 71 crashes since 2000 according to NHTSA [16]. Unfortunately, no conclusive finding has been reached despite the efforts in trying to repeat the failures in a variety of laboratory conditions. These intermittent faults are also suspected to be the main reason for other catastrophes.

Intermittent faults or NFF problems pose significant barriers in applying traditional methods for reliability prediction, which are often empirical, and population based. From the examples, we can find that intermittent faults are often tightly related to the environmental conditions and operation histories of the individual system. They can hardly be repeated due to unknown random disturbances involved. Therefore, laboratory testing and assessment can only provide a reference on the “average” characteristics of the whole population and are insufficient to provide accurate modeling and prediction for everyone. To reduce the maintenance cost and eliminate safety hazards caused by NFF, robustness-thinking-based product design and manufacturing and the paradigm of PHM need to shift from empirical to data supported and from population based to individual based.

Along with the challenges, the fast development of information and sensing technology has enabled the collection of many in situ measurements during operations and provided the capability of real-time data management and processing for everyone. These advancements provide us great opportunity to develop sophisticated models with increasing accuracy of prognostics for individual items. For instance, many different types of data during the whole lifecycle of the products can be easily retrieved, especially in critical applications. These data could include product design, verification and validation tests, production process information, quality records, operation logs, and sensor measurements.

Businesses including companies of automotive, wind energy, oil and gas, engineering, manufacturing, and others are constantly challenged to reduce time to market, reduce product development cost, and reduce production costs by increasing manufacturing productivity while maintaining product quality and reliability. Hence, PHM technology has become of particular interest for industries. It allows maintaining the high standard of operational performance by detecting impending failures, while increasing equipment

availability through a more effective maintenance scheduling supported by a prognostic capability. PHM permits the reliability of a system to be evaluated in its actual lifecycle conditions, to determine the advent of failure, and mitigate the system risks. Hence, health assessment, as a part of diagnostic, is the process of assessing the current health of a system. Data-driven methodologies in PHM are closely related with those in some other major research directions, such as statistical quality control, reliability engineering, and robust engineering. It is worthwhile to briefly discuss their relations with PHM.

Statistical quality control is an area that has been extensively studied for many decades. The main objective is to detect abnormalities or changes in a process. It is generally applied to many homogeneous units and focuses on identifying the abnormal ones which may be traced back to process faults. PHM, on the other hand, focuses more on how faults happen and how to predict future faults so that optimal maintenance policy can be made, rather than fault detection.

The research in PHM is closely related to those in reliability engineering, such as failure prediction and maintenance. Many methods in PHM stem from those originally developed in reliability engineering. However, they have different focuses of interests. Traditional reliability engineering focuses on the modeling and prediction of the entire product population, without much emphasis on variability of the individuals and their respective working conditions. Therefore, reliability engineering is most valuable for manufacturers' product design and warranty policy making where population characteristics are crucial, while PHM is most valuable for end users who care more about the specific units they have on hand.

Compared to PHM, which emphasizes online monitoring and dynamic updating as indicated in Chapter 5 (Section 5.2.3.1: Activities of Prognostics and Health Management (PHM) and Reliability Over the Product Lifecycle), robust engineering, from an engineering physics perspective, focuses on developing conceptual design robustness and further optimizing robustness in detailed design, such as parameter design and tolerance design, during the early design stage. PHM and robust design are implemented at different stages. Robust engineering is applied mostly during the system planning, concept design, and detail design phase, instead of its operating phase where PHM is applied. Robust design focuses on improving the fundamental function of the product or process, thus facilitating flexible designs and concurrent engineering. Robust design emphasizes on desensitizing the harmful side effects of noise (referred to as uncontrollable user environment). When variability occurs, Taguchi said this is because the physics active in the design and environment promotes change [17]. Noise environment can be categorized into five categories:

- 1) Piece-to-piece variation, such as rubber thickness.
- 2) Change over time, such as failure from material wear, or changes in force or dimension with time.
- 3) Customer use, such as open-hole wellbore size.
- 4) Environmental conditions, such as temperature variation.
- 5) System interfaces and interactions, such as elements outside dimension variations and open-hole size.

