16

Control of Manufacturing Quality

The definition of quality has evolved over the past century from meeting the engineering specifications of the product (i.e., conformance), to surpassing the expectations of the customer (i.e., customer satisfaction). Quality has also been defined as a loss to customer in terms of deviation from the nominal value of the product characteristic, the farther the deviation the greater the loss.

The management of quality, according to J. M. Juran, can be carried out via three processes: planning, control, and improvement. *Quality planning* includes the following steps: identifying the customer's needs/expectations, designing a robust product with appropriate features to satisfy these needs, and establishing (manufacturing) processes capable of meeting the engineering specifications. *Quality control* refers to the establishment of closed loop control processes capable of measuring conformance (as compared to desired metrics) and varying production parameters, when necessary, to maintain steady-state control. *Quality improvement* requires an organization's management to maximize efforts for continued increase of product quality by setting higher standards and enabling employees to achieve them. A typical goal would be the minimization of variations in output parameters by increasing the capability of the process involved by either retrofitting existing machines or acquiring better machines. Among the three processes specified by Juran for quality management, the central

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issue addressed in this chapter is quality control with emphasis on on-line control (versus postprocess sampling): measurement technologies as well as statistical process control tools.

Cost of quality management has always been an obstacle to overcome in implementing effective quality control procedures. In response to this problem, management teams of manufacturing companies have experimented over the past several decades with techniques such as (on-line) statistical process control versus (postprocess) acceptance by sampling, versus 100% inspection/testing and so on. For example, it has been successfully argued that once a process reaches steady-state output in terms of conformance, it would be uneconomical to continue to measure on-line every product feature (i.e., 100% inspection), though a recent counterargument has been that latest technological innovation in measurement devices and computer-based analyzers do allow manufacturers to abandon all statistical approaches and instead carry out real-time quality control. Furthermore, it has been argued that new approaches to quality control must be developed for products with high customization levels achievable in flexible manufacturing environments.

No matter how great is the cost of quality control implementation engineers must consider the cost of manufacturing poor quality products. These lead to increased amounts of rejects and reworks and thus to higher production costs. Dissatisfaction causes customers to abandon their loyalty to the brand name and eventually leads to significant and rapid market-share loss for the company. Loyalty is more easily lost than it is gained. As will be discussed in greater detail later in this chapter, quality is commonly measured by customers as deviation from the expected nominal value. When

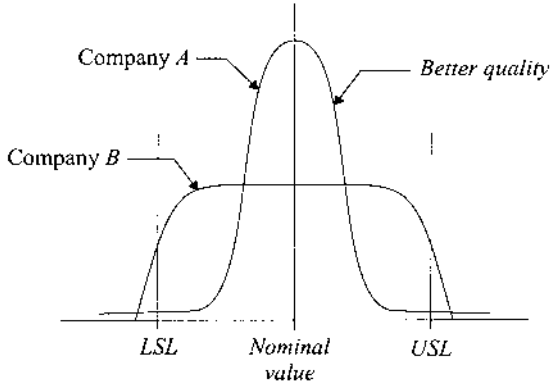

FIGURE 1 Quality control.

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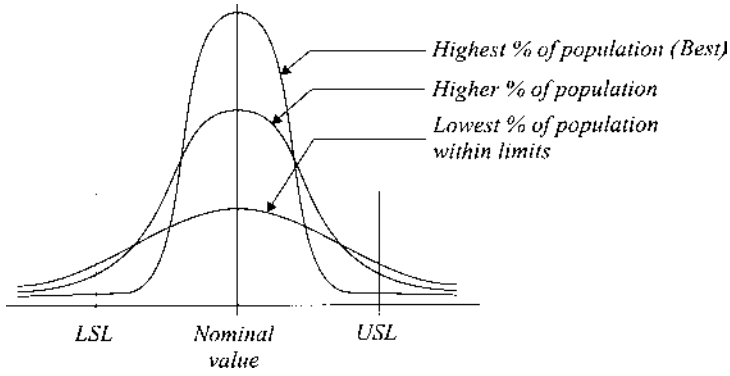

FIGURE 2 Variability about the nominal value.

two companies manufacture the same product, and equal percentages of their product populations fall within identical specifications (i.e., between LSL and USL: lower and upper specification limits, respectively), the company with the lower variation about the nominal value provides better customer satisfaction (Fig. 1). Naturally, a company with the lowest variation as well as the lowest percentage of the population of their products within their specification limits will have the best quality and the highest customer satisfaction (Fig. 2).

It has been erroneously argued that high-quality products can only be purchased at high prices. Such arguments have been put forward by companies who scrap their products that fall outside their specification limits and pass on this cost to the customers by increasing the price of their within-limits goods. In practice, price should only be proportional to the performance of a product and not to its quality. For example, a Mercedes-Benz car should deserve its higher price in comparison to a Honda or a Ford because of its higher performance with equivalent quality expectation by the customers.

16.1 MODERN HISTORY OF QUALITY MANAGEMENT

Quality management in the U.S.A. suffered a setback in the early 1900s with the introduction of F. W. Taylor's division-of-labor principle into (mass-production-based) manufacturing enterprises. Greater emphasis on productivity came at the expense of quality when workers on the factory floor lost ownership of their products. Quality control became a postprocess inspection task carried out by specialists in the quality-assurance department disconnected from the production floor.

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The subsequent period of the 1920s to the 1940s was marked by the utilization of statistical tools in the quality control of mass produced goods. First came W. A. Shewart's process control charts [now known as statistical process control (SPC) charts] and then the acceptance by sampling system developed by H. F. Dodge and H. G. Romig (all from Bell Laboratories).

The 1950s were marked by the works of two modern pioneers of quality, W. E. Deming and J. M. Juran. Although both advocated continued reliance on statistical tools, their emphasis was on highlighting the responsibility of an organization's high-level management to quality planning, control, and improvement. Ironically, however, the management principles put forward by Deming and Juran were not widely implemented in the U.S.A. until the competitiveness of U.S. manufacturers was seriously threatened by the high-quality products imported from Japan in the late 1970s and the early 1980s. Two other modern pioneers that contributed to quality management in the U.S.A. have been A. V. Feigenbaum and P. Crosby.

Prior to the 1960s, products manufactured in Japan were plagued with many quality problems, and subsequently Japanese companies failed to penetrate the world markets. Behind the scenes, however, a massive quality improvement movement was taking place. Japanese companies were rapidly adopting the quality management principles introduced to them during the visits of Deming and Juran in the early 1950s as well as developing unique techniques locally. One such tool was K. Ishikawa's cause-and-effect diagram, also referred to as the fishbone diagram, which was developed in the early 1940s. The Ishikawa diagram identified possible causes for a process to go out of control and the effect of these causes (problems) on the process. Another tool was G. Taguchi's approach to building quality into the product at the design stage, that is, designing products with the highest possible quality by taking advantage of available statistical tools, such as design of experiments (Chap. 3).

In parallel to the development of the above-mentioned quality control and quality improvement tools, the management of many major Japanese organizations strongly emphasized company-wide efforts in establishing quality circles to determine the root causes of quality deficiencies and their elimination in a bottom-up approach, starting with the workers on the factory floor. The primary outcome of these efforts was the elimination of postprocess inspection and its replacement with the production of goods, with built-in quality, using processes that remained in control. Japanese companies implementing such quality-management systems (e.g., Sony, Toshiba, NEC, Toyota, Honda) rapidly gained large market shares during the 1970s to the 1990s.

In Europe, Germany has led the way in manufacturing products with high quality, primarily owing to the employment of a skilled and versatile

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labor force combined with an involved, quality-conscious management. Numerous German companies have employed statistical methods in quality control as early as in the 1910s, prior to Shewhart's work in the late 1920s. In the most of the 20th century, the "Made in Germany" designation on manufactured products became synonymous with the highest possible quality. In France and the United Kingdom, awareness for high quality has also had a long history, though, unlike in Germany, in these countries high quality implied high-priced products.

Participation in NATO (the North Atlantic Treaty Organization) further benefited the above-mentioned and other European countries in developing and utilizing common quality standards: in the beginning for military products but later for most commercial goods. The most prominent outcome of such cooperation is the quality management standard ISO-9000, which will be briefly discussed in Sec. 16.6.

16.2 INSPECTION FOR QUALITY CONTROL

Inspection has been loosely defined in the quality control literature as the evaluation of a product or a process with respect to its specifications—i.e., verification of conformance to requirements. The term testing has also been used in the literature interchangeably with the term inspection. Herein, testing refers solely to the verification of expected (designed) functionality of a product/process, whereas inspection further includes the evaluation of the functional/nonfunctional features. That is, testing is a subset of inspection.

The inspection process can include the measurement of variable-valued features or the verification of the presence or absence of features/parts on a product. Following an inspection process, the outcome of a measurement can be recorded as a numeric value to be used for process control or simply as satisfying a requirement (e.g., defective versus acceptable), i.e., as an attribute. Increasingly, with rapid advancements in instrumentation technologies, two significant trends have been developing in manufacturing quality control: (1) automated (versus manual) and (2) on-line (versus postprocess) inspection. The common objective to both trends may be defined as reliable and timely measurement of features for effective feedback-based process control (versus postmanufacturing product inspection).

Tolerances are utilized in the manufacturing industry to define acceptable deviations from a desired nominal value for a product/process feature. It has been convincingly argued that the smaller the deviation, the better the quality and thus the less the quality loss. Tolerances are design specifications,

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and the degree of satisfying such constraints is a direct function of the (statistical) capability of the process utilized to fabricate that product. For example, Process A used to fabricate a product (when "in control") can yield 99.9% of units within the desired tolerance limits, while Process B also used to fabricate the same product may yield only 98% of units within tolerance.

