A FORENSIC PURSUIT OF PROCESS LIABILITY

WILLIAM STIMSON

In an action under the U.S. False Claims Act, the evidence may indicate substantial damages derived from the defendant's operations. A forensic systems approach based on the concept of process liability may then be effective to determine the existence of dysfunctional processes and the consequent risk of defective product in large numbers. This approach combines the strengths of best business practices with systems theory and offers process liability as a basis for recovery.

There are some truths about systems—all systems—and they are available to us in our pursuit.

Introduction to Process Liability

To my knowledge, the theory of process liability was first defined by attorney Leonard A. Miller,[1] who reasoned that it was more efficient to go after a root cause than to pursue a multitude of effects. Focusing on industrial pollution, Miller argued that for every process a certain amount of pollutant is an integral part and is therefore a byproduct of the process. The performer is liable for the reasonably foreseeable results of the products. If pollution results in harm or injury, the performer is responsible and the process is at issue. Miller sees three ways in which the process of manufacturing could influence the outcome or resolution of a tort suit:

1. as an element in the balancing of the equities;
2. as a form of relief; and
3. as a new cause of action.

These uses of the process of manufacturing and any others that might be developed, are what Miller chooses to call "process liability." Process liability, under the applications of product liability, would not look to the product to find a basis for recovery, but rather would look to the process employed in manufacturing the product. In all other respects, process liability would echo product liability. This is possible because the rationale between the two is similar.

Although framed in environmental pollution control, Miller's arguments were expressed in general terms so their applicability to universal business operations is straightforward and provides a solid grounding for this paper.

Miller distinguishes random error from misfeasance, saying that in process liability there should also be a limit based on the concept of fault. If the defendant can show consistent use of the best available technology, then there should be no process liability. The purpose of this doctrine is to promote the usage of the process of manufacturing that would least pollute the environment. Therefore, liability should not be imposed where an industry uses the best available methods of controlling pollution. This limitation on process liability does not mean that an industry would not be liable for another tort merely because it was not liable for process liability.

Products and Processes

Focusing on pollution as a byproduct of a given manufacturing process, Miller asserts a causal relation of process to product:

> The amount of pollution is determined by the process of manufacturing, as well as the devices used to recapture pollutants after production. In a sense then, the process becomes the product. The process is determinative of the extent of the pollution product. It is this relationship which is at the base of the theory of process liability. If a process is a product, then just as the manufacturer is liable for the reasonably foreseeable consequences of the usages of his product, so should he be responsible for the consequences of the process of manufacturing employed. If he creates pollutants and they injure, he should be responsible and his process of manufacturing should be at issue.

Whether this causal relation can be extended to the attribute of an activity or product other than pollution may be debated. ISO 9000,[2] the international standard for performance management, defines a process as a set of interrelated or interactive activities that transforms inputs into outputs. It defines a product as the result of such a set. Thus, the industrial world formally accepts the causal relation of process to product.

So also, the field of medicine seems to agree. For example, epidemiological studies examine associations between an exposure variable and a health outcome. In assessing the causal nature of an observed association, a set of criteria named after its developer, Bradford Hill, provide an aid to analysis (Dryer, 1994). Briefly, the Bradford Hill criteria of cause and effect are:

- Strong correlation;
- Consistency of evidence;
- Sequence of events;
- Plausibility;
- Coherence with respect to natural history; and
- Repetition through experiment.

The criteria do not ensure causality, but offer aspects of the relation between an exposure and an outcome that are the most likely interpretation. Item by item, the criteria can be reasonably applied to the relationship of a process to its products. We shall see in the next section of this article that in his seminal book, *Economic Control of Quality of Manufactured Product,* Walter Shewhart[3] does just that by describing product variability as a byproduct of the process that makes it.

While on this subject, the terms "process" and "system" have no standard meaning in business or industry and are often used as distinct entities. But in systems theory they are regarded as the same thing. Kalman et al.[4] defined a system as a mathematical abstraction—a dynamic process consisting of a set of admissible inputs, a set of single-valued outputs, all possible states, and a state transition function. Since a system is a dynamical process in systems theory and a process is dynamical by definition of ISO 9000, the terms are considered equivalent in this paper and are used interchangeably throughout.