The result of noise may be degradation in quality (soft failure) or a malfunction failure (hard failure). A product is said to be robust when it is insensitive to the effects of sources of variability, even though the sources themselves have not been eliminated. The power of

integrated robust engineering and PHM is an engineering disciplined approach that provides a framework and discipline to minimize or eliminate potential birth defect in concept design, strengthen product health conditions through robust optimization in detail design, including parameter design and tolerance design. Critical parameters (both products and processes) identified as health indicators during robust design and optimization are excellent health indicators for PHM in its operating phase applications such as manufacturing, maintenance, field, and others. These identified health indicators have much higher engineering confidence guiding conventional reliability engineering and PHM activities.

In case of data-driven methods, there is a need to identify and extract indicators (i.e., precursors to failure) through raw data gathered from the process. As a prior event analysis, prognosis is to predict whether a fault is impending and estimate how much time remains before a likely failure occurs using dynamics of these indicators. Although numerous PHM methodologies have been proposed with application on data from different areas, a few studies have recently investigated PHM regarding application in health indicators identification. However, identification of health indicators through robust engineering has better engineering confidence and is proactive and predictive.

The goal of health assessment is to provide information on the current condition of an operation system (i.e., its degradation state). Parameters corresponding to degradations can be detected through collected data, but the states of system are usually difficult to observe directly. The most common indicator of a proved failure state is the production of out-of-specification products. System's health assessment thus implies the integration of methodologies to extract from the original set of data relevant indicators of a system's critical characteristics. The availability of many different data types throughout a manufacturing process allows the development of several types of indicators, with the combination of multiple data-driven methods.

PHM is a technology to enhance effective reliability and availability of a product in its lifecycle conditions by detection of current and approaching failures by providing for mitigation of the system risks and is a maintenance policy aimed at predicting the occurrence of a failure in components and consequently minimizing unexpected downtimes of complex systems and have been studied by many researchers from many different engineering fields to increase system reliability, availability, safety, and to reduce the maintenance cost of engineering assets. Many works conducted in PHM research concentrate on designing robust and accurate models to assess the health state of components for applications to support decision-making. Prior knowledge to implement PHM in complex systems is crucial to building highly reliable systems. PHM implementation steps consist of:

- critical component analysis,
- appropriate sensor selection for condition monitoring (CM),
- prognostics feature evaluation under data analysis, and
- prognostics methodology and tool evaluation matrices.

PHM systems are some of the main protagonists of the Industry 4.0 revolution (Biggio and Kastanis [18]). Efficiently detecting whether an industrial component has deviated from its normal operating condition or predicting when a fault will occur is the main challenge these systems aim at addressing. Furthermore, they could potentially and drastically reduce the often-conspicuous costs associated with scheduled maintenance operations. The increasing availability of data and the stunning progress of machine

learning (ML) and deep learning (DL) techniques over the last decade represent two strong motivating factors for the development of data-driven PHM systems.

PHM is an engineering field whose goal is to provide users with a thorough analysis of the health condition of a system and its components [12]. To this extent, PHM employs tools from data science, statistics, and physics in order to detect an eventual fault (anomaly detection) in the system, classify it according to its specific type (diagnostic), and forecast how long a system, e.g., machine, will be able to work in presence of this fault (prognostic) (Kadry [19]).

1.10.1 Health Indicators in Prognostic Health Management: Critical-to-Quality (CTQ) and Critical-to-Reliability (CTR)

In PHM, health indicators play a crucial role in predicting and mitigating potential failures and ensuring the reliability and quality of products throughout their lifecycle. Among these health indicators, CTQ and CTR parameters are paramount. Identifying and selecting these parameters are best achieved through RdfR, ensuring that products not only meet quality standards but also perform reliably under various conditions.

1.10.2 Critical-to-Quality (CTQ) Parameters

CTQ parameters are essential attributes that directly affect the quality of a product as perceived by customers. These parameters are derived from customer requirements and specifications and are critical for ensuring that the product meets or exceeds customer expectations. CTQ parameters can include factors such as performance, durability, aesthetics, and user-friendliness.

Significance of CTQ Parameters

- **Customer Satisfaction:** Ensuring that CTQ parameters are met is crucial for customer satisfaction and retention.
- **Market Competitiveness:** High-quality products that meet CTQ standards are more competitive in the market.
- **Brand Reputation:** Consistently meeting CTQ standards enhances brand reputation and trust.
- **Regulatory Compliance:** Adhering to CTQ parameters ensures compliance with industry standards and regulations.

