Exploring Medical Device Reliability and Its Relationship to Safety and Effectiveness

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***Abstract*—It may seem intuitive that reliability is essential for modern products that need to be safe and effective, particularly healthcare and medical devices. One would expect to find reliability cited in regulations, engineering articles, and consensus standards. Yet typical industrial processes in which high reliability is needed often do not explicitly provide evidence to support a safety and effectiveness (S&E) argument. The lack of a consistent and standardized framework for achieving reliability that is tied explicitly to safety and effectiveness undermines S&E evaluation. Regulators and manufacturers who are unable to take full advantage of the information generated by the reliability engineering processes fail to maximize product S&E. This paper explores a reliability engineering framework to provide the arguments, claims, and evidence important to product S&E, and the artifacts suitable for integrating reliability into S&E assessments.**

***Index Terms*—medical device, reliability, safety, effectiveness, design for reliability.**

I. What is Reliability?

The objective of any system or device is the performance of intended function or functions from the perspective of the patient/customer as well as other relevant groups, including regulators and manufacturers. The term often used to describe the overall capability of a system to accomplish its mission is "system effectiveness". ***Effectiveness*** [E] is influenced by all life cycle activities, including research, design, manufacturing, use, and disposal of the product. Thus, the effectiveness of a system is a function of all the attributes of the system, such as design adequacy, performance measures, safety, reliability, manufacturability, maintainability, and sustainability. Reliability [R] and safety [S] are major attributes determining effectiveness [E], and we present their relationships and interdependencies in this paper.

According to the Institute of Electrical and Electronic Engineers (IEEE), "Reliability is the ability of a system or component to perform its required functions under stated conditions for a specified period of time." This ability is often quantified in terms of probability. In lay terms, ***reliability*** is synonymous with ***dependability***, and even dictionaries define reliability in terms of dependability. But the term ***reliability*** is much more narrowly defined within the systems engineering community. The International Electromechnical Commission (IEC) defines dependability as "availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance" [2]. This definition introduces a new term: ***availability***. Availability is the degree to which a component or system is operational and accessible when required for use, and, like ***reliability***, is often expressed as a percentage or a probability. A system has many qualities and characteristics. Reliability is sometimes called a "time-oriented" quality because it concerns the future function and performance of the product. Thus, reliability, like any other quality, must be defined and evaluated by the customer and must capture the total experience of the customer with the system or product [1].

Maintainability is another system design parameter that has an impact on the effectiveness of a system. Failures will occur no matter how reliable a system is. A system's ability to be maintained, that is, retained in or restored to an effective usable condition, is important to system effectiveness. Maintainability is a characteristic of system design, as is reliability. ***Availability*** measures the reliability and maintainability of a system in terms of a combined index and relates this measure to effectiveness. Availability is based on the question, "Is the system available in a working condition when it is needed?"

Reliability as a time-oriented quality or characteristic is concerned with "time to failure," which is a random variable. There are many life distributions that are used to model the "time to failure" random variable [1], [3]. We develop measures for reliability using various characteristics of these distributions, such as mean, variance, percentiles of life, and failure or hazard rate. Historically, reliability has often been expressed as the mean time between failures (MTBF) and maintainability as the mean time to repair (MTTR). Availability represents the fraction of time that a system is in a functioning condition. Thus, the inherent availability is obtained by dividing MTBF by $(\mathrm{MTBF} + \mathrm{MTTR})$. Availability measures can be generalized to consider all the elements of time associated with the life of a system, such as storage, standby, logistics, and administrative support, in addition to corrective and preventive maintenance time.

Very early on, the engineering profession realized that MTBF is not always the most useful measure of system reliability. For example, for many single-use devices such as syringes, the mission life may be measured in seconds (or less!). A better definition of reliability for such systems is the likelihood (or probability) that the system will correctly perform the intended function when needed under stated conditions. MTBF is the first moment of the life distribution and it does not capture issues with the variability or the cumulative experience of the customer with the system, both of which are important for effectiveness.

Similarly, many systems, and particularly those systems that implement safety functions, exist for most of their life in standby mode, and are called into service only occasionally-typically upon the failure of a primary system. As an example, an uninterruptible power supply with standby systems the system has to "ready" to serve if called upon, and it may even incorporate monitoring functions to enable it to self-activate when needed. After activation, the system must continue to perform for as long as needed.