In keeping with the Kalman definition, a system may be an electronic or mechanical device, or collection of various devices. But an organization such as a bank, a manufacturing facility, a service enterprise, or a government is also a system and systems theory can be applied to it. Many researchers such as two of my former professors, Dragoslav Šiljak[5] and John Gibson[6] have done so and others continue to do so.

Process Dysfunction and Liability

A dysfunctional process is one that is unstable and incapable of achieving its intended purpose. One or more of its modes are out of control. How does process liability apply to dysfunctional processes? The link is revealed in Miller's assertion that pollution is a byproduct of the industrial process. So also, Shewhart[7] has shown that variation in the critical values of a product is a byproduct of the industrial process. Grant & Leavenworth[8] summarized Shewhart in this way:

> Manufactured product is always subject to a certain amount of variation as a result of chance. Some stable system of chance causes is inherent in any particular scheme of production and inspection. Variation within this stable pattern is inevitable. The reasons for variation outside this stable pattern may be discovered and corrected.

Hence, a stable system of random variation in key product values is inescapable. As this random variation is a byproduct of the process, then Miller's reasoning in regard to pollution can be extended to product variability. Some of the variability will be nonconforming to requirements. It will be shown herein that systemic product variability follows from process variability This result is seen in automobile recalls, where a large number of defective products are found as a result of process dysfunction. The risk of nonconforming product increases exponentially with the duration of dysfunction.[9] The system is broken and the quality of its products is dubious at best. Hence, process liability follows from product liability.

Standards of Performance

A forensic investigation of any type is fundamentally an audit. You compare the descriptive system to the normative—what it is to what it should be. A reference standard is necessary to the comparison. If the system of operations is in litigation, forensic analysis will require a standard of performance. Such a standard must be able to stand up in court. Randall Goodden says that for a management system to protect a company against product liability, it must have a fully documented system of control procedures.[10] Control procedures support the claim of good business practices and standards of care. A comprehensive set of documented control procedures usually resides in the standard that defines the system.

The most commonly used such standard is ISO 9001,[11] an international set of controls for management systems that is often required in contracts of performance. However, in the absence of a contract requirement for a specific standard, any equally capable standard may do, even a locally developed one. The issue in litigation is whether the performer is prudent in standards of care and due diligence. Hence a forensic systems investigation is best accomplished by a team: systems and subject-matter experts for technical issues and attorneys for legal guidance, direction, and relevance to the litigation strategy.

In sum, a performer offers to provide a product or service to a customer. A contract is drawn up listing customer requirements and the intended use of the product or service. There may also be specifications on the performance, such as constraints of cost and time or the requirement to perform in a certain way, say in accordance with given industrial or international standards. In the event of customer disappointment, a forensic investigation may be required in which it becomes apparent that a given process may be a contributing factor in an adverse outcome. Both plaintiff and defense attorneys may well consider a forensic systems approach in their strategies.

The name, "ISO 9000" is somewhat ambiguous. It is properly used in two ways: First, ISO 9000 is a set of standards for quality management systems, and, secondly, it is the first standard in the set, which includes, as of this writing:

- ISO 9000:2005, containing the fundamentals and vocabulary used in the set;
- ISO 9001:2015, containing control requirements; and
- ISO 9004:2009,[12] containing guidelines for performance excellence.

The reader will note that each standard has a different date. This condition comes about because the standards are revised according to demand, but the forensic team will be concerned only with a standard whose date of issue corresponds to the period in litigation. As many cases before the law go on for years, a standard appropriate to a given litigation may not be the most current.

Standards ISO 9000 and ISO 9004 are advisory. However, their contractual status may be underestimated. In the United States, guidance standards such as ISO 9000 and ISO 9004 are viewed as components of a series along with ISO 9001 that can be used to examine issues such as product safety. Guidance documents that are part of a series can be used to establish a company's due diligence and duty of care and can be used by the courts to establish evidence of negligence.[13] Though guidelines presented in ISO 9004 are not contractual, a plaintiff could argue that they should be reflected in the management system of any company registering to ISO 9001 as a set of good business practices.

