SECTION 27
PROCESS INDUSTRIES

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QUALITY MANAGEMENT IN THE PROCESS INDUSTRIES

In the process industries, as in other sectors of the economy, Quality Management is the umbrella framework for managing the quality of a product. The philosophy, managing procedures, and technology should provide an operational system in which Marketing, Research and Development, Production, and Support personnel can work together to meet increasingly stringent customer requirements.

The system must deal with all facets of a product's life span from the product's conception through commercialization and subsequent improvements, as shown in Figure 27.1. When a product initially is developed, the emphasis is on designing quality into the product through optimizing functionality and producibility. For established products, the emphases are on maintaining and continually improving product conformance to quality requirements.

The most significant quality improvements are accomplished in those businesses that broadly implement a quality management system. The "system" feature:

- Provides an implementation process
- Interconnects the operational techniques
- Requires and expedites communications in the organization.

The system feature is the vehicle that drives quality improvements as a business strategy. The system approach is particularly important in the process industries.

CHARACTERISTICS OF THE PROCESS INDUSTRIES

The "process industries" have special needs in the technology for quality management. The process industries typically have continuous processes, or batch processes with many batches per year of a given product type.

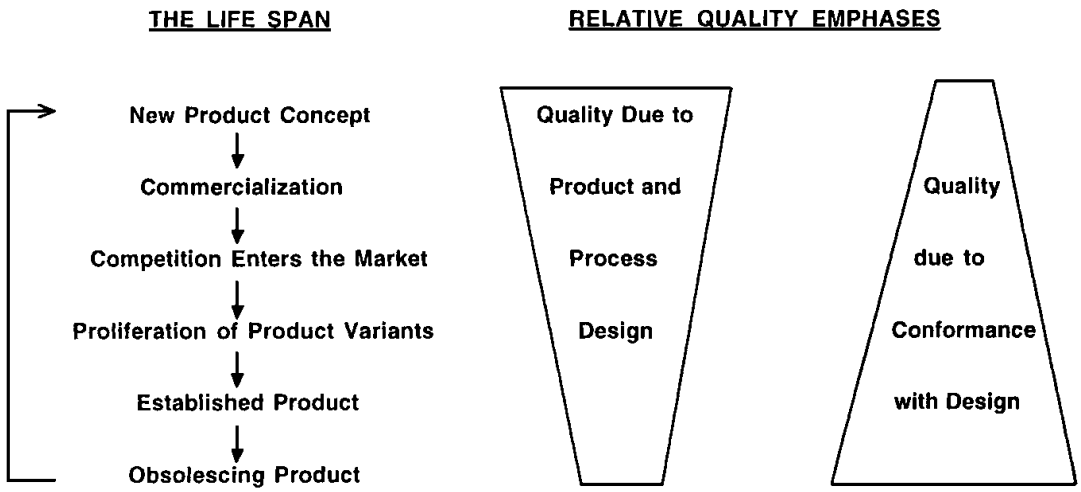

FIGURE 27.1 The product life span. [*From Marquardt* (*1991*).]

Typical products of the process industries are:

- Solid materials:

  Pieces, particles, powders

  Discrete or continuous sheets

  Chopped or continuous filaments
- Liquid materials:

  High and low viscosity
- Gaseous materials:

Such products can be sampled in specified volumes or weights at specified production points to measure a quality property. The property value may vary throughout a volume or quantity of product, and may change with time. Often the relationship between a measured property and the functionality of the end-use product is not fully understood.

Frequently, the process industry product is an input material for the customer's process. The product must meet this customer's processing requirements as well as requirements of the end user of the ultimate product. Such products are examples of the generic product category called "processed materials."

The foregoing features distinguish the process industries from the mechanical industries, where the emphasis is on the making of parts or the assembly of parts, that is, products of the generic product category called "hardware."

Most existing quality control methodology was developed for hardware products of the mechanical industries, so it may not be too surprising to find that emphases and methodologies in this section are often different from the traditional quality control literature. However, small parts made in large quantities often benefit from the statistical methodologies for processed materials.

DEALING WITH LARGE MEASUREMENT VARIABILITY

A primary difference between the process industries and the mechanical industries is the amount of variability associated with measurement processes. In the mechanical industries, measurement variability often is, or is perceived to be, small or negligible, usually less than 10 percent of total variability. Many measurements in the mechanical industries are based on properties that have absolute or near absolute reference standards, such as dimension, weight, or electrical or optical properties.

These measurements often are of a nondestructive nature, so that the same sample of material can be measured multiple times.

In the process industries, measurement variability is typically larger, often about half, and occasionally as high as 80 percent of the total variability. Most process industry measurements are complex, highly specialized, and not traceable to absolute standards. Examples are measurements of:

- Relative viscosity of a polymer
- Dyeability of a textile yarn
- Speed of a photographic film
- Strength of a plastic film

Many of these measurements involve destructive testing as well, so that local product nonuniformities cannot be disentangled from the measurement variability. In the process industries, measurement variability must therefore be taken explicitly into account in virtually all quality management activities. These include setting product specifications, control of the production process, product characterization and release, and planning experiments to seek improvements.

In recent years, products of the mechanical industries increasingly require tighter manufacturing tolerances, and incorporate components or mechanisms that have process industry characteristics. The technology in this section should be particularly attractive to mechanical industry producers facing such trends.

FUNDAMENTAL CONCEPTS

Generic Product Categories. International standardized terminology (e.g., ISO 9000-1:1994) recognizes that the term "product" encompasses four "generic product categories:"

- Hardware
- Software
- Processed materials
- Services

(See Section 11, Table 11.4, for further detail.)

Every Product Is the Result of a Process. The term "production process" has wide applicability. For example, the product units from a production process may be:

- "Processed materials" from a process industry company
- "Widgets" from a hardware manufacturer
- "Test results" from a laboratory
- "Confirmed reservations" from a travel agency
- "Sales made" from a sales organization
- "Deliveries completed" from a distribution organization

Each of these situations involves a production process. Each process creates product units that have measurable properties relating to quality as perceived by the customer. For example, the customers of a distribution organization may perceive quality in terms of the timeliness of deliveries, delivery to the proper destination, and physical condition of the delivered item.

It is important to approach the subject of quality from this viewpoint that *all work is accomplished by a process*, whether in Marketing, Manufacturing, Delivery, Research and Development, Personnel, or other functions. See ISO 9000 (1994).

Facets of Quality. Discussion and communications about quality have often been unproductive because of failure to distinguish among the four facets of quality (see ISO 9000 1994). The four facets are described in Section 11. Two facets (quality of product design and quality of conformance with product design) receive explicit discussion in this section because of specific needs in the process industries.

Quality of Product Design. To meet customer needs a product design has to provide the intended characteristics and functionality. For example, when different chemical forms of processed materials are designed for the same markets, we may judge a particular product to have superior quality of product design because it offers additional or enhanced features that improve functionality. Quality of product design can be quantitatively measurable characteristics such as strength, speed, chemical resistance, or subjective characteristics like styling, texture, or odor.

There is an important link between quality of product design and quality of conformance with design. If a product consistently provides its intended functionality despite typical variations in the environments in which the product is produced and used, the product design is said to be "robust." The attainment of robustness in product design has received a great deal of emphasis in recent years.

Quality of Conformance with Product Design. Quality of conformance with design (or, more simply, quality of conformance) refers to the uniformity of the characteristics and the consistency of functionality of all product units produced day after day. Good quality of conformance means that the characteristics, properties, features, and functionality consistently satisfy their intended specifications.

A BALANCED APPROACH TO ACHIEVE EXCELLENCE IN QUALITY

The Quality Management Success Triad. Quality management requires three coequal and interrelated facets (Marquardt 1984):

- Quality philosophy and policy
- Quality management systems
- Quality technology systems

These three facets form the quality management success triad (Figure 27.2). The achievement of continued excellence in managing the quality of products requires that balanced attention be given to all three facets and the linkages among them. Too often, quality management systems have emphasized only one or two of these facets.

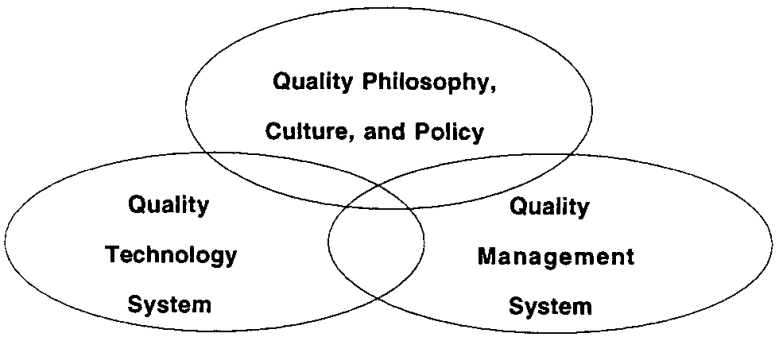

FIGURE 27.2 The quality management success triad. [*From Marquardt* (*1991*).]

Quality Philosophy, Culture, and Policy. The operation of any enterprise reflects the underlying philosophy of those who lead it. Thus, philosophy is the first facet. It affects the operation of financial systems, the choice of product types, the attitudes on external social issues, the approach to employee safety and health, and many other aspects of the business. In short, the management philosophy shapes the culture of the organization.

The process that is most central to the role of top management is the strategic planning process. If quality management principles are effectively applied in top management's strategic planning, that process can be a mechanism to drive quality leadership throughout the enterprise. (See Section 14, Total Quality Management.)

Quality Management System. The second facet is the management procedures that are used to achieve, monitor, control, and improve the functional, financial, and human relations performance of the enterprise. Management procedures include mechanisms for allocating, organizing, and improving resources.

Management procedures should incorporate quantitative metrics and other criteria ("report cards") to monitor and evaluate the performance of the organizational units and personnel. Metrics which have exclusive focus on costs, yields, and output, provide disincentives toward achieving high product quality. Thus, report-card design is a key element of quality management. This is an important but difficult area because many disincentives are subtle and not easily foreseen during quality systems design (Marquardt 1994).

Quality Technology System. Quality Management strategy is complete only when we include the third facet—technology elements that are used to achieve, monitor, control, and improve the quality of the products. To appreciate the importance of this third aspect, we need only look at the effect that new technology has had throughout world history. Repeatedly, new technology has been the driving force behind great changes in the arts, in philosophy, in life style. New technology gives birth to new tools, which affect economic costs and opportunities, and are the driving force behind changes in the strategy of competition between individuals, businesses, or nations.

QUALITY PROBLEMS IN THE PROCESS INDUSTRIES

Systems Problems Versus Worker Problems. Many quality professionals of wide experience (Deming 1967, 1972, 1982; Juran 1974), have observed that about 85 percent of quality problems are management or systems problems and only 15 percent are worker problems. This experience applies to the chemical process industries. A management or systems problem is one that the individual production worker did not create, has no influence over, and usually does not have the proper information and tools to diagnose. Diagnosis and correction of such systems problems are management responsibilities, although production workers often play a crucial role.

Chronic Quality Problems. In processed material manufacturing it is particularly important to distinguish between chronic problems and rare-event quality problems. For an established product that has been in production for some time, a good quality management system can dramatically reduce or eliminate "chronic" quality problems. (See Section 5, The Quality Improvement Process,) Some symptoms of chronic quality problems in the process industries are

- A large proportion of total production is affected.
- A large proportion of product is downgraded from first quality, using euphemistic labels such as "special lots," "subcodes," etc.
- A regular practice exists of segregating product for shipment to specific customers on the basis of their specific quality needs.

- First-pass yields to first-grade product are chronically low.
- Complex pricing arrangements persist for specific customers and/or lots, where the prices do not stem from actual differences in mill costs or marketing costs.