1.10.3 Critical-to-Reliability (CTR) Parameters

CTR parameters are attributes that are essential for the reliable performance of a product over its expected lifespan. These parameters focus on the product's ability to function under various conditions without failure. CTR parameters include factors such as mechanical integrity, thermal stability, and resistance to wear and tear.

Significance of CTR Parameters

- **Product Longevity:** Ensuring that CTR parameters are met increases the lifespan of the product.
- **Operational Safety:** Reliable products reduce the risk of failures that could lead to safety hazards.

- **Maintenance Costs:** Products that meet CTR standards require less maintenance and have lower lifecycle costs.
- **Customer Trust:** Reliable products build customer trust and loyalty, leading to repeat business.

1.10.4 Identification and Selection of CTQ and CTR Parameters

The identification and selection of CTQ and CTR parameters are critical steps in ensuring product quality and reliability. These steps are best achieved through RDR, a methodology that emphasizes designing products to perform reliably under various conditions.

1.10.4.1 Robust Design for Reliability (RDR)

RDR involves designing products that can withstand a wide range of operating conditions and variations. It focuses on minimizing the impact of variability on product performance, ensuring that critical parameters are consistently met. RDR incorporates principles from robust design and reliability engineering to achieve these goals.

Steps in Identifying and Selecting CTQ and CTR Parameters

- **VoC Analysis:** Collect and analyze customer feedback to identify key quality and reliability requirements.
- **Requirement Clarification:** Define clear and measurable requirements for CTQ and CTR parameters based on customer needs and industry standards.
- **Risk Assessment:** Conduct risk assessments to identify potential failure modes and their impact on CTQ and CTR parameters.
- **Statistical Analysis:** Use statistical methods to analyze data and identify critical parameters that significantly affect quality and reliability.
- **Design of Experiments (DOE):** Conduct experiments to test the impact of various factors on CTQ and CTR parameters and identify optimal design solutions.
- **Simulation and Modeling:** Use simulation tools to model product performance and predict the impact of variability on CTQ and CTR parameters.
- **Validation and Testing:** Validate the identified CTQ and CTR parameters through rigorous testing and real-world trials.

1.10.5 Health Indicators in Prognostics and Health Management

In PHM, health indicators, including CTQ and CTR parameters, are used to assess the health of a product and predict potential failures. By continuously monitoring these indicators, PHM systems can provide early warnings of potential issues, allowing for proactive maintenance and risk mitigation.

Implementation of Health Indicators in PHM

- **Sensor Integration:** Integrate sensors to continuously monitor CTQ and CTR parameters in real time.
- **Data Analytics:** Use advanced data analytics to process sensor data and identify trends and anomalies.
- **Predictive Modeling:** Develop predictive models to forecast potential failures based on health indicators.

- **Maintenance Scheduling:** Use predictive insights to schedule maintenance activities and prevent unexpected failures.
- **Feedback Loop:** Create a feedback loop to update design and manufacturing processes based on insights from PHM systems.

The identification and selection of CTQ and CTR parameters are crucial for ensuring the quality and reliability of products. RDR provides a structured approach to identify and manage these critical parameters, ensuring that products perform consistently under various conditions. Integrating these parameters as health indicators in PHM systems allows for proactive maintenance and risk mitigation, enhancing product lifecycle safety and reliability. By continuously monitoring and managing CTQ and CTR parameters, organizations can achieve higher customer satisfaction, operational efficiency, and competitive advantage in the market.

Digitalization is a fundamental driver of Industry 4.0 and Supply Chain 4.0, a novel paradigm which enhances production efficiency through information and communication technologies. These technologies also provide the foundation for Predictive PM for industrial components and systems, whereby CM data is employed to perform three tasks:

- 1) Detection of abnormal states, by identifying deviations from normal operating conditions in production processes, manufacturing equipment, and products.
- 2) Diagnostics, by classifying abnormal states.
- 3) Prognostics, by predicting the evolution of abnormal states up to failure.