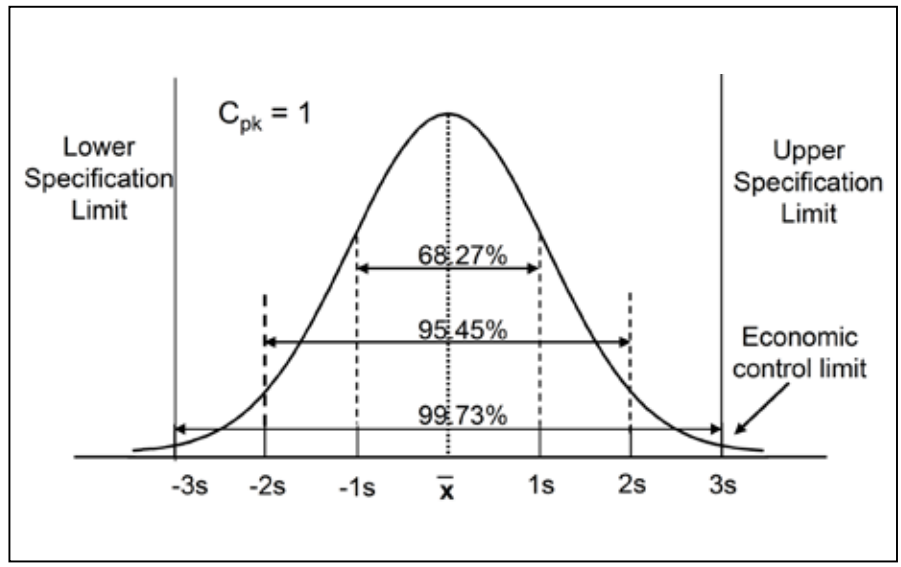


Figure 1. A Capability of Unity Superimposed Upon a Process Distribution

Process Stability and Capability

Every product or service has a key value or values that ensure its conformance to customer requirements. (Henceforth, for brevity the term "product" also applies to service.) A process must be established to provide these products. However, there is no such thing as a perfect process. A process may be designed and set up to provide products with a defined key value, but the resulting series of products will vary somewhat in key value from product to product.

Some of the process variation may be nonconforming to requirements and so there must be some way to distinguish acceptable variation from that which is not. There are two industrial conventions to address this issue: that of process stability and that of process capability. In regard to the first, if the variation of key values is bounded, then its probability distribution is defined and measureable. The process is then regarded as stable. Limits above and below the average value can be placed on the distribution. Such limits are called control limits and are so selected that to exceed them would be considered a rare event. The variation within the control limits represents the chance causes defined by Shewhart.

If there is any variation beyond the control limits, the process is considered unstable because such variation is normally improbable. Hence, industrial convention assumes the presence of an external disturbance acting upon the process. If the disturbance is not identified and eliminated, the result may be process dysfunction and unlimited product nonconformity. Therefore, process stability is a necessary first condition for acceptable performance.

Yet, stability says nothing about how good the process is. The variation of key values is bounded, but whether the values meet customer requirements is not indicated by process stability. The metric used to determine whether the process output meets requirements is called "process capability." Knowing that no process is perfect and some variation will always exist, process designers will consider how much variation about a key value a product may assume and still meet customer requirements. This range of off-design key values is considered acceptable and is delineated by limits called specification limits.

Therefore, in the design of a product and the design of a process that can produce the product, we have two concerns regarding the inherent variation from the chance causes defined by Shewhart. The first is whether the variation is bounded within control limits. If so, then this establishes process stability. Its probability distribution is defined and measureable.

The second concern is how much of the distribution lies within specification limits. This area defines the statistical proportion of the variation that meets customer requirements. The capability of the process is then determined by the ratio of the specification limits to the control limits. The greater this ratio, the greater the process capability.

This configuration is shown in Figure 1, in which the control limits happen to coincide with the specification limits, yielding a capability, $C_{pk} = 1$. Many industries require a capability of at least 1.67.[14] The well-known Six Sigma criteria offer a capability of 2, which would represent fewer than 5 nonconformities per million. (As an aside, I prefer not to get into the argument of "goodness" before a jury. Probability arguments are extremely technical. Rather, I look for evidence of a systemic process failure in which a defective product is certain.)

Modeling Process Dysfunction

A process is said to be completely observable if all of its dynamic modes of motion can be ascertained from measurements of the available outputs.[15] Observability is a major issue in forensics because without it, proof of product fitness to customer requirements is impossible. This proof is achieved with processes of verification and validation and are a requisite of every industry. Hence, product fitness must be observable. Inadequate processes of verification and validation render a system unobservable and are major nonconformities in management.