The most severe symptom (and consequence) of chronic quality problems is

- Erosion of market share, specifically due to better quality of competitive product

True Rare-Event Quality Problems. In sharp contrast to chronic problems are the true rare-event problems. A true rare-event quality problem is a source of product nonconformity presumed to be entirely absent in all normal product. In processed materials these typically are nonconformities that occur because of occasional equipment malfunctions, occasional bad supplies of raw material, and the like. These rare-event problems are often called sporadic problems. (See Section 5, The Quality Improvement Process). The key symptoms are

- A very small proportion of total production is affected, typically only a small fraction of 1 percent of product units over a year's time. True rare-event problems are not representative of the usual production population.
- Each instance of quality breakdown can be presumed to be due to a specific unusual malfunction. These malfunctions should be sought out and corrected. Often the cause can only be diagnosed by analysis of patterns of rare-event failures whose occurrences have been recorded over an extended period of time.

Routine sampling of products will never be frequent enough to detect and weed out a majority of the "true rare events" that do occur. When detection is necessary because of a high economic stake for a particular type of rare event, it is usually better to monitor the appropriate production process conditions continuously and to trigger an alarm (or better still, initiate an automatic corrective action) when a process breakdown occurs, rather than attempt to discover the "needle in a haystack" by extensive testing of final product. The responsibility for elimination of rare events should be focused toward personnel in product design, production process design, and maintenance, rather than toward the process control and product release personnel, who can neither detect nor correct most true rare events in the normal course of their work.

Chronic Quality Problems That Appear to Be Rare Events. Often in the process industries quality problems appear to be rare events, but really are chronic quality problems. These "apparent rare events" arise as follows:

- *Slippage of the process average:* As illustrated in Figure 27.3*a*, the output from an "on-aim" process will have a distribution of values for any product characteristic (i.e., property). If, as in Figure 27.3*b*, slippage occurs causing the process average to deviate from its aim point, then a small fraction of the product coming from a tail of the distribution may be outside acceptable limits. If the quality management system does not alert production personnel to the slippage of the average, these apparent rare events may only be detected by the customer, and may result in customer complaints. These apparent rare events are representative of the usual production population when such slippage occurs, and the occurrence of such problems can be detected early and can be eliminated by standard quality management procedures using regular sampling methods.
- *Low-count defects:* Many important product characteristics, such as defects or nonconformities, are quantifiable only by counting their frequency of occurrence in a sample of the product. A product characteristic that gives a low count (perhaps fewer than one nonconformity per sample on the average) may, nevertheless, be a phenomenon that is continuously or usually present in normal product, even though only infrequently counted in a typical routine sample. Such counts are representative of the usual production population and when their frequency increases (a form of process slippage), the problems can be detected and can be eliminated by quality management procedures.

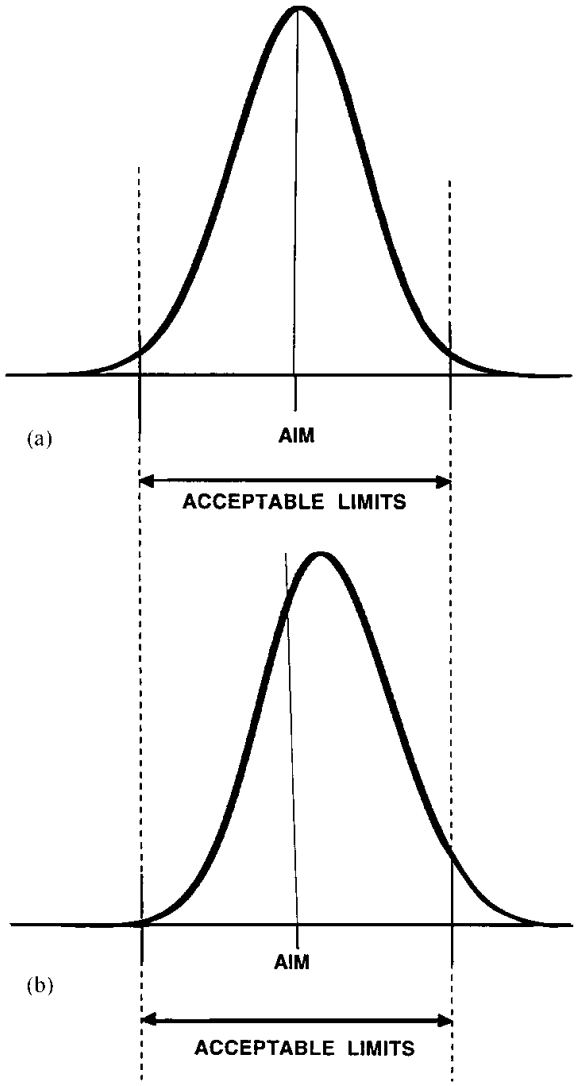

FIGURE 27.3 Effect of slippage of process average. (*a*) Process average is on-aim; negligible proportion of product is outside acceptable limits. (*b*) Process average is off-aim; larger proportion of product is outside acceptable limits. [*From Marquardt* (*1991*).]

In many production organizations, the "firefighting" effort spent chasing after both true and apparent rare-event problems exceeds the effort spent on actually solving the chronic problems. Some firefighting is almost inevitable, but the bigger danger is that the chronic problems often are not recognized as problems to be solved, but come to be viewed as a necessary way of life. Nevertheless, chronic problems usually carry the larger economic stake, by far.

On-Aim Control Contrasted with In-Limits Control. The implicit process control concept that has traditionally been employed in many process industry production sites is "in-limits" control. Under this concept, process measurements are taken periodically. If the measured data fall anywhere within the acceptable limits for the product, the process status is considered to be acceptable. Commonly, the "within acceptable limits" decision is made on the basis of each successive single measured test result, or the average of a small subgroup of test results. This procedure disregards the inherent variability, which gives rise to the distribution shown in Figure 27.3 even when the process average is held constant. Under the "in-limits" control paradigm the acceptable limits usually are equated with the product specifications and are usually wider than the inherent process variability. The

process is allowed to run indefinitely in the condition shown in Figure 27.3*b*. Customers of such producers of processed materials may learn to accommodate to the tail of the distribution that is above the upper limit. For example, customers may adjust the conditions of their own production process to compensate for the actual location of the producer's process average. Subsequently, a change in the producer's raw material or process procedures may cause the process average to shift to a value below the aim point—but still within the acceptable limits. Now the customers must contend with a distribution having a tail that goes outside the opposite limit, or with a transition-period mixture of the two distributions. Such shifts are a sure way to cause customer complaints and loss of business.

The "on-aim" control concept, which is central to good quality management, does not allow indefinite operation with the process average displaced from its aim point. As soon as the accumulated evidence from the statistical process control scheme shows that the process is off-aim, action is taken to bring the process back to its aim point. This is based on the understanding that customer satisfaction and marketplace performance are better when the product is maintained close to its aim point.

DESIGNING THE PRODUCTION PROCESS

Strategic Aspects of Economy of Scale. In the process industries, the design of the production process has an enormous impact on the ability to achieve consistently high product quality. Both the intended characteristics and the uniformity of the product are affected by production process design. Achievement of the desired average characteristics of the product is a major goal in production process design. Likewise, the achievement of product uniformity during continuous process operation with a single product variety is also a major goal in production process design. Unfortunately, achievement of product uniformity under discontinuous operation due to multiple product varieties has not often been adequately incorporated as a major goal in production process design. The resulting quality problems and their penalty on long-term financial performance have often been severely underestimated.

The economies of scale in production process design are always obvious to the designer. They lead to process designs with large single-line continuous processes, or batch processes with very large batches. Typically, at the time of process design for a new product, or for expansion of capacity for an existing product, the new capacity requirement appears to focus on only one or a few product varieties. Hence, the tendency is to design a large single-line continuous process or a batch process with very large batches. The potential for good product uniformity may appear to be high for such process designs due to inherent blending of the large process holdup volumes and the economic feasibility of sophisticated instrumentation and control. However, as a product line matures, it is typical for the marketplace to demand a larger number of product varieties. Good marketing strategy will hold proliferation of product varieties to a minimum. Nevertheless, a mature market usually involves many important segments requiring different product varieties.

Building Flexibility into the Production Process. The only fully satisfactory answer is to build flexibility into the original production process design. To "design it right the first time" means recognizing the inevitability of proliferation of product types. It means designing the process with

- Small in-process volumes
- Short lag times
- No blending vessels
- Quick, reliable transition procedures

One promising strategy is to construct a series of small-volume plants, bringing smaller increments of capacity on-line only when needed by the current product volume, and retaining design flexibility to incorporate features needed by the evolving mix of product types demanded by the market. Each

continuous process production line, or each batch facility, would then be small enough to allow (for each product variety it produces) a production run length that involves sufficient sampling intervals for effective process control. Multiplant production strategy can then encompass both a flexible multivariety product mix and consistently good quality of conformance. Long-term financial performance should be favorably impacted.

The concept of Continuous Flow Manufacturing (CFM) can enhance this strategy. Under this concept the equipment and facilities in each smaller-volume production line are dedicated full time to that product. If multiple product types are simultaneously produced, each has it own full-time dedicated equipment. This eliminates unnecessary variability introduced into the product by using different combinations of equipment each time the product is run. The dedicated equipment strategy (and often personnel, too) facilitates prompt diagnosis and correction of off-aim results due to specific pieces of production facilities.

Process controllability is fundamental. A continuous process that runs year-round on a single product variety is ideal from a controllability viewpoint. A batch process that produces hundreds of batches of a single product variety year-round is comparable. In both cases, the regular, frequent opportunities to sample and measure intermediate and final product make it feasible to employ control strategies that detect small quality deviations or trends before they become serious, and to feed back corrective action to prevent serious deviations. Production run lengths for controllability purposes must be measured in numbers of sampling intervals. For good controllability, a production run must be much longer than the combined effect of all lags in the system. These include inherent process lags caused by physical holdup volume or chemical reaction time, lags due to sampling and measuring the product properties, and lags due to the response time of the control procedure. Usually this means a minimum production run of several weeks for good controllability in large-scale production lines. Small-scale production lines with fully automated computer-controlled sampling, measurement, and feedback may achieve good controllability in shorter production runs.

Another promising strategy is to construct a higher-volume plant whose design focuses upon quick, reliable transition procedures. Production facilities capable of such transitions between product styles have been devised and implemented in a number of mechanical industries. There are examples in automobile assembly operations. Modular process design is employed, permitting quick, reliable exchange of modules for the differing product styles. Computerized changes in control settings may be involved. The key requirement is that the process will reliably start up on-aim for all product properties immediately after changeover.

In the process industries, continuous process designs with small in-process volumes, short lag times, no blending vessels, and quick reliable transition procedures are a direct analog of the flexible manufacturing systems (FMSs) that have been successful in the mechanical industries. FMS supports the goal of just-in-time (JIT) inventory management. However, just-in-time cannot function properly unless the supplier has a flexible production process. Without a flexible production process, combined with an effective quality management system, efforts to comply with JIT for customers will merely result in the customer's raw materials inventory being carried by the supplier as a final product inventory. In that event, the general economy is in no better position than before.

The process industries, by and large, have not yet implemented process designs with this degree of modularity so as to achieve quick, reliable changeover.

THE ROLE OF PRODUCTION SCHEDULING AND INVENTORY CONTROL

An existing production facility built with large continuous processing equipment, or large batch equipment, will be forced to adapt to the evolving multivariety product mix. Production planning personnel tend to adopt production strategies that optimize only the direct cost of inventory, customer response time, and the like. They often ignore the indirect cost of inadequate product quality. The inevitable result in a continuous process is a production strategy calling for frequent rotation among all product varieties. This requires many short production runs. Serious quality problems are

certain to result because each production run may be nearly over before it is possible to attain and maintain on-aim operation. The large process holdup time may inherently defeat all process control strategies From such a situation, the "transition" product made at the beginning of each run (in a continuous process) is a large fraction of the total production. Various approaches have been used in attempting to cope with these problems:

- Large mixing vessels can be used to blend final product for the purpose of smoothing out property variations, especially those due to transitions. This adds to the mill cost of the product due to increased investment, larger in-process inventory, and increased manufacturing labor. Moreover, the functionality of processed material blended to a nominal average property level usually is not the same as the functionality of product made uniformly at the intended level.
- The transition material can be reworked or recycled to bring it within specifications after further processing. This adds to mill cost and decreases net production capacity. Moreover, reworked processed material usually does not have the same functionality as material originally made to specifications.
- A portion of transition or recycled material can be included with, or blended into, regular shipments of on-aim product. This increases inventory and handling costs and increases the risk of nonfunctionality in customer use.
- The transition or recycled material can be discarded or sold at a reduced price. This has obvious economic penalties.