Prior to a brief review of different inspection strategies, one must note that the measurement instruments should have a resolution (i.e., the smallest unit value that can be measured) an order of magnitude better than the resolution used to specify the tolerances at hand. Furthermore, the repeatability of the measurement instruments (i.e., the measure of random errors in the output of the instrument, also known as precision) must also be an order of magnitude better than the resolution used to specify the tolerances at hand. For example, if the tolerance level is ± 0.01 mm, the measurement device should have a resolution and repeatability in the order of at least ± 0.001 mm.

16.2.1 Inspection Strategies

The term inspection has had a negative connotation in the past two decades owing to its erroneous classification as a postprocess, off-line product examination function based solely on statistical sampling. As discussed above, inspection should actually be seen solely as a conformance verification process, which can be applied based on different strategies—some better than others. However, certain conclusions always hold true: on-line (in-process) inspection is better than postprocess inspection 100% inspection is better than sampling, and process control (i.e., inspection at the source) is better than product inspection.

On-line inspection: It is desirable to measure product features while the product is being manufactured and to feed this information back to the process controller in an on-line manner. For example, an electro-optical system can be used to measure the diameter of a shaft, while it is being machined on a radial grinder, and to adjust the feed of the grinding wheel accordingly. However, most fabrication processes do not allow in-process measurement owing to difficult manufacturing conditions and/or the lack of reliable measurement instruments. In such cases, one may make intermittent (discrete) measurements, when possible, by stopping the process or waiting until the fabrication process is finished.

Sampling: If a product's features cannot be measured on-line, owing to technological or economic reasons, one must resort to statistical sampling inspection. The analysis of sample statistics must still be fed back to the process controller for potential adjustments to input variables to maintain in-control fabrication conditions. Sampling should only be used for processes that have already been verified to be in control and stable for an

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acceptable initial buildup period, during which 100% inspection may have been necessary regardless of economic considerations.

Source inspection: It has been successfully argued that quality can be better managed by carrying out inspection at the source of the manufacturing, that is, at the process level, as opposed to at (postprocess) product level. For fabrication, this would involve the employment of effective measurement instruments as part of the closed-loop process-control chain. For assembly, this would involve the use of devices and procedures that would prevent the assembly of wrong components and ensure the presence of all components and subassemblies—for example, using foolproofing concepts (*poka-yoke* in Japanese).

16.2.2 Measurement Techniques

Measurement is a quantification process used to assign a value to a product/process feature in comparison to a standard in a selected unit system (SI* metric versus English, U.S. customary measurement systems). The term metrology refers to the science of measurement in terms of the instrumentation and the interpretation of measurements. The latter requires a total identification of sources of errors that would affect the measurements. It is expected that all measurement devices will be calibrated via standards that have at least an order of magnitude better precision (repeatability). Good calibration minimizes the potential of having (nonrandom) systematic errors present during the measurement process. However, one cannot avoid the presence of (noise-based) random errors; one can only reduce their impact by (1) repeating the measurement several times and employing a software/hardware filter (e.g., the median filter) and (2) maintaining a measurement environment that is not very sensitive (i.e., robust) to external disturbances.

As will be discussed in the next subsections, variability in a process' output, assuming an ideal device calibration, is attributed to the presence of random mechanisms causing (random) errors. As introduced above, this random variability is called repeatability, while accuracy represents the totality of systematic (calibration) errors and random errors. Under ideal conditions, accuracy would be equal to repeatability.

Since the objective of the measurement process is to check the conformance of a product/process to specifications, the repeatability of the measurement instrument should be at least an order of magnitude better than the repeatability of the production process. Thus random errors in measuring the variability of the output can be assumed to be attributable

* Système International.

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primarily to the capability (i.e., variance) of the production device and not to the measurement instrument. As will be discussed in Sec. 16.3, the behavior of random errors can be expressed by using a probability function.

In Chap. 13, a variety of measurement instruments were discussed as a prelude to manufacturing process control, which includes control of quality. Thus in this section, we will narrow our attention to a few additional measurement techniques to complement those presented in Chapter 13.

Mechanical Measurement of Length

Length is one of the seven fundamental units of measurement—the others are mass, time, electric current, temperature, light intensity, and amount of matter. It is commonly measured using simple yet accurate manual (mechanical) devices on all factory floors worldwide. The vernier caliper is frequently used to measure length (diameter, width, height, etc.) up to 300 to 400 mm (app. 12 to 14 in.) with resolutions as low as 0.02 mm (or 0.001 in.). A micrometer can be used for higher resolution measurements, though at the expense of operational range (frequently less than 25 mm), yielding resolutions as low as 0.002 mm (or 0.0001 in.). Micrometers can be configured to measure both external and internal dimensions (e.g., micrometer plug gages).

Coordinate measuring machines (CMMs) are typically numerical control (NC) electromechanical systems that can be used for dimensional inspection of complex 3-D-geometry product surfaces. They utilize a contact probe for determining the x, y, z coordinates of a point (on the product's surface) relative to a reference point on the product inspected. The mechanical architecture of a CMM resembles a 3-degree-of-freedom (Cartesian) gantry-type robot (Chap. 12), where the probe (i.e., end-effector) is displaced by three linear (orthogonal) actuators (Fig. 3). Some CMMs can have up to five degrees of freedom for increased probing accuracy on curved surfaces.

Mechanical-probe-based CMMs can have an operating volume of up to 1 m^3, though at the expense of repeatability (e.g., 0.005 mm). There also exist a variety of optical-probe-based (noncontact) CMMs, which increase the productivity of such machines to carry out inspection tasks. However, mostly, CMMs are expensive machines suitable for the inspection of small batch or one-of-a-kind, high-precision products. Owing to their slow processing times, they are rarely employed in an on-line mode on factory floors.

Surface finish is an important length metric that has to be considered in discrete part manufacturing. Besides checking for surface defects (e.g., cracks, marks), engineers must also verify that a product's surface roughness satisfies the design specification. Stylus instruments have been commonly

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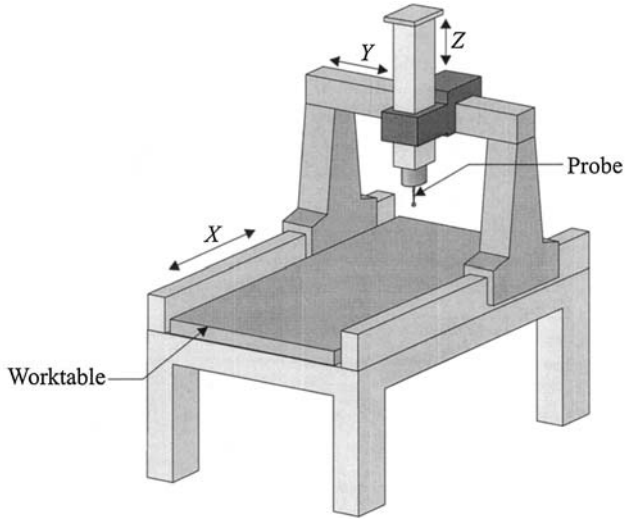

FIGURE 3 A coordinate measuring machine architecture.

utilized to quantify surface roughness: typically, a diamond-tip stylus is trailed along the surface and its vertical displacement is recorded. The roughness of the surface is defined as an average deviation from the mean value of the vertical displacement measurements (Fig. 4),

$$R_a = \frac{1}{L}\int_0^L |y(x)|\,dx \tag{16.1}$$

where L is the sampling length.

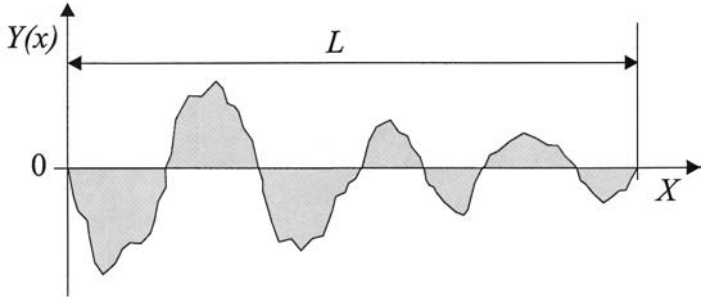

FIGURE 4 Surface profile.

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Mechanical systems such as the stylus instrument can measure roughness in the order of thousandths of a millimeter (or microinches). However, it should be noted that, despite the minimum force applied on the stylus tip, a trace might be left on the surface owing to the minute diameter of the diamond tip. Thus for surface roughness measurements that require higher precisions, an interferometry-based device can be used for nondestructive inspection.

Electro-Optical Measurement of Length

A variety of electro-optical distance/orientation measurement devices have been discussed in Chap. 13 and thus will not be addressed here in any great detail. These devices can be categorized as focused beam (i.e., use of a laser light) or as visual (i.e., use of a CCD camera) inspection systems. The former systems are highly accurate and in the case of interferometers can provide resolutions as low as half a light wavelength or better. The latter (camera-based) systems are quite susceptible to environmental disturbances (e.g., changes in lighting conditions) and are also restricted by the resolution of the (light receiving) diodes. Thus, for high-resolution systems, CCD camera–based inspection systems should be coupled to high-resolution optical microscopes.