An unobservable process may be unstable and incapable. If allowed to remain dysfunctional it will provide a continual stream of questionable product fitness that can lead to litigation and forensic

concerns. Auto recalls are examples of operational but dysfunctional systems. In the Ford-Firestone litigation of 2001, the companies faced lawsuits of tens of millions of dollars and product recall costs in the billions—all because of defective tires.[16] The defective tires were a result of an unobserved dysfunctional process.

A dysfunctional process may provide nonconforming products in large quantity, yet liability cannot be determined if evidence of such products is not available. The problem in forensics is that there may be insufficient evidence in discovery to estimate the volume or risk of nonconforming products, nor is it likely that a defendant performer would make its processes available for experiments by litigants. The correlation of process to product can be established, but correlation does not prove causation. Yet with strong correlation, domain knowledge may be sufficient to establish the root cause of defective product.

Although correlation does not imply causation, causation does imply correlation. Therefore, the evidence of correlation of process to product is a first and necessary condition for causality.

Production and service operations often perform iterative cycles in which products are provided in a continuous stream. This sequence is called a time series, and mathematical models are often used in the design of such production systems. For example, auto-regressive (AR) models may be used to study the serial correlation of current data to prior data of the same random variable. One can then study the effect of correlation of key values in a series of identical products.

Generally, there will be little or no correlation, but only the acceptable variation of chance causes. If there is consistent correlation when there should be none, then there is a disturbance to the process that increases the variation. An AR model of a serially producing process will show that given strong correlation, the value of a process output increases exponentially and if a key value, it will eventually be nonconforming to specifications.[17] This behavior is shown in Figure 2, where the curve made by observed samples begins a geometric increase in the product key value, indicating process instability and systemic failure. By six iterations, the series exhibits explosive behavior and completely unacceptable key values.

Research and analysis of dysfunctional processes establish two salient inferences:

1. Duration plays a crucial role in dysfunctional processes. Controls that are missing or ineffective for sustained periods lead to process instability and such evidence stands by itself without recourse to the larger population of evidence.
2. Technical knowledge of product and process can identify key variables and causal relationships, and supported with correlation, the two are necessary and sufficient for establishing a causal hypothesis.

Cause and effect are essential components of human reason. Although causality cannot in principle be proven, given the proper conditions there is a high probability of connection between process and product. These conditions are the use of rigorous procedures in causal inference and sufficient knowledge of the domain of concern. If failure data are available in discovery, then by using well-known statistical methods the forensic team can establish the level of risk of producing a nonconforming product. However, even if failure data are not available, the forensic team can establish this risk with correlation data that is usually available in discovery.

Internal Control of Operations

Process stability is maintained by internal controls. Internal controls are required by the Sarbanes-Oxley Act of 2002 to ensure the transparency of financial audits.[18] However, careful reading of the act reveals that the conversation goes beyond financial operations and applies to corporate operations across the board.[19] As ISO 9001 provides internal controls for operations, it is often a very useful reference for forensic systems analysis.

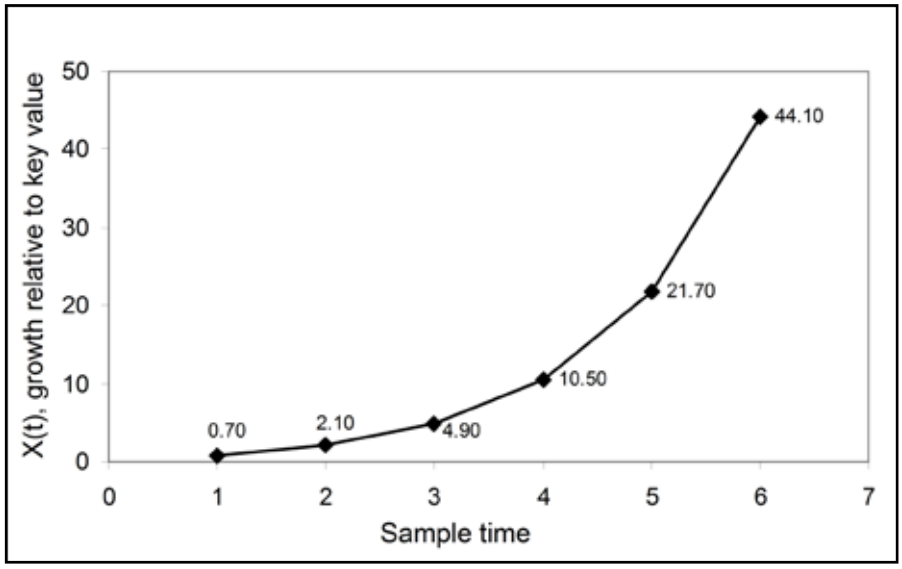
In Sarbanes-Oxley, internal control is defined as a process designed to provide reasonable assurance regarding the effectiveness of operations, reliable records and reports, and compliance with regulations. They are called "internal" because they are integrated in a closed loop with the process that they are to control. Figure 3 is a simple diagram of this arrangement, in which the process and the control form a single feedback system. At some level of perception, every stable system looks like this, whether an electronic device, a manufacturing plant, or Bank of America.