Analogous problems occur in a large-batch facility that must produce many product varieties. Each variety may require only one or a few batches per year. This degrades the ability to keep production personnel and procedures tuned to a constant state of "standard process" operation. Every batch is handled like an experimental run. The typical result is large batch-to-batch variability.

Whether continuous or batch, the symptoms of chronic quality problems are then encountered. Obvious partial answers are to reduce the number of product varieties being marketed, to revise production planning to require longer production run lengths (continuous processes) or increased number of like batches run each year, and to improve start-up control strategies to get the process on-aim as promptly as possible. The principal part of the answer must come from better production process design strategy.

THE PRODUCTION PROCESSES CRITICAL FOR QUALITY MANAGEMENT

Especially in the process industries, several processes within the "production" operation are critical in accomplishing quality of conformance. Critical production processes generate and use data. The information flows in various paths throughout the network of processes.

In Figure 27.4 the critical production processes are diagrammed. The production process itself is one of five types of processes that operate together:

- Production process
- Sampling processes
- Measurement processes
- Decision/control processes
- Computing processes

The shipped product cannot have consistently good quality of conformance unless all of these critical processes work together properly. In addition to the production process, each of the other processes also must be considered.

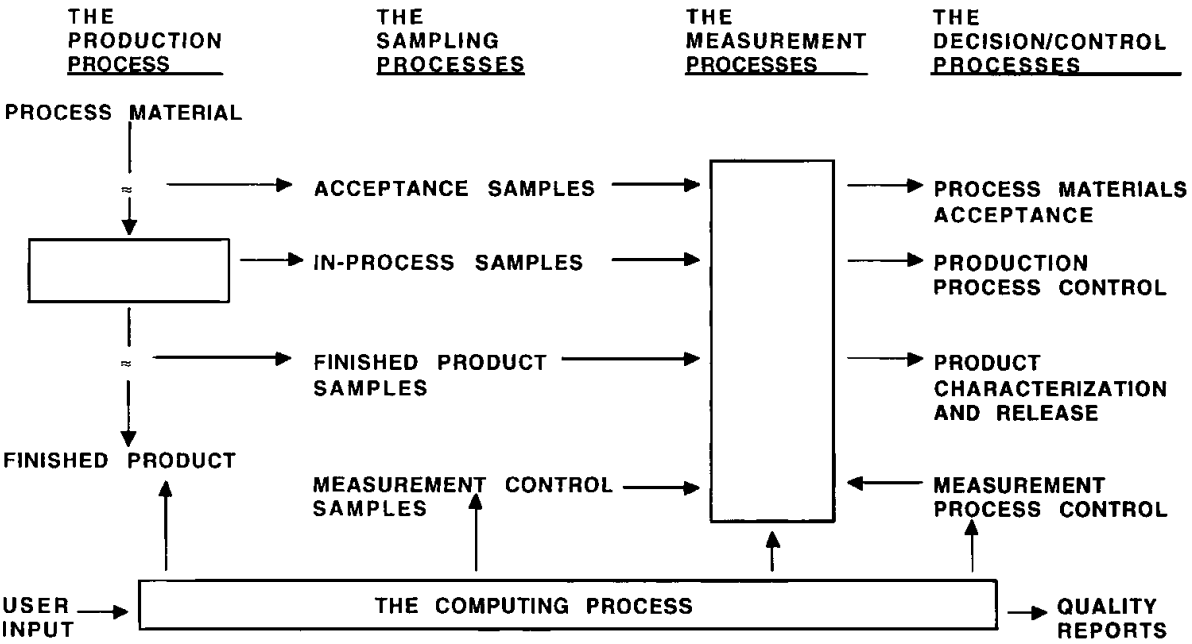

FIGURE 27.4 Critical production processes. [*From Marquardt* (*1991*).]

The Sampling Processes. When samples are taken for any of the purposes shown in Figure 27.4, the required structure and size of the sample must be determined quantitatively. This sampling plan will depend on where the major sources of product and measurement variability are present. Moreover, the sample must be taken in a way that makes it truly typical of the material which it must represent, so that:

- "Acceptance samples" of incoming materials may be required to verify conformity to their required specifications. In a well-developed quality system, suppliers' measurements can be relied upon, which minimizes the amount of acceptance sampling required, thus reducing redundant costs in the value-adding chain from supplier to producer.
- "In-process samples" are needed for production process control.
- "Finished product samples" are needed for production process control, for product characterization, and for product release.
- "Measurement control samples" are needed to keep the measurement processes accurate.

The samples that result from these processes must be tagged with identifications telling where they came from and how and when they were obtained.

Most quality management procedures are applied to a single property at a time. Although a single physical test sample is, in practice, frequently used to obtain test results for multiple product properties, the term "sample" in this section normally refers to a single product property sample.

The Measurement Processes. The output of the measurement processes is numbers (the measured property values for each sample submitted). Some measurement processes are conducted in the laboratory, while others are done on the production floor. Some are highly automated, while others are labor intensive. The measurement processes often are as complex as the production process, and are just as capable of going out of control. If reported test results have large measurement error, they may cause improper actions to be taken in the decision processes. This can cause the product uniformity to be poorer than if the process were left alone.

The Decision/Control Processes. The decision processes are of two types:

- "Process Control" decisions leading to actions to maintain the production process and the measurement processes on-aim.
- "Accept and Release" decisions leading to actions regarding product disposition to ensure that only conforming process materials are used and only conforming product is released.

The Computing Processes. Computer hardware and software typically implement parts of all of the preceding processes. Data from the measurement processes may be entered and stored in a computer database, either manually or by automatic instrument data entry. Automated instrumentation may be used to produce sample measurements. Data collected from these processes are then used as input to the control and decision processes. Diagnostic data analysis software may be used to produce graphs, reports, and other quantitative summaries to detect quality problems and monitor quality status.

The computer hardware and software processes involved in these tasks may be complex. The reliability and adequacy of the hardware and software used in these computing systems need to be given attention.

CONCEPTS OF STANDARD PROCESS AND STANDARD PRODUCT

Production Process Specifications. To ensure the production of a product that consistently meets customer requirements, the production process must be consistent, for example, from day to day and month to month. The set of product properties listed on the product specifications should, to the best of the producer's knowledge, encompass all the characteristics of the product that affect its ability to satisfy the needs of customers. However, it is not enough to rely upon the consistent satisfaction of established product specification limits. There are two reasons for this:

- The product properties for which specification limits have been established may not capture all the important characteristics of the product that affect its functionality in anticipated applications.
- Some customers may use the product in end uses or environments not anticipated by the producer, and these may be suitable end uses, but the producer's tests do not directly ensure consistent functionality in these applications. In such situations, there may be failures in quality of conformance despite the producer's best intentions. An "insurance policy" is needed.

The Standard Process as an Insurance Policy. Insistence upon a uniform production process is the principal mechanism by which a producer can ensure against the unknown risks just described. A uniform production process from one point in time to another, and from one production facility to another, tends to ensure the consistency of the product properties the producer does not measure, in the same way that it tends to ensure consistency of the properties and characteristics the producer does measure. Thus, there is need for "production process specifications" which define a "standard process." These complement the product specifications. The "standard process" is an essential tool for achieving conformance capability. Standard process protocols should be documented and readily available to all production personnel. In an organization that operates in compliance with the International Standards ISO 9001 or ISO 9002 (ASQC 1996), these protocols are among the "procedures" and "work instructions" available to all relevant personnel. If the standard process is treated as a secret, there can be no standard process.

For each process and each product type, "standard process" conditions should be specified, together with fixed "process limits" for each process setting or processing procedure. The standard process and process limits should be documented formally as "standard operating procedures."

Moves of manipulatable control variables within the documented "standard operating conditions" are permitted for process control, but limited as to allowable magnitude and authorization level required for the move. If more than one process line is producing the same product type, the lines may be operated at different conditions within the standard process if this is required to maintain on-aim control of product properties on each process line.

Definition of the process limits must sometimes be a matter of judgment; but wherever possible, the process control variable limits should be determined by conducting a statistically designed process calibration experiment surrounding the standard process conditions as a center point. (See Section 47, Design and Analysis of Experiments.) When limits for process control variables are specified on the basis of judgment, a rule of thumb is to set limits that exclude the most extreme 2 percent of process conditions used during extended past periods during which a consistently acceptable product was produced.

The concept of standard process also includes the following:

- No change may be made in the operating conditions of any production process for "testing" or "experimental" purposes without prior notification of all potentially affected organizational functions. By definition, product made under test or experimental conditions is not made under the standard process.
- No change may be made in:

  design of the product itself (or introduction of a new product)

  production process equipment

  raw materials or incoming parts (except routine replacements-in-kind of expendable items or materials)

without prior notification of all potentially affected organizational functions. By definition, product made after such changes is not standard product until the changes have been qualified, that is, it has been verified that the product meets all customer requirements and meets product specifications for all regular finished product characteristics for an extended period of time.

Control of Both Production Process and Measurement Process. Continual on-aim control of the production process is a part of the standard process and is a fundamental concept of good quality management. The production process control scheme is designed to promptly detect a shift of specified magnitude by the process average away from the aim point. System design procedures should ensure that the values of the specified shift and the product specification limits are mutually compatible.

Continual control of the accuracy of the measurement processes also is an essential part of the standard process concept. System design procedures should ensure that a measurement drift of specified size will be detected more promptly than is required for detecting a comparable drift in the production process. In that manner, measurement problems are discovered and fixed before they can cause problems in production process control or in product release decisions.

Every Process in a Quality Management System Must Be Audited. A quality management system enables objectivity and integrity in assessing the true status of product functionality. Its role is parallel to the financial system which enables objectivity and integrity in assessing the true economic status of a product.

Periodic financial audits are universally accepted as a means to ensure integrity of a producer's financial management system. Likewise, periodic audits of every process in a quality management system are essential to maintain continued system integrity.

Conforming Product. "Conforming product" is, by definition, product that is in conformance with product design specifications and is produced from standard materials in conformance with the standard process. It is the ultimate purpose of a quality management system to

produce only conforming product. It is important to provide tools to assess product conformance and to deal with situations where existing process performance does not consistently meet performance goals.

QUALITY EVALUATION BASED ON TRUE PRODUCT VARIABILITY FOR CRITICAL PROPERTIES

Each product property can be classified according to how it will be administered within the producer's quality management system. Critical properties are those properties for which the made-product total variability is so wide as to cause persistent difficulty in meeting current or near-term anticipated customer's needs. The lower and upper limits between which a critical property must fall in order to conform to specifications can be called "unit tolerance limits." These are limits on the scale of true product values with which shipped product units are to comply. The product specification format in Figure 27.5 shows the information needed to state adequately the quantitative true product value unit tolerance limits.

Both the customer and the producer evaluate product quality on the basis of final product characteristics. The customer needs to determine how well the product received will meet user needs. The producer needs an accurate evaluation of the quality of the product shipped. Variability in critical product characteristics is the enemy of quality of conformance. Variability in the measurement of critical product properties can make attainment of quality extremely difficult. Every quantitative value observed, however, is subject to variability introduced by the process of sampling and measuring the product characteristics. That is, every observation has the following structure:

$$\text{Observed value} = \text{true value} + \text{measurement error}$$

The statistical term "measurement error" refers to the net effect of all sources of sampling or measurement variability that cause an observed value to deviate from the true value; the term does not imply that an error or mistake has been made. Thus, the true value of a product characteristic is a value that does not contain any sampling or measurement error. A fundamental quality management system concept is the notion of quality evaluation based on true value for critical properties.