Another limitation of MTBF as a measure of system reliability is that many systems today are so reliable that failures occur only in the most unusual-and often unforeseeable-circumstances. Statistical tools are of limited use in predicting such failures or in providing any insight into system performance. For that reason, the reliability engineering community has largely disavowed the failure prediction methodology in favor of the so-called physics-of-failure (or chemistry/biology of failure) approach, which focuses on systematic elimination of failure points and contributory factors no matter how frequently or infrequently they may lead to failures.

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Another example of the limitation of MTBF can be found in the domain of software reliability. For large commercial software applications, one can measure how often failures of different types arise in the use of the product. Such information may be very useful in making prudent business decisions concerning when a new product is fit for release and how many resources should be devoted to tech support and product remediation. However, when a software defect has the potential to cause injury or death, software reliability, as defined in this way, becomes meaningless.

The distinction is often made that hardware systems are subject to aging and wear, which are conducive to statistical analysis such as MTBF calculations. The argument is often made that software is not subject to aging and wear. All software failures are deterministic. The truth is that most hardware failures are deterministic as well. In fact, it can be argued that so-called "random failures," whether hardware or software, are simply those failures for which the root cause is not yet completely understood, and for which a mitigation strategy has not been identified. This really is the strongest motivation for the physics-of-failure approach.

II. Reliability as Expectation of User Needs

We have pointed out in section I that reliability must be defined and evaluated by the user and the customer. We use the word customer in a very broad sense. In systems thinking, anyone who the device or equipment affects or impacts is the customer. The concept of reliability *as an expectation of a clinical user's needs* is often insufficiently defined to convey to the design engineer how to develop design, manufacturing, and assembly specifications for a medical device. Reliability is most important in life-supporting/life-sustaining devices where failure cannot be tolerated. For non-life-supporting or sustaining devices, it is sufficient for the device to fail gracefully into a safe state or alert the user. The design engineer needs well-formulated design requirements regarding these types of behaviors to fully understand the intended clinical use. These behaviors drive the establishment of appropriate functional, safety, and use requirements, alternatively called behavioral, interface, and performance requirements. These lead to the development of manufacturing specifications to build a reliable product, so that the product will achieve the desired performance for a specified period of time in a defined use environment. The clinician needs a device to perform an intended use safely and effectively; the engineer responds with a device that has a set of specifications governing its performance and reliability.

Consider the following scenarios:

- An anesthesiologist uses a pulse oximeter during surgery to monitor the physiologic status of the patient and expects the readings to be reliable in order to provide safe and effective care.
- An orthopedic surgeon implants a hip prosthesis in an elderly patient and expects the device to withstand the stress loads reliably for 10 years to restore normal mobility safely and effectively.
- An emergency room physician moves monitors around the ER, constantly bumping the monitors into stationary objects, dropping them on concrete floors, and spraying them with liquids-and needs the devices to function reliably during procedures to diagnose clinical events safely and effectively.
- An electro-physiologist has an expectation that the leads implanted for a cardioverter-defibrillator will function for its intended lifetime.
- An emergency responder inserts a needle through clothing to inject life-saving drugs. The needle must reliably puncture both the outer clothing and the skin, but still remain patent to deliver the payload.

The previous examples touched upon a number of different interpretations of the word ***reliability***. When we use probability or characteristics of the underlying life distribution to measure reliability, it must be emphasized that reliability is a relative (conditional probability) measure of the performance of the system. It is relative to the following:

- definition of function from the viewpoint of the customer, user, or other elements of society;
- definition of failure or unsatisfactory performance from the viewpoint of the customer;
- definition of intended or specified life for the device;
- customer's operating and environmental conditions during different life-cycle phases.

Thus, reliability as a probability number changes with

- intended definition of function and is different for different functions for any system;
- usage and environmental conditions;
- actual or perceived definition of satisfactory performance from the viewpoint of the customer;
- time-because reliability is dynamic and the characteristics or behavior of the system changes with time due to inherent degradation processes built into the system.