For surface roughness measurement, interferometric optical profilometers can be used for the inspection of highly smooth surfaces in a scale of

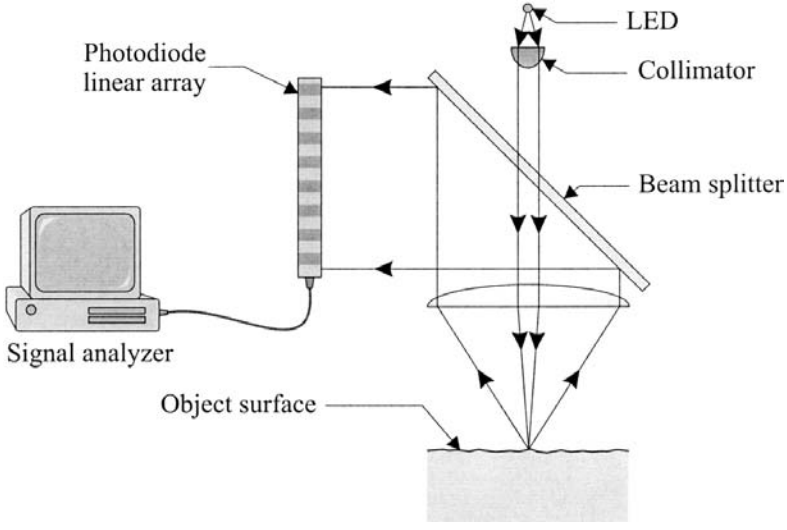

FIGURE 5 An optical surface roughness inspection instrument.

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nanometers, such as optical lenses and metal gages used to calibrate other measurement instruments. In the case of intermediate microroughness products, one can utilize a light scattering technique, in a scale of better than micrometers: such devices correlate the intensity of specularly reflected light to surface roughness (R_a). Smoother surfaces have a higher fraction of the incident light reflected in the specular mode (versus diffusive) with a clear Gaussian distribution. Such a commercially available (Rodenstock) surface-roughness-inspection instrument is shown in Fig. 5.

X-Ray Inspection

Electromagnetic radiation (x rays or gamma rays) can be effectively utilized for the inspection of a variety of (primarily metal) products in on-line or off-line mode. Measurements of features are based on the amount of radiation absorbed by the product subjected to (in-line) radiation. The intensity of radiation and exposure times are dictated by material properties (i.e., attenuation coefficient). The amount of absorbed radiation can be correlated to the thickness of the product (in-line with the radiation rays) and thus be used for thickness measurement or detection of defects.

In the most common transmissive x-ray radiographic systems, the radiation source is placed on one side of the product, while a detector (e.g., x-ray film, fluorescent screen) is placed on the opposite side (Fig. 6). In cases where one cannot access both sides of a product, the x-ray system can be used in a backscattering configuration: the detector, placed near the emitter, measures the intensity of radiation scattered back by the product. The thicker the product, the higher the level of backscatter will be.

Computed tomography (CT) is a radiographic system capable of yielding cross-sectional images of products whose internal features we wish

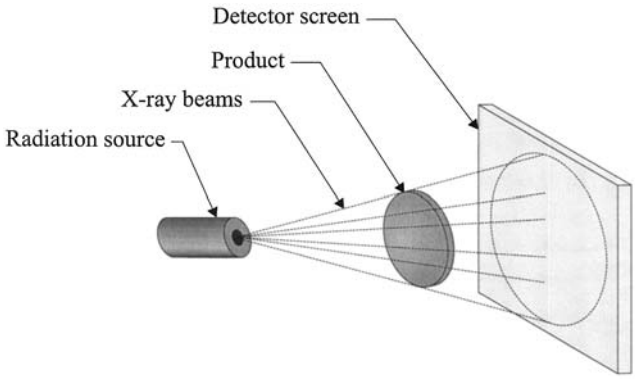

FIGURE 6 Transmissive x-ray imaging.

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to examine. CT machines typically utilize a fan-beam-type x-ray source and a detector array (placed on opposite sides of a product) rotating synchronously around an axis through the product (Fig. 7). A series of x-ray images (up to 1,000) that are collected after a complete 360° rotation around the product are then reconstructed into a cross-sectional 2-D image via mathematical tools. Through an (orthogonal) translation along the rotational axis, several 2-D cross-sectional images can be collected and utilized for 3-D (volumetric) reconstruction. One must note, however, that CT is primarily useful for product geometries with low aspect ratios—i.e., nonplanar. Furthermore, even with today's available computing power, CT-based image analysis may consume large amounts of time unacceptable for on-line inspection.

X-ray laminography is a variant of the CT system developed for the inspection of high-aspect-ratio products. A cross-sectional image of the product is acquired by focusing on a plane of interest, while defocusing the planes above and below via blurring of features outside the plane of interest (i.e., reducing their overall contrast effect). This laminographic effect of blurring into the background is achieved though a synchronized rotational motion of the x-ray source and the detector, where any point in the desired focal plane is always projected onto the same point in the image (Fig. 8). During the rotation of the source and detector a number of images are taken and subsequently superimposed. Features on the focal plane maintain their sharpness (since they always occupy the same location in every image and

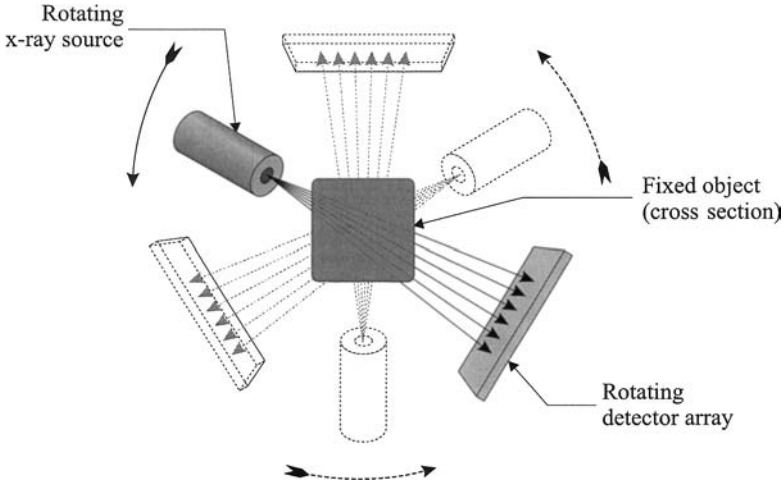

FIGURE 7 Computed tomography.

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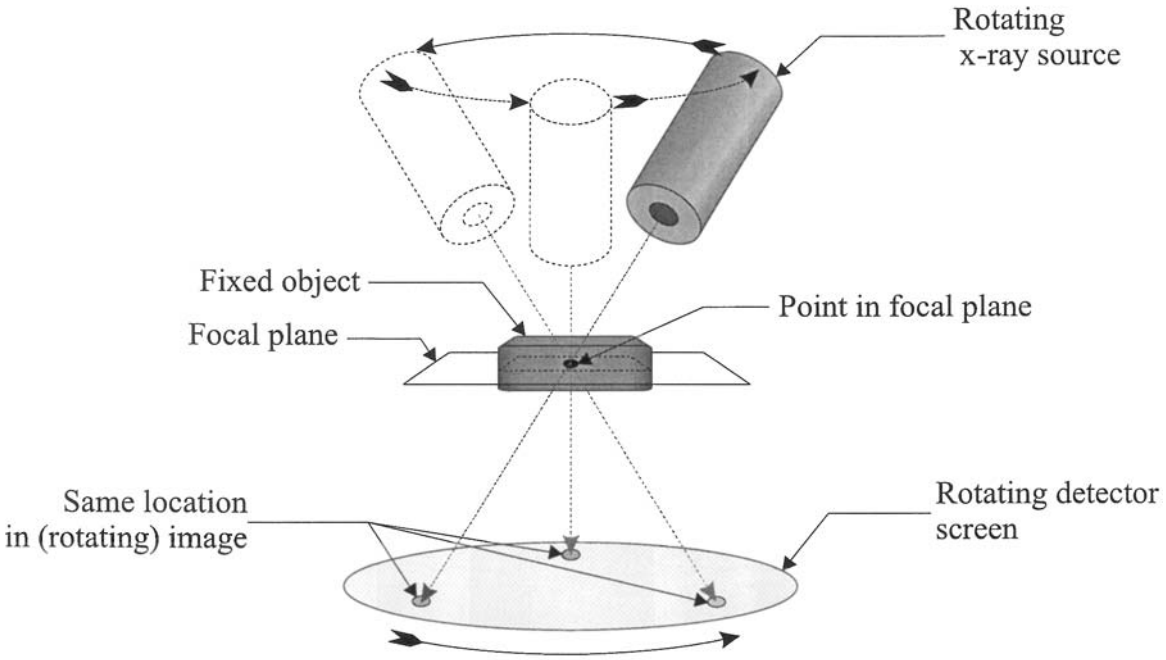

FIGURE 8 X-ray laminography.

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yield perfect overlapping), while out-of-plane features get blurred into a (gray) background (since they never occupy the same location in every image).

As in CT systems, different 2-D cross-sectional images, obtained by translating the product in an orthogonal direction, can be used to reconstruct a 3-D representation of the product. However, one must first overcome the blurring effect generated by the laminographic movement of the source–detector pair.

In all x-ray radiography systems, transmissive, CT, and laminography, mirrors can be used to reflect the image formed on a phosphor screen onto a visible-light CCD array camera for the automatic analysis of measurement data.

16.3 BASICS IN PROBABILITY AND STATISTICS THEORIES

Statistics theory is concerned primarily with the collection, analysis, and interpretation of experimental data. The term experiment is a generic reference to any process whose (random) outcome is measured for future planning and/or control activities. Probability theory, on the other hand, is concerned with the classification/representation of outcomes of random experiments. It attempts to quantify the chance of occurrence of an event. The term event is reserved to represent a subset of a sample space (the complete set of all possible outcomes of a random experiment).