In response to the emerging challenges as well as opportunities, taking advantage of robust design, as we discussed in this chapter on reliability earlier, to identify key product characteristics or system health characteristics or health indicator and determine appropriate PHM based on the findings from risk assessment, e.g., design failure mode and effect analysis (DFMEA), we provide an approach with best practices in this book to bridge the gaps, which may be leading to further improvement of lifecycle reliability through robustness development and PHM.

1.11 The Importance of Digital Quality in Lifecycle Reliability Through Robustness Development and Predictive Health Management

Digital quality is a transformative approach that leverages advanced digital technologies to enhance the reliability of products throughout their entire lifecycle. Integrating digital quality with robustness development and PHM ensures that products are not only designed for robustness but also maintained at optimal performance levels throughout their lifespan.

This comprehensive strategy significantly enhances lifecycle reliability, reduces downtime, and improves overall product performance and customer satisfaction.

1.12 Digital Quality in Lifecycle Reliability

Digital quality refers to the use of digital tools, technologies, and processes to ensure that products meet high standards of quality and reliability throughout their lifecycle.

This involves a combination of advanced analytics, simulation and modeling, real-time monitoring, and data-driven decision-making to enhance product robustness and reliability.

Advanced Data Analytics

- Implement big data analytics to identify patterns and predict potential reliability issues across the entire product lifecycle.
- Use ML algorithms to optimize not just design and manufacturing, but also operational performance and maintenance schedules.
- Develop real-time monitoring systems that track product performance from production through end of life.

Digital Twin Technology

- Create digital twins that evolve with the product, from design through disposal.
- Use digital twins for predictive maintenance, reliability optimization, and lifecycle management.
- Integrate digital twin data with product lifecycle management systems for a holistic view of product performance.

IoT and Connected Products

- Implement Internet of Things (IoT) technologies to gather real-time data on product performance throughout its operational life.
- Use connected product data to inform not just future design improvements, but also current product maintenance and upgrades.
- Develop PHM capabilities based on comprehensive IoT data.

Blockchain for Quality Assurance

- Implement blockchain technology for secure and transparent quality records across the entire product lifecycle.
- Use smart contracts to automate quality control processes from production through maintenance and disposal.
- Ensure the integrity and traceability of quality-related data throughout the product's life, including maintenance and repair records.

1.12.1 Robustness Development

Robustness development focuses on designing products that can perform reliably under a wide range of conditions and stresses. It involves identifying potential failure modes and implementing design strategies to mitigate these risks.

Advanced Simulation and Modeling

- Computer-aided Design (CAD) and Engineering (CAE): Utilize CAD and CAE tools to create detailed digital models of products. These models are used to simulate different operating conditions and identify potential failure points.

- **Finite Element Analysis (FEA):** Apply FEA to analyze the physical behavior of products under various loads and stresses. This helps in optimizing the design for robustness.
- **Multi-physics Simulations:** Implement multi-physics simulations to understand complex interactions within products as they age and undergo maintenance.

Failure Mode and Effects Analysis (FMEA)

- **Systematic Risk Assessment:** Conduct FMEA to identify potential failure modes, their causes, and their effects on the system. This allows for proactive design modifications to enhance robustness.
- **Mitigation Strategies:** Develop and implement mitigation strategies based on FMEA findings to address identified risks.
- **Digital FMEA:** Implement digital FMEA tools that can be updated in real time based on field data and performance insights.

Robust Design Techniques

- **Robust Design for Reliability (RDfR):** Incorporate RDfR principles to ensure that products are designed based on robust design principles with reliability as a key objective.
- **Tolerance Design:** Implement tolerance design to ensure that product components fit and function together reliably, even with variations in manufacturing processes.
- **Design for Manufacturability and Assembly (DFMA):** Integrate DFMA principles to ensure that products are not only robust but also easy to manufacture and assemble consistently.

Augmented and Virtual Reality in Design

- Use AR/VR technologies for virtual prototyping, design reviews, and maintenance planning.
- Implement AR-assisted assembly, maintenance, and repair processes.
- Develop VR training programs for quality control, maintenance, and end-of-life procedures.

1.13 Predictive Health Management (PHM)

PHM is a proactive approach that uses real-time data, advanced analytics, and ML to monitor and predict the health of products and systems. This allows for timely maintenance and repairs, reducing downtime, and extending the product's operational life.