The Sarbanes-Oxley definition of internal control is useful to the forensic systems team because it is process oriented and conforms to traditional notions of system stability and effectiveness. Moreover, it responds to legal requirements, as must all operational activities that appear in a contract. In forensics, "regulations" include appropriate laws and standards.

Therefore, the task of the forensic systems team is to determine whether the internal controls in litigation are effective, reliable, and compliant. An adverse decision by that team will be challenged, so it is incumbent upon them to know why and how controls work and whether they are doing what they are supposed to be doing.

Physically, controls are those hardware and software devices necessary to the process, such as monitoring and recording devices, embedded computers and associated software, position and rate controls, counters, and cameras. The documented

Figure 2. A Response Curve of an AR Time Series With Strong Correlation



procedures are those that describe the setup and initial conditions of the process and of the product, rules and regulations, instructions on process operation, technical manuals, and schematics, as well as associated information needed for proper operation. Skills include those necessary or appropriate to the process operation and maintenance, and the operators with those skills. The measures of effectiveness (MOE) include those metrics necessary to verify and validate both the process and product to ensure the attainment of process objectives and contract requirements.

In examining the effectiveness of a process, the forensic systems team will look for evidence of the presence or absence of proper, competent, and timely skills, procedures, MOE, and proper procedures and instruments for verification and validation. Proper refers to those metrics, procedures, and devices that are accepted industrywide and by the customer and that maintain test integrity. The team will further consider whether the process inputs were acceptable—those described in the company flowchart and in the formally approved procedures.

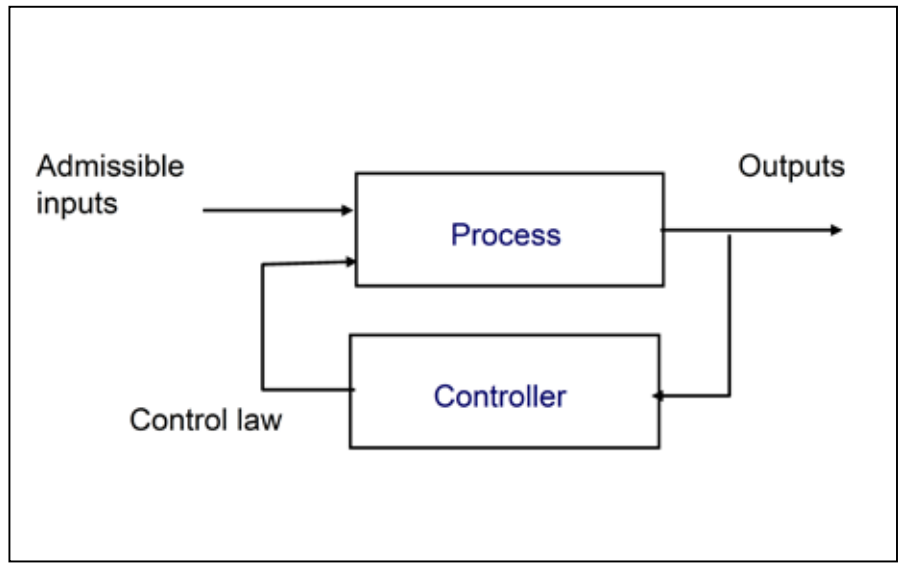


Figure 3. A Generalized Internal Closed-Loop Control System

Controls can be rather abstract. Management, too, is a control by responsibility, authority, and accountability. Control is achieved through responsibility by precisely defining and assigning the task and metric of the performance function. Metric refers to the index of performance used to measure the achievement of the task. This is true whether the function is performed by human or machine, although we usually use "responsibility" in reference to humans and "responsive" in reference to processes or procedures. A general view of responsibility thus defined frees us from preconceived limitations about people and processes, because processes must be responsive whether human, machine, or human-machine.