The customer and the producer both seek a common basis for discussion and evaluation of the product quality, a quantitative "true value" basis free of any sampling or measurement error. Straightforward statistical methods provide procedures for quantifying separately variability due to true product and variability due to measurement. These procedures require some extra effort. They are cost-effective for those critical, hard-to-control properties where quality of conformance really counts in the marketplace. Use of procedures to characterize product quality of conformance on a true value basis is valuable for both producer and customer

The inevitable presence of measurement variability is one reason for the necessity of using statistical methods in product quality work. The other reason is that the true property values of product units also vary from unit to unit. Thus, we are always faced with the necessity of making decisions about a variable product in the face of noisy measurements on that product. Especially in the process

Property	Product unit	Intended value	Unit tolerance limits		Test method
			Lower	Upper	
1					
2					
3					
…					

FIGURE 27.5 Format for true product value quantitative specifications. [*From Marquardt* (*1991*).]

industries, it is not uncommon to find that the measurement variability is as large as, or larger than, the true product variability. Statistical analysis of variance techniques are used to break up the total variance observed for a product property into useful "variance components." It is then possible to quantify true product variability separately from measurement variability and to estimate the proportion each variance component contributes to the total variance. For critical properties it is desirable to express the product specifications on a true-value basis.

IMPORTANCE OF OBJECTIVELY DESCRIBED PRODUCT SPECIFICATIONS

To design and produce a product that will meet customer requirements, we must be specific about what those requirements are. The necessary content and format of a product specification form a primary vehicle by which a producer and a customer can communicate about the satisfaction of customer requirements. The product specifications document the best approximation of the translation of customer needs and requirements into measurable product properties which can be used by the producer to manage the production process. Especially in the process industries, a small set of defined measurable product properties cannot always fully describe the needs and requirements of all end users. Consequently, the product specifications must be seen as an ever-evolving document reflecting the current understanding of the producer and customers as partners in the translation process.

Three crucial matters have often been ignored by producers in setting specification limits:

- Definition of the product unit
- Definition of the test method to be used
- Appreciation of the role of component sources of variability

Meaningful, technically sound product specification limits can be developed only when the product unit, the test method, and the variance components are all taken into account.

Product Specifications — Content and Format. A product specification serves both as a documentation of the (specified or implied) agreement between the customer and a producer and is a compendium of information on the product (ASQC 1996b). Ideally, the customer is directly involved in setting product specifications. In many situations, the agreement is between the producer's Marketing and Production organizations, with Marketing representing many customers' needs. The specification contains two types of information:

- *Descriptive information on the product:* Name, identification code, chemical composition, engineering designs and drawings, uses and functionality, units of measurement, delivery units and conditions, and other qualitative characteristics of the product as well as proper, safe handling and storage information.
- *Quantitative specifications for measurable product properties:* Numerical values of intended levels of properties and ranges or limits. Most products have from 10 to 100 such measured properties listed on their product specifications. Many products have one, or several properties in their "critical few." These quantitative specifications (intended values and limits):

  Document the best current definition of the product, in measurable terms, that is expected to meet the needs of customers and that can be supplied commercially by the producer with current technology and facilities

  Are for a prescribed measurement method

  Can apply only to properties that can be measured on shipped product

The specifications are incomplete unless all of these items are provided. The entry under "test method" usually is a code reference to a document describing the standard test method (including test equipment, materials, and protocol). For some critical properties, such as impurity levels, only a lower or an upper one-sided tolerance specification may be needed.

Three terms may be interchangeable in some contexts, but may be numerically different in other contexts (Figure 27.6). For clarity of meaning, use each term where appropriate.

The value of the aim point X_0 used in production process control usually is set equal to the intended value.

For noncritical properties, the unit tolerance limits on the product specification format are replaced by observed value limits, usually 3 to 4 standard deviations of a test result above and below the intended value. The format shown in Figure 27.7 can be used.

Definitions of Product Unit Terms. A product may be gathered into various unit quantities for specific purposes, for example, a warehousing unit, a shipping unit, or a customer-use unit. It is important to define precisely a "product unit" of finished product to which product specifications will apply. This is essential for quantitatively defining product quality and applying the correct sampling system and statistical procedures. The term "product unit" applies equally to a physical product, a software product, or a service. For processed materials selection of the appropriate unit of finished product in a given instance should take into account two features:

- The physical units (bags, rolls, bottles, pallets, etc.) in which the finished product is handled by the producer.
- The physical units in which the customer will use the product.

The product unit for product specifications is best selected as the smallest conveniently handled quantity of product within which a customer will likely detect a significant departure from intended functionality, if such departure exists. Considerable discretion often is available in selecting a product unit for quality management purposes. The product unit may be as small as the "unit

Term	Usage
Intended value	The value of a property which specifies the product functionality *intended by the product design* (and documented in the product specification) for every product unit.
Aim value X_0	The value of a property which specifies the value *intended to be achieved by the production process* for every product unit made.
Average value	The value of a property which specifies the *average* value actually achieved by the production process, averaged over many product units.

FIGURE 27.6 Definitions of product specification terms. [*From Marquardt* (*1991*).]

Property	Intended value	Observed value limits		Test method	Product Unit
		Lower	Upper		
1					
2					
3					
…					

FIGURE 27.7 Format for observed value quantitative specifications. [*From Marquardt* (*1991*).]

quantity of sampled material" from which a single "test result" is obtained, or it may be many "adjacent" multiples of that unit quantity. Although the product unit choice could vary from property to property, it is operationally helpful to select the same product unit for all product styles and properties in a given product line.

Generic Concepts of Product Unit and Unit Tolerance Limits. The terms "generic product unit" and "generic unit tolerance limits" (GTLs) may be used in this discussion for true product value quantitative specifications without reference to any specific form of product unit. In most of the illustrative discussions, the product is a processed material that can be sampled and measured at various points in the product unit. The GTLs apply to the true average of the property over an entire product unit. If the product is an item whose property is only realizable and measurable at one point in the product unit, then the GTLs apply to the true value at that point. Accordingly, these product-unit-concepts apply equally to process industry products and mechanical industry products.

Definition of product specifications for product properties that are subject to aging requires special clarification. The term "shipped product" is not usually meant to include aging shifts, except for the aging that occurs in the normal time lag from production until sampling for product characterization and release, usually less than a few days. In each such instance where aging is involved, the time lags should be part of the product specifications.

Unit Package—the Common Case. In the most common case, the appropriate choice of product unit is "unit package." The unit tolerance limits for critical properties then apply to the true average of the shipped product property for the entire unit package. The unit package should be a unit of product such that within-package variability is not a predominant source of variability. It can be noted that product from the process industries often undergoes physical blending during normal use by customers, resulting in some degree of averaging of property values that may vary throughout each product unit.

Examples of such products and their typical unit package definitions are presented in Figure 27.8.

The continuous filament yarn example needs special discussion. It is an example where the end-use product (a textile fabric) is constructed from multiple unit packages by a process (knitting or weaving). Some "blending" occurs because of the random allocation of yarn tubes to adjacent yarns in a fabric, but the continuity of each threadline is maintained. The resulting blending is not as effective in reducing visual fabric defects as is the blending of staple fiber where each filament is short and is separately blended. Nevertheless, extensive experience indicates that a tube of yarn is an operationally desirable product unit for quality management purposes.

Unit tolerance limits are, in this case, unit package tolerance limits. If within-package variability must be controlled, it can itself be treated as a property of the package. To simplify presentation of concepts and terminology in this section, the discussion is restricted to the package structure. Other product unit definitions should be selected only for special needs.

Variance Components for the Unit Package Case. The terms "variance" and "variance components," respectively, describe the overall, total variability and the meaningful component sources of variability of product properties and measurement methods. These terms have precise mathematical definitions that are used in computations.

Product	Unit package
Staple fiber	Bale of staple
Powdered pigment	Bag of powder
Pelletized elastomer	Bag of pellets or pallet of bags
Paint	Can of fluid or carton of cans
Insecticide	Metal drum of fluid
Continuous filament yarn	Tube of yarn
Photographic film	Box of film sheets or roll of sheet material

FIGURE 27.8 Typical products and their unit packages. [*From Marquardt* (*1991*).]

When the product unit is a package, the product variance components are defined as shown in Figure 27.9. These components are always present, although their magnitudes will differ from one product and property to another. For any choice of product unit, measurement variance components are always present.

The time interval corresponding to the "same nominal test time" must be defined in context. In many cases, it should be one laboratory shift. Typically, a "nominal test time" is the time interval over which a group of samples, submitted at the same time, would normally be tested. VST, defined in this manner, includes all short-term sources of measurement variability that affect a test result, including differences among multiple instruments or multiple operators that may typically be assigned to analyze the several samples. If the measurement is a destructive one, the VST component inextricably includes the local product variability associated with the quantity of product used to measure a test result, as well as the short-term measurement variability itself. VLT includes all long-term sources of measurement variability.

A "test result" is a single numerical value that is the end result of carrying out a test method for a specific property. A "test method" is a specified (documented) set of test equipment, test materials, and test protocol, whose input is a specified unit quantity of sampled material. The test protocol may require more than one test specimen to produce one test result. For example, the protocol may require averaging measurements from several test specimens.

The five variance components for the package unit can conveniently be visualized in the nested structure shown in Figure 27.10.

Variance component	Symbol
Lot-to-lot variance about the true process average	VLL
Package-to-package variance about the true lot average	VPP
Within-package variance about the true unit package average	VWP
Short-term measurement variance of nominally identical, disguised samples tested at the same nominal test time	VST
Long-term measurement variance; all measurement variance in excess of short term	VLT

FIGURE 27.9 Definitions of variance components for the unit package. [*From Marquardt* (*1991*).]

<table>
<tr><td rowspan="4">Total variance</td><td rowspan="3">Total true product property variance</td><td>External to lot (VLL)</td><td></td></tr>
<tr><td rowspan="2">Within lot</td><td>Package-to-package within lot (VPP)</td></tr>
<tr><td>Within package (VWP)</td></tr>
<tr><td rowspan="2">Total measurement variance</td><td>Short-term (VST)</td><td rowspan="2"></td></tr>
<tr><td>Long-term (VLT)</td></tr>
</table>

FIGURE 27.10 Components of variance structure for the unit package. [*From Marquardt* (*1991*).]

Product Specifications and Market Requirements. Historical practice in setting product specification limits has varied from one situation to another. In the process industries, defining both customer requirements and requirements for incoming materials has been difficult because the requirements are rarely known precisely, and have been based on experience and judgment.

The problem of basing specifications on incomplete information is particularly acute when one organizational unit gains a monopoly on input to specification setting. Where specifications have been provided initially by Research and Development, they may reflect the technical judgment of the Research and Development group based on the limited experience of the laboratory and pilot projects. Where specifications have been provided by Marketing, they may reflect Marketing's desire to meet customer requirements, without regard to technical capability to do so in Production. And where Manufacturing dominates the setting of specifications, those specifications are likely to be easily met in production but ignore the needs of the customer, or fail to take into account the conditions imposed by a new technology. None of these unilateral procedures can ever be totally satisfactory because none of the involved parties has all the information necessary to make the proper judgment. That is why, in everyday production and marketing practice, the product specification limits often have become a source of friction or have been ignored altogether.