An anesthesiologist expects the readings of a pulse oximeter to be reliable, in the sense that he or she needs to be able to rely (or depend) upon the readings. Reliability in this sense encompasses all aspects of a system's performance, including accuracy, environmental influences, and many other factors. Each of these scenarios has in common an expectation of reliable performance in a clinical setting, yet these clinical needs for reliability are often not well translated into engineering design requirements. The engineering process for achieving reliability must take into account the various clinical needs, wants, and desires to achieve a technologically and economically viable product that is safe and effective. Standards, systematic design processes, and regulatory oversight have evolved to achieve these objectives.

III. Reliability-Safety Space

The IEC in 60513:1994, Fundamental Aspects of Safety Standards for Medical Electrical Equipment, provides an engineering framework for assuring safety by considering both basic safety and essential performance as objectives of risk management. Basic ***safety*** [definition 2.1] is defined as freedom from conditions and circumstances that may cause direct physical harm, such as electric shock, fire, or burns. Essential performance relates to the risk generated when a device does not perform properly [definition 2.4] and is dependent on the individual situation in which a device is used properly, misused, or abused. The IEC standards for the safety of electromedical devices (IEC 60601 family) define requirements to achieve basic safety and essential performance. IEC 60601, 3rd ed., addresses reliability by stating that "reliability of functioning is regarded as a safety issue (for life-supporting equipment) and where interruption of an examination or treatment is considered as a hazard for the patient."

FDA regulations (§ 860.7 (d)(1)) approach safety and effectiveness from a clinical perspective by stating, "There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks." Effectiveness (§ 860.7 (e)(1)) is defined thus: "There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results." The regulations (§ 860.7 (b)) go on to identify four relevant

factors that should be considered when assessing S&E: "(1) The persons for whose use the device is represented or intended; (2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use; (3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and (4) The reliability of the device."

We can define safety as "the ability of a system or device to perform its required functions under stated conditions for a specified period of time without causing death, injury, occupational illness, damage or loss of equipment or property or damage to the environment." As with reliability, we can quantify ability using probability measures and use terms and as mean time between mishaps or accidents with all the limitations mentioned for MTBF.

Safety, like reliability, is a characteristic of design and must be incorporated in the system at the design stage. The system must be designed for safety. ***System safety*** is a standardized engineering and management discipline that integrates the consideration of man, machine, and the environment in planning, designing, testing, operating, and maintaining systems to achieve acceptable risk within the constraints of operational effectiveness and suitability, time, and cost throughout all phases of the system life cycle. To improve safety, we have to understand hazards, which are defined as any real or potential conditions that can cause injury, illness, or death to personnel; damage to or loss of a system, equipment, or property; or damage to the environment. A hazard is an existing potential condition that will result in a mishap when actualized. Like failures in reliability, hazards are a unique characteristic/entity of the system that can be recognized and described and that present potential mishap risks. A hazard description contains three elements: 1) A source, an activity or a condition that serves as the root; 2) The mechanism, a means by which the source can create or result in the mishap or harm; and 3) an outcome, the mishap or harm that results [4]. We use the word hazard when we talk about hazard rate for safety assessment, which is analogous to failure rate for reliability. This also shows the interface between safety and reliability, because failure rate and hazard rate are sometimes used interchangeably. Most hazards and safety risks can be neutralized or controlled and mitigated. It is very important to establish clear objectives, parameters, and methods for risk assessment and management, and integrate them into reliability, safety, and effectiveness. Many of the design for reliability paradigms can be applied for safety, and we can use the synergy by considering reliability and safety in the same space. Safety, just like reliability, is considered and assessed for hardware, software/firmware, and the human element.

Most of the frameworks in FDA regulations specify that reliability should be considered but do not explicitly define what is expected, leaving the design engineer with possibly confusing directions and definitions. The following section uses the activities of the engineering paradigm called "design for reliability" to explore related standards and FDA activities from the perspective of reliability. The goal is to show that the frameworks have similar characteristics and objectives. Thus, leveraging evidence from one framework may benefit the others.

IV. The Design for Reliability Paradigm

Reliability is an inherent attribute of a system resulting from research, concept, and design, just as is the system's capacity, performance, or power rating. The reliability level is established and incorporated at the design phase, and subsequent testing and production will not raise the reliability without a basic design change. Reliability improvement or growth results from design change-based causation established by development testing or experimentation. Reliability can be an abstract concept that is difficult to grasp and measure, and many organizations may find themselves unable to implement a comprehensive reliability program primarily because of the lack of understanding on the part of both management and technical system design personnel. This is not to say that the system designers or managers in the organization are not interested in a reliable product, but rather the pressures on the design engineer, and very often on the organizational structure, impede and slow the development of an effective reliability program. Design reliability methods should be integrated with the methods for assuring safety and effectiveness (S&E).