Control is achieved through authority by ownership of the resources necessary to a task. This may be contrary to the view that authority lies in a title of some kind, but without the resources, authority is a meaningless word. Matrix management is a good example of a title without resources. In matrix arrangements, a project manager is given a task, a designated budget, and a schedule but is then dependent on line managers for resources. Line managers operate on their own schedule and rarely on that of a project manager. Thus, the project manager may have little control of the task. Control is achieved through accountability by imposing a cost function for a performance that fails to achieve objectives. One must account for failure to achieve or maintain the task optimally. Thus, accountability is the control used to provide the motivation to attain the goal. The cost function is usually nonlinear, imposing a greater weight in proportion to the deviation from target. Whether the function is performed by human or machine, "accountability" aptly describes the sensitivity and liability of the function, and thus is used here in a very general sense.

It is possible to design a process with an inherent cost function. For example, the speed of an automatic lathe is controlled by a number of weighted factors. If the lathe becomes dull, the lathe will increase speed in compensation. The cost is increased by running the lathe at a higher speed. Similarly, if a project falls behind schedule, the project manager may call for the expenditure of more labor hours. The cost function is the mechanism requiring the additional compensation.

One might argue that the terms "responsibility" and "accountability" are redundant. This may be true in the dictionary, but is usually not the case in industry and government. In organizational usage, responsibility has come to refer to the assignment of a function or task. The task may not always be achieved. For example, a production manager may be responsible for both the schedule and fitness of a product, but only accountable for the schedule. If the schedule slips to the point where the time for acceptance testing is impacted, the supervisor will often not hesitate to abandon the testing. Accountability means that the task *must* be achieved or a cost is paid.

Suppose that testing is abandoned in order to avoid a late delivery. This carries with it a certain cost of quality, say customer dissatisfaction. For if a faulty part is delivered to the customer, the company will pay a much higher cost of quality than might have been the case if testing had taken place and the fault located in the shop. The customer will hold the company itself accountable for the delivery of a faulty part.

Lack of accountability by the performer favors short-term penalties against long-term penalties, even though the latter almost certainly will be greater and can lead to liability. This adds a distorted and invisible element in the decision-making process and can occur when there is poor correlation between those who make strategic decisions (higher management) and those who make tactical decisions (shop supervisors). For example, at the higher levels of management, productivity is a goal and a key indicator. In the shop, it is a mandate: Get the product out the door!

Operational controls follow the mathematical and physical laws of systems theory. If an operational control is not in conformance to these laws, it probably does not work. For example, if there is no feedback in an operational structure, then there is no control in that structure.

Management, too, is an operational control. Responsibility, authority, and accountability are controls that determine the effectiveness and efficiency of any system.

Misfeasance in Operations

Process dysfunction from loss of control has many random causes: wear and tear, rotation of operators, and faulty setup, to name just a few. These events are usually quickly discovered and corrected. However, sustained dysfunction is a major casualty and in my experience, may be caused by management misfeasance. This conclusion is reinforced by experts such as Deming[20] and Juran,[21] who estimate that about 90 percent of system problems are management responsibility. For example, an inappropriate change in a test procedure or in equipment can render a process unstable and if not corrected, can cause sustained dysfunction.

Misfeasance occurs when good manufacturing practices are abandoned or changed and can occur in any phase of performance, from design and fabrication through testing and delivery. If negligence can be established, the risk of liability is greatly increased, as trial courts are showing increasing interest in the management of quality assurance.[22]

Misfeasance refers to improper performance, whereas malfeasance is illegal performance. However, misfeasance can lead to malfeasance; for example, when there is such intense focus on meeting production quotas that proper procedures are abandoned. I call this condition "forced production," and I must say that, in my experience, it is not rare.

Misfeasance in operations can alter controls, thereby creating dysfunctional processes. Some examples of misfeasance in operations include:

- Improper controls;
- Nonstandard design procedures;
- Unverified and unvalidated design;
- Unmonitored outsourcing;
- Ineffective flow down;
- Substandard purchased parts;
- Ghost inventory;
- Forced production;
- Abuse and threats;
- Tests waived by management; and
- Altered test procedures and results.