Whenever customer needs for a critical property are known, the specifications should be based on these needs. If customer needs are not precisely known, the specifications should result from a consensus-forming process among Production, Marketing, and the customer. Research and Development should play an explicit supporting role in this process. Production should provide data describing the inherent magnitude of variability in the finished product and in the measurement procedures, based not upon idealized process or measurement capability, but upon the actual historical performance. All parties should understand that wider specifications could increase the producer's yield and conformance and reduce production costs. Narrower specifications, on the other hand, may result in a more competitive product and larger market share and should reduce customer complaints and claims paid to customers for shipped product that does not perform as expected.

In practice, there is not usually a sharp point of demarcation between good product and bad product. Product having actual product levels not far outside the specifications may perform adequately for its intended use, in most instances. Hence, companies should use the terms "conforming" and "nonconforming" to specifications and avoid, in this context, terms such as good, bad, and defective. This usage is consistent with current terminology in quality systems standards (ISO 8402:1994).

As process improvements are implemented, the product variability should decrease and become clearly narrower than the specification limits. Some customers may develop uses for the product that depend upon the "de facto specification limits" that are narrower than the documented specification limits. It will then become necessary to agree on narrower specification limits to recognize the new trade needs. Alternatively, the property might be removed from the "critical property" list because the process performance is now consistently better than trade needs.

Often, in the process industries, the trade need is not well known, or there are so many different end uses, each with its own specification limits requirement, that it is impractical to develop quantitative data on trade need for all segments of the market. In this case, the producer's process performance can be used as input to discussions between the producer and customer (or between the producer's Production and Marketing organizations so long as the customer is properly represented), where the intent is to arrive at mutually agreeable specification limits.

MEASURING QUALITY OF CONFORMANCE WITH PRODUCT DESIGN

Quantitative Definition of Conformance. "Conformance" is defined quantitatively as the percent of product units which meet product specifications, assessed over a suitable period of time. This quantitative definition of conformance applies to critical properties whose product specifications are on a true product value basis. In various contexts, we need to distinguish:

- "Conformance of product made," which refers to the percent of all product units made which meet true product value specification limits
- "Conformance of product shipped," which applies to the product units released for shipment and refers to the percent of released product units which meet true product value specification limits. When a formal lot release procedure is in place, the product units shipped may not include all product units made.

In this section, the term "conformance" always means conformance of product made, unless explicitly stated to mean conformance of product shipped. Both conformance of product made and conformance of product shipped can be estimated using appropriate computing methods. The definition of "conformance of product shipped" carries with it an assumption: the product units shipped are the same as the product units released.

Goal Conformance as a Fixed Reference for Product Specifications. An appropriate "goal conformance" level should be selected. Once selected, the goal conformance becomes the fixed reference point against which product quality of conformance is thereafter reckoned.

Typical values of goal conformance are 99 percent or 99.7 percent, but the appropriate value depends upon product characteristics and other factors. For marketing and internal administrative convenience the goal conformance level should be the same for all products within a product line. As uniformity improves for a given product, the width of the product specification range can decrease, with goal conformance held constant.

The approach recommended here differs from the "6σ" approach used widely in the mechanical industries. The "6σ" approach keeps the specifications constant, and strives to continually improve the percent conformance to become virtually 100 percent. The approach recommended here keeps the goal conformance constant at a value (99 percent or 99.7 percent) that can be quantitatively assessed with moderate sample size, and strives to continually narrow the width of the product specification range. Both approaches have the same ultimate intent.

Experience Curves as Measures of Continual Improvement. To display progress (or lack thereof) in continual improvement, a useful tool is a plot of the standard deviation for a single product unit (package) versus calendar time. Such plots are examples of "experience curves."

Experience curves can be plotted for properties whose specifications are on a true-product value basis or an observed value basis. In the latter case, the plotted standard deviation contains both true product variability and measurement variability. Various forms of experience curves can be useful.

For example, for properties having true product value specification limits, the width of the product specification range provides a formal measure of quality of conformance. The width is a specified multiple of the standard deviation of true product unit values for any specific property. The width of the specification range should become smaller periodically as the product uniformity is improved.

REFERENCE BASES FOR MEASUREMENT CALIBRATION AND PRODUCT CONTROL

Hierarchy of Reference Bases. Each routine test measurement method is itself an on-going process subject to all the ills that befall production processes. Each such process needs a reference basis. The measurement process is the reference basis for the production process. "Recognized standards" and/or "control samples" are used as reference bases for the measurement process. Reference bases are used for the purpose of maintaining measurement procedures and equipment in satisfactory condition to run routine analyses.

Recognized Standards as Reference Bases. Many test methods are direct measurements of dimension, weight, time, temperature, electrical quantities, and the like. Such measurements usually are the most important properties for many products of the "mechanical industries." These measurement methods periodically must be calibrated within each manufacturing plant and each test laboratory against secondary standards of high accuracy, stability, and uniformity. The secondary standards are, in turn, calibrated against primary standards of ultimate accuracy, for example, at the National Institute of Standards and Technology (NIST), in a traceable sequence of steps. The end result is that such measurements can have small variance and small bias if suitable attention is given to

- Periodic calibration against recognized standards
- Test equipment maintenance
- Standardized test procedures
- Operator training

Some products require high absolute accuracy of such direct measurement; this may present serious problems. Elaborate metrology programs may be required to ensure adequate calibration, standardized procedures, maintenance, and training.

Control Samples as Reference Bases. In the process industries, many test methods are incapable of direct traceability to recognized standards. Since they are simulations of customer-use conditions, they are indirect, multistep, unique to a product, or otherwise nonstandard.

These test methods usually involve some direct measurements that can be accurately calibrated individually but not collectively as a total test procedure. Adequately maintaining these test methods requires more than just a good metrology program, more than just periodic calibration, equipment maintenance, standardized procedures, and operator training. For these test methods "control samples" must be used as reference bases, and control procedures must be used to maintain control.

A control supply is a quantity of regular first-grade product, properly characterized and validated, that is retained for use in testing subsequently manufactured product. Many issues in measurement control center on the proper choice and use of control samples and the control supplies from which they are taken.

CONTROL OF THE MEASUREMENT PROCESS

Test Method Administration. Good test method administration, whether physically located in a laboratory or elsewhere, requires regular calibration of test instruments against recognized standards. Examples are

- A standard weight to calibrate the zero setting of a weighing scale
- A standard white reflecting plate to calibrate a colorimeter
- A standard solution to titrate a chemical test instrument

It must be clearly understood, however, that these calibration procedures are not subject to many of the actual sources of variability and bias in taking, preparing, and conducting measurements of routine production samples. Consequently, virtually all test methods need statistical process control such as Twin Metric control or Cumulative Sum (CUSUM) control of the full measurement process. (See Section 45 for a discussion of CUSUM control.)

Twin Metric control, a form of CUSUM control, offers exceptionally favorable balance among control scheme performance, simplicity, and intuitive user interface; this section refers to Twin Metric control (Marquardt 1993, 1997; Marquardt and Ulery 1991, 1992) as a prototype for state-of-the-art statistical process control in today's computerized working environments. (See Section 45, Statistical Process Control for additional discussion of statistical process control.)

Availability of Means of Calibration. By employing a suitable control supply for a measurement process, procedures such as Twin Metric control can be used very effectively to detect drifts, level changes, and sensitivity changes, so that appropriate corrective action may be taken. Quite analogous to production control applications, Twin Metric or CUSUM for measurement control are equally valid for situations where a predetermined calibration knob exists and for situations where no such designated control variable is available.

Specification of Aim point X_0. The measurement process control, such as Twin Metric, will normally use the nominal value of a control supply as the aim point, X_0. Often, the true average is not as important as the uniformity of measurements by different instruments using that control supply or by a single instrument using that control supply at different times. Thus, it is important that the control supply property level remain stable with time, or at least that any changes of the control be adequately characterized. The measurement control aim point, X_{0M}, should be near the production process aim point, X_0. Multiple measurement control supplies and statistical process control schemes may be necessary to satisfy this objective when the measurement is used for several products which have different property levels.

Specification of Other Statistical Process Control Parameters. The relationship between the design of the measurement process control scheme and the design of the production process control scheme is important.

The acronym ARL (for *a*verage *r*un *l*ength) is commonly used (Bissell 1986; Champ and Woodall 1987; Kemp 1961; Lucas 1973, 1976, 1982, 1985*a*, 1985*b*; Marquardt 1997, Page 1961) for the average number of process control sampling intervals before a control scheme will produce a signal. ARL(0), the value of ARL when the process average is on-aim, should be large. ARL(1), the value of ARL when the process average is off-aim by one multiple of the process standard deviation (SPROC), should be small. For example, the classic Shewhart chart with control limits at ±3 SPROC has ARL(0)=370, ARL(1)=44. Twin Metric control and CUSUM control provide combinations of ARL(0) and ARL(1) that are far better than Shewhart charts. ARL, measured in this (dimensionless) way in number of sampling intervals, can be converted to units of elapsed time or units of production volume if desired. To ensure product quality in routine production the relationship between production process control and measurement process control should be an explicit element of design. Figure 27.11 displays the correspondence between parameters of production process control and parameters of measurement process control.

The standard Twin Metric design procedure described by Marquardt (1997) is used in selecting the parameters for both production process control and measurement control. However, different criteria are applied.

Production process control parameter	Translation	Measurement process control parameter
X_0	Process aim point	X_{0M}
ARL(Δ)	Average number of $ARL_M(\Delta)$ measurements to produce a signal when process is off-aim by (Δ) (SPROC)	
SPROC	Process standard deviation	$SPROC_M$

FIGURE 27.11 Parameters for production and measurement control. [*From Marquardt* (*1991*).]

A measurement process control scheme should be designed so that a measurement level change from X_{0M} will be signaled and corrective action is taken before the change results in a production process control signal and an unnecessary adjustment in the production process.

Let D be a fixed magnitude of production process shift that is important to detect promptly in the measured product property level.

Further, let $\Delta = D/SPROC$.

$ARL_M(\Delta)$ should be smaller than $ARL(\Delta)$. A practical place to begin is to set $D = SPROC$ (i.e., $\Delta = 1$), and try to have $ARL_M(\Delta) \leq \frac{1}{2} ARL(\Delta)$, where ARL and ARL_M are expressed in the same units of time. The intent is to allow time to correct the measurement problem after its detection before a production process signal occurs.

To satisfy the desired inequality, the following design variables are available:

- *SPROC and $SPROC_M$:* $SPROC_M$ is likely to be smaller than SPROC for the same sampling interval, sample size, and structure because the measurement control supply is likely to be more uniform than routine product made, even during periods of good production process control.
- *ARL(Δ) and $ARL_M(D)$:* Since the ARLs are to be compared in the same units of elapsed time, the inequality can be satisfied more easily if the sample interval for measurement control is shorter than the sample interval for production process control.
- *ARL(0) and ARLM(0):* It is usually possible to have a value of $ARL_M(0)$ (for the on-aim measurement process) which is smaller than the value of ARL(0) (for the on-aim production process). This is because false alarm signals on the measurement process can usually be tolerated more readily than false alarm signals on the production process. Having $ARL_M(0) < ARL(0)$ pushes the relationship between $ARL_M(\Delta)$ and $ARL(\Delta)$ toward satisfaction of the inequality.

This discussion of the effect of design variables on ARLs applies to all forms of statistical process control (e.g., Twin Metric, CUSUM, or even Shewhart charts).

SPROCM Estimation. A simple, robust estimate of the measurement process standard deviation SPROCM can be determined by the mean square successive difference (MSSD) method. Marquardt (1993) discusses the MSSD method and useful generalizations.

Sampling Frequency and Test Protocol. As a general rule, samples for Twin Metric or other statistical process control of a measurement process should be tested each day (or each shift), preferably at a random time. An exception would be infrequently measured properties for which control samples need to be taken only when routine production samples are being processed through the measurement process. Another exception would be a test method that tends to require frequent recalibrations. In that case more frequent measuring of the control supply may be needed.

Test results from the measurement control supply should be obtained using the same test protocol as is used for test results from production samples.