The study of risk in modern times can be traced to the Renaissance period in Europe, when the mathematicians of the time, such as B. Pascal in the mid 1600s, were challenged by noble gamblers to study the games of chance. In 1730, A. de Moivre suggested that a common probability distribution takes the form of a bell curve. Next came D. Bernoulli's work on discrete probability distributions and T. Bayes' work on fusing past and current data for more effective inference, both in the mid-1700s. In the early part of the 1800s, C. F. Gauss further enforced the existence of a bell curve distribution based on his extensive measurements of astronomical orbits. He observed that repeated measurements of a variable yield values with a given variance about a mean value of the variable. Today, the bell-curve distribution is often called the Gaussian probability distribution (or the "normal" distribution).

16.3.1 Normal Distribution

Probability distributions can be classified as discrete or continuous. The former type is used for the analysis of experiments that have a finite number

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of outcomes (e.g., operational versus defective), while the latter type is used for experiments that have an infinite number of outcomes (e.g., weight, length, life). Both types have a number of different distributions within their own class: for example, binomial versus Poisson for discrete and Gaussian (normal) versus gamma for continuous probability distributions. In this chapter, since our focus is on the statistical quality control of manufacturing processes whose outputs represent continuous metrics, only the normal distribution is reviewed.

In practical terms, the variance of a process output (for a fixed set of input control parameters) can be viewed as random noise superimposed on a desired signal. For a perfectly calibrated system (with no systematic, nonrandom errors), the variance in the output can be seen as a result of random noise present in the environment and that cannot be eliminated. This noise, ε, would commonly have a normal distribution with a given variance, $\sigma^2 \neq 0$, and zero mean, $\mu = 0$, value (Fig. 9).

For the case where the desired output signal, μ ($\neq 0$), is superimposed with normally distributed noise, represented by the variance, σ^2, the random measurements of the output variable, X, are represented by the probability distribution function

$$f(x) = \frac{1}{\sigma\sqrt{2\pi}} \exp\left(-\frac{1}{2}\left[\frac{x-\mu}{\sigma}\right]^2\right) \quad -\infty < x < \infty \tag{16.2}$$

where the variable, X, is of the continuous type and $f(x) \geq 0$. One must note that, although, for a specific variable value, x_0, the corresponding $f(x_0)$ value is nonzero, the actual probability of this measurement value to occur in practice is near zero [i.e., $P(X = x_0) \approx 0$]. This is true because there exist

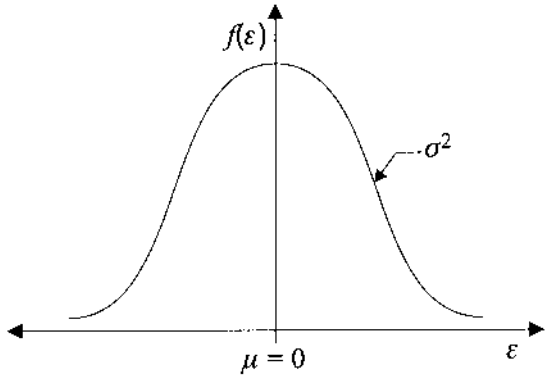

FIGURE 9 Normally distributed noise.

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infinite possible of outcomes to the experiment, Eq. (16.2), where each outcome has a near zero probability of occurrence. Therefore, in continuous probability distributions, the probability of occurrence is specified for a range of measurements, as opposed to for a specific outcome.

The probability of X being in a given range $[x_1, x_2]$ is defined by the integral of the probability function (Fig. 10):

$$P(x_1 < X < x_2) = \int_{x_1}^{x_2} f(x)\,dx \tag{16.3}$$

The lack of computers and hand-held electronic calculators prior to the 1950s, which could have been used for the calculation of integrals [such as the one in Eq. (16.1)], led to the normalization of the Gaussian distribution with respect to (μ_x, σ_x) and generation of quick-reference lookup tables. The normalization was achieved by using the transformation variable

$$Z = \frac{X - \mu_x}{\sigma_x} \tag{16.4}$$

where $P(x_1 < X < x_2) = P(z_1 < Z < z_2)$. The Z-distribution is characterized by $\mu_z = 0$ and $\sigma_z{}^2 = 1$ (Fig. 11).

Evaluation of the integral in Eq. (16.3), for a normal distribution, Eq. (16.2), yields the probability values commonly referred to in engineering measurements:

$$P(\mu_x - \sigma_x < X < \mu_x + \sigma_x) = P(-1 < Z < 1) \cong 68.26\%$$
$$P(\mu_x - 2\sigma_x < X < \mu_x + 2\sigma_x) = P(-2 < Z < 2) \cong 95.44\%$$
$$P(\mu_x - 3\sigma_x < X < \mu_x + 3\sigma_x) = P(-3 < Z < 3) \cong 99.74\%$$

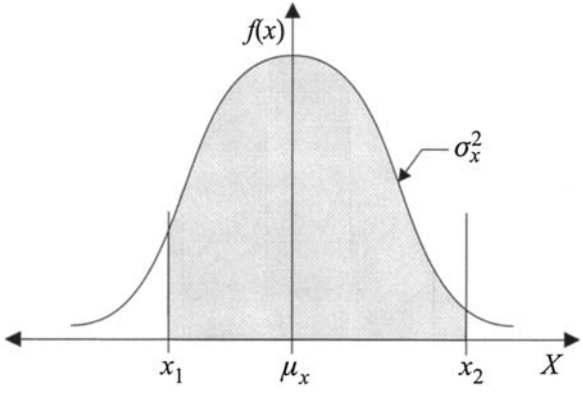

FIGURE 10 Probability of $(x_1 < X < x_2)$.

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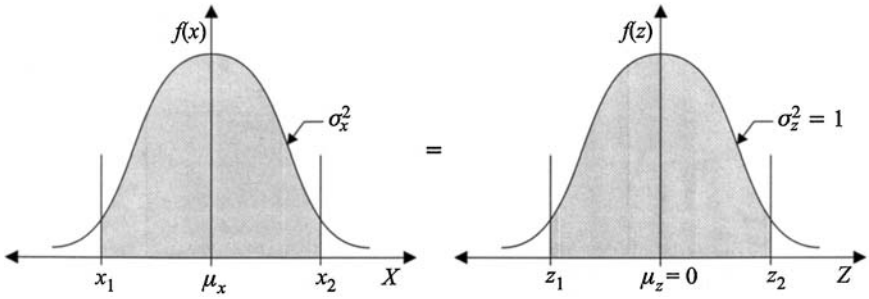

FIGURE 11 Equivalence of probability distributions.

16.3.2 Sampling in the Normal Distribution

As discussed in Sec. 16.3.1, if one knows the two metrics (statistics) (μ_x, σ_x) of a normally distributed population of measurements, the probability of a random outcome to be in the range [x_1, x_2] can be calculated using Eq. (16.3). However, in practice, the statistics (μ_x, σ_x) are not readily available, but must instead be approximated by sampling. Based on a sample drawn from the infinite-size population, one would estimate the upper and lower limits for the true (μ_x, σ_x) values at some confidence level. The first step in understanding this estimation process, however, is the analysis of the sampling process.

For a normally distributed population of measurements (i.e., random outcomes of an experiment), samples of size n are characterized by the metrics sample mean, $\overline{X}$, and sample variance, S^2:

$$\overline{X} = \frac{1}{n}\sum_{i=1}^{n} x_i \qquad \text{and} \qquad S^2 = \frac{1}{n-1}\sum_{i=1}^{n}(x_i - \overline{X})^2 \tag{16.5}$$

Furthermore, it can be shown that the distribution of sample means is characterized by a normal distribution and the distribution of sample variances can be defined by a chi-squared distribution.

Distribution of Sample Means

The mean values of samples of size n, $\overline{X}$, drawn from a population of normally distributed individual x_i values, $i = 1$ to n, also has a normal distribution with the statistics

$$\mu_{\overline{x}} = \mu_x \qquad \text{and} \qquad \sigma_{\overline{x}}^2 = \frac{1}{n}\sigma_x^2 \tag{16.6}$$

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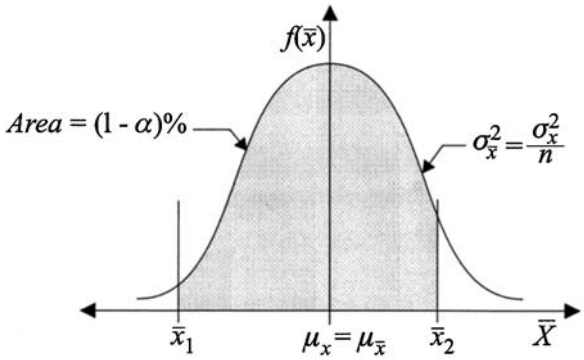

FIGURE 12 Sample mean distribution.

Therefore, based on Eqs. (16.2), (16.3), and (16.6), one can calculate the probability of a randomly drawn sample of size n to have a mean value in the range $[\bar{x}_1, \bar{x}_2]$ (Fig. 12):

$$P(\bar{x}_1 < \overline{X} < \bar{x}_2) = \int_{\bar{x}_1}^{\bar{x}_2} f(\bar{x}) d\bar{x} \tag{16.7}$$

As an example, let us consider that a machine is set to produce resistors of a nominal resistance value equal to 2 ohms. Based on the process capability of the machine, one assumes that a normally distributed noise affects the output of this machine, where $\mu_\varepsilon = 0$ and $\sigma_\varepsilon^2 = 0.01$. Analysis of this population's statistics indicates that a randomly chosen resistor has a resistance value, X, in the range 1.743 to 2.257 ohms with 95% certainty (probability). Furthermore, the analysis also indicates that a future randomly chosen sample of $n = 30$ resistors would have a mean value, $\overline{X}$, in the range 1.953 to 2.047 ohms with 95% probability, since $\mu_{\bar{x}} = 2$ and $\sigma_{\bar{x}}^2 = 0.002$.