A frequent example of management misfeasance is the neglect of the processes of verification and validation. Verification and validation are major controls. Without them, the process may well be open loop, unstable, and out of control. This neglect is sometimes deliberate and justified, although falsely, as a reduction of waste.

The most copied system of operations in the world may be the Toyota Production System. The Toyota Production System assigns a set of tasks in three categories: value added, non-value added, and non-value added but necessary. Validation and verification fall into the third group. Processes that do not fit in these categories are to be eliminated as unnecessary or wasteful.

In the United States, "Lean" is the translated American Toyota system.[23] Very often Lean is implemented with only two categories: value added and non-value added. Also very often, validation and verification are assigned to the second set. Then if the production schedule slips, the tests are abandoned or reduced under the guise that the performer is being Lean. The result is an open-loop, unstable process with unproven output.

In litigation, the forensic systems team will be confronted with a vigorous assertion that product fitness is fundamental to corporate strategy. And it may well be. But at the tactical level, there are trade-offs. Verification and validation cost money and take time, often a lot of time. In my experience, the overwhelming cause of process dysfunction and nonconforming products is found where verification and validation are considered non-value added activities.

Forensic Issues in Reliability and Warranty

While some products are meant to be disposable, others such as appliances might be expected to last a long time. The durability of some products is marked on the package, light bulbs being an example. The term "durability" is generally understood to refer to how long a product can be useful. However, it is not a technical term and has no meaning to engineers. It means whatever the producer wants it to mean. When referring to how long a product can meet customer requirements, engineers use the term "reliability" and define it rigorously[24]: "Reliability is the probability that an item will perform a required function without failure under stated conditions for a specified period of time."

The beauty of this definition is that once the operating conditions are stated and the lifetime estimated, the definition of reliability becomes a specification. It can be written into a contract. Reliability, then, is quality that endures. Today, we often say that "reliability is quality over time."[25] Product reliability is not haphazard, but results from risk-based design and may be an issue in forensic considerations. The metrics of reliability are:

1. MTBF (meantime between failures) for reparable items such as computers;
2. MTTF (meantime to failure) for non-reparable items such as light bulbs; and
3. PFD (probability of failure on demand) for single-use items such as body armor, airbags, or guided missiles.

Reliability is a statistical measure. Meantime refers to the average lifetime of a population of products. As with any average, roughly half the products will fail sooner and half later than the specified time. So if you are buying a product in quantity and expect a certain reliability of that quantity, you must track the performance life of the products that you have purchased. If the average of this record is approximately the average specified by the producer, then you have received what you paid for. If not, then false claims may be appropriate.

In product design, reliability is estimated with mathematical methodologies such as Weibull analysis.[26] However, the final test of the design comes from the failure data of products in use. Field data from warranties are particularly useful in this post-hoc analysis. If there is a strong correlation of design data and field data, the design and subsequent fabrication are validated. If the two data sets differ substantially, then the products may not meet customer requirements and the discrepancy should be analyzed. False claims and litigation may follow.

A warranty is an obligation that a product sold is as factually stated or legally implied by the seller and provides for a specified remedy in the event that the product fails to meet the warranty. Both warranty and reliability are keyed to product failure and because warranty implies a period of acceptable product performance, warranty and reliability are often thought to be equivalent. However, they are not the same thing nor are they equivalent. Warranty,

continued on page 77

A Forensic Pursuit of Process Liability *continued from page 68*

like durability, is not an engineering term and means only what the producer wants it to mean.

Warranty is usually easily litigated because its conditions are clear. Possibly for this reason many attorneys choose to pursue warranty issues rather than issues of reliability, even when reliability is pertinent. What good is a two-year warranty on a $200 tire if its tread separates prematurely and the passengers are killed? What good is a five-year warranty on a $700 vest of armor if, when 20 9 mm Parabellum rounds are fired at it, all 20 rounds penetrate? While the warranty offers compensation to the buyer, it does nothing for the user. Reliability offers a safety factor to the user and if systemic failure occurs, reliability, too, can be easily litigated.

The forensic systems team will be concerned first with whether reliability studies were ever done by the producer, and secondly whether they were done appropriately and correctly. The evidence of life testing will be:

1. Defined and documented life test procedures in accordance with accepted standards;
2. Life test records and reports of MTTF, MTBF, and PFD in accord with specifications;
3. Test procedures, specification requirements, and test objectives are defined á priori; and
4. À posteriori changes to test procedures and results are justified.