SELECTION AND PREPARATION OF CONTROL SAMPLES

Control Supply Selection. Control supplies for measurement control should come from regular product typical of routine production. Candidate control packages should be "validated" before final selection as the control supply. The validation process should include several criteria:

- The production process should be qualified as within "standard process" limits and as operating "on-aim" during the period when the control packages were produced.

- Test results from the candidate control packages should fall within the product specification limits for all properties.
- Samples used to estimate the values of X_0 and $SPROC_M$ of the control supply should span many nominal test times to ensure that long-term measurement variability is well represented. Normally, the value of X_0 must be estimated by the average of a series of measurements on the control supply itself, covering at least 30 calendar days. This value of X_0 should be based on at least 60 sets of measurement data covering at least 90 days.
- Where the control supply is to be used at more than one production site, validation may be appropriate on an interlaboratory basis.

Control Sample Preparation. The control supplies should be stored in an environment that will prevent damage and minimize degradation. If the product is a discrete, particulate, or liquid material, the control samples for measurement on a given day should each represent a random sample from the original package(s), either by virtue of being taken from a random location in the package(s) each time, or by virtue of thorough stirring or blending of the control package(s). If the product is a continuous sheet, filament, or the like, then control samples used for the actual measurement should be spaced widely enough to be a representative sample of the whole package. When this is not practical, use of multiple or composite control samples is especially important.

Control samples should be identified in a manner that does not call special attention to them as distinct from regular production samples. The goal is to avoid special treatment (hence distortion of level or variability) by measurement operators.

Composite, Multiple, and Staggered Control Samples

Composite Control Samples. Some measurement methods allow sample quantities to be obtained from several control packages and then plied, blended, or composited into a single control sample to give a single test result. When plying, blending, or compositing is feasible, it provides a useful procedure to reduce the contribution of within-control-package variability and (provided two or more packages are composited) the contribution of between-package variability to SPROCM. Compositing does not reduce the contribution to SPROCM from short- and long-term measurement variability.

Multiple Control Samples. Using the average of separate test results from multiple control samples is more effective for reducing SPROCM than a single test from a composite control sample. The average of separate test results from multiple control samples reduces the contribution of within- and between-control-sample variability to SPROCM, to the maximum degree feasible, and also reduces the contribution from measurement error, especially the short-term measurement variance component. Typically, this greater effectiveness of multiple control samples outweighs the cost savings from composite control samples.

Staggered Control Samples. Where the control supply uses multiple control packages, they should be replaced preferably on a staggered schedule rather than all at once. For example, if eight control packages are maintained (whether for compositing or for multiple control samples), a practical scheme would be to replace (the oldest) two at a time. Such staggering is helpful to maintain a stable control supply average age, hence a stable control supply average level, when consistent control level changes due to aging are present.

Control Samples at More Than One Level. Where multiple products have a wide range of levels on a measurement or where two families of products are produced—a type that runs high in the data range and a type that runs low in the data range—then two separate measurement control procedures, such as Twin metric with control supplies at the two levels, may be advisable.

USING CONTROL SUPPLIES

Control Samples as Computational References. For some test procedures there is large variability from one test time to another, but these large systematic errors at any one test time affect equally all samples processed at the same time. The best approach to such problems is tighter control of the test method operating conditions and procedures to reduce the time-to-time variability that inflates the long-term measurement variance component. In situations where a practical route has not yet been found to reduce the time-to-time variability, it is common to calibrate all the routine samples run at a given time by simultaneously analyzing some control samples. Then the reported test result is determined by referencing the raw test results computationally to the control sample results from the same test time. In the simplest instance the referencing is done by simple differencing:

$$\text{Reported test result} = \text{OV}_{\text{PS}} - \text{OV}_{\text{CS}}$$

where OV_{PS} = process sample observed value and OV_{CS} = control sample observed value.

The consequence of this approach is that the short-term measurement variance component for the reported test result is double that for the process sample observed value. This comes about because the variance of a difference is the sum of the variances, assuming the observed values are statistically independent with respect to short-term sources of variability. Under the assumption that the routine samples and the control samples have the same variance, the variance of their difference is double the variance of one observation. Hence, the use of a control sample as a computational reference is beneficial only if the reduction in the long-term measurement variance is substantially greater that twice the value of the short-term measurement variance. The short-term measurement variance inflation can be made less than a doubling by using, as computational references, the average of several simultaneously analyzed control samples.

Sometimes an observed value is referenced to a control by ratio rather than difference. Propagation of error theory shows that the inflation of the short-term measurement variance component due to a ratio is quantitatively similar to the inflation due to a differencing operation, so the same guideline is appropriate.

Multiple Measurement Process Configurations. When any one of many measurement process configurations, such as multiple instruments or multiple operators, may be used in routine testing of the same product property, it is necessary that all such measurement process configurations be maintained at the same value of X_0. To maintain the same value of X_0, it is desirable to use the same controls for all. This enables expeditious detection of biases among instruments or operators. For example, where there are multiple instruments, Twin Metric schemes could be maintained for each instrument, the average of all instruments, or differences between each instrument and the average of all instruments. Obviously, not all of these should be used for any one application.

Confirming the Effectiveness of a Measurement Adjustment or Calibration. When a measurement Twin Metric or CUSUM signal is received and proper action is taken, it is advisable to carry out additional testing with controls to confirm that the action has in fact returned the measurement process to the aim point. Such a confirmation step is particularly advisable when the adjustment or calibration of the measurement is known to be inaccurate or has a history of poor behavior.

TESTING PRODUCT WHEN MEASUREMENT PROCESS IS OFF-AIM

When the measurement process is detected to be off-aim and reaction to this knowledge returns the measurement process to the aim point quickly, no special steps need be considered in dealing with the product or the production process. If the measurement process is not returned promptly to the

aim point, the measurement process output should not be reported or used to control the production process or to characterize the product. Simply stated, when the measurement process is off-aim too long, then the product is not being produced under standard operating procedures and should be given special marketing treatment.

A backup measurement method (often less automated, slower, and more costly per test result) may be available for emergency use. This backup method must itself be periodically validated to maintain its accuracy for when it is needed.

VALIDATING NEW MEASUREMENT METHODS

If we cannot measure a problem adequately, we cannot correct it either. For this reason, periodic adoption of new/better measurement methods is a principal route to quality improvement.

Whenever it is proposed to substitute a new measurement method for an existing method to measure the same characteristic of the product, it is necessary to establish that the new method is adequate for the needs. It is not enough to demonstrate that the new method is cheaper, faster, less labor intensive, and the like. It must have three performance characteristics:

- The slope (sensitivity) of the average response of the measurement process must be sufficiently large versus the property measured to provide the needed average responsiveness.
- The variability of the measurement process must be small enough in comparison to the slope of the average response so that an adequate signal-to-noise ratio is obtained.
- The measurement process, with its documented test protocol and its procedures for periodic calibration, must be demonstrated to be stable and reliable in actual use.

The first two performance characteristics can only be demonstrated by a designed experiment. (See Section 47, Design and Analysis of Experiments.)

The third performance characteristic can be demonstrated by an extended simultaneous overlap period during which both the old and the new methods are used, allowing the measurement variability sources for the new measurement method (i.e., SPROCM and/or VST, VLT) to be estimated under conditions of actual use. During the time when data are collected for purposes of estimating the value of X_0 and SPROCM for the new method, the old test method should remain in place for purposes of process control and product characterization.

The relationship between the old and new methods may often be demonstrated by scatter plots and calculations. However, it must be understood that the observed numerical correlation coefficient between two measurement methods will be lower than the correlation between the true average responses due to the measurement variances for both methods (Hald 1952, p. 615). Moreover, the new measurement method may not measure precisely the same product characteristic as the old method. This is a vexing problem for many processed material products. This points up a fourth important performance characteristic that any measurement method applied to final product must have:

- Measurements from the new method must correlate with customer use requirements.

Here again, experimental design methods are the tools to establish adequacy of the measurement method.

ESTIMATING AND MAINTAINING VARIANCE COMPONENTS FOR THE PRODUCT AND MEASUREMENTS

Previously in this section the "package" form of product unit was defined, and with it, the five variance components that are needed. The tool called "analysis of variance" (ANOVA) is the statistical

method for separating the total observed variability in a measured product property into sources of variation, and for estimating the magnitude of variation that can be attributed to each source. (See Section 47, Design and Analysis of Experiments.)

Analysis of variance should be used in many ways, including

- To analyze "routine production process data" that are obtained to monitor the process average and variability, and to provide information to periodically update the quality system design.
- To analyze on-going "maintenance data" that are obtained to maintain current estimates of the measurement process and within-package variance components. When the maintenance data are combined with the routine production process data, all five variance components can be estimated separately and updated regularly.

Analysis of Variance Using Production Process Data. One-way analysis of variance, also known as "among and within groups ANOVA," is a statistical method for isolating two sources of variation in a measured product property and for estimating the magnitude of variation that can be attributed to each of the two sources. (See Section 47, Design and Analysis of Experiments.) This discussion is intended to highlight the relevant concepts of ANOVA and to illustrate the calculations required when the product unit is a package. In practice, the ANOVA computations should be computerized as part of the software system.

Guideline for Obtaining Variance Components Data. The variance components estimates should be based on data that:

- Provide at least 60 degrees of freedom for the estimate of each component
- Cover at least 60 production days
- Cover at least 90 calendar days

When both routine production data and maintenance data are being collected regularly (e.g., daily), this guideline is straightforward to implement. There are strong reasons for this guideline, both theoretical and practical.

In theoretical terms, the guideline is important to ensure enough data so that variance component estimates are adequately close to their true values. The theoretical effect of degrees of freedom in the precision of estimating a simple variance (single variance component) for a random sample is shown in Table 27.1.

Thus, 60 to 90 degrees of freedom are required to get a variance estimate that will be within 25 to 30 percent of the true value with reasonable confidence. Small variance component estimates derived from ANOVA calculations may have somewhat greater statistical variability. This level of accuracy is necessary and is sufficient for the various uses of the variance components.

TABLE 27.1 Confidence Limits on Estimate of Variance.

Degrees of freedom	90% Confidence limits on the ratio: estimated variance/true variance
4	0.18, 2.4
10	0.39, 1.8
60	0.72, 1.32
90	0.77, 1.25

Source: Donald W. Marquardt (1991). *Product Quality Management,* DuPont Engineering, Wilmington DE.

In practical terms, the guideline is also important. From experience with a wide variety of applications, it has been found that adequate stability of process and measurement variances can only be obtained when sampling covers the elapsed time periods prescribed in the guideline.

Variance Component Estimates from Production Process Data. The two mean squares calculated in the one-way ANOVA are not themselves the variance components (i.e., VLL, VPP, VWP, VST, and VLT). The within-lot mean square is only influenced by sources of variability occurring within a lot. The lot-to-lot sum of squares, on the other hand, is influenced not only by lot-to-lot sources of variability but within-lot sources as well.

Call the within-lot variance component VPPU, for the package product unit case, where the U stands for "uncorrected." VPPU is the source from which VPP is calculated, but it must be "corrected" for the effects of other within-lot variance components. Call the lot-to-lot variance component VLLU. If three packages were sampled per lot, the lot-to-lot mean square is an estimate of:

$$\text{VPPU} + 3 \times \text{VLLU}$$

The one-way ANOVA table can now be completed as in Section 47, Design and Analysis of Experiments, and expressions for expected mean squares can be used to solve for estimates of VPPU and VLLU.

These expressions for the expected mean squares are exact for the true (population) values of the mean squares and variance components. The estimates of the variance components are obtained by substituting the estimates for the population values, and solving for VPPU and VLLU. The expected mean square expressions in Figure 27.12 show that VPPU = MSWL directly; then VLLU = (MSLL − VPPU)/*a*.