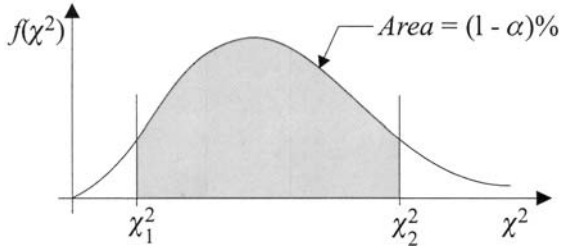

FIGURE 13 Chi-square distribution.

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Distribution of Sample Variances

The variance values of samples of size n, S^2, drawn from a population of normally distributed individual x_i values, $i=1$ to n, would have a chi-squared (χ^2) distribution (Fig. 13),

$$f(u) = \left(2^{k/2}\,\Gamma\left(\frac{k}{2}\right)\right)^{-1} u^{(k/2)-1}e^{-u/2} \qquad u > 0 \tag{16.8}$$

where the variable u refers to χ^2, Γ is the gamma function, and $k=n-1$ The variance, S^2, is expressed as a function of the χ^2 variable in Eq. (16.8) as follows,

$$\chi^2 = \frac{kS^2}{\sigma_x^2} \tag{16.9}$$

Based on the integration of Eq. (16.8), between the two limits $[\chi_1^2, \chi_2^2]$, one can calculate the probability of a randomly drawn sample of size n to have a variance value in the range $[s_1^2, s_2^2]$, where the conversion from S^2 to χ^2 is achieved via Eq. (16.9),

$$P(s_1^2 < S^2 < s_2^2) = P(\chi_1^2 < \chi^2 < \chi_2^2) = \int_{\chi_1^2}^{\chi_2^2} f(\chi^2)d\chi^2 \tag{16.10}$$

For the above-considered example of a population of resistors with a normal distribution, $\mu_x=2$ ohms and $\sigma_x^2=0.01$, let us consider drawing a random sample of size $n=30$. Based on Eqs. (16.8) to (16.10), it can be shown that the variance of this sample would be in the range $(0.0055 < S^2 < 0.0158)$ with 95% certainty (probability), where $\chi_1^2=16.047$ and $\chi_2^2=45.722$.

16.3.3 Estimation of Population Statistics

In Sec. 16.3.2 above, the behavior of sample statistics was discussed while assuming that the population statistics, (μ_x, σ_x), are known. In practice, however, the population statistics are not known and must be estimated using the statistics of one or more randomly drawn samples. The outcome of this estimation process is a range for the population mean and a range for the population variance: $[\mu_L, \mu_U]$ and $[\sigma_L^2, \sigma_U^2]$ for a $(1-\alpha)$% confidence level, where $(1-\alpha)$ is the area under the distribution curves between the two limits (Figs. 12 and 13).

For example, let us consider a randomly chosen sample of size $n=30$, whose statistics are $\bar{x}=1.98$ ohms and $s^2=0.012$. It can be shown that, based

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on these sample statistics, for a confidence level of 95%, the estimated ranges of the population statistics would be

$$1.9285 < \mu_x < 2.0315 \qquad \text{and} \qquad 0.0076 < \sigma_x^2 < 0.0217$$

We are only 95% confident that the above ranges are valid. There exist a 5% chance that the sample drawn may not have its statistics within the 95% confidence-level limits set about the true (μ_x, σ_x) values of the population, thus yielding invalid range estimates for the population statistics.

Although we can estimate ranges (i.e., confidence intervals) for both μ_x and σ_x as will be discussed later in this chapter, most quality-control procedures only recommend the use of a (large) sample's statistics as the population statistics: $\mu_x \cong \overline{X}$ and $\sigma_x^2 \cong S^2$.

16.4 PROCESS CAPABILITY

Specification limits (or tolerance limits) define conformance boundaries for a product's characteristics as specified or dictated by design requirements. Such limits must be carefully defined as constraints to be satisfied and not arbitrarily chosen. One must remember that the tighter the tolerance limits, the higher the cost of achieving them.

The problem of satisfying the specification limits can be formulated as a typical optimization problem, where the objective function to be minimized is the deviation of an individual product characteristic value, X, from the desired nominal value, μ_x,

$$\begin{aligned} &\text{Min}(X - \mu_x) \\ &\text{subject to} \qquad LSL_x \le X \le USL_x \end{aligned} \tag{16.11}$$

where LSL_x and USL_x are the specification limits on X.

The quality (or cost) ramifications of satisfying the specification limits of a product characteristic have commonly been addressed by evaluating the capability of a process to satisfy these limits. All process capability indices used by the manufacturing industry attempt to quantify the variance of the process output with respect to the engineering-defined range of specification limits. Assuming a normal distribution of output values about a desired mean value, most indices employ a variance range of $\pm 3\sigma_x$. The commonly used C_{pk} index is

$$C_{pk} = \min\left[\frac{\mu_x - LSL_x}{3\sigma_x}, \frac{USL_x - \mu_x}{3\sigma_x}\right] \tag{16.12}$$

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As an example, let us consider the production of resistors by a machine whose population variance is defined as $\sigma_x^2 = 0.01$. If the specification limits on the desired $\mu_x = 2$ ohms were to be set as $LSL_x = 1.85$ ohms and $USL_x = 2.3$ ohms (note the unequal limits), then the C_{pk} index would assume a value of 0.5. The higher the value of C_{pk}, the lower the percentage of products outside the specification limits. For this example, using Eq. (16.3), one can determine that about 6.8% of products fall outside the specification limits.

In practice, as mentioned above, the population statistics (μ_x, σ_x^2) are not available. A simple approach to coping with this problem is to use a sample's statistics, ($\overline{X}$, S^2), as approximations to population statistics: that is, use $\mu_x \cong \overline{X}$ and $\sigma_x \equiv S$ in Eq. (16.12). A $\hat{C}_{pk}$ value obtained using these approximated values can be called a middle-of-the-road or a liberal estimate of the true index value. Alternatively, one can calculate a range for $\hat{C}_{pk}$ using the two ranges determined for the population statistics for a certain $(1-\alpha)\%$ confidence level (Fig. 14),

$$\frac{\mu_L - LSL_x}{3\sigma_U} < \hat{C}_{pk} < \frac{USL_x - \mu_U}{3\sigma_U} \tag{16.13}$$

where $[\mu_L, \mu_U]$ and $[\sigma_L^2, \sigma_U^2]$ are the lower and upper limits of the population's statistics calculated from a sample's statistics.

The process capability index is a simple measure of variance normalized with respect to the product specification limits. A process could be quite capable of manufacturing one product (e.g., $C_{pk} \geq 1.5$), while labeled a poor process for another product (e.g., $C_{pk} \leq 0.5$), while having the same variance, σ_x^2, during the manufacturing of both products.

For a perfectly calibrated process, the variance is a result of random-error mechanisms. Thus, when faced with a process capability problem, the manufacturing engineer must cope with a common practical dilemma in

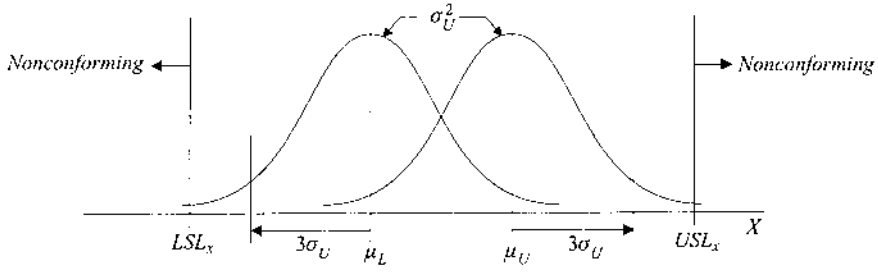

FIGURE 14 Approximation of process capability range.

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order to provide the customers with products within the specification limits: (1) Acquire and utilize a new machine/process that can yield an acceptable C_{pk} value, or (2) inspect all the products and scrap those outside the specification limits. The latter is a short-term solution and should be employed only for unusual and very infrequent product orders. The former solution must be chosen if the C_{pk} index is frequently lower than the acceptable value.

16.5 STATISTICAL PROCESS CONTROL

All manufacturing processes must be controlled in a closed loop mode. The input variables of a process should be adjusted in real time in response to unacceptable deviations of the output variables from their nominal values. In the context of statistical process control (SPC), the question that needs to be answered is, Is the deviation from the nominal, $\Delta X = |\mu_x - X|$, statistically significant to require intervention in the input variable, ΔY? The common answer is that we should change the input variable value of a process only in response to an assignable cause other than a random mechanism. The SPC concept is discussed below first via an example.

Let us consider a bottle-filling operation: bottles of a soft-drink company are required to be filled on average with 330 mL liquid, (i.e., $\mu_x = 330$ mL). The machine used for this process is controlled via a timer that regulates the flow of liquid into each bottle. For a constant filling rate of 150 mL/sec, the timer is set to keep the liquid flow on for 2.2 seconds, corresponding to $\mu_x = 330$ mL per bottle. This (calibrated) machine is known to have a timing variance that translates into an output variance of $\sigma_x^2 = 4$ (i.e., variance in volume of liquid filled) per bottle. Thus, assuming a normal distribution, one can conclude that the output of this machine, X, is expected to have the population statistics of $\mu_x =$ 330 mL and $\sigma_x^2 = 4$.

In order to provide (closed loop) feedback control to this process, the bottles are weighed after they have been filled and the amount of volume is calculated. It is assumed that variations in (empty) bottle weights are negligible compared to variations in liquid volumes. As discussed above, the objective of SPC is to determine whether variations in output are due to only a random mechanism or to other assignable causes as well. The SPC process advocates monitoring variations through sampling, $\overline{X}$. It can be shown that variations due to assignable causes can be better detected by examining sample statistics, ($\overline{X}$, S) versus individual X values.