Conclusions

Very often in a civil lawsuit, the litigation involves technical issues in which expert witnesses will be needed to pursue the case. If the technical issues relate to a performer's operations, then its management is at issue. Teamwork between the attorneys and expert witnesses ensures an assembly of evidence relevant to the litigation and minimizes the risk of judgmental error. In regard to systems performance, there are five conclusions to this article:

1. A management system is properly an entity in the law.
2. A process is nonconforming if one or more of its controls are nonconforming.
3. If the control nonconformity is systemic, there is a risk that the process will provide nonconforming products and this risk is proportional to the delay in correcting the nonconformity. As a function of this delay, the risk of nonconformity increases to certainty.
4. Although often considered non-value adding, on the contrary, process verification and validation activities are very often the effective controllers for process stability.
5. The success of litigation may depend upon the perspective attorneys have of the role of management in operations, for this role could be an important component of their legal strategy and will certainly help to develop an effective discovery. ⊙

William Stimson holds a bachelor's degree in mathematics, a master's in electronic engineering, and a doctorate in systems engineering. Over a period of 35 years he worked and studied in the design, development, and testing of large computer-embedded systems. Stimson served for 12 years as an expert witness for the Department of Justice and for various private law firms, specializing in the study of the correlation between process dysfunction and operational misfeasance.

Endnotes

[1]Leonard A. Miller, *Air Pollution Control: An Introduction to Process Liability and Other Private Actions*, 5 New Engl. L. Rev. 163-72 (1970).

[2]Am. Nat'l Standard & Am. Soc'y for Quality, ANSI/ISO/ASQ Q9000-2005: Quality Management Systems—Fundamentals and Vocabulary (2005).

[3]Walter A. Shewhart, Economic Control of Quality of Manufactured Product (1931).

[4]Rudolph E Kalman et al., Topics in Mathematical System Theory 74 (1969).

[5]Dragoslav D. Siljak, Large Scale Dynamic Systems (1978).

[6]John E. Gibson, Designing the New City (1977).

[7]Shewhart, *supra* note 3, at 301-20.

[8]Eugene L. Grant & Richard S. Leavenworth, Statistical Quality Control 51 (1988).

[9]William A. Stimson, Forensic Systems Engineering 145-48 (2018).

[10]Randall Goodden, *How a Good Quality Management System Can Limit Lawsuits*, Quality Progress 55-59 (June 2001).

[11]Am. Nat'l Standard & Am. Soc'y for Quality, ANSI/ISO/ASQ Q9001-2015: Quality Management Systems—Requirements (2015).

[12]Am. Nat'l Standard & Am. Soc'y for Quality, ANSI/ISO/ASQ Q9004-2009: Quality Management Systems—Managing for Sustained Success of an Organization (2009).

[13]James W. Kolka, ISO 9000: A Legal Perspective 61 (1998).

[14]Eaton Corp., Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP), slide 102 (2015) (PowerPoint presentation) (on file with author).

[15]Siljak, *supra* note 5.

[16]Dana Schubert & Harper Baird, Firestone's Tire Recall (2011), http://danielsethics.mgt.unm.edu/pdf/Firestone%20Case.pdf.

[17]George E.P. Box & Gwilym M. Jenkins, Time Series Analysis: Forecasting and Control 88 (1978).

[18]The Sarbanes-Oxley Act of 2002, H. R. 3763, Pub. L. 107-204, 116 Stat. 745 (July 30, 2002).

[19]William A. Stimson, The Role of Sarbanes-Oxley and ISO 9000 in Corporate Management 101-08 (2012).

[20]William E. Deming, Out of the Crisis 315 (1991).

[21]J.M. Juran, Juran On Quality By Design 428 (1992).

[22]Thomas C. Boehm & Jeffrey M. Ulmer, *Product Liability Beyond Loss Control—an Argument for Quality Assurance*, Quality Mgmt. J. 11 (Apr. 2008).

[23]Jeffrey K. Liker, The Toyota Way 7 (2004).

[24]Grant & Leavenworth, *supra* note 8, at 582.

[25]R.H. Lochner & J.E. Matar, Designing for Quality 4 (1990).

[26]J. McLinn, The Weibull Function and How to Understand It, Industrial Course Presented at Blue Ridge Community College and the American Society for Quality (Feb. 13, 2009).