Neither VPPU nor VLLU is an estimate of any of the five desired package product unit variance components, VLL, VPP, VWP, VST, or VLT. Both VPPU and VLLU are estimates of combinations of the variance components. As mentioned earlier, VPPU includes all sources of variability occurring within the lot, namely, VPP, VWP, and VST, while VLLU includes all sources of variability occurring external to lots, namely, VLL and VLT. In fact:

VPPU estimates VPP + VWP + VST

VLLU estimates VLL + VLT

Estimating VWP, VST, and VLT From the Maintenance Sampling Plan. It is important to estimate and update all variance components on a regular basis, using data accumulated during on-going operation of the system. The routine production process data normally are used for production process control and sometimes for product release, in addition to their use in estimating and updating variance components. As described earlier, estimates of

$$\text{VPPU} = \text{VPP} + \text{VWP} + \text{VST}$$

$$\text{VLLU} = \text{VLL} + \text{VLT}$$

come from the routine production process data.

Source	Sum of squares	Degrees of freedom	Mean square	Expected mean square
Lot-to-lot	SSLL	DFLL	MSLL	VPPU + $a \times$ VLLU
Within-lot	SSWL	DFWL	MSWL	VPPU
Total	SSTOT	DFTOT	MSTOT	

Note: a is the number of packages sampled per lot.

FIGURE 27.12 ANOVA table with expected mean squares. [*From Marquardt* (*1991*).]

To be able to estimate all five variance components, extra production samples—the "maintenance samples"—are required at regular time intervals. Typically, a group of maintenance samples is submitted to the measurement facility daily whenever the process is making the product. The maintenance data are used to estimate and, periodically, to update ("maintain") the values of VWP, VST, and VLT.

Maintenance Sampling for Measurement Components of Variance. The minimum adequate extra sampling for maintenance of VWP, VLT, and VST requires a group of four samples to be submitted routinely at scheduled intervals (e.g., daily) to be measured for each sampled property, a so-called ABCD plan. The four maintenance samples for the ABCD plan are designated A, B, C, and D. A fixed sampling strategy should be used in selecting the A, B, C, and D samples. For example:

- Sample A might always be taken from near the "top" or "outside" of the package.
- If so, then sample B should always be taken in a fixed adjacent relationship to A, for example, immediately "after" or "below."
- If A is taken near the "top" or "outside," then C should be near the "bottom" or "inside."
- Sample D should always be taken immediately "after" or "below" sample C.

A and C are tested "today"; B and D are tested at a later time, for example, "tomorrow."

The lag between the times of testing the (A, C) and the (B, D) samples ideally should be long enough for all long-term sources of measurement variability to come into play. Sometimes a 1-day lag is not enough, and VLT may be underestimated if a longer lag time is not used.

Note: Care should be taken in defining what is meant by a "test time." If the routine production process samples are taken and tested daily, then the test time for maintenance sampling should be 1 day as well; if the routine samples are tested during each shift, especially if the process is controlled and product is released by shift, the maintenance sampling test time could be a shift. In any case, A and C are tested right away (within the test time definition) and B and D are tested later (often, the next shift or tomorrow).

One degree of freedom is sacrificed to remove any fixed effects when estimating each of VWP, VST, and VLT according to the procedure outlined in the following paragraphs.

Contrast Method of Variance Components Estimation. The data from the ABCD plan can be analyzed by general ANOVA procedures similar to those outlined in Section 47. The simple computing procedure recommended here for the special ABCD structure, the "contrast method," gives results identical to the general ANOVA, uses convenient numerical procedures, and supplies useful diagnostic information.

For the *i*th maintenance set, $i = 1, 2, \ldots, R$, where R is the number of maintenance sets of data, compute three quantities (contrasts):

$$\mathrm{WP}_i = (-\mathrm{A}_i - \mathrm{B}_i + \mathrm{C}_i + \mathrm{D}_i)/2$$

$$\mathrm{LT}_i = (-\mathrm{A}_i + \mathrm{B}_i - \mathrm{C}_i + \mathrm{D}_i)/2$$

$$\mathrm{ST}_i = (+\mathrm{A}_i - \mathrm{B}_i - \mathrm{C}_i + \mathrm{D}_i)/2$$

When the samples are taken in the recommended fixed sampling pattern, it becomes possible to:

- Test for the existence, or monitor the magnitude, of a consistent average slope within packages (top to bottom or outside to inside, as the case may be)
- Test for the existence, or monitor the magnitude, of a consistent average degradation or bias between the samples analyzed "today" and those analyzed "tomorrow"
- Test for the existence, or monitor the magnitude, of a consistent average change of slope (interaction) within a package

The presence of consistent profiles or biases of these types will not inflate the variance component estimates. However, such consistent profiles or biases represent possibly serious deficiencies in the product or the measurement processes. Technical programs should be initiated to eliminate the biases if their magnitudes are large enough to be important in practice.

The next step in the contrast method determination of the variance components is to compute the following three averages:

$$\overline{\text{WP}} = \frac{1}{R}\sum_{i=1}^{R} \text{WP}_i$$

$$\overline{\text{LT}} = \frac{1}{R}\sum_{i=1}^{R} \text{LT}_i$$

$$\overline{\text{ST}} = \frac{1}{R}\sum_{i=1}^{R} \text{ST}_i$$

Next, compute the three mean squares:

$$\text{MSWP} = \frac{1}{R-1}\sum_{i=1}^{R} (\text{WP}_i - \overline{\text{WP}})^2$$

$$\text{MSLT} = \frac{1}{R-1}\sum_{i=1}^{R} (\text{LT}_i - \overline{\text{LT}})^2$$

$$\text{MSST} = \frac{1}{R-1}\sum_{i=1}^{R} (\text{ST}_i - \overline{\text{ST}})^2$$

Finally, the variance components are calculated as:

$$\text{VWP} = \frac{\text{MSWP} - \text{MSST}}{2}$$

$$\text{VLT} = \frac{\text{MSLT} - \text{MSST}}{2}$$

$$\text{VST} = \text{MSST}$$

and each has $R-1$ degrees of freedom.

The ABCD ANOVA calculations correspond exactly to those for a two-way crossed ANOVA, where both the within-package and long-term factors are crossed with each other and only one replicate is included in the data. The expected mean squares apply to this two-way crossed ANOVA model. The short-term "factor" is really the interaction plus short-term measurement. In much collective experience, this factor effect has never been statistically significant.

Estimating and Maintaining VLL and VPP. Estimates of VLLU and VPPU and estimates of VWP, VST, and VLT are combined as follows:

$$\text{VPP} = \text{VPPU} - \text{VWP} - \text{VST}$$

$$\text{VLL} = \text{VLLU} - \text{VLT}$$

This completes the calculations of all five package product unit variance components.

In practice, the variance component updating procedures (including calculating initial estimates of all components) should be done by computer. The data are entered into the computer database lot

by lot (daily, by shift, or whatever) as they become available. The ANOVA software, both routine ANOVA and maintenance ANOVA, should contain diagnostic procedures to warn of any outlying test results, outlying averages, flinching, or unusual patterns in the data. Useful diagnostic procedures include sample sequence plots and histograms, CUSUM sequence plots, and sequence plots of lot averages and of maintenance contrasts.

If routine production process data have missing observations, the routine ANOVA formulas must be modified. It may be best simply to discard incomplete routine or maintenance data sets, so long as at least 60 complete sets are available in both cases for analysis. The causes of the missing data should be investigated periodically, using techniques such as Pareto analysis of the circumstances when data are missing.

The procedure that has been described here for collecting and analyzing routine production data and maintenance data will produce values of VLL, VPP, VWP, VST, and VLT that estimate the variability encountered with the way the plant processes and the measurement facilities are being operated.

PRODUCT CHARACTERIZATION

Having determined quantitatively the five variance components as described in the foregoing paragraphs, it is straightforward to calculate the implied conformance of product made. If the process is operating on-aim, first calculate

SPROD = true product standard deviation, the standard deviation of the true product property from product unit to product unit

$$= \frac{\text{VLL} = + \text{VPP}}{2}$$

Then calculate

$$Z = \frac{\text{UTL (High)} - \text{UTL(Low)}}{2\ (\text{SPROD})}$$

The UTLs are the unit tolerance limits (Figure 27.8). Then find the conformance of product made using a two-sided table of the cumulative normal distribution.

Some representative table values are presented in Table 27.2.

For example, if the UTLs are 2.5 multiples of SPROD above and below X_0, then the Z value is 2.5 and the conformance of product made is 98.8 percent.

If the process is operating off-aim, two values of Z must be calculated, one for each tail of the distribution.

$$Z_1 = \frac{\text{ProcessAverage} - \text{UTL(Low)}}{\text{SPROD}}$$

$$Z_2 = \frac{\text{UTL(High)} - \text{ProcessAverage}}{\text{SPROD}}$$

Then find the conformance corresponding to each of Z_1 and Z_2 using a one-sided table of the cumulative normal distribution. Some representative values are presented in Table 27.3.

Then the conformance of product made is obtained by adding the two conformances and subtracting 100. The conformance of product made decreases steadily as the process average moves off-aim.

For example, suppose the actual process average is one multiple of SPROD above X_0. If the UTLs are 2.5 multiples of SPROD above and below X_0 then the value of Z_1 is 3.5 and the value of Z_2 is 1.5. The conformance of product made is then 99.98 + 93.32 − 100 = 93.30%.

If an effective process control scheme is in place, it is unlikely that the process average would be off-aim as much as one multiple of SPROD for the entire period of producing a shipment of product

TABLE 27.2 Percent Conforming Product for Representative *Z* Values—On-Aim Process

Z	Conformance, percent
1.00	68.3
1.50	86.6
2.00	95.5
2.50	98.8
2.58	99.0
3.00	99.7

Source: Donald W. Marquardt (1991). *Product Quality Management,* DuPont Engineering, Wilmington DE.

TABLE 27.3 Percent Conforming Product for Representative *Z* Values—Off-Aim Process

Z	Conformance, percent
1.0	84.13
1.5	93.32
2.0	97.72
2.5	99.38
3.0	99.86
3.5	99.98

Source: Donald W. Marquardt (1991). *Product Quality Management,* DuPont Engineering, Wilmington DE.

for a customer. However, it also is unlikely that the process average would be precisely on-aim for the entire period. Thus, for this hypothetical example, the effective conformance of product made will likely be somewhere between 98.8 and 93.3 percent on a true-product-value basis.

It is well to remind ourselves at this point that only critical properties are candidates for treatment on a true-product-value basis. Often, with such properties the measurement variance (VST + VLT) is a substantial fraction of the total variance (VLL + VPP + VWP + VST + VLT). Then the interval UTL(high) − UTL(low) will be substantially smaller than the typical range of routine measurements from the process. Statistical process control becomes more difficult, and any attempt to improve conformance by releasing only product that is within "release limits" becomes inherently ineffective. This is a quite common circumstance in the process industries for such critical properties.

The prevalence of this circumstance is one reason why the most effective statistical control procedures, such as Twin Metric or CUSUM, are worthwhile in the process industries.

USE OF THE VARIANCE COMPONENTS FOR IMPROVEMENT OF THE QUALITY MANAGEMENT SYSTEM

Variance components are to be developed and maintained only for properties that are "critical," that is, properties that require careful control and are most in need of improvement.

The five variance components are invaluable information for purposes of quality management system improvement. A simple Pareto analysis, that is, ranking of the five variance components from largest to smallest is a first step. Suppose the VPP component is the largest, being, say, half of the total of the five variance components. It is then clear that the biggest quality management problem

is with the product itself; in particular, the predominant source of product variability is among packages within a lot. That knowledge immediately directs improvement attention to those features of the production process that can contribute to variability within a lot. On the other hand, suppose VST is the largest, being half or more of the total of the five variance components. This indicates that the biggest quality management problem is with the measurement system, and comes from the short-term sources of measurement variability. Improvement attention should then be directed to those aspects of the measurement process that can contribute to short-term variability in the measurement.