Real-Time Monitoring and Data Collection

- **IoT Sensors:** Deploy IoT sensors to continuously monitor the condition of products and collect real-time data on various parameters such as temperature, vibration, and load.
- **Data Logging:** Implement data-logging systems to store and manage the collected data for further analysis.
- **Edge Computing:** Implement edge-computing solutions for real-time data processing and rapid response to potential health issues.

Advanced Analytics and Machine Learning

- **Predictive Analytics:** Use predictive analytics to analyze historical and real-time data to predict potential failures and maintenance needs. This helps in scheduling preventive maintenance before issues arise.
- **Machine Learning Algorithms:** Develop ML models to identify patterns and trends in the data that indicate potential reliability issues. These models improve over time with more data and usage.
- **Digital Twin Integration:** Use digital twins to compare actual product performance with expected behavior and predict future performance.

Condition-based Maintenance (CBM)

- **Dynamic Maintenance Schedules:** Implement CBM to adjust maintenance schedules based on the actual condition and performance of products rather than fixed intervals. This ensures maintenance is performed only when needed, reducing unnecessary downtime and costs.
- **Proactive Repairs:** Conduct proactive repairs and replacements based on predictive insights to prevent unexpected failures.
- **Automated Maintenance Workflows:** Develop automated systems that trigger maintenance workflows based on PHM insights, ensuring timely and efficient maintenance actions.

Cybersecurity in PHM

- **Integrate cybersecurity considerations** into the PHM process from design through disposal.
- **Implement secure-by-design principles** in connected products that remain robust throughout the product's life.
- **Develop processes for ongoing security updates and vulnerability management** throughout the product's operational life.

1.13.1 Integration of Digital Quality, Robustness Development, and PHM

Lifecycle Reliability Management

- **Holistic Approach:** Integrate digital quality, robustness development, and PHM into a holistic lifecycle reliability management strategy. This ensures that reliability is considered from the initial design phase through to end-of-life disposal.
- **Continuous Improvement:** Implement continuous improvement processes to regularly review and enhance reliability strategies based on feedback and new data.
- **Adaptive Design Processes:** Develop design processes that can quickly incorporate insights from PHM and field data to enhance product robustness in future iterations.

Collaborative Platforms

- **Integrated Digital Platforms:** Use integrated digital platforms to facilitate collaboration between design, engineering, manufacturing, and maintenance teams. This ensures that all stakeholders have access to the latest data and insights.

- **Cloud-based Solutions:** Leverage cloud-based solutions to store and share data across the organization, enhancing accessibility and collaboration.
- **Cross-functional Data Analytics:** Implement analytics tools that can process and analyze data from various sources (design, manufacturing, field use) to provide comprehensive reliability insights.

Customer Feedback and Insights

- **User Data Analysis:** Collect and analyze user data to gain insights into how products are used in real-world conditions. This helps in identifying areas for improvement and enhancing future designs.
- **Customer Engagement:** Engage with customers to gather feedback and address reliability issues promptly. This fosters customer satisfaction and loyalty.
- **Predictive Customer Support:** Use PHM insights to proactively engage with customers before issues arise, offering preventive maintenance or upgrades.

Supply Chain Integration

- **Extend RfDR principles** to suppliers and manufacturing partners to ensure robustness throughout the supply chain.
- **Implement blockchain technology** for supply chain transparency and traceability.
- **Develop collaborative PHM strategies** that include key suppliers and partners.

By implementing this comprehensive approach to digital quality, robustness development, and PHM, organizations can significantly enhance the lifecycle reliability of their products. This integrated strategy not only improves initial product quality and reliability but also provides valuable insights for continuous improvement, innovation, and effective health management throughout the product's lifecycle. The result is improved product performance, reduced downtime, significant cost savings, and higher customer satisfaction, ultimately leading to a stronger competitive position in the market.

1.14 Critical Parameter Development and Management (CPD&M): A Comprehensive Overview

Critical parameter development and management (CPD&M) is a systematic approach to product development and lifecycle management. It is a cornerstone of modern systems engineering, focusing on identifying, analyzing, and managing the most crucial parameters that govern the functionality, performance, and reliability of engineered systems. CPD&M is not just a development tool; it is a comprehensive strategy that spans the entire product lifecycle, from initial concept to post-launch management and even end-of-life considerations.