In the bottle-filing example, it can be shown that [via Eqs. (16.6) and (16.7)] samples of size $n = 5$ have their sample mean values in the range

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$327.3 < \overline{X} < 332.7$ in 99.74% of cases. Thus, in the absence of any identifiable trend, if 99.74% of the samples collected at regular intervals have their means in the above range, while the sample variances also satisfy a random behavior requirement, one can choose not to vary the input variable (i.e., the timer value of 2.2 sec). This SPC-based control example is schematically illustrated in Fig. 15. The specific details of calculating the appropriate control limits and examining the sampling data for determining random versus assignable-cause-based variance are discussed in the subsections below.

It is important to note that control limits for SPC define only statistical capability limits of the specific process considered. They define population percentages expected to be within statistical limits about the mean value of the population (i.e., upper and lower control limits, *UCL* and *LCL*, respectively). For example, when sampling a process output that has a normal distribution, one can expect 99.74% of sample means to be within the range $\mu_{\overline{x}} - 3\sigma_{\overline{x}} \leq \overline{X} \leq \mu_{\overline{x}} + 3\sigma_{\overline{x}}$, where $\mu_{\overline{x}} = \mu_x$ and $\sigma_{\overline{x}} = \sigma_x/\sqrt{n}$.

SPC limits are not specification limits (tolerances), which are specified by product designers/engineers regardless of the process variance that defines the statistical control limits. A process can be perfectly in control (operating subject to statistical random errors) while yielding a large percentage of defects: this phenomenon indicates a poor process capability and not any control problems.

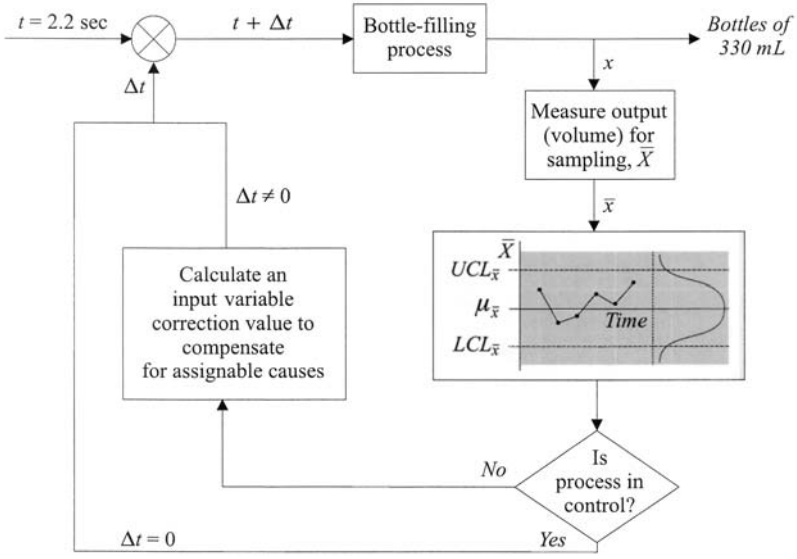

FIGURE 15 Statistical process control example.

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16.5.1 $\overline{X}$-R Control Charts for Variable Data

SPC can be carried out by monitoring the magnitude of (continuous) variable output data or by monitoring the (binary) conformity of a product to desired specification. The former is commonly called the SPC of variable data, while the latter is called the SPC of attribute data. The focus of this section is only on the determination of control charts for variable data.

The most commonly used control charts for variable data are the $\overline{X}$-R charts (R: range), which must be utilized as a pair. The $\overline{X}$ chart is used to track potential deviations from the desired population mean value, μ_x, while the R-chart is used to track potential changes in process variance, σ_x^2. A process is in control if both charts indicate compliance.

Control charts provide a graphical user interface for the tracking of the process output with respect to its expected statistical behavior. A control chart is a two-dimensional plot of a sample statistic versus time. Compliance with process control requirements can be checked by verifying that an expected proportion of sample statistics are within the control limits as well as by monitoring trends.

In an $\overline{X}$ chart, the SPC control limits should be calculated for a certain statistical range utilizing the true mean value for the population of measurements, which we assume to have a normal distribution. In practice, this range is, typically, set to include the 99.74% of the sample means, though it could be set for any other percentage:

$$LCL_{\bar{x}} = \mu_x - \frac{3\sigma_x}{\sqrt{n}} \qquad \text{and} \qquad UCL_{\bar{x}} = \mu_x + \frac{3\sigma_x}{\sqrt{n}} \tag{16.14}$$

where n is the size of the samples collected.

In the absence of true (μ_x, σ_x) values known to us, we must use approximations. Historically, these population statistics have been approximated by

$$\mu_x = \mu_{\bar{x}} \equiv \overline{\overline{X}} \qquad \text{and} \qquad \sigma_x \cong \frac{\overline{R}}{d_2} \tag{16.15}$$

where

$$\overline{\overline{X}} = \frac{1}{k}\sum_{j=1}^{k} \bar{x}_j \qquad \text{and} \qquad \overline{R} = \frac{1}{k}\sum_{j=1}^{k} R_j = \frac{1}{k}\sum_{j=1}^{k} (x_{\max} - x_{\min})_j$$

Above, $\bar{x}_j$ is the mean value of the jth sample, $j = 1$ to k (k is usually about 20), collected prior to starting the SPC process; R_j is the range of all x_i, $i = 1$

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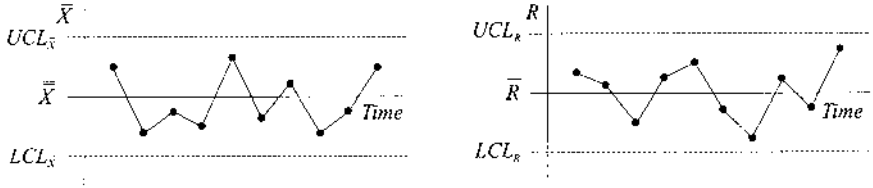

FIGURE 16 $\bar{X}$-R charts.

to n (n is usually 4 to 6), measurements within this sample; and, d_2 is a correction factor, whose value is a function of the samples' size, n.

The limits for the $\bar{X}$ and R charts based on the above approximations are, then, defined as (Fig. 16)

$$LCL_{\bar{x}} = \bar{\bar{X}} - 3\frac{\bar{R}}{d_2\sqrt{n}} \quad \text{and} \quad UCL_{\bar{x}} = \bar{\bar{X}} + 3\frac{\bar{R}}{d_2\sqrt{n}} \tag{16.16a}$$

$$LCL_R = \bar{R} - 3\frac{d_3}{d_2}\bar{R} \quad \text{and} \quad UCL_R = \bar{R} + 3\frac{d_3}{d_2}\bar{R} \tag{16.16b}$$

where d_3 is a correction factor whose value is a function of the samples' size, n. One must note that LCL_R cannot have a value below zero.

The use of a range of measurements, R, as opposed to sample variance, S, can be attributed to the absence of portable electronic calculators (or personal computers) on the factory floors of the first half of the 20th century. (In the next subsection, the use of $\bar{X}$-S charts will be reviewed.)

The approximation of σ_x in Eq. (16.16a) is an acceptable solution to the unavailability of population variance. However, the approximations used in the definition of the R chart may not be acceptable to some. As discussed in Sec. 16.3.2, sample variances S, follow a chi-squared distribution. However, the distribution used for the R values in Eq. (16.6b) is Gaussian, with some correction factors (d_2, d_3). This approximation may yield unacceptable conclusions at the extremes (near control limit values).

16.5.2 $\bar{X}$-S Control Charts for Variable Data

The pair of $\bar{X}$-S charts may also be utilized for SPC purposes. As for $\bar{X}$-R charts, it has been customarily assumed that both sample mean and sample variance values have normal distributions. In the absence of true μ_x and σ_x

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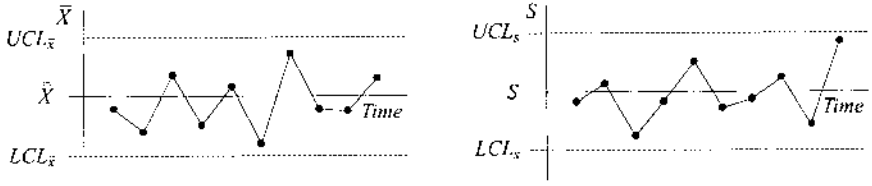

FIGURE 17 $\bar{X}$-S charts.

values, the following approximations have been used to define the control limits for 99.74% population ranges (Fig. 17):

$$LCL_{\bar{x}} = \bar{\bar{X}} - 3\frac{\bar{S}}{c_4\sqrt{n}} \quad \text{and} \quad UCL_{\bar{x}} = \bar{\bar{X}} + 3\frac{\bar{S}}{c_4\sqrt{n}} \tag{16.17a}$$

$$LCL_s = \bar{S} - 3\frac{\bar{S}\sqrt{1-c_4^2}}{c_4} \quad \text{and} \quad UCL_s = \bar{S} + 3\frac{\bar{S}\sqrt{1-c_4^2}}{c_4} \tag{16.17b}$$

where $\bar{S}$ is the mean of the k samples' standard deviations used to calculate the control limits (each sample of size n), and c_4 is a correction factor used to compensate for the normal distribution approximation of the actual chi-squared distribution of the sample variances. As for R charts, LCL_s cannot have a value below zero.