In the absence of such quantitative information about the magnitude of key sources of variability, many companies have worked for years on the wrong part of the system and have failed to achieve the improvement they sought. Periodic updates of the variance components provide quantitative evidence of the degree of success of improvement efforts.

USE OF THE VARIANCE COMPONENTS FOR ROUTINE SAMPLE DESIGN

The MSSD (mean square successive difference) method was recommended in a foregoing paragraph as the means to estimate the standard deviation, SPROC, for process control purposes. The MSSD method is recommended for SPC on both critical and noncritical properties.

For those few properties on which variance components are developed and maintained, the variance components provide guidance in designing the structure of the Twin Metric or CUSUM sampling plan. For that purpose the following formula can be used to take account of the expected relationship between the sampling plan structure and the value of SPROC, where

NPP = total number of packages sampled per lot

NWP = total number of distinct samples per lot

NST = total number of test results per lot

NLT = total number of test times per lot

For example, if there is one observation for each of four packages sampled in each lot, and these are submitted to the laboratory for analysis in two groups at different times, the numbers are NPP=4, NWP=4, NST=4, and NLT=2.

The goal is to make SPROC as small as practically feasible. The routine SPC sampling plan is described by the denominators in the formula. The formula shows that, for most purposes, one observation per package is optimum unless VST is by far the largest variance component. Similarly, NLT is often set to 1 unless VLT is a large variance component. In situations where a formal product release system is deemed necessary, the variance components are essential to effective release system design and evaluation. (See Li and Owen 1979; NBS 1959; Owen and Boddie 1976; Owen and Wiesen 1959.)

QUALITY MANAGEMENT SYSTEM UPDATES

Intent, Definition, and Timing of an Update. The quality management system will reliably produce the claimed product quality levels if all functions of the system are properly designed, and carried out as designed. To guarantee continued compliance with the quality management system design, all system elements must be updated on a periodic basis. The activities necessary to accomplish the update serve as part of an internal audit of the system. It is important to document the administrative procedures and the organizational responsibilities to ensure that the necessary preparations are completed correctly on a timely basis.

The activities that take place during the update often identify specific data problems, quality management system design problems, or the like. Fixing any of these can lead to an improvement in the

system or its utilization, and lead to actual product improvements. Used in this manner, the update is an excellent source of ideas for continual improvement.

An update refers to:

- Assembly of data
- Calculation of variance components, SPROCs, etc., using the most recent data
- Calculations of system performance criteria (conformance, yield, and cost) for the period since the last update
- Calculations of predicted system performance criteria
- Recording of this information
- Discussions among Production, Marketing, and other appropriate personnel to decide whether any changes are needed in any component of the quality management system
- Documentation of the decisions taken

In preparation for an update, Production personnel analyze the accumulated data since the last update. For critical properties of high-volume products, the variance components and other statistics should be updated, say, quarterly. Updates for lower-volume products may only be practicable at longer intervals.

AUDITS

Every process in a quality management system should be audited periodically to ensure the objectivity and integrity of system performance. (See Section 11.) In many situations, such internal quality audits serve an additional role as precursors to external audits for external quality assurance requirements.

When audits and their resulting reports are wisely administered, audits are perceived by all participants as a mutually helpful vehicle to improve the quality system and the product quality.

Preparation of an audit plan should include a detailed review of everything that has been agreed to be done in implementing the quality management system.

Obviously, not everything can be audited at frequent intervals. The audit plans should establish audit priorities and audit schedules that reflect the priorities. High-priority items will be audited frequently, low-priority items infrequently.

Lower-Level and Higher-Level Audits. At each organizational level the audit team should consist of persons who collectively have knowledge of the activities being audited and their proper procedures. To ensure objectivity, at each audit level the team should not be composed entirely of local personnel. The nonlocal personnel can include: higher-level management; technical personnel or supervision from the corresponding organization at another site; technical personnel or supervision from a distinct, but related, organization at the same site; and personnel from staff specialties such as Research and Development, Statistics, Marketing, and Quality Management Systems.

Numerical Audits and Procedures Audits. In discussing periodic system updates, it was noted that the activities necessary to accomplish an update serve as key parts of the numerical aspect of an internal audit of the quality management system.

When developing routine system updates, the integrity of the numerical data should be questioned by graphical examination of data. In particular, the histograms of maintenance data and of routine product data should be inspected to detect flinching, outliers, or other anomalies. Time plots of these data are also informative, especially for revealing any long-term trends, cycles, or other patterns. The accuracy of data entry, storage, and manipulation should be spot-checked.

Procedures audits must include on-site observations of actual quality procedures. The objective is to assist the audited site in complying with quality management principles. Inspection details will differ from situation to situation, but should include:

- Verification that original data are accurately and promptly entered into the database system (computer or manual) with no form of flinching (Marquardt 1994).
- Verification that Twin Metric or CUSUM signals are followed by prompt and effective action.
- Verification that product release decisions are being made and followed properly.
- Verification that process materials acceptance decisions are being made and followed correctly.
- Verification that designs for Twin Metric or CUSUM and for product release are updated correctly and whenever required.
- Verification that standard operating conditions and standard operating procedures are being followed.
- Verification that standard procedures are properly documented and current versions (only) are readily available to those who need them.
- Verification that accurate records are kept.
- Verification that Production operators, inspectors, laboratory technicians, and others are following proper procedures, including:

  Production equipment checkout and control

  Process instrumentation calibration

  Sample taking

  Sample preparation and handling

  Laboratory instrument calibration

  Laboratory control sample validation and handling

  Product packaging and handling

  Product labeling
- Verification that action has been taken to correct quality system deficiencies identified in previous audits.

A written report should be prepared after each audit, and follow-up procedures should be established to verify that any quality management system deficiencies uncovered by the audit are corrected.

ACKNOWLEDGMENTS

The contents of this section are adapted and updated from portions of a comprehensive book on product quality management produced in 10 successive editions by the corporate group which I managed within the DuPont Company from 1964 through 1991. In all, 16 members of the group were co-authors of that book. All of them are skilled statisticians with a great deal of experience in dealing with process industry problems in practice.

I served as overall editor, and was the principal author of most of the portions I have chosen to adapt for this section of Juran's Handbook. Some of the chosen topics derive from important early technical initiatives of several of the other 15 co-authors. In particular, K. A. Chatto and R. E. Scruby pioneered in the 1960s in the use of variance components, the package structure for the variance components, the use of true-value specifications, and the ABCD maintenance plan. W. H. Fellner and others extended that work. The discussion in this section describes only the most straightforward practical uses of that body of work. J. M. Lucas pioneered in the 1970s in the use of CUSUM and important CUSUM enhancements for process control in a computer-friendly computational form with practical design methods. This section incorporates the CUSUM approach, which is so important in the process industries, only by reference to key papers in the literature. My intent in preparing this section has been to focus upon key quality management issues in the process industries and, in doing so, to build upon other sections of Juran's Handbook.

REFERENCES

ASQC (1987). *Quality Assurance for the Chemical and Process Industries: A Manual of Good Practices,* American Society for Quality Control, Milwaukee, WI.

ASQC (1996*a*). *ISO 9000 Guidelines for the Chemical and Process Industries,* 2d ed., American Society for Quality Control, Chemical and Process Industries Division, Chemical Interest Committee, Milwaukee, WI.

ASQC (1996*b*). *Specifications for the Chemical and Process Industries,* American Society for Quality Control, Chemical and Process Industries Division, Chemical Interest Committee, Milwaukee, WI.

Bissell, A. F. (1986). "The Performance of Control Charts and CUSUMs Under Linear Trend." *Journal of the Royal Statistical Society,* series C, vol. 35, p. 214; corrigendum to ibid., vol. 33, pp. 145–151.

Champ, C. W. and Woodall, W. H. (1987). "Exact Results for Shewhart Control Charts with Supplementary Runs Rules." *Technometrics,* vol. 29, pp. 393–399.

Deming, W. E. (1967). "What Happened in Japan." *Industrial Quality Control,* vol. 24, pp. 89–93.

Deming, W. E. (1972). "Report to Management." *Quality Progress,* vols. 5, 2, 3, and 41.

Deming, W. E. (1982). *Quality, Productivity, and Competitive Position.* Massachusetts Institute of Technology, Center for Advanced Engineering Study, Cambridge, MA.

Hald, A. (1952). *Statistical Theory with Engineering Applications.* John Wiley & Sons, New York.

ISO 9000 (1994). International Standard. *Quality Management and Quality Assurance Standards—Guidelines for Selection and Use,* International Organization for Standardization, Geneva, Switzerland. Available through American National Standards Institute, New York; also available as ANSI/ASQC Q9000:1994 from American Society for Quality Control, Milwaukee, WI.

Juran, J. M., ed. (1974). *Quality Control Handbook,* 3rd ed., McGraw-Hill, New York, p. 18-3

Kemp, K. W. (1961). "The Average Run Length of the Cumulative Sum Chart When a `V' Mask is Used." *Journal of the Royal Statistical Society,* series B, vol. 23, pp. 149–153.

Li, L. and Owen, D. B. (1979). "Two-Sided Screening Procedures in the Bivariate Case." *Technometrics,* vol. 21, pp. 79–85.

Lucas, J. M. (1973). "A Modified V-Mask Control Scheme." *Technometrics,* vol. 13, pp. 833–847.

Lucas, J. M. (1976). "The Design and Use of V-Mask Control Schemes." *Journal of Quality Technology,* vol. 8, pp. 1–12.

Lucas, J. M. (1982). "Combined Shewhart-CUSUM Quality Control Schemes." *Journal of Quality Technology,* vol. 14, pp. 51–59.

Lucas, J. M. (1985*a*). "Counted Data CUSUMs." *Technometrics,* vol. 27, pp. 129–144.

Lucas, J. M. (1985*b*). "Cumulative Sum (CUSUM) Control Schemes." *Communications in Statistics, Theoretical Methods,* vol. 14, no. 11, pp. 2689–2704.

Marquardt, D. W. (1984). "New Technical and Educational Directions for Managing Product Quality." *The American Statistician,* vol. 38, pp. 8–14.

Marquardt, D. W. (1991). *Product Quality management,* DuPont Engineering, Wilmington, DE.

Marquardt, D. W. (1993). "Estimating the Standard Deviation for Statistical Process Control." *International Journal of Quality and Reliability Management.* vol. 10, no. 8, pp. 60–67.

Marquardt, D. W. (1994). "Report Card Issues in Quality Management." *Quality Management Journal,* vol. 1, no. 3, pp. 16–25.

Marquardt, D. W. (1997). "Twin Metric Control-CUSUM Simplified in a Shewhart Framework." *International Journal of Quality and Reliability Management,* vol. 14, no. 3, pp. 220–233.

Marquardt, D. W. and Ulery, D. L. (1991). "Twin Metric-A Strategy for Improved SPC." *IMPRO 1991 Conference Proceedings,* Juran Institute, Inc., Wilton CT.

Marquardt, D. W. and Ulery, D. L. (1992). "Twin Metric Control-Improving SPC to Meet Supply Chain Realities of the 1990s." *Transactions of the 46th Annual Quality Congress,* American Society for Quality Control, pp. 367–373.

NBS (1959). "Tables of the Bivariate Normal Distribution Function and Related Functions." *Applied Mathematics Series 50,* National Bureau of Standards, U.S. Government Printing Office, Washington, DC.

Owen, D. B. and Boddie, J. W. (1976). "A Screening Method for Increasing Acceptable Product with Some Parameters Unknown." *Technometrics,* vol. 18, pp. 195–199.

Owen, D. B. and Wiesen, J. M. (1959). "A Method of Computing Bivariate Normal Probabilities." *The Bell System Technical Journal,* pp. 553–572.

Page, E. S. (1961). "Cumulative Sum Charts." *Technometrics,* vol. 3, pp. 1–9.