TABLE I
Design for Reliability Elements

	DESIGN for RELIABILITY (DfR) ELEMENTS
1	Define realistic product requirements and constraints
2	Define the product life-cycle environment
3	Select components that have the requisite level of quality
4	Identify potential failure modes, sites, and mechanisms
5	Design to the usage and process capability of the product
6	Verify the reliability of the product in the expected environment
7	All manufacturing and assembly processes must have requisite capability
8	Use closed-loop management for product life-cycle usage

With increasing system complexity and limited understanding of the users' requirements and use conditions, reliability becomes an elusive and difficult design parameter. It becomes more difficult not only to define and achieve as a design parameter, but also to control and demonstrate in production and thus to ensure as an operational characteristic under the projected environmental conditions of use. However, past history has demonstrated that, where reliability is recognized as a necessary and important program development component-and with the practice and implementation of various reliability engineering methods throughout the evolutionary life cycle of the system-reliability can be quantified during the specification of design requirements, can be predicted by testing, can be controlled during production, and can be sustained in the field. We also believe that all of these activities have a strong impact on S&E.

We have chosen a reliability paradigm, design for reliability (DfR) [3], [5], as a mechanism for analyzing activities and comparing the results with FDA's evaluations to assure safety and effectiveness. The DfR paradigm (see Table I) considers reliability to be the ability of a product to properly function within the specified performance limits for a specified period of time under defined life-cycle application conditions. Manufacturers have internal processes meant to ensure safety and effectiveness and may manage product reliability within these processes or separately. Below we discuss each of these DfR elements individually in relation to safety and effectiveness, FDA regulations, and consensus standards.

DfR 1. Define realistic product requirements and constraints determined by factors such as the life-cycle application profile, required operating and storage life, performance expectations, size, weight, and cost. The product requirements should be based on both the customer's needs and the manufacture's capability to meet those needs.

The output of the Design Input Process (as specified by the Quality System Regulations) are a subset of the customer's needs (basic needs), wants (performance needs), and desires. This subset is determined by the manufacturer's economic and technological capabilities.

The way to get good product requirements from your design input process is to have a robust design [6] and development process, which requires a robust design and development plan. CDRH expects accurate and complete product requirements, because a device whose intended use is not understood clearly (and hence captured in its requirements documents) is not likely to be designed and manufactured safely. CDRH uses premarket review to assess the S&E of designs, where the focus is on product requirements and design decisions, and uses the

Quality System Regulation to assure that there is a robust process that yields a product with the intended requirements reaching the market [21 CFR 820.30 b&c; ISO 13485:2003 §7.2.1 & 7.3.2].

The anesthesiologist wants the pulse oximeter to report saturation values with a minimal amount of signal dropout regardless of how much the patient moves (a common source of error in oximeters). Without reliable (e.g., accurate and uninterrupted) monitoring throughout the physiologic event, a rapid decline in physiologic status might not be detected early enough to take effective countermeasures. This clinical need translates to engineering requirements for the performance of the signal acquisition and processing systems, e.g., movement artifact rejection.

DfR 2. Define the product life-cycle environment by specifying all relevant manufacturing, assembly, storage, handling, shipping, operating, maintenance, and disposal conditions for the fielded product.

The expectations for these seven items are specified in detail in the Quality System Regulation (21 CFR 820). CDRH also seeks to determine if the manufacturer has captured the important aspects of the product life-cycle environment prior to release of the device and during periodic inspections [21 CFR 820.30 b&c; ISO 13485:2003 §7.2.1 & 7.3.2]. CDRH is concerned with who will use the device (e.g., general users, expert clinicians) and whether it can be used safely in its intended use environment (e.g., home, hospital, transport). CDRH assesses the adequacy of product labeling with respect to training and operation. CDRH is concerned that the manufacturer has given consideration to shipping, maintenance, and disposal activities during design development. These considerations are often better evaluated with an inspection than with a paper review, but they are part of the production process that needs to be evaluated to assure quality and robustness of the product.