16.5.3 Implementation and Interpretation of Control Charts

SPC is based on monitoring output data and providing feedback information to the process controller. The monitoring and analysis of output data is carried out through sampling theory. Once the type of control charts is chosen ($\bar{X}$-R versus $\bar{X}$-S), the next step is gathering data for the calculation of control limits: for most applications, it is recommended that 20 to 30 samples ($k = 20$ to 30), each of the same size $n = 4$ to 6, be collected and approximations for population statistics be established. These are

For $\bar{X}$-R charts,

$$\mu_{\bar{x}} \cong \bar{\bar{X}} \quad \text{and} \quad \sigma_{\bar{x}} \cong \frac{\bar{R}}{d_2\sqrt{n}}$$

$$\mu_R \cong \bar{R} \quad \text{and} \quad \sigma_R \cong \frac{\bar{R}d_3}{d_2}$$

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For $\overline{X} - S$ charts;

$$\mu_{\overline{x}} \cong \overline{\overline{X}} \qquad \text{and} \qquad \sigma_{\overline{x}} \cong \frac{\overline{S}}{c_4\sqrt{n}}$$

$$\mu_s \cong \overline{S} \qquad \text{and} \qquad \sigma_s \cong \overline{S}\frac{\sqrt{1 - c_4^2}}{c_4}$$

The control limits for the SPC charts need to be calculated from the desired population range to be considered. In Secs. 16.5.1 and 16.5.2, the 99.74% range was utilized in the derivation of these limits. Once the control limits have been established from preliminary training data, the process can be started and its output monitored by frequent sampling: The exact frequency of data collection is a function of the reliability of the process and the cost of data collection.

Interpretation of data gathered is simply the application of probability theory: First, the limits chosen dictate what percentage of data could be allowed to fall outside the limits (e.g., 0.26% for the 99.74% limits used in this section). Second, if we assume a reasonable approximation of the center lines (i.e., $\mu_{\overline{x}}$, μ_R, and μ_s) the data points should be equally distributed on both sides of the center lines. We can claim that the probability of having two consecutive points on one side of the center line is equal to ($50\% \times 50\% =$) 25%, for three consecutive points it is 12.5%, and so forth. Therefore rules can be established to monitor out-of-the-ordinary sequences of occurrences, e.g., 7 out of 7 consecutive, 10 out of 11 consecutive, 14 out of 17 consecutive points one side of the centerline could be considered as indicating a process going out of control, since each case would approximately have a 1% chance of occurrence.

Other symptoms of a process potentially going out of control include cyclic behaviors, high ratios of data points near the control limits (in contrast to the expected normal behavior of having most points around the centerlines), sudden spikes, trends of points showing steady increase/decrease in values, and so on.

16.6 ISO 9000

ISO 9000 is a family of standards on quality management systems and related supporting standards on terminology and specific tools. In ISO 9000, quality refers to "all product features that are required by the customer." Quality management refers to "all actions that an organization must carry out to ensure that its products conform to the customer's requirements: quality assurance, quality control, and quality improvement." Quality

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assurance encompasses all planned activities required to provide adequate confidence that a product/process fulfils the quality requirements, such as documenting plans and specifications, reporting results, and so on. Quality control encompasses all operational procedures necessary to fulfill the quality requirements, such as measuring conformity in real time using appropriate sensors and providing feedback to the process controller. Quality improvement encompasses all actions that yield beneficial changes in quality performance, such as reducing the spread of variations in a manufacturing processes, or reducing failure rates.

ISO 9000 dictates the way an organization carries out its work and not directly the result of this work. It is about processes and not products. It specifies generic requirements for compliance, as opposed to most other standards that specify technical engineering specifications or other precise criteria to be used consistently as rules or guidelines to ensure that products, processes, and services are fit for their purposes.

16.6.1 ISO 9000:1994

One of the original standards established for quality management programs was issued by the U.S. Department of Defense, MIL Q 9858A, in 1959. This standard was followed by NATO's Allied Quality Assurance Publication (AQAP-1) in 1968 and by the U.K. Ministry of Defense standard Def Stan 05-08 in 1970. By the mid-1980s, many countries had developed quality management standards that no longer heavily targeted military products as did their predecessors during the period 1960 to 1980. In 1987, the first international quality management standard was issued by the International Organization for Standardization (ISO). However, most of the countries involved (over 25) in the development of this standard adopted national equivalents, as opposed to the original ISO standard. The subsequently published ISO 9000 series (family) of standards in 1994 (known as ISO 9000:1994) were, however, more successfully adopted by the participating countries.

The ISO 9000:1994 family of standards allowed organizations to choose one of three standards, tailored for specific quality management system applications, ISO 9001, ISO 9002, and ISO 9003 for registration. All organizations, however, were encouraged to implement the fourth standard, ISO 9004, which stated the exact quality management requirements that would lead to certification under one of the three quality assurance standards, ISO 9001, ISO 9002, or ISO 9003. The primary members of the 1994 version of the ISO 9000 family were

ISO 8402:1994: Quality management and quality assurance vocabulary
ISO 9000:1994: Guidelines for the selection and application of ISO 9001, ISO 9002, and ISO 9003

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ISO 9001:1994: Model for quality assurance in design, development, production, installation, and servicing
ISO 9002:1994: Model for quality assurance in production, installation, and servicing
ISO 9003:1994: Model for quality assurance in final inspection and test
ISO 9004:1994: Guidelines for quality management and quality system elements

Despite exact equivalence in content, different countries still adopted their own coding and some varied application procedures of the ISO 9000:1994 family of standards: In the U.S.A., ANSI/ASQ Q9000 was issued by the American National Standards Institute (ANSI); in Canada, CAN/CSA-ISO 9000 was issued by the Canadian Standards Association (CSA); in the U.K., BS 5750; in France, NF-EN 29000; in Germany, DIN ISO 9000; and, in Japan, JIS Z 9900. These standards have been used extensively as the basis for independent quality system certification for over 400,000 organizations worldwide.

The ISO 9000:1994 family of standards contained a common set of 20 principles/requirements to be complied with for certification:

1. *Management responsibility*: The organization's management shall define and document its policy for quality and provide adequate resources for its implementation.
2. *Quality system*: The organization shall establish a quality system to ensure that products conform to specified requirements, including preparation of quality control plans, identification of measurement techniques and tools, and so on.
3. *Contract review*.
4. *Design control*: The organization shall establish and maintain procedures to control the design of products to ensure that requirements are met.
5. *Document and data control*.
6. *Purchasing (evaluation of subcontractors)*.
7. *Control of customer supplied product (storage and maintenance)*.
8. *Product identification and traceability*.
9. *Process control*: The organization shall ensure that production, installation, and servicing processes that affect quality are carried out under controlled conditions.
10. *Inspection and testing (procedures)*.
11. *Control of inspection, measuring, and test equipment*.
12. *Inspection and test status (results)*.
13. *Control of nonconforming product*.
14. *Corrective and preventive action*.

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15. *Handling, storage, packaging, preservation, and delivery of products.*
16. *Control of quality records.*
17. *Internal quality audits.*
18. *Training*: The organization shall provide training to all personnel performing operations affecting quality and verify qualifications on the basis of education, training, and/or experience.
19. *Servicing.*
20. *Statistical techniques*: The organization shall identify the need for statistical techniques required for quality control of processes and products.

16.6.2 ISO 9000:2000

Since ISO protocol requires that all standards be reviewed at least every five years to determine whether they should be confirmed, revised, or withdrawn, the 1994 versions of the ISO 9000 family of standards were revised by the ISO's Technical Committee (TC) 176 in 2000. The original ISO 9000 family (developed during the late 1980s and the mid 1990s) contained more than twenty standards and documents. This proliferation of standards was a concern to many users and customers. The latest revisions of the core series standards in the ISO 9000 family, ISO 9000:2000, were published on December 15, 2000. ISO 8402 and part of the content of ISO 9000 were merged into a new ISO 9000:2000 standard. The earlier three (quality assurance) standards, ISO 9001, ISO 9002, and ISO 9003, were integrated into the new ISO 9001:2000. ISO 9004:1994, though maintaining its code, was also substantially revised.

As of 2001, ISO 9000 certification is to be achieved only through adhering to ISO 9001:2000, the practices described in ISO 9004:2000 may then be implemented to make the quality management system effective in achieving the quality assurance goals. ISO 9001:2000 and ISO 9004:2000 have been formatted as a consistent pair of standards to facilitate their use. Organizations must upgrade their quality management systems to meet the requirements of ISO 9001:2000 by December 15, 2003, in order to maintain an accredited certificate.

Currently, the primary ISO 9000 family standards are

ISO 9000:2000: Quality management systems—fundamentals and vocabulary.

ISO 9001:2000: Quality management systems—requirements. This is the requirement standard needed to assess an organization's ability to meet customer and applicable regulatory requirements.

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ISO 9004:2000: Quality management systems—guidelines for performance improvements: This standard provides guidance for continual improvement of the quality management system.

ISO 10007:1995: Quality management—guidelines for configuration management. This standard provides guidance to ensure that a complex product continues to function when components are changed individually.

ISO/DIS 10012: Quality assurance requirements for measuring equipment—Part 1. Metrological confirmation system for measuring equipment. This standard provides guidance on the main features of a calibration system to ensure that measurements are made with the intended accuracy.

ISO 10012-2:1997: Quality assurance for measuring equipment—Part 2. Guidelines for control of measurement of processes. This standard provides supplementary guidance on the application of statistical process control when it is appropriate for achieving the objectives of Part 1.

ISO/TS 16949:1999: Quality systems—automotive suppliers—particular requirements for the application of ISO 9001:1994. This standard provides sector specific guidance to the application of ISO 9001 in the automotive industry.

ISO 19011: Guidelines on quality and/or environmental management systems auditing.