Fundamental Concepts of CPD&M

- 1) **Definition and Scope:** CPD&M is a structured process that identifies and manages parameters critical to a product's performance, reliability, and quality. These parameters, known as critical parameters, are those that pose significant risks during

development, manufacturing, packaging, maintenance, and throughout the product's lifecycle.

- 2) **Cross-functional Collaboration:** At its core, CPD&M is a collaborative effort involving diverse teams of engineers and technical specialists. This cross-functional approach ensures a holistic view of the product, considering all aspects from design to manufacturing and beyond.
- 3) **Lifecycle Management:** CPD&M extends beyond the development phase, encompassing the entire product lifecycle. This comprehensive approach ensures that critical parameters are managed effectively from conception to end-of-life, maximizing product performance and reliability.

1.14.1 The CPD&M Process

1.14.1.1 Initial Parameter Identification

The process begins with a comprehensive analysis of all design parameters. From this extensive set, the team identifies those parameters that pose the highest risk to product performance—these are designated as critical parameters.

1.14.1.2 The Seven Metrics

When a parameter is suspected to be critical, it undergoes rigorous evaluation based on the following seven metrics:

- **Measurability:** Assessing how accurately and consistently both input (X) and output (Y) variables can be measured.
- **Stability:** Evaluating the consistency of Y and controlling X variables over time.
- **Adjustability:** Examining how effectively Y can be adjusted by manipulating specific X variables across desired performance ranges.
- **Independence, Interactivity, and Statistical Significance:** Analyzing how X variables interact and their individual and combined effects on Y variables.
- **Hyper-sensitivity:** Measuring the degree of responsiveness between Y variables and their controlling X variables under nominal conditions.
- **Robustness:** Assessing how well Y variables maintain performance in the face of unwanted variations, particularly under stressful conditions.
- **Capability (Cp and Cpk):** Evaluating the process capability under both nominal and stressful conditions.

1.14.2 Continuous Improvement

Parameters that fail to meet all seven metrics satisfactorily are designated as critical and managed meticulously. The goal is to improve their performance, understand their context within the design, and potentially remove them from the critical list.

Applications of CPD&M

Proactive Development

- CPD&M can be applied proactively during technology and product/process development, ensuring that critical parameters are identified and managed from the earliest stages of design.

Reactive Management

- In post-launch scenarios, CPD&M can be used to optimize production processes and manage the product throughout its lifecycle.

Reverse Engineering

- CPD&M can be employed to back-derive an existing design's governing parameters, isolating critical parameters for cost reduction and lifecycle management decisions.

Integration with Other Methodologies**Prognostics and Health Management (PHM)**

- Critical parameters identified through CPD&M serve as key health indicators in PHM systems, enabling predictive maintenance and risk management strategies.

Digital Quality Implementation

- CPD&M integrates seamlessly with digital quality methods, leveraging real-time data analytics for continuous monitoring and adjustment of critical parameters.

Robust Design for Reliability (RDfR)

- CPD&M supports RDfR by identifying the parameters most crucial to product reliability, enabling the design of more resilient products.

The 12-Step CPD&M Process

- The 12-step CPD&M process will be explained in detail in Chapter 4.

Benefits and Challenges of CPD&M**Benefits**

- Enhanced product reliability and performance.
- Reduced development and lifecycle costs.
- Improved understanding of product behavior.
- More effective risk management.
- Enhanced ability to meet regulatory requirements.

Challenges

- Requires significant resources and expertise.
- Can be time consuming, especially in complex systems.
- Necessitates a cultural shift toward data-driven decision-making.
- May require substantial investment in measurement and analysis tools.

CPD&M is a powerful and comprehensive approach to product development and lifecycle management. By meticulously identifying, analyzing, and managing critical parameters, organizations can create products that are not only high performing and reliable but also cost effective throughout their lifecycle.

The integration of CPD&M with other methodologies like PHM, digital quality implementation, and RdFR further enhances its effectiveness, providing a robust framework for engineering excellence.

As products become increasingly complex and operate in evermore demanding environments, the importance of CPD&M will only grow. Organizations that master this approach will be well positioned to lead in their respective industries, delivering products that consistently meet and exceed customer expectations while maintaining a competitive edge in the global marketplace.

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