The ER scenario, where a product operates in a physically and electromagnetically challenging environment, necessitates requirements for the ability of the circuit boards, assemblies, and cases to withstand shock and vibration and prevent the ingress of fluids. The clinical needs and operational environment establish the product design and manufacturing requirements.

DfR 3. Select the parts (materials) that have sufficient quality and are capable of delivering the expected performance and reliability in the application. The materials and parts must be characterized. Variability in material properties and manufacturing processes may induce failures. Knowledge of the variability is required to assess the design margins.

Those things that may induce failures are safety and effectiveness issues. Where the design variability in material properties and manufacturing processes impacts the safety of devices, FDA is concerned [21 CFR 820.30 d; ISO 13485:2003 §7.3.3]. FDA regulations direct that acceptance criteria be established for the performance of incoming parts [21 CFR 820.80] to make sure the finished device conforms to design outputs. For example, FDA expends considerable effort in assuring that the sterility of a product's packaging is appropriately set and maintained, which involves both product and process evaluation. Sterile packaging must undergo sufficient testing to assure that it maintains its integrity over the life of the product.

Consider an infusion pump with an air leak due to a leaky seal that causes the dose delivered to be inaccurate, leading to a loss of effectiveness and unsafe conditions. The design should have taken into account the reliability of the components to assure that adequate performance could be achieved and maintained. Alternatively, consider the same pump with a reliable seal that may deliver an electric shock to a user due to an insulation failure in the power supply. This unsafe condition can cause physical harm, and hence the pump would be unreliable from an electrical safety perspective even though it may effectively deliver the correct amount of the drug in the specified time.

DfR 4. Identify the potential failure modes, failure sites, and failure mechanisms by which the product may be expected to fail.

The process of design validation is a powerful mechanism for identifying device failures under conditions of expected use, unexpected use, misuse, and abuse. CDRH focuses on finished device failure but pays attention to design components when failure of those components can be linked to potential injury. CDRH is concerned at both the premarket and postmarket stage with the quality of the risk analysis and the failures that could potentially impact safety and effectiveness [21 CFR 820.30 g; ISO 13485:2003 §7.1; ISO 14971:2007].

For the orthopedic case, the hip implant must have sufficient strength and fatigue resistance properties to support the loads during expected use, unexpected use, misuse, and abuse, leading to material property requirements based on an average person's weight, height, and level of physical activity. Can the clinician know exactly the maximum stresses the device will undergo in expected use, unexpected use, misuse, and abuse? What activity will lead to cracks in the implant or wear in the joint? What if the patient is in an automobile accident and experiences a severe impact beyond everyday levels? The design outputs will result in a tradeoff between form, fit, function, and cost.

DfR 5. Design to the usage and process capability of the product (i.e., the quality level that can be controlled in manufacturing and assembly), considering the potential failure modes, failure sites, and failure mechanisms. The designed product must satisfy the manufacturability, quality, reliability, and budget requirements and constraints and be available to the customers in a timely manner.

CDRH is concerned with assuring that the manufacturer has adequately captured the usage environment, properly formulated the usage environment design requirements, and has the manufacturing processes under sufficient control to assure quality [21 CFR 820.70, 820.75; ISO 13485:2003 §7.5]. How these assurances are achieved is not explicitly stated. Manufacturers can choose the tools and processes that best achieve their specific purposes.

The electro-physiologist must discern between failures due to the reliability of the different leads (pace-sense or high-voltage conductors), potential insulation breaks, or attachment mechanisms. The risk posed by each is different: some lead failures may require surgery to correct, whereas others can be left in place; some lead failures are due to the attachment point coming loose; some attachments come loose because of a lead failure [see Transvenous Implantable Cardioverter-Defibrillator Leads: The Weakest Link, William H. Maisel, MD, MPHCirculation. 2007;115:2461–2463].

DfR 6. Qualifications should be conducted to verify the reliability of the product in the expected life-cycle conditions. Qualification tests should provide an understanding of the influence of process variations on product reliability. The goal of this DfR step is to provide a physics-of-failure basis for design decisions, with an assessment of all possible failure mechanisms for the anticipated product. If all the processes are in control and the design is valid, then further product testing is not warranted and is not cost effective. If there are reasons for uncertainty, testing may be necessary, such as for replacement parts qualification due to the Reduction of Hazardous Substances directives.

FDA requires product performance to be verified (conformance to its specifications) [21 CFR 820.30 f; ISO 13485:2003 §7.3.5; ISO 14971:2007 §6.3] and validated (conformance to user needs and requirements) [21 CFR 820.30 g; ISO 13485:2003 §7.3.6]. Where qualification produces evidence that a component or system is adequate for its intended use and provides a rationale to tie the evidence to the claim, FDA uses this to support verification of product performance and safety assessment.

An X-ray machine is installed in an operating room environment using a scaffolding to support its weight as it is positioned over a patient. Qualification was performed by performing 100 imaging proce-

dures without moving the tube between uses. The tube is heavy and in actual clinical use, is moved frequently, causing the gantry to sag and eventually snap due to metal fatigue. The gantry was inadequately qualified to support the weight of the tube in its actual use environment.

DfR 7. All manufacturing and assembly processes must be capable of producing a product within the statistical process window required by the design. Therefore, characteristics of the process must be identified, measured, and monitored. Regardless of how well a product is designed, it cannot be reliable unless the variability in the manufacturing processes is controlled (not necessarily minimized). Each process may involve screens and tests to assess statistical process control.

FDA regulators exert oversight of the manufacturing process through the Quality System Regulation [21 CFR 820] or ISO 13485:2003]. This is accomplished through pre- and post-market inspections.

A particular *in vitro* diagnostic test relies on wicking a precise amount of urine past a spot of substrate to capture the analyte of interest and initiate a color change reaction proportional to the concentration of analyte. The speed that urine is wicked by paper used in an *in vitro* diagnostic pregnancy test kit is a critical parameter for whether the device works or not. Understanding and controlling the variability of the paper characteristics, the volume of substrate deposited, and the substrate spot diameter, are critical to producing a functioning test. If the paper manufacturer changes some aspect of the paper, but continues to market it under the existing product, this may cause the test to stop working because it can have a different wicking speed. If the new paper causes the drops deposited during the manufacturing process to spread out and dry too slowly, this may reduce the sensitivity of the test.

DfR 8. Manufacturers must manage the life-cycle usage of the product using closed-loop management procedures. This includes realistic inspection and maintenance procedures.

CDRH expects a manufacturer to monitor and control its quality system processes [21 CFR 820]. FDA requires reports on product failures (MDRs and Medwatch) that impact S&E, and FDA manages the recall process when these devices are found to be unsafe.

Consider a monitoring system with requirements that state the device is to detect premature labor based on monitoring maternal contractions. After the product is on the market and in more general use, it is discovered that the effectiveness of the device is due to the nurse calling every other day and is not due to any measurements derived from the contractions. While the device performs as specified and is reliable in collecting the maternal contraction signal, it is unreliable as an indicator of preterm labor. The manufacturer is obligated to monitor the reliability and effectiveness of their device after it is placed on the market. When the clinical community understands the true performance of the device, the manufacturer has to update how their device is used to account for actual clinical practice.

V. Conclusion

Medical device manufacturers and FDA CDRH have a responsibility for assuring the safety and effectiveness (S&E) of medical devices. This paper shows that a key aspect of S&E is the assessment of reliability. While CDRH has pre- and post-arket activities to assess how well the manufacturer captures the design requirements, how well the manufacturer produces the device according to their internal specification, and how well the device performs in actual use, the FDA does not have a legal definition for reliability, nor does it have a required reliability assessment model. In addition, design for reliability methods, activities, and philosophies should be integrated with activities for safety and effectiveness management.

This paper has identified key reliability practices which can aid the FDA as well as manufacturers. The examples in the paper are meant to show both parties the value of reliability evidence in demonstrating S&E.

Future work will address where there are similarities, differences, and gaps between the reliability assessment processes of FDA and manufacturers. Addressing and understanding the root causes of these differences will be beneficial to both parties to avoid conflicts and enable both parties to achieve their S&E objectives. By aligning industry and FDA practices, medical device S&E will be improved, and resource utilization by both the manufacturer and the FDA should become more efficient. This paper is meant to begin the process of evaluating the activities and objectives of both industry and FDA.

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