As mentioned above, the revised ISO 9001 and 9004 constitute a consistent pair of standards. Their structure and sequence are identical in order to facilitate an easy transition between them. Although they are standalone standards, their new structures promote enhanced synergy between the two. It is also intended that the ISO 9000 standards have global applicability and be used as a natural stepping stone towards total quality management (TQM).

The revised ISO 9000:2000 series standards are based on eight quality management principles that provide management with a framework to guide their organization towards improved performance.

Customer focus: Organizations should strive to exceed current and future customer expectations. (Improved customer loyalty leads to repeat business.)

Leadership: Organizations should encourage leaders to create an internal environment in which people can become fully involved in achieving the organization's vision. (Providing people with the required resources, training, and freedom to act with responsibility and accountability.)

Involvement of people: People at all levels of an organization should be fully involved. (Motivated, committed, and involved people lead to innovation and creativity.)

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Process approach: A desired outcome can be achieved more efficiently when activities and resources are managed as a process. (Focused and prioritized improvement opportunities.)

System approach to management: Identifying, understanding, and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives. (Integration and alignment of processes that will best achieve the desired results.)

Continual improvement: Continual improvement of the organization's overall performance should be a permanent objective of the organization. (Flexibility to react quickly to opportunities.)

Factual approach to decision making: Effective decisions can only be carried out based on the (factual) analysis of data and information. (Ensuring that data and information are sufficiently accurate and reliable and analyzing data and information using valid methods.)

Mutually beneficial supplier relationships: An organization and its suppliers are interdependent, and an effective relationship will enhance their competitiveness. (Flexibility and speed of joint response to changing customer expectations can optimize costs and resources.)

The revision of the ISO quality management system standards (yielding ISO 9000:2000), while retaining the essence of the original requirements, has repositioned the 20 elements of the ISO 9001:1994 and the guidelines of ISO 9004:1994 into the following eight classes:

1. Scope
2. Normative references
3. Terms and definitions
4. Quality management system
   - 4.1. General requirements
   - 4.2. Documentation requirements
5. Management responsibility
   - 5.1. Management commitment
   - 5.2. Customer focus
   - 5.3. Quality policy
   - 5.4. Planning
   - 5.5. Responsibility, authority, and communication
   - 5.6. Management review
6. Resource management
   - 6.1. Provision of resources
   - 6.2. Human resources
   - 6.3. Infrastructure
   - 6.4. Work environment

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7. Product realization
   - 7.1. Planning of product realization
   - 7.2. Customer-related processes
   - 7.3. Design and development
   - 7.4. Purchasing
   - 7.5. Production and service provision
   - 7.6. Control of monitoring and measuring devices
8. Measurement, analysis, and improvement
   - 8.1. General
   - 8.2. Monitoring and measurement
   - 8.3. Control of nonconforming product
   - 8.4. Analysis of data
   - 8.5. Improvement

REVIEW QUESTIONS

1. Define quality and quality management.
2. Should the cost of quality management be added to the cost of the product or should it be recovered through increased market share?
3. Consider two makes of (electrical) batteries, A and B. The population of batteries of Make A has a mean life longer than that of Make B. However, the (life) variance of Make A is significantly larger than that of Make B. Discuss the following two issues: quality versus performance and the pricing of the two makes.
4. Define inspection versus testing.
5. Define destructive versus nondestructive inspection/testing.
6. Define accuracy versus repeatability (also known as precision).
7. Discuss on-line versus postprocess inspection.
8. Discuss 100% versus sampling-based inspection.
9. Discuss the use of coordinate measuring machines (CMMs) for inspection purposes.
10. Discuss the need for x-ray-based inspection in manufacturing. Elaborate on x-ray-based inspection for mass production versus for one-of-a-kind production.
11. What is computed tomography (CT)?
12. Can product life be represented using a Gaussian (normal) probability distribution? Explain.
13. Define population statistics versus sample statistics. Discuss the estimation of population statistics using finite-size sample statistics.
14. What is process capability? Discuss its use in product design.

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15. What is statistical process control (SPC)? Can a process in total (statistical) control yield defective products (i.e., with feature values that are outside the product's specification limits)?
16. Compare the use of $\overline{X}$ charts versus $\overline{X}$ charts in SPC.
17. Provide a step-by-step SPC implementation procedure.
18. What is the primary purpose of ISO 9000?

DISCUSSION QUESTIONS

1. Computers and other information management technologies have been commonly accepted as facilitators for the integration of various manufacturing activities. Define/discuss integrated manufacturing in the modern manufacturing enterprise and address the role of computers, especially in the context of quality management.
2. Discuss the concept of progressively increasing *cost of changes* to a product as it moves from the design stage to full production and distribution. How could you minimize necessary changes to a product, especially for those that have very short development cycles, such as portable communication devices?
3. Information collected on failed products may provide valuable information to manufacturers for immediate corrective actions on the design and manufacturing current and/or future lines of products. Discuss how would you collect and analyze product failure (or survival) data for industries such as passenger vehicles, children's toys, and computer software.
4. The performance of a multicomponent product or system (e.g., the force required to close a car door) would be significantly improved as the dimensional parameters of the individual components approach their respective nominal values. In order to address this issue, some designers tend to narrow the acceptable ranges of these parameters (i.e., select stringent specification limits, tolerances) without any regard to the capability of the manufacturing processes to be used in fabricating the individual components. Discuss the above issue of tolerance specification in the profitable production of multicomponent products that will meet customer (quality) expectations.
5. Nondestructive quality control techniques are widely utilized in the manufacturing industry. Discuss the need for destructive testing in terms of government regulations, lack of reliable nondestructive testing techniques, testing time and cost, and so on. Use exemplary products during your discussion and state features that would be tested.

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6. Go–no-go gages/setups/etc. have long been used in mass-production environments to ensure that every single part shipped to a customer meets the engineering specifications. Discuss if such techniques may contribute to the quality control of the manufacturing process even though they do not provide much feedback on the statistical behavior of the process. Under what conditions could go–no-go quality checks be useful or necessary?
7. Tool wear can have a detrimental effect on satisfying the (geometric) dimensional specifications of a machined part, including its surface finish, especially for hard materials and complex three-dimensional surfaces. Discuss possible remedies to this problem in terms of on-line depth-of-cut compensation in turning, milling, and drilling. Address the issues of on-line sensory feedback (i.e., measurement of tool wear or object dimensions) and microscale depth-of-cut compensation using secondary (e.g., piezoceramic based) actuators (e.g., placed under the tool holder in turning).
8. In mass-production environments, it is a common practice to have 100% inspection until the manufacturing process reaches a stable state, and then to employ statistical control methods to maintain the highest possible quality levels. Discuss a comparable viable quality-assurance strategy for one-of-a-kind or small-batch-size manufacturing.
9. SPC was developed as a monitoring tool that can identify problematic trends in production that may lead to quality problems. SPC can be considered as a "virtual sensor." Discuss the use of SPC in closed loop feedback control of fabrication processes, where manufacturing parameters are adjusted in an adaptive mode in response to the output of the SPC "sensor."
10. SPC is a process monitoring technique, whose objective is to ensure that the process is performing to its utmost capability defined by a statistical variation index. A fully calibrated process that is in control may, however, produce a large percentage of defectives, whose engineering specifications are outside those defined by its design. Although the process is in control, it is incapable of meeting the stringent engineering specifications. Compare SPC limits to engineering specification limits in elaborating on the above scenario. Discuss approaches to supplying a customer with a desired threshold percentage of parts that meet the engineering specifications, even when faced with a process capability problem in which the machine/system cannot meet this threshold percentage requirement.
11. Quality improvement is a manufacturing strategy that should be adopted by all enterprises; that is, although quality control is a primary concern for any manufacturing company, engineers should attempt to

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improve quality: In statistical terms, all variances should be minimized, and furthermore where applicable the mean values should be increased (e.g., product life, strength) or decreased (e.g., weight) appropriately. Discuss the quality improvement issue and suggest ways of achieving continual improvements. Discuss also whether companies should concentrate on gaining market share through improved product performance or/and quality or only through cost/price.

12. The achievement of product specifications can be significantly improved with the availability of sensors that can provide the manufacturing process with feedback information while the fabrication of the product is ongoing. Discuss the role of postproduction quality control techniques in such environments, i.e., as complementing online quality-control strategies.

13. Production machines' (statistical) capability in terms of providing different levels of precision must be considered at the design stage of the product. Discuss the impact of this data on the decision-making process during the product development stage with respect to the following scenarios and others: proceed with the design of a product whose several components might have to be contract manufactured owing to the absence of economic in-house manufacturing capability; adopt a strategy of producing many components, using the ones that meet specifications and scrapping the rest; design, produce, and market products that only fractionally meet the design specifications; purchase better machines.

14. The factory of the future will be a totally networked enterprise. Information management in this enterprise will be complex. In regards to planning, monitoring, and control, discuss the level of detail of information that the controllers (humans or computers) would have to deal with in such environments. For example, some argue that in a hierarchical information management environment, activities are more of the planning type at the higher levels of the hierarchy and more of the control type at the lower levels. It has also been argued that the level of details significantly decreases as you ascend the enterprise ladder.

15. In the factory of the future, no unexpected machine breakdowns will be experienced! Such an environment, however, can only be achieved if a preventive maintenance program is implemented, in which all machines and tools are modeled (mathematically and/or using heuristics). These models would allow manufacturers to schedule maintenance operations as needed. Discuss the feasibility of implementing factory-wide preventive maintenance programs in the absence of our ability to model completely all existing physical phenomena and

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furthermore our lack of a large variety of sensors that can monitor the states of these machines and provide timely feedback to such